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Submitter Information

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General Comment

Supportive Comments on Petition for Rulemaking PRM-20-028, PRM-20-029, and PRM-20-030

I write in support of the petitioners' positions that there has never been a scientific basis for the Linear Non Threshold (LNT) theory. I believe the three petitioners have well summarized data that conclusively demonstrates that there indeed exists a threshold, below which there are no harmful effects of radiation. Accordingly, I shall not attempt to provide an exhaustive list of references in this statement of support. I do note that variability in natural background radiation, either due to geology or to elevation or to both, among various places across the United States, far exceeds the limits for exposure to the public provided in 10 CFR 20.1301. Epidemiological studies do not support increased cancer in these populations. LNT predictions fail even with cohort sizes in the range of 10,000,000 to 100,000,000 individuals.

In my view, it is inaccurate to summarize the petitioners' position in 80 FR 35870 by stating that they are ". . . requesting that the NRC amend its 'Standards for Protection Against Radiation' regulations and change the basis of those regulations form the Linear No-Threshold (LNT) model of radiation protection to the radiation hormesis model." While the petitioners have discussed hormesis, none have suggested individuals be intentionally exposed to radiation for the hormetic benefit. The mischaracterization of the petitioners' request has likely negatively biased many readers' view against the petitions. Based on the increasing number of presentations at technical meetings devoted to the topic of replacing the LNT theory with a scientifically defensible threshold theory, it appears that there is overwhelming support in the scientific community; in particular for items 1 and 2 "Recommended Changes for 10 CFR Part 20" at the conclusion of Dr. Marcus' PRM-20-028.

LNT has resulted in the regulatory basis for As Low As Reasonably Achievable (ALARA). It should be acknowledged that no other hazard or chemical contaminant is so regulated - other than non-ionizing electromagnetic radiation, likely guilty by association. (For a more complete regulatory analysis, please refer to my attached presentation at the Health Physics Society midyear meeting, February 2001, Radiation Safety and ALARA Considerations for the 21st Century). There are no ALARA limits for exposure to or spill cleanup criteria for methyl ethyl ketone, tetra ethyl lead, dioxins, etc. Only radiation is so stigmatized by the regulations despite mankind having evolved in the presence of radiation. This stigmatization has resulted in the boisterous assertions that 'there is no safe level of exposure to radiation' and the falsehood that 'radiation (sic) is the most deadly substance known to man.' A quick review of the comments to these petitions reveals numerous such emotional statements, not based on any science. It is untenable to expect the uninformed population to eliminate their hysteria when the scientific community - including government regulators - refuse to do so and in fact perpetuate such hysteria with ALARA requirements. ALARA ended debate on Below Regulatory Concern (BRC) standards and has resulted in a defacto 10 micro-Sievert (1 millirem) per year standard which cannot be reliably measured. This 10 micro-Sievert per year standard serves as the regulatory basis in at least one state for a permit program for radiological air discharge, ostensibly in accord with the Clean Air Act. It is well documented that people have died during evacuations due to unfounded fear they would be harmed - fear based on ALARA and the theoretical predictions of the non-scientific LNT theory. Real lives have been lost in the name of radiation safety due to the theoretical 'lives saved' predictions of the LNT theory. It is irresponsible to ignore the science and continue to blindly support the LNT theory.

Respectfully submitted,

Glenn Roberts
Certified Health Physicist

Attachments

ALARA 2000MidYearHPS

ALARA: Great Philosophy but Too Subjective for Regulation

By Glenn Roberts

CHP, CIH, CSP, CET, CHMM

Prepared for the 34th Mid-Year Topical Meeting of the Health Physics Society

ALARA - Great Philosophy

- Responsibility of all safety professionals
  - Executive management
  - Dedicated safety personnel
  - Front line supervisors
  - Production workers, maintenance, . . .
- Applies to all industries and workplaces
  - not limited to the nuclear industry

ALARA - Great Philosophy

- Applies to all potential hazards
  - Physical hazards; fire, falls, freezing, . . .
  - Biological hazards; infection, pathogens, . . .
  - Chemicals; toxins, carcinogens, . . .
- Applies to all potentially hazardous materials - NOT just Radioactive Materials or Radiation

Why not Regulate ALARA?

- Regulations should be clear and concise
- Demonstrative of compliance must be objective measures
- The word “reasonable” is subjective
- Reasonableness is subject to interpretation
- ALARA is subject to dispute and litigation

Why not Regulate ALARA?

- Interpretation of REASONABLE depends on:
  - Situation
  - Point of view
  - Changing technology
  - Theory versus application
  - Number of lawyers involved
  - Politics

Regulations

- Development incorporates conservative assumptions
- Limits are reasonably low as written
- ONLY apply ALARA requirements to radioactive materials and radiation

Regulations

- Different approach fuels public
  - fear & hysteria
  - mystique & apprehension
  - confusion & misconceptions
  - opinion that radiation is different from other hazards
- Problems for licensees and regulators

CFR Search Results

- All 50 Titles
- "AS LOW AS"
  - as low as reasonably achievable
  - as low as practical
  - as low as possible
- 83 documents (sections) returned; e.g., 20.1101

CFR Search Results

- Regulatory uses of "as low as"
  - basis of the regulation
  - required minimums
    - dimension
    - physical location
  - advisory

CFR Search Results

- Regulatory uses of "as low as"
  - Minimum Detection Limits
  - Required in label
  - Onset of observable effects
  - After over exposure has already occurred
- ALARA concept limited to:
  - Radiation Standards; FDA, DOT, EPA
  - Non-ionizing radiation - guilty by association!

Common uses of "as low as"

Basis of the regulation - 14 CFR § 36.5

. . . the noise levels in this part have been determined to be as low as is economically reasonable, technologically practicable, and appropriate to the type of aircraft . . .

Common uses of "as low as"

Minimum Physical dimension

14 CFR 77.25

"Approach surface. . .of each runway. . .
(1) . . .expands uniformly to a width of:
(iv) 4,000 feet for . . . visibility minimums as low as 3/4 statute mile.

Common uses of "as low as"

Minimum Physical Location

33 CFR § 118.85

"Each such light [on a vertical lift bridge] … shall be securely mounted as low as practicable on the end of the pier, …"

Common uses of "as low as"

Advisory - 21 CFR § 101, App. A

"Keeping the back pressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

Common uses of "as low as"

Minimum Detection Limit

40 CFR § 63.104

"… using any EPA-approved method … sensitive to concentration as low as 10 parts per million …"

Common uses of "as low as"

Required in Label - 40 CFR § 721.1225

"EPA has further determined that discharge of this substance [Benzene, 1,2-dimethyl-, polypropene derivatives, sulfonated, potassium salts] may cause toxicity to fish and aquatic organisms at concentrations as low as 25 ppb.

Common uses of "as low as"

Onset of Observable Effects

29 CFR § 1910.1025 & App. C

"Studies have indicated that lead levels as low as 50 μg/100g [result in] definite decreased hemoglobin, …"

"… blood lead levels as low as 50 μg/100g is manifested by slowing of motor nerve conduction velocity …"

Common uses of "as low as"

After Over Exposure

29 CFR § 1910.1028

"Whenever an employee is removed from benzene exposure … transfer … where benzene exposures are as low as possible, but in no event higher than the action level."

CFR Search

- "REASONABLE" or "REASONABLY"
- 21,648 documents
- including 8,767 in Titles 10, 29, 40, & 49
- Many uses - but NONE applied to any type of hazardous exposure

Reasonable CFR's

- Reasonable costs, fees, . . .
- Reasonable efforts, time, . . .
- Reasonable cause, grounds, . . .
- Reasonable offers, accommodations, . . .
- "… any other reasonable means of protection …" 40 CFR
- "… continuous monitoring … when conc.'s of vinyl chloride could reasonably exceed the allowable concentration." 29 CFR 1910.1017

ALARA Uses Outside of 10 CFR

- 21 CFR § 361.1 [FDA] Radioactive drugs for certain research uses.

- 40 CFR § 192.22 [EPA] Supplemental. Standards [residual radioactivity]

- 40 CFR § 192.32 [EPA] Standards. [uranium byproduct materials]

ALARA Uses Outside of 10 CFR

- 49 CFR § 173.443 [DOT] Contamination control.

- 47 CFR § 73.614 [Telecommunication] "The effective radiated power . . . shall be as low as the state of the art permits, …"

Other Efforts to Locate ALARA Concepts in Regulations

- Professional Contacts
- Environmental Attorneys
- Personal Search of the Regulations
- Results - Conceptual Instances with Different Practical Application
  - Agriculture Commodities
  - Food Contaminants

Other ALARA Concepts in Reg's

- Agricultural Commodities - 40 CFR § 180.1 (f) "… when exempted … will not be considered unsafe … if: (1) The poisonous or deleterious pesticide residues have been removed to the extent possible in good manufacturing practice; and (2) …"
- Nearly identical language in FDA Reg's 21 CFR § 170.19 Pesticide chemicals in processed foods.

Other ALARA Concepts in Reg's

FDA 21 CFR 109.7 Unavoidability

"Tolerances and Action Levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substances concerned and do not establish permissible levels of contamination where it is avoidable."

Hazardous Material Exposures

Not required by OSHA to be ALARA
i.e., 29 CFR 1910.1001 Asbestos

When engineering controls not feasible to reach PEL, use controls to reduce "… exposure to the lowest levels achievable … and supplement [with] respiratory protection"

Clean Air Act

ALARA Upside Down and Backwards

- The CAA allows industry to trade or sell CAA credits or allotments
- If one company is below the limit, they can sell their excess pollution "rights" to another company that can't, or chooses not to, meet the maximum quantity
- What would be the public response if this concept was applied to radiation?

What power plant would you rather live near?

Downwind ALARA???

Legal Definition of Reasonable

U.S. v. Carroll Towing Co. (1947)

- Unattended barge brook free of moorings, rammed tanker, sank
- Resulting liability litigation
- Hon. Learned Hand defined a mathematical formula
- Still widely used test of negligence
- Basis of the "reasonable person" standard

Legal Definition of Reasonable

$$B < P \times L$$

- B = Cost of prevention
- P = Probability of occurrence
- L = Cost of Liability (Damage)

Some factors are difficult to determine and subjective; i.e., the value of a life

At best a rough guideline, at worst misleading in its apparent simplicity

"Reasonable" is Subjective

IS IT REASONABLE?

- For a city to restrict effluent concentrations to 2% of the Federal Limit?
- To make it unlawful to discharge tap water?
- To arbitrarily restrict fence line doses beyond limits while simultaneously removing the ability to demonstrate compliance by calculation?

"Reasonable" is Subjective

IS IT REASONABLE?

- To sue when no measurable exposures have occurred?
- To sue when no consequences have occurred?
- To apply risk probabilities to population doses?

"Reasonable" is Subjective

IS IT REASONABLE

To argue in a court of law that:

"It is fairly well accepted by all scientists, nationwide, who have consistently issued reports about regulations and opinions that say 'There is no known safe dosage of radiation'."

No ALARA for Pesticide Use

- September 22, 2000, NBC Evening News regarding mosquito pesticide spraying in residential neighborhood:
  - "Used in this manner, the EPA has concluded there are no harmful effects to people, their pets, or the environment."
- Why can't we say that about radiation?

Conclusion

- Allow professionals to implement ALARA
- Do not require it by regulation
- ALARA, in practice not regulation, should apply outside the bounds of radiation
- Regulating ALARA
  - is inconsistent with most regulatory agencies
  - adds to the thought that “radiation is different”