

# MATERIALS OVERVIEW



# Topics

- **Overview**
  - **Licensing (G-109)**
  - **Inspection (G-108)**
- **Medical Applications**
  - **Nuclear Medicine (H-304)**
  - **Brachytherapy etc (H-313)**
- **Industrial Applications**
  - **Radiography (H-305)**
  - **Irradiators (H-315)**
  - **Well Logging (H-314)**
  - **Gauges (fixed & portable)**

# What is the NRC's Mission Statement?

**The mission of the U.S. Nuclear Regulatory Commission is to ensure adequate protection of the public health and safety, the common defense and security, and the environment in the use of nuclear materials in the United States.**

# Regulatory Skills

## Licensing and Inspection

# Regulatory Authority

- **Atomic Energy Act of 1954**
- **Energy Reorganization Act of 1974**
- **Energy Policy Act of 2005**
- **Title 10 Code of Federal Regulations**

# NRC Jurisdiction

## NRC Responsible for:

**byproduct material\***  
**source material**  
**special nuclear material**

## NRC NOT Responsible for:

**NORM\*\*** (Naturally Occurring Radioactive Material)  
**x-ray machines**  
**non-ionizing radiation** (lasers, microwaves etc)

\* see next slide

\*\* non-discrete sources

# Energy Policy Act of 2005

The term "byproduct material" now includes –

- any discrete source of radium-226 that is produced for a commercial, medical, or research activity; or
- any material made radioactive by use of a particle accelerator and produced for a commercial, medical, or research activity
- any discrete source of naturally occurring radioactive material (NORM) produced for use in a commercial, medical, or research activity that would pose a threat similar to the threat posed by a discrete source of radium-226

# NRC is Not Alone in Regulating Radioactive Material

**Environmental Protection Agency (EPA)**

**Department of Transportation (DOT)**

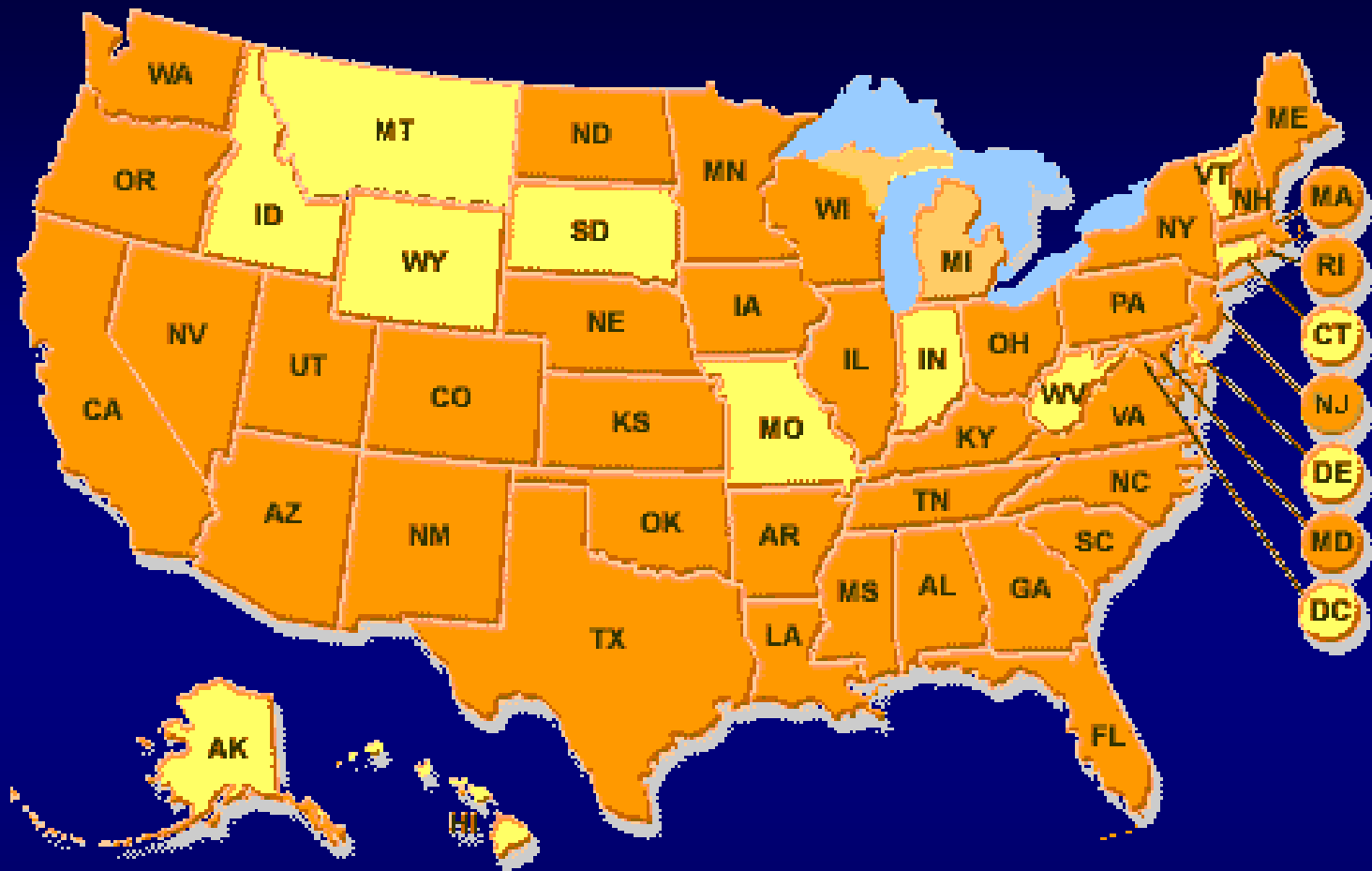
**Department of Labor (DOL) - Occupational Safety and Health  
Administration (OSHA)**

**Department of Health and Human Services (HHS) - Food and  
Drug Administration (FDA) - National Center for Devices and Radiological  
Health (NCDRH)**

**Department of Energy (DOE)**

**Agreement States** (regulate all radiation sources except Nuclear Power  
Plants and Federal Facilities)

**Non-Agreement States** (regulate non-NRC radiation sources)



- Agreement States (37)
- Non-Agreement States (NRC Jurisdiction) (12+DC+PR+USVI+Guam)
- States with letters of intent to become Agreement States (1)

# 2009-2010 NUREG 1350

NAS

State	Number of Licenses	
	NRC	Agreement States
Alabama	17	458
Alaska	56	0
Arizona	10	372
Arkansas	6	228
California	47	2,007
Colorado	20	354
Connecticut	192	0
Delaware	61	0
District of Columbia	42	0
Florida	14	1,720
Georgia	16	521
Hawaii	37	0
Idaho	81	0
Illinois	37	742
Indiana	289	0
Iowa	4	193
Kansas	11	300
Kentucky	10	449
Louisiana	13	550
Maine	2	125
Maryland	74	638
Massachusetts	26	500
Michigan	533	0
Minnesota	13	187
Mississippi	6	333
Missouri	294	0
Montana	84	0

State	Number of Licenses	
	NRC	Agreement States
Nebraska	6	153
Nevada	5	270
New Hampshire	5	78
New Jersey	480	0
New Mexico	15	186
New York	32	1,461
North Carolina	18	680
North Dakota	9	66
Ohio	46	748
Oklahoma	21	297
Oregon	4	435
Pennsylvania	66	926
Rhode Island	1	56
South Carolina	11	417
South Dakota	44	0
Tennessee	19	608
Texas	47	1,670
Utah	10	188
Vermont	37	0
Virginia	71	431
Washington	19	437
West Virginia	179	0
Wisconsin	22	336
Wyoming	84	0
Others*	158	0
Total	<del>2,429</del>	<del>19,100</del>

New AS

AS

~3,000    ~19,530  
13%       87%

# Harmonization

The NRC will determine which of its regulations and program elements should be adopted by an Agreement State to maintain a compatible program.

In addition, an Agreement State should have legally binding requirements to maintain adequate protection of public health and safety.

MD 5.9 describes the criteria and process NRC staff should follow to determine which NRC regulations and program elements should be adopted by an Agreement State for compatibility as well as for health and safety.

# Compatibility Categories and Health and Safety Identification

**A - Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC;**

**B - Program element with significant direct trans-boundary implications. The State program element should be essentially identical to that of NRC;**

# Compatibility Categories and Health and Safety Identification

**C - Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met;**

**D - Not required for purposes of compatibility;**

**NRC - These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act or provisions of 10 CFR regulations.**

# Compatibility Categories and Health and Safety Identification

**H&S - Program elements identified as H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.**

# Master Materials Licensees (MML)

**MML has more authority than a Broad Scope Licensee  
(similar to an Agreement State but still a licensee)**

- **US Navy (USN) - Region I**
- **Department of Veterans Affairs (VA) - Region III**
- **US Air Force (USAF) - Region IV**

**Very Large Broad Scope Licensees but not MMLs**

- **Department of Agriculture (USDA)**
- **Cardinal Health (formerly SYNCOR)**

# NRC Regulations (Title 10)

## Basic Radiation Protection (Parts 19/20)

➡ **General Byproduct** (Part 30/31/32/33)  
**Source Material** (Part 40)  
**Special Nuclear Material** (Part 70)

➡ **Medical** (Part 35)  
➡ **Industrial** (Parts 34/36/39)  
**Reactor** (Part 50 Appendix I)  
**Waste** (Parts 60/61/63)  
**Transportation** (Part 71)

**Safeguards** (Parts 73/74/75)  
**Enforcement** (Parts 2/21)

A decorative gold crosshair consisting of a vertical line and a horizontal line intersecting in the upper left quadrant of the slide.

# **MATERIALS LICENSING**

# License is [like] a Contract

**It is a document that:**

- **permits activities**
- **restricts activities**
- **is legally binding upon the licensee**
- **incorporates, by reference, documents submitted as part of the application for a license, which provide information to show that public health and safety will be protected**

**licensee is responsible for actions of employees and agents**

# Types of Licenses

(10 CFR Part 30)

- **Exempt - no license (e.g., smoke detector)**



- **General License - license comes with device (e.g., EXIT signs)**



- **Specific License - application and approval process**
  - **Limited**
  - **Broad Scope (e.g., Universities & Medical Centers)**
  - **Master Materials (USAF, USN and VA)**
- **NUREG-1556 Consolidated Licensing Guidance (21 vol)**

# NUREG-1556 Series

- 1 Portable Gauge Licenses
- 2 Industrial Radiography Licenses
- 3 Applications for Sealed Source and Device Evaluation and Registration (SS&D)
- 4 Fixed Gauge Licenses
- 5 Self-Shielded Irradiator Licenses
- 6 10 CFR Part 36 Irradiator Licenses
- 7 Academic, Research and Development, and Other Licenses of Limited Scope (ARDL)
- 8 Exempt Distribution Licenses
- 9 Medical Use Licenses
- 10 Master Materials Licenses
- 11 Licenses of Broad Scope

# NUREG-1556 Series (cont)

- 12 Possession Licenses for Manufacturing and Distribution
- 13 Commercial Radiopharmacy Licenses
- 14 Well Logging, Tracer, and Field Flood Study Licenses
- 15 Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
- 16 Licenses Authorizing Distribution to General Licensees
- 17 Licenses for Special Nuclear Material of Less than Critical Mass
- 18 Service Provider Licenses
- 19 Reciprocity (NRC Licensees working in Agreement States and vice versa)
- 20 Administrative Licensing Procedures
- 21 Possession Licenses for Production of Accelerator RAM

# Performance Based Licensing

**Greater reliance on licensee statements and promises. Less emphasis on administrative documentation of program details. This should result in more flexibility for licensee and less time spent by NRC reviewing and approving future non-significant administrative changes.**

**For example, licensee must state that they have a Radiation Protection Program that addresses all radiation safety requirements but need not submit the program documentation for review during licensing. The existence and adequacy of the program will be verified during a subsequent performance based inspection.**

# Materials License Application

## (NRC Form 313)

<b>NRC FORM 313</b> (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40		<b>U.S. NUCLEAR REGULATORY COMMISSION</b>		<b>APPROVED BY OMB: NO. 3150-0120</b> Estimated burden per response to comply with this mandatory collection request: 4.4 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 Records and FOIA/Privacy Services Branch (T-6 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by internet e-mail to <a href="mailto:infocollects@nrc.gov">infocollects@nrc.gov</a> , 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.		<b>EXPIRES: 10/31/2008</b>	
<b>APPLICATION FOR MATERIAL LICENSE</b>							
<b>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.</b>							
<b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b>  DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001  <b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b>  <b>IF YOU ARE LOCATED IN:</b>  ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, 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 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415				<b>IF YOU ARE LOCATED IN:</b>  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, 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 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-4005			
<b>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.</b>							
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> 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  TELEPHONE NUMBER _____			
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 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 (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, 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	
<b>FOR NRC USE ONLY</b>							
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS		
			\$				
APPROVED BY				DATE			

NRC FORM 313A (AUS) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
<b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b> (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]		
Name of Proposed Authorized User		State or Territory Where Licensed
Requested Authorization(s) (check all that apply) <input type="checkbox"/> 35.400 Manual brachytherapy sources <input type="checkbox"/> 35.600 Teletherapy unit(s) <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 <input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s) <input type="checkbox"/> 35.600 Remote afterloader unit(s)		
<b>PART I -- TRAINING AND EXPERIENCE</b> <i>(Select one of the three methods below)</i>		
* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.		
<input type="checkbox"/> <b>1. Board Certification</b>		
a. Provide a copy of the board certification. b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought. c. Skip to and complete Part II Preceptor Attestation.		
<input type="checkbox"/> <b>2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above</b>		
a. Go to the table in section 3.e. to document training for new device. b. Skip to and complete Part II Preceptor Attestation.		
<input type="checkbox"/> <b>3. Training and Experience for Proposed Authorized User</b>		
a. Classroom and Laboratory Training <input type="checkbox"/> 35.490 <input type="checkbox"/> 35.491 <input type="checkbox"/> 35.690		
Description of Training	Location of Training	Clock Hours
Radiation physics and instrumentation		
Radiation protection		
Mathematics pertaining to the use and measurement of radioactivity		
Radiation biology		
Total Hours of Training:		

NRC FORM 313A (AUS) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION		
<b>AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)</b>			
<b>Preceptor Attestation (continued)</b>			
<b>Third Section</b>			
<b>For 35.690: (continued)</b>			
<input type="checkbox"/> I attest that _____ has received training required in 35.690(c) for device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.			
<input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			
<b>AND</b>			
<b>Fourth Section</b>			
<input type="checkbox"/> I attest that _____ has achieved a level of competency sufficient to achieve a level of competency sufficient to function independently as an authorized user for:			
<input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			
<b>Fifth Section</b>			
Complete the following for preceptor attestation and signature:			
<input type="checkbox"/> I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:			
<input type="checkbox"/> 35.400 Manual brachytherapy sources <input type="checkbox"/> 35.600 Teletherapy unit(s)			
<input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 <input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)			
<input type="checkbox"/> 35.600 Remote afterloader unit(s)			
Name of Preceptor	Signature	Telephone Number	Date
License/Permit Number/Facility Name			

# Medical Training and Experience Forms - NRC Form 313A (AUS)

# Sample License

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

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## 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		
1. Manuel U. Seeds	3. License number 99-02200-01	
2. Suite 106 3 Physician Circle Parkway Anytown, Pennsylvania 02200	4. Expiration date September 30, 2014	
	5. Docket No. 030-02200 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 permitted by 10 CFR 35.400	A. Sealed Sources (US Atomic Model US-I-125-10L)	A. 500 millicuries
9. Authorized use:		
A. Any manual brachytherapy procedure permitted by 10 CFR 35.400, for which the patient can be released under the provisions of 10 CFR 35.75. (087)		

## CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Suite 106, 3 Physician Circle Parkway, Anytown, Pennsylvania. (001)
11. The Radiation Safety Officer for this license is Manuel U. Seeds, M.D.(033)
12. Licensed material is only authorized for use by, or under the supervision of: (014a&b, AU only)
  - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
  - B. The following individuals are authorized users for medical use as indicated:

### Authorized Users

Manuel U. Seeds, M.D.

### Material and Use

10 CFR 35.400

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 2 PAGES

## MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number  
99-02200-01

Docket or Reference Number  
030-02200

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." (146)
14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations. (038)
  - A. Application dated July 20, 2004

For the U.S. Nuclear Regulatory Commission

# Tie Down Condition

Date \_\_\_\_\_ By \_\_\_\_\_

Division of Nuclear Materials Safety

# Licensee's Statement of Disposal of Material Prior to License Termination (NRC Form 314)

<b>NRC FORM 314</b> (4-2008) 10 CFR 30.36(j)(1); 40.42(j)(1); 70.38(j)(1); and 72.54(k)(5)(1)(1)		<b>U.S. NUCLEAR REGULATORY COMMISSION</b>		<b>APPROVED BY OMB: NO. 3150-0028</b>	<b>EXPIRES: 08/31/2010</b>
<b>CERTIFICATE OF DISPOSITION OF MATERIALS</b>					
LICENSEE NAME AND ADDRESS			LICENSE NUMBER		DOCKET NUMBER
			LICENSE EXPIRATION DATE		
<b>A. LICENSE STATUS (Check the appropriate box)</b> <input type="checkbox"/> This license has expired. <input type="checkbox"/> This license has not yet expired; please terminate it.					
<b>B. DISPOSAL OF RADIOACTIVE MATERIAL</b> (Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments) The licensee, or any individual executing this certificate on behalf of the licensee, certifies that: <input type="checkbox"/> 1. No radioactive materials have ever been procured or possessed by the licensee under this license. <input type="checkbox"/> 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner: <input type="checkbox"/> a. Transfer of radioactive materials to the licensee listed below:  <input type="checkbox"/> b. Disposal of radioactive materials: <input type="checkbox"/> 1. Directly by the licensee:  <input type="checkbox"/> 2. By licensed disposal site:  <input type="checkbox"/> 3. By waste contractor:  <input type="checkbox"/> c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.					
<b>C. SURVEYS PERFORMED AND REPORTED</b> <input type="checkbox"/> 1. A radiation survey was conducted by the licensee. The survey confirms: <input type="checkbox"/> a. the absence of licensed radioactive materials <input type="checkbox"/> b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA. <input type="checkbox"/> 2. A copy of the radiation survey results: <input type="checkbox"/> a. is attached; or <input type="checkbox"/> b. is not attached (Provide explanation); or <input type="checkbox"/> c. was forwarded to NRC on: _____ Date _____ <input type="checkbox"/> 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and <input type="checkbox"/> a. The results of the latest leak test are attached; and/or <input type="checkbox"/> b. No leaking sources have ever been identified.					
The person to be contacted regarding the information provided on this form:					
NAME		TITLE		TELEPHONE (Include Area Code)	E-MAIL ADDRESS
Mail all future correspondence regarding this license to:					
<b>C. CERTIFYING OFFICIAL</b> <b>I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT</b>					
PRINTED NAME AND TITLE			SIGNATURE		DATE
<b>WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 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.</b>					

# Goals of Licensing

- **limit access and use of radioactive material**
- **permit use of RAM by qualified individuals**
- **assure an adequate level of safety**
- **provide flexibility**
- **impose minimum restriction**

# COMPARISON OF VALID NRC LICENSE AND COUNTERFEITED GAO LICENSE

## Valid License Issued by NRC (Redacted)

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 4 PAGES

### 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	
1. [Redacted] Inc.	3. License number [Redacted]
2. [Redacted]	4. Expiration date March 31, 2017
	5. Docket No. [Redacted] 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. Cesium 137	A. Sealed Sources [Redacted]	A. 60 millicuries total, and no single source to exceed the maximum activity specified in the device's certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State
B. Americium 241	B. Sealed Sources [Redacted]	B. 200 millicuries total, and no single source to exceed the maximum activity specified in the device's certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State

9. Authorized use:

A. and B. In Troxler Electronic Laboratories Models 3400 series, and 4840B, and CPN International Model MC series portable gauging devices for measuring physical properties of materials.

## License Counterfeited by GAO (Redacted)

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 4 PAGES

### 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	
1. [Redacted]	3. License number [Redacted]
2. [Redacted]	4. Expiration date March 31, 2017
	5. Docket No. [Redacted] 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. Cesium 137	A. Sealed Sources [Redacted]	A. No single source to exceed the maximum activity specified in the device's certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State
B. Americium 241	B. Sealed Sources [Redacted]	B. No single source to exceed the maximum activity specified in the device's certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State

9. Authorized use:

A. and B. In Troxler Electronic Laboratories Models 3400 series, and 4840B, and CPN International Model MC series portable gauging devices for measuring physical properties of materials.

# GAO Sting

# Sealed Source & Device Registry Sample



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MD-497-S-107-S

DATE: January 18, 2001

PAGE 1 OF 7

SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)

DISTRIBUTOR: Nucletron Corporation  
7080 Columbia Gateway Drive  
Columbia, Maryland 21046  
Phone: 410 312-4100  
Facsimile: 410-3 12-4197

MANUFACTURER: Mallinckrodt Medical B .V.  
Westerduinweg 3  
NL-1755 LE Petten  
The Netherlands

ISOTOPE: Iridium-192

MAXIMUM ACTIVITY: 12 curie (444 GBq)

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: Yes ☐ No ☒

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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NO: MD-497-S-107-S

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SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)

DESCRIPTION:

The source is constructed of iridium-192 metal [source pellet dimensions 0.65 millimeters (mm) diameter, 3.6-mm length], which is single encapsulated in a stainless steel (AISI 316L) cylindrical capsule (capsule dimensions 0.9 mm diameter, 4.5 mm length). The source is at one side hemispherical and the other side welded to a metal plug and stainless steel flexible cable. At the other end of the cable a metal engraved tail is welded. The source cable is 2018 mm in length and consists of two sections. The first section is 1868 mm in length and 0.9 mm diameter with 19 strands of wire that are right crosslaid. A second section of more flexible cable has been welded to the distal end of the source cable and is 150 mm in length and 0.72 mm in diameter consisting of 7 strands of 7 stranded wire rope that is also crosslaid.

LABELING:

The source tail end-piece is engraved with a unique serial number and marked with a color code for type recognition.

DIAGRAMS:

See Attachments I & II

CONDITIONS OF NORMAL USE:

Sources will only be used in conjunction with model 105.999 (Nucletron Corporation MicroSelectron-HDR Version 2). Information pertaining to the operation and handling of the source in conjunction with the above device can be found in the Sealed Source and Device Sheet MD-497-D-108-S.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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NO: MD-497-S-107-S

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SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)

PROTOTYPE TESTING:

Mallinckrodt Medical B.V. has tested the sources in accordance with ISO 2919 and ISO 1677 requirements. The testing was conducted under the consultation of the Ministry of Medical Investigation and Testing (BAM) located in Berlin, Germany. The source achieved to classification designation ISO/C53211. This rating is comparable to model DRN 07735 (source formerly registered as CIL BV) in the MicroSelectron-HDR Classic. The cable portion of source was tested to withstand a curve (radius  $\geq 30$  mm) without permanent deformation and 150 mm from the cable part at the source side distal end must withstand a curve (radius  $\geq 15$  mm) without permanent deformation. The cable tensile strength is  $> 200$  Newton (N)

EXTERNAL RADIATION LEVELS:

For 12-curie source:

DOSE RATE IN AIR

<u>5 Centimeters</u>	<u>30 Centimeters</u>	<u>100 Centimeters</u>
2.3 E <sup>3</sup> R/hr	64 R/r	5.76 R/hr

QUALITY ASSURANCE AND CONTROL:

In addition to Mallinckrodt's regular quality control checks, all source welds are visually checked for weld sufficiency and all welded connections are mechanically tested by a pull test of 15 N of force for up to three (3) minutes. All sources are leak tested prior to shipment.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MD-497-S-107-S

DATE: January 18, 2001

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SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed only to persons specifically licensed by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.
- The source shall be leak tested at (6) month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.
- The source shall not be subjected to environmental or other conditions of use which exceed the ISO/C53211 classification.
- Handling, storage, use, transfer and disposal is to be determined by the licensing authority. Since these sources exhibit high surface dose rates when unshielded, the sources should be handled only by experienced licensed personnel using adequate remote handling equipment and procedures.
- This registration sheet and the information contained with the references shall not be changed or transferred without written consent of the Maryland Department of the Environment-Radiological Health Program.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and data submitted, we conclude that the model DRN 07736 (formerly 105.002) source is acceptable for licensing purposes. We conclude that this source would be expected to maintain its containment integrity for normal and accidental conditions which might occur during routine use.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MD-497-S-107-S

DATE: January 18, 2001

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SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)

REFERENCES:

The following supporting documents for the Model DRN 07736 source are hereby made part of this registry document.

The Nucletron Corporation application for evaluation received October 4, 1996; letters with attachments dated:

1. November 20, 1996;
2. November 26, 1996;
3. February 6, 1997;
4. July 20, 1998;
5. March 25, 1999;
6. April 22, 2000; and
7. November 3, 2000

DATE: 1/18/2001 REVIEWED BY: *Robert E. Hanley*  
DATE: 1/18/2001 CONCURRENCE: *Douglas K. McAbie*  
DATE: 1/22/2001 PROGRAM MANAGER I: *Carl E. Trump*  
DATE: 1/23/2001 ENVIRONMENTAL MANAGER: *Robert E. Hanley*

ISSUING AGENCY:

Maryland Department of the Environment  
Radiological Health Program  
2500 Broening Highway  
Baltimore, Maryland 21224



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MD-497-S-107-S

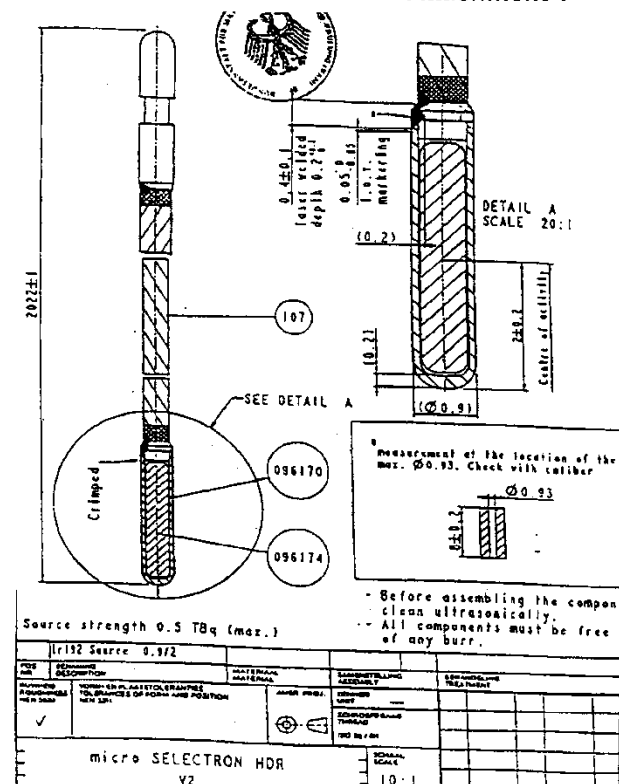
DATE: January 18, 2001

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SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)  
Baltimore, Maryland 21224

Attachment 1



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO: MD-497-S-107-S

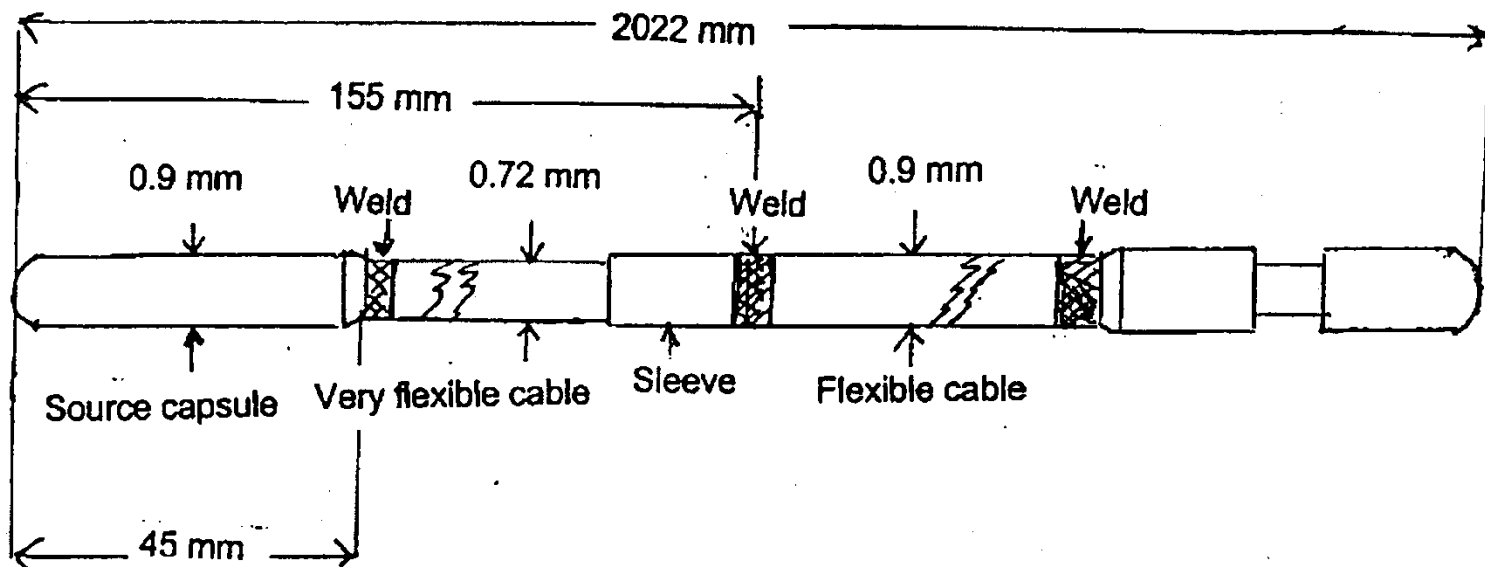
DATE: January 18, 2001

PAGE 7 OF 7

SOURCE TYPE: Medical Gamma Afterloading Source

MODEL: DRN 07736 (formerly 105.002)

**Attachment 2**



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# **END OF MATERIALS LICENSING**

A decorative gold crosshair consisting of a vertical line and a horizontal line intersecting in the upper left quadrant of the slide.

# **MATERIALS INSPECTION**

# Who's Responsible for Radiation Safety?

- **The licensee is ultimately responsible for the safety of its activities**
- **NRC and States assure protection of the public health and safety through regulation of the users.**
- **Proper design, fabrication and construction, procedures and training contribute towards safe operations, but we cannot inspect a licensee into safety.**

# Authorization

- **10 CFR 30.52 Inspections**
  - **Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.**
  - **Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.**

# Inspection Policy

## Inspection Manual Chapter

**2800 Materials Inspection Program 9/28/05**

## Inspection Procedures (samples)

**87121 Industrial Radiography Programs 8/22/05**

**87122 Irradiator Programs 12/31/02**

**87123 Well Logging Programs 11/25/03**

**87124 Fixed and Portable Gauge Programs 11/25/03**

**87126 Industrial/Academic/research Programs 9/28/05**

**87127 Radiopharmacy Programs 7/1/08**

**87132 Brachytherapy Programs 12/06/05**

## Temporary Instructions (samples)

**2800-030      Verification of the Status of Devices Authorized  
For Use Under a General License**

**2800-037      Safety Procedures For Panoramic Irradiators**

# Purpose of Inspections

- **Performance** - to determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public
- **Compliance** - to determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission requirements
- **The inspector's job is to identify problems, not violations**

# Announced vs Unannounced

- **Manual Chapter 2800 states that all routine materials inspections should be performed on an unannounced basis**
- **Initial inspections – should be announced**
- **Inspectors may announce inspections of licensees located in remote areas**

# Priorities

**Frequency  
In  
Months**

Priority	Earliest	Due Date	Latest
I	9	12 (1 yr)	15
II	18	24 (2 yr)	30
III	27	36 (3 yr)	45
V	48	60 (5 yr)	72

**Note: time interval between inspections based on level of hazard**

**new licensees or an existing licensee which obtained an amendment for medical therapy “other emerging technology” must be inspected within one year of license issuance and every year after that until operations commence**

An iceberg floating in the ocean. The tip of the iceberg is above the water line, and the much larger base is submerged. The image is used as a metaphor for research methods, where the visible tip represents a small portion of the total data or activity being studied.

**records  
review**

**surveys**

**interviews**

**demonstration  
of activities**

**observation  
of activities**

# Inspection Activities

The inspector evaluates licensee performance relative to the following Focus Elements:

- security and control of licensed material;
- shielding of licensed material;
- comprehensive safety measures;
- radiation dosimetry program;
- radiation instrumentation and surveys;
- radiation safety training and practices; and
- management oversight

# Documenting Violations

## Summary

- **Is there a requirement?**
- **Is it enforceable?**
- **Is it applicable?**
- **Are there any exemptions?**
- **Document your findings**

# NRC FORM 591M

## (IMC 2800 Enclosure 5)

Used to document clear inspections and all non-willful, non-repetitive Severity Level IV violations and non-cited violations, for which licensee management can correct while the inspector is present or can correct easily (e.g., leak test)

ENCLOSURE 8	
NRC FORM 591M PART 1 (10-2003) 10 CFR 2.201	
U.S. NUCLEAR REGULATORY COMMISSION	
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION	
1. LICENSEE/LOCATION INSPECTED:	
2. NRC/REGIONAL OFFICE	
REPORT	
3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)
5. DATE(S) OF INSPECTION	
LICENSEE:	
<p>The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:</p>	
<input type="checkbox"/> 1. Based on the inspection findings, no violations were identified.	
<input type="checkbox"/> 2. Previous violation(s) closed.	
<input type="checkbox"/> 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.	
_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):	
<input type="checkbox"/> 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.	
(Violations and Corrective Actions)	
Licensee's Statement of Corrective Actions for Item 4, above.	
I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.	
Title	Printed Name
LICENSEE'S REPRESENTATIVE	Signature
NRC INSPECTOR	Date

NRC FORM 591M PART 1 (10-2003)

**Form signed by inspector and licensee management representative, confirming acceptance of violation(s) and acknowledging corrective actions**

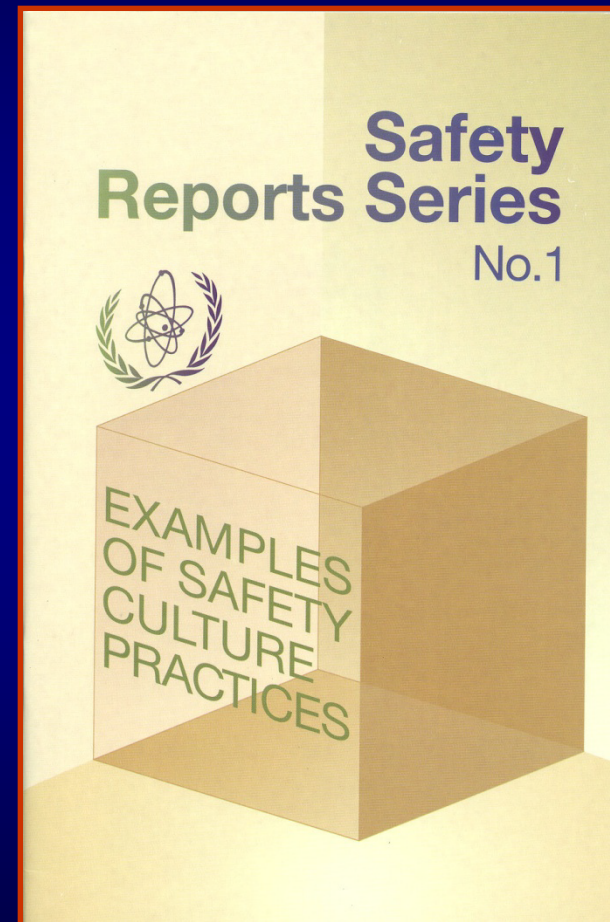
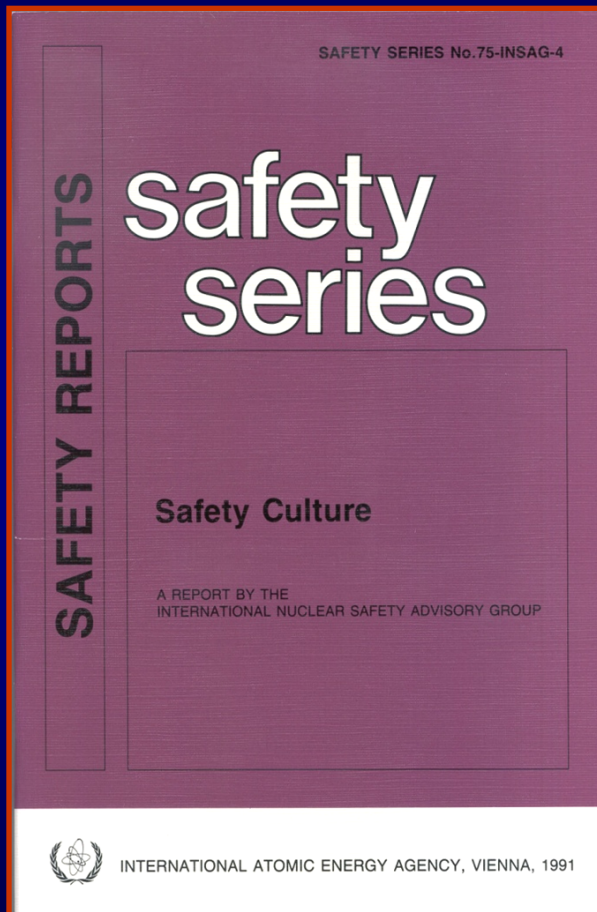
<b>NRC FORM 591M PART 2</b> <small>(10-2003)</small> <small>10 CFR 2.201</small>		<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	
<b>SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION</b>			
<b>1. LICENSEE</b>  REPORT		<b>2. NRC/REGIONAL OFFICE</b>	
<b>3. DOCKET NUMBER(S)</b>	<b>4. LICENSE NUMBER(S)</b>	<b>5. DATE(S) OF INSPECTION</b>	
(Continued)			


# **“Safety Culture”**

**The inspector should develop a general sense of the licensee’s safety culture for licensed activities (for example):**

- workers have a “questioning attitude” and generally adhere to procedures,**
- workers are duly cautious when engaged in licensed activities,**
- worker relationships with supervisors are conducive to raising safety concerns**

# “Safety Culture”



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# **END OF MATERIALS INSPECTION**