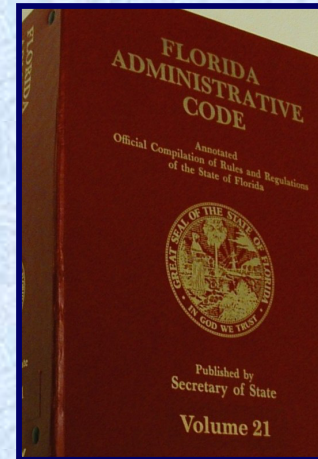


Federal & State Regulations



Federal & State Regulations

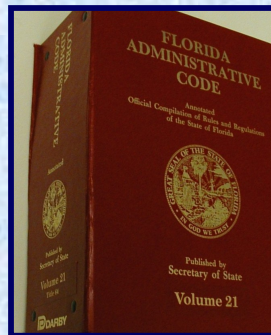
Learning Objectives

- Understand federal & equivalent state regulations applicable to ind. radiography, with emphasis on:
 - Licensing & registration of radiation sources
 - Jurisdiction & reciprocity
 - Safety evaluations of sources & devices (SS&DR)
- Describe how radiography licensees address regulatory requirements

Federal & State Regulations

U.S. Code
State Statutes = *Laws*

Code of Federal Regulations
State Administrative Codes = *Regulations*
(How to implement the laws)



Federal Regulations - X-ray Machines



U.S. Food and Drug Administration



Title 21, Code of Federal Regulations (CFR) Food & Drugs

Chapter I Food & Drug Administration,
 Dept. of Health & Human Services

Part 1000 General

Part 1020 Performance Standards for
 Ionizing Radiation Emitting Products

Federal Regulations: 21 CFR

Part 1020 Performance Standards for Ionizing Radiation Emitting Products

Sec. 1020.31 Radiographic equipment

- Applies to equipment used to record of images, except equipment using an image intensifier or CT x-ray systems



Federal Regulations: 21 CFR, Part 1020

Sec. 1020.40 Cabinet x-ray systems

Definitions

X-ray system



Cabinet x-ray system



Federal Regulations: 21 CFR



Enforcement



21 CFR Part 1

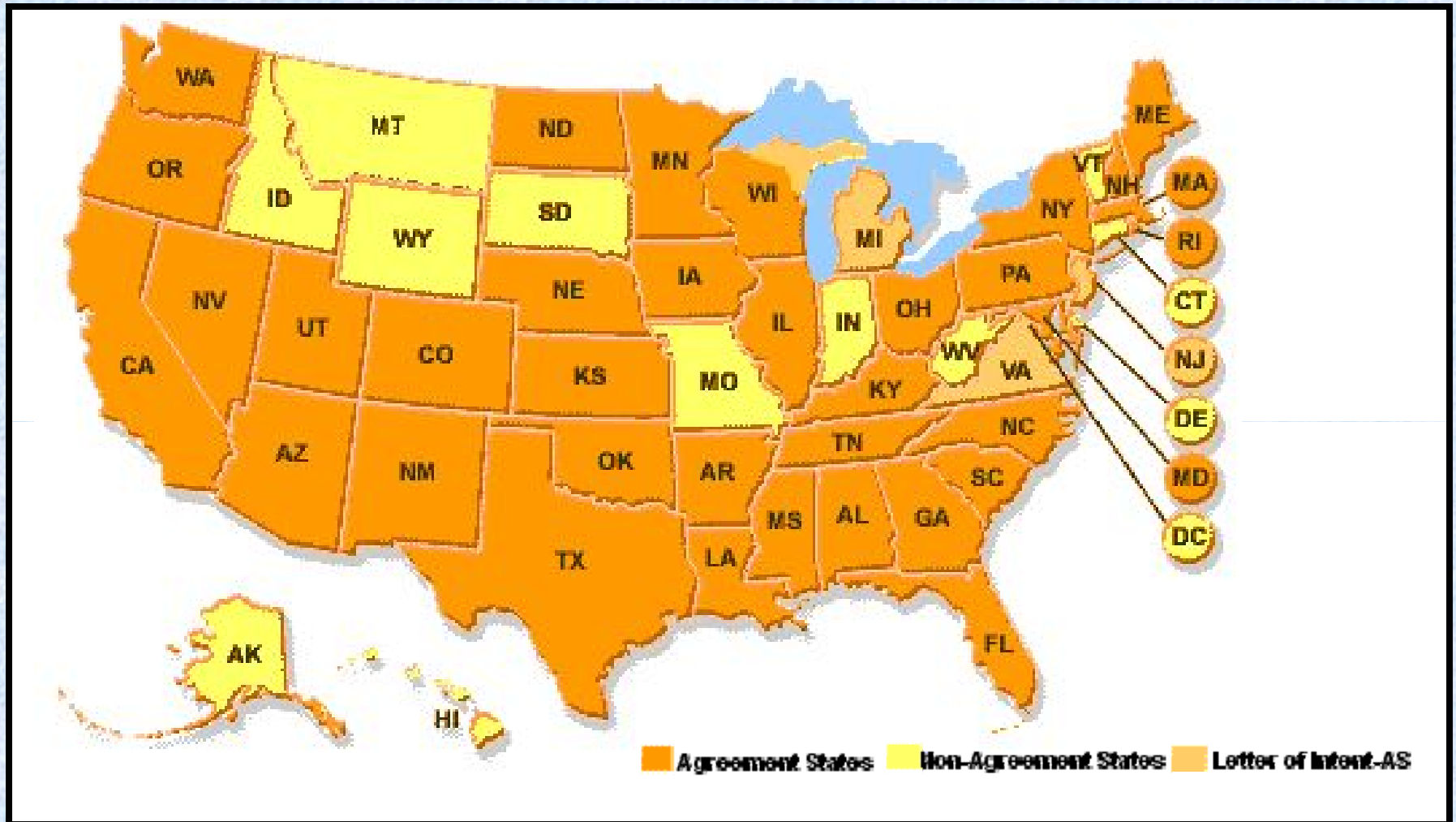
FDA general enforcement regs

21 CFR Part 7

FDA enforcement policy

- FDA doesn't conduct routine inspections
- FDA response to an allegations is to ask mfr. to correct problem voluntarily
- FDA can get injunctions & prosecute violators

The Regulatory Landscape for RAM



38 states have an agreement w/ the NRC to allow state regulation of radioactive materials within their borders.

Federal & State Regulations

Jurisdiction & Reciprocity

10 CFR Part 150

Exemptions & Continued Regulatory Authority in Agreement States and in Offshore Waters

"...any person holding a specific license from an agreement state... is hereby granted a general license to conduct the same activity in non-agreement states... and offshore waters."

Federal & State Regulations

Reciprocity for Ind. Radiographer Certification

Independent Certifying Organizations

States

AL	IL	ND
GA	IA	TX
	LA	

ASNT



Federal & State Regulations

Jurisdiction & Reciprocity

Licensees are subject to:

- **NRC regulations**
- **All terms & conditions of their specific license**
- **Advance notification: at least 3 days notice before engaging in licensed activities**
- **File Form 241, "Report of Proposed Activities in Non Agreement States" with appropriate NRC Regional Administrator**

Licensing Requirements

10 CFR Part 150

Standard Rules of General Applicability to Domestic Licensing of Byproduct Material

- **General Provisions**
- **Exemptions**
- **Licenses**
- **Records, Inspections, Tests & Reports**
- **Enforcement**

NUREG-1556, Vol. 2

Program Specific Guidance About Industrial. Radiography Licenses

NUREG-1556
Vol. 2

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About
Industrial Radiography Licenses

Final Report

Manuscript Completed: August 1998
Date Published: August 1998

Prepared by
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Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Applicable Regulations

It is the licensee's responsibility to have up-to-date copies of applicable regulations, be familiar with them, & abide by them

10 CFR Part 19

10 CFR Part 20

10 CFR Part 21

10 CFR Part 34

10 CFR Part 71

Applicable Regulations

It is the licensee's responsibility to have up-to-date copies of applicable regulations, be familiar with them, & abide by them

10 CFR Part 2

10 CFR Part 30

10 CFR Part 40

10 CFR Part 150

10 CFR Part 170

10 CFR Part 171

How & Where To File

NRC Form 313

NRC FORM 313 10-2004 10 CFR 31.32, 33, 34, 35, 36, 37, and 40		U.S. NUCLEAR REGULATORY COMMISSION APPROVED BY OMB: NO. 3150-0126 Estimated burden per response to comply with this mandatory collection request: 7 hours. Submission of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety and, except as noted, reporting burden estimate to the Records and Communications Service Branch (1-5 P&S), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to nrcinfo@nrc.gov, and to the Desk Officer, Office of Administration and Regulatory Affairs, NRC HQ, 1200 25th St., Office of Management and Budget, Washington, DC 20503. If a media 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.			
APPLICATION FOR MATERIAL LICENSE					
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.					
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF RADIATION MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001		IF YOU ARE LOCATED IN: ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, ILLINOIS, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, VERMONT, VIRGINIA, WISCONSIN, WYOMING, FILE APPLICATIONS TO: MATERIALS LICENSES BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION 1 200 WATERVILLE ROAD, SUITE 270 LITTLE ROCK, AR 72202-4002			
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, ILLINOIS, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, VERMONT, VIRGINIA, WISCONSIN, WYOMING, FILE APPLICATIONS TO: LICENSED ASSISTANCE TEAM DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF RADIATION MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION, REGION 1 200 WATERVILLE ROAD LITTLE ROCK, AR 72202-4002		ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, ILLINOIS, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, VERMONT, VIRGINIA, WISCONSIN, WYOMING, FILE APPLICATIONS TO: RADIATION MATERIALS LICENSES BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION 1 200 WATERVILLE ROAD, SUITE 270 LITTLE ROCK, AR 72202-4002			
PERSONS LOCATED IN ALABAMA: STATE FILE APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WANT TO POSSESS AND USE LICENSED MATERIAL IN THEIR STATE TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.					
1. IS THIS AN APPLICATION FOR: (Check appropriate box) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. REMOVAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) TELEPHONE NUMBER: _____			
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED 		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION TELEPHONE NUMBER: _____			
SUBMIT FORMS 3 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. ISOTOPES AND FORMS: _____ B. PHYSICAL FORM: _____ C. QUANTITY: _____		6. PURPOSES 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 FREQUENTLY IN RESTRICTED AREAS: 			
9. FACILITIES AND EQUIPMENT: 		10. RADIATION SAFETY PROGRAM: 			
11. WASTE MANAGEMENT: 		12. LICENSE FEE: (See 10 CFR 170.20 and 170.21) FEE CATEGORY: _____			
13. CERTIFICATION: (Must be completed by applicant. THE APPLICANT UNDERTAKES THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE TRUE AND CORRECT TO THE BEST OF THE APPLICANT'S KNOWLEDGE AND BELIEF.) THE APPLICANT AND ANY OFFICIAL ENDORSING THIS CERTIFICATION ON BEHALF OF THE APPLICANT (NAMED IN ITEM 3) CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMANCE WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 31.32, 33, 34, 35, 36, 37, 38, 39, 40, AND 41, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THE APPLICANT'S KNOWLEDGE AND BELIEF. WITNESSED: BY U.S.C. SECTION 161(a) ACT OF JUNE 30, 1949 (AS AMENDED), PENALTY FOR MAKING A FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER GOVERNED BY JURISDICTION.					
CERTIFYING OFFICER - TYPE PRINTED NAME AND TITLE 		SIGNATURE _____ DATE _____			
FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY					
NRC FORM 313 (10-2004)				PRINTED ON RECYCLED PAPER	

Contents of an Application

License Action Type

- New, renewal, amendment

Applicant Name & Mailing Address

- Legal name of corporation or other legal entity
- Timely notification of transfer control; requires prior written consent
- Notification of bankruptcy proceedings

Contents of an Application

Addresses Where Licensed Material Will Be Used

- Street address or other descriptive address of:
 - Each permanent radiographic installation
 - Each field station
- Specify "temporary jobsites anywhere in the U.S." or offshore waters

Person To Be Contacted About Application

- Typically the RSO

Contents of an Application

RAM: Sealed Sources & Devices



Contents of an Application

**Individuals Responsible for Rad. Safety Program
Training & Experience**

Radiation Safety Officer



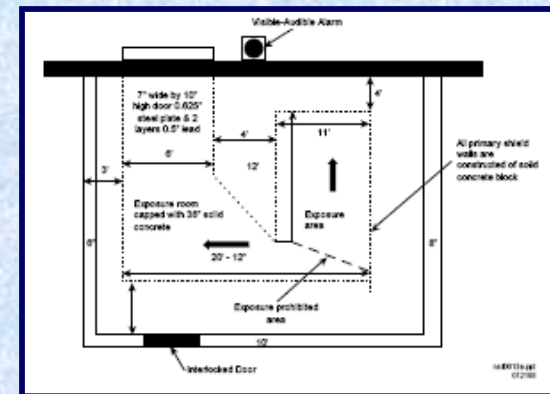
Contents of an Application

Training For Radiographers & Assistants **10 CFR 34.43**



Facilities & Equipment

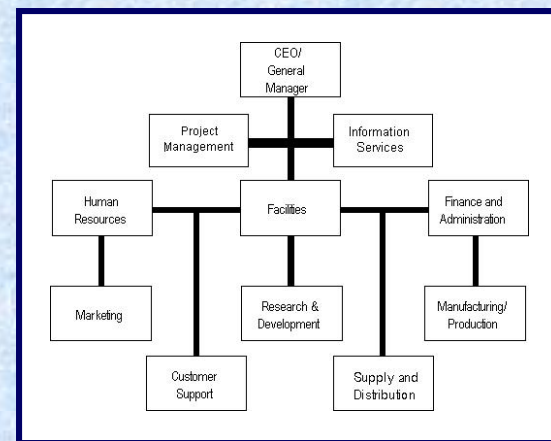
- Facility diagram(s) & detailed supporting info
- RAM storage area diagram
- Permanent radiographic installation(s) at principal facility & any field sites & detailed supporting info on construction, rad. levels
- Safety equipment (e.g., visible/audible alarm)
- Description of security measures (now considered restricted information)



Radiation Safety Program


RSP must contain the following elements:

- RSP organization structure & responsible individuals
- Steps to keep exposures ALARA
- Description of facilities & equipment
- Worker qualifications (training & experience)
- O&E procedures
- Internal audit program
- Records management



Operating & Emergency Procedures

**Procedures must be
specific to company's
activities**

	NDE RADIATION SAFETY MANUAL	Chapt. RSM 6
	CHAPTER 6	Rev. 4
		Page 1 of 23
OPERATING PROCEDURES		
<u>CONTENTS</u>		
6.0	PURPOSE & SCOPE	
6.1	RADIATION SAFETY & RADIOGRAPHIC PERSONNEL	
6.2	RADIOGRAPHIC EQUIPMENT	
6.3	PERSONNEL MONITORING (PM) DEVICES	
6.4	SURVEY METERS	
6.5	RECORDS	
6.6	DAILY EQUIPMENT INSPECTION	
6.7	SECURITY OF RADIOGRAPHIC EQUIPMENT	
6.8	TRANSPORTATION OF RADIOACTIVE MATERIAL	
6.9	RADIOGRAPHIC OPERATIONS – GENERAL	
6.9	RADIOGRAPHIC OPERATIONS – GAMMA	
6.10	RADIOGRAPHIC OPERATIONS – X-RAY	
RSM CHAPTER 6 – OPERATING PROCEDURES		TABLE OF CONTENTS

Additional Requirements

- **Leak Testing**
- **Dosimetry**
- **Daily Inspection & Maintenance of Equipment**
- **Quarterly Inspection & Maintenance**
- **Controlling Access to Radiographic Areas**
- **Procedure for Identifying & Reporting Defects**
- **Source Retrieval**
- **SS&D Registry**

SS&D Registry

Sample SDDR: Source Production's Model SPEC 150 Radiographic Exposure Device

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

NO: LA612D111S DATE: DECEMBER 20, 1994 PAGE 1 OF 12

DEVICE TYPE: Radiographic Exposure device

MODEL: SPEC 150

MANUFACTURER/DISTRIBUTOR: Source Production & Equipment Company
113 Teal Street
St. Rose, LA 70087-9691

SEALED SOURCE MODEL DESIGNATION: SPEC G-60

ISOTOPE: Iridium -192 MAXIMUM ACTIVITY: 5550 GBq
(150 Curies)

Depleted Uranium
(Shielding) 17kg
(37 lbs)

LEAK TEST FREQUENCY: N/A

PRINCIPAL USE CODES: A - Industrial Radiography

CUSTOM DEVICE: ___YES XX NO

Federal & State Regulations



Questions?