



# **ACMUI's Comments on the Advance Notice of Proposed Rulemaking for 10 CFR Part 20**

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# General Recommendations

## ACMUI supports

- Issue #1:** Change of 10 CFR Part 20 to align with the ICRP 103 methodology and terminology.
- Issue #2:** Decrease in the occupational dose limit for the lens of the eye to 50 mSv (5 rem).
- Issue #5:** The use of SI units in radiation protection regulations

## ACMUI does not support

- Issue #3:** Decreasing the dose limit for the embryo/fetus of a declared pregnant occupational worker from 5 mSv (500 mrem) to 1 mSv (100mrem).
- Issue #4:** Revising or adding regulatory requirements regarding a licensee's as low as reasonably achievable (ALARA) program.
- Issue #6:** Expansion of additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR 20.2206(a).

# Part 20 ANPR: Issue #1

## Update 10 CFR Part 20 to Align with ICRP 103 Methodology and Terminology

The ACMUI supports replacing the terminology “Total Effective Dose Equivalent” with “Effective Dose”

- “Total Effective Dose Equivalent” is an outdated term, and no longer used other than in NRC’s regulatory literature.
- “Total Effective Dose Equivalent” while similar in concept to “Effective Dose” differs largely in technical detail: it uses (a) Quality Factor rather than  $w_R$  and (b) different tabulations of the tissue weighting factor,  $w_T$  (not all tissue/organs included).

# **Part 20 ANPR: Issue #2**

## **Occupational Dose Limit for the Lens of the Eye**

The ACMUI supports changing the occupational dose limit to the lens of the eye from 15 rem to 5 rem.

- Recent human epidemiological studies have suggested that reduced transparency of the lens of the eye may occur at significantly lower doses of ionizing radiation than previously estimated, termed “radiation cataract”.

# Part 20 ANPR: Issue #2 (Cont.)

- Personnel exposed to byproducts material include:
  - Repair or maintenance of cyclotrons
  - Those who are involved in fluoroscopic x-ray procedures (e.g. interventional radiologists performing  $^{90}\text{Y}$  microsphere therapies, cardiologists performing intravascular brachytherapy, and x-ray personnel in the room).
- In a relatively busy interventional suite, the estimated annual dose to the lens of the eye ranges from 4 to 8 rem.

# Part 20 ANPR: Issue #2 (Cont.)

- There are 3 broad categories of shielding:
  - 1) Protective leaded eyewear (glasses)
  - 2) Portable/moveable transparent scatter-shielding screen
  - 3) Personal protection whole body suit with leaded acrylic face shield (protecting the eye) and apron
- Protective lead glass will decrease the lens dose by a factor of 5 to 10, and the scatter-shield screen will decrease the lens dose by a factor of 5 to 25.

# Part 20 ANPR: Issue #2 (Cont.)

## Implications of the change from 15 rem to 5 rem

- This will require changes in fluoroscopic x-ray safety programs making the use of personal leaded glasses or eye protector shield a:
  - “Mandatory” practice for physicians/trainees at the table
  - “Recommended” for the ancillary staff.
- If there is significant non-uniformity in the radiation field in terms of the body versus the eye, those personnel may need to utilize “eye-specific” dosimeters usually worn with a head strap above the eyebrows.

# Part 20 ANPR: Issue #3

## Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker

The ACMUI **does not** support reducing the dose limit to the embryo/fetus of a declared pregnant woman from 500 mrem (5 mSv) to 100 mrem (1mSv).

- The risk of cancer from *in utero* radiation exposure is a controversial subject.
- While the dose limit to the embryo/fetus should certainly be kept as low as reasonable, there is no scientific data of increased risk in declared pregnant occupational women with the current 500 mrem dose limit.



# Part 20 ANPR: Issue #3 (Cont.)

- The ACMUI does not know of a source of data other than that gathered by vendors providing individual monitoring devices.
- Based on our collective knowledge, deep effective dose equivalent measurements from individual monitoring devices assigned to declared pregnant women remain well below 500 mrem over the gestation period.
- Latest NCRP Report No. 174 “Preconception and Prenatal Exposure Health Effects and Protective Guidance” continues to recommend dose limit of 50 mrem/gestation month.

# **Part 20 ANPR: Issue #3 (Cont.)**

- Potential negative impacts of lowering the dose limit were described in NRC SECY-12-0064:
  - 1) More restrictive limit could result in an increase in individuals choosing not to declare their pregnancy, in order to ensure their continued employment.
  - 2) It could also increase in non-compliance of wearing proper dosimetry in order to keep their occupational dose within the lower limit.
  - 3) It could result in an inappropriate bias in the selection of female applicants.

# Part 20 ANPR: Issue #4

## Individual Protection - ALARA Planning

The ACMUI **does not** support adding specific ALARA planning and implementation requirements to the 10 CFR Part 20 regulations.

- The current Part 20 requires ALARA programs but does not provide specific ALARA planning and implementation requirements and so allows licensees to design ALARA requirements that are most appropriate to their activities.
- The medical users of radioactive materials rarely experience situations where workers' doses approach regulatory limits. Many of them already utilize administrative control levels to maintain doses ALARA.

# **Part 20 ANPR: Issue #4 (Cont.)**

- The risks and safety cultures of different industries and different licensees within the same industry differ so much that providing the same compliance-based requirements on all licensees will not be effective.
- Defining what may be “reasonably achievable” is an inherently subjective process.
- The best methodology would be to maintain the status quo and not impose any further prescriptive requirements.

# Part 20 ANPR: Issue #5

## Metrication – Units of Radiation Exposure and Dose

The ACMUI supports the change to use of the International System of Units (SI) in radiation protection regulations

- The use of both international and traditional units should be used consistently throughout the regulation with emphasis on the SI unit first as the regulatory standard, followed by the conventional unit in parentheses. This should be done as a means to effect the transition to the sole use of SI units in the future.
- This should not cause undue burden or hardship upon any licensee or class of licensees as all nations other than the U.S. have already accomplished the transition to SI units.

# Part 20 ANPR: Issue #6

## Reporting of Occupational Exposure

The ACMUI does not support expansion of additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR20.2206(a).

- The ACMUI does not believe that the NRC should act as the nation's repository of occupational radiation exposure data, as the NRC does not have regulatory authority over all ionizing radiation sources.
- It also does not make sense to collect national data for only one area of occupational radiation exposure – considering the more extensive use of x-rays.

# **Part 20 ANPR: Issue #6 (Cont.)**

- Occupational doses have low averages for medical-use licensees and licensees which support them. Accordingly, many of these workers are not even assigned personal dosimetry. Thus, requiring national occupational dose tracking of those radiation workers who do require individual monitoring could lead to unrealistically high estimates of average occupational doses for medical licensees.
- Moreover, occupational dose does not include doses received from background radiation, medical administration of diagnostic or therapeutic doses, or voluntary participation in medical research programs.

# **Part 20 ANPR: Issue #6 (Cont.)**

NRC does not regulate all uses of radioactive materials – most are regulated by Agreement States. If the purpose of a central database is to assess total annual occupational exposures for radiation workers, the NRC's limited regulatory authority would not make it the ideal federal entity to manage such a central database.



# Cumulative Effects of Regulation

- The ACMUI recommends NRC use a similar implementation plan as that used for the last significant change of 10 CFR Part 20 in 1991 where the licensee could choose to implement the regulatory change anytime within a given time frame.
- The ACMUI recommends a time frame of at least three years to allow implementation of procedure, training, hardware, and software changes needed to comply with the new regulatory requirements.

# **Acronyms**

**ACMUI – The Advisory Committee on Medical Uses of Isotopes**

**ALARA – As Low As Is Reasonably Achievable**

**ANPR – Advanced Notice of Proposed Rulemaking**

**CFR – Code of Federal Regulations**

# **Acronyms**

**DCF – Dose Conversion Factors**

**ICRP – International Commission on Radiological Protection**

**NCRP – National Council on Radiation Protection & Measurements**

**NRC – The U.S. Nuclear Regulatory Commission**

**SI – International System of Units**