

United States Nuclear Regulatory Commission

The Application of the Graded Approach to

Physical Protection of Radioactive Sources in

the United States

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Regulatory Options:

One For All

- a single set of regulations is applicable in circumstances
- consider exemptions or amendments

Tailored

- each licensee's requirements are specific to their case

Graded

- licensees / uses / circumstances are grouped
- different sets of regulations are applicable based upon group

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]

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

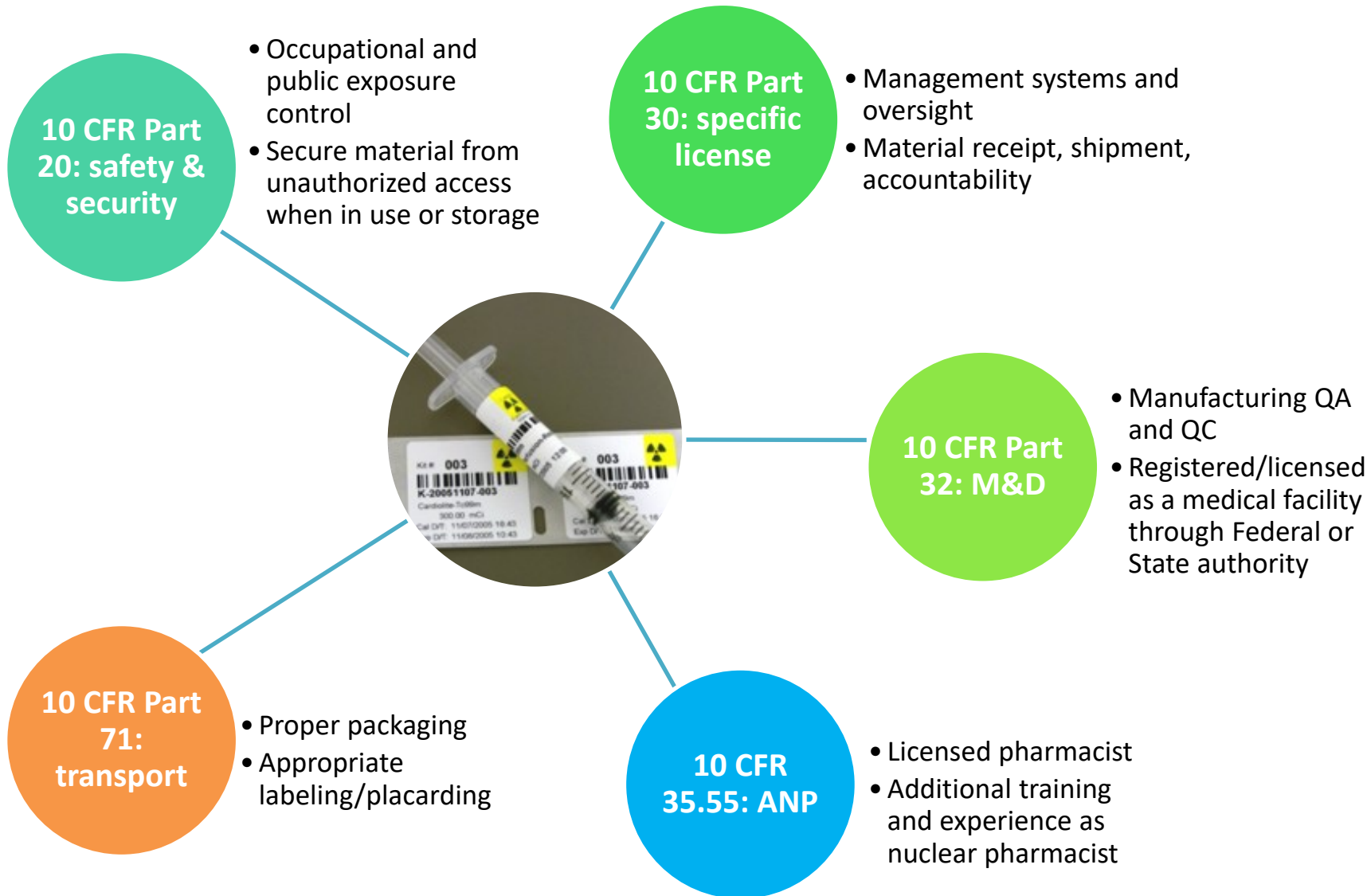


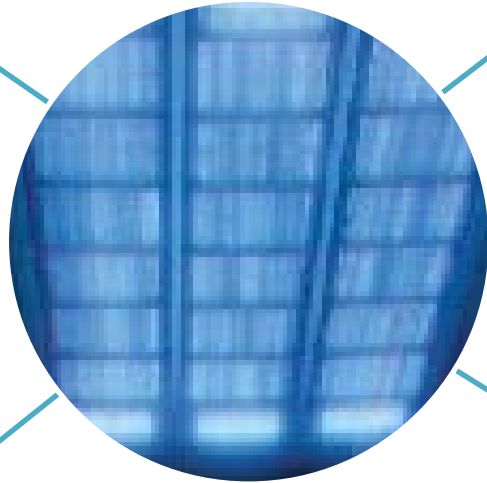
Image: CentraMed Radiopharmacy

10 CFR Part 20: safety & security

- Occupational and public exposure control
- Secure material from unauthorized access when in use or storage

10 CFR 37: enhanced security

- T&R personnel
- Security plans and procedures
- Detect, assess, respond to all unauthorized access (performance based)
- Report suspicious activities
- Detect, assess, respond to removal of material from the security zone (prescriptive)



10 CFR Part 36: irradiators

- Facility shielding and access control
- Attendance during operation

10 CFR Part 30: specific license

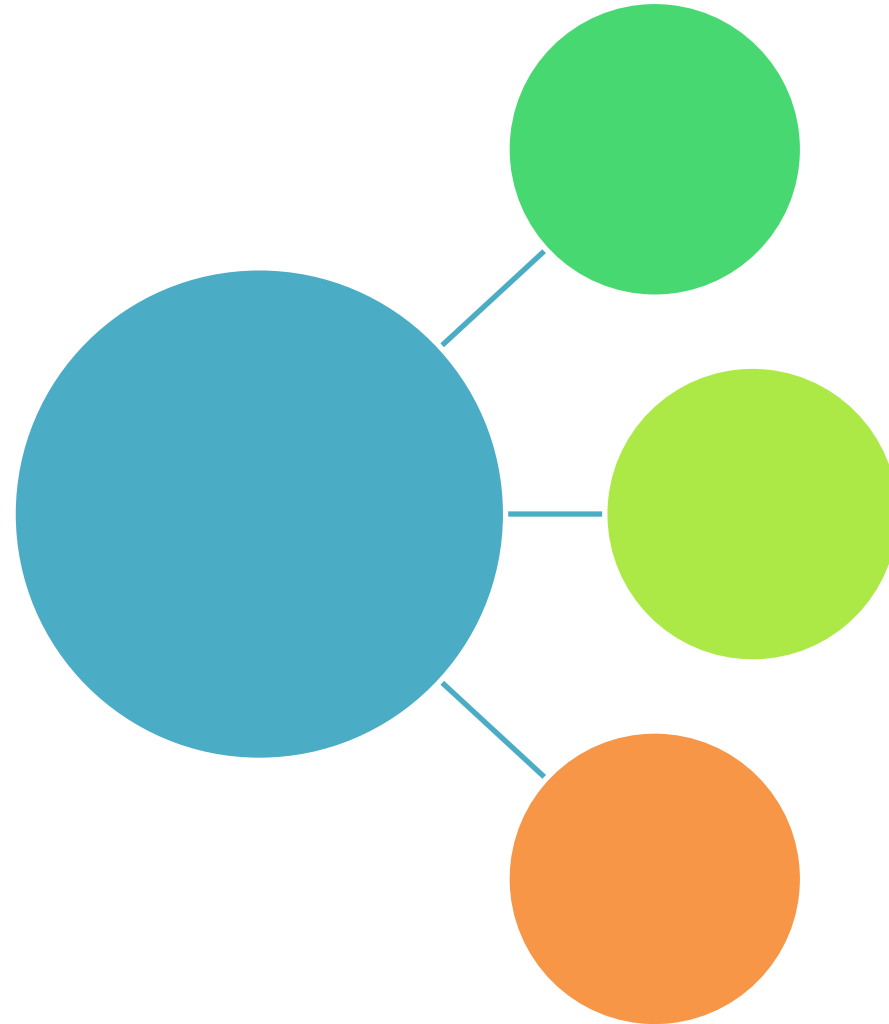
- Management systems and oversight
- Material receipt, shipment, accountability

Example 2: panoramic irradiator

Inspection focus areas:

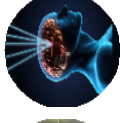
- Security and control of material
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- Radiation dosimetry
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Another example?



Conclusion

- ✿ All licensed radioactive material has security requirements commensurate with the associated risk
- ✿ 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
- ✿ NRC and Agreement States have developed, and enforce, security requirements that:
 - ✿ optimize the regulator's limited financial and professional resources; and
 - ✿ acknowledge and complement the authorities of other entities
- ✿ Graded approach does mean that both the regulator and the licensee must be technically competent to fully understand ALL requirements, not just bits and pieces



THANK YOU



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Procedures**



**NRC Public
Website
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NRC 10 CFR Part 37
