

United States Nuclear Regulatory Commission: Function, Framework, Alternative Technologies

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Topics

- Introduction to the Nuclear Regulatory Commission
 - Agreement States
 - Statements of Policy
- The rulemaking process(es)
- Risk-based or risk-informed
- Sources of information:
 - Regulatory basis/assessment
- Safety-Security integration – the requirements
- Alternative technologies

Introduction to the Nuclear Regulatory Commission

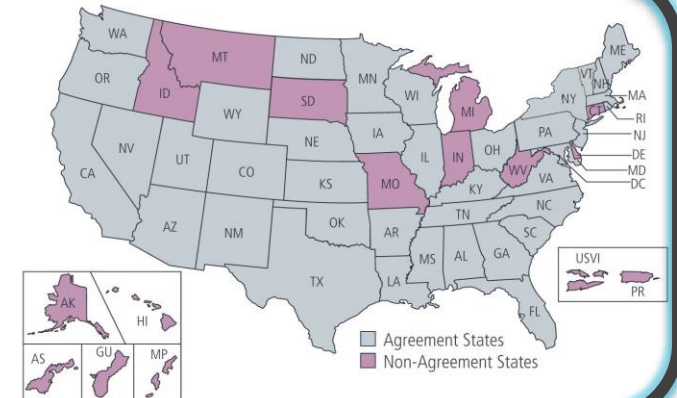


License and regulate the Nation's civilian use of radioactive* materials to ensure adequate protection of the public health and safety, promote the common defense and security, and to protect the environment.

~19,300 total specific licenses in the US civilian sector for use of radioactive material

- ~2,800 regulated by the NRC
- ~16,500 regulated by Agreement States

~31,000 total general license device holders



*"radioactive" includes byproduct, source, and nuclear materials

Statements of Policy

Commission's general attitude or opinion on a topic

- provide a clear understanding of their expectations of how the regulated community should act in specific circumstances
- to explain clearly how the Commission and the NRC intends to conduct itself

Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination.
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.



[7590-01-P]

REGULATORY COMMISSION

[NRC-2010-0209]

U.S. Nuclear Regulatory Commission

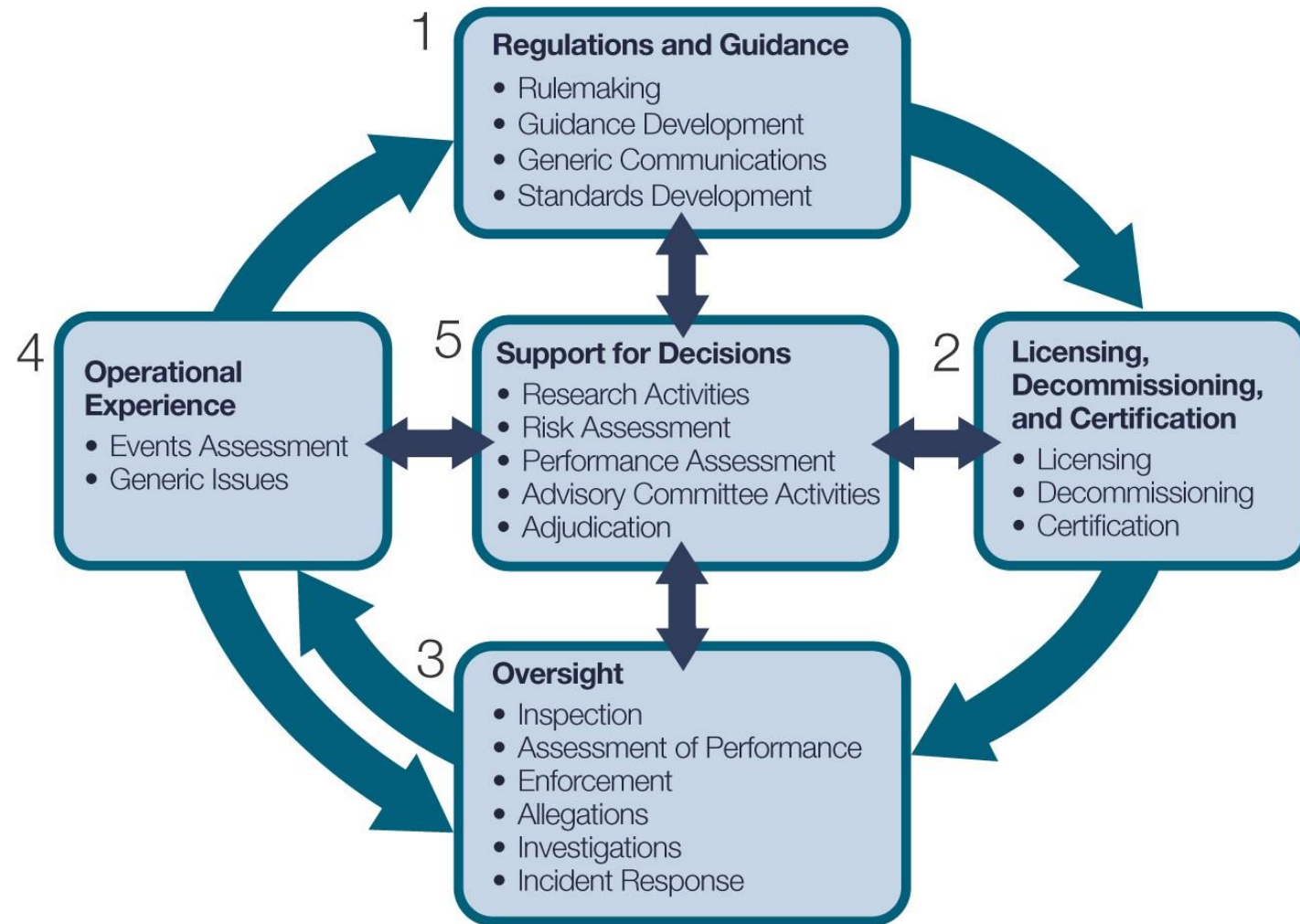
on the Protection of Cesium-137 Chloride Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Final Policy Statement on the Protection of Cesium-137 Chloride Sources.

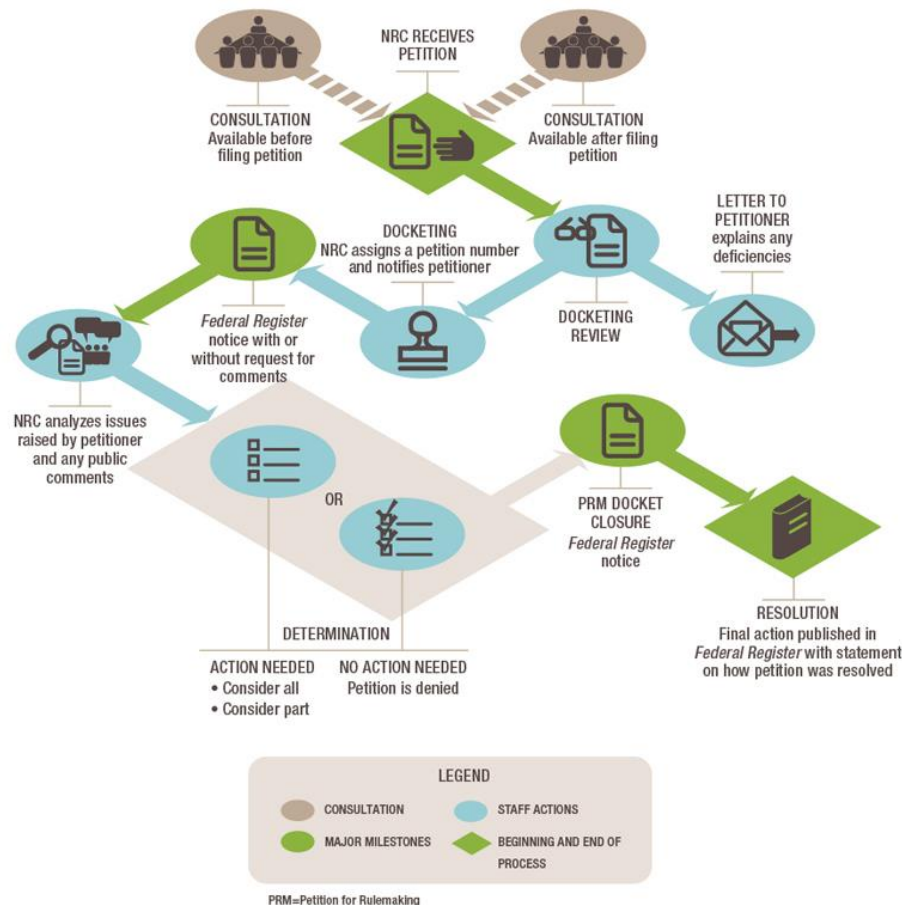
SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a statement of policy on the protection of cesium-137 chloride (CsCl) sources. This statement sets forth the Commission's policy regarding secure uses of these sources at the present and states the Commission's readiness to respond with additional security requirements, if needed, should the threat environment change. The purpose of this policy statement is to delineate the Commission's expectations for security and safety of these sources.

The overall rulemaking process:

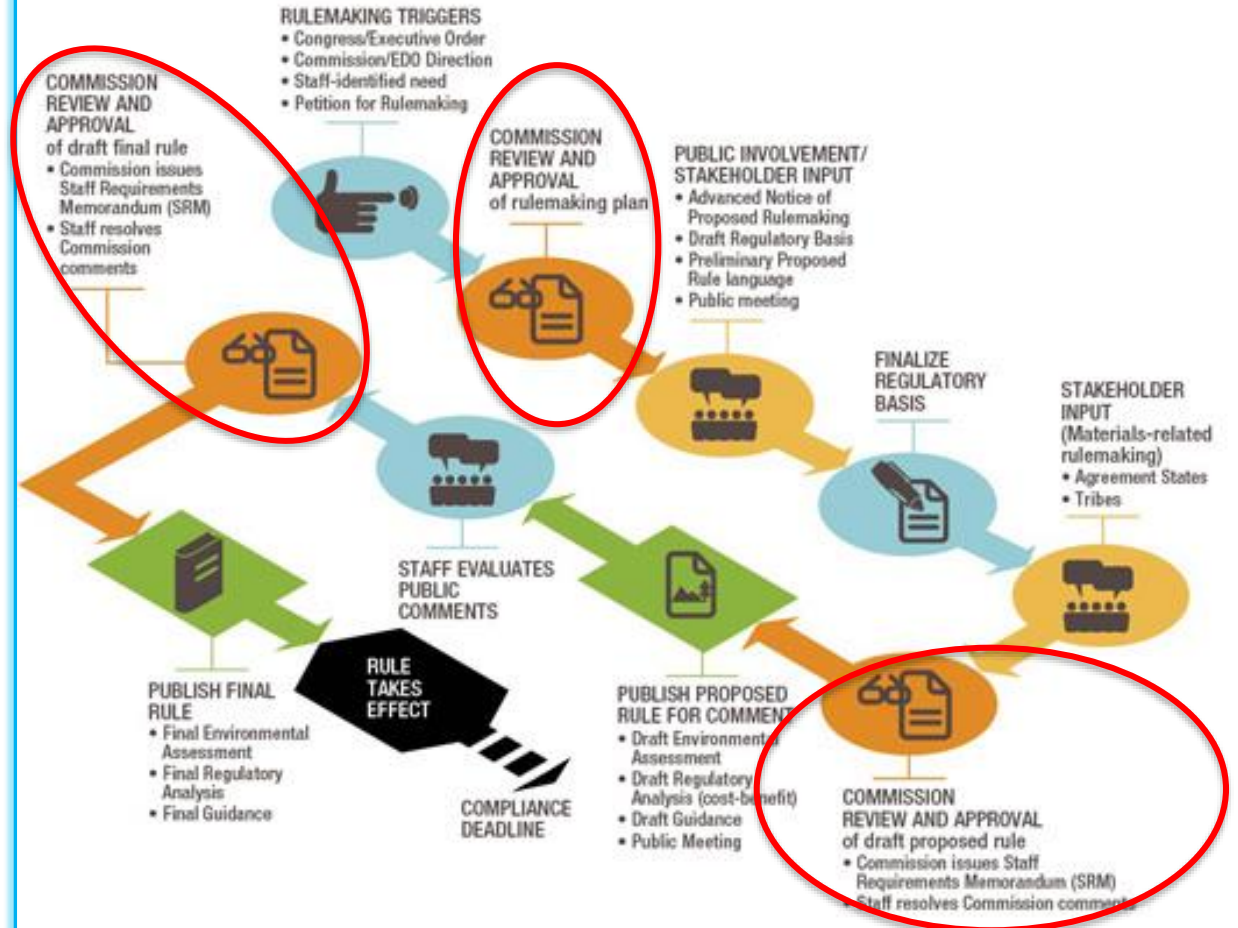


Rulemaking

Typical Petition for Rulemaking Process



A Typical Rulemaking Process



Risk-based vs. Risk-informed

What can go wrong?

How likely is it?

What would be the consequences?

High Probability, High Consequence.

An expedition to Mount Everest has a high probability of serious consequences, such as a fatal fall or frozen extremities. As a result, the overall risk is considered to be very high.



Low Probability, High Consequence.

A skydiving accident, in which the parachute fails to open, can also have severe consequences (including fatality). However, the risk is acceptable to many people because using the proper safety precautions can adequately reduce the probability of an accident. As a result, the overall risk is considered to be moderate.



High Probability, Low Consequence.

A unicyclist has a relatively high probability of falling. However, the consequences of such an accident are relatively minor. The unicyclist usually lands on his or her feet or, at worst, takes a tumble. Thus, even though the probability of falling is high, the consequences are so minor that the overall risk is low.



Risk-based vs. Risk-informed

What can go wrong?



How likely is it?

Category 1 & 2

	RADIOGRAPHY					
	Theft (7 Events)		Left on Tailgate	Shipping	Abandon	Weather
	Truck+ Device	Device (Only)				
LOST	4	3	7	5	7	1
RECOVERED	4	2	7	5	7	1
TOTAL EVENTS	27					

Category 3

	Radiography		
	Lost in transit	Weather	Dropped in Ocean
LOST	2	1	1
RECOVERED	2	1	0
TOTAL	4		

What are the potential consequences?

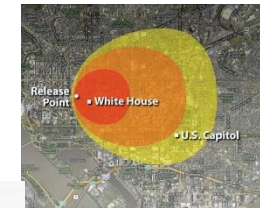
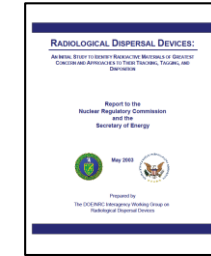


...and what should/can we do to prevent it?

- A. Reasonable assurance of adequate protection
- B. Absolute protection (zero risk)

What information comes in:

- Intelligence – domestic and international
- Official reports – suspicious and actual
- Studies and reports:
 - Other US agencies
 - NAS
 - International partners (IAEA)
- Operating experience – domestic and international
- “related” events
- Petitions for rulemaking
- Commission direction / legislation



NRC's Graded Approach – 3 “groups”

Exempt

10 CFR 30.14 – 30.22

- Low concentrations of radioactive material used by the public, such as smoke detectors, marine compasses, watch hands, static eliminators
- No appreciable safety or security impact, therefore no requirements for users

General

10 CFR Part 31

- Devices for detecting, measuring, gauging, producing light, producing an ionized atmosphere
- Inherent safety via engineering design
- Loss, theft, damage, and/or malfunction must be reported
- Cannot be abandoned
- Limited scenarios for transfer, including for disposal, from initial user to other

Specific

- All other radioactive and nuclear materials
- 10 CFR Part 19 Notices, instructions and reports to workers: inspection and investigations
- 10 CFR Part 20 Standards for protection against radiation
- 10 CFR Part 21 Reporting of defects and noncompliance
- Other applicable regulations

NRC's Graded Approach – within the Specific License

All radioactive and nuclear material that is neither exempt nor held under the general license. Includes all industrial, medical, research, calibration, manufacturing, distribution, and accelerator-produced uses of material. Minimum 2 independent physical barriers for portable gauges

Additional control measures specific to modalities of use.
Part 32: manufacture or distribute
Part 33: broad scope activities
Part 34: industrial radiography
Part 35: medical
Part 36: panoramic irradiator
Part 39: well logging

Additional explicit physical protection measures for radioactive material quantities $\geq$ category 2 (roughly the same as the *Code of Conduct on the Safety and Security of Radioactive Sources*)

Enhanced physical protection
[10 CFR Part 37]

Modality-based [various parts]

Basic performance-based control measures for safety and security
[10 CFR Part 20 & 10 CFR Part 30]

Selected Regulations – 10 CFR Part

19	Notices, instructions and reports to workers: inspection and investigation
20	Standards for protection against radiation
21	Reporting of defects and noncompliance
32	Specific domestic licenses to manufacture or transfer certain items containing byproduct material
33	Specific domestic licenses of broad scope for byproduct material
34	Licenses for industrial radiography and radiation safety requirements for industrial radiographic operations
35	Medical use of byproduct material
36	Licenses and radiation safety requirements for irradiators
37	Physical protection of category 1 and 2 quantities of radioactive material
39	Licenses and radiation safety requirements for well logging
40	Domestic licensing of source material
61	Licensing requirements for the packaging and land disposal of radioactive waste
70	Domestic licensing of special nuclear material
71	Packaging and transportation of radioactive material



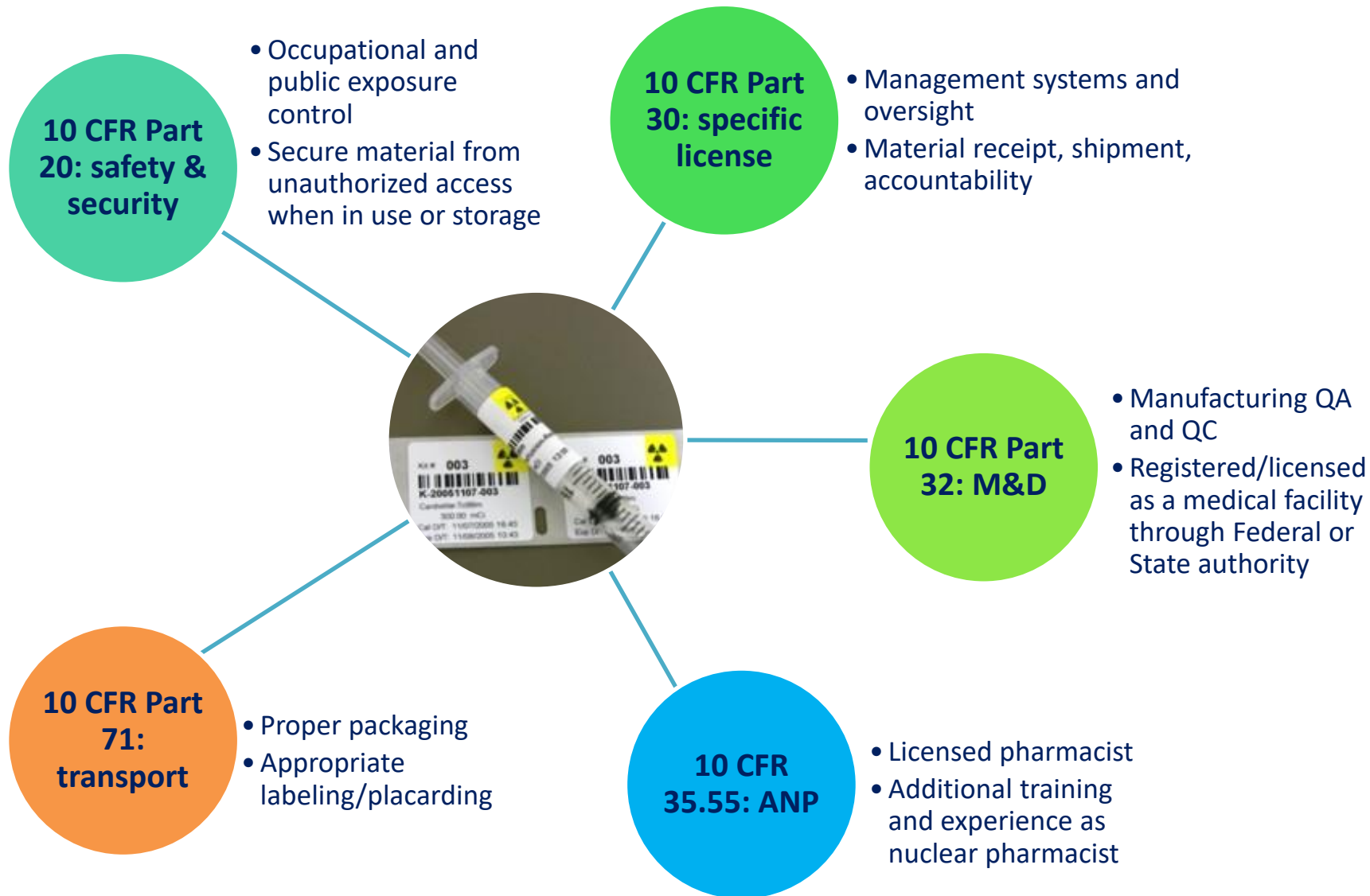


Image: CentraMed Radiopharmacy

Example 1: radiopharmacy

Inspection focus areas:

- Security and control of material
- Maintain shielding of material
- Comprehensive safety measures
- Radiation dosimetry
- Radiation instrumentation
- Knowledgeable and trained staff
- Internal management systems and oversight

Example 2: panoramic irradiator

Inspection focus areas:

- Security and control of material
- Maintain shielding of material
- Comprehensive safety measures
- Radiation dosimetry
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- Knowledgeable and trained staff
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Non-isotopic Technologies

Remember:

- NRC mission is to **license and regulate the Nation's civilian use of radioactive and nuclear materials to ensure adequate protection of the public health and safety, promote the common defense and security, and to protect the environment**
- NRC authority is limited to radioactive and nuclear materials – no authority over machine generators of radiation
- NRC does not regulate the sectors (medical, research, energy, construction, ...)
- NRC, to maintain objectivity and independence, **does not promote any technology** or influence business decisions

Alternative Technologies

Relevant activities:

- 2005** Atomic Energy Act established the *Radiation Source Protection & Security Task Force* – alternative technologies, both non-isotopic and lower activity, are included
- 2008** NAS *Radiation Source Use and Replacement*
- 2011** *Policy of the U.S. Nuclear Regulatory Commission on the Protection of Cesium-137 Chloride Sources*
- 2016** GARS *Transitioning from High-activity Radioactive Sources to Non-radioisotopic (Alternative) Technologies*
- 2019** *Non-radioisotopic Alternative Technologies White Paper*

Conclusion

- All licensed radioactive material has security requirements commensurate with the associated risk posed by radiation
- Graded approach allows the NRC and Agreement States to ensure consistent adequate protection while enabling beneficial uses of radioactive materials across the United States
- Fully integrating safety and physical protection measures allows licensees to develop custom programs that complement their specific needs and meet all regulatory requirements – including those of other authorities

THANK YOU



**NRC Radioactive
Materials Security**



**NRC Public
Website
(www.nrc.gov)**



NRC 10 CFR Part 37