



Patients' Rights Advocate's Comments on the Training and Experience Requirements

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Ethical Framework for Evaluating Impact of T&E Regulations

- Beneficence
- Justice
- Autonomy

The Safety Test

- Does existing or proposed T&E regulation adequately protect clinicians, patients, and the public from harm?
- Is existing or proposed T&E regulation unnecessarily restrictive such that it inhibits patients' access to necessary care?

“700 Hours” Safety Test

- Effectively limits designation as authorized user to a narrow subset of clinical specialties. Physicians cover those 700 hours in residency training: comprehensive knowledge
- Is the depth of knowledge acquired in residency training for these clinical specialties necessary for safe use of all radiopharmaceuticals?

Examples of the Extremes

- Zevalin: 700 hours. Too much?
- Iodine 131: 80 hours. Too little?

Acronyms

- T&E – training and experience