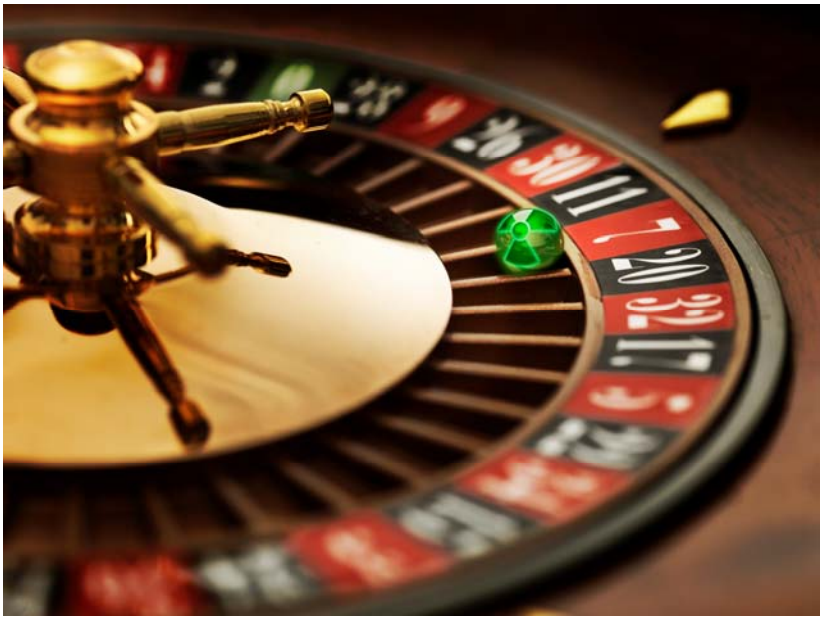
RADIOACTIVE ROULETTE:

How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety



A report by the Staff of Edward J. Markey (D-MA)
Chairman, Subcommittee on Energy and Environment
Energy and Commerce Committee
U.S. House of Representatives
March 18, 2010

EMBARGOED UNTIL THURSDAY MARCH 18, 2010
12:01 AM

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EXECUTIVE SUMMARY

In 1997, the Nuclear Regulatory Commission (NRC), in response to a proposal initiated by its own staff, weakened its rules surrounding the release of patients treated with radioactive iodine. The rules were changed away from a system used in Europe and other countries that requires the hospitalization of patients emitting high levels of radiation in order to protect children and other members of the public from being irradiated to one that allows most treatments to be performed on a less expensive outpatient basis.

NRC's weaker, current regulations depend on the ability of medical professionals to assess the living conditions of patients and use the results of this assessment to calculate the likely radiation dose to those people the patient might come into contact with. It is unclear whether such a calculation could be accurately performed for a patient choosing to recover from treatment with radioactive iodine in a hotel, since it would be impossible to characterize every hotel's layout, or know whether the hotel staff or other hotel guests included vulnerable populations such as pregnant women or children.

Despite reports from individuals and State regulatory authorities that patients are choosing to recover from treatment with radioactive iodine in hotels – thus unwittingly exposing members of the public to radiation –the NRC has consistently refused to ban or limit this practice, and indeed, has never even issued guidance in this area to its licensees. Instead, the NRC actually twice voted to reject NRC staff proposals that would have required reports of dangerous radiation doses delivered to members of the public, through exposure to released patients, to be submitted. One such vote would have only required notification of exposures that are ten times as high as NRC's own regulatory dose limits for released patients. Rather than addressing or remedying the problem, the NRC instead chose to actively ignore it.

Of the 3,700 facilities licensed to perform treatments using radioactive iodine, the NRC directly oversees only 500 of them, with the remainder overseen by State regulators. The NRC collects no information regarding the adequacy or enforcement of its regulations in the 3,200 facilities overseen by the States. Nor does it require the States to report back instances of severe violations. Even for the remaining 500 licensees, the NRC doesn't keep sufficient records to enable it to determine whether patients chose to recover in hotels – in fact, it doesn't even track how frequently its own inspectors request additional documentation regarding regulatory compliance from licensees.

While internal NRC documents indicate a clear awareness by the NRC that some patients treated with radioactive iodine do choose to recover in hotels, and that its regulations allow for this practice to be continued, the NRC Office of General Counsel, in a brief submitted to a federal court in opposition to a citizen petition urging strengthening of the NRC regulations in this area, stated that "NRC's rule does not permit or encourage doctors to send treated patients to hotels."

In summary, rather than protect public health and safety, NRC has turned a blind eye to the radiation standards used in many other parts of the world, a deaf ear to reports of problems with its own less stringent regulations, and has consistently opposed attempts to strengthen its standards –

to the point of submitting inaccurate or misleading statements to a Federal Court. Simply put, the NRC has gambled with public health and safety.

RECOMMENDATIONS

1) The NRC should immediately commence a rulemaking to return to its pre-1997, dose based regulations surrounding the treatment of patients with radionuclides, and ensure that its regulations are made to be consistent with the International Commission on Radiological Protection (ICRP). Hospitalization should be mandatory for those patients who are treated with doses of I-131 above internationally accepted threshold limits.

2) Patients should be prohibited from recovering from such treatments in hotels, and specific written and verbal guidance in opposition to hotel release should be provided both to medical licensees and to patients.

3) The NRC should immediately commence a rulemaking to determine whether its current regulations for safe radiation exposure levels adequately, and in a manner consistent with international standards, protect the most vulnerable populations – pregnant women and children – and make revisions where necessary.

4) The NRC should aggressively enhance its oversight of medical licensees to better identify, track and respond to potential regulatory violations, including its oversight of such activities by Agreement States.

5) The NRC's Inspector General should investigate, and NRC should then take all appropriate action, regarding conflicting statements made by its Office of General Counsel (OGC) as to whether NRC regulations permit the release of patients to hotels. These include OGC's April 2008 concurrence with an NRC document that provided assistance to a regional office, which stated that "release to a hotel was not prohibited by the regulations,' and the conflicting statement made by OGC in a legal brief submitted to the U.S. Court of Appeals for the Ninth Circuit on November 4, 2008, which inaccurately states that "NRC's rule does not permit or encourage doctors to send treated patients to hotels."

BACKGROUND AND EARLY HISTORY

Medical Practices Involving Radioactive Materials

Millions of patients are treated each year with radioactive compounds (called radionuclides) for diagnosis or treatment of diseases such as cancer. These patients can expose others around them to radiation until the radioactive material administered to them has been eliminated from their bodies or the radioactivity has decayed. The field of nuclear medicine was developed in the 1950s initially using radioactive iodine (I-131) to diagnose and then treat thyroid disease. Iodine-131 is among the most widely used radionuclides in the medical field, because of its short half-life and medical effectiveness.

Iodine is essential for proper function of the thyroid gland, which uses it to make the thyroid hormones. The thyroid is equipped with an active system or "pump" for moving iodine into its cells. Because of this property doctors are able to use I-131 treatment to successfully destroy thyroid cancer cells as well as treat an overactive thyroid, a condition called hyperthyroidism.

The thyroid cannot tell the difference between radioactive and non-radioactive iodine. It will take up radioactive iodine in whatever proportion it is available. When normal healthy cells are exposed to this radiation it can lead to cancer formation, because the same toxicity that makes I-131 capable of destroying cancer cells also makes it capable of damaging healthy thyroid cells -- damaging them to the point where it causes thyroid cancer to develop years later. Small children and babies in the womb are particularly sensitive to radiation-induced cancer as a result exposure to I-131. A stark illustration of this took place after the accident at the Chernobyl nuclear reactor, which caused numerous thyroid cancers and other thyroid disorders in Belarusian children (as well as children in other countries) due to exposure to radioactive iodine. However, exposed individuals in Poland did not experience such an increase because they ensured that prophylactic non-radioactive iodine was provided to its citizens [1].

In fact, the authoritative International Commission on Radiation Protection (ICRP), which offers recommendations for regulatory and advisory agencies to help in the management of radiological risks, warned that just one kiss from a thyroid patient treated with the radioisotope I-131 can double a child's risk of thyroid cancer.[2] Additionally, in 1986, the Nuclear Regulatory Commission (NRC), which has jurisdiction over the medical uses of radioisotopes, called I-131 "The most radiotoxic byproduct material used for medical use," and indicated that there were two ways that an I-131 patient can be dangerous to others: (1) external radiation dose, simply from being near someone emitting radiation, and (2) internal dose, from contamination, when I-131 is ingested, or inhaled, or absorbed through the skin.[3]

[1] http://www.birdflumanual.com/resources/Self_Defense/files/Guidance%20for%20use%20of%20KI%20for%20nuclear%20emergency%20USG.pdf
[2] ICRP Publication 94: Release of Patients after Therapy with Unsealed Radionuclides (March, 2004)
[3] 50 F.R. 30616 and 51 F.R. 36932

The Nuclear Regulatory Commission's Early Steps to Protect the Public from Radiation

There are two ways in which radiation levels can be measured. A measure of how much radioactivity is in the material administered to the patient is described in "curies (or millicuries, where one millicurie is one thousandth of a curie)," while the radiation dose that a person, such as a family member, receives from an irradiated patient is expressed in "rem"s.[4] Converting from an amount emitted to a dose received depends on several factors including the proximity of the person receiving the dose to the patient emitting it. Thus, while it is possible to assess how much radiation is emitted by a patient if one knows how much radioactive iodine he or she received, the only way one could calculate the dose received by a member of the public, as a result of exposure to the patient, is if one also knows specific information such as how far away the member of the public was from the patient, for how long, whether the member of the public came into direct physical contact with the patient, and other factors..

To reduce the risk of exposure to others from radiation emitted from the patient, NRC maintains regulations governing the release of patients from medical care after they are given radiopharmaceuticals. Until 1997, the NRC controlled this risk by requiring patients given large doses of I-131 to remain hospitalized in radiological isolation until the level of radioactivity in their bodies dropped below 30 millicuries, consistent with international standards.[5] Hospitalization protected members of the public from both internal radiation, caused by contamination by patients' saliva, sweat, and other bodily fluids, and external radiation, caused simply by proximity to the patient.

NRC documentation relating to this 30-millicurie release rule, the NRC stated that this "limit provides an adequate measure of public health and safety" and that the "validity of the assumptions" necessary to calculate approximate dose rates emanating from the patient to a member of the public "are tenuous." According to NRC, in order to determine the approximate dose a person would receive from a treated patient requires making assumptions and approximations of the biological half-life of the radioactive material in the specific patient, duration of time spent near other individuals, and exact distance of household members.[6]

[4] Note: in the International System of units, the becquerel (Bq) is the unit of radioactivity, while the dose received is expressed in sieverts (Sv)
[5] 51 F.R. 36932
[6] 51 FR 36945

THE 1990S: THE NRC BEGINS TO YIELD TO PRESSURE TO RELAX PROTECTIONS

Regulatory Confusion: Protection from Radiation Exposures from Patients Falls Through the Cracks

In 1987, President Reagan, in recognition of increased awareness of the hazards of radiation, especially to unborn children, approved new guidance directing federal agencies to implement the current International Commission on Radiation Protection (ICRP) recommendations, which substantially lowered acceptable radiation levels for occupational radiation protection.[7] The President's guidance noted that the ICRP's recommendations were "now in use, in whole or substantial part, in most other countries." The Presidential guidance went further, stating that the unborn child of a radiation worker should receive a maximum of 0.5 rem during the entire period of gestation.

In 1991, the NRC, as part of new rules amending general radiation standards to incorporate these new occupational limits recommended by the President, also set dose limits for protecting members of the public from radiation of 0.1 rem and required notification of the NRC and the individual if the dose received exceeded this threshold.[8] However, this rule did not clarify whether these new general limits on public exposure to radiation were also meant to apply to public exposures created by the release of patients treated with radioisotopes.

When the 1991 rule was promulgated, there was no discussion of whether the dose limits for the individual members of the public were intended to apply to the release of patients treated with radioisotopes.[9] If this new 0.1 rem rule *did* apply, then patients treated with I-131 would have to remain hospitalized longer, until their radioactivity was reduced to an appropriate level. This could have caused regulatory confusion for the medical community because a patient with 30 millicuries of radioactive material in their body that was deemed releasable from the hospital under NRC regulations was likely to emit radiation at levels that would create exposure to family and others exceeding the new 0.1 rem safe limit.

Pressure to Relax the Regulations from the Medical Community Begins

Beginning in 1990, the NRC received a series of three petitions for rulemaking submitted by Dr. Carol S. Marcus (a nuclear medicine practitioner), by the American College of Nuclear Medicine (ACNM), and by the American Medical Association (AMA), requesting that the patient release rule be amended to ensure that radiation emitted by patients treated with radionuclides would not be treated the same way as radiation emitted by other sources.

These petitions went beyond a request to clarify whether the new more stringent radiation protection regulations applied to patients treated with radionuclides. The first of these petitions which was submitted by Dr. Marcus in 1991 (and then amended in 1992) requested that NRC raise the radiation dose limits to members of the public from 0.1 rem to 0.5 rem, if the exposure was

[7] 52 F.R. 2822 (January 27, 1987). The President's Guidance noted ICRP Publications 26 and 30 which were published in 1977 and 1978.
[8] 10 C.F.R. § 20.1301
[9] SECY-96-100

due to patients treated with radioactive materials.[10] These petitions also asserted that if the 0.1 rem exposure dose limit promulgated by the NRC in 1991 also applied to doses received as a result of patient exposure it "would be extremely expensive"[11] since it would require longer hospitalization of patients who could have at the time been released under NRC's patient release rules because their systems contained under 30 millicuries.

In the original petition submitted by Dr. Marcus, she requested the elimination of the 30 millicurie rule for all radionuclides other than I-131, clearly making a distinction because of the toxicity of this isotope. However, after "discussing the issues at leisure" with "members of the NRC, Society for Nuclear Medicine"[12] and other nuclear-medicine related stakeholders, Dr. Marcus wrote an addendum to the petition that proposed to eliminate the 30 millicurie rule for I-131 as well, thereby allowing for most I-131 patients to be treated as outpatients. This new proposed change in regulations would allow for doctors to treat almost all thyroid cancer patients at their private practices as outpatients, rather than following the practices used for decades which involved the referral of these patients to hospital facilities for treatment and subsequent radiological isolation in order to protect the patients' families and the public from radiation exposure.

Oddly, the original petition submitted by Dr. Marcus was reportedly requested by NRC staff. The NRC petition process is intended to enable members of the public to propose regulatory actions for consideration by the Commission. However, in this case, the petition process was apparently used by the NRC staff to solicit a petition that resulted in a request to weaken the Commission's own regulations for members of the public exposed to patients treated with radiation – at the same time that the Commission was strengthening its regulations for members of the public exposed to radiation from any other source. In letters relating to the petition, Dr. Marcus explains that this was the second time in two years that the NRC staff had used a rulemaking petition from her to weaken an earlier NRC decision, describing the resulting rulemaking as an "inside job from the start."[13]

Dr. Marcus's petition (in both the original and amended form) also proposed to replace the 30 millcurie release limit with the very same sorts of estimated dose calculations that rely on assumptions regarding the patient's distance from members of the public they might expose to radiation that the NRC previously deemed to be "tenuous" when it promulgated its original regulations.

1997:- NRC Gives In

In 1994, the NRC published a proposal that essentially adopted the Marcus petition to change the patient release limit from an activity-based standard of 30 millicuries (measuring the patient's radioactivity) to a dose-based standard of 0.5 rem (calculating, based on assumptions, the predicted exposure of family or others in proximity to the patient).[14] This dose-based standard also failed to take into account direct contact with the exposed individual, as would occur with a kiss or with a breastfeeding infant. This was codified on January 29, 1997, when the NRC finalized its new rule that abolished the 30

[10] PRM-20-20 from Dr. Marcus was published in the FR on June 12, 1991 (56 FR 26945)
[11] No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008),
[12] Appendix B, page 1
[13] Appendix B, page 4
[14] *See* 59 Fed. Reg. 30724 (June 15, 1994).

millicurie maximum limit for outpatient treatment.

The Commission's decision flew in the face of international basic safety standards, adopted just the year before by the International Atomic Energy Agency (IAEA). These standards declared that to be considered adequate, national radiation safety programs must provide for hospitalizing patients given 30 millicuries or more of I-131.[15] These regulations have been adopted by most Member States of the European Union and are still the baseline approach taken by the international community, although many countries now think that 30 millicuries is too lax a standard. In the European Union, the requirement to hospitalize is usually for those receiving doses of greater than 11 to 16 millicuries, in Germany, the limit is 7 millicuries and in Japan the limit is 14 millicuries.[16]

In place of radiological isolation in a hospital, the new NRC rule required two things (1) that physicians perform an individualized analysis of the patient's living situation to determine how much radiation others would receive, and only release patients "not likely" to expose other individuals. (2) that medical licensees (*e.g.*, hospitals) would provide written instructions to patients on how to keep doses to others "as low as is reasonably achievable."[17] This assumed the ability and willingness of newly released thyroid cancer patients – highly radioactive, ill, and under stress both from the disease and its treatment – to maintain sufficient distance from others to ensure that no other person received an external radiation dose exceeding 0.5 rem. It also assumed that physicians would have the ability to perform such a calculation about a wide variety of typical living situations expected to be utilized by their patients. However,nothing in the NRC rulemaking documents suggests that NRC considered the possibility that patients would choose to recover in hotels, with layouts and occupancies that are unknown to a physician.

In short, the Commission adopted a rule that not only assumed a significantly less stringent "safe" dose of radiation exposure than most of the rest of the world, but it additionally adopted a protocol for implementing the regulation that required physicians to make imprecise calculations related to the likely living circumstances and behaviors of patients, rather than simply setting a dose above which patients could not be released from the hospital.

[15] International Basic Safety Standards (Vienna, 1996).
See http://www.pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf
Note: in the international System of units, the becquerel (Bq) is the unit of radioactivity. The BSS states that hospitalization should occur at 1100 MBq (Megabecquerels), which is approximately equal to 30 millicuries.
[16] International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," Annals of the ICRP Vol. 34(2) (March 2004). p 53.
[17] http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html

SEE NO EVIL, HEAR NO EVIL

The NRC Stamps Radiation Exposure Reports "Return to Sender" – Twice

Shortly after the NRC weakened its regulations allowing patients emitting radiation to leave the hospital, the NRC staff realized there was an inconsistency in the Commission's rules. Under another 1991 rule, in most scenarios, exposure that occurs in excess of general threshold limits must be reported to the NRC and to the individual who was exposed.[18] This 1991 rule didn't explicitly refer to exposures that came about as a result of contact with or proximity to a patient treated with radioactive iodine.

On August 3, 1999 the NRC altered its guidelines that require reporting of radiation exposures to specifically exclude exposures that occurred as a result of contact with or proximity to patients treated with radioactive materials released from the hospital, – claiming that rules related to the release of patients treated with radionuclides should all reside in the same section of NRC's regulations.[19] The NRC staff then put together a recommendation to revise the regulations that relate to the medical use of isotopes, proposing to add a requirement for a licensee to report events in which an individual receives a dose in excess of 0.5 rem (the limit for which a patient can be released) as a result of being exposed to a treated patient. In October 2000, the NRC Commissioners unanimously rejected this recommendation and instead told the NRC staff to develop an alternative proposal – one that would only require such notification to take place if the dose received to the individual exceeded 5 rem, or ten times NRC's patient release dose limit and 50 times NRC's more general 0.1 rem safe dose limit for members of the public.[20]

As the NRC staff began to develop its new proposal and it engaged with stakeholders and solicited comments from Agreement States, it became clear that some States had already experienced problems related to NRC's patient release regulations.

On July 24, 2001, Joseph Klinger of the Illinois Department of Nuclear Safety wrote the NRC[21] providing comments on the need for a reporting requirement. In Mr. Klinger's letter he responded to a comment by NRC's Advisory Committee on the Medical uses of Isotopes (ACMUI) which claimed that the "low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditures."[22]

> "The (Illinois Nuclear Safety) Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility for them...."

Mr. Klinger goes on to state that Illinois has had issues with NRC licensees who have disregarded aspects of the patient release criteria, and subsequently "rebuffed the State's inquiries

[18] 10 C.F.R. § 20.2203
[19] SECY-99-201
[20] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf
[21] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf
[22] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/2002-0111scy.html

about doses to the public."

In discussing NRC's claim that reporting requirements would be too onerous for the licensees and physicians, the New Jersey State Department of Environmental Protection wrote[23]:

> " NRC's concerns for their rules to be less intrusive into the practice of nuclear medicine may result in them being more intrusive on the general public as a result of increased patient excreta contaminating trash which sets off radiation monitors at landfills and incinerators."

The Washington State Department of Health also wrote to the NRC in 2001[24], expressing its view that the issue was not reporting of radiation exposures, but rather that the root of the problem was the 1997 rule itself. In referring to the part of the rule that requires physicians to perform an individualized calculation, the State felt that the rule allowed the physician to "adjust the assumptions made" for occupancy and other factors so that patients can be released with incredibly high levels of residual activity – even making the point that the regulation allows licenses to retroactively tweak the numbers used in the calculations to 'prove' that the threshold limit was not exceeded, therefore keeping the licensees in compliance with NRC regulations. This comment highlighted similar problems with the calculations that NRC itself deemed to be "tenuous" when it first codified the 30-millicurie patient release regulation.[25]

A representative from the Alabama Department of Public Health found issue with the fact that NRC's proposed reporting requirements (5 rem) were not equivalent with its patient release requirements (0.5 rem). Stating "this change seems to muddy the waters even further…by saying that if you exceed the specified (release) limits you don't need to report it to the NRC. It appears to trivialize your own limits and says they are of no consequence".[26]

In June 2002, after considering these and other reports, the NRC staff submitted a proposed rule that would have required medical licensees, whenever they learned that a released patient had caused someone to receive a radiation dose in excess of 5 rem, or ten times NRC's patient release dose limit and 50 times NRC's more general 0.1 rem safe dose limit for members of the public, to report the event to NRC and the overexposed person. Even this proposal was rejected by the NRC Commissioners (by a vote of 3 to 2).

In the minority, then-NRC Chairman Richard Meserve [27] observed that "members of the public who may have received involuntary doses from the release of patients will never be informed of their exposure." He goes on to state "We have thus ignored the very individuals who have the greatest stake in assuring that there is a reporting and notification process."

Chairman Meserve also noted "As a result of not moving forward with this proposed regulation, the NRC will lose the insight into compliance with our regulations that the reporting

[23] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf
[24]http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf
[25] 51 FR 36945
[26] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf
[27] http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf

requirements provide. We will thus not have this tool as a means to assess the effectiveness of our regulatory program."

The Crane Petition to Strengthen Regulations

In 2005, Mr. Peter Crane, a former NRC attorney who, as a thyroid cancer patient had received multiple I-131 treatments in the 1980's and 1990's, filed a petition for the NRC to begin a rulemaking to partially revoke its 1997 rule.[28] He particularly objected to the part of the rule that allows patients to be released with more than the equivalent of 30 millicuries of I-131 in their systems, stating that the 1997 rule change:

> "has had precisely the adverse effects on health and safety that were predicted at the time by States and other commenters, and that were brushed aside by the NRC. Patients treated for thyroid cancer with radioactive I-131 are now being sent home to their families under conditions that guarantee that family members would receive larger and potentially harmful doses of radiation, under uncontrolled conditions."

In January 2006, Mr. Crane submitted further comments to the public docket for his petition.[29] In these comments he discussed situations in which patients treated with I-131 on an outpatient basis, take public transportation home, potentially exposing other passengers; patients who vomit after returning home or while returning home on public transportation; and patients who are advised to go to hotels, where they present a radiation hazard to other guests, the housekeepers who clean their rooms, and subsequent occupants of their rooms. This petition put particular emphasis on the hotel issue, writing:

> "And what about the next hotel guest, who arrives, possibly pregnant or with small children, in a room just vacated by a radioactive patient?" Transferring the radiation burden to unsuspecting third parties represented, he wrote, "a public health issue and a moral issue that NRC cannot in conscience ignore."

One year later, NRC's patient release rule was discussed at a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).[30] During this meeting Dr. Douglas Eggli, a nuclear medicine physician, complained that ever since the release rule went into effect "the chances that I can get an insurance authorization for a hospitalization to isolate them, even when I have family situations that require it, it's fighting tooth and nail with the insurance companies."

The Chairman of the Committee Dr. Leon Malmud put it even more strongly:[31]

> "… all patients are discharged upon treatment. We whisk them out the doors as fast as possible."

[28] 70 FR 75752
[29] Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule
[30] Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007
[31] Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

"There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay."

In 2008, NRC denied the Crane petition claiming that the patient release rule did not warrant re-examination.[32] In the docket for the Crane petition, NRC stressed that those opposing the petition "doctors, medical physicists, and radiation safety officers, as well as several medical professional organizations" – "stated that reverting from the current release criteria back to the 30 millicurie (pre-1997) rule would result in additional and unnecessary healthcare costs." NRC's denial made no mention of the concerns related to patients being released to hotels.

Concurrent with its denial of the petition, NRC issued a non-binding "Regulatory Issue Summary (RIS)" [33] that advised its medical licensees of the International Commission on Radiation Protection (ICRP) 2004 findings[34], which stated that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." This informational summary explained that the current regulatory standards had been based on the assumption that the risks of internal doses to individuals exposed to released patients were small compared to the external exposures. However, NRC said, ICRP cautioned that the opposite was true, and that saliva from released patients "could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." NRC therefore advised licensees that in implementing the current rule, they should "take into account whether the released patient may come in contact with infants or young children," and if so, provide additional instructions. Finally, NRC said, "Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children."

NRC did not explain why it had waited from April 2004, when ICRP Publication 94 appeared, until May 2008, when the RIS was issued, to communicate this warning from an authoritative international safety body. NRC also did not address the question of whether infants and young children could be exposed to radiation if a patient was released to a hotel.

[32] 73 F.R. 29445
[33] http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf
[34] International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," Annals of the ICRP Vol. 34(2) (March 2004)

WARNINGS CONTINUE TO MOUNT, AND CONTINUE TO BE IGNORED

NRC conducts weak oversight, but even limited inspections reveal regulatory violations and policy confusion

In a response to a request for information by Congressman Edward J. Markey [35], the NRC indicated that of the 3,700 facilities licensed to perform treatments using radioactive iodine, the NRC directly oversees only 500 of them, with the remainder overseen by State regulators. The NRC collects no information regarding the adequacy or enforcement of its regulations in the 3,200 facilities overseen by the States. In fact, according to NRC "Agreement States do not send their inspection reports to the agency nor do they let the agency know about any violations they may cite. Violations related to patient release are not normally reported to the NRC."

Even for the remaining 500 licensees that are under NRC 's direct authority, the NRC doesn't request or retain records that would enable it to determine whether patients choose to recover in hotels. In a letter to Chairman Markey on March 5, 2010, NRC states that it "does not keep a record of how many times inspectors have requested records" as a result of observing potential deficiencies in meeting patient release criteria. NRC additionally notes that when such records are requested, they are "reviewed at the licensee's site during the inspection." Consequently, NRC has no way of tracking how frequently these types of violations in patient release criteria may be occurring in medical facilities across the country.

However, during the limited routine inspections NRC conducted between 2001 and 2008, it noted four licensees who violated the patient release rule. In all of these cases the licensees failed to perform the individualized analysis that is required by NRC regulations to ensure that individuals who come into contact with the patient do not receive a radiation dose above the default limit (0.5 rem). In two release cases that occurred at the Forbes Regional Hospital in Pennsylvania,' the NRC inspector noted that the patients received doses that were 5 times higher than the pre-1997 threshold dosage, which would have required default hospitalization at 30 millicuries.[36]

In response to these incidents, NRC issued a "Notice of Violation"[37] that required the licensees to take corrective actions to prevent recurrence of this patient release error. Since these facilities either claimed that they were unaware of the requirement for calculations or did not keep records for these calculations, the corrective actions were comprised of staff training sessions and education on NRC requirements as well as a commitment to keep records relating to the individualized analysis going forward.

There was no mention of whether the patients that were released by these licensees went to a hotel after their treatment, but inspectors are unlikely to request this information since NRC does

[35] See: U.S. NRC response to Congressman Edward Markey, March 5, 2010
[36] See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 2: 10CFR 35.75 Severity Level IV Violations for I-131 therapy.
[37] See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 2: 10CFR 35.75 Severity Level IV Violations for I-131 therapy.

not maintain or require licensees to maintain records regarding the destinations of released patients.

Release of Patients to Hotels: NRC Admits that It Isn't Prohibited and Realizes it Occurs

In its response to Chairman Markey's inquiry[38], the NRC did disclose and identify four cases involving two medical licensees in which patients were released to hotels immediately after I-131 treatment. In both cases, the patients provided written notification of their plans to stay in a hotel, and NRC inspectors only discovered the information because they had made a broader request for records from the licensees. During a 2007 inspection of MedStar Georgetown Medical Center in Washington, DC, the inspector noted that the facility had released two patients to area hotels to recover in 2006. For one of these patients the licensee justified the release to a hotel, by showing in a retroactive calculation that the likelihood of the patient exposing members of the public with doses over the threshold limit would have been low.

A similar situation occurred at the University of Virginia, where the NRC discovered during a 2008 inspection that the licensee was incorrectly performing dose calculations and as a result was releasing patients who exceeded the patient release limit. After the NRC instructed the licensee of the correct dose calculation methodology, the licensee retroactively performed the patient specific analysis and determined that it would not have been in violation of the NRC release rule since the calculated dose fell below the 0.5 rem limit (though in one case, the retroactive calculation indicated a 0.498 rem dose would have been received, barely below the regulatory limit). At this same facility, the NRC discovered that in 2007, the facility had released two I-131 patients to recover in nearby hotels. These patients, who were also sisters, shared one room in the hotel and would have contributed a combined dosage of over 0.5 rem to any guests or hotel staff.

As a result of these two inspections that occurred within a year of each other, the NRC Region 1 Division of Nuclear Materials Safety wrote to NRC headquarters[39] to gain clarification on whether releases to hotels were allowed under NRC regulations, and specifically whether the standard calculations that are performed as a part of the patient release process are also valid when patients are released to a hotel. The technical assistance also requested that NRC provide additional guidance for patients who go to a hotel, noting that "these types of releases are not uncommon." In fact, the technical assistance referenced a *USA Today* article that performed a survey of thyroid patients and found that 4% of the patients checked into hotels or other accommodations instead of going home and 2% of patients used public transportation after being released from the hospital. The survey also noted that only 86% of the outpatients went directly home after being treated, meaning there is plenty of opportunity for these patients to expose members of the public to radiation unwittingly.[40]

[38] See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010
[39] Region 1 Technical Assistance Request. November, 28, 2007. See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5
[40] It kills thyroid cancer, but is radiation safe? Steve Sternberg and Anthony DeBarros, USA Today, November 18, 2007.

On June 12, 2008, in response to this technical assistance request, the NRC informed Region 1[41] that the "licensees acted in accordance with existing NRC regulations and that these regulations "do not prohibit the release of a patient to a hotel." The NRC Office of General Counsel (OGC) reviewed and concurred with this assessment of current regulations in April, 2008.

NRC also stated in the June 12 document that it would develop additional instructions to be provided to patients released to a hotel. This guidance has yet to be developed. NRC notes in its response to Mr. Markey on March 5, 2010 that NRC staff plans to "review the guidance relating to the release of I-131 therapy patients to hotels." However, the guidance that the NRC says it plans to review[42]doesn't include any mention of patient release to hotels whatsoever, making it unclear what such a review will entail.

States take matters into their own hands

Since the NRC regulations do not prohibit releases to hotels and to date the NRC has not given States or licensees any guidance in this area, some States have begun to develop and implement their own guidance, which they largely attribute to the 2004 ICRP Publication 94 that advises licenses to especially take into consideration the potential for released patients to expose infants and children to radiation. In a 2008 Minnesota Department of Health (MDH) notice to licensees, MDH warned against sending patients to hotels stating that it should not be considered an alternate means of separation from children and that the "practice has proven to cause significant exposure concerns to hotel property, housekeeping staff, and guests."[43]

In 2009, both the Washington State Department of Health and the New York City Office of Radiological Health sent similar letters[44] to their licensees emphasizing that the patients should not be advised to go to a hotel immediately after release. New York City explained that

> "a hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids."

NRC's Office of General Counsel Inaccurately Tells a Federal Court that Patient Release to Hotels isn't Permitted

On July 9, 2008, Mr. Crane filed a petition for review in the U.S. Court of Appeals for the Ninth Circuit regarding the denial of his NRC petition for rulemaking. Mr. Crane argued in his brief to the court that the NRC failed to adequately address the significant safety issue of releasing treated I-131 patients from the hospital to hotels.

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[41] NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

[42] http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf and NUREG-1556, Volume 9 Revision 2

[43] MDH Information Notice 2008-04, www.health.state.mn.us/divs/eh/radiation/radioactive/infonot0408.pdf

[44] NYC Information Notice ORH 2009-01, http://www.ci.nyc.ny.us/html/doh////downloads/pdf/radioh/radioh-Info-noticeorh.pdf and State of Washington Information Notice, March 26, 2009; See Appendix C

In NRC's November 2008 brief to the court, the Office of General Counsel (OGC) called Mr. Crane's description of patients sent to hotels "unverifiable and unscientific." In spite of this very same office's April 2008 concurrence with NRC's opinion that release to a hotel was "not an uncommon practice" and was not prohibited by NRC regulations, this OGC filing declared to the court that: "NRC's rule does not permit or encourage doctors to send treated patients to hotels."[45]

It was decided on August 19, 2009 that Mr. Crane, a thyroid cancer patient and survivor, lacked standing to bring the case because he was not currently undergoing or about to undergo treatment with radioactive iodine, and was therefore unaffected by the NRC rule. The court did not decide on the merits of the case, including Mr. Crane's claim that some radioactive patients were going to hotels and creating a hazard to other guests and hotel staff.

[45] No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008), p. 39.

Appendix A – Detailed Chronology

1986- NRC issued regulations that required the hospitalization of patients with the equivalent of 30 millicuries or more of radioactive iodine 131 (I-131) in their systems. (This was consistent with the International Basic Safety Standards on radiation protection) NRC called I-131 "the most radiotoxic byproduct material used for medical use," and indicated that there were two ways that an I-131 patient can be dangerous to others: (1) external radiation dose, simply from being near someone emitting radiation, and (2) internal dose, from contamination, when I-131 is ingested, or inhaled, or absorbed through the skin.

1987-President Reagan, in recognition of increased awareness of the hazards of radiation, especially the potential dangers to unborn children, approved new guidance directing federal agencies to implement the current International Commission on Radiation Protection (ICRP) recommendations, which stated basic principles for occupational radiation protection and recommended a safe dose of 0.5 rem for pregnant women that were occupationally exposed.[1] The President's guidance noted that the ICRP's recommendations were "now in use, in whole or substantial part, in most other countries."

1991 - The NRC issued new rules amending general radiation standards and set dose limits for protecting members of the public from radiation of 0.1 rem, and required notification of the NRC and the individual if the dose received exceeded this threshold.[2] The rule did not explicitly specify whether these rules applied to doses given to members of the public due to exposures from patients treated with radionuclides.

1992- NRC gave public notice of the receipt of an original and amended petition submitted by Dr. Carol Marcus. The original petition requested that the 30-millicurie limit for the release of patients be eliminated for all radiopharmaceuticals except I-131, and was reportedly initiated by NRC staff. The amended petition requested elimination of the 30-millicurie limit for all radiopharmaceuticals, and recommended that patients treated with radioactive iodine be released from the hospital if a calculation performed by a physician could demonstrate that radiation received by family members or a member of the public was unlikely to exceed 0.5 rem, five times NRC's safe radiation limit for members of the public.

March 1996- The International Atomic Energy Agency (IAEA) issued its Basic Safety Standards (BSS) entitled "Radiological Protection for Medical Exposure to Ionizing Radiation."[3] This safety guide is one part of a series of international standards based on worldwide consensus, knowledge of biological effects of radiation and principles for protection from undesirable effects. The BSS declared that to be considered adequate, national radiation safety programs must provide for hospitalizing patients given 30 millicuries or more of I-131 and that in some

[1] 52 F.R. 2822 (January 27, 1987). The President's Guidance noted ICRP Publications 26 and 30 which were published in 1977 and 1978.
[2] 10 C.F.R. § 20.1301
[3] International Basic Safety Standards (Vienna, 1996).
See http://www-pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf

countries a level of 10 millicuries is used as an example of good practice.[4] I-131 is the only nucleotide that IAEA recommended specific standard for.

January 29, 1997-NRC adopted the amended 1992 petition and published revisions to its regulations, which authorized the immediate release of most patients treated with I-131 (or any other radioactive material) as long as the likely exposure to others would not exceed 0.5 rem, or five times NRC's own safe level for members of the public. This rule stated that for patients with more than 30 millicuries of radioactive content in their bodies, an individualized analysis of the patient's living situation was necessary to determine the likely dose to others, and as long as that dose wasn't expected to exceed 0.5 rem, the patient could be released from the hospital. The rule presented two scenarios – hospitalization, and release to one's home. It did not, however, discuss the possibility that a patient might wish to recover in a hotel, whether release to a hotel was permissible, and how such an individualized analysis might be performed for a hotel.

1998- A European Commission document entitled "Radiation Protection Following Iodine-131 therapy (exposures due to out-patients or discharged in-patients[5])" stated that "sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days." This risk is particularly high for infants and children who may come in contact with bodily fluids, such as saliva and sweat, as well as a treated patient's breath, all sources of I-131 radiation. "As a general rule, treatment of thyroid cancer patients using radioactive iodine will only be performed in conjunction with hospitalization of the patient."

August 3, 1999- NRC adopted a revision to its regulations that ensured that the safe radiation levels for the public would exclude from consideration doses given to members of the public as a result of exposure to a patient treated with radionuclides, citing the 1997 regulations that governed patient release.[6] This clarification meant that if a member of the public was exposed to more than 0.5 rem from a patient treated with radioisotopes, that exposure would not need to be reported to the NRC. [7]

October 23, 2000: The NRC unanimously rejected a staff proposal to require reporting of radiation doses of greater than 0.5 rem to members of the public as a result of exposure to a patient treated with radioisotopes[8], even though this level was NRC's own regulatory dose limit for patients treated with radioisotopes. Instead, staff was directed to develop a proposal that would only require notification of radiation doses to members of the public of greater than 5 rem – ten times NRC's own regulatory dose limit and fifty times its safe dose level for members of the public.

[4] Note: in the international System of units, the becquerel (Bq) is the unit of radioactivity. The BSS states that hospitalization should occur at 1100 MBq (Megabecquerels), which is approximately equal to 30 millicuries.
[5] See http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/097_en.pdf
[6] 10 CFR 20.1301 and SECY-99-201
[7] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0118/2000-0118scy.html
[8] See http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf

2001- Illinois's Department of Nuclear Safety wrote to the NRC stating that Illinois has experienced issues with patients being released under circumstances that may cause exposure to the general public. Illinois stated that "Simply because NRC does not keep records on such events does not mean that such events are not occurring." The difficulty with these events, Illinois said, is that "hospitals will accept no responsibility for them." [9]

June 21, 2002 – In response to the October 23, 2000 direction from then-NRC Chairman Richard Meserve, NRC staff proposed an amendment to NRC's patient release regulations that would require medical licensees to notify the NRC if the licensee became aware that an individual received or is estimated to have received a dose of 5 rem -which was ten times higher than NRC's own patient release regulations dose thresholds-[10] as a result of being exposed to a radioactive patient and fifty times its safe dose level for members of the public.

August 27, 2002- NRC Commissioners rejected (by a vote of 3 to 2) the staff proposal requiring that it be notified if a released patient causes a family member or member of the public to receive a dose of 5 rem - ten times higher than NRC's own patient release regulations dose thresholds and fifty times its safe dose level for members of the public.[11]

March 2004- The International Commission on Radiation Protection (ICRP) issued Publication 94: Release of Patients after Therapy with Unsealed Radionuclides[12], which states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." This statement was repeated in the new comprehensive radiation safety recommendations in ICRP Publication 103, The 2007 Recommendations of the International Commission on Radiological Protection,[13] which specifically states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine. The ICRP recommended that the threshold for permissible radiation exposure of pregnant women and children be lowered to 0.1 rem, one fifth of what the NRC permits for patients released from the hospital. The NRC did not pass along the ICRP's warnings to its medical licensees until May 2008.

September 2, 2005-Peter Crane, a former NRC attorney and thyroid cancer patient who received multiple I-131 treatments in the 1980's and 1990's, filed a petition for rulemaking calling for partial revocation of the patient release criteria rule.[14] He objected to the part of the rule that allows release of I-131 patients with 30 millicuries or more in their systems asserting that the 1997 issued rule was defective on legal and policy grounds. Mr. Crane objected to the current patient release criteria stating that it "creates unwarranted hazards as patients are sent out the door," where they may come into close contact with family members and members of the public."

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[9] See Appendix 2
[10] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf
[11] http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf
[12] International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," Annals of the ICRP Vol. 34(2) (March 2004)
[13] International Commission on Radiation Protection, ICRP Publication 103: "Recommendations of the ICRP," Annals of the ICRP Vol. 37/2-4 (2007)
[14] 70 FR 75752

January 30, 2006-Peter Crane submitted comments to the public docket for his petition citing concern about patients being released to hotels and unsuspecting hotel cleaning staff coming into contact with radiologically contaminated bathroom surfaces, linens, etc. The comments also note the problem of patients vomiting (in public or private spaces) after treatment and members of the public coming into contact with the radioactive vomitus.[15]

October 22, 2007 - The NRC's patient release rule was discussed at a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes. Dr. Douglas Eggli, a nuclear medicine physician, complained that it had become impossible to get insurance companies to pay for inpatient treatment, "even when I have family situations that require it." The committee's chairman, Dr. Leon Malmud, agreed stating: "Their wonderful insurance stops because it is no longer necessary for them to be an inpatient." As a result, he said: "All patients are discharged upon treatment. We whisk them out the doors as fast as possible."[16]

November 28, 2007-After an inspection revealed that patients with high doses of I-131 were knowingly discharged to a hotel, NRC's Region 1 Office made a request to NRC headquarters for technical assistance to determine whether release to a hotel was permissible under the NRC patient release rule. Referring to hotels, the technical assistance request noted that "these types of releases are not uncommon," cited some press reports on the topic, and questioned whether the required dose calculation analysis for patient release that takes into account occupancy can be performed in a valid manner for releases of patients to hotels. The Region also requested information on additional instructions to be provided to patients if they are released to hotels.[17]

April 23, 2008- The NRC Office of General Counsel (OGC) reviewed and approved the NRC headquarters response to the technical assistance request for NRC's Region 1 Office, which stated that "release to a hotel was not prohibited by the regulations."[18]

May 12, 2008- NRC issued a non-binding "Regulatory Issue Summary (RIS)" to its medical licensees, alerting them to the ICRP Publication 94 published in March 2004.[19] The RIS states that "Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children." But the report did not address the release of patients to hotels, nor did it mention anything about the mandatory requirement to calculate individualized doses to household members prior to releasing patients.

May 21, 2008- The NRC published in the Federal Register its denial of Mr. Crane's petition for rulemaking, saying that the NRC's patient release rule needed no reexamination, and citing/publishing its May 12, 2008 RIS as a means of addressing risks to infants and young

[15] Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule
[16] Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007
[17] Region 1 Technical Assistance Request. November, 28, 2007. See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5
[18] NRC Safety Inspection Report Number 2007-002. Licensee: University of Virginia. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 4
[19] http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf

children. [20] The NRC discussed and rejected the lower dose threshold for pregnant women and children urged by the ICRP.

May 28, 2008- The Minnesota Department of Health (MDH) issued a notice which advised its medical licensees of NRC's RIS and added its own warning: "MDH would discourage physicians from suggesting that patients use hotels as an alternative means of separation from infants or young children. That practice has proven to cause significant exposure concerns to hotel property, housekeeping staff, and guests."[21]

June 12, 2008 – In its response to NRC's Region 1 Office's request for technical assistance, the NRC stated that "releasing patients from a hospital to go to a hotel or other temporary accommodation is not an uncommon practice" and that current regulations do not "limit the location to which the (treated) individual must be released," and "do not prohibit the release of a patient to a hotel" To address this issue the NRC stated that "guidance for release of radiotherapy patients to hotels" and "additional instructions" to be provided to patients released to hotels "will be developed". [22] This promised guidance and instructions were never developed.

July 9, 2008 – Mr. Crane filed a petition in the U.S. Court of Appeals for the Ninth Circuit to review the NRC's denial of his petition for rulemaking. Briefs were filed in the fall of 2008, in which Mr. Crane argued that the NRC failed to adequately address the significant safety issue of releasing treated I-131 patients from the hospital. The petition also addressed the inconsistencies between NRC's regulations and international safety standards.[23]

November 4, 2008 – In its brief to the U.S. Court of Appeals for the Ninth Circuit in opposition to Peter Crane's petition for review of the NRC's denial of his original petition, NRC's Office of General Counsel (OGC) called Mr. Crane's description of patients sent to hotels "unverifiable and unscientific." In spite of this very same office's concurrence with the June 2008 NRC headquarters opinion that release to a hotel was not prohibited by NRC regulations, and the clear awareness on the part of the NRC that release of radioactive patients to hotels was not an uncommon practice, OGC declared to the court that: "NRC's rule does not permit or encourage doctors to send treated patients to hotels."[24]

March 26, 2009- A notice from the State of Washington Department of Health advised its licensees to "actively discourage patient use of hotels immediately after release"[25]

June 29, 2009 - The New York City Department of Health issued guidance to all medical licensees that specifically warned against sending patients to hotels.[26] It stated that "a hotel

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[20] 73 F.R. 29445
[21] MDH Information Notice 2008-04, www.health.state.mn.us/divs/eh/radiation/radioactive/infonot0408.pdf
[22] NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5
[23] No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Petitioner Peter G. Crane.
[24] No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008), p. 39.
[25] See Appendix C
[26] http://www.nyc.gov/html/doh/downloads/pdf/radioh/radioh-Info-noticeorh.pdf

presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids."

August 19, 2009 – A decision was issued in the U.S. Court of Appeals for the Ninth Circuit for Mr. Crane's petition for review.[27] The court accepted the NRC's argument that Mr. Crane, a thyroid cancer patient, lacked standing to bring the case because he was not currently undergoing or about to undergo treatment with radioactive iodine, and was therefore unaffected by the NRC rule. The court did not reach a conclusion regarding the merits of the case, including Mr. Crane's claim that some radioactive patients were going to hotels and creating a hazard to other guests and hotel staff.

October 13, 2009- Chairman Edward J. Markey sent a letter to NRC Chairman Greg Jaczko highlighting issues with patients being released to public hotels and questioning NRC's enforcement of patient release criteria. Mr. Markey stated: "I am concerned that current NRC regulations….may result in some unnecessary, unwitting and inappropriate exposures of individuals to dangerous levels of radiation."[28]

November 17, 2009- Chairman Greg Jaczko replied to Mr. Markey's letter stating "the NRC believes the current regulation (10 CFR 35.75) provides adequate protection to members of the public, provided that adequate instructions are provided at discharge to the patient and the family members." The letter also stated that the regulation "does not limit the location to which the individual may be released nor does it specifically address the release of patients to hotels." The response indicated that the need to perform an individualized analysis of a patient's living situation would also apply to those patients who go to hotels after their release from the hospital. In response to a question on protecting vulnerable populations the NRC states "there is no distinction between the dose limits that apply to other members of the public and those that apply to pregnant women and young children".[29]

January 14, 2010- Mr. Markey wrote another letter to NRC Chairman Jaczko, stating that he "remains extremely concerned that the Commission is abdicating its responsibility to protect the health and safety of the American people." In discussing particular concern for patients released to hotels, where they could expose pregnant hotel workers or children of guests, he states for "hotels it would be difficult, if not impossible, to come up with credible assumptions with which to estimate the dose received by an unknown person at an unknown distance when performing the sort of individualized analysis referenced in the 1997 guidance…" Mr. Markey specifically requested an investigation into NRC's inspection records of facilities licensed to use I-131 in medical treatments.[30]

[27] http://www.ca9.uscourts.gov/datastore/memoranda/2009/08/19/08-72973.pdf
[28] http://markey.house.gov/docs/signed_isotope_nrc_letter.pdf
[29] http://markey.house.gov/docs/nrcltomarkeyisotopes.pdf
[30] http://markey.house.gov/docs/11410nrc.pdf

March 5, 2010-Chairman Jaczko responded to Mr. Markey's inquiry.[31]
Notable Points:

- NRC may have recognized that pregnant women and children are different than grown men in their sensitivity to radiation and is considering possible revisions to the regulations that set dose limits for pregnant women and children. However, no timeline or process is provided for this revision.
- NRC has 3,700 I-131 licensee and Agreement State medical use facilities, but only inspects 500 of these facilities for compliance with patient release criteria, with the remaining not subject to NRC oversight. Although the remainder of these facilities are subject to State regulation and enforcement, NRC neither requests nor receive reports of any kind related to State inspections.
- The NRC noted a few examples in which enforcement actions were taken as a result of violations in patient release. These violations included the failure to perform individualized analysis before release and failure to provide written instructions to the patient on how to reduce exposures to others. This included cases in which patients were discharged to hotels.
- The NRC response declared that regulations do not prohibit doctors from sending patients to hotels and believes that physicians can reasonably calculate dose estimates for patients who go to a hotel, by using assumptions on building geometry and other factors.
- The Commission will <u>not</u> reconsider its decision to <u>not</u> be notified if harm has occurred as a result of patient exposure to the public, because the NRC is "not aware of any scenario in which a member of the public received a 0.5 rem exposure from a released patient." Since the NRC twice voted not to be told if such events occur, it is unclear how it would have become aware of such a scenario in the first place.

[31] See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010

Appendix B

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

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UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

November 9, 1992

Samuel Chilk, Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, DC 20555

Subject: Letter of Peter Crane dated 10/31/92 regarding PRM-20-20, PRM-35-10, PRM-35-10A, and the 23 October 92 meeting of the ACMUI

Dear Mr. Chilk:

I am writing to correct the scientific mistakes and misunderstandings contained in Mr. Crane's letter of 31 Oct. 92, and to point out that certain opinions ascribed to me by Mr. Crane are grossly inaccurate. Fortunately my opinions are amply documented, in writing, in your office, so this should be quite straightforward. I recommend that Mr. Crane review my Petition dated 12/26/90, my important Addendum of 6/12/92, and my comments of 3/14/92 concerning the ACNM Petition.

My Petition was written at the request of Hal Peterson, who was embarrassed at the uncorrected errors in 10 CFR Part 20, and who urged me to "write a Petition YESTERDAY". At the time, the new Part 20 was supposed to go into effect 1 Jan 92, and we did not have many months to waste. I argued at the time that I did not want to write another petition (I wonder why?), but he insisted it was the only option open, and that is how I spent Christmas Eve, 1990. It was hastily done, and recommended honoring the methodology of NCRP no. 37, getting rid of the "30 mCi rule" for all radionuclides other than I-131, and retaining the 5 mSv maximum for members of the public from patient sources; this is in keeping with the most recent recommendations of NCRP, ICRP, and the IAEA. I recommend that Mr. Crane review this literature as well, as NRC asserts frequently that it uses such sources for its standards.

Much later, after discussing the issues at leisure in much more detail with members of NCRP, ACNP, SNM, and NRC, I wrote an Addendum covering the "30 mCi" issue. Due to the fact that the "30 mCi" value was embarrassingly based on a naive mistake by the AEC in the early 1950's and never fixed thereafter, and due also to the fact it is not mentioned anywhere in NCRP no. 37 (nor should it have been), I made a scientifically valid case for a "default" value of I-131 patient discharge which came out to 33

mCi. However, there is excellent reason to raise that number, especially for athyreotic carcinoma patients with normal renal function. NCRP no. 37 lists limits of 50 mCi for certain home situations and 80 mCi for even more restrictive home situations. Mr. Crane should familiarize himself with these qualifiers, because he is obviously unfamiliar with these long-accepted concepts. NCRP no. 37 is the law in California; the "30 mCi rule" does not exist here. We in California try to base our policies on scientifically valid health physics.

When the ACNM Petition was submitted, I used my comment opportunity to remind NRC that my Petition was drowning at the bottom of Mr. Roecklein's "in" pile, and that it needed resolution. The concept of sending patients home with 400 mCi of NaI-131 was ludicrous. Although I could theoretically concoct a situation where it could possibly be justified, there are not too many patients who would qualify as hermits in isolated areas. In any case, I stated:

"The one aspect of the petition that causes me some concern is the claim of safety of an outpatient dose of 400 mCi. I have not reviewed data supporting this argument and would appreciate the opportunity to do so. Although I'm sure that safety could be satisfied, it would appear to require some very specific circumstances".

As there are no data that could possibly support this except in highly unusual situations, the point is moot. Mr. Crane should also know that I requested that ACNP (absolutely not related in any way whatsoever to ACNM), SNM, the American College of Radiology, and Jack Goodrich, M.D., past ACMUI member, make similar points in their comment letters. I explained to the American Hospital Association that this was NOT a good way to save money, and made a presentation against the ACNM Petition at last Spring's CRCPD meeting at the request of Terry Frazee of the State of Washington.

I hope that NRC clearly understands that <u>I am not now, nor have I ever been, a member of the ACNM</u> nor an espouser of 400 mCi I-131 doses dispensed to patients in an uncontrolled manner. However, NRC's "30 mCi" rule is scientifically unfounded and constitutes bad physics, just as ACNM's claims are unsupported by scientific data.

<u>All I am trying to do is challenge NRC to make an intellectually defensible, scientifically valid regulation based on best available scientific data and scientific judgment</u>. I urge NRC to entertain only scientific discussion, and eschew scientifically

for data on childhood thyroid cancer near Chernobyl. I recommend that Mr. Crane read Hull AP: Post Chernobyl childhood cancers reported. The Health Physics Newsletter, vol. 20, Nov. 1992, (cover story). There are some interesting problems with Russian "data" at this point.

Mr. Crane's naivete´ concerning the first Petition I wrote in June, 1989, with Mr. McElroy's help, is surprising. Mr. Cunningham instructed Mr. McElroy to help me write the Petition. I didn't know how to write regulatory language, and it was Mr. McElroy's job to help me do that. NRC had written some very poor quality and dangerous regulations in 1987, and Mr. Cunningham realized that the language had to be fixed, and asked us to do it together. It was an "inside" job from the start. Mr. Cunningham gave us some very tough boundary conditions, but we did the best we could. This was before NRC rammed through the petitioner's "Gag Rule" without opportunity for public comment. If I were to write my <u>own</u> petition to change Part 35 today, with none of Mr. Cunningham's constraints, I would get rid of nearly everything in it, and upgrade education and experience criteria for nuclear medicine physicians so that NRC stopped licensing incompetent physicians who don't even know what Part 20 is, let alone the basic science necessary to comply with it. Nuclear Medicine would be subject to performance standards only. The only reason we have completely prescriptive regulation is that performance standards require thorough understanding and judgment, and NRC itself cannot seem to rise to that level. So yes, Mr. Crane, the staff "is passing judgment on a petition that the staff itself helped to write", and I did not "misspeak".

Mr. Crane is a lawyer. It is not surprising that he is thoroughly unfamiliar with the areas of nuclear medicine, nuclear pharmacy, and basic nuclear sciences, because he has never had any education, training, or experience in these fields. However, one may expect certain professional behavior from a lawyer. For openers, one would expect him to read the obvious background material on a case, so that he would be aware of the facts. It is well known that I do not deprive the NRC of my opinions on subjects involving my expertise, and a short search on Mr. Crane's part would surely have yielded the facts he so desperately lacked. Although he would not have understood my calculations, he could have asked an expert for some help. He could even have called me! He would, however, have been expected to understand the English. It is not acceptable professional behavior for an NRC lawyer to attempt to deceive NRC about the opinions of an NRC advisor and consultant, refuse to even bother with the facts, and expect NRC licensees to continue to support him with User Fees. I object to his continued employment at NRC.

uninformed nuclear hysteria from any source. NRC's independent status insures it does not have to honor outside opinion flawed by ignorance. One would hope NRC would not have to honor inside opinion flawed by ignorance, either.

Mr. Crane asks NRC to regard him somehow as a knowledgeable professional on the subject of I-131 for thyroid cancer, based on his personal experience with the disease. Having read Mr. Crane's present missive, and a previous related document at the time the Commission signed the scientifically insupportable "Quality Management" thing, let me assure you, as a knowledgeable professional on the subject of I-131 for thyroid cancer, that Mr. Crane is well-qualified to be a patient, and nothing more. For example, if Mr. Crane really had a partial thyroidectomy in 1973 and then 2 doses of 29.9 mCi each 10 and 11 years later to ablate the remnant, it is no wonder he had recurrences, and it is surprising he isn't in malpractice court. Knowing the excellence of NIH, however, I would tend to doubt the validity of his account.

As far as his story about his confinements, let me explain that one does not need "thick paper" on the floor, only absorbent material with a plastic backing. As far as "smelling strongly of seaweed", this is pure confabulation. In the first place we do not give iodine, we give iodide. Iodide does not smell like seaweed. Second, the mass of 150 mCi of I-131 is $(150)(131)(8)(24)(60)(60)(8.87 \times 10^{-17})$ = 1.2 micrograms. Normal stool contains 10-50 micrograms per day. The average person contains 30,000 micrograms of the element iodine, and another microgram or so , even if converted to a volatile form, should not make his deodorant fail. Mr. Crane's story about his contaminated computer case is indeed a physics first. "....radiation from stray drops of urine had probably penetrated the thick concrete walls of the bathroom and reached the case. A month later, the case had cooled down to the point that I could collect it from Radiation Safety." Quick, Mr. Bernero! We need at least three contracts to starving DOE labs to understand this new phenomenon. "Beta creep"? Good God! Have all our shielding calculations been for nought all these years? My Uncle Joe Fertik, who designed the 14 foot concrete vault around the very first Oak Ridge reactor after W.W. II, died last year at 94, and never knew. If a gamma ray sneaked through and hit the case it should last no more than about a picosecond at most. A <u>month</u> ? Wow!

Mr. Crane makes some other interesting statements, quoting such incontrovertibly superb scientific sources as the New York Times

In addition to being of no value as a nuclear expert, he is, in my opinion, behaving in an unacceptable manner for a lawyer.

Thank you for the opportunity to comment on this most informative comment letter.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

cc: Peter Crane
Commissioner Ivan Selin
Commissioner Gail de Planque
Commissioner Forrest Remick
Commissioner Kenneth Rogers
Commissioner James Curtiss
Hugh Thompson, Deputy EDO
Robert Bernero
Richard Cunningham
John Glenn, Ph.D.
William Parler, Chief Counsel
Joan McKeown
Peter Almond, Ph.D.
Ted Webster, Ph.D.
Gerald Pohost, M.D.
Judy Brown
Curtis Scribner, M.D.
Steve Collins
Barry Siegel, M.D.
Mel Griem, M.D.
Dan Flynn, M.D.
Capt. Wm. Briner
Mark Rotman
Myron Pollycove, M.D.

CSM:sfd

Appendix C

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
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TDD Relay Services: 1-800-833-6388

INFORMATION NOTICE

March 26, 2009

TO: All Medical Licensees Authorized Therapeutic Use of Iodine-131

FROM: C. DeMaris
Medical Licensing

SUBJECT: **Release of Therapy Patients Administered Iodine-131**

Please discourage the use of hotels following treatment. It has recently been brought to our attention that Regulatory Guide 8.39 does not specifically reference where a patient should reside when released after a therapeutic dose of Iodine-131. It is presumed that most, if not all, patients go home although there is nothing in the Guide preventing a patient from using a hotel.

A specific public complaint has been raised that a patient using a hotel immediately following release could, under certain circumstances, present an unnecessary risk of exposure to others, especially infants and children. We believe the concern is consistent with the International Commission on Radiological Protection's Publication 94, *Release of Patients after Therapy with Unsealed Radionuclides*. This publication cautions that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

At present, it is our understanding that you neither advise nor encourage the use of a hotel. Nevertheless, we believe it is prudent to eliminate this potential.

We recommend that you actively discourage patient use of hotels immediately after release.

This notice requires no specific response from you. If you have any questions, I can be reached at 360-236-3223.

Thank you for your time and cooperation.