New Boss in Town Touts Self-Regulation

NRC's new director of industrial and medical nuclear safety reveals desire to streamline the bureaucracy

In recent American history, the image of the outsider administration coming into Washington to elbow aside insiders and do things right has captured the public's imagination, certainly helped propel the current one into office, and now may play a part in the Nuclear Regulatory Commissions's (NRC) dealings with nuclear medicine. Carl Paperiello, PhD, who stepped in as director of the NRC's Division of Industrial and Medical Nuclear Safety on July 1, comes to Washington for the first time, with a load of field experience in health physics. Refreshingly frank, Papariello brings a clear wish-list to make the NRC an efficient organization nurturing nuclear medicine. The only problem, as many critics of the new-kid-in-town scenario have pointed out, is that Washington eternally poses a dilemma: an outsider lacks knowledge of Washington's labyrinthine bureaucracy, which a leader must join before effecting changes; yet in becoming a part of it, you yourself must change. In an interview with *Newsline*, Papariello spoke of these, and other, changes.

Making Use of Experience

Paperiello is certainly geared to make an impact. After getting his BA in physics at LaSalle College, he took a doctorate in nuclear physics at Notre Dame in 1970 then worked in the New York State Health Department until 1975, eventually becoming senior research scientist in the Division of Labs and Research and gaining expertise in occupational health physics and environmental radiochemistry. After certification as a health physicist, he joined the NRC in 1975 as an inspector in Region 1 (the Philadelphia office), doing reactor health physics inspections, and in 1978 became section chief of the byproduct materials inspection program of Region 3. When he was named branch chief in 1980, he returned to the reactor side of the business—environmental monitoring, radiation protection, and emergency protection. In 1985, as director of Region 3's Division of Reactor Safety, he was, he said, doing "basically reactor engineering—an interesting situation: a health physicist supervising a bunch of engineers." After a stint as Region 3's deputy regional administrator, he went to Washington in March of this year, preparing for the office he took July 1. These two-plus decades in health physics have given him some general attitudes about the nuclear medicine industry, how it handles safety, and where it needs help.

"There is a broad spectrum of performance among licensees in general," he said. "In the materials area you'll find licensees who are extremely good, very large organizations that are well-managed. And then you have, obviously, organizations that are managed more poorly. 'Small' does not mean 'poor,' but when you have 7,000 licensees it's not unusual to have a few who don't perform well. So a major part of our job is to identify those who perform poorly and to either get the problems fixed or have them stop using nuclear material. And that's not just medical. Right now, there is a lot of concern—or at least press concern—over the medical side; but the reality of it is that there are problems on the other side as well."

In trying to identify poor performers and fix problems, Papariello has already experienced the Washington triumvirate—"the various media, the congressional staffs, and the Congress itself," he said, all of which manifest

Carl Paperiello

public opinion, which in turn controls "much of what you can do." Acknowledging that, he has general goals for the regulation of nuclear medicine within the NRC. "I would like a certain amount of stability which I don't see right now. A major problem in my own organization is there are a lot of things we do that are not very systematic. Our guidance to our license renewers is unorganized. As I pointed out to the Commission on my medical review, we have licensing guides that are out of date, some badly out of date."

Putting Regulations On-Line

But the major constraint to accomplishing these goals, he feels, are resources—mostly human resources—and their efficient use. "We are basically handling so much reactive work right now," he said, "it's very difficult to fix problems." He also points out that proper use of a certain part of the physical plant itself—the computers—could

greatly benefit both regulators and regulated. "I'll give you an example," he said. "We handle a lot of paper here: why shouldn't the code of federal regulations be on computer? If somebody calls up a region and wants a licensing guide, we send it out. But why don't we have that on a computer bulletin board and download it? We have things that were put on paper years ago and never change, but... if we had all of our licensing guides on a bulletin board that was readily accessible, it would be very easy to change it." In sum, uses of physical and human resources interact. "[Computers] are the areas where we could gain efficiency, and if we gained efficiency, that would free up human resources to do things that need to be done."

Papariello muses on the problems of disseminating information and how they affect performance. "We still run into hospitals that have never heard of the QM [Quality Management] rule, about six to ten of them since I've been here. So it's not even a question of whether they adequately implemented the rule. You start running into hospitals and RSO's [radiation safety officers] in the nuclear medicine area who have been asked, 'Do you have current copies of part 35?' and they did and they were too busy to read it. How many people are aware that there's a new part 20 that goes into effect as of January 1? It's not that people shouldn't know it, but, again, with somewhere in the order of 2,000 medical licensees, it may be twenty or so haven't heard of it."

Implementing Nuclear Medicine-Friendly Policy

Though on general questions of policy, Paperiello frankly states he has to be careful, he has a ready response about his nuclear medicine policy. "Besides cleaning up our licensing guidance, we are probably going to modify the inspection program," he said. "It's going to involve all licensees, more performance-oriented inspection, and inspection frequencies. We will inspect medical licensees either in one year in the case of therapy (either HDR or teletherapy) or in three years for other nuclear medicine." Also to increase efficiency, he has recommended that inspection frequency be based on performance. "If we do an inspection and it's clear," he said, then "the next inspection, rather than being at the fixed time that we have now, would be extended. And if the performance were poor and we had a lot of problems, then the next inspection would be done more frequently. We would concentrate our efforts on people who have problems and try to avoid people who don't have problems."

He also wants to re-examine the relation between the radiation safety officer and management. "Part 33, which is broad scope licensing, says you're going to have a radiation safety officer and a radiation safety committee," he said, "but other than approving authorized users, there is not a great deal of specificity of what the radiation safety officer is supposed to do. Part 35 is more specific, but probably doesn't go far enough. I understand there's a proposed change, and people are thinking about radiography, where it's more definitive. My belief is—and I've told the Commission this—we need to look at part 30, which then would cover all material licensees, and define the duties of a radiation safety officer and the responsibilities of a licensee management to support the radiation safety function."

A major problem for RSO's, as he points out, is that, outside the current part 35, the regulations do not acknowledge their existence, much less define what an RSO should do. "We are working on a new reg to describe what a radiation safety officer does at a typical radiation medicine facility—not just oncology, but nuclear medicine and the like," he said. "But I'm proposing that we go out with advance notice of proposed rule-making; so something like this is a ways off, and in fact people are going to hear about it long before anything comes to pass, and we'll have time to comment on it."

Such long advance notice—of about three years, he said—is typical of his ambition of working cooperatively with the industry. "The feedback I'm getting from licensees is they would like much longer lead times on things that we're thinking about doing. Advance notice of proposed rule-making is a good way to go, because what I would like to go for, if we have any rule changes, is performance-based rules, with the industry developing the way that they would be implemented, because you know your programs' nuts and bolts better than we do."

Dealing with the NRC as a Whole

But as up-front as he is about nuclear medicine policy, he is less revealing about broader NRC policies. The Commission recently added a $62,000 annual fee to each research reactor in the country (see "News Briefs"), though Paperiello said he knew no more about the fee than the fact it was levied. Also, there has been a recent spate of NRC fines of nuclear medical facilities, and he warned not to search too deep for a reason. "Never look for conspiracy when chaos will provide an adequate explanation in Washington," he said. "I'll tell you what we do see, though. When there are significant rule changes (and the QM rule is one of them), you'll start seeing a flurry of civil penalties because of violations of the new rule."

New as he is to Washington, though, Paperiello already takes into consideration the forces of Congress and public opinion when recommending policy changes to the Commission. The Senate hearings chaired by John Glenn (D-OH), which arose after the Cleveland *Plain-Dealer* carried a series of news stories alleging crises and mishaps within nuclear medicine, has posed a challenge for the NRC.

"What I recommended to the Commission," Paperiello said, "and what they have [approved], is that we don't have, within the agency, a unified, documented policy or procedure in one

(continued on page 35N)

News Briefs

ment of health. MEDWatch can also be used to report suspected contamination, questionable stability, defects, and poor packaging and labeling of regulated products.

Health care providers interested in requesting forms or the new FDA *Desk Guide to Adverse Event and Product Problem Reporting* can call 1-800-FDA-1088. ■

Thallium-201 Scintigraphy Improves Life Expectancy in Heart Attack Survivors

A study published in the *International Journal of Technology Assessment in Health Care* (1992; 9,1: 97-101) comparing thallium-201 scintigraphy, ambulatory cardiac monitoring (ACM), and exercise tolerance testing (ETT) with no testing whatsoever has shown that the noninvasive methods are better at detecting silent ischemia in heart attack survivors.

The study proved that any of the three tests were better than no testing (i.e., medical treatment only). Researchers estimated that each of these noninvasive techniques provided approximately a four-month gain in the life expectancy of a 55-year-old man with an average life expectancy of 16 years.

A second study compared the ability of ACM alone, electrophysiologic studies, and ACM followed by ETT to identify an effective and safe medication to control potentially life-threatening erratic heartbeats in heart attack survivors. The researchers found the three methods to be equally effective, but that ACM required fewer resources than EPS.

These studies were supported by grants from the Center for General Health Services Extramural Research of the Agency for Health Care Policy and Research and by a cooperative agreement between the Health Care Financing Administration, the RAND Corporation and Harvard University. ■

New Boss

(continued from page 24N)

place that says how the NRC is going to react to a report of a misadministration. Part of the problem with the Glenn hearings and the *Plain-Dealer* series is that issues came up, and if you couldn't find somebody with a corporate memory, nobody here knew anything about it, then there was that perception that the NRC doesn't know what's going on. A great deal of the issue is that we didn't know; you had different events happening, maybe at similar times, and the agency reacted to almost the same events very, very differently. The question is why, and the answer is: there is no policy."

Paperiello gave the NRC an outline of a management directive to remedy the problem of the NRC's disunity in responding to misadministration reports. The elements of the directive include on-site inspection of the problem facility, with a medical consultant to find out what the probable consequences are, and the assurance that the information gets into a central file and that the information is retrievable. "I live in the field, and some people in Washington think, 'Well, we know what we want to do.' If you haven't put that in a procedure and issued it to somebody in Chicago, they don't know what's going on. So different regions did different things. In fact, even in Region 3 where I was deputy regional administrator, in response to similar events over a period of three or four years, we did different things. So, if you want the staff to do something, and you want to know what they did and make it retrievable, you need a procedure out on the street."

Another set of Congressional hearings, this time in the House of Representatives under the chairmanship of Congressman Mike Synar (D-OK), has also got the NRC on its toes over the Agreement State Program and how the commission monitors it. "The chairman has told Congressman Synar that what we will probably be doing–what we are in fact working on—is to come up with common performance indicators for both the agreement states as well as the NRC regions to have some kind of measure of program adequacy: how do you know that the agreement states, and even you, are doing a good job? We don't have any good common quantitative measures of performance. Most of our effort in that response [to the hearings] is to develop some kind of indicators.

"The other issue that Synar brought up—and I don't know [the NRC's] final resting point—is over the years we have found that we were unable to find [states] compatible and unable to find them adequate. It's not that we've said they were inadequate, but we withheld findings. How bad would it have to be before the commission would take action to terminate the agreement? The commission doesn't have a written policy on that—and I assume the commission is going to react to that. But I don't think there has been a firm decision on how that's going to be addressed. The issue on the performance indicators is more certain; that has been discussed with the agreement states."

Straightforward as his proposals sound, he acknowledges that putting them into practice in the NRC is another matter. "What I'm finding in this agency," he said, "is that getting all the various offices to concur in" a policy is a trick in itself. "The attorneys have to agree to it, and the researchers have to agree to it...and everybody wants to do some of their own word engineering." Perhaps he has put a label on what he has found out about Washington so far: that it is a city of word engineers, and cleaning up town means both asserting the letter of the law and clamping down a good hard sentence. Just the job for a straight speaker like Paperiello.

Lantz Miller

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