Authorized User Training and Experience Requirements

WHY?

Michael L. Fuller
Director
Virginia Department of Health
Radioactive Materials Program

michael.fuller@vdh.Virginia.gov

(804) 864-8168

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Objective

To convince you to support the OAS Board and encourage the NRC to remove the requirements to license Authorized Users

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The Board believes that by removing the time-consuming responsibilities of verifying training and experience, developing training and experience requirements for new radiopharmaceuticals, and licensing Authorized Users it would allow regulators to devote more time to radiation protection practices for both current and future pharmaceuticals. The Board believes that our regulatory authority is established to protect public health and safety and we recognize that this authority is in tension with our need to stay out of the practice of medicine. The existing regulatory structure with its very specific training requirements for physician authorized users, many of whom do not actually handle radioactive material, is at odds with a risk-informed, performance-based approach to radioactive materials regulation.

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A Little Bit of History Goes A Long Way

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- 1946 - Distribution of radioisotopes by Manhattan Project publically announced
  - Dept. of the Army initially had oversight of isotope production and use
- 1947 – Congress created the AEC
- ACMUI Grew out of this Dept. of the Army subcommittee

- Initially, ACMUI did all of what is now considered licensing for medical use (who, what, training, credentials, etc.)
- Focus was on the clinical use and medical research (imaging and therapy)

- AEC/NRC regulations came later
  - 1960s – 1st Part 35 created
  - 1986 – 1st Part 35 that looks anything like we have now (modalities)
  - 2002 – Major Update – lots of T&E changes
  - 2019 – Big revision –numerous changes

Where Did the Hours Come From Anyway?

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Please Consider the Following Arguments

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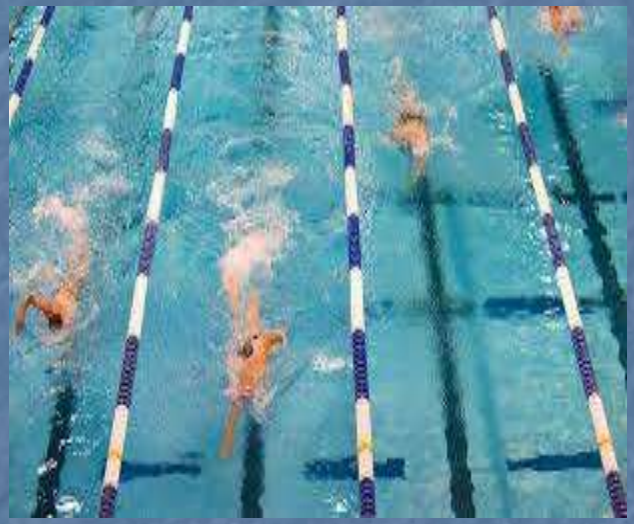
Medical Policy Statement

The following is the final Medical Use Policy Statement to guide NRC's future regulation of the medical use of byproduct material.

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

65 FR 47654 (August 3, 2000)

We Should Swim In Our Lane



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Status Quo Is Easy

- Doesn't solve the problem
- Protects certain groups

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If We Had to Come Up With a Regulatory Basis for the T&E Regulations, What Would It Be?

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If We Stop Naming Authorized Users On Licenses, What Are We Left With?

10 CFR Part 35.41 (or AS equivalent)

and

Inspections

35.41 is all we need – in fact, it's better!

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Other Points to Consider

- Frees Up Valuable Resources
- Credentialing - *FUGGETABOUTIT!*
- Supervision - *REALLY?*

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Opportunity to Demonstrate that We are True Regulatory Partners

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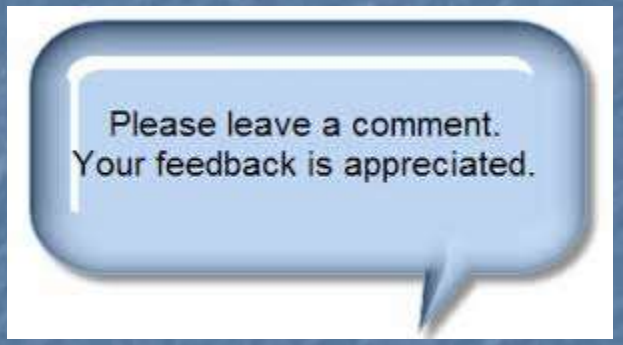

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