

OBJECTIVES AND EXPERIENCE OF RISK GOVERNANCE IN THE USA

by

Gail Charnley, PhD

Health Risk Strategies

Washington, DC

charnley@healthriskstrategies.com

www.healthriskstrategies.com

INTRODUCTION

The evolution of risk governance in the United States - and now in Europe - towards decisions informed by risk is a response to the demand for more transparency and democracy in risk decision-making. This paper addresses some of the ways that we in the US are trying to achieve greater transparency and effectiveness in risk governance. First, it describes the evolution of risk governance in the US in general and the roles of science, law, and policy. Then it addresses more specifically the evolution of risk governance as it applies to nuclear waste, and how the many inconsistencies resulting from that evolution have led to poor performance in terms of efficiency and effectiveness. Next it recommends greater reliance on risk as the basis - or common currency - with which to improve nuclear risk governance and increase transparency. Finally, it discusses public concerns and risk perceptions as they relate to radioactive waste, and tries to clarify what probabilistic risk assessment can and cannot do.

RISK GOVERNANCE IN THE US

Our approach to risk governance in the US has been evolving over the past several decades, guided in part by science but to a greater extent by a series of laws and judicial decisions. Initially, the US based its risk management decisions more on what we might characterize today as a precautionary approach, not a risk-based or riskinformed approach. Before health risk analysis developed as a discipline, precaution

guided environmental health risk management decision-making in the US for many years /1/.

For example, in the 1950s the zero-risk Delaney clause required the Food and Drug Administration to ban outright any food and color additives that had been shown to produce tumors in humans or laboratory animals, no matter how large or how insignificant the potential risk to humans might be /2/. In the 1970s, a legal basis for precaution was established by the DC Circuit Court with the Ethyl decision involving banning leaded gasoline /3/. At the time, there was great debate about the wisdom of taking such a radical step when the benefits of doing so were unclear. But the Court affirmed EPA's decision to take a precautionary approach and ban lead anyway, even in the absence of scientific evidence adequate to demonstrate exactly what the risks from the lead were or what the benefits of removing it would be. In other words, the Court acknowledged that EPA could make decisions based on a precautionary policy even if they weren't completely supportable scientifically. As it turned out, banning leaded gasoline was a great environmental success story - the single most important contributor to the virtual elimination of lead from air and from most children's blood. Some even believe that the reductions in crime rates we're seeing now are a long-term effect of banning lead. In 1980, however, the Supreme Court's Benzene decision overturned the precautionary policy basis of the Ethyl decision and substituted a risk-based principle /4/. The Benzene decision struck down a workplace standard for benzene exposure that was based on a policy of trying to reduce concentrations of benzene as far as technologically possible without considering whether existing concentrations posed a significant risk to health. The Court decided that benzene could be regulated only if it posed a "significant risk of material health impairment" /5/. Although the Court did not define "significant risk of material health impairment" and stressed that the magnitude of the risk need not be determined precisely, the decision strongly implied that some form of quantitative risk assessment is necessary as a basis for deciding if a risk is large enough to deserve regulation.

More recently, a precautionary approach was embedded in the risk-based guidance of the 1996 Food Quality Protection Act, which regulates pesticides /6/. The FQPA requires

that pesticide tolerances now be made ten times more stringent than they would be otherwise with the thought that doing so would protect children. This puts the burden of proof on the pesticide manufacturers to demonstrate that, based on the science, children are unlikely to be at greater risk from their products than adults. Whether passage of the FQPA is signaling a swing of the pendulum back towards a focus on precaution and away from risk remains to be seen.

To a large extent, the body of US laws that seek to establish practices that will ensure safety - or at least mitigate risk - from chemical or other contaminant exposures were established before risk assessment was a well-recognized and codified discipline. Most of the methodology of risk assessment was developed in reaction to the calls by those laws to define limits on exposure that will “protect the public health with an adequate margin of safety” or lead to “a reasonable certainty of no harm.” That is, in passing the laws, the US Congress called on the regulatory agencies to develop means to assess risks so as to define quantitative exposure levels that would achieve the stated qualitative goals of health protection /7/. In order to do that, the methodology of risk assessment emerged so that decisions about managing risks could be based on some knowledge of the nature and magnitude of the risks of concern.

At the same time, we have a legal tradition in the US that relies heavily on establishing a factual basis for decision-making. The Administrative Procedure Act requires that regulatory decisions in the US be justified by an extensive factual record that is subject to judicial review /8/. In other words, before a decision about regulating a particular risk to health or the environment can be made in the US, a scientifically and legally defensible body of evidence must be generated that characterizes the nature and magnitude of the risk and justifies the action proposed to reduce that risk. If regulated or other affected parties believe that the risk management action is not justified, they may challenge the proposed action in court. In many cases, the court decides that more scientific information or better justification is needed before an action or decision can be taken. So when Europeans call for decisions based on “the precautionary principle” in international forums, they are challenging one of the core premises of the American legal culture.

We believe in the US that the risks of arbitrary government action are so great that it is better to pay the costs of procedural delay and elaborate legality than to run the risk of unjustified government actions. In other words, we in the US prefer to err on the side of avoiding false positives when it comes to environmental health protection. That appears not to be the case in Europe or in most of the rest of the industrialized world, including Canada, where government regulatory decisions are not subject to judicial challenges in court to nearly the same degree as they are in the US and, as a result, tend to err on the side of avoiding false negatives. As a consequence, the necessary procedures for marshalling and analyzing scientific evidence before decisions are made about environmental health protection are nowhere near as great in Europe, for example, as they are in the US.

One of EPA's former deputy assistant administrators, Michael Shapiro, has said that in his experience at EPA, only about 10% of the manipulation of scientific data done by EPA was necessary to reach a decision; the other 90% was required to build the record for court review.

One of the reasons judicial review works in the US is that it promotes greater transparency for decision-making. More transparency in matters of science- and risk-based risk management decision-making leads to better and more consistent decisions. When proponents of a risk management decision are required to produce justification for that decision that can stand up to public oversight in the form of judicial review or some other transparent oversight process, a more consistent and efficient basis for such decisions develops.

RADIOACTIVE WASTE DISPOSAL

A transparent approach to risk governance as it relates to radioactive waste in the US is still evolving. Thus far, the evolution of nuclear waste governance in the US has been patchy, uncoordinated, and anything but efficient. From the discovery of radioactivity in 1895 to the middle of the 20th century, radioactive material was regulated by individual states. In the mid-20th century, the Army Corps of Engineers managed the first large-

scale uses of radioactive materials as part of producing the world's first nuclear weapons and was, of course, secret until after World War II.

Nuclear weapons manufacturing and other uses of radioactive materials under the wartime program were first regulated federally in 1946 by the Atomic Energy Act. The Act established the Atomic Energy Commission to oversee all nuclear activities and classified nuclear materials into three categories - source, byproduct, and special nuclear - that have been preserved in subsequent revisions of the Atomic Energy Act and by other laws and regulations. The aim of the Atomic Energy Act was to ensure the security of nuclear materials, however, and not to control their radiologic hazards, presumably in part because the hazards of radioactivity were not yet fully appreciated or understood. As our understanding of the hazard has evolved over the past 60 years, new regulations have evolved as well, but they did so in a patchwork and disorganized way. Because the governance of nuclear materials evolved as a patchwork, constrained by the original definitions of the three categories of materials, no consistent and articulated risk basis for that evolution developed /9/.

Different laws and different organizations control different nuclear activities and wastes. The Nuclear Regulatory Commission controls commercial nuclear activities. The Energy Research and Development Administration, now replaced by the Department of Energy, controls defense nuclear activities. The Environmental Protection Agency sets radiation protection criteria and standards and issues radiation protection guidance for federal agencies. Individual states are responsible for the disposal of low-level radioactive wastes generated in that state. Wastes containing naturally occurring radioactive materials from non-nuclear activities such as mining, oil and gas production, and water treatment, are regulated by the federal government if they contain uranium or thorium in concentrations greater than 0.05% by weight and by individual states if they contain uranium or thorium in concentrations less than 0.05%.

Federal law defines low-level radioactive waste only by exclusion: low-level waste is not spent nuclear fuel, high-level waste from fuel reprocessing, transuranic waste, or byproduct material from uranium or thorium ore processing. There is no legal upper limit

or lower limit for the level of radioactivity required to classify a material as low-level waste. From a risk point of view, then, the level of radioactivity in waste may be low enough to be essentially undetectable or high enough to produce acute harm to humans or serious contamination incidents, but the actions required to treat that waste may be identical and not necessarily consistent with its potential to produce harm /9/.

For example, commercial nuclear facility decommissioning produces debris, rubble, and contaminated soil involving large volumes of materials having small quantities of radioactive contamination, including concrete, plastics, metals and other building materials, equipment, and packaging. These materials are considered “slightly radioactive solid materials.” The US Nuclear Regulatory Commission estimates that decommissioning of the existing commercial power reactor facilities may generate about 8 million cubic meters of slightly radioactive solid materials, about 90% of which is concrete. Currently these wastes are regulated and disposed of as Class A wastes, which means they must be disposed of underground at a near-surface facility licensed by the Nuclear Regulatory Commission instead of, say, at a commercial landfill. One of the only three such licensed facilities in the US has found that the debris and rubble it receives comprises about 90% of the total low-level-waste volume it receives and about 1% of the radioactivity.

Meanwhile, discrete radioactive sources that are no longer useful, such as sealed sources used in medical diagnostics, industry, and research, can meet the same definition of low-level waste and be disposed of in the same type of facility, although they may contain highly reactive nuclear materials.

Thus the US is not a model of risk governance efficiency when it comes to radioactive material and provides a poor example in this particular area. But we have at least recognized our inefficiency and some efforts have been made recently to remedy the situation, namely, by developing a risk-informed approach to the disposal of low-level radioactive wastes.

A US National Academy of Sciences committee has been convened, sponsored by the Army Corps of Engineers, the US Department of Energy, the US Environmental Protection Agency, the Nuclear Regulatory Commission, and a coalition of states, to evaluate and recommend options for improving the current patchwork system of risk governance for low-level radioactive wastes /9/. The goal of the committee (on which I serve) is to develop a means to rely on health risk as the common currency for making risk management decisions about different types of radioactive waste. As it stands today, the present system of controls for such waste may be overly restrictive in some cases, leading to excessive costs and other burdens on waste generators, but neglects other wastes that could pose an equal or higher risk that should be more restrictively controlled. The current system is inconsistent with the Benzene decision and the requirements of the Administrative Procedure Act discussed above, but because the current system was created by Congress, too, it is not subject to the same stringency of judicial review. A more consistent and harmonised approach is now being sought in the US that would bring regulation of radioactive waste disposal more in line with chemical regulation by focusing on different wastes' inherent radiologic and toxicologic properties rather than on their origins.

HARMONISING NU-LEAR AND CHEMICALS RISK GOVERNAN-E

Probabilistic risk assessment methods for radiation hazards are well established, but there is a discrepancy between the levels of risk that are considered negligible for radiation exposures and for chemical exposures. In the case of individual chemicals, exposure limits are generally set to keep incremental upper-bound lifetime cancer risks for workers below one per thousand over a 45-year period of workplace exposure and, for the general population, below a range of one per 10,000 to one per million over a 70-year lifetime of exposure to the limits. In the case of radiation, the current occupational exposure limit in the US is a whole-body equivalent dose corresponding to a lifetime excess total cancer risk of more than one in ten if experienced annually over a working lifetime, assuming a linear dose-response relationship and lifetime exposure at the occupational limit /10/.

Other occupational exposure limits, recommended by the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements, are equivalent to a lifetime cancer risk of one in one hundred, assuming about a 50-year exposure duration at the exposure limit in the absence of ALARA standards. Those risk estimates are well above those associated with similarly extreme scenarios of lifetime exposure to chemical carcinogens at the level of their occupational standards /10/.

Of course, ALARA generally prevents exposures at or near the limit, but ALARA does not provide a basis for making efficient risk management decisions or to make risk comparisons. ALARA allows little transparency with regard to risk; the effectiveness of its restrictions are obfuscated by definitions expressed in terms of rem instead of in terms of lifetime cancer risk, for example. Workers who know what their annual exposures are in terms of millirem do not know, generally, what that means in terms of their health risk. The ICRP and others who study these issues may understand the relationship between rem and risk, but few others do. Furthermore, risk management decisions based on ALARA cannot be compared in terms of their efficiency or effectiveness; risk management actions informed by risk can be targeted towards the more likely or larger risks first, their effectiveness in terms of risks prevented can be estimated, and the efficiency of different actions can be compared. The same principles apply to deterministic versus probabilistic safety assessment.

Harmonising risk governance of radioactive materials and chemicals, for example, presents several challenges, however /10/. Risks from radiation and from chemicals are estimated differently; most importantly, radiation exposure limits integrate all ionizing radiation exposures, while chemical-specific exposure limits consider each chemical individually. Regulation of risks from chemical exposures distinguishes among individual chemicals, the different types of toxicity they can produce, such as cancer, nervous system toxicity, and reproductive toxicity, and the routes by which exposure occurs, such as oral, dermal, or inhalation. Risk-informed regulation of nuclear generation and waste disposal would be much more straightforward than regulation of chemicals because, regardless of which radionuclide is of concern or its source, cancer or death

produced by whole-body exposure to radiation are generally the outcomes of concern. In addition, harmonising nuclear and chemical risk assessment might lead to less of a need to isolate nuclear waste, for example, from hazardous waste.

ROLE OF PROBABILISTIC RISK ASSESSMENT IN RISK DECISIONS

One of the reasons that we refer to a “risk-informed” approach instead of a “risk-based” approach is that risk assessment is not meant to be the only determinant of a risk decision. Feasibility, effectiveness, cost, and even politics can play a role in risk decisions, but risk assessment is the means by which science and scientific information are considered. Risk assessment provides a framework for organizing scientific information in order to clarify what is and is not known about a particular risk. The results of a probabilistic risk assessment are useful for setting risk management priorities, targeting resources, and guiding choices among different safety measures. Risk assessment is a component of a larger decision-making process that begins with a negotiated set of risk management goals. Figure 1 depicts a framework for risk management decision-making proposed by the US Presidential/Congressional Commission on Risk Assessment and Risk Management /11/. The six-stage process is circular because the process of decision-making should be iterative; like hypotheses generated by the scientific process, decisions should be modified as new information becomes available. It begins with clarification of the problem to be solved and agreement on the questions that the risk assessment will address; stakeholders are involved throughout the process. In this context, risk assessment is seen as a decision-driven activity, directed toward informing choices and solving problems, with the purpose of enhancing practical understanding and illuminating practical choices.

Risk assessment and risk management are not isolated processes; the negotiated goals of risk management should dictate the questions that risk assessment addresses /12/.

Figure 1: Environmental Health Risk Management Decision-Making Framework

In contrast to deterministic approaches to nuclear safety, risk-informed approaches permit comparison of different safety measures in terms of their efficiency and

effectiveness; clarification of how much of a public health benefit may result from different levels of safety investment; and permits evaluation of risk tradeoffs, such as nuclear energy and clean air versus coal-fired generation and air pollution. Because risk-informed approaches are transparent, they make apparent how risk has been estimated and accounted for, improving public confidence in whatever choices of safety measures are made.

There are many examples of situations in the US demonstrating the benefits of risk-informed decision-making. As more scientific information about health risks from asbestos, lead, and diesel emissions has become available, exposure to those substances has been progressively limited, leading to more effective public health protection. Failure to rely on scientific information about the health risks from the pesticide Alar, used on apples, led to needless panic and widespread bankruptcy of the apple industry. Cleanup of contaminated former industrial sites is guided by risk information, so that those posing the greatest risks to public health are addressed first. In fact, a recent report from the US Office of Management and Budget shows that the benefits of environmental regulations outweigh the costs /13/, although another report has shown that 60,000 more lives could be saved annually if investments in environmental risk management were guided by probabilistic risk assessment /14/.

PUBLIC RISK PERCEPTION

As in Europe, there is persistent and widespread concern in the US about all aspects of radioactive waste management and disposal. A number of individuals have testified to the National Academy of Sciences low-level waste committee expressing their considerable distrust of the radioactive waste regulatory system due to its complexity, inflexibility, and inconsistency /9/. While we hope that moving to a risk-informed approach to managing radioactive wastes will help make the system simpler, more flexible, and consistent, not everyone supports a risk-based approach to radiation protection. Many believe that basing risk decisions on probabilistic risk assessment is inappropriate because risk assessment is unscientific, undependable, and generally a tool of industry and government used to justify decisions.

Rather than try to convince such people that risk assessments are accurate and scientific and should be trusted, it may make more sense to emphasize that risk assessment should be used as a decision-making tool and not as a mathematical means of calculating real risks. Risk assessment provides a uniform framework that can be applied to different types of wastes in order to rank them according to their potential hazard. Such a ranking can be used to guide decisions about which risk management actions are most appropriate for which wastes, and which wastes should be give first priority. In other words, the results of risk assessments can be used to target risk management resources most effectively. Most people seem to understand the need to set priorities for society's resources, even if they don't trust the methods of risk assessment. Of course, improving stakeholder involvement would also help improve trust.

CONCLUSIONS

We know that there are health risks associated with the generation of nuclear energy and the transport and disposal of radioactive waste, but as long as radioactive waste governance is based on the source of the waste and not on risk, as long as occupational safety is based on ALARA and not on risk, and as long as nuclear safety is based on deterministic actions instead of probabilistic risk analysis, the extent to which those approaches protect - or fail to protect - public health is not known. When risk decisions are not informed by the common currency of risk, the effectiveness of decisions about how to limit risks, whether a result of nuclear generation or waste disposal, cannot be determined. If the ultimate concern is the protection of public health, then some transparent measure of the nature and extent of nuclear practices' threats to public health is needed as a guide to how best to reduce, limit, or eliminate such risks.

Nuclear safety practices should be harmonised according to the common currency of risk. Doing so may help us target risk management resources more efficiently and protect our health more effectively, not to mention improve public trust.

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