DANIEL K. INOUYE
HAWAII

APPROPRIATIONS
Chairman, Subcommittee on Defense

COMMERCE, SCIENCE AND TRANSPORTATION
Chairman, Subcommittee on Communications

Chairman, SELECT COMMITTEE ON INDIAN AFFAIRS

Chairman, DEMOCRATIC STEERING COMMITTEE

Member, COMMITTEE ON RULES AND ADMINISTRATION

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November 1, 1993

Mr. Dennis Rathbun
Director, Office of Congressional Affairs
Nuclear Regulatory Commission
Mailstop 17A3
Washington, DC 20555

Dear Mr. Rathbun:

I wish to share with you a letter from Dr. Don Tolbert, a medical physicist at Tripler Army Medical Center in Hawaii, regarding the Nuclear Regulatory Commission's (NRC) proposed revision of Title 10, Part 20 of the Code of Federal Regulations. As you know, this revision proposes to lower the annual limit of radiation treatment given to individual members of the general public from 0.5 rems to 0.1 rems, by January 1, 1994.

Within applicable rules and regulations, would you please comment on Dr. Tolbert's concerns? Thank you for your attention to this matter.

Aloha,

DANIEL K. INOUYE
United States Senator

DKI:kgf
Enclosure

cc:Dr. Don Tolbert

DEPARTMENT OF THE ARMY
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER
TRIPLER AMC, HAWAII 96859-5000

Radiation Therapy Service
HSHK-DRT

February 23, 1993

Honorable Daniel K. Inouye
U.S. Senator from Hawaii
Prince Kuhio Federal Bldg
Room 7325
Honolulu, HI 96813

Dear Senator Inouye:

In 1985, the Nuclear Regulatory Commission (NRC) proposed a revision in the Title 10 of the Code of Federal Regulations, Part 20. This Part is entitled "Standards for Protection Against Radiation". Of major importance, is the change in the annual limit for individuals of the general public. This limit has been at 0.5 Rems since circa 1976. The NRC wishes to lower the limit to 0.1 Rems and have announced plans to do that by January 1, 1994.

I am a medical physicist. As such, I am concerned about the optimal use of radiation. Radiation cannot be used optimally unless appropriate protection is an integral part of use. As you can well imagine, the cost of protection increases dramatically as limits of exposure are lowered. Part of this increased cost incidentally, is for people such as myself to evaluate protection needs in view of more stringent protection criteria.

I have looked at only the tip of a monumental iceberg of cost to medical institutions (see the enclosed paper that was presented to a Symposium on "Current Regulatory Issues in Medical Physics" sponsored by the American College of Medical Physics in April of 1992). My very conservative estimate approaches $300,000,000.

There are learned groups that suggest consideration of the 0.1 Rem limit - for certain situations. One consideration for implementing anything of this nature is certainly economic. Financial models for implementing programs to keep exposures as low as reasonably acheivable are available. These models require consideration of the cost for protection, as well as the cost of the health detriment associated with the exposure to be eliminated (see the first and last two pages of the enclosed article).

To my knowledge, the NRC has not produced an economic impact statement regarding this revision. This is deplorable during these times of economic restraint, and shows poor example. My professional society is pursuing the means to force the NRC to be accountable. My hope is that you will examine this issue. If the NRC is not required to justify new regulations with an economic impact statement, then why.

I appreciate your consideration and look forward to your reply.

Very Sincerely,

Don Tolbert

Don Tolbert, Ph.D.
Certified by the American Board of Radiology in Radiological Physics, & Fellow of the American College of Medical Physics

*ddt
Enclosure

ECONOMIC IMPACT ON INSTITUTIONS TO COMPLY WITH TITLE 10 CODE OF FEDERAL REGULATIONS PART 20 REGULATIONS

By: Don Tolbert, Ph.D., Tripler Army Medical Center, Radiation Oncology Service, TAMC, HI 96859-5000

PREFACE:

An axiom of radiation safety is that as protection requirements become more restrictive, the cost of protection increases. How the cost will increase depends upon circumstances. To examine the overall economic impact, the cost for protection must be considered along with the savings encountered as a result of the increased protection. Specifically this refers to reducing the cost of health detriment.

The purpose of this paper is examine specific areas where protection costs will increase, in the context of optimizing the overall cost of radiation protection.

OPTIMIZING RADIATION PROTECTION COSTS:

NCRP Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel" includes a cost-benefit model for optimizing radiation protection. In the language of ALARA, the report states:

> "A level of radiation protection that is ALARA implies neither maximum protection nor maximum resource expenditure, but rather that detriments and resource expenditures have been optimized to yield the greatest net benefit."

In place of "radiation effect", more precise terms of "risks" and "detriment" are preferred. The ICRP defines "risk" as the probability that a given individual will incur a particular radiation-induced effect as a result of the dose received. The word "detriment" is defined as the probability of harm induced in an exposed group of people, taking into account both the probability and severity of all possible harmful effects. ("Cost-Benefit Analysis in the Optimization of Radiation Protection", ICRP Report No. 37, 1983.) Risk and detriment are therefore measures of probability, not certainty.

There is both an objective, and subjective component to health detriment. Examples of "subjective" health detriments are: psychological response to exposure, societal desire to avoid radiation risk in a disproportionate manner compared to other risks, or a desire to obtain public or worker goodwill by providing greater radiation protection than is otherwise warranted.

If we denote the cost of achieving a given level of protection by X($), and the cost of the objective health detriment by Y($), the maximum benefit occurs when the sum of the costs of radiation protection and radiation detriment is minimized, i.e.

$$1) \qquad X(\$) + Y(\$) = \text{minimum}$$

Note that Y($) contains only the "objective" detriment. NCRP Report No. 107 considers only the "objective" health detriments "because subjective detriment is not based on biological response, and its dependence on dose equivalent is problematic."

REGULATORY CHANGES IN 10 CFR PART 20:

On December 20, 1985 the Nuclear Regulatory Commission (NRC) published the original Proposed Rule Change for Part 20 of Title 10, Code of Federal Regulations. The new Part 20.1301(a) states that -

"Each licensee shall conduct operations so that - - -

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with Part 20.2003, and

(2) The dose in any unrestricted area from external sources does not exceed 0.002 (0.02 mSv) in any one hour."

The new Part 20.1301(c) states that - - -

"The licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragrapph (a) of this section;

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose as low as is reasonably achievable."

On May 21, 1991 the NRC issued the above (and other) revisions to its standards for protection against ionizing radiation, 10 CFR Part 20. Although the revised part became effective on June 20, 1991, licensees may defer implementation of the revised rule until January 1, 1993. Licensees continue to be required to comply with the old version until the time they adopt the new version. Therefore between June 20, 1991 and January 1, 1993, both the old and new versions are in effect.

SHIELDING:

Requiring a limit of 1 mSv annually to individual members of the public has obvious implications regarding shielding. This is of particular concern for megavoltage radiation oncology equipment. While the NRC governs only Cobalt units, the impact of it's regulations on safety issues outside of its jurisdiction is considerable. Medical/health physicists would most likely design shielding for a linear accelerator based upon 0.1 mSv per week (corresponding to 5 mSv annually) since the NRC has stipulated that 0.02 mSv per week is required for public safety.

The impact of requiring 0.02 mrem per week is examined here for the following conditions:

Primary Barrier (Distance = 7 meters)

Occupancy Factor = 1

Use Factor = 0.25

Workload (R/week @ 1 meter):

60,000 (Cobalt)

100,100 (10 and 18 MV)

The Workloads, Use Factors, Occupancy Factors, and concrete thicknesses for Cobalt and 10 MV x-rays were taken from the recommendations of NCRP Report No. 49 ("Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MEV"). The curves shown in E.12, APPENDIX E of NCRP Report No. 51 ("Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities") were used for the 18 MV quality x-ray beam.

The additional concrete and percentage increase in shielding required for the 0.02 mSv/week limit is shown in the following

Modality	Additional Conrete (In.)	% Increase
Cobalt	6 to 7	16
10 MV	12	16
18 MV	12	15

The impact upon secondary barriers is approximately the same for both scatter and leakage conditions.

The situation of minimum cost would be that for adding the additional shielding at the time of construction. Construction costs vary from one geographical region to another. The cost of concrete in Hawaii (density 147 lbs per cubic feet) is approximately $175 per cubic yard. If the length and height of one wall is 30 and 10 feet, respectively, the cost of additional concrete only, and for one wall of the Cobalt unit facility is approximately $1,100. If three walls require additional shielding, the total cost may be $4,000 (Note: the cost of additional concrete has been increased by 20% to account for labor and formwork).

It will cost more of course to add additional shielding to an existing structure. Steel or lead is likely to be the shielding material of choice because of space considerations. The cost of steel (in Hawaii) would be approximately $80,800 for one wall of the Cobalt unit and $117,500 for the higher energy megavolt units. Access costs have not been included. Including these costs, and again assuming three walls are modified, the total construction cost may be $360,000 and $530,000, respectively (Note: The cost of additional shielding due to steel alone has been increased by 50% to account for "access" costs). Using the lower cost figure, and conservatively assuming that 500 of the 1500 radiation oncology facities would have to add additional shielding, the total cost would be at least $180,000,000.

ON THE USE OF IODINE-131 IN NUCLEAR MEDICINE:

The activity below which a patient may be released from the hospital was derived using information from NCRP Report No. 37 ("Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides"). This activity limit was based upon confidence that no individual member of the public receive more than that allowed in Part 20. The limit corresponding to the annual limit of 5 mSv is 30 mCi.

Consider an individual containing an activity of 30 mCi. Relating that activity to an annual equivalent dose of 5 mSv, one can say:

2) 30 mCi x (1.44 x T1/2(30) Hrs.) x R(mSv/mCi*Hr) = 5 mSv

Multiplying 1.44 by the half-life of a radioactive entity yields the average life assuming the source has emitted radiation at a

constant rate. T1/2(30) above represents the effective half-life for a patient which contains thirty millicuries of activity. R(mSv/mCi*Hr) simply represents the exposure rate per mCi. The R value probably should be expressed at a particular distance, and it can be obtained from NCRP Report 37. For the purpose here, it doesn't matter what the value is, only that it exists, and that it remains constant in its use with expression 2) above and 3) below.

Correspondingly, if we let X(mCi) denote the level of activity which would provide confidence that no member of the public would receive more than 1 mSv annually, one can say:

3) X(mCi) x (1.44 x T1/2(x) Hrs.) x R(mSv/mCi*Hr.)) = 1 mSv

Here T1/2(x) refers to the effective half-life for patients which contain the activity necessary for discharge and consistent with the new limit for public exposure.

Combining 2) and 3), the value of X(mCi) becomes:

4) X(mCi) = 6 x T1/2(30) / T1/2(x)

The decay of activity in patients receiving therapeutic amounts of Iodine-131 shows a variation in effective half-life values. Initially, the effective half-life ranges from twelve to sixteen hours as most of the activity leaves the patient via urination. As residual activity decays, and well below the 30 mCi level, the effective half-life can be as long as four to five days.

Modifying the factor of "6" in expression 4) by 0.13 (using the extremes of the above range) is probably unrealistic. A modification factor of 0.3 is probably an upper limit. This would place the activity below which individuals of the general public should receive 1 mSv or less, at less than two mCi's.

To examine the potential economic impact of this, consider that in 1989 there were 5,000 I-131 administrations for cancer of the thyroid, 10,000 I-131 administrations for metastatic surveys, and 35,000 I-131 administrations for hyperthroidism (Carol Marcus, M.D., private communication). Conservatively assume four days of hospitalization for each of the hyperthyroid patients, one day of hospitalization for the metastatic survey patients, an extra three days for the thyroid cancer patients, and $600 per day hospitalization costs. The total additional cost for this would be over $100,000,000.

OTHER PARTS AFFECTED BY PART 20 REVISIONS:

Only a small portion of the cost of protection has been examined above. Other Parts of 10 CFR affected by the changes in Part 20 includes those dealing with Radiography, Well Logging, Licensing of Source Material, High Level Radioactive Waste Disposal, Low Level Radioactive Waste Disposal, Intermediate Storage of Fuel and High Level Radioactive Waste Disposal, and other Parts relating to the nuclear power industry.

A systematic evaluation of the limits in these Parts has not been done for this report, however implicit and/or explicit exposure limits expressed in these Parts, will be affected by the requirement that individual members of the general public may now

be exposed to one-fifth of the previous limit. This will require additional shielding. This is a cost that must be borne by the Licensee.

REDUCING THE COST OF HEALTH DETRIMENT:

The above shows an obvious and very significant increase in the cost for protection. In order to justify the need for revising the limit from 5 to 1 mSv, the savings resulting from a reduction in the health detriment must be demonstrated. What is the cost of objective (not to mentione subjective) health detriment, as expressed in expression 1) above?

SUMMARY:

Revising the limit to individual members of the general public from 5 to 1 mSv has not been given proper attention. There are members of the NRC Medical Advisory Committee that never saw the proposed changes before publication in the Federal Reister. Was the Medical Advisory Committee asked to comment, as is normally the case when proposed rule changes are being considered?

The author would like to take this opportunity to formally request that the NRC withdraw implementation of revised Part 20 until a more credible analysis of economic impact can be performed. This analysis must include the economic benefit due to reducing the health detriment (see expression 1)) which would result from the reduced exposure.

ACKOWLEDGEMENTS:

The author would like to expecially thank Carol Marcus, M.D. for her help in gathering information contained in this report. Similarly I would like to thank Mr. Wayne Herlick for his estimate of shielding costs.

Additionally I would like to thank Brent Murphy, M.S., Marc Coel, M.D., and M. Pattel, Ph.D. for their technical review of certain aspects. I would also like to thank Ms. Mattie Pringle for her editorial review.

DANIEL K. INOUYE
HAWAII

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Chairman, Subcommittee on Defense

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November 1, 1993

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Nuclear Regulatory Commission
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Washington, DC 20555

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Aloha,

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DKI:kgf
Enclosure

cc:Dr. Don Tolbert

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DEPARTMENT OF THE ARMY
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER
TRIPLER AMC, HAWAII 96859-5000

Radiation Therapy Service
HSHK-DRT

REPLY TO ATTN OF

February 23, 1993

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U.S. Senator from Hawaii
Prince Kuhio Federal Bldg
Room 7325
Honolulu, HI 96813

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 2, 1994

The Honorable Daniel K. Inouye
United States Senate
Washington, DC 20510-1102

Dear Senator Inouye:

I am responding to your letters of November 1, 1993, and January 19, 1994, regarding the concerns of Dr. Dun Tolbert about the NRC's radiation protection regulations in 10 CFR Part 20.

The NRC published a final rule amending its radiation protection regulations on May 21, 1991 (56 Federal Register 23360). NRC licensees are required to comply with the rule no later than January 1, 1994. However, this rule was proposed for public comment on January 9, 1986 (51 Federal Register 1092). More than 800 sets of comments from organizations and individuals were received during the 296-day comment period.

JBlaha MLesar MBridges-EDO 9502

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2. TYPE OF DOCUMENT X Correspondence ____ Hearings (Qs/As)

3. DOCUMENT CONTROL ____ Sensitive (NRC Only) X Non-Sensitive

4. CONGRESSIONAL COMMITTEE and SUBCOMMITTEES (if applicable)

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5. SUBJECT CODES

(a) ____

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