

U.S. NRC  
UNITED STATES NUCLEAR REGULATORY COMMISSION  
*Protecting People and the Environment*

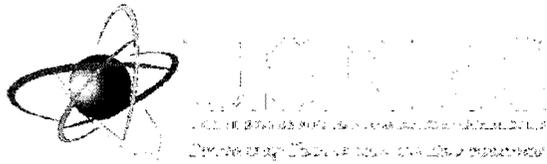
# **Quality in Radiation Therapy: The Important Dimensions of Quality from a Regulatory Agency's View Point**

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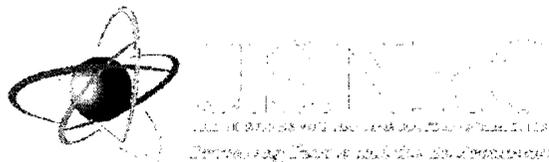
AAPM-ASTRO Safety Conference

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## Questions To Be Addressed

- What does quality in radiation therapy mean to the NRC?
- How does NRC measure or determine that quality practices are being followed or implemented?
- What does NRC recommend to be pro-active in reducing the probability of incidents?



## What NRC Doesn't Do

- NRC avoids involvement with medical practice issues, except as they relate to worker, public, and/or patient radiation safety.
- Ref: NRC Medical Use Policy Statement (2000) at <http://www.nrc.gov/reading-rm/doc-collections/commission/policy/65fr47654.pdf>



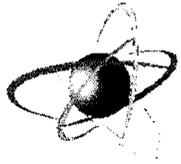
## What NRC Does (1<sup>st</sup> question-quality)

- NRC emphasizes, through training and experience requirements, properly qualified responsible individuals being authorized for medical use.
- Ref: 10 CFR Part 35 (Medical Use Regulations) at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/>



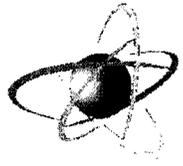
## **What NRC Does (1<sup>st</sup> question-quality) (cont.)**

- NRC emphasizes, through written directive requirements, proper carrying out of physicians' (Authorized Users') intentions.
- Ref: 10 CFR 35.40 (Written Directives) at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0040.html>



## What NRC Does (1<sup>st</sup> question-quality) (cont.)

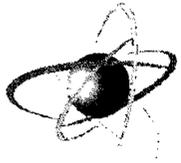
- NRC requires that individuals supervised by an authorized individual: Be instructed in the licensee's pertinent procedures, regulations, & license conditions; and Follow those instructions plus instructions from the authorized individual.
- Ref: 10 CFR 35.27 (Supervision) at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0027.html>



## **What NRC Does (1<sup>st</sup> question-quality) (cont.)**

NRC has many technical requirements for quality-related procedures, such as:

- Determining activities of dosages [35.63];
- Labeling vials and syringes [35.69];
- Calibration measurements of sources and source-containing devices [35.432, 632, etc.];
- Calibrations of measuring & dosimetry instrumentation [35.60, 630];
- Acceptance testing of treatment planning systems [35.457, 657].



## What NRC Does (2<sup>nd</sup> question-measure)

- NRC requires licensee self-reporting of specific types of medical events, as possibly indicative of procedural problems needing attention, not as potential violations, and not necessarily reflecting actual or potential patient harm.
- Ref: 10 CFR 35.3045 (Report and Notification of a Medical Event) at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>



## **What NRC Does (2<sup>nd</sup> question-measure) (cont.)**

- NRC cooperates with Federal and State partners and Congress re: medical event reporting development and implementation.



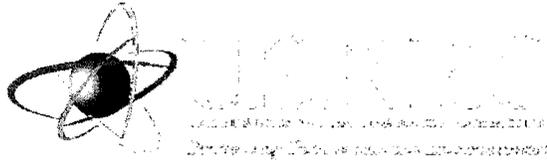
## **What NRC Does (2<sup>nd</sup> question-measure) (cont.)**

- NRC requires self-reporting by licensees (manufacturers and users) of equipment non-conformities or defects relating to substantial safety hazards.
- Ref: 10 CFR Part 21 (Reporting of Defects and Noncompliance) at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>



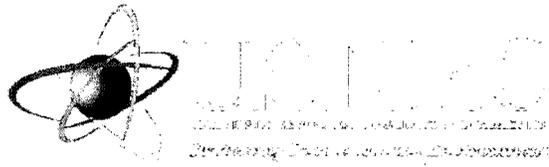
## **What NRC Does (2<sup>nd</sup> question-measure) (cont.)**

- NRC inspects licensees for compliance with licensee commitments and NRC's risk-informed, performance-based regulations.
- Ref: NRC Inspection Manual at <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/>



## **What NRC Does (3<sup>rd</sup> question-recommend)**

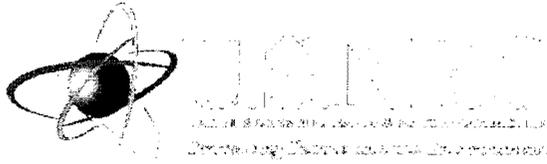
- NRC issues (and web-posts) Information Notices, to alert medical use licensees to problems encountered by other medical use licensees, for possible avoidance.
- Ref: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/>



## **What NRC Does (3<sup>rd</sup> question-recommend) (cont.)**

- Example recent Information Notice (7/09).

IN-03-022, “Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations,” Supplement 1



## **What NRC Does (3<sup>rd</sup> question-recommend) (cont.)**

- NRC provides guidance to licensees, on methods to maintain user, public, and patient radiation safety, and regulatory compliance.
- Ref: Program - Specific Guidance About Medical Use Licenses (NUREG-1556, Vol. 9, Rev. 2) at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>

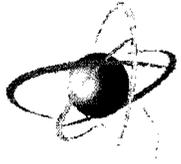


## **What NRC Does (3<sup>rd</sup> question-recommend) (cont.)**

- Example recent supplement to guidance (5/08).

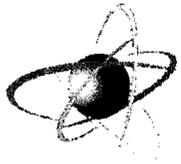
Enclosure to RIS-08-11, “Precautions to Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration of Iodine-131”

- Ref: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2008/index.html>



## **What NRC Does (3<sup>rd</sup> question-recommend) (cont.)**

- An upcoming supplement to guidance will provide specific recommendations to licensees considering the release of treated patients to facilities other than private residences.



## Summary

### NRC

- has regulatory requirements related to radiation safety quality in medical use of radioisotopes, including therapeutic use,
- has measures of licensee performance, and
- provides recommendations to licensees for establishing and maintaining quality performance.



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Questions?

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