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United States Nuclear Regulatory Commission

Protecting People and the Environment

Overview of ACMUI Activities

Bruce Thomadsen, Ph.D.

ACMUI Chairman

May 9, 2014

ACMUI Purpose

- The ACMUI exists to advise the NRC staff, and thus you, the Commission, on policy on medical uses of radionuclides.
- Also, provide technical assistance and serve as consultants.

Membership Positions

- Health Care Administrator
- Nuclear Medicine Physician
- 2 Radiation Oncologists
- Nuclear Cardiologist
- Diagnostic Radiologist
- 2 Medical Physicists
- Nuclear Pharmacist
- Radiation Safety Officer
- Patients' Right Advocate
- Agreement State Representative
- U.S. FDA Representative

Some topics addressed by the ACMUI in the last 6 months

- Refining some aspects of the 10 CFR Part 35 Rulemaking,
- Considering some of the uncertainties in the assumptions involved with patient release following iodine-131 therapy,

ACMUI Topics (Continued)

- New methods for production of molybdenum-99 from low-enriched uranium,
- Inspection guidance for permanent brachytherapy with respect to potential medical events,

ACMUI Topics (Continued)

- Medical events involving yttrium-90-labeled microspheres,
- The definition for abnormal events,
- Classifications for, qualification for users of, alpha-emitting radiopharmaceutical,

ACMUI Topics (Continued)

- Classification for the ViewRay device,
- Nuclear medicine generator break-through problems, generator design and qualitiy assurance requirements.

Additional ACMUI Topics

- **Safety culture in various aspects of applications,**
- **The organizational relationship between the Committee and the Commission**

Current ACMUI Topics

- Continuing discussions of:
  - Patient release
  - Radionuclide availability
  - Medical events and the reliability of specific procedures
- The NRC's medical use policy
- The ACMUI bylaws

Credit to the Past ACMUI Chair

Much of the credit for the current effective operation of the ACMUI stems from the insight and guidance of the immediate past chair, Leon Malmud, M.D., who managed to bring persons together.

Future

- **Over much of the last decade, a strong, cooperative relationship has developed between the ACMUI and the NRC Staff.**
- **We will work hard to maintain this functional, respectful spirit.**

Acronyms

ACMUI – The Advisory Committee on Medical Uses of Isotopes

FDA – The Food and Drug Administration

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ACMUI's Position on Patient Release

Pat Zanzonico, PhD, DABR

ACMUI

May 9, 2014

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ACMUI, 12/10/10
"Patient Release Report"

- **Medical use of radionuclides**
  - **Widely recognized health benefits**
  - **Public doses ≈ Background levels**
  - **Avoid burdensome regulatory control**

- **Doses to other individuals can be safely controlled**
  - **Current 10 CFR 35.75 dose-based release criteria: 5-mSv (500-mrem) dose limit per event**
  - **Patient and caregiver post-release instructions adapted to individual circumstances**

- **10 CFR 35.75 release criteria consistent with national and internal dose-constraint standards**

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10 CFR 35.75 "30-mCi Rule"

Dose- vs Activity-Based Release Criteria

- **Dose: A more meaningful and direct metric of radiation risk than activity**
- **Patient activity does <u>not</u> predict dose to other individuals**
- **ACMUI endorses current 10 CFR 35.75 dose-based release criteria**

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Dose-Based Release Criteria: Issues Associated with Outpatient Therapy

- **Negligible (<10%) dose contribution of internalized contamination**
- **Patient release to non-residence locales**
  - **Hotels**
- **Patient transportation post-treatment**
  - **Public vs private**
- **Patient vomiting post-treatment**
  - **Frequency uncertain**
- **Clarity and consistency of post-release precautions**
  - **NCRP Report 155**

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Dose Contribution of Internalized Contamination

- **Significant peer-reviewed literature**
  - **>20 papers**
  - **Thyroid uptake measurements**
  - **Range of precautions**
- **Results consistent with minimal internal-dose contribution**

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Patient Release to Non-Residence Locales: Hotels

Illustrative Anaysis

- Activity for thyroid cancer: 175 mCi ^{131}I
- Internal dose negligible
- Attenuation factors: Patient, 0.60; Walls, 0
- Total-Body time-activity function: 95%, 8-hr T_e; 5%, 7-day T_e

	Conservative	***Realistic***
Activity excreted into bed linens	50 %/day	5 %/day
Time workers hold linens (@ 0.3 m)	30 min/day	10 min/day
Time workers/other guests @ 1 m from Patient	3 hr/day	1 hr/day
Time patient and adjoining-room guests in respective beds (@ 2 m)	12 hr/day	8 hr/day

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Patient Release to Non-Residence Locales: Hotels *cont*

Results of Illustrative Anaysis

	Conservative			Realistic		
	EDE (mrem)					
Days at hotel immediately post-therapy	***1***	***2***	***3***	***1***	***2***	***3***
Hotel Housekeeper	**69**	**83**	**91**	**0.9**	**1.1**	**1.2**
Hotel Laundry Worker	**39**	**47**	**52**	**0.08**	**0.09**	**0.1**
Guests in Adjoining Rooms	**54**	**65**	**71**	**17**	**21**	**22**
Other Hotel Workers / Other Guests	**30**	**36**	**39**	**0.8**	**1.0**	**1.1**

< 100 mrem

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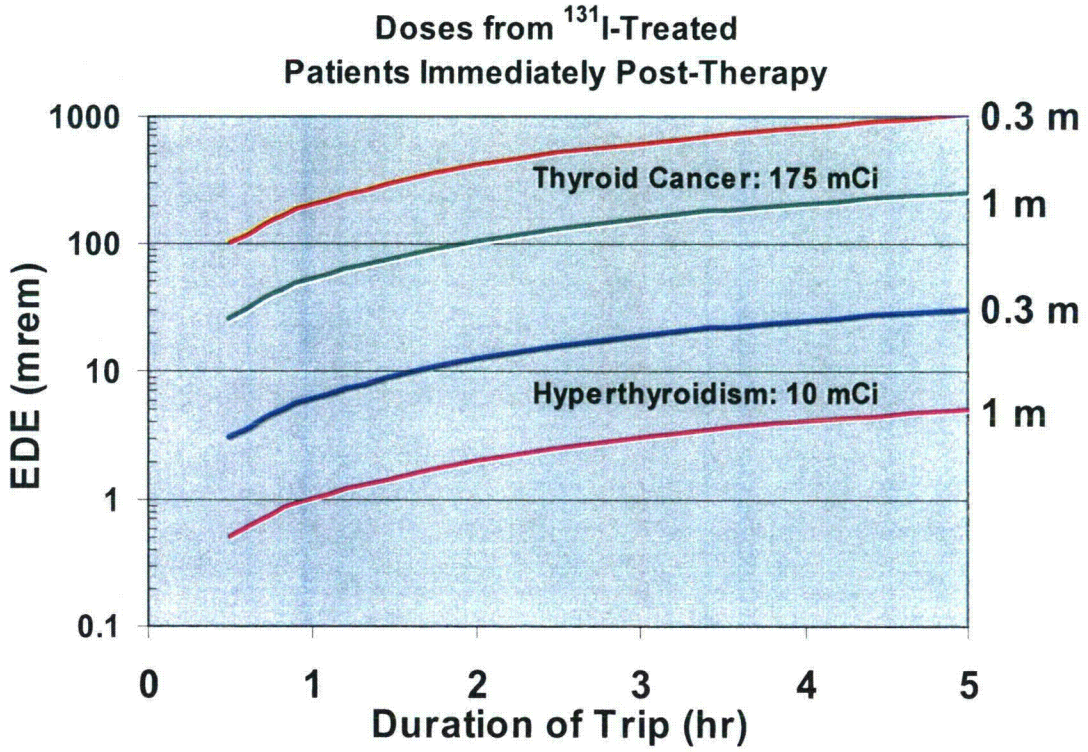
Post-Therapy Transportation from Hospital
(not included in Sub-Committee Report)



Culver and Dworkin. J Nucl Med 33: 1402, 1992
NCRP Report No 124, 1996

- **Patients treated with >100 mCi**
  - **Avoid public transportation**
  - **Avoid long (>1 hr) trips**
  - **Travel in car seated alone in back seat**
  - **Driver other than household member**
- **Patients treated with <100 mCi**
  - **No restrictions on modes of travel**

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ACMUI's Position on Patient Release

- **Medical use of radionuclides safely serves public interest and should not be burdened by excessive regulatory controls**

- **Doses to other individuals from released radioactive patients can be safely controlled by current dose-based 10 CFR 35.75 release criteria**

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Abbreviations and Acronyms

- **ACMUI:** Advisory Committee on Medical Uses of Isotopes
- **CFR:** Code of Federal Regulations
- **EDE:** Effective dose equivalent
- **hr:** hour
- **NCRP:** National Council on Radiation Protection and Measurements
- **T_e:** Effective half-life

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Reliability of Radiation Safety Instructions for Patients Released Following I-131 Therapy

Laura Weil

ACMUI Patients' Rights Advocate

May 9, 2014

Assumption

Patient release is safe because patients are receiving and following good instructions to minimize radiation exposure to others.

Two problems

- **Timing of instructions to patients**
- **Quality of instructions**

Patient Testimony

"I am due to have my RAI the first week in August ... I have a million and one questions on it and all I get told by my nuclear medicine dr is I will get instructions the day I get the RAI...I will be coming home right after receiving it. Asked to be admitted to the hospital ~ was told it was not necessary (I have 4 children, married and live in an apartment)."[1]

Patient Testimony

"I've noticed is that patients are often given vague or inadequate instructions. Radiation safety is a difficult subject to boil down to a page or two of instructions. This seems to lead to much patient confusion and stress... Add some emotion, stress, fear, hypo[thyroid] symptoms and you are asking for problems. Luckily I have a background in radiation safety or I would have been totally blindsided by the precautions that were expected. There has to be a better way of conveying the message!"[1]

Patient Testimony (2 patients with same dose of ^{131}I)

"So your Dr. told you 1 week?? [isolation] Mine said I am good to go back to work on Monday??? [5 days after treatment] I teach Kindergarten!!!! I feel like the guidelines are so different from Dr. to Dr. - it seems as though they would be the same??? I am erring on the side of safe and staying away for a week."[1]

Patient Testimony

10 year old was treated at a university hospital. Mother was given virtually no instructions for post-treatment period, other than to stay far away from patient in the car on the long drive home. With another young child at home, mother was given no instructions to isolate the patient from her sibling, or about solitary sleeping or bathroom use, eating utensils, and laundry. Suspicious re lack of precautions, mom accessed ThyCa for information. She sent her younger child to relatives for 3 days.[6]

Greenlee's survey: protections for breastfeeding mothers and infants

- 7% of respondents recommended avoiding breast-feeding only when the therapeutic activity was >30 mCi, and half did not see a need to avoid breast-feeding beyond the first 48 hours after radioiodine treatment.[4,5]

American Thyroid Association Breastfeeding guidelines

- **ATA guidelines state breastfeeding must stop 6 weeks prior to treatment and not be resumed (safe after subsequent pregnancies) for the protection of both mother and child.**

In Summary

We should not rely on the assumption that the public health is protected by assuming that the best case scenario of patient care is universally applied.

The assumption of adequate and timely patient instruction must be verified.

References

1. www.Inspire.com

2. Richard T. Kloos, M.D. (2011) Survey of Radioiodine Therapy Safety Practices Highlights the Need for User-Friendly Recommendations. Thyroid 21:2 97-99.
3. Greenlee MC, et al. (2011) Current safety practices relating to I-131 administration for diseases of the thyroid: a survey of physicians and allied practitioners. Thyroid 21:2 151–160.
4. Weil notes. Interview at ThyCa conf. 2012

Abbreviations and Acronyms

- **RAI: Radioactive Iodine**
- **ThyCa: Thyroid Cancer Survivors Association**
- **mCi: millicurie**
- **mSv: millisievert**
- **ACMUI: Advisory Committee on the Medical Uses of Isotopes**
- **Nuc Med: nuclear medicine**
- **ATA: American Thyroid Association**

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ACMUI Views on Revision to the NRC's Medical Uses Policy Statement

Bruce Thomadsen, Ph.D.

ACMUI Chairman

May 09, 2014

ACMUI Comments

- The ACMUI was asked to consider if the NRC should look into revisions to the policy on medical uses of byproduct materials.
- A subcommittee was formed to study the issue.

Subcommittee Membership

- Philip Alderson, M.D.
- Milton Guiberteau, M.D.
- Chris Palestro, M.D.
- John Suh, M.D.
- James Welsh, M.D.
- Bruce Thomadsen, Ph.D., Chair

A Brief History of the Policy: 1979

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

A Brief History of the Policy: 1979

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards are inadequate.

A Brief History of the Policy: 1979

3. **The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.**

A Brief History of the Policy: 2000

1. The NRC will continue to regulate the uses of radioisotopes in medicine as necessary to provide for the radiation safety of workers and the general public.

A Brief History of the Policy: 2000

2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

A Brief History of the Policy: 2000

3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

A Brief History of the Policy: 2000

4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

Some Concerns (1)

There have been some concerns that some rules, for example involving the definition of medical events and training and experience, may have unduly affected medical practice without increasing safety.

Some Concerns (2)

The revision of Part 35 seems to have alleviated these concerns and brought the rules into line with the policy.

ACMUI's Recommendation

The ACMUI feels that the current statement provides for medical uses of radionuclides safely for patients, subjects, staff and the general public while avoiding intrusion into the practice of medicine, and no revision is warranted at this time.

Acronyms

ACMUI – The Advisory Committee on Medical Uses of Isotopes

NRC – U.S. Nuclear Regulatory Commission

FDA's Radiation Regulatory Responsibilities

Presented at Nuclear Regulatory Commission Briefing

May 09, 2014

Rockville, Maryland

Orhan H. Suleiman MS, PhD, FAAPM, FHPS

Senior Science Policy Advisor

Office of New Drugs (ODE IV)

Center for Drug Evaluation and Research

The opinions I express today may not necessarily reflect the official position of the Food and Drug Administration (FDA) or the Department of Health and Human Services (DHHS). Similarly, the mention of any commercial products are neither an official endorsement or criticism of the product by me, the FDA, or DHHS.

Ground Rules

- Congressional Statutes define both NRC and FDA's responsibilities.
- Standards educate, define good practice.
  - Voluntary standards- Guidance, NUREG, Reports, Society publications, etc.
  - Regulations are Mandatory standards, requiring enforcement.
  - When is this warranted?

Food, Drug and Cosmetic Act (FDCA) - 1906

- Law has been amended more than 200 times.
- Laws* incorporated as subchapters within Title 21.
  - Subchapter D- Drugs (Part 300- original statute - 1906);
  - Subchapter F- Biologics (Part 600)
  - Subchapter H- Medical Devices (Part 800 - 1976)
  - Subchapter I - Mammography (Part 900 - 1992)
  - Subchapter J - Radiological Health (Part 1000-1968)

* These products associated with radiation

FDA Organization

- **Office of the Commissioner**
  - National Center for Toxicological Research
- **Office of Medical Products and Tobacco**
  - Center for Drug Evaluation and Research
  - Center for Biologics Evaluation and Research
  - Center for Devices and Radiological Health
  - Center for Tobacco
- **Office of Foods and Veterinary Medicine**
  - Center for Veterinary Medicine
  - Center for Food Safety and Nutrition
- **Office of Global Regulatory Operations and Policy**

Radiation Emitting Electronic Products (Radiation Control for Health and Safety Act of 1968)*

- Mandatory Emission Performance Standards
- Includes consumer and medical products
- Microwave ovens, lasers, cell telephones
- X-rays (medical and security products)

* Center for Devices and Radiological Health

Medical Device Act of 1976*

- 510 (k) – predicate device, substantial equivalency to preamendment devices
- Class I – Minimal controls
- Class II- Special controls
- Class III
  - High risk devices
  - May require clinical trials for premarket approval (PMA).
  - *Center for Devices and Radiological Health

What does it take to get a drug approved?

Human Subject Research under an Investigational New Drug (IND) Application

- Phase I- Safety "n ~ 20 – 80"
- Phase II- Efficacy "n < several hundred"
- Phase III- Large scale studies "n ~ several hundred to several thousand"

New Drug Application

- NDA Process:
  http://www.fda.gov/cder/regulatory/applications/nda.htm#Related%20Topics:

- Application Fee for NDA ~ $1 M+

Manufacturing Inspection

New Drug manufacturing sites inspected prior to approval.

International manufacturing sites inspected by FDA staff.

FDA does not delegate it's regulatory authority to other agencies.

Any regulated product's manufacturing site is subject to FDA inspection.

Drug, biologic, or device?

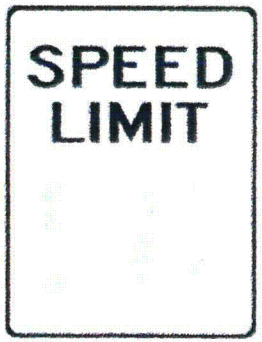
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

Y-90 Microspheres, tiny physically sealed sources (resin/glass) which are physically trapped in tiny hepatic blood vessels – classified as medical device.

Y-90 labeled monoclonal antibodies target CD20 antigen which were originally classified as biologic, now a therapeutic cancer drug. Mechanism of interaction is chemical.

My Regulatory Concerns

- Technologies are increasingly complex
- Statutory authorities are complex and do overlap
  NRC-FDA Memorandum of Understanding (MOU)
- Regulatory balance - General vs Prescriptive
- Education versus Regulation (Voluntary vs Mandatory)
- When does safety warrant a mandatory standard?



Acronyms

- CBER – Center for Biologics Evaluation and Research
- CDER – Center for Drug Evaluation and Research
- CDRH – Center for Devices and Radiologic Health
- DHHS – Department of Health and Human Services
- FDA – Food and Drug Administration
- FDCA – Food, Drug, and Cosmetic Act
- IND – Investigational New Drug
- NDA – New Drug Application
- NUREG – NRC technical report designation
- PMA – Pre-Market Approval

Thank You

Questions?

10903 New Hampshire Ave
Silver Spring, Maryland

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General Views on the Regulation of Medical Uses of Byproduct Material – Part 35

Susan M. Langhorst, Ph.D., CHP
ACMUI Radiation Safety Officer
May 9, 2014

NRC Medical Use Policy

NRC will, when justified by the risk to the patient, regulate the radiation safety to patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

Medical use of radiation is different.

It involves purposely exposing an individual to radiation to diagnose or treat what can be a serious or life-threatening illness.

Medical use of radiation is different.

Most NRC regulations -

radiation risk, dose limits, and ALARA

Notable exception -

no NRC regulations set a dose limit for patients; recognize personal benefits

Medical use of radiation is different.

Medical use regulation requires resources and expertise to develop rules that protect the patient and does not adversely impact the patient-physician relationship.

NRC's Medical staff & resources?

- 6 FTE assigned to NRC Medical Team
- Lack practicing medical professionals (physicians and medical physicists) on NRC Staff
- ACMUI – Advisory committee to NRC Staff
- Who routinely provides the Commission with medical use advice?

Medical use of radiation is different.

- "Patient centered"
- Requires unique regulatory model which recognizes and respects culture of healthcare
- NRC's Medical Use Policy - promote patient safety without inhibiting patient access to medical care

- **No medical diagnosis or therapy comes with a guarantee of success no matter how hard we all try to make it so.**
- **It is a challenge to set reasonable controls and to choose reasonable compliance measurements in support of patient safety.**

Challenge of Implementing NRC Medical Use Policy

Measuring and Documenting Compliance?

Establishing Compliance Measures?

Medical use of radiation is different.

Determining reasonable, understandable, and consistent regulatory control of patient safety deserves more resources, different models of using medial expertise, and a more combined effort between NRC, including Agreement States, and the medical community.

Acronyms

ACMUI – The Advisory Committee on Medical Uses of Isotopes

FTE – Full time equivalent staff

NRC – U.S. Nuclear Regulatory Commission

STATEMENT OF PETER CRANE
NRC Counsel for Special Projects (Retired)
before the
Advisory Committee on the Medical Uses of Isotopes
Meeting of May 8-9, 2014

My name is Peter Crane, and I appreciate the opportunity to submit a statement to this May 2014 meeting of the Advisory Committee on the Medical Uses of Isotopes. I am a retired NRC lawyer who spent 23 years with the agency, and my interest in the regulation of medical isotopes is both professional and personal. As a survivor of thyroid cancer, treated successfully for a recurrence with radioactive iodine 131, I probably have as great an appreciation as anyone here for the vital and life-saving role of these isotopes in diagnosing and curing cancer. Where I have sometimes differed with members of this Committee is on the appropriate precautions to be taken when I-131 is used, so that in treating the cancer patients of today, we do not unintentionally create the patients of tomorrow.

This meeting takes place against the backdrop of the excellent Staff Requirements Memorandum issued by the Commissioners on April 28 – the most positive step that the Commission has taken in this area since a previous Commission, quite possibly without realizing it, radically deregulated nuclear medicine treatments in 1997. Working within the framework of the existing patient release rule, the new SRM does a great deal both to address well-understood current problems and to obtain the information that might support further reforms. If it doesn't do 100 percent of what I would like to see, particularly with respect to radioactive patients in hotels, it nevertheless represents enormous progress, for which the Commission deserves great credit.

Laura Weil, the Patients' Rights Advocate on this Committee, has done a fine job of studying and documenting the inadequate and inconsistent safety guidance that released I-131 patients commonly receive. Clearly that message has got through. We have also had two Commissioners go to the horse's mouth, meeting with small groups of patients to learn first-hand about their experiences. The Commission has now acted to remedy the deficiencies in this area through the development of standardized guidelines for licensees to use in instructing patients about safety measures, and a form to make sure that patients receive and understand those instructions. It has also directed the staff to create a website where patients can get clear and consistent information.

Dr. Zanzonico of this Committee will confirm, I am sure, that over the past few years, I have repeatedly praised the model guidelines for I-131 patients that he wrote and that appear in NCRP Report No. 155, published in 2006.[1] Dr. Zanzonico is one of five co-authors of that excellent report, which belongs in the office of every Commissioner. His instructions are detailed and crystal clear, and I hope they serve as a starting point as the new model guidelines are prepared in response to the SRM.

---

[1]National Council on Radiation Protection, Report No. 155, *Management of Radionuclide Therapy Patients* (2006). The guidelines appear at pages 166-168. That report incorporated and updated an earlier NCRP report, No. 37, issued in 1970, which created the analytic framework for outpatient treatments above the 30-millicurie limit, while making clear that this was to be a rare exception, with a maximum I-131 dose of 80 millicuries, mandatory notification of local health departments, and yellow wristbands with the trefoil symbol to mark such patients as radiation hazards.

Going back to those instructions and that report in the last few days, I find a great deal to recommend, including the following five points:

1. An instruction that in the first day after treatment, the bed linens of the I-131 patient should be laundered separately and put through the rinse cycle twice. Quite obviously, that precludes sending radioactive I-131 patients to hotels, where their bed linens will be washed along with everyone else's. (p. 167)

2. An instruction that patients should flush the toilet twice after using it, should "rins[e] the shower stall, tub, or sink thoroughly after use," and should "wipe up any spills of urine, saliva and/or mucus" with tissues or disposable toweling and flush them down the toilet. *Id.* That makes perfect sense, but it also makes it all the more inexplicable that when the ACMUI subcommittee estimated radiation doses to hotel housekeepers who clean contaminated rooms, no consideration was given to the doses received while cleaning sinks and toilets. The entire bathroom was off limits. The obvious contradiction there needs to be addressed.

3. The report confirms that the release limits are on an annual, not a per-release basis. It says, at p. 145: "the foregoing limits are annual totals and, therefore, do not apply to individual treatments but collectively to all treatments a patient may receive in a given year." Quite right, and it's time we heard the last of the notion that NRC standards, unlike all national and international radiation standards, are on a per-release basis.

4. The maximum allowable radiation dose to members of the public – defined as "persons who have no familial connections to the patient and for whom there is no emotional benefit" – is one millisievert, or 100 millirems, per year. (At p. 19.) Given that the NRC rule says that anyone, regardless of age, sex, and pregnancy or nursing status, can receive **five times** that amount, I take this to mean that the authors of the report want the rule to be revised, presumably in favor of the kind of split standard we see in Part 20, with a 500 millirem limit for some persons and 100 millirems for others. I couldn't agree more. That definition also makes clear that both the hotel housekeeper and the hotel guest staying in the room adjoining the patient's are members of the public, subject to the 100 millirem per year standard.

5. Through-the-wall exposures are problematic and must be taken into account. Here's what the report says on that, in the hospital context: "Other patients confined in the medical facility may be unintentionally exposed to patients receiving radionuclide therapy. The usual source of this exposure is occupancy of a room immediately adjacent to a patient receiving therapy." (At p. 19.) If this is true in the hospital, it plainly applies also to persons staying in hotels or multi-family dwellings.

So I want to commend Dr. Zanzonico and his co-authors for a very sensible and clear-sighted approach to these issues, and I hope that the rest of this Committee agrees on all five points. All of this goes to show, incidentally, just how very mainstream my own views are.

Finally, I would like to return to a concern that Jim Luehman of the NRC staff raised as long ago as 2010: cumulative radiation doses to hotel workers who work in hotels that receive many I-131 patients from nearby cancer centers, and who may therefore clean a number of contaminated rooms in the course of a year. The ACMUI subcommittee did not address that issue, however, and though the question has repeatedly been put to Dr. Zanzonico, as the Committee's foremost expert on these matters – most recently by Commissioner Magwood, at the thyroid patients' conference in Philadelphia last fall – I have yet to hear a responsive answer. I would urge Dr. Zanzonico to give us the benefit of his expertise and judgment on this point. If the answer is that this is a non-problem, tell us why. If, on the other hand (and I hope this is not the case), the answer is that the repeated exposure of chambermaids to I-131 contamination, even without their knowledge, is an acceptable price to pay for keeping down the cost of health care, then say so, and at least we will have a basis for discussing the issue openly.

I myself can see no medical, legal, or moral justification for exposing a hotel housekeeper, possibly pregnant or nursing, to radiation in the workplace with neither her informed consent nor appropriate training and gear. My views are informed by the fact that my daughter once had a job making beds and cleaning bathrooms in a Seattle hostel. I know how I would have felt if I had learned that with only a pair of rubber gloves to protect her, she had unwittingly cleaned a room and bathroom contaminated with high levels of I-131. I cannot believe that anyone here would feel at all differently if it were their own daughter or granddaughter. Sooner or later, this grave wrong will surely be righted, and when that happens, I hope it will be with the support and assistance of this Committee.

Thank you.

Peter Crane
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