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Patient Release Health and Safety

A REVIEW OF CURRENT REGULATIONS AND PRACTICES

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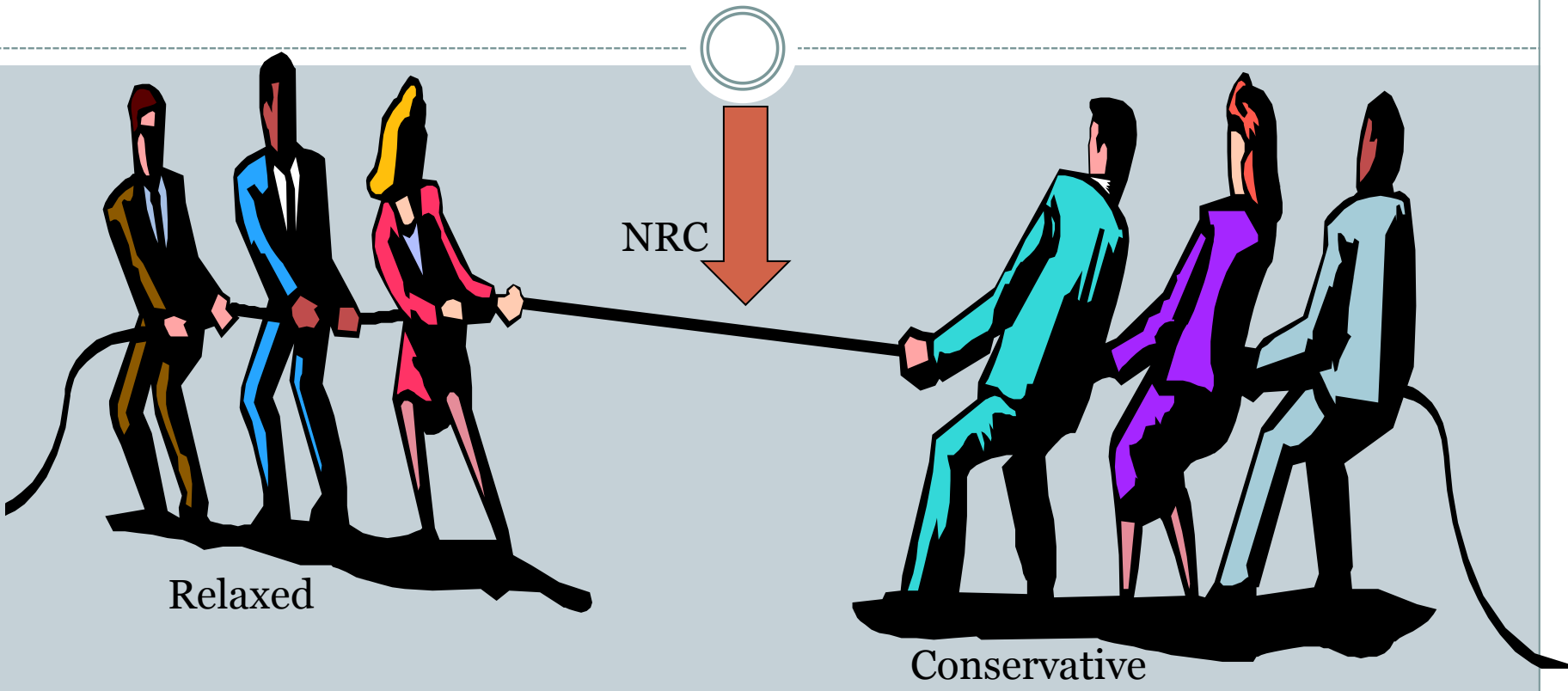
Patient Release Criteria



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Previous Rule

- The current rule in 10 CFR Part 35.75 became effective in 1997. Prior to 1997, patient release was based on:

  A licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either: (1) The measured dose rate from the patient or human research subject is less than 5 millirems per hour at a distance of 1 meter; or (2) The activity in the patient or the human research subject is less than 30 millicuries.

- A major advantage of the previous rule was that release was based on directly measurable criteria, namely retained activity or dose rate from the patient.

- A significant disadvantage of the previous rule was that it made no allowance for the specific conditions of the patient following release.

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Current Rule

- *A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem).*

- The current rule is based on dose to a member of the public. It does not provide the licensee with a measurable quantity to be used for releasing the patient.

- A model is therefore required to translate the release criterion into an operational quantity.

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- The model suggested by NRC for use by licensees to determine the release criteria is described in Regulatory Guide 8.39, “Release of Patients Administered Radioactive Materials.”

- The model provides two main options for the licensee: use default parameters, or use patient specific parameters.

- Model parameters include effective half-life of the radioisotope, duration of exposure of a member of the public, attenuation of radiation in the patient and the target, etc.

- It is interesting to note that use of the default parameters in the model leads to a release criterion that is nearly identical to the 30 mCi retained activity criterion in the old rule. This is coincidental.

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- The Commission directed NRC staff to review publicly available data on doses being received by members of the public as a result of application of the 10 CFR Part 35.75 release criteria. The review is to include surveys of the technical literature as well as performance of measurements in areas where data is sparse or unavailable. Assessment of the rule itself is not within the scope of this work.
- The objective is to see how well patient release practices are working and the extent to which the dose criterion is being met.

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- In addition, the Commission directed staff to re-examine the methods used in Regulatory Guide 8.39 to calculate dose to members of the public, and to recommend changes as deemed appropriate.

- The items to be reviewed include:
  - Use of point source and point target.
  - Use of the gamma ray constant.
  - No credit for self absorption in patient or target.
  - No credit for biological elimination .
  - Occupancy factor of 0.25.

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Current Status of Work

- There appears to be sufficient data in the literature to reach reliable conclusions on exposures of members of the public, both external and internal. With the exceptions of exposure to hotel and nursing home workers.
- NRC is conducting calculations using state-of-the-art anthropomorphic phantoms and Monte Carlo calculations to represent the patient and the target and to calculate doses.
- Calculations are designed to assess doses in various situations, such as public transportation, hotels, at home, etc.

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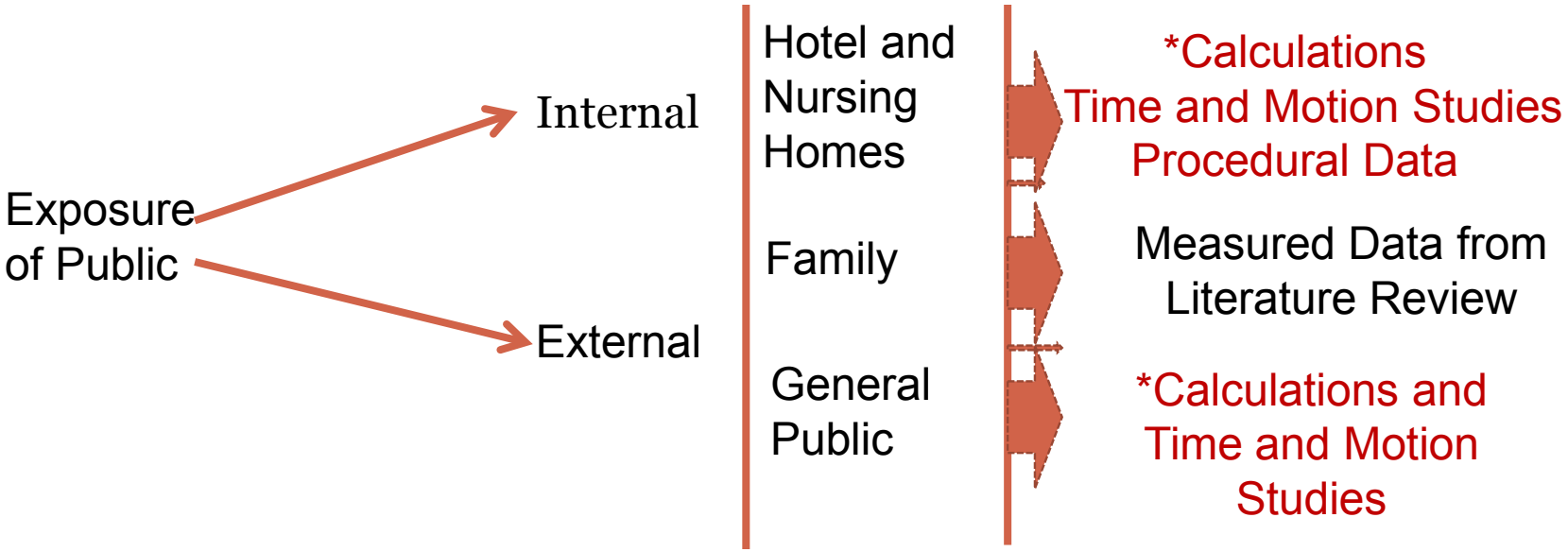
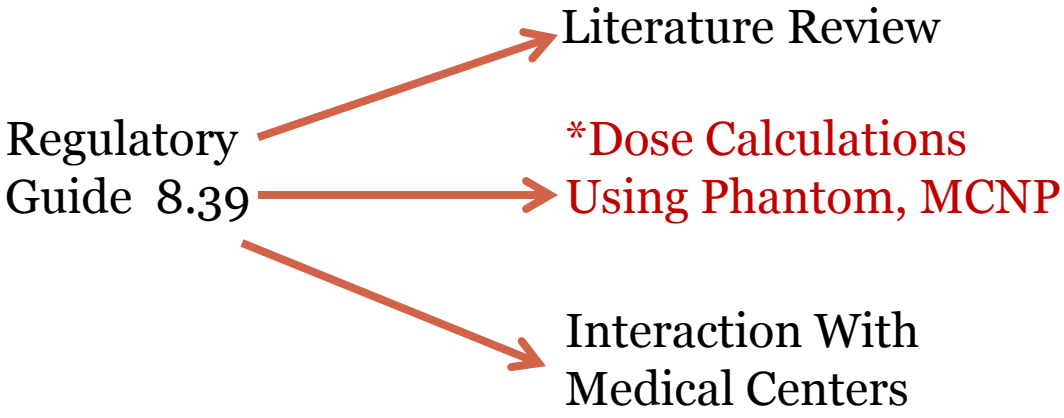
Current status of Work

- It is still unclear if any NRC-initiated measurements will be needed. This will be determined as the literature review progresses.
- NRC staff have been in contact with several medical facilities to discuss their patient release practices and calculations, and any data they have concerning exposure of members of the public.
- The work is scheduled to be completed by the end of 2016.

Summary





*If needed