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January 29, 2021

Chairman Christopher T. Hanson
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Hanson,

As an NRC old-timer, I would like to congratulate you on your elevation to the Chairmanship, and wish you every success in your new position.

I myself began work at the agency only ten weeks after it opened its doors in 1975, as legal assistant to one of the first five Commissioners, and later served in the Office of General Counsel. I retired in 1999.

In 46 years of observing the NRC, I have seen high points and low points, but overall a conscientious effort to serve the American people's needs, as the Commissioners and the staff have perceived those needs. There is just one area, however, in which the NRC has fallen seriously short: the regulation of the medical uses of isotopes, specifically the isotope iodine 131, which is used to diagnose and treat thyroid cancer. It is the most dangerous of all medical isotopes, and a patient who has received an oral dose of it may give off more radioactivity than a nuclear power plant emits in a year.

I myself am a thyroid cancer patient, first operated on in 1973, when I was 26. After being diagnosed with a recurrence in the late 1980's, I received five high-dose I-131 treatments, for a total of 700 millicuries. Recent blood tests indicate that there are still some cancer cells in my body, but for now, they are kept under control by the thyroid hormone that I take daily.

At the time I was treated with I-131, the NRC's radiation protection standards were as good as any in the world. That changed in 1997, when a reckless NRC deregulation dismantled decades of sound practice, with the result that high-dose I-131 treatment, until then exclusively an inpatient procedure, became in short order an outpatient procedure in the vast majority of cases. Today, the U.S. is an outlier in the world radiation protection community, at the bottom of the pack, below Iran, Bangladesh, Indonesia, and South Africa. American children now enjoy sub-Third World protection, and the responsibility for this lies entirely with the NRC.

Please do not take my word for it. I urge you to contact former Chairman Allison Macfarlane, who told me shortly before she left office of her deep regret at having been unable to right this wrong. She didn't have the votes.

Some years ago, when William D. Magwood IV was on the Commission, I prepared an essay for him, titled "How We Got Here," describing the tortuous history of the NRC's regulation of medical isotopes. He asked if he could share it with others, and I of course agreed. I have edited it slightly, and it is attached.

I-131 is unique in the hazard it presents to those who come in contact with the patient, either by proximity (**external dose**) or through inhalation, ingestion, or touch (**internal dose**). The NRC explained this in a well-reasoned 1986 rulemaking. But in 1997, the NRC was eager to deregulate, and not overly fastidious about how it reached that goal. Ignoring warnings from half a dozen state regulatory bodies, it chose to rely on a medical consultant with eccentric, even zany, opinions about radiation. Rejecting mainstream science, he believed that I-131 was not carcinogenic, and that radiation was essential to health. (In one article, he argued that if a major nuclear accident occurred, any health effects from the radiation would be **beneficial**.) Following his lead, the 1997 deregulation declared that internal dose did not matter, and that the release of patients could be based on the likely external dose to any other person. This was an approach that the NRC had considered and rejected, for good cause, in 1986. It has never explained what was wrong with the 1986 analysis.

In 2005, I filed a petition with the Commission, asking for a rulemaking to address the deficiencies in the 1997 rule. After the comments came in, to the docket and on Facebook, I became aware that many I-131 patients were being treated on an outpatient basis and then released to hotels. That meant that their bedrooms and bathrooms were being cleaned by hotel workers – for the most part women of childbearing age, some of them presumably pregnant – who were unaware of the contamination and without the training or equipment to handle it. This, I said in a communication to the docket in 2006, was "a medical and moral issue that the NRC cannot in conscience ignore."

But the NRC **did** ignore it. In denying my petition in 2008, the NRC staff never even mentioned the issue of radioactive patients in hotels. I filed a petition for review in the Ninth Circuit Court of Appeals, one of a number of courts where, over the course of 20 years, I had defended NRC actions when I was in the Office of General Counsel. My brief emphasized the agency's failure to address the hotel issue.

The response of the NRC was to attack my credibility, and say that the staff had not thought the allegation merited a response. The court was told that the NRC rule did not "permit or encourage" licensees to send radioactive patients to hotels; that this was not in fact occurring; and that I had "recanted" my charge that this was happening.

None of this was remotely true. Though I did not know it at the time, a few months earlier, NRC headquarters had responded to a query from a regional office by saying that nothing in the NRC's rules prevented licensees from sending radioactive patients to hotels; that this was a not uncommon occurrence; and that it raised safety issues that the staff intended to address. The regional office's inquiry had been prompted by a prominent story in *USA Today* that reported that a significant fraction of radioactive patients went to hotels after treatment.

The case was dismissed on grounds of standing; the NRC had argued that my cancer was so far in the past that I was unaffected by the Patient Release Rule. (In fact, thyroid cancer

patients are under medical surveillance for life, because recurrences are possible even decades after treatment.) There is no way to know whether there might have been a different result if the court had been given an accurate understanding of the facts.[1]

In 2011, the staff at last issued the long-promised guidance, recommending, but not requiring, that licensees refrain from releasing radioactive patients to hotels. When I asked a staff official in a public meeting why it had taken so long to carry through on the 2008 commitment, he replied that the staff had been asked to delay until the lawsuit was resolved. It is hard to avoid the conclusion that success in court took priority over protecting hotel workers and their unborn children.

In 2012, I submitted a paper to an international conference on radiation in medicine, held in Bonn, Germany, under the auspices of the International Atomic Energy Agency. (I may have been the only person there who traveled on his own nickel.) What struck the attendees as "sensational," in the words of the rapporteur, was the revelation that in the United States, patients were being discharged to hotels. They were shocked, and rightly so. The cornerstone of radiation protection is informed consent, and these workers were being exposed without their knowledge. A copy of my paper is attached.

Today, radioactive patients continue to be discharged to hotels every day. The NRC staff has estimated that five to ten percent of I-131 patients go to hotels and motels. (In one notable case, a patient so contaminated a motel room that the next person to stay there set off the radiation alarms at the nuclear power plant where he worked.) Licensees routinely ignore the NRC's non-binding guidance, because there are no consequences for doing so. To be sure, some hospitals, including Washington Hospital Center, act responsibly, and treat everyone receiving 30 millicuries or more of I-131 as an inpatient, but they are exceptions to the rule.

Far more typical is the Seattle hospital where a technologist told me that in ten years, the hospital had given just one inpatient treatment for thyroid cancer, and that they administered doses of up to 200 millicuries on an outpatient basis. I asked whether they

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[1] This behavior on the part of the NRC lawyer or lawyers was utterly unlike anything else I have seen, before or since, in 46 years of observing the normally exemplary work of the Solicitor's office. It is noteworthy that 30 years earlier, when the lawyer who briefed and argued the case was in the Justice Department, he was held in contempt by a federal district court judge. *See* "A Lawyer and Agent of F.B.I. Are Held In Contempt on Files," New York Times, Feb. 9, 1978. The newspaper quoted the judge as saying of the two men that their tactics "have been to delay, to stall, to deceive and to do anything they can to frustrate this litigation. ... They place themselves above the law, they defy the Congress, which has set the rules of discovery. They are in defiance of orders of this court." He added that he would be "amazed" if their actions had the approval of top officials in the organizations they represented.

My own reputation for truth and veracity is not for me to speak to, but I would offer as character witnesses the Commission's current Executive Director for Operations, General Counsel, and Secretary, all of whom are former colleagues, as well as former Chairman Macfarlane.

released patients to hotels. The reply was, "Of course. A lot of our patients come from Alaska, and they can't board flights right away." I said, "You know the NRC advises against that." He replied, "That was taken into account." I said, "You know the State of Washington also advises against." He replied, "That was also taken into account."

At another Seattle-area hospital, a technologist told me that they had ceased to give inpatient treatment after a patient so contaminated the grout between the tiles of the shower that they were unable to get it clean, and had to shut up the room for many months.

For many years, I have been co-facilitator of the Seattle Thyroid Cancer Survivors Association (ThyCa) group. I also participate extensively on line, offering support and guidance to other patients, especially those new to the disease. (Sometimes it reassures patients to know that there is such a thing as a 47-year survivor.) Remembering as I do the era when the resources for new patients were essentially non-existent, it is deeply rewarding for me to be able to help light the path for others.

Over the years, I have been able on a few occasions to help secure inpatient treatment for patients who clearly needed it, but who faced intransigent providers and insurers. (Allison Macfarlane could tell you about one such case.) I remain in touch with some of them today. But for every one that I have been able to help, there are hundreds more who take what they are offered, because they are given no choice.

In 2019, I filed a new petition for rulemaking, this time with scores of co-signers. I withdrew it in March of 2020, principally on the grounds that the middle of a pandemic was no time to be altering the status quo with regard to hospitalization of I-131 patients. But the points made in the petition remain valid, and presumably the time will come when the pandemic is behind us, and it can be resubmitted.

The central problem remains the NRC staff's obdurate insistence that internal dose is unimportant, when in fact, according to the Centers for Disease Control and other national and international authorities, internal dose is critically important for children, who are far more at risk than are adults from the effects of radiation. A second issue is that the NRC has outsourced the protection of the public from providers, who are subject to the agency's regulatory authority if they fall short, to the individual patients, who are beyond NRC's control. These patients may or may not be adequately informed, and even if informed, may or may not care what happens to the stranger whom they expose to radiation. (The difficulty of persuading people to wear masks against the COVID virus shows how idle it is to pretend that every I-131 patient can be counted on to do the right thing.) Third, the NRC's rules, which allow anyone, including babies and pregnant women, to receive 500 millirems of radiation from a released patient, are out of step with national and international standards by a factor of five. Fourth, the net effect of the current rule has been to take the decision of whether to hospitalize patients out of the hands of doctors and give it instead to insurance companies, who all too frequently

could not care less that the patient has small children at home.

The hard fact is that no meaningful change can be accomplished without a rule change, something to which the NRC staff has been adamantly opposed. Instead it has offered Band-Aid solutions -- differing from the original product in that they lack adhesive. Regrettably, the Advisory Committee on the Medical Uses of Isotopes, despite some worthy individual members, has overall played an unhelpful role, including on occasion intervening to prevent the NRC staff from providing vitally important information to the Commission.

Any reexamination of the current rule would surely produce blowback. Sometimes, however, a leadership role, and with it the moral responsibility for safeguarding the lives of others, requires action that is not universally popular. I do not doubt that your decision to ban hard liquor from all TKE fraternity houses fell in that category. Here the stakes are no less high: protecting children, born and unborn, from cancer and mental impairment.

All that I and others in the thyroid cancer community are seeking is to ensure that American children are protected as well as children in the Third World. Though it doesn't seem like a lot to ask, achieving that goal would not be simple, for metaphorically speaking, the Commissioners of the 1990's not only let the horses out of the barn, they also burned down the barn and sold the land where it stood. Rebuilding the responsible regulatory program of the pre-1997 years would be a challenge, but someday, this wrong must be righted.

I would appreciate the opportunity to meet with you and/or your staff by telephone or Zoom.

Sincerely,

/s/

Peter Crane
Counsel for Special Projects, USNRC, retired

Attachments: "How We Got Here"
Paper presented to IAEA conference in Bonn, Germany, 2012
Photo of child in Cincinnati incident
Photographs of two young women whom I helped to get inpatient treatment
Photograph of myself in NIH, 1990, showing isolation room with plastic-covered furniture, to facilitate decontamination

January 24, 2021

HOW WE GOT HERE:
A Brief History of Medical Regulation at the Nuclear Regulatory Commission

Introduction and Summary

In 1976, news of a medical catastrophe involving a radiation therapy machine in an Ohio hospital reached officials at the Nuclear Regulatory Commission. Because an inexperienced employee had miscalculated the decay rate of a radioactive source, more than 400 cancer patients at Riverside Hospital in Columbus had been overdosed with radiation At least ten patients had died and scores more had been seriously harmed. Although proper care for the injured patients depended in part on knowing the cause of their injuries, the hospital had been slow to inform them.

In the aftermath, the NRC Commissioners enacted a rule requiring the prompt notification of patients in serious mishaps involving NRC-licensed nuclear materials. But the doctors whom the NRC regulates pushed back strongly, working behind the scenes with the NRC's own technical staff, which was no less adamant in fighting the rule.

Years of strife followed, between the licensee community and the NRC staff, on the one hand, and the Commissioners on the other, until the 1990's, when a different set of Commissioners, tired of controversy, eager to appease the doctors, and threatened with budget cuts by a Congressional appropriations committee, capitulated. They approved a massive deregulation, relying principally on one scientific advisor with bizarre views about radiation – he believed, for example, that if a major nuclear accident occurred, any health effects would be beneficial – that has made this country an outlier in the world radiation protection community.

Today, Bangladeshi, Iranian, and South African regulators protect their countries' children better than the NRC protects American children, as the Commission has known at least since 2014, from a survey of other countries' practices conducted by the NRC staff and forwarded to the Commission in that year. Only in the United States are patients with high levels of radioactive iodine 131 in their systems being sent home to their children, or to hotels, where they contaminate the rooms that housekeepers, unaware of the residue, will clean.

How did this medically unacceptable and morally repugnant situation come to pass? This essay tries to offer some answers, from one person's perspective.

I. The Wrong Kind of Graph Paper

By a quirk of law, the regulation of nuclear medicine, the medical specialty in which radioactive isotopes are used to diagnose and treat disease, is assigned to the government agency responsible for regulating the construction and operation of nuclear power plants. Created in 1975 out of the ashes of the Atomic Energy Commission, the Nuclear Regulatory Commission took over the AEC's regulatory responsibilities, including the duty to oversee the use of medical isotopes. At the time, U.S. standards and practices were fully consistent with international norms. Today, however, thanks to a radical deregulation by the NRC in 1997, this country lags far behind not only Europe and Japan but also a host of Third World countries, from Indonesia to Iran.

The particular safety issue is whether patients who have been made radioactive by , and therefore hazardous to others, by oral doses of the isotope iodine 131: whether they should be hospitalized, as is the practice in most of the world, or treated as outpatients and released, as is now usual in the U.S.

It might be assumed that a deregulation of such consequence would have been undertaken only after the most careful consideration of the scientific evidence. Such an assumption would be incorrect. The NRC Commissioners – five political appointees, none with experience in the medical area – blundered into deregulation, pressured by the doctors they were supposed to regulate and seriously misled by their own technical staff.

How all this came about is a long and tangled story, with a cast of characters that includes a bungling medical physicist, an NRC consultant with a sinister past, a rebellious NRC staff official determined to checkmate the Commission, a sometimes potty-mouthed nuclear medicine doctor, and last but not least, a three-year-old child.

In 1975, when I joined the NRC, medical issues were not at the top of anyone's agenda. The agency had far too much else to think about, principally operating safety and nuclear plant licensing. At the time, there were projections of a thousand operating reactors by the year 2000, and it was to license that construction and operation of those nuclear plants that the agency had been created. Nuclear medicine was to the NRC rather as Guam is to the U.S. Congress – a responsibility, to be sure, but an extremely low priority. The medical area of the NRC staff was the fiefdom of an AEC holdover who ran it with little oversight or interference from the

Commission, the Executive Director for Operations (i.e., the head of the NRC's technical staff), or anyone else.

But in the spring of 1976 an event came to light that abruptly raised the Commission's consciousness of medical issues. At Riverside Hospital, in Columbus, Ohio, a medical catastrophe had occurred. Large numbers of cancer patients were being treated with radiation from a machine that housed a cobalt-60 source. Because such sources decay with the passage of time, treatment times have to be increased to produce a constant output of radiation. For many years, an experienced team of consultants had calculated treatment times and performed the necessary periodic calibrations of the machine. But in an effort to cut costs, the hospital had decided instead to hire its own health physicist, Joel Axt, to do the work in-house. Young and inexperienced, he was unaware that the decay of the Co-60 source was a semi-logarithmic rather than an arithmetic function, and using ordinary graph paper, he calculated that the source was decaying far more quickly than it actually was. As time passed, and treatment times were increased by ever greater amounts, the overdoses to patients became progressively more severe. Over 400 patients were over-radiated, and at least one of them was known to have died. (In fact, many more had died than the Commission first realized.[1]) When the errors were detected, Axt falsified the records in an effort to cover up his error, he was quickly found out. Fired by the hospital, he moved to California and made a new career as an optometrist.

In the aftermath of the Riverside disaster, the Commissioners grappled with its implications. What had actually happened to the patients, and how would they or their survivors learn about the overdoses? The result was that the Commissioners directed the staff to evaluate the cases of each of the patients harmed in the incident and ensure that they were notified. For the future, they set in motion the creation of a rule that would require certain kinds of "misadministrations" – medical mistakes that included overdoses or underdoses beyond a certain percentage, irradiation of the wrong organ, etc. – to be reported to the NRC, to the patient's referring doctor, **and to the patient himself or herself**. It was the last of these that stuck in the craw of the medical community and the NRC technical staff. They saw in it a dangerous precedent.

To evaluate the 400+ Riverside cases, the staff turned to Dr. Eugene L. Saenger of the University of Cincinnati Medical Center. He ended the analysis after just three cases. It was later reported

[1]http://www.columbusmonthly.com/content/stories/2010/08/the-riverside-radiation-tragedy.html

that he had been concerned about creating ammunition for lawsuits.[2] Either the Commissioners did not know that their directive had been disregarded or they knew but did not care.

Dr. Saenger and the NRC staff were of one mind where the "misadministration reporting rule" was concerned: they detested it. At the proposed rule stage, Saenger wrote comments warning that doctors would perjure themselves rather than report information that might expose them to malpractice suits. (The implication was that they had a right to do so.) The NRC staff, for its part, tried repeatedly to persuade the Commissioners to reconsider the rule, but in vain. Forced under protest to administer and enforce the rule, the staff knew exactly whose expert advice it wanted when evaluating misadministration cases: Dr. Saenger's. It is reasonable to suppose that he was chosen for the same reason that he had proven so useful on the Riverside cases: to ensure that whenever possible, hospitals and doctors would be let off the hook.

The enactment of the misadministration rule led to years of bitter internal warfare between the Commission and the staff. The medical staff's attitude was one of defiance, but its repeated demands that the Commission rescind the rule were slapped down, with increasing impatience, until at last the Executive Director for Operations, tired of expending capital in a losing cause, refused to give his assent to any more such submissions. The matter seemed settled at last, and when the staff proposed a comprehensive revision of the medical regulations in 1984, the cover memo informed the Commission that the provisions of the misadministration rule had been left untouched. It seemed that the medical staff had at last reconciled itself to living with the Commission's decision, since previously, it had missed no opportunity to lobby for the rescission or weakening of the rule. Not until a year or two later was it discovered, purely by chance, that in fact the revision included a subtle but significant change to the misadministration rule, one that would make it next to impossible to find that a doctor had violated the rule. Foisted on an unsuspecting Executive Director for Operations and Commission, this rule change by stealth may be unique in the history of American administrative law. Once it came to light, the rule was returned to its previous wording.

II. Turn Off Your Tape Recorders

In the summer of 1986, a report by NRC's Office for the Analysis and Evaluation of Operational

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[2]http://www.apnewsarchive.com/1992/NRC-Says-It-Didn-t-Thoroughly-Examine-Ohio-Radiation-Overdoses/id-b03b91fc195b94201e158adb818faa9f

Data (AEOD) happened to cross my desk, dealing with the safety of reusable iodine-125 "seeds," manufactured by 3M for use in brachytherapy. In brachytherapy, a sealed radioactive source is placed directly into a tumor, temporarily or permanently, to deliver concentrated radiation at close range. These seeds, which contained a large amount of radioactivity – 40 millicuries – were intended to be used several times. The incident that had prompted AEOD's investigation had occurred in 1984, in the very nuclear medicine department where the NRC's consultant on misadministrations, Dr. Saenger, was in charge. The seeds in question had been placed in a plastic catheter, inserted in a patient's tumor for a prescribed amount of time, and then removed from the catheter and returned to the lead "pig" where they were stored. But the seeds are tiny, and the technologist prying them from the catheter had, without noticing it, put a nick into one of them, releasing I-125 in gaseous form. Contamination spread around the nuclear medicine department. By the time it was detected, 60 staff members had measurable amounts of the isotope in their bodies.

At that point, the leaking seed was already in a second patient, Jennifer H., a young woman of 25 with a brain tumor. In a new catheter, inserted into her brain through a hole drilled in her skull, the seed was continuing to ooze I-125. Carried through her bloodstream, it accumulated in her thyroid, a gland always avid for iodine in any form.

A footnote to the AEOD report explained that the staff had found the event not to be a "misadministration," because the hospital, having discovered the leak while Jennifer's five-day treatment was in progress, had decided not to remove the catheter, and instead to let the therapy continue. This puzzled me for two reasons. First, the legal theory made no sense, since a mistake is a mistake, and permitting it to continue does not alter that fact. Even more striking, however, was the factual account that underlay this erroneous legal conclusion. It was bogus, I suspected, and when I obtained the records on the event, I felt sure. The hospital had not tested her urine until the treatment was completed, nor given her potassium iodide to protect her thyroid from the radioactive iodine, nor put her in isolation and restricted her from having visitors. Nor had the hospital's thyroid specialist been called in to see her, though he had examined the 60 contaminated staff members.

The failure to take these steps made clear that in reality, there had been no medical decision to let the treatment continue. On the contrary, the hospital staff had been wholly unaware that the seed had leaked inside Jennifer's brain until, at the conclusion of the treatment period, they removed the catheter, held a radiation detector to her neck, as NRC rules required, and discovered that her

thyroid was radiologically hot.

The AEOD staff member analyzing the safety of reusable seeds had not suspected anything amiss with the hospital's story, nor was there any reason he should have. To realize that the hospital's story did not hold water, one either had to work in the medical field or, like me, have personal experience of treatment with radioactive iodine. At the time, I had been a thyroid cancer patient for 13 years, and had only recently been given two doses of radioactive iodine 131. As a result, I was well aware of the precautions that are taken with patients known to have radioactive iodine circulating freely in their systems. It seemed odd that the NRC's medical staff, with its knowledge of the subject, would not also have realized that the hospital's account was untrue. It was hard to avoid the suspicion that the NRC staff, to accommodate its consultant Dr. Saenger, had winked at the deception. It did not occur to me at that point that the NRC staff might actually have proposed the false account.

I wrote a memo to Commissioners' assistants describing the issues and recommending that the Office of Investigations be asked to investigate the apparent false report provided to the NRC by the hospital. The Commission agreed, prompting a vehement objection from the NRC staff, which argued that nothing untoward had happened and that there was nothing to investigate. To skeptics, this only reinforced suspicion that the NRC staff had known all along that the hospital's story was fabricated, and that it was now afraid that investigating the hospital's role would reveal its complicity in the deception. The staff also contacted the hospital, ostensibly to find out Jennifer's condition (she had died of her brain tumor in 1985), but in so doing, putting Dr. Saenger and his colleagues on notice of the NRC's renewed interest in the case, and eliminating the element of surprise for the investigators.

Meanwhile, the staff conceded to the Commissioners that the event had in fact been a misadministration, and reclassified it accordingly. (It turned out that a staff lawyer had said from the start that it was a misadministration, but had been ignored.) It was also designated as an "Abnormal Occurrence" – that is, a mishap serious enough to require inclusion in a semi-annual NRC report to Congress. As such it was described in detail in a notice published in the Federal Register. But though the hospital could not have been unaware of these developments, the NRC staff was careful never to send it any official notification that the event had been reclassified. As a result, the University of Cincinnati Medical Center could profess to be under no obligation to notify Jennifer's family, who remained in the dark. The regulators and the regulated understood each other perfectly. Meanwhile, the NRC staff did its best to hamstring and delay the

investigation ordered by the Commissioners.

Three years passed, and the investigation still had not reached its conclusion. In 1989, in response to my complaints about the NRC's failure to pursue the case, I was made part of a team that included an Office of Inspector General investigator, Keith Logan, and an Office of Investigations staffer from NRC's regional office in Chicago, Hal Walker. (The former office looks at wrongdoing by NRC employees, the latter at misconduct by NRC licensees.) We arrived at the University of Cincinnati Medical Center to meet with Dr. Saenger and several other hospital employees. While a court reporter recorded the meeting, Logan began by saying that he wanted to ask questions about the misadministration that occurred at the facility in 1984. A hospital official interjected that no one had ever informed *them* that it was a misadministration.

Logan then asked if anyone in the group had files on the incident. Two staffers said that they did, and retrieved them from their offices. They included handwritten notes on a 1984 telephone call from an NRC staffer in the Chicago regional office who had begun by saying, "Turn off your tape recorders," and then explained the plan: the hospital should inform the NRC that the leak was discovered during the course of Jennifer's treatment and the doctors made a medical decision to allow the treatment to continue nevertheless, and on this basis, the NRC would find that no misadministration occurred. Apparently, the NRC staff, on the advice of its lawyer, had initially told the hospital orally that the event was a misadministration, and when Dr. Saenger objected, looked for a way to find otherwise.

Thus the false story provided by the hospital had actually been the NRC's idea. We also learned from this visit that in addition to the 60 staff members whose irradiation the hospital had reported, two more people had been exposed to radiation through contact with Jennifer. These were her mother, Mildred H., and her three-year-old daughter, Katrina T.

Keith Logan, the Office of Inspector General investigator scrutinizing the way that NRC employees had handled the case, had begun with lower-level staffers and was working his way upward, rung by rung. With two weeks left to go in the investigation, and only three senior officials still to be interviewed, he was abruptly fired, and the investigation was then shut down without further interviews. Though the Office of Investigations felt sorry for Logan and hired him, they could only offer him a job at the GS-13 level, whereas previously he had been a GS-15. Even after the revelation that Katrina and her grandmother had also been irradiated, the NRC

staff remained adamant in its refusal to notify the hospital that a misadministration had occurred, presumably because to do so would have alerted Katrina's family to the possibility of bringing suit against the hospital. The NRC, created by Congress to ensure that members of the public are not harmed by the activities of the agency's licensees, seemed to have adopted precisely the opposite philosophy: that its job was to protect licensees from the public.

Over the next two years, I continued to demand notification for Katrina and family, and came to be seen, not necessarily without reason, as an annoyance. This helped create a climate in which I felt compelled to quit the agency in 1991 and take a job as a member of the Nuclear Claims Tribunal in the Republic of the Marshall Islands. I left, however, with a promise volunteered by the then General Counsel, William C. Parler, that if I wanted to return, and he was still in that position, he would rehire me. Going to the Marshalls turned out to have been a mistake, both because of my 7-year-old daughter's school situation there and my own medical needs. Mr. Parler was good as his word, and I rejoined the NRC a year later.

Katrina might still be waiting today for the notification she was owed, but for the fact that in late 1993, the story of the Cold War human radiation experiments broke, and some of the most horrific turned out to have been perpetrated by none other than Dr. Saenger and his associates at the University of Cincinnati. They had been conducted between 1960 and 1971, under license from the Atomic Energy Commission.

III. An Outrageous Tale of Government Perfidy

Dr. Saenger's subjects for the radiation experiments were poor people, taken from the charity wards of the Cincinnati General Hospital. They were subjected to massive doses of whole-body radiation, all coming from one direction, to simulate the effect of a tactical nuclear weapon exploded in a battlefield situation. (The Department of Defense wanted to know how long soldiers could go on fighting after such a bomb was detonated.) Of the 88 subjects, 55 were African-American. They were selected on the basis, in part, of low educational level. Four were children, the youngest nine years old.

Early in 1994, a Senate committee headed by John Glenn asked the NRC for all the information it had on Dr. Saenger. That document request would, the NRC immediately realized, encompass seven years' worth of memos from me, including many urging that Katrina and her family had a right to know of the exposure to her mother and herself. Within 24 hours of receiving Glenn's

request, the NRC had informed the University of Cincinnati that it was obligated to notify the family of the misadministration that had occurred in 1984.

The late Joe Fouchard, then head of Public Affairs, was an old AEC hand. He said to me at the time, "When I saw they were asking about Gene Saenger, I thought, 'uh-oh,' because the trouble with Gene Saenger's patients was, they didn't die as fast as they were supposed to." The point was that Dr. Saenger was supposed to be experimenting on goners, people so near death that any effects of the radiation would hardly matter or be noticeable. But not having enough goners to work with, he had taken what was available, including people who were functioning quite well, even holding down regular jobs, notwithstanding that their disease ultimately was not curable.

Though Saenger and his colleagues claimed to have obtained consent forms from the patients, family members denounced these as forgeries. In an April 1994 hearing before Senator Glenn, the granddaughter of one subject testified, "The spelling of her name is different and the writing is not the same." The massive doses of whole-body radiation – the equivalent of up to 20,000 chest x-rays – often sent patients into immediate, catastrophic, and irreversible decline, with days of vomiting and bleeding, followed by death within two or three months. Emetics, if given in advance, could have ameliorated their symptoms, but at the cost of interfering with the experiments' objective, which was to duplicate the experience of soldiers in battle. Satisfying DOD's need for information took precedence over reducing the patients' suffering. Anti-emetics were not administered, nor were patients given any warning of what they were about to endure. The daughter of one subject, who lived only 74 days after being irradiated, testified: "He couldn't eat. He couldn't sit up. Whatever came out of him, whatever spittle, we had to save and send back to the hospital." ("Relatives Say Signatures of Patients in Radiation Tests Were Forgeries," *New York Times*, April 12, 1994.)

Dr. Saenger himself originally said that the radiation had shortened the lives of eight of the subjects. Later, apparently appreciating the possible consequences of that statement – it could have been seen as a confession to manslaughter if not murder -- he changed his position, and said that none of the subjects had died prematurely. Despite ample evidence to the contrary, he was steadfast in his insistence that the purpose of the experiments had been to benefit the patients. Around this time, one of the Cincinnati papers carried a story saying that the University had released a collection of documents that showed how Saenger had orchestrated false testimony by University personnel when a Senate committee was first investigating the radiation experiments in about 1971.

A group of former subjects and their survivors sued Dr. Saenger and his fellow doctors, as well as two Navy physicians involved in the experiments, the City of Cincinnati, and the hospital. The defendants moved to dismiss the case on constitutional grounds. The district judge, Sandra Beckwith, a Republican appointee, in rejecting the motion, wrote that the facts alleged in the complaint told an "outrageous tale of Government perfidy," and that if they were accurate, the Government had treated the plaintiffs and their loved ones "like so many laboratory animals." Enumerating the various excuses made by the Nazi doctors on trial at Nuremberg for their medical experiments on non-consenting subjects, Judge Beckwith declared:

> The ... Defendants, many of whom were physicians, were not acting as physicians when they conducted experiments on unwitting subjects at Cincinnati General Hospital. Rather, the Defendants were acting as scientists assembling cold data for the Department of Defense. ... If the Constitution were held to permit the acts alleged in this case, the document would be revealed to contain a gaping hole. This is so in part because the alleged conduct is so outrageous in and of itself, and also because a constitution inadequate to deal with such outrageous conduct would be too feeble in method and doctrine to deal with a very great amount of equally outrageous activity.

Dr. Saenger and his codefendants, faced with the prospect of going to trial before Judge Beckwith, prudently agreed to settle. In addition to financial compensation, the proposed agreement included a provision for a plaque at the hospital in memory of the victims, who would be identified by their first names and an initial. Judge Beckwith rejected the proposed settlement, insisting that the patients' full names should appear. The change was made. The judge was present for the unveiling of the plaque – like the patients' loved ones, she held a lighted candle – and many years later told an interviewer that she regarded the case as the high point of her career.

Afterwards, the Government apologized, but Dr. Saenger himself never did. Today, there is a professorship at the University of Cincinnati that bears the name of Dr. Saenger and his wife, and it is now held by Dr. Edward Silberstein, one of his co-defendants.

IV. A Pretty Aggressive Person

Sometime in the late 1980's, when the Cincinnati case was still under investigation, a factually somewhat similar case arose, and the staff proposed to have Dr. Saenger serve as its consultant.

The General Counsel's office advised that there might be a conflict of interest, and when the staff explained to Dr. Saenger that his services were not desired on the case, he took offense, and declared that he would not again be a consultant to the NRC.

The medical staff needed a new expert on misadministrations, and it found one in the person of Dr. Carol S. Marcus, a nuclear medicine physician and professor at UCLA with an M.D. and a Ph.D, long experience in the field, strong views, and a penchant for sending letters, always on UCLA letterhead, that combined evident scientific erudition with extreme crudity of expression. On October 23, 1989, for example she wrote to Dr. Anthony Tse of the NRC staff:

> You mentioned to me that someone at NRC raised the point that NRC should tightly regulate the practice of Nuclear Medicine and of Nuclear Pharmacy because "innocent bystanders" are subject to irradiation by patients with radiopharmaceuticals in them. NRC must therefore decide whether such innocent bystander irradiation is "acceptable....."
>
> In the first place, Tony, this is just power-hungry horseshit. In the second place, the irradiation of innocent bystander [*sic*] is well covered in NCRP Report No. 37....

The NCRP [National Council on Radiation Protection] report to which Dr. Marcus referred was a 1970 study that created the analytic method for allowing patients, in exceptional cases, to be treated with radioactive iodine 131 as outpatients in amounts greater than the 30-millicurie limit imposed by the AEC (and later NRC). We will return to this subject shortly.

The trade press quickly focused on Dr. Marcus. On February 26, 1990, *Inside N.R.C.* carried a story, "Nuclear Physicians on the Warpath Over NRC's 'Infuriating Interference," that began:

> "Vicious," "grotesque," "horrible," and "hopelessly repulsive" are some of the kinder, gentler epithets used by one of the most outspoken physicians riled at NRC's effort to broaden its health and safety purview over the practice of nuclear medicine.

Dr. Marcus, quoted in the article as describing herself as a "pretty aggressive person," had an explanation for why the Commission was "acting like a bunch of antinuclear hysterics" and conducting a "vicious assault on the practice of medicine":

> "I'll tell you why," she said. "The nuclear industry is dead, and they know it. So what do they do? They've got to find something to regulate – something with the word 'nuclear' in

it. That's why."

Possibly in an effort to co-opt and control her, the Commission in 1990 appointed Dr. Marcus to the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). But if the Commissioners thought that the new responsibilities would cause her to tone down her rhetoric, they were seriously mistaken. It seemed instead that the Commission's indulgence had encouraged her to new excesses. For example, in a letter to the NRC of January 24, 1992, she wrote:

> The Commission, with its oversimplifications of medical and pharmacy practice, required willing pawns to do its work. A sort of Darwinian evolution took place in which the scientifically unfit, a few individuals with very poor attitudes, and several cowards inherited the duty.... In order to support the Commission's desires, and advance their own power agendas, the present staff uses fraud in any convenient form. Data are misrepresented, omitted, ignored, or manufactured for convenience. ... The recent humiliation of NRC by staff of OMB when NRC's fraudulent version of the "Quality Management Rule" was uncovered is astounding but predictable. Instead of NRC's upper management retracting the material and apologizing, a delegation of NRC staff and management went into frenzied, paroxysmal "superlying" to cover the original lying, and earned the contempt of all concerned. Some of the statements made in writing by NRC staff to justify the Rule describes actual deaths of patients caused by physicians which in fact did not occur. This would itself constitute a libel suit, but in this case has no point; no damage will be done because no one believes the NRC anyway. Pitiful, isn't it? ... I do not believe that the Medical Use Program is compatible with honesty, integrity, or even simple human decency.

Notwithstanding these and similar letters, the Commission, under Chairman Ivan Selin, named Dr. Marcus to a second two-year term on the Advisory Committee in 1992. As amazed as anyone, she was quoted in the trade press as saying, "Can you believe it? They reappointed me."

At one point, Dr. Marcus wrote to the Commissioners demanding that they send James Lieberman, a senior official of the NRC Office of Enforcement, to a mental hospital. He then posted the letter on the wall outside his office for the amusement of passersby. Someone not amused by her, however, was the Mr. Parler, the NRC's General Counsel. On November 3, 1993, Dr. Marcus wrote to Dr. Carl Paperiello, a senior NRC official, that a colleague had informed her that "after listening to Marjorie Rothschild [a lawyer in the Office of General Counsel] for 2 days,

that OGC had determined that after receiving a radiopharmaceutical, a patient was not allowed to ever have intercourse again." Dr. Marcus gleefully expanded on this theme: if the patient used a condom, she could then test the semen for radioactivity, etc. In response, Parler wrote a sharply worded three-page memorandum to the Commission in which his revulsion and contempt were undisguised. Though not phrased in these terms, its message was that if the Commissioners were too gutless to object to the abuse of NRC staff members, including those reporting to him, it would be over his strong protest.

But for some on the NRC staff, Dr. Marcus had her uses. If staff officials were dissatisfied with a Commission decision, she could serve as a proxy or shill, submitting what would to all appearances be a petition for rulemaking from a concerned NRC licensee, and thereby bypassing senior staff management, including the Executive Director for Operations. This first occurred in 1989 with the so-called Radiopharmacy Rule, which Dr. Marcus, in a November 9, 1992, letter to the NRC Secretary, indiscreetly but quite accurately described as "an 'inside job' from the start." Not only had a senior staff official requested that she submit the petition, she told the Commission, he had also assigned a subordinate to help draft it to his specifications.

The revelations incensed the Executive Director for Operations, James Taylor, and the NRC quickly changed its rules to prohibit this sort of collaboration between the NRC staff and outside parties. To make sure that the message was understood, he issued an announcement to all employees, and repeated it annually for the next several years. In included notice that if his directive was disregarded, and a petition for rulemaking was filed at the behest or with the assistance of the NRC staff, that fact would have to be revealed to the Commission and the public.

In hearings before the Senate Governmental Operations Committee in May 1993, Chairman John Glenn was perhaps most disturbed by the idea of collusive rulemaking. The following exchange took place with NRC Chairman Ivan Selin:

> Chairman Glenn. In 1990, the NRC Office of Inspector General, OIG, found that NRC headquarters staff, again, without the knowledge of the Commission, provided improper assistance to medical groups by helping them prepare a petition for rulemaking that would weaken the current regulation. Now, if we had a nuclear power lobby coming in, I'm sure people would be out the door before nightfall if they were writing regulations in-house over there for the industry to submit to you. What has the NRC done to assure that this

problem will not be repeated?

Mr. Selin. That same IG report had another section which is also quite damning. It said that essentially, in spite of the fact that your intuition and your sense of what is right and what is wrong, said these are the wrong things to do, we had no regulation which these people violated, and it was another sign of the – –

Chairman Glenn. Except common sense.

Mr. Selin. Exactly, Senator.

Chairman Glenn. The staff doesn't, in my office or yours or anybody else's, go off half-cocked on their own and make decisions to weaken regulations or help the industry or whomever is out there to weaken regulations. And they would be out of my office before nightfall in my office if they did.

So I presume you have done something to make sure that they are not doing that now without bringing it to the Commission's attention.

Mr. Selin. We have done three things. We started at the top. We fixed the internal guidance to make it absolutely clear that these two types of things cannot be permitted to happen — either the staff marketing a petition to outside groups, or the staff dealing with outside groups in areas that would lead to a conflict.

The second thing is that the EDO issues not only once, but annually, a statement calling people's attention to this point. And the third is the specific people who were involved in thus — it was discussed with them about what they should and should not do. But we cannot retrospectively do more than that, because they did not violate our written requirements. And as much as that goes against common sense, we can't have ex post facto justice. So we have fixed the requirements; it is clear to the people that they did wrong, and that particular thing will not happen again.[3]

What Selin neglected to say was that at that moment, another collusive rulemaking was in progress, also involving Dr. Marcus. It would result in making U.S. radiation protection

[3] *See* "Federal Regulation of Medical Radiation Uses," Hearing before the Committee on Governmental Affairs, United States Senate, 103rd Cong., 1st Sess., (May 6, 1993), at 18-19.

standards for nuclear medicine probably the laxest in the world.[4]

V. Write a Petition YESTERDAY

NRC's loosening of radiation protections was the unforeseen result of an initiative by President Ronald Reagan to tighten such protections. Persuaded by the Environmental Protection Agency that unborn children were at risk, Reagan in 1987 ordered all federal agencies to reduce radiation exposure limits. Accordingly, the NRC in 1990 lowered the ceiling for exposure of the public to radiation from NRC-licensed activities by a factor of five: from 500 millirems per year to 100 millirems. The new standard had no practical effect on nuclear power plants and most other NRC-licensed facilities – their emissions are far below 100 millirems annually – but it did have the potential to disrupt treatments with nuclear medicine. The NRC had not specified whether the rule change was intended to include exposures to the public from patients treated with radioactive materials. It was a point that could have easily have been clarified, with a minimum of bureaucratic fuss: for nuclear medicine, the 500 millirem standard was supposed to remain in place. (In fact, the NRC issued such a clarification in 1995.) But instead of going through channels to suggest a supplementary notice, an NRC staff member turned to Dr. Marcus, and by her account, telephoned her to insist that she "write a petition YESTERDAY." She agreed.

Filed in December 1990, Dr. Marcus's petition asked for a clarification that the 500 millirem standard was still in effect for persons exposed to nuclear medicine patients, and also requested something else: the elimination of the 30 millicurie activity limit (above which hospitalization is required) for every radioactive isotope except one. Henceforth, release of patients would be based not on the amount of radioactivity in their systems, but rather on the maximum dose anyone else was likely to receive from them. To determine the dose to others, licensees would follow the method described in NRCP Report No. 37, as described earlier.

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[4] Senator Glenn was also concerned about the more than eight years it had taken the NRC to notify the University of Cincinnati that it was legally required to notify Katrina T.'s family of the misadministration. Selin replied: "The big problem there wasn't the notification. It was the reluctance of the staff to recognize that this was in fact a misadministration. Once it was decided that it was a misadministration – which took far too long to get to that point – the notification was fairly prompt." This was untrue. After a few minutes spent on another topic, Glenn said: "Let me go back to the University of Cincinnati. In 1986 the NRC officially declared the University of Cincinnati incided a misadministration. Why did it take until January 1993 to formally notify the University of Cincinnati?" At that point, Selin retreated, and gave a detailed answer that contradicted what he had said before. Glenn politely did not ask him why he had not said this the first time. *Id.* at 19-21.

The sole isotope for which Dr. Marcus proposed to retain the 30 millicurie activity standard was iodine 131, the most toxic and dangerous of all radiopharmaceuticals. It was, plainly, a special case. But after the NRC gave notice of the receipt of her petition, a professional society representing nuclear medicine doctors, the American College of Nuclear Medicine (ACNM), filed its own petition, which made no such exception for I-131. Indeed, the ACNM declared that even 400 millicuries of the isotope could safely be given to outpatients. Not to be outdone, Dr. Marcus then amended her petition to eliminate the exception for I-131. When in a comment to the NRC I referred to her as endorsing the ACNM position, she was indignant, and wrote to the NRC to protest:

> 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. (Letter of November 9, 1992.)

In 1992, the staff published a notice of the receipt of the petitions, along with a request for comment. Six states, including New York, Alabama, Arizona, and Texas, filed submissions indicating disquiet with the idea of releasing patients with high levels of I-131 in their systems. New York, for example, pointed out that the authors of NCRP Report No. 37 intended that this be reserved for exceptional cases, with an absolute activity ceiling of 80 millicuries. (Local health departments were also to be notified, and the patients were to wear wrist bands with the yellow trefoil symbol indicating a radioactive hazard.) Texas observed that the NCRP was emphatically opposed to exemptions from the 30 millicurie activity limit for I-131, and in 1983 letter had written to the American Heart Association that it viewed an 8 millicurie activity limit as preferable.

But when the staff published a proposed rule in 1994, there was no mention of this. It was as though none of these cautions had ever been sounded. As far as the Commission and the public were given to understand, this measure was essential to preserve the status quo, and a consensus of commenters warmly approved of it.[5]

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[5]A few years ago, I telephoned one of the state regulators, an individual highly respected in the field, to express my concerns about the current state of public health under the patient release rule. He asked, "What do you want me to do about it?" I suggested that he might write to the Commission. He replied, "Did they listen to us the last time?"

By 1994, Dr. Marcus had good reason to believe that she had the complete and unqualified support of Chairman Selin, and while she continued to abuse the staff, she had only positive things to say about him. On December 8, 1994, she wrote to Selin to complain of the "nonsense that results when unqualified NRC bureaucrats conjure up inane requirements to amuse themselves, justify their existence, and appear busy," and offered this suggestion:

> Unbudget all of NRC's "Medical" Section. ... [T]hese staff are out of control, doing everything imaginable to justify their existence and thwart your wisdom. ... Machiavelli's advice ("The Prince") to leaders in your situation is to kill them. I would moderate this; unbudgeting will do just fine.

A few weeks later, on January 10, 1995, Dr. Marcus wrote to Dr. Carl J. Papierello, then Director of the NRC's Division of Industrial and Medical Nuclear Safety:

> Your peculiar stubbornness on this issue is ignorant, irrational, and scientifically and medically without foundation. I cannot respect your opinion, and believe that if you do not even know what Nuclear Medicine is, you certainly are not entitled to any opinions about it. Your gratuitous suggestion that the way to resolve the conflict ... is for us to stop being appropriate and start writing silly prescriptions that suit the staff in your non-medical "Medical Section" is the typical perversion of the more dysfunctional members of your Agency.[6]

Two weeks later, on January 24, 1995, Dr. Marcus was writing to Chairman Selin to demand to know why her petition had yet to be granted. She had met with him in his office in September 1994, she said, gone over the proposed rule with him, and explained the staff's "serious scientific, mathematical, and medical mistakes." She continued:

> You agreed with my points, stated that NRC "had not done its homework", and vowed that it would be repaired. Given the fact that I did all the physics, math, pharmacokinethics [*sic*], and pathophysiology for NRC, and contributed model calculations, model language and the pertinent references, one would assume that it would require no more than about

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[6]The NRC was not the only recipient of such communications. To the Food and Drug Administration, she wrote on January 5, 2005: "...**FDA actions have killed tens of thousands of patients by depriving them of PET scans.** While this hasn't made the front pages of the nation's newspapers, it should. The sordid and unforgivable details of a vicious and malevolent plot to destroy PET by the FDA was the subject of a federal lawsuit...." [Emphasis in the original.]

> an hour of NRC time to complete the rule. After all, it was NRC that asked me to write a petition on the subject in the first place, in December of 1990.

Although federal agencies' rulemaking, in contrast to adjudication, is not by a law an "on-the-record proceeding," comments on a proposed rule from interested parties normally take place on the rulemaking record, with an even playing field for all participants. That was not the case here.

Writing to Chairman Selin on February 13, 1995, Dr. Marcus's subject was the NRC's Quality Management Rule, which she described as a "disgusting abortion." She wrote:

> Chairman Zech's original Staff Requirements Memorandum on the subject was so vicious and naive that it was blotted out entirely with felt pen and is sent out from the Public Document Room entirely blacked out. Fortunately we obtained a virgin copy when an infuriated NRC employee tucked it into another document as an Addendum, and then suggested that we request the document. ... When NRC staff concocted false data with which to support the need for a "Quality Management" rule, the entire food chain of management failures, including the Commission, signed off on the data in draft form.

Once Chairman Selin had left office, Dr. Marcus's view of his leadership appeared to change. In an April 18, 1996, letter to Chairman Shirley Jackson, she wrote, with respect to Senator Glenn's 1993 hearing and the newspaper articles that occasioned it:

> Chairman Ivan Selin, trying to keep his job when President Bush lost re-election, could not deny the importance of the Plain Dealer allegations without admitting poor leadership on his part. He therefore took the easy way out and thanked the Cleveland Plain Dealer, abusing the medical community as much as possible to "look good." ... It worked. Selin kept his job. ... Senator John Glenn, eager to wave the bloody radiation flag to win a few more votes, held a farcical "hearing."

Vilifying a federal agency and maligning its Commissioners and staff might seem an unlikely way to achieve positive results, but there is no doubting Dr. Marcus's brilliant success in achieving her goals. She won across the board. Her petition was granted, the misadministration rule was cut back, and the hated Quality Management rule was abolished altogether in 2002.[7] Meanwhile her offensive comments about the NRC continued unabated on the RADSAFE

[7] 67 FR 20370, April 24, 2002.

bulletin board. I have again substituted asterisks where the vocabulary was especially pungent.[8]

Nor did it stop there. Once the Patient Release Rule was in place, and the NRC issued guidance for licensees to use in calculating whether they were in compliance, Dr. Marcus was still dissatisfied. Although in 1992, she had declared in a letter to the NRC that the idea of releasing patients with 400 millicuries of I-131 in their systems was "ludicrous," she now urged licensees to disregard the NRC guidance and instead follow Society of Nuclear Medicine guidance that would allow patients to be released after outpatient doses of up to 457 millicuries of I-131.[9]

The foregoing is only a partial account; a full one would take a book. My mantra is always, "Don't take my word for it." But readers who study the subject in depth will come to agree with me, I think, that here the NRC has failed the public grievously, and it does so to this day.

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May 2014 (revised January 2021)
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[8]1. "It is a real shame that the President does not choose Commissioners with enough brains, education, experience, and management talent to avoid being cuckolded by their staff, management, and lawyers. We could certainly use some intelligent life on the 17th and 18th floor." [Dr. Marcus to RADSAFE, August 12, 1999]
2. "[T]he criminalization of human error, much of which is insignificant and all of which is rare, is venomous, perverted, and terminally dysfunctional. It is amazing that the Commissioners cannot get this simple idea through their skulls." [Dr. Marcus to RADSAFE, December 20, 1999].
3. "The answer is to CHANGE THE STANDARD.... Alas, for years, the NRC has not had the b*lls and brains to do this." [Dr. Marcus to RADSAFE, February 11, 2000.]
4. "Unfortunately, the Commissioners have no competence in nuclear medicine or nuclear pharmacy, and succumb to whatever bullsh*t the staff and management con artists feed them. ... Will Chairman Meserve get smart enough to cut through this vicious circle, excrete [former Chairman] Jackson's mess and continue the good work started by Chairman Ivan Selin and Commissioner E. Gail de Planque?" [Dr. Marcus to RADSAFE, July 20, 2000.]

[9]Health Phys. 2007 Dec;93(6):667-77. "Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with 131I." Siegel JA, Marcus CS, Stabin MG. Regrettably, that SNM guidance, published in 2004, was marketed to the licensee community as having NRC's approval as an acceptable substitute for the agency's own guidance, and Dr. Marcus herself stated explicitly, "NRC accepts this as an alternate to its own guidance document." The advertising included a quotation attributed to the NRC that in reality was a statement about a 2002 publication, with words inserted to make it seem to apply to the 2004 document. In 2013, at my prompting, the NRC staff asked the Society of Nuclear Medicine and Medical Imaging for the source of its claim that its guidance had NRC's blessing, and the organization altered its advertising.

RADIATION PROTECTION ISSUES ASSOCIATED WITH OUTPATIENT TREATMENT OF THYROID CANCER USING HIGH DOSES OF IODINE-131: THE U.S. EXPERIENCE

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For Session "Protecting patients, carers, comforters, and the public in nuclear medicine"

ABSTRACT

The United States Nuclear Regulatory Commission (NRC) sets no maximum activity level for the release of patients treated with radioactive iodine 131 (I-131). For decades, NRC used an activity-based standard, 1110 MBq, but since 1997, it has allowed medical licensees to use a dose-based standard by which patients can be released without regard to activity level, provided that the probable dose to any other person will not exceed 5 mSv. This limit, applicable even to infants and nursing mothers, far exceeds ICRP, IAEA, and NCRP standards. Outpatient treatment has become the norm in the U.S., even for doses of 7400 MBq and above, as insurance companies refuse to pay for inpatient care. Radioactive patients are frequently released to hotels, where they are a hazard to other guests and above all to housekeepers, who are typically women of childbearing age and may be pregnant or nursing. The dose to unsuspecting hotel workers violates a cardinal principle of radiation protection, informed consent. The NRC has also failed to ensure that practitioners and patients receive appropriate guidance about limiting exposure to others. The 15-year U.S. experience with dose-based standards for I-131 suggests that a major revision of the NRC's rules on radioactive patients is overdue.

1. INTRODUCTION

United States law gives the Nuclear Regulatory Commission (NRC), the agency which oversees nuclear power plants, the incidental duty of regulating the use of radioactive materials in medicine [1]. For decades, the NRC and its predecessor, the Atomic Energy Commission (AEC), required hospitalization for all patients administered 1110 MBq or more of iodine 131 (I-131) [2]. In 1997, however, in response to requests from medical licensees, the NRC changed its rules and began allowing doctors to administer high doses of I-131 on an outpatient basis [3]. The NRC's current rules, unchanged since 1997, present safety issues with respect to therapy doses of I-131 for thyroid cancer, therapy doses for hyperthyroidism, and diagnostic doses for thyroid cancer. This paper focuses exclusively on therapy doses for thyroid cancer.

2. DISCUSSION

2.1 The NRC rule change of 1997

Under the NRC rules in place since 1997, medical licensees treating patients with I-131 can choose between using the 1110 MBq activity standard as a default value and using a dose-based standard, under which patients can be released regardless of activity level if they are found unlikely to expose any other person to 5 mSv in a year [4]. This 5 mSv dose limit applies equally to all persons, irrespective of age, pregnancy status, and relationship to the patient. Only if the external dose to others is likely to exceed 1 mSv do the NRC's rules require licensees to provide patients with guidance on precautions for reducing radiation exposure to others.

In 1985, the NRC stated, accurately, that patients treated with I-131 are "a source of external radiation and can be a source of radioactive contamination" [5]. In 1997, however, the NRC declared that internal dose from contamination was insignificant, except for babies and nursing mothers, and stated: "[I]nternal exposures will not be considered in this analysis other than for the breast-feeding infant" [6]. The NRC conceded that exposure to patients' family members could be better controlled in a hospital setting, but pointed out that sending patients home would mean lower radiation doses to frequent hospital visitors, such as members of the clergy, and hospital orderlies [7].

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The NRC's decision that its limits on I-131 should be made less stringent came just as international and national bodies were moving in the opposite direction, toward **more** stringent controls on the isotope. ICRP 60 (1991) had reduced dose limits to the public to 1 mSv per year, and the IAEA's Basic Safety Standards (1996) prescribed hospitalization for any I-131 treatment of more than 1110 MBq [8, 9]. For many nations, moreover, the 1110 MBq activity limit of the BSS was **insufficiently** strict. As of 1998, activity limits in the EU Member States ranged from 95 to 800 MBq, with most between 400 and 600 MBq [10].

2.2 Effects of the NRC rule change

Once the new rule was in place, many physicians found that insurance companies were refusing to pay for inpatient treatment with I-131 on the grounds that it was no longer necessary. For a doctor to insist on hospitalization was, therefore, to risk not being reimbursed. At a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes in 2007, two doctors (both supporters of the current rule, it should be stressed) candidly acknowledged the dominant role of insurers in the decision whether to hospitalize patients for I-131 therapy [1] [11].

A recent survey of 311 health professionals found that 15% **never** hospitalized patients for I-131 doses below 7363 MBq; 6% **never** hospitalized for doses below 11,063 MBq; and only 22% **invariably** hospitalized for doses between 7363 and 11,063 MBq [12]. In 2002, after receiving reports that released I-131 patients were exposing members of the public to radiation, the NRC Commissioners considered and rejected a proposal to require a report to the NRC if a patient caused a dose to another person of 50 mSv or more [13]. If hard data pointing to the rule's adverse effects is sparse, it is in part because the NRC has chosen not to receive it.

2.3 Radioactive patients in hotels

In changing its rules, the NRC assumed that patients would either meet the criteria for release, in which case they would go directly home, or remain hospitalized. It had not foreseen a third possibility: that some patients, either because the criteria for home release could not be met or because they lived far away, might be sent to hotels. This presents serious risks to hotel chambermaids, who in the U.S. are typically women of childbearing age. These workers do not "knowingly and willingly" accept their exposure to radiation. Unlike hospital staff and the families of patients sent home, they are unaware of the contamination and cannot take even basic precautions. A chambermaid may receive a substantial internal dose, and if she is pregnant or nursing, her baby's thyroid may also be affected. If the hotel is near a cancer center, moreover, she may clean numerous contaminated rooms in a year. Guests in adjoining rooms may also receive external radiation doses through the walls. Current estimates are that between 4 and 5 percent of patients go to hotels after receiving therapeutic doses of I-131 [14].

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[1] Dr. Douglas Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries [7400 MBq], 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...."

Dr. Leon Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries [3700 MBq and 7400 MBq] of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... 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. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**. The health care workers are concerned and the hospital will not allow them to stay." [Emphasis added.] [Transcript at pp. 126-130.]

In 2009, the New York City Department of Health issued a directive to medical licensees warning in forceful terms against sending radioactive patients to hotels [15]. In 2011, the NRC published a non-binding notice that "strongly discouraged" licensees from doing so [16]. The practice nevertheless continues, and even has defenders. In a March 2011 article in an online medical journal, *ASCO Post,* Dr. R. Michael Tuttle, a distinguished thyroidologist at Memorial Sloan-Kettering Cancer Center in New York, was quoted as saying that Sloan-Kettering gives outpatient doses of up to 7400 MBq of I-131 [17]. "We are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle reportedly said, adding, "Many patients don't have a choice, because they are flying in for their treatments." In context, the implication was that if they returned home to countries with stricter standards, airport radiation detectors would identify them. Currently, the chance that a radioactive patient will be identified in a hotel or motel is virtually nil, unless, as happened in Illinois in 2007, the person occupying a room just vacated by an I-131 patient happens to work in a nuclear power plant, and the contamination on his skin sets off the plant's radiation alarms [18].

2.4 The NRC reaffirms the 1997 rule

In 2005, the present writer, a retired NRC lawyer who had in the past received I-131 treatments totaling over 28,000 MBq, filed a petition asking the NRC to revisit its rules on release of radioactive patients [18]. A supplementary filing in 2006 raised the issue of radioactive patients in hotels and the resulting risk to chambermaids [19]. The NRC denied the petition in 2008, in a decision that rejected the idea of adopting a 1mSv limit for infants and children, and made no mention of hotels [20]. (In 2009, a federal court dismissed the resulting appeal on procedural grounds, accepting the NRC's argument that because the petitioner's I-131 treatments had occurred long in the past, he was insufficiently affected by the NRC's rule to be allowed to challenge it in court [21].) At the same time that it denied the petition, the NRC issued a "Regulatory Issue Summary" [22] that drew medical licensees' attention to ICRP 94 [23] and ICRP 103 [24] and their warnings about the hazard to infants and children from I-131 patients. Acknowledging that the 1997 rule had been based on the assumption that internal dose presented insignificant risks, the NRC notice asked doctors to "consider" hospitalizing patients with children at home. It made clear, however, that the request was not binding.

2.5 The current situation

Not only is U.S. practice regarding radioactive patients unconservative by comparison with world practice, it has failed to provide appropriate safety guidance to aid licensees and patients in minimizing radiation doses to others. Although NCRP 155 [25] (a report which reaffirms earlier NCRP recommendations of a 1 mSv dose limit for children, pregnant women, and the public) includes sample precautions for thyroid patients treated with I-131, the NRC has not recommended their use. Instead, current NRC guidance suggests that licensees obtain and use a pamphlet issued in **1987**, when the 1110 MBq activity standard still applied [26]. The NRC's approach to human I-131 patients contrasts with its stringent rules for cats treated with I-131 for feline hyperthyroidism Typically administered doses of 111 to 222 MBq, they must be hospitalized for a minimum of 72 hours [27].

3. CONCLUSION

The IAEA has recently revised the BSS to eliminate the 1110 MBq activity limit on I-131, and endorsed the dose-based approach to protecting the public from treated patients [28]. In its February 23, 2010 "Position statement on release of patients after radionuclide therapy" [29], the IAEA implied that "global harmonization" had been achieved among ICRP 94, SRS 63 [30], EC publication Radiation Protection 97 [10], and the NRC's 1997 guidelines. Any such apparent harmonization is purely illusory, however, so long as the IAEA adheres to the 1 mSv dose standard for exposure to the public, while the NRC's standard is 5 mSv, even for infants and pregnant women. The IAEA and ICRP have yet to address the pressing issue of highly radioactive patients sent to hotels. The exposure of unsuspecting and unprotected hotel chambermaids to I-131 contamination is medically and ethically unacceptable and deserves condemnation. A revision of the NRC's regulations to bring them into conformity with international norms is overdue.

REFERENCES

[1] UNITED STATES CONGRESS, Atomic Energy Act of 1954, 42 United States Code [U.S.C.] 2201 et seq., Energy Reorganization Act of 1974, 42 U.S.C. 5801.
[2] OFFICE OF THE FEDERAL REGISTER, 51 Federal Register [FR] 36932 (Oct. 16, 1986).
[3] U.S. NUCLEAR REGULATORY COMMISSION, Criteria for the Release of Individuals Administered Radioactive Material, 62 FR 4120 (Jan. 29, 1997).
[4] U.S. NUCLEAR REGULATORY COMMISSION, 10 Code of Federal Regulations 35.75.
[5] U.S. NUCLEAR REGULATORY COMMISSION, 50 FR 30616 (July 26, 1985).
[6] U.S. NUCLEAR REGULATORY COMMISSION, NUREG-1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material (Feb. 1997) 16.
[7] U.S. NUCLEAR REGULATORY COMMISSION, 62 FR 4123 (Jan. 29, 1997).
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP Publication 60: 1990 Recommendations of the ICRP, Annals of the ICRP Volume 21/1-3, Pergamon Press, Oxford (1991).
[9] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OGANISATION, NUCLEAR ENERGY AGENCY OF THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
[10] EUROPEAN COMMISSION, Radiation Protection 97, Radiation Protection Following Iodine-131 Therapy (exposures due to out-patients or discharged in-patients), Office for Official Publications of the European Communities, Luxembourg (1998).
[11] U.S. NUCLEAR REGULATORY COMMISSION, Advisory Committee on the Medical Uses of Isotopes, Meeting Transcript (Oct. 27, 2007) 177, 187-191.
[12] GREENLEE, C. et al., current safety practices relating to I-131 administration for diseases of the thyroid: a survey of physicians and allied practitioners, Thyroid **21** (2011) 151.
[13] U.S. NUCLEAR REGULATORY COMMISSION, Commission Voting Record, SECY-02-0111, Proposed rule to amend 10 CFR Part 35 to require licensees to notify of an individual receiving a dose exceeding 50 millisieverts (5 rem) from a patient released under 10 CFR 35.75 (Aug. 27, 2002).
[14] STERNBERG, S., It kills thyroid cancer, but is radiation safe?, USATODAY (Nov. 19, 2007).
[15] NEW YORK CITY DEPT. OF HEALTH AND MENTAL HYGIENE, Information Notice ORH 2009-01 (June 29, 2009).
[16] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2011-01, NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences (Jan. 25, 2011).
[17] BATH, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).
[18] ALONSO-ZALDIVAR, R., Alarm over radiation from thyroid cancer patients, Associated Press (Oct. 20, 2010).
[19] CRANE, P.G., Petition for Partial Revocation of the Patient Release Criteria Rule (Sep. 2, 2005); see 70 FR 75752 (Dec. 2, 2005); Comment #11 on Petition, NRC Docket No. PRM-35-18 (Jan. 30, 2006).
[20] U.S. NUCLEAR REGULATORY COMMISSION, Peter G. Crane, Denial of Petition for Rulemaking, 73 FR 29445 (May 21, 2008).
[21] U.S. COURT OF APPEALS FOR THE NINTH CIRCUIT, *Peter G. Crane v. U.S. Nuclear Regulatory Commission et al.*, No. 08-72973 (unpublished memorandum, Aug. 19, 2009).
[22] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2008-11, Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131 (May 12, 2008).
[23] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004).
[24] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 103, Ann. ICRP 37 I, Elsevier, Amsterdam and New York (2007).

[25] NATIONAL COUNCIL ON RADIATION PROTECTION & MEASUREMENTS, Management of Radionuclide Therapy Patients, NCRP Report No. 155, NCRP, Bethesda (2006).
[26] U.S. NUCLEAR REGULATORY COMMISSION, Consolidated Guidance About Materials Licenses (NUREG-1556), Vol. 9, Rev. 2, App. U, U-11.
[27] UNITED STATES NUCLEAR REGULATORY COMMISSION, Memorandum to Thomas Essig re Summary of July 9, 2002, Public Meeting with Radiocat, LLC, re Release of Cats Treated with I-131.
[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, Interim Edition, IAEA Safety Standards Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Position statement on release of patients after radionuclide therapy, IAEA, Vienna (2010-02-23).
[30] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients after Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).

BIBLIOGRAPHY

AMERICAN THYROID ASSOCIATION et al., Joint Statement on Radioactive Precautions Following Radioactive Iodine Therapy (Oct. 20, 2010)

BARRINGTON, S.F.., et al., Measurement of the internal dose to families of outpatients treated with I-131 for hyperthyroidism, Eur. J. Nucl. Med. Mol. Imaging **35** (2008) 2097-2104.

BARRINGTON, S.F., et al., Radiation exposure of the families of outpatients treated with radioiodine (iodine-131) for hyperthyroidism, Eur. J. Nuc. Med. **26** (1999) 686-692.

BEASLEY, C.W., et al., Release instructions for hyperthyroid patients treated with I-131, Thyroid **21** (2911) 1163-1165.

BRITISH INSTITUTE OF RADIOLOGY, Working Party of the Radiation Protection Committee, Patients leaving hospital after administration of radioactive substances, Br. J. Radiol. **72** (1999) 121-125.

DE KLERK, J.M.H., I-131 Therapy: Inpatient or outpatient? J. Nucl. Med. **41** (2000) 1876-1878.

EUROPEAN COMMISSION, Radiation Protection 100, Guidance for protection of unborn children and infants irradiated due to parental medical exposures, Office for Official Publications of the European Communities, Luxembourg (1998).

GRIGSBY, P.W., et al., Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma, J. Am. Med. Assn. **283** 17 (2000) 2272-4.

HENNESSEY, J.V., et al., comments regarding practice recommendations of the American Thyroid Association for radiation safety in the treatment of thyroid disease with radioiodine, Thyroid **11** (2912) 336-338.

JACOBSON, A.P., et al., Contamination of the home environment by patients treated with iodine-131: initial results, Am. J. Public Health, **68** 3 (March 1978) 225-230.

KLOOS, R., Survey of radioiodine therapy safety practices highlights the need for user-friendly recommendations, Thyroid **21** (2011) 97-99.

LANGHORST, S., et al., Advisory Committee on the Medical Use of Isotopes (ACMUI), Patient Release Report (2010)

MARKEY, E.J., "Radioactive Roulette: How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety," report by staff of Rep. Markey, U.S. House of Representatives (2010)

MONSIEURS, M., Real-life radiation to relatives of patients treated with iodine-131: a study in eight centres in Flanders (Belgium), Eur. J. Nucl. Med. Mol. Imaging **25** (1998) 1368-1376.

PANZEGRAU, B., et al., Outpatient therapeutic I-131 for thyroid cancer, J. Nucl. Med. Technol. **33** (2005) 28-30.

REINERS, C., LAßMANN, M., Radioiodine (I-131) treatment of hyperthyroidism: radiation protection and quality assurance, Eur. J. Nuc. Med. **26** (1999) 683-685.

RÉMY, H., et al., Thyroid cancer patients treated with I-131: radiation dose to relatives after discharge from the hospital, Thyroid **22** (2012) 59-63.

SHAPIRO, D., MOELLER, D., population exposures from radionuclides in medicine – as low as reasonably achievable? Am. J. Public Health **68** (1978) 219.

SIEGEL, J.A., et al., licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with I-131, Health Phys. **93** 6 (2007) 667-677.

SISSON, J.C., et al., Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations of the American Thyroid Association, Thyroid **21** (2011) 335-346; *see also* Correction, Thyroid **21** (2011) 689.


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