Rulemaking Comments

From: James Lambert [cathum2009@yahoo.com]
Sent: Friday, December 30, 2011 5:49 PM
To: Rulemaking Comments; Regs4rp Resource; Cool, Donald
Cc: JERRY HENSLEY; Fassell John; GOVERNMENTRELATIONS@ASRT.ORG
Subject: FLUOROSCOPIC RADIATION PROTECTION
Attachments: Don Cool U S NRC Discussion to Revise Radiation Protection Regulations.pdf

Rulemaking.comments.ncr@.gov, Regs4rp@ncr.gov

In review of Docket ID: NRC-2009-0279 provided by Mr. Donald Cool, Phd with the US NRC to the ICRP meeting October 2011. The statement regarding the Lens of the Eye is incorrectly stated. It should read 20 mSv (2 rem) over 1 year not to exceed 50 mSv in 5 years. The document is attached.

Issue Change the Occupational Dose Limit?

Feedback:

-Little support for change to regulation? Who did you ask?

-Certain Groups of licensees continue to have individuals above 20 mSv/yr (2 rem)? YES, Hundreds of Nurses, CVT's and RT's and Anesthesiologists are exposed each day in the State of California.

Were they asked how they felt about Occupational Radiation Exposure?

-Legal Boundry for enforcement needs to remain as is? WOW!!! Please tell me that any of you would step in my shoes and accept the Radiation Doses that I was forced to endure and my friends recieved has placed me over the recommended dose. ACUTE OCCUPATIONAL RADIATION EXPOSURE is in some instances an assault with a deadly weapon as the doses which my patients endured were leathal and the exposure I received is certainly damaging. Reiviewing ICRP documentation on Organ Specific Biological Effects I cannot understand how we cannot consider changing many of these dose factors.

1. JCAHO Sentinal Event 15 Gy of exposure. This is definitally a leathal dose of Radiation for a Cardiac Fluoroscopic Procedure. The ICRP states specific Organ Tissue Thresholds which will certainly cause permanent damage to Heart Muscle at significantlly lower levels. So if the treatment causes more harm than benefit and the Patient Suffers, Staff are exposed and Health Care costs rise who is benefiting. The NRC because they have failed to properly inform the Health Care Workers that are exposed to Radiation that the fact is your risk of damage from Radiation Exposure has been Reduced from 15000 mRem to the Lens of the Eye to 2000 mRem to per year. I would say that that is a very significant change and I feel it is necessary for your department to notify all Health Care Workers of the ICRP changes and let them decide if they wish to risk their eyesight to work in this field of Medicine.

-ALARA has not helped reduce exposure what so ever. I reported a definite violation of all principals of ALARA. I was fired and CDPH RHB claimed the hospital was in compliance. This report is Public Record. I will be presenting it in detail to establish the very poorly conducted survey which violated my Civil Rights under Calif Code Title 17 in regards to an Investigation requested by and individual or group and my right to be present to ensure setup is correct. The set-up is incorrect and I will be conduction a repeat survey upon court order in January. The numbers will not be good and I believe the procedure which I assisted on May 20, 2009 exceed 15 Gy of Patient Exposure and therefore by definition is a Sentinel Event covered up by CDPH RHB. The data produced by CDPH RHB was in total support of the Hospital and in no way showed any concern for my personal health.

-Many do not believe changes in risk justify change to limit? WHO ARE MANY. These are Nurses, CVT's, RT's and Anesthesiologists right? REALLY! I WOULD LIKE TO KNOW WHO THE MANY ARE.

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My concern is in regards to Details of Technical Options and Issues for Revision of 10 CFR Part 20. Specifically Occupational Radiation Dose and Newly established guidelines adopted by the ICRP on April 21, 2011. and why these standards are not acceptable in the United States. The fact is, Cath Labs do not practice ALARA. When Dr. Cool states that there is little support for change he obviously has not informed the CNA and UHW unions that represent these employee's to get their feedback. This is of National Concern and you have not properly informed the Occupational Workers in the Medical Industry about these risks. I will be happy to assist you in informing Health Care Workers of current ICRP guidelines and we will see if the People that are being Exposed have any concern. WE KNOW that the Hospitals and Physicians Profiting from this Abusive Practice could care less about the Healthcare Workers that Risk Their Lives Every Day to Save the Lives of Others. Or is that what the government will make the public believe. Health Care is taking a beating and again our government does not Expose the Truth and I am sure years down the road the NRC will take no responsibility in the fact that they did not follow Internationally Accepted Standards of Care. Why? Does the Insurance Industry realize that some of these procedures cause more harm than benefit and the cost of medical care rises while the patient suffers.

The chances of one of your family members having a procedure in a Cardiac Cath Lab is greater than 1 in 6. I want to treat everyone of my patients with the same care I wish for my family, the BEST. I work every day treating Sick patients of every Race, Age, Sex often having HIV, HEP-C, MRSA and other medical conditions. I treat them as I wish my family to be treated regardless of their situation because that is what Health Care Workers DO! I accept that the patients I treat come with their personal issues but I cannot accept that the United States of America will not protect me from Occupational Radiation Exposure. I put my life and the health of my family on the line every day. Will my government please protect me from Acute Occupational Radiation Exposure.

I am one of those Occupational Radiation Healthcare Workers that is exceeding these doses due to increased numbers of High Radiation Fluoroscopically Guided Procedures. I work in Interverntional Cardiology and Electrophysiology and I asure you that just in the State of California there are Hundreds of Nurses, CVT's, RT's and Anesthesiologists that are being exposed to doses in excess of the ICRP Standards . In February 2009 I was exposed to 500-700 mRem of exposure to the collar during ONE procedure, 181 minutes of fluoroscopy and 9 hours of anesthesia time.. Fluoroscopically Guided Inteventional Surgical and Therapeutic procedures are in the early stages of developement and this abuse of Radiation will continue as Unskilled Physicians perform these procedures with no regards to Radiation Safety. They just want to implant that $40,000 device so they can pay their childerns college tuition. My five year dose also exceeds 50 mSv or 5 Rem. The patient received severe radiation burns and certain organ damage. Patients are receiving 6 Gy/hr at this facility due to old equipment manufactured in 1976 and 1984 these systems do not display radiation dose output. Why is this acceptable?

Valve Surgeries, Abdominal Aortic Grafts, Carotid Stents, Cerebral Embolization, Stem Cell Therapy, Electrophysiology AF Ablations are all Fluoroscopically guided procedures developing in major centers and proliferating to many centers with unskilled Physicians with no REAL understanding of Radiation Protection preforming these High Radiation Procedures. Nurses, Technologist and Anesthesiologists across the country are being exposed to this Radiation on a Daily Basis. The majority of facilities are responsible but many States do not require a Radiologic Technologist to be present in CATH LAB procedures. This means that no one is looking out for patients and staff regarding radiation exposure.

My Reason For Supporting Lowering Occupational Radiation Exposure. My personal experience. I pleaded for the Physician to stop (in patients medical record) and she would not. I reported to my Supervisor and Radiation Safety Officer of the Hospital. Ten months later I was told nothing and my workload increased due to my complaints. . I was fired for requesting to be removed from High Dose Radiation area until CDPH RHB investigated. CDPH RHB investigated an additional procedure May 20, 2009 where I was exposed to 164 minutes of fluoroscopy and 57 cine runs. CDPH RHB stated " I received 150-225 mRem to eye during that one

procedure and that did not exceed the monthly occupational dose. ACUTE RADIATION EXPOSURE must be considered. It is one thing to debate whether 200 mRem or 500 mRem should be the monthly limit. WHAT should the DAILY LIMIT BE? My eyes were cooked, I have Glaucoma, Opitic Nerve Damage and Subcapsular Cataract. The Report by the CDPH RHB which was submitted to numerous State and Federal Agencies is completely misleading and much of its content is scientifically incorrect. I am now being told by CDPH RHB that they follow the NRC guidelines and I have the NRC stating that the CDPH RHB is responsible for Radiation Producing Machines. OSHA is not sure if they have jurisdiction and continue to investigate.

The problem here is far more serious as I dig deeper. No One Knows what is going on and CDPH RHB has given permission to all Physicians to USE AS MUCH RADIATION AS POSSIBLE.

One other item of concern. I attempted to get my life time Radiation Exposure from Landaur Dosimetry and found out something very interesting. I as an Occupation Health Care Worker in a High Radiation Area cannot get copies of my Personal Life Time Radiation Record without consent from my prior employers. Now this information is contained under my Social Security Number and I see no reason for keeping it from me. Until I went to their web site and realized that all of the information that they provide is not to protect Health Care Workers but how to prevent legal problems for the Employer.

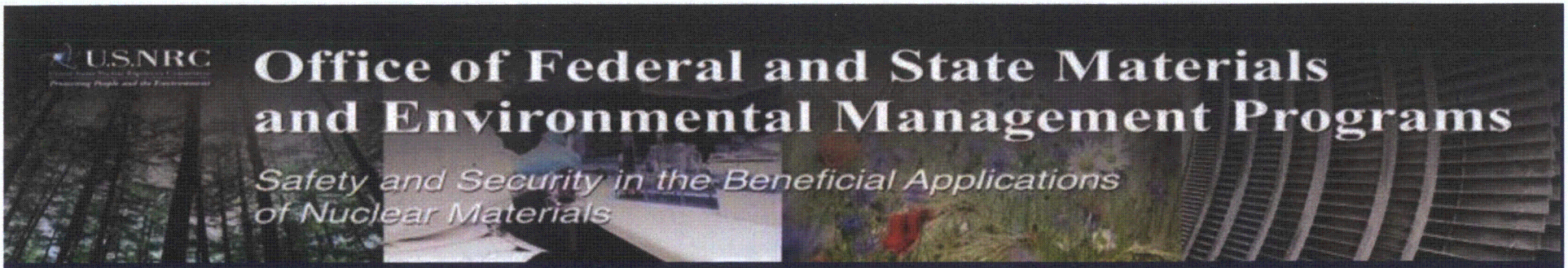
Limiting Occupational Radiation Exposure will Require Operating Physicians to Comply and Be Aware of ALARA. If physcians are suspended from operating for exceeding occupational dose to themselves then you have also limited the exposure for many patients and staff. My current employer and all of the Cardiologist that I work with have all embraced the idea of reducing exposure and we have sacrificed some image detail during fluoroscopy but have reduced exposure by 1/2.

Physicians and Hospitals have a Financial interest in ignoring these Radiation Exposure Limits and the fact is your average Cardiologist is performing 1/4 of the procedures that your average Scrub Nurse or Technologist perform on a weekly basis. Nurses must inform a physician when Medication Conflicts occur or when limits of conscious sedation are met. As a Radiologic Technologist with 27 years of experience I have no control over Radiation Dose and when I Reported my concerns, the Hospital and Physican were supported and I was terminated for not wanting to work under these conditions. I am concerned that Safety is being ignored because the affects of Radiation Exposure are delayed for many years as clearly documented by the ICRP. Why would the United States not adopt these standards?

I have forwarded this document to numerous agencies and California State Senate, Govenor Brown, CNA, UHW and Cal OSHA.

Happy New Years

James Lambert CRT ARRT (CT)



U.S. NRC Discussion of Options to Revise Radiation Protection Recommendations

2011 ICRP International Symposium

Donald A. Cool, Ph.D.
Senior Advisor Radiation Safety and International Liaison

NRC - Who We Are

- Atomic Energy Act of 1954 formed the Atomic Energy Commission
- The Energy Reorganization Act of 1974 established the independent U.S. NRC to regulate commercial uses of nuclear material.
- Energy Policy Act of 2005 added new types of Byproduct Material

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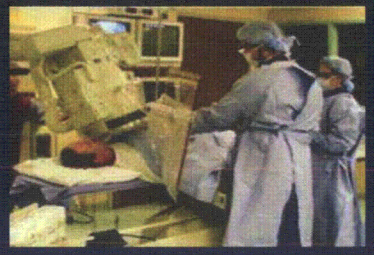
NRC - What We Regulate

- **Nuclear reactors** - commercial power reactors, research and test reactors, new reactor designs

- **Nuclear materials** - nuclear reactor fuel, radioactive materials for medical, industrial and academic use



- **Nuclear waste** – transportation, storage and disposal of nuclear material and waste, decommissioning of nuclear facilities

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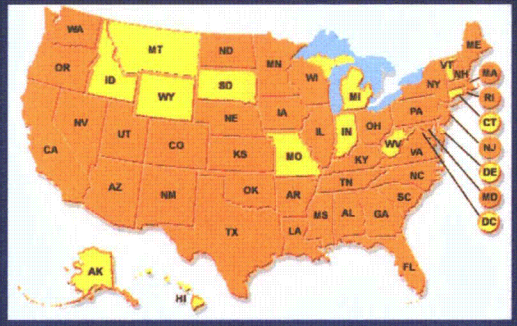
Who Does What?

- **NRC and States** regulate radioactive materials
  - Authority relinquished by Agreements to States (37)
  - Adequacy and Compatibility requirements
    - Some things essentially identical
    - Some things States can be more restrictive
    - Some things (reactors) reserved to NRC
- **States** regulate machine produced radiation
  - X-ray, CT, Mammography, Fluoroscopy, etc.
  - Most State radiation protection requirements match for materials and machine produced radiation



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Other Responsible Organizations

- Federal
  - EPA – General and Environmental Standards
  - DOE – Military, Promotion, Education
  - HHS – Medical and Devices
  - DHS – Security and Emergency Response
- Interagency Steering Committee on Radiation Standards
  - Forum for Federal agencies to keep abreast of national and international radiation protection activities
  - Identifying interagency issues and coordinating their resolution

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Background of Regulations

- NRC regulations last revised in 1991
- Requirements in Part 20, Licensing Parts
- NRC staff analysis indicated areas warranting consideration for revision
- Commission approved staff recommendation to engage stakeholders and initiate development of technical basis materials on April 2, 2009

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Outreach Activities

- Phase I of outreach included:
  - Presentations to numerous organizations and groups
  - FRN published inviting inputs (72 FR 32198)
- Phase II Workshops
  - FRN published with issues and questions (75 FR 59160)
  - Workshops in Washington, Los Angeles, and Houston
- Phase III Comment – Lens of the Eye
  - FRN published asking for feedback (76 FR 53847)
  - Comments due by October 31, 2011

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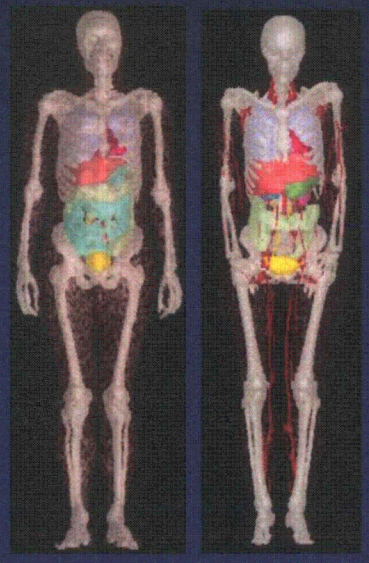
TED and Numerical Values

- Issue: Update terms and scientific information?

- Feedback:
  - General support for updating numerical values and scientific base
  - Mixed views on terminology
  - Many suggested delaying rulemaking until ICRP completes work on dose coefficients
  - Some discussion of moving from Regulation to Guidance



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Occupational Dose Limits

- Issue: Change the Occupational Dose Limit?

- Feedback:
  - Little support for change to regulation
  - Certain groups of licensees continue to have individuals above 20 mSv/yr (2 rem)
  - Legal Boundary for enforcement needs to remain as is
  - ALARA has resulted in achieving desired dose reductions
  - Many do not believe changes in risk justify change to limit

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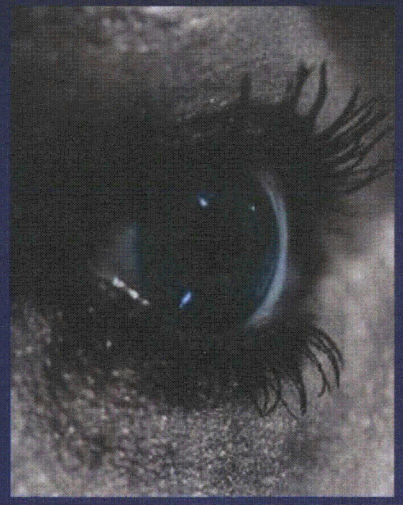
Lens of the Eye

- **Issue: New Recommendation from ICRP**
  - ICRP recommendation is now 20 mSv (2 rem) over 5 years, with a maximum of 50 mSv (5 rem) in any one year
  - Part 20 limit is 150 mSv (15 rem) per year
  - Fluoroscopy and other procedures contribute significantly
- **Feedback:**
  - Caution needed in making any changes
  - Numeric value for LDE could be the same as the numeric value of TED, to avoid compliance issues



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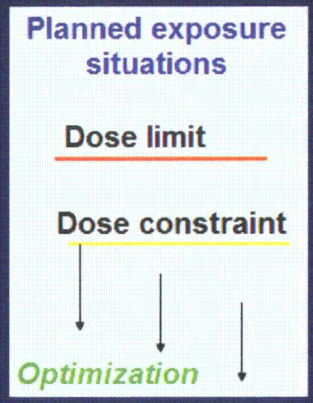
ALARA Planning

- Issue: Add to requirements for ALARA?

- Feedback:
  - Most licensees do planning to reduce exposures and use a variety of criteria to trigger actions
  - Little support for using the term "constraint"
  - Many concerned that any numerical values in regulations will be a *de facto* limit
  - Some support for explicitly requiring planning, but with reservations of what inspectors would be expecting in licensing programs



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Path Forward

- Policy paper for Commission consideration in April 2012
- Development of Technical Basis to support Commission decisions
- It is still "too soon to tell" what the staff will ultimately recommend
- Comments and views welcomed

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Interagency

- NRC working with interagency through ISCORS to keep them up to date on stakeholder dialogue
- Federal Agencies funding for development of dose coefficients
- Discussions underway on need to update Federal Guidance documents (EPA lead)

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Resources

- Web pages

  http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html

- Email Address: regs4rp@nrc.gov

  Rulemaking.Comments@nrc.gov

- Rulemaking Web Site:

  http://www.regulations.gov

  Docket ID: NRC-2009-0279

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Questions?

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