Postmodern Management
Restructuring Radiation Control Programs

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The term “postmodernism” is usually reserved for art and architecture. It is not generally used to describe a management style. But it is an exact description of an emerging trend for governmental managers. There is a deconstruction of the bureaucracy. Notice the use of the word “deconstruction” and not destruction. This is not a wrecking ball approach to management, but a careful dismantlement of the hierarchical structure of government.

The military model of command and control is being replaced with a more egalitarian approach – one where everyone gets to voice their opinion, and become a leader. There is renewed emphasis on thinking out of the box, using creativity, and not doing things the way they have always been done. A new spirit of cooperation is growing between the regulated community and the regulators. The emphasis is on results that matter – using a risk-based prioritization. Indicators are collected to measure conditions, trends, and results. The improved public understanding of science can increase their involvement in decision-making.

What led to this burgeoning partnership? How do our respective professional organizations fit within this model? How can our partnership enhance public health and safety? What are the caveats?

The Conference of Radiation Control Program Directors (CRCPD) is a nonprofit organization made up of individuals in state and local government who regulate and control the use of radiation sources. Affiliate membership is available to individuals, regardless of employer affiliation, who have expressed an interest in radiation protection. The CRCPD's mission statement is "A partnership dedicated to radiation protection".

In this talk, I will describe the structure and function of the CRCPD, our strategic plan, our recent achievements and plans for the future, and how AAPM members can become involved with CRCPD activities. After the "thinking globally" portion of the talk, I will describe how the AAPM members can "act locally" and become a valuable resource for the state radiation control program director in their immediate area. I will stress opportunities for input in rulemaking and policy determination.

Governmental change has not occurred in a vacuum. It has occurred because of a change in attitude in the regulated community and in the general population. The change is stinginess. Everyone is concerned about how his or her tax money is spent. They see some draconian cost-cutting measures being instituted in their workplace and they think that government should be instituting similar cost-cutting measures.

As I develop the theme of postmodern management think about how it may help you to achieve your goals. I will use some of the federal government’s reengineering processes as examples, but I will talk about what states should do and what we should avoid. This will lead to a discussion of the proper state and federal roles in radiation protection, as well as roles for surrogate regulators.

Regulatory Compliance as a cost-cutting measure

Economic and environmental/ health policies can be mutually reinforcing. The regulated community used to comply with governmental regulations because they were afraid of significant fines and penalties – or even criminal liability. They used to try to achieve compliance at minimum cost. Now, many companies go beyond regulatory compliance to reap tangible benefits from activities usually required by government regulations. The concept is named "Continual Improvement", and it is an integral part of the ISO 14000 (international voluntary) environmental management standards.

Another voluntary program the European Commission's Eco-management and Audit Scheme (EMAS) has been running since 1995. Somewhat stricter than ISO 14000, it requires that companies establish and standardize environmental management and reporting systems and that they present and publicize detailed reports on their environmental management and performance. This is an interesting parallel with the Joint Commission on Accreditation of Healthcare Organization's (JCAHO's) ratings of facilities. I have heard hospitals advertise their JCAHO rating on the radio as a way of enticing patients to choose their facilities and their physicians.

The health care industry is changing, with cost playing a much greater role in decision-making and prioritizing. I'm sure that some of the number crunchers may think it is a good idea to institute some cost cutting measures to decrease the medical physicist's involvement. Some health care professionals already think that the state inspector's report is equivalent to a visit by a medical physicist. While we each have important reasons for our presence at a health care facility, we are hardly interchangeable! It becomes important to emphasize that the corporate structure should view regulation as an opportunity rather than a threat. Radioactivity that has no benefit constitutes waste, and presents an opportunity to revisit the process, to reduce costs and increase efficiency, an opportunity to become more competitive, and an opportunity to improve public relations. Medical physicists and state regulators have an important, mutually reinforcing message to deliver.

Surrogate Regulators

Surrogate regulators, including investors, shareholders, banks, real estate agents, insurance companies, and accounting firms become even more influential than traditional government regulators. An insurance company in New Jersey, Horizon Blue Cross/ Blue Shield, decided that the state standards for x-ray machines were not optimizing image quality at their provider facilities. They imposed a set of quality assurance standards on those facilities, and enforced those standards by refusing reimbursement if facilities did not comply. At least four other insurance companies have also imposed quality standards on their providers, leading to a chaotic system of conflicting and confusing standards for medical and chiropractic offices.

Another example is the American College of Radiology (ACR) which administers several accreditation programs. To comply with them takes time and effort above and beyond compliance with regulations, but the payoff is something called "deemed status". When the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) performs its review at a hospital, they "deem" the ACR accredited areas as satisfactory without inspecting them.

The new corporate emphasis on continual improvement brings with it an encouraging change in attitude in the way regulators and the general public is viewed. Traditionally, regulators have been viewed as the "enemy" and companies often placed themselves in an

unfortunate “us vs. them” position. The companies who believed they know what was best for all often viewed the general public in a much more condescending manner. However, now, both are viewed more as partners in a process that can be mutually beneficial. We, as regulators need to seize this change. It is good for us and it is good for our mission.

So, what is expected from the regulators, now? According to NRC Commissioner Nils Diaz,

> Being a regulator does not imply some sort of umpire-like detachment, in which our only legitimate role is to call the balls and strikes accurately. I think the public expects more from regulators, and rightly so. We, who are public servants, have an obligation to add value by facilitating the processes we oversee and making them better. When you are talking about providing a benefit to the American People, there is more to health and safety regulation than preventing things from going wrong or taking enforcement actions when they do. As regulators we should also be thinking about how to make things to right: ensure safety, and to do so efficiently and effectively. Regulation is not free: the people of America pay for it.

Government has never been under such scrutiny. Not only do we have to do the “right things”, but we have to “do the right things right” with the least amount of resources. It has taken longer for some states to feel the pinch, but all of us have undergone some downsizing, reprioritizing, and reengineering. It is only a hypothesis of mine, but I believe that smaller states have had to “make do” for a long time, and that the larger states took longer to experience the pinch of too many responsibilities and too few resources. The resourcefulness of the smaller states can be an example for the larger states. Where do the states get together to share their experiences?

Conference of Radiation Control Program Directors

The CRCPD has voting members representing each state, and all state staff are eligible to be associate members. Currently, there are about 600 members representing state government. However, there are 216 affiliate members, who are part of the community we regulate, 51 emeritus or honorary members, and 13 international members. The organization began in 1968, and has grown in membership, involvement, and advocacy over the years. And our one unique product, the Suggested State Regulations for the Control of Radiation (SSRCR), is becoming an avenue for unifying the regulation of all sources of radiation.

No federal organization has authority over all sources of radiation, and that has resulted in a mixture of federal and state agencies setting the standards for various aspects of the use of sources of radiation. Probably every state has used the CRCPD model regulations to develop its own regulations. The model regulations are comprehensive, integrated, and accepted by the principal regulatory agencies, the regulated community, and the public. However, it must be stressed that the SSRCR is written by volunteers within the committee framework of the CRCPD, and the products have not been as timely as one would have liked.

Technological improvements are providing new challenges to our regulatory structure. We don't want to build such rigid regulatory requirements that it precludes the use of wonderful new tools for the diagnosis and treatment of disease. Yet, we are mandated to regulate unnecessary radiation exposure. We could use a little help in anticipating changes or at least reacting quickly with some common sense guidelines for using new technology safely. Our

SSRCR committees are open to any of our members to serve as advisors. Advisors are not provided with funding to attend the meetings, but are treated as active members of the committees and are expected to work just as hard as everyone else. Could you contribute your ideas in the regulation writing process? Let me just warn you that it is harder than you think….

The CRCPD's Chairperson is the spokesperson and ombudsman for the organization. The CRCPD has a six member Board of Directors who set the policy for the organization and the Chair will only vote in the event of a tie. Each Board member serves for 3 years. The Chair-elect and Past Chair are Board members, but have some standing duties. The Chair-elect is also Chair of the strategic planning committee, and has an obligation to run a feedback mechanism called the Member's Forum at the annual meeting. The Past Chair puts together the annual conference, lining up speakers and determining structure.

The Treasurer is also Chair of the Suggested State Regulation Council. The nine Suggested State Regulation Committee Chairs report to the Council Chair, who, in turn reports progress to the Board. The Healing Arts Council with 10 committees, Environmental Nuclear Council with 16 committees, and General Council with 15 committees are each chaired by one of the Board Members-at-Large.

One of the most frequently asked questions about the CRCPD is "which committee is in charge of that?" It may seem that the Healing Arts Committees may have some overlap with the Suggested State Regulation committees. The separation is so that the healing arts committees can gather information, assess data, and make recommendations to enable the SSR committees to concentrate on putting the recommendations into regulatory language. If the SSR committees had to do the research to justify the regulations as well as drafting the language, it would be too burdensome for the volunteers. We try to spread the work to as many minds as we can while delineating the tasks as "charges" to the committees. A number of committees have been dissolved after their charges were completed, with thanks to all of the members for their hard work.

The "best seller" for the CRCPD is the Directory of Personnel Responsible for Radiological Health Programs. It is published in January of each year, and provides names, addresses, and phone numbers for:

- all state programs
- all federal agencies (including the Center for Disease Control and Prevention, Department of Agriculture, Department of Energy, Department of Transportation, Environmental Protection Agency, Federal Emergency Management Agency, Food and Drug Administration, National Institute for Occupational Safety and Health, National Institute of Standards and Technology, and the Nuclear Regulatory Commission),
- Canada and Mexico
- all low-level waste compacts
- CRCPD Board members
- All CRCPD committees
- CRCPD award recipients
- Annual meeting dates and locations
- Listing of all CRCPD publications with prices.

CRCPD receives funding from a number of sources. Some federal agencies provide funding from an umbrella grant which is administered through the FDA. Others provide direct

support for particular projects. Private organizations also provide funding for particular projects, such as the ACR support for the NEXT studies. Since there is no one dominant source of funding for CRCPD, we seem to always be looking toward the next funding source. Our dues provide only partial support for the wide range of activities in which we are engaged. Our federal funding precludes us from lobbying Congress, but we would be permitted to testify if asked.

If someone asked me the most important function of the CRCPD, I would say it was in creating a supportive atmosphere, where radiation regulators can share experiences and admit mistakes without fear of reprisal. We have such camaraderie among the state and federal agencies that I think the feds have felt comfortable in telling us what is really happening behind the scenes. Our annual meeting has a cordial feel to it that allows us to disagree in a friendly manner, with no lingering hard feelings, but a good exchange of honest opinions. And if you are really notable, our resident song-writer will include you in a ditty.

The CRCPD has taken strong positions on a number of issues. These are embodied in "Resolutions." Generally, if a committee feels strongly about a particular subject, they will draft a resolution for consideration by the voting members. The resolution is offered at the first session of the annual meeting, discussed during the conference, and then, if a motion is made from the floor, the resolution is voted on at the second session. This is the mechanism for the strongest statement of opinion from the organization.

There are other statements of "official CRCPD" opinion. These range from survey results, to positions by committees, to positions endorsed by the Board of Directors. It is difficult to gauge the effectiveness of CRCPD's positions, but it is clear that the mechanism for adopting a position helps to bring all of the facts to the group, and enhance the cohesion among the members. Many of the position statements and resolutions are used as a mechanism to send a strong message to the federal agencies about an issue that is of importance to the states.

Let's look at the changing federal role by examining changes within the two big federal agencies that most medical physicists interact with. State programs also are influenced by the Environmental Protection Agency's policies, but generally, these are not in the medical arena.

Food and Drug Administration (FDA)

The federal government's reengineering efforts have been assisted (?), enhanced (?), and certainly accelerated by Congress. Congress passed the Food and Drug Administration Modernization Act (FDAMA) to guide the FDA's reengineering efforts. They must have read the same management books that I did because I recognized each of the strategies that they employed.

Since congressional attention had been focussed on FDA by complaints from the regulated community, FDA began by improving their relationship with stakeholders by asking for their help in the process redesign. FDA clearly stated their goals – to be fast, fair, and smart. They have developed objective measures to indicate progress in those areas.

FDA put the responsibility for demonstrating compliance and assuring safety firmly in the hands of the manufacturers. Manufacturers can use a third party to assess conformance with consensus standards, but this does not constitute device approval – just conformance. They encouraged the use of consensus standards where they existed, and they have a list of acceptable standards from groups like IEC, ANSI, NFPA, and NEPA. Recognizing there is a global market

for the products, FDA has gotten involved with the development of international standards and encourages their use, where appropriate.

As states, we can't get involved in the development of international standards, but we can inspect radiation producing devices at their point of use, giving important feedback to the FDA on whether the devices are functioning as designed. The FDA was recently looking for feedback on their reengineering processes and wanted to know what were the most important things for them to spend their scarce resources on. One good thing for states and physicists to do would be to tell FDA that we consider their work with international standards a very important function – one that should be fully funded and supported by the agency because it is beyond our means for the most part.

FDA had a significant backlog of product reviews, so they decided to categorize them in three groups – expedited, streamlined, and standard reviews, to try to spend their scarce resources on those reviews that matter most. The workload is categorized by risk with the option to transfer people from low-risk reviews to higher risk approvals to decrease the backlogs in the most critical area.

FDA realized that they needed to improve the targeting of problems. They were collecting data from postmarket reporting. But most of the time was spent on data entry, instead of data analysis. They realized they could improve the process by electronic submission of data, harmonization with international reporting, and by getting a denominator for the data from the manufacturer. Knowing how many problems are reported is only useful if you also know how many are in use. Do we use the FDA data to influence our inspection schedules? Should we?

Nuclear Regulatory Commission (NRC)

The NRC also experienced some congressional influence that accelerated its internal processes for becoming more efficient. Budget hearings forced the NRC to discuss their risk-informed approach. In the nuclear power plant area, the NRC has concentrated their efforts in four major areas: regulatory oversight, integrated assessment, probabilistic risk assessment, and use of indicators. Each of these areas has some application to state programs because the principles of good management, good regulation, and good public service can be extrapolated to any regulatory agency.

NRC has altered their regulatory oversight approach. They are examining the amount of interaction the NRC should have with licensees in order to protect public health and safety, and the types of actions that should be taken in response to various findings. In the best of all worlds, all regulatory agencies would only inspect the facilities that were not in compliance. All of those that were already taking the necessary steps to protect health and safety would not need our prying eyes. The question is how do you identify the facilities that need inspection to prod them into compliance vs. the facilities that are performing even beyond the regulatory requirements? Maybe there is a role for licensee self-assessments that allows reduced government oversight. Do states use self-assessments to reduce the time they spend at "good" facilities? Can medical physicists help us to identify the "good" facilities? Would it be useful to you if we could identify the poor performers?

In the nuclear power plant area NRC uses an integrated assessment process for focusing their attention on poor performing plants. They also realize the importance of clearly communicating assessment results to the public and the industry. Is there some kind of report card that state radiation programs could use to prioritize our inspection scheduling? Are we

spending our time on the right facilities? Are we informing the public about our inspection findings? Should we?

One of the NRC ideas that I think has great potential for application to state programs is the use of probabilistic risk assessment information in the oversight process. NRC is using the idea in their nuclear power plant surveillance to ensure that the plant areas with the highest safety risk get the greatest inspection focus. What would be useful for state programs is to perform a risk ranking of the facilities we regulate, and the radiation producing devices within those facilities, and then determine the probabilistic risk of something going wrong to determine the right inspection interval.

But all of these ideas require indicators. We need the means for measuring safety performance and improving or declining performance trends. We need to determine the linkages between indicators and risk. And in an area we have not even begun to explore, we should consider the possible use of financial data in the assessment process.

Caveat

As I talk about this great vision for cooperation between regulators and the regulated community, I have to remind myself to take off the rose colored glasses once in a while. I recently read Claudia Clark's book, Radium Girls, about the radium dialpainters in New Jersey, Connecticut, and Illinois. When young American men went off to war in 1917, young American women went off to work. World War 1 trench warfare had made the wristwatch crucial at the front and popular at home. They used glow in the dark paint – radium laced paint – applied with a brush in dialpainting studios.

There were two pathways of exposure – ingesting through lip pointing of brushes and inhalation of airborne dust.

In 1917, Katherine Schaub and Irene Rudolph, both aged 15, began work in the Radium Luminous Materials Corporation in Orange, NJ, earning $20/week. They left work in 1920 and 1921 respectively. In 1922, at age 20, Irene Rudolph began to have trouble with her mouth. Her dentist extracted a tooth, and found that her jawbone was rotting. He carefully removed the infected portion, but found that he had to repeat the operation several times. Her condition was complicated by her anemia.

In the 1920s in New Jersey, two state organizations ostensibly protected worker health – the Department of Labor and the Board of Health. Irene Rudolph's case was reported to the Newark health officials and the state Department of Labor. They visited the Radium Luminous Materials Corporation plant but found nothing that conflicted with state factory laws. Irene Rudolph's symptoms were similar to phossy jaw – a condition that was well known to the NJ officials due to a fireworks plant nearby. A chemist was employed to analyze the radium paint for phosphorus, but he found none. His report said that radium may be the cause of the illness, not phosphorus, but it was ignored. Irene Rudolph died in July 1923. The cause of death listed on the death certificate was "phosphorus poisoning".

By January 1924, there were three dead women and two more ill. The causes of death listed were "Anemia with Contributory Trench Mouth" and "Pneumonia".

In 1923, there was a general attitude that radium was good for you. Radium medicine was popular. A medical clinic reviewed their work on radium administrations and recommended

radium injections of 50-100 micrograms repeated every 10 days to a maximum of 300 micrograms. The Surgeon General of the United States recommended radium. Diseases from arthritis to sexual dysfunction, leukemia to senility could be cured. The same companies that employed dialpainters were producing radium for medical purposes.

It wasn't until 1925 that the dialpainters filed suit seeking redress for radium poisoning. The attendant publicity swayed public opinion. After 1925, radium poisoning was generally accepted medically, but it was not recognized in court or by the legislature until 1931.

In 1928, the U.S. Public Health Service held a "voluntary conference" on radium poisoning. Government emphasized voluntary cooperation between public agencies and private organizations as a compromise between disorderly laissez faire capitalism and dangerous state control. Embedded in this voluntarist solution was the assignment of control to allegedly neutral scientists.

It was 1928, and the solution was partnerships between the regulators and the regulated community. It is 1999, and I'm talking about partnerships between the regulators and the regulated community. Have we come full circle? It didn't provide protection for radium dialpainters in 1928. Will it provide adequate protection of public health and safety in 1999?

How Shall Ye Be Judged?

In the radium dial painting story, the federal, state, and local government agencies did not fare too well under the scrutiny provided by history. Government regulations permitted these industries to close their eyes and put profits ahead of the health of their workers, and it took horrible suffering and death before anyone took notice. Even then, it was "voluntary" action. How will history view our 1999 radiation control programs?

We are being graded on our numbers. In an article discussing our Governor's performance, the argument was made that the Department of Environmental Protection was issuing fewer enforcement penalties than her predecessor and that equated to weaker enforcement. But does it?

In the New Jersey Radiation Protection Program in the x-ray machine program, in FY97, we issued 920 enforcement actions, and in FY98 we issued 308 enforcement actions. However, we have instituted field notices of violation for our x-ray inspections, which are handed to the administrator or physician upon completion of the inspection. It allows 30 days to come into compliance. We find that 76% of the facilities do come into compliance within the timeframe. With the old enforcement procedure, it took 30 - 90 days to even mail them out to the facility, and the compliance rate was only 63% without follow-up. So compliance is now achieved without penalty 60 days earlier, but it looks like we have weaker enforcement. If we are being graded by enforcement figures, they clearly don't equate to improved image quality or optimized dose.

In the mammography program the indicators are much more direct. We have data from the Nationwide Evaluation of X-ray Trends (NEXT) program in 1985 showing dose at 2.2 milligrays and only 60% acceptable image quality. We have data from NEXT in 1988 and 1992, showing a trend of decreasing dose and increasing image quality. And we have data from 1997 showing doses of less than 2 milligrays and greater than 90% acceptable phantom images. Now those are parameters that directly measure the effectiveness of a regulatory program.

We have NEXT data for chest, abdomen, lumbar-spine, dental and fluoroscopy. We could have regulations that encourage the trend to optimize patient dose while increasing image quality if we take the lessons learned from mammography and apply them to other modalities.

We also have surrogate regulators for the medical community. Insurance companies are "enforcing" quality assurance standards through their reimbursement programs. If they will only reimburse facilities that have adequate QA programs, they have a certain level of excellence within their scope of influence. However, that leaves some facilities, perhaps those available to people without insurance, to function without QA, unless state regulators intervene. How will history judge us if we don't raise the standard of care?

We will be judged. We should set the parameters so the judgement is fair. We should not let the agendas of outside organizations pre-judge our actions. We have to be proactive about choosing indicators and providing data about our programs. The data will then be available for our management, outside organizations, and the public to use in their judgement of our performance.

Partnerships

We are trying to walk the thin line between burdensome state control and laissez faire capitalism. We are trying to protect the public while not restricting the profitability of industry within our borders or restricting the availability of new technological tools for diagnosis and treatment. Within the regulated community, there are hospital administrators, radiology managers, medical physicists, radiologic technologists, physicians, and chiropractors. Some of the surrogate regulators include insurance companies, accrediting bodies, advocacy groups, and the news media. We have to coordinate with other regulators at the federal level and sister agencies at the state level. There are professional organizations that provide information to their members, nationally and internationally.

Our best customer

Although all of us keep the public's health and safety foremost in our minds as we go about regulating, we rarely proactively seek input from "the public". We answer the occasional irate phone call, we prepare talks to the regulated community, we have pamphlets on radon to send to homeowners, but we don't go out and listen to the public. Maybe it is because we presume that the public knows what we are doing and trusts us to protect them. Or maybe it is because we think that the public won't understand what we do.

In 1997, Americans were asked survey questions involving elementary concepts such as the molecule and the revolution of the Earth around the sun. They achieved a mean score of only 55, unchanged on the same survey since 1988. How can such basic scientific understanding be lacking in the technological world in which we live? Isn't it necessary for individuals if they are to make a reasonable living? Isn't it necessary if American industries are to compete effectively with those abroad? Isn't it required for simple good citizenship? Can a citizen make good judgements about technological issues if they lack scientific understanding? But maybe citizens need an understanding of economics, political science, history, cultural differences, and numerous other fields to reach good radiation policy decisions. As a scientist, I think that science should take precedence, but those in other fields think exactly the same way about their specialties.

As a scientist, I am concerned that this ignorance of scientific concepts will lessen public support for research as well as regulatory programs. I want to do something to help ameliorate

the sad state of science understanding. But I also know that many public policy issues lie at the intersection of the natural sciences and other branches of knowledge – the social sciences and the humanities. So I want to work to create an interdisciplinary background for informed public discussion.

It worries me that the "neutral" scientist was in the middle of the voluntary actions of the 1920's involving dial-painters. Even when the chemist wrote that he suspected radium poisoning, his ideas were ignored, in part, because he did not have access to policy makers. If he had been able to influence the political process, it would not have taken over 10 years for the judicial and legislative branches of government to recognize radium poisoning. I am encouraged that scientists today are willing to work with others to find mutually agreeable solutions to the radiation protection issues. In particular, I think the addition of economists, social scientists, political scientists, and attorneys can add perspective to the "pure" scientific debate. There are differences between 1928 and 1998. Science does not stand alone. And if we can keep that history in mind as we move forward, I think the postmodern management style can be even more effective.

So here is the picture of postmodern management that I see: international standards developed jointly with all levels of regulators and regulated community; quality improvement measures enforced by surrogate regulators and economic incentives; prioritized and focused inspections using indicator systems; multidisciplinary participation in regulatory policy; and enhancement of public participation.

In closing, I hope that we will be able to explore mutual goals and define concrete actions that each of us can take to improve our working relationship and make our respective roles complementary.

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