Remsburg, Kristy

From: Peter Crane [mailto:kinderhook46@yahoo.com]
Sent: Wednesday, August 06, 2014 3:44 PM
To: Woollen, Mary
Subject: "How We Got Here"

Mary -- good talking with you. Here's my essay on the medical issues

-- Peter

HOW WE GOT HERE:

One Person's View of the History of Medical Regulation and Deregulation at the NRC

When the NRC came into existence in January 1975, its medical regulations, standards, and practices were in complete harmony with national and international norms. Today, at least with respect to the release of patients, the NRC is an outlier, deviating radically from world practice. How did this happen? The answer is a long and tangled story, now known only to a few old-timers, having less to do with reasoned policy choices and more to do with individual personalities than might be imagined. The cast of characters 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 ACMUI member, and last but not least, a three-year-old child.

Medical issues were not at the top of anyone's agenda when I joined the NRC at the beginning of April 1975, as an assistant to Commissioner (later Chairman) Marcus A. Rowden. The agency had far too much else on its plate, principally operating safety and nuclear plant licensing. (At the time, there were projections of a thousand operating reactors by the year 2000.) The medical area was the fiefdom of an AEC holdover who ran it with little oversight or interference from the Commission, the EDO, or anyone else. Probably the only activity that got less attention from the Commission was well logging.

But in the spring of 1976 an event came to light that raised the Commission's consciousness of medical issues. At Riverside Hospital, in Columbus, Ohio, the inexperienced in-house health physicist was unaware that the decay of the radioactive source was a semi-logarithmic rather than an arithmetic function. 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, some very seriously, and at least one of them was known to have died. (In fact, many more had died than the Commission first realized.[1])

In the aftermath, the Commissioners grappled with the implications of the event. What had actually happened to the patients, and how would they or their survivors learn about it? The upshot was that the Commission directed the staff to evaluate the cases of each of the patients harmed in the incident and ensure that they were notified. Also, over the bitter opposition of the staff, the Commission set in motion the creation of the misadministration reporting rule, which provided for reporting mistakes beyond a certain threshold to the NRC, the patient's reporting physician, and the patients themselves.

To evaluate the 400+ Riverside cases, the staff turned to Dr. Eugene Saenger of the University of Cincinnati Medical Center. He ended the analysis after just three cases. It was later reported that he had been concerned about creating ammunition for lawsuits.[2] Dr. Saenger and the staff were of one mind where the rule was concerned. At the proposed rule stage, he wrote highly critical comments in which he warned that doctors would perjure themselves before they reported information that might expose them to malpractice suits. When the Commission nevertheless adopted the rule in final form, he became the staff's chosen consultant on misadministration cases.

The enactment of the misadministration rule led to years of internal warfare between the Commission and the staff. The medical staff's attitude was one of defiance, but all the efforts to get the Commission to rescind the rule were slapped down, one after the other, until at last the EDO, tired of expending capital in a losing cause, refused to forward any more to the Commission. The matter seemed settled at last, and when the staff proposed a comprehensive rewrite of Part 35 in about 1984, the cover memo informed the Commission that the provisions

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[1]http://www.columbusmonthly.com/content/stories/2010/08/the-riverside-radiation-tragedy.html I had forgotten, if I ever knew, the efforts of the health physicist to cover up the event. He later moved to California and became an optometrist.

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

of the misadministration rule had been left untouched. Since in the past, no opportunity had been missed to lobby for the rescission or weakening of the rule, it seemed that the medical staff had reconciled itself to living with the Commission's decision after all. Not until a year or two later was it discovered, purely by chance, that in fact the misadministration rule **had** been touched – a change had been slipped in that would make it next to impossible to find that a doctor had violated it. Foisted on an unsuspecting EDO and Commission, this rule change by stealth may be unique in the history of American administrative law.[3] Once it came to light, the rule was returned to its previous wording.

One more attempt to change the rule was rejected by the Commission on a 3-2 vote, with Chairman Lando Zech in the majority, in the spring of 1989. Weeks passed without the SRM memorializing the vote being issued, contrary to normal practice. When, a day or two before Zech's term was to end, Marjorie Rothschild, an OGC lawyer handling medical issues (she is the wife of NRC's Associate General Counsel, Trip Rothschild), tried to find out the reason for the holdup, someone in the staff gave away the game by gloating, "You're about to lose your majority!" On learning that the medical staff was trying to run out the clock and nullify his vote, Zech ordered the SRM issued without delay, and it was signed out on the last day of his term, June 30, 1989.

So where does the little girl come in? In the summer of 1986, a paper crossed my desk, a report by NRC's Office for the Analysis and Evaluation of Operational Data (a staff office that no longer exists) on a technical issue: the use of reusable iodine-125 seeds, manufactured by 3M for use in brachytherapy. The incident that triggered the concern had occurred two years earlier in, of all places, in the nuclear medicine department headed by the NRC's consultant, Dr. Saenger. A reusable seed had inadvertently been nicked in the process of removing it from the plastic catheter by which it was inserted into a patient's tumor. When it went into the next patient, a young woman of 25 with a brain tumor, it was leaking I-125, which flowed into her bloodstream and concentrated in her thyroid. Not only was she irradiated, but so were 60 staff members in the hospital.

As we learned later, the hospital was in a tizzy. They knew they had a contamination incident affecting scores of employees, but could not figure out the source of it, since the leaking seed

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[3]It came up in hearings before Senator Glenn in 1993.

was by then sealed away in the patient's brain for the five-day duration of the treatment. Wondering whether the radiation could be coming from her, they did a wipe test of the inside of the lead hat she was wearing, but when it came up clean, they ruled out the possibility that the leak was related to the seed in her head. Only after the source was removed at the end of the treatment, and her thyroid was found to be full of iodine, did the penny drop: the contamination of the hospital and the 60 staff members **had** come from the seed in her, but before her treatment began.

A footnote to the AEOD report mentioned that the event had been determined by the staff not to be a misadministration **because a medical decision had been made to leave the leaking seed in place during the course of the treatment**. As a legal matter, this made no sense, since a mistake is a mistake, and what you do after you discover it doesn't erase or alter that fact. But even more striking was the factual account (as reported to the NRC) that formed the predicate for this erroneous legal judgment. It could not possibly have happened this way, I thought, and though AEOD would have had no reason to suspect anything amiss, it seemed odd that the medical staff had not done so.

To know that the story didn't hold water, you either had to work in the field or, like me, have had personal experience, as a patient, of the precautions that are taken when someone is in the hospital and is known to have radioactive iodine circulating freely in the bloodstream. Here, none of the appropriate precautions had been taken: she had not even been restricted from having visitors. Nor had they tested her urine, the very first thing they would have done (along with holding a radiation detector to her throat and giving her a thyroid blocker) if they had actually believed that the seed in her brain was leaking. The next day, therefore, I wrote a memo to Commissioners' assistants, recommending that this be referred to the Office of Investigations for investigation of a possible false statement provided to the NRC by the licensee. The Commission agreed, and referred it to OI. At some point, Chairman Zech sent a note to the General Counsel, complimenting me for having discerned and followed up on a problem that would otherwise have escaped the agency's attention.
The staff objected vehemently to the referral, saying that nothing untoward had happened and that there was nothing to investigate. (This did nothing to allay suspicion that it had known all along that the hospital's story was not truthful.) The staff also contacted the hospital, ostensibly to find out the status of the patient, Jennifer H., who by then had died of her brain tumor. Intentionally or otherwise, they thereby put the hospital on notice of the NRC's interest

in the case, and eliminated any element of surprise for the OI investigators.

Meanwhile, the staff conceded that the event was a misadministration (it turned out that a staff lawyer had said so from the start, but had been ignored), classified it as an Abnormal Occurrence, and reported it as such in the Federal Register and to Congress. What it was careful not to do, however – and this was the crucial point – was to give formal notification of these facts to the hospital, which could therefore view itself as under no obligation to inform the patient's family.

Fast forward to 1989, and the investigation is still dragging on. I am now part of a team that includes an OIG investigator, Keith Logan, and an OI investigator from Region III, Hal Walker. We go to Cincinnati to visit the facility and meet with Saenger, the RSO, and a couple of other staff people. Logan begins, "I'd like to ask some questions about a misadministration that occurred here in 1984 – ." A hospital official interjects at this point, "No one has ever informed **us** that it was a misadministration." Logan asks if anyone has files on the incident. Two staffers say they do. They disappear and return with files that include handwritten notes on a call from an NRC staffer in the Region III office who begins by saying, "Turn off your tape recorders." He then explains the plan: the hospital will inform the NRC that a medical decision had been made during the course of the treatment to allow it to continue, notwithstanding the leak, and the NRC will then find that no misadministration occurred. 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 hospital personnel whose irradiation we knew about, two more people had been irradiated, through contact with the patient: her mother, Mildred H., and her three-year-old daughter, Katrina T.[4]

Even after all this information was obtained, however, the NRC still refused to send the University of Cincinnati its formal notification that a misadministration occurred, so the little girl and her family remained in the dark. It was all about protecting the hospital from bad publicity and a lawsuit. I myself was in the middle of a recurrence at the time, with kids aged

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[4]Keith Logan did not get to finish his investigation. He had begun with lower-level players and was moving up. With two weeks left to go in the investigation, and three key senior persons yet to interview, he was fired from his GS-15 position in OIG. He was fortunate to be able to get a job with OI, though at the GS-13 level. The investigation was then closed out without interviews of the senior individuals. Logan has since gone on to make an impressive career: http://www2.kutztown.edu/academics/colleges-and-departments/liberal-arts-and-sciences/departments/criminal-justice/faculty/keith-logan-.htm

two and four when it was discovered in 1988, and this fact played a part in my strong feelings on the subject. I felt that if I didn't do what I could to see that this motherless child received justice, I had no right to hope that people would someday come to the aid of my little kids, if I weren't around to look out for them. So I kept on demanding notification for the family, and came to be seen, rightly or wrongly, as a pain in the neck on this issue. This contributed to creating 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 Marshall Islands. I left, however, with a promise volunteered by the then General Counsel, Bill Parler, that if I wanted to return, and he was still in that position, he would rehire me. The Marshalls turned out not to be a great idea, principally because of my 7-year-old daughter's school situation there, and I came back to the NRC in 1992.

Back to the University of Cincinnati for a moment. At the end of December, 1982, Irvin Lee Ashcraft, an employee in the nuclear medicine department, had contacted Region III to tell them, in confidence, that from a safety standpoint, the department had serious safety problems. He followed this up with another letter in February 1983. Had the NRC taken these communications seriously, the 1984 misadministration might have been prevented, but instead, breaching the request for anonymity, the RIII staff turned Ashcraft's name over to Saenger, whose response was to try to have him fired. He was instead issued a five-day suspension.[5]

Katrina T. might still be waiting today for the notification she was owed, but for the fact that in late 1992 or early 1993, the story of the Cold War human radiation experiments broke. Some of the most horrific turned out to have been perpetrated by Dr. Saenger and his associates at the University of Cincinnati, under license from the AEC, between 1960 and 1971.[6] His subjects were poor people, taken from the charity wards of the Cincinnati General Hospital, who were

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[5]The U.S. Department of Labor later ruled that though retribution by Saenger for legally protected activity was clearly part of the motivation for the suspension, there might have been other grounds for the adverse action, and it therefore did not order back pay.
http://www.oalj.dol.gov/PUBLIC/WHISTLEBLOWER/DECISIONS/ALJ_DECISIONS/ERA/83ERA07A.HTM

[6]See, for example, "Eugene Saenger, Controversial Doctor, Dies at 90," New York Times, October 11, 2007. http://www.nytimes.com/2007/10/11/us/11saenger.html Pages 385-397 of the final report of the Advisory Committee on the Human Radiation Experiments describes the Cincinnati experiments in detail. https://archive.org/details/advisorycommitte00unit

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. (DOD wanted to know how long soldiers could go on fighting after such a bomb was detonated.) Of the 88 subjects, 55 were African-American, and four were children, the youngest nine years old. A Senate Committee headed by John Glenn asked the NRC early in 1993 for all the information it had on Dr. Saenger. That document request would, the NRC realized, pull in seven years' worth of memos from me on the case of Jennifer H. and Katrina T. Within 24 hours of receiving it, the NRC 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 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. When the story became public, the families understandably felt terrible, none worse than a woman whose father had wanted to break off the treatments, saying to her, "They're killing me!" She had insisted that they continue, saying that they were meant to help him.

Saenger himself originally said that the radiation had shortened the lives of eight of the subjects. Later, apparently appreciating the possible consequences of that admission, he said that **none** of the subjects had died prematurely, and he adamantly insisted, despite copious evidence to the contrary, that the purpose of the experiments was to benefit the patients.

Around this time, one of the Cincinnati papers carried a story saying that the University had released a trove 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. The Government was also a defendant. The defendants moved to dismiss, saying that as a matter of constitutional law, there was no claim that could be heard. The district judge, Sandra

Beckwith, a Republican appointee, issued a ruling that said that if the facts alleged in the complaint were correct, the Government had treated the plaintiffs and their loved ones "like so many laboratory animals," and that if the Constitution was not broad enough to support a suit of this kind, there was something very wrong with it. At that, the defendants prudently settled the case, and as one of the conditions of the settlement, there is now a plaque on the wall of the hospital in memory of the victims.[7] (An early version of the settlement agreement was rejected by the judge because the plaque would not have carried the victims' full names.) Though the Government apologized, Dr. Saenger never did so.

Back to the NRC. 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. OGC advised that there might be a conflict of interest, and when the staff advised Saenger that his services were not desired on the case, he took offense, and said that he would no longer be a consultant to the NRC.

The medical staff found a new expert in the person of Dr. Carol 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 writing letters unique in content and vocabulary. The docketed letters, all written on UCLA letterhead, speak for themselves. The following example, from a letter to the NRC of January 24, 1992, is typical:

> 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

[7]http://www.enquirer.com/editions/1999/04/03/loc_uc_radiation_suit.html

> 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.

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."

I first became aware of Dr. Marcus's penchant for abuse in 1989, when I read a letter from her, written on UCLA letterhead, to Dr. Anthony Tse, a mild-mannered scientist in NRC's Office of Research, that included the line, "Tony, this is power-hungry horsesh*t." (The asterisk is mine, not hers.)

Dr. Marcus was appointed to the ACMUI in 1990. At an all-employees meeting in 1992, Dr. Donna Beth Howe, a particular target of her ire, raised the issue of abuse directed at employees of NRC. Everyone knew who was being talked about. Chairman Ivan Selin brushed her off with a comment about how criticism of federal employees went with the territory, so I got up to support her and make the point that there was a difference between criticism and abuse, and we were talking about the latter. Ed McGaffigan then spoke out strongly to denounce that kind of rhetoric, saying that it made him give less weight, not more, to the letter-writer's position. Dr. Marcus at one point demanded that the Commission send Jim Lieberman of the Office of Enforcement to a mental hospital. Highly amused, he posted the letter on the wall outside his

office for all to read.[8]

Someone who was not amused by her was William C. Parler, the 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 for 2 days, that OGC had determined that after receiving a radiopharmaceutical, a patient was not allowed to ever have intercourse again." Dr. Marcus elaborated on this theme: if the patient used a condom, she could then test the semen for radioactivity, etc.[9] Bill Parler, who had a strong sense of loyalty and honor, and old-fashioned notions of gentlemanliness where women were involved, took umbrage. He wrote a stiff three-page memo to the Commission, the gist of which was that if the Commissioners were unwilling to defend NRC staff members, including his subordinates, from this kind of abuse, he at least wanted to make clear that he viewed communications of this sort as unacceptable.[10]

But Dr. Marcus had her uses. In two cases where staff members were dissatisfied with a Commission decision, and unable or unwilling to work through channels, she was called on to serve as a proxy or shill, submitting what was on its face appeared to be a normal petition for rulemaking from a concerned licensee. This happened in about 1990 with the so-called Radiopharmacy Rule, which Dr. Marcus, in a November 9, 1992, letter to the NRC Secretary, candidly and accurately described as "an 'inside job' from the start." Not only had a senior staff official requested that she submit the petition, he had assigned a subordinate to help her draft it, all of which she explained to the Commission.[11]

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[8]Notwithstanding these and similar letters, the Commission, under Selin, named Dr. Marcus to a second two-year term in 1992. As amazed as anyone, she was quoted in the trade press -- *Inside NRC*, I believe -- as saying, "Can you believe it? They reappointed me."

[9]This was symptomatic of Dr. Marcus's sense of humor. Just recently, she observed April Fools Day of 2014 by posting on the RADSAFE bulletin board a copy of letter that she sent to California regulators in 1998, proposing that the urine of I-131 patients be captured and the radioactive iodine recycled for use in other patients. The recipient had found it hilarious, she assured the listserv.

[10]Dr. Marcus, as an ACMUI member, was entitled to compensation for the work she did for NRC. The Office of the Secretary could answer the question of whether the NRC was paying for the letters, written on UCLA letterhead and apparently typed by a secretary, that she wrote to the agency, sometimes with newspaper cartoons or comic strips (e.g. Calvin and Hobbes) attached.

[11] When OGC explained that Dr. Marcus was barred on conflict-of-interest grounds from taking part in

The then EDO, the late Jim Taylor, had come out of the Navy's nuclear submarine program, and had strong ideas about chain of command. Irate that his authority had been bypassed in this way, he put out an announcement to all employees, and reissued it annually for several more years, forbidding this kind of assistance to petitioners, and stating that if it took place nevertheless, that fact had to be revealed in the rulemaking documents.

In the May 1993 hearings before the Senate Governmental Operations Committee, 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?
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> 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 – –
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> Chairman Glenn. Except common sense.
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> Mr. Selin. Exactly, Senator.
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> 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

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ACMUI discussions of this petition, her answer was that there could be no conflict of interest, since it had been drafted to NRC staff specifications with the help of an NRC staff member, and that if it had represented her own views, it would have turned out quite differently. When Bill Parler refused to change his mind, she wrote to the Director of the Office of Government Ethics, declaring the NRC a "national embarrassment," and demanding that he investigate the "grave ethical breaches" caused by Mr. Parler's role as Designated Agency Ethics Official.

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.

But it is a broader example of the fact that in these highly complex and technical areas — which are very small, and the medical one is not the only one — we have been going for too long, until about 4 years ago, on common sense rather than formalizing the regulations to make it clear in the letter that what you have so aptly characterized as common sense will be expected.

What Chairman Selin neglected to say was that at that moment, another collusive rulemaking was in progress, and it too involved Dr. Marcus. This petition ultimately led to the Patient Release Rule adopted in 1997.

The background for this was that in December 1990, before Jim Taylor had put in place the limits on staff assistance to petitioners, another NRC staffer, dissatisfied with a Commission decision, had seen Dr. Marcus as the way to attack it collaterally. The Commission had just approved Part 20, reducing the limits for exposure to radiation from NRC-licensed activities, and to the displeasure of this individual, it had not specified whether the 100 millirem limit to members of the public applied to persons exposed to radiation from released patients. By Dr. Marcus's account, he urged her to file a petition for rulemaking "YESTERDAY" to deal with the release of patients. She did so, submitting a petition that would eliminate the activity level for all isotopes except I-131, for which the 30-millicurie limit would continue to apply. Then,

however, a professional association of nuclear physicians filed its own petition, with no exception for I-131, declaring that this isotope could be used safely on an outpatient basis in amounts of up to 400 millicuries. Not to be outdone, Dr. Marcus then amended her petition to eliminate the exception for I-131.[12]

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 comments 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, which created the analytical model for basing release on dose to others rather than activity in the patient, intended that this be reserved for exceptional cases, with an absolute 80-millicurie limit. 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 told, this measure was essential to preserve the status quo, and a consensus of commenters warmly approved of it.[13]

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

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[12]All of this could easily have been avoided if the individual staffer had gone through channels and asked for a clarification to explain that the amendment of Part 20 had not been intended to supersede or alter the provisions of Part 35. The Commission finally did make that clarification, in 1995, but by then, the petitions had acquired a life of their own, and the agency was already on the path to a radical and fundamental shift in its approach to protecting public health in the medical area. The staff's chosen consultant on the rulemaking was a well-known hormesis advocate who rejected the idea that I-131 was carcinogenic.

[13]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?"

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.[14]

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 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 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, and there is an even playing field for all participants. That was not the case here.

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[14]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.]

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."[15]

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[15]The purpose of Dr. Marcus's 16-page letter was to protest the Commission's having scheduled a meeting to hear from Professor Robert Adler, the lone dissenter on a National Academy of Sciences/Institute of Medicine committee that had studied the NRC's medical program and issued a report in late 1995. (He is now Acting Chairman of the Consumer Product Safety Commission.) The Commission had earlier heard from the committee's majority, which, though it did not include Dr. Marcus, largely reflected her views. If I remember correctly, the meeting with the committee members had been scheduled for a Tuesday, but Professor Adler was deliberately not informed until the last minute. He had been in his office after hours the previous Friday when someone from the committee called, intending to leave a message about the meeting that he would not find until Monday at the earliest. Surprised when he picked up the phone, she blurted out, "Oh! You're still there!" By then, it was too late for him to change his Tuesday schedule and attend, but when he explained the reasons for his absence to the NRC Secretary, the Commissioners, evidently irritated by the attempt to keep him from attending, scheduled a separate meeting with him later on, to Dr. Marcus's outrage. Her letter was replete with allegations of "fraudulent data," and included such colorful statements as, "The NRC was frothing at the mouth in rabid anticipation." The idea that there might be something inappropriate about third parties telling the Commission whom they could and could not meet with had evidently not

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.[16] Meanwhile her offensive comments about the NRC continued unabated on the RADSAFE bulletin board. I have again substituted asterisks where the vocabulary was especially pungent.[17]

Nor did it stop there. Once the 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.[18]

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crossed her mind.

[16] 67 FR 20370, April 24, 2002.

[17]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.]

[18]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

This is, as indicated in the heading, is only a partial account of the events that have taken place in the medical area in the past decades. A full account would take a book. It is just one person's perspective, and my mantra is, as always, "Don't take my word for it." But to the best of my knowledge, it is accurate, and if you consulted others with an institutional memory for these events, I think they would agree that personalities more than principles were the driving force in creating the current divergence between American and international radiation protection standards in the medical area.

Peter Crane
May 2014
kinderhook46@yahoo.com

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make it seem to apply to the 2004 document. In 2013, 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.