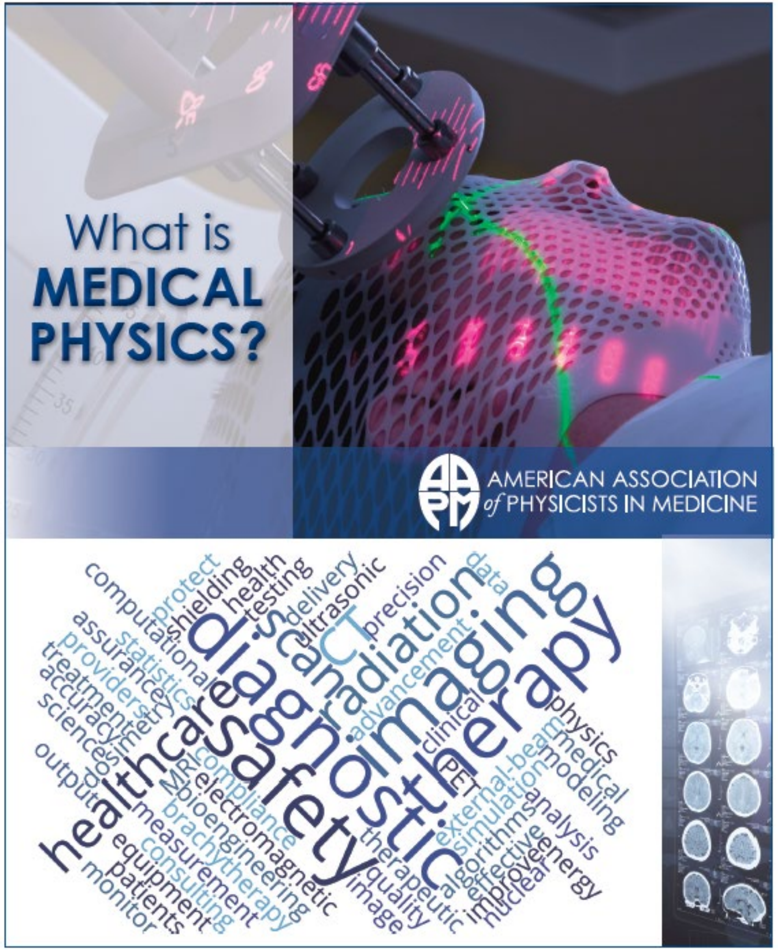
AAPM COMMENTS TO NRC QUESTIONS

Cynthia McCollough, PhD, DABR, FAAPM, FACR, FAIMBE
Past president, AAPM



Medical Physics is an applied branch of physics involving the application of physics concepts and methods to the diagnosis and treatment of human disease.

OVERVIEWS OF SCIENTIFIC RESEARCH (E.G., NON-LNT OR OTHER MODELS) THAT COULD INFORM THE NRC'S RECOMMENDATIONS FOR CHANGES TO ITS RADIATION PROTECTION FRAMEWORK, INCLUDING ADOPTION OF DETERMINATE DOSE LIMITS AND LEVELS FOR ACCEPTABLE LIFETIME OCCUPATIONAL DOSES.

- While most recent studies of low-dose radiation effects support LNT **for the purposes of radiation protection**, this model may not accurately reflect biological responses at low doses.
- As such, it is inappropriate to use LNT to estimate health effects from low-level radiation exposures experienced by large populations over extended periods.*
- Instead, determinate dose levels should be established, below which **risk estimates** are scientifically unreliable and potentially misleading.

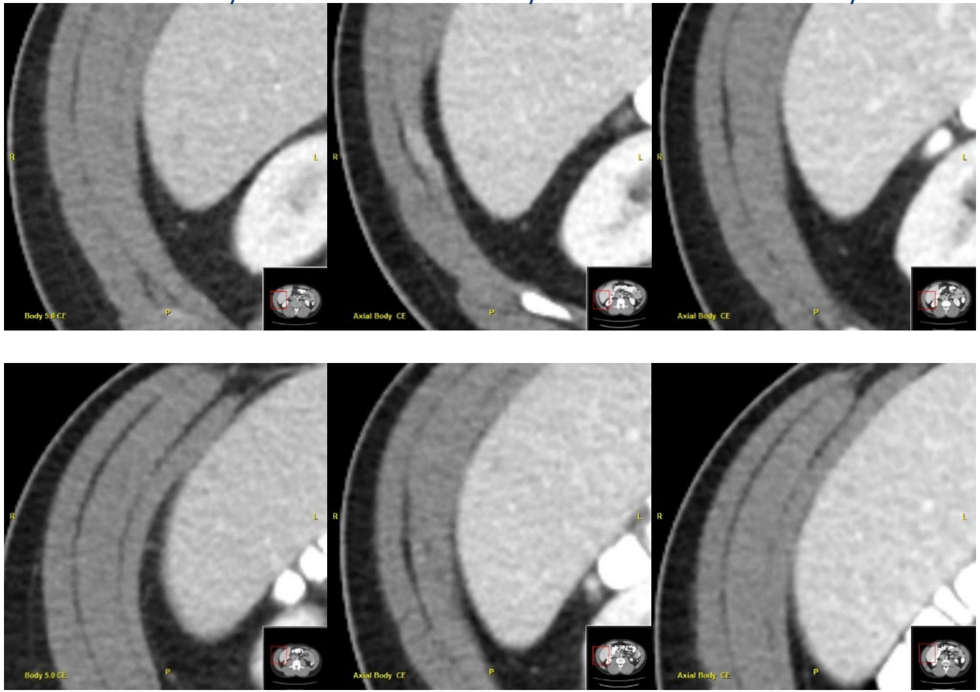
- The NRC currently has lifetime occupational dose limits that have not been burdensome for the majority of medical stakeholders.

*ICRP Publication 103, Chapter 4, paragraph (161)

ALARA and Medical Imaging

Low dose protocols with iterative reconstruction

5.0 mGy 5.2 mGy 5.5 mGy



6 months prior 12 months prior 18 months prior

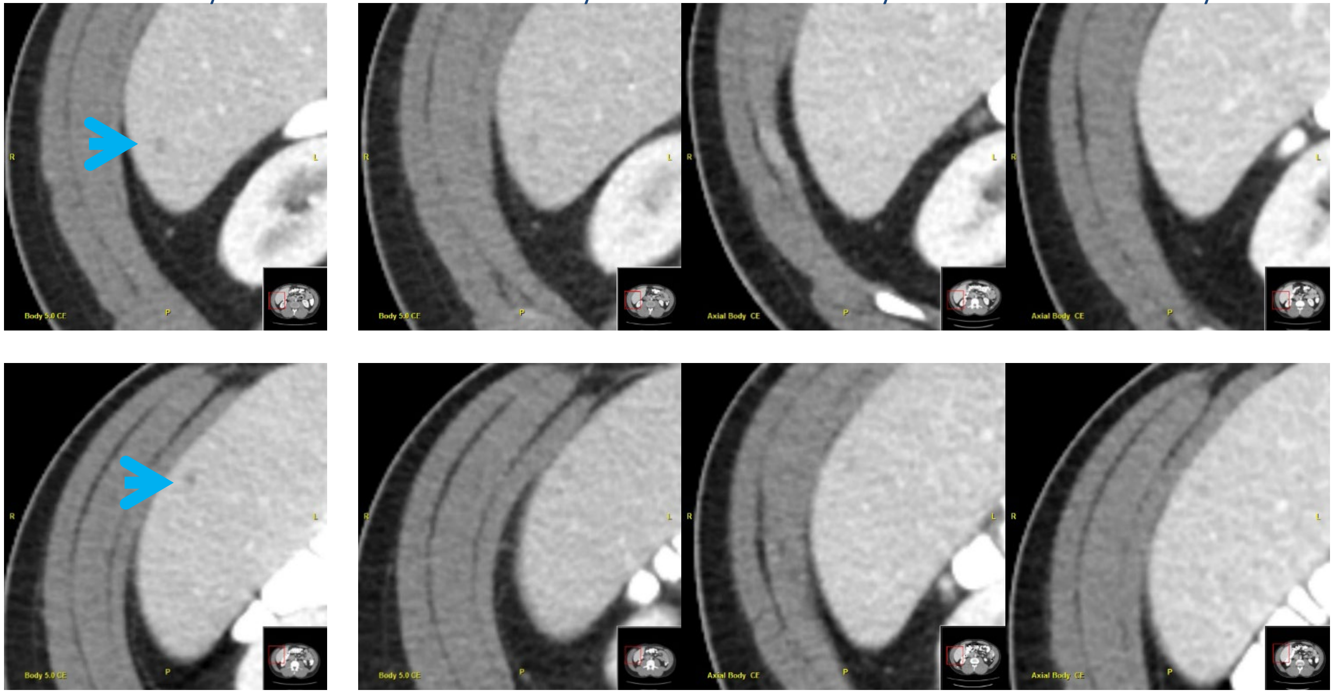
Favazza *et al.*, Use of a channelized Hotelling observer to assess CT image quality and optimize dose reduction for iteratively reconstructed images, *JMI, 2017*

ALARA and Medical Imaging

Standard dose protocol

Low dose protocols with iterative reconstruction

8.5 mGy | 5.0 mGy | 5.2 mGy | 5.5 mGy



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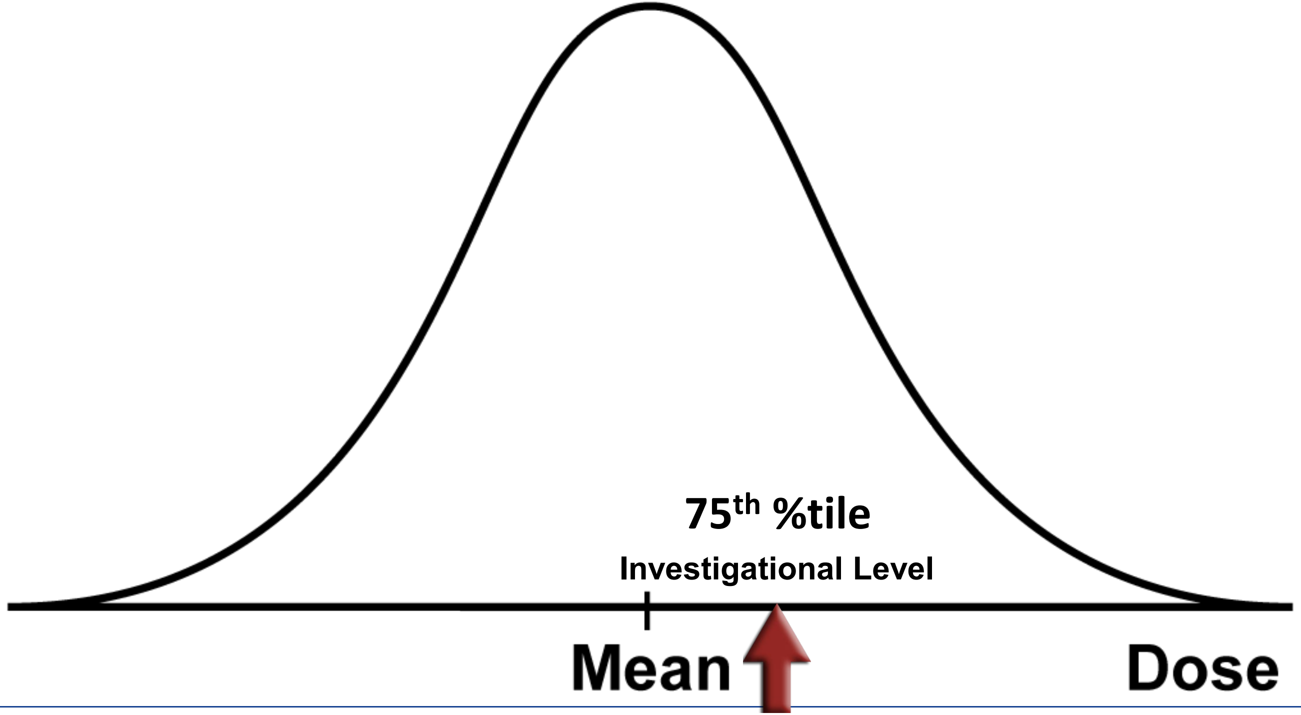
Favazza *et al.*, Use of a channelized Hotelling observer to assess CT image quality and optimize dose reduction for iteratively reconstructed images, *JMI, 2017*

SUMMARIES OF DATA AND EXPERIENCE THAT QUANTIFY THE IMPACT OF ALARA ON STAKEHOLDERS, AND INSIGHTS ON THE POTENTIAL IMPACTS OF REMOVING ALARA FROM NRC REGULATIONS

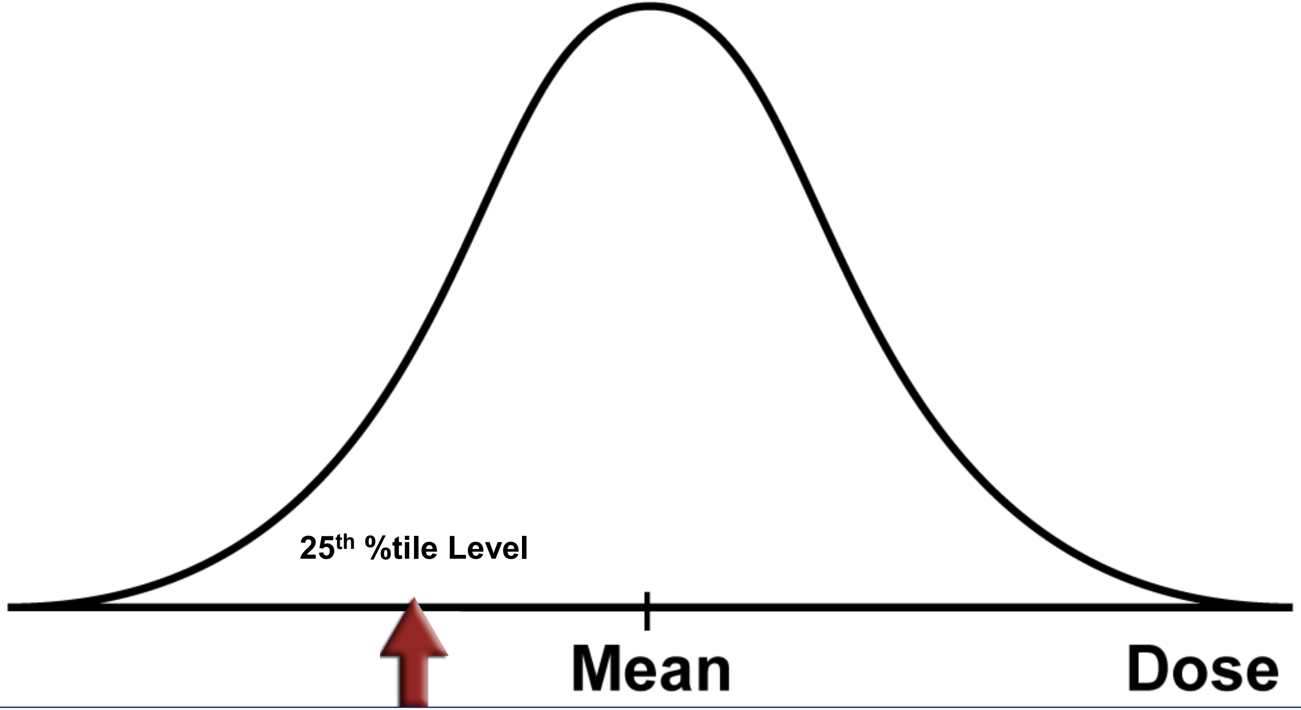
- The ALARA principle is foundational concept in radiation protection, but **its misapplication can have unintended consequences**.
- <u>Emphasis is often placed on dose minimization</u>. This can lead to **excessive dose reduction** that **compromises the diagnostic utility of medical imaging**.
- The medical community has long endorsed the ICRP and NCRP concepts of **justification** and **optimization** for imaging and therapy.*
- Regulatory guidance should **balance dose reduction with ensuring medical benefit**, rather than <u>promoting dose reduction as an end in itself</u>.

*ICRP Publication 138: Ethical Foundations of the System of Radiological Protection. Annals of the ICRP, 47(1)

DIAGNOSTIC REFERENCE LEVELS



"LOW ENOUGH" DOSE LEVELS?



INSIGHTS ON DEFINING DOSE VALUES BELOW WHICH ALARA EFFORTS WOULD NOT BE REQUIRED BY REGULATION.

- The application of ALARA in medical imaging can be taken too far.
- A more targeted, evidence-based application of **optimization** (such as DRLs) would improve regulatory clarity, prevent unnecessary operational burdens, and safeguard the integrity of medical uses of radiation.
- Regulatory agencies should establish clear guidance on the lower boundaries of dose where continued ALARA efforts are no longer required.
- Regulators should adapt enforcement to reflect the low-risk nature of minimal exposures and focus **protective efforts where they yield the most benefit**.

OCCUPATIONAL DOSE LIMITS (RADIATION WORKERS)

Exposure Type	NRC Limit (USA)	ICRP Recommendation
Effective dose (annual)	50 mSv (5 rem)	20 mSv/year *averaged* over 5 years; no more than 50 mSv in any single year
Lens of the eye	150 mSv (15 rem)	20 mSv/year (updated from 150 mSv in ICRP 60)
Skin / extremities	500 mSv (50 rem)	500 mSv/year
Pregnant worker (fetus)	5 mSv for entire pregnancy	1 mSv to fetus after pregnancy is declared

INSIGHTS ON POTENTIAL TRANSITION FROM ANNUAL STOCHASTIC DOSE LIMITS TO STOCHASTIC LIMITS BASED ON LONGER PERIODS (E.G., PUBLIC DOSE LIMIT OF 500 MREM OVER FIVE YEARS AND OCCUPATIONAL DOSE LIMIT OF 25 REM OVER FIVE YEARS) WHILE RETAINING CURRENT DETERMINISTIC DOSE LIMITS (E.G., OCCUPATIONAL SKIN DOSE LIMIT).

- Transitioning to longer averaging periods may offer **greater flexibility** in managing occupational exposure, especially in environments where workloads can vary over time.
- **Annual dose limits** currently serve as **practical triggers for dose investigation and safety review**. Moving to <u>longer-term limits could delay the detection of high exposures in shorter timeframes</u> unless appropriate internal monitoring is maintained.
- Adopting a framework similar to ICRP Pub. 103 could align NRC practice with global norms
- A longer time period for stochastic limits <u>would not reduce the burden for medical licensees</u>; it would introduce additional record-keeping and more complex tracking systems.
- Regulatory guidance that would **allow credit for the use of radioprotective lenses** (i.e, to apply a reduction factor as is used for protective aprons) **would be beneficial**.

COST-BENEFIT DOLLAR PER PERSON-REM

INSIGHTS FOR MODIFYING NRC'S COST-BENEFIT DOLLAR PER PERSON-REM GUIDANCE AT LOW DOSES CONSIDERING LOWER RISK AND UNCERTAINTIES OF HEALTH EFFECTS AND RESULTING ECONOMIC IMPACTS ON STAKEHOLDERS.

- At low doses (below ~100 mSv), all risk estimates become increasingly uncertain
- Maintaining current **cost-per-rem values at low doses can impose excessive compliance costs**, potentially diverting resources from more effective safety measures or innovation.
- Incorporating **dose levels below which cost-benefit requirements are relaxed or waived** (e.g., <1 mSv/year) could significantly streamline regulatory burden.
- Guidance should emphasize optimization of radiation protection **and medical/societal benefit** without incurring disproportionate economic costs, recognizing that **zero risk is unattainable and that some low-level exposure is unavoidable and acceptable**.
- Modifications should involve structured decision-making that emphasizes stakeholder consultation to understand economic impacts and maintain public trust, while clearly communicating the scientific rationale for adjustments.

RECOMMENDATIONS FOR IMPROVEMENTS

RECOMMENDATIONS FOR IMPROVEMENTS TO THE NRC'S RADIATION PROTECTION REGULATORY FRAMEWORK THAT WOULD IMPROVE OUTCOMES FOR LICENSEES WHILE MAINTAINING ADEQUATE PROTECTION OF EXPOSED INDIVIDUALS.

- **Align with ICRP recommendations and international standards**
- Establish levels—such as **below 1 mSv/year**—where additional dose reduction efforts are not required. This <u>focuses resources on exposures with meaningful risk and reduces unnecessary regulatory burden</u>.
- <u>Streamline regulatory requirements for low-level exposures</u> by simplifying reporting and control below optimized clearance or exemption levels.
- Adopt Diagnostic Reference Levels in medical imaging to guide dose optimization flexibly, **prioritizing clinical utility over rigid limits**.
- Enhance stakeholder engagement and communication to ensure that "reasonable" dose optimization reflects practical and clinical realities, **including medical benefit.**
- **Adopt SI units**

THANK YOU