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PAPERS ON THE NUCLEAR REGULATORY DILEMMA

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DISCLAIMER

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Introduction and Summary

These four papers investigate issues relating to the long-term regulation of nuclear energy. They were prepared as part of the Institute for Energy Analysis' project on Nuclear Regulation funded by a grant from the Mellon Foundation and a smaller grant by the MacArthur Foundation. Originally this work was to be supplemented by contributions from the Nuclear Regulatory Commission and from the Department of Energy. These contributions were not forthcoming, and as a result the scope of our investigations was more restricted than we had originally planned.

The literature on how to improve regulation of nuclear power is enormous. Most of this literature is devoted to short-term remedies for the regulatory impasse. Rather than go over old ground we attempted here to identify a few issues that were, either directly or indirectly, relevant mostly to the mid- or longer-range regulation of nuclear energy.

No new nuclear plant has been ordered in the United States since 1978. The 24 reactors now under construction will largely be completed by the end of the decade. Unless new reactors are ordered, there will be no reactors for NRC to license. Why should one worry about changing the relation between NRC and the nuclear industry if NRC has no new reactors to license?

The answers of course are obvious: part of the reason for the moratorium is the utilities' disaffection for nuclear energy that results from what it regards as an unworkable regulatory regime. If the regulatory regime could be improved, one might hope that this in itself would improve the outlook for a resurgence of new nuclear plants. Two of the papers, by Barkenbus and by Freeman, therefore address reasonably short-range questions: how can nuclear regulation be improved in a situation where NRC's main job continues to be the licensing of new reactors.

The other two papers address broader questions that to a degree bear on the scientific underpinning for regulation of hazardous industry. The first paper confronts the limits to science: how can regulation be managed when the scientific base on which the regulatory regime is based is itself very uncertain. The second paper considers probabilistic risk assessment. Can PRA be made sufficiently reliable to allow its use eventually as the basis for licensing?

In the following we summarize the main points that are covered in these papers.

A. Underlying Scientific Issues

1. Regulators demand more of science than science can deliver. Whether one is dealing with Probabilistic Risk Assessment, the health effects of low levels of radiation, or the future demand for energy, regulatory policy often demands answers to questions that science cannot answer. Though every effort must be made to reduce the levels of uncertainty, particularly in PRA, we suggest that where possible, public policy be reframed so as to avoid the requirement of answers to the unanswerables. In particular, technical fixes, such as inherently safe reactors (ISR), might eventually obviate the need to depend on PRA for licensing. Though this is a long-range possibility, the payoff from the development of an ISR could be very large.

2. De minimis levels for radiation and core-melt probability ought to be established. We recommend adoption of a de minimis for low levels of radiation at a value "below demonstrable effect." Similarly we suggest that estimated core melt probability below some small value (10^{-6} or 10^{-7} per reactor year) be regarded as "Acts of God," and be treated accordingly. What this negligible core melt probability should be is negotiable--reactors with this core melt probability probably ought to be considered to be so safe that any accident in them would be an "Act of God."

3. "Body counting" in PRAs should be confined to high estimated exposures. At present, consequences from core melt accidents are estimated on the basis of no-threshold models. Since most long-term effects are calculated to result from exposures of many people to levels so low as to be beyond demonstrable effect, the resulting very large "body counts" do not accurately represent what is known about casualties from large-scale core melts. We therefore recommend that consequences estimated in PRAs be divided into two categories: (a) where the exposures are substantial, estimate casualties; (b) where the exposures are below demonstrable effect, report "and x individuals will receive exposures below demonstrable effect."

4. PRA can and must be improved. Were PRA a reliable instrument, and were it so perceived, it could, in principle, be used as a regulatory or even licensing standard: i.e., only reactors for which PRA predicted core melt probabilities below a certain level would be licensed. At present the uncertainty in PRA is estimated (by Rasmussen) to be a factor of 10 either way. We would urge that all effort be devoted to reducing this uncertainty to no more than a factor of 2 or 3 either way. Though we have not studied the feasibility of achieving so ambitious a goal, we believe that NRC ought to exert strong effort toward achieving this goal.

B. The Role of NRC

1. Industry and public concerns must both be addressed if regulatory reform is to succeed. Current and past regulatory and licensing reform efforts have been flawed since they have addressed only the concerns of industry, and neglected the concerns of a general public skeptical of nuclear power's safety. Efforts to "streamline" the regulatory process for industry, therefore, are invariably seen as diminishing, rather than adding to, safety. Yet many of the industry's complaints about the prescriptiveness and open-endedness of nuclear regulation today are legitimate and need to be resolved before further plant orders will be forthcoming. In order to convince Congress to act it must be shown that industry and larger public concerns can be reconciled in a common approach.

2. Performance Standards must be established. The basis for such an approach may rest in a tradeoff between the requirement for higher design or performance standards in new reactors (satisfying public concerns) and a prohibition against the intrusive and prescriptive regulation of these reactors (satisfying industry concerns). This tradeoff is already embodied in the nuclear regulatory policies of some European countries. It is time for either Congress or the NRC to establish clear performance standards ("safety goals") for the licensing of future reactors--safety standards that go well beyond those of current generation reactors and which would make the reactors virtually immune from a core meltdown accident. With the inclusion of such standards in a regulatory reform package, it should be possible to obtain Congressional consent for industry-supported measures such as one-step licensing, pre-licensed sites, and a prohibition on backfitting (except under extraordinary circumstances).

Our project could come to no agreement as to some of the "mechanics" involved in establishing safety or performance standards for the licensing of new reactors. Thus Freeman and Weinberg would not object to the establishment of standards expressed in Probabilistic Risk Assessment (PRA) terms. PRAs, therefore, could constitute the primary basis for licensing. Barkenbus, by contrast, explicitly rules out the use of PRA in standard setting and licensing, claiming that the uncertainties in PRA analysis are too large to obtain a credible, quantitative estimate of core melt probability; and regardless of its predictive ability, the PRA methodology is too inscrutable in light of public suspicions. Consequently, Barkenbus asserts that new reactors must be based upon the principles of inherent and demonstrable safety.

C. The Role of Congress

1. Congress should decide how safe is safe enough. A strong case can be made that decisions as to "how safe is safe enough" ought to be made by elected representatives and not appointed regulators. The key decisions facing nuclear power are political in nature, and only secondarily, technical. Regulatory reform must encompass and deal forthrightly with these political elements.

Congress has yet to establish clear safety standards for the construction and use of nuclear power. The Atomic Energy Act of 1954--the bedrock of nuclear power legislation in this country--simply states that nuclear power should present "no undue risk," or that "adequate protection to the public's health and safety" should be assured. Such vague pronouncements are no longer sufficient guides to continued and future operations. Congress, as the governmental body most clearly linked to public input and opinion, needs to provide more explicit direction to the nuclear regulatory body it oversees (the NRC), and to the nuclear industry.

2. Congress can provide direction by

(a) Promulgating NRC's safety goals. Qualitative goals could be established and supported similar to those set forth in the proposed safety goal statement of the NRC. Two of NRC's specific qualitative goals were (1) Individual members of the public should be provided a level of protection from the consequences of nuclear power plant accidents such that no individual bears a significant additional risk to life and health; (2) Societal risks to life and health from nuclear power plant accidents should be as low as reasonably achievable and should be comparable to or less than the risks of generating electricity by viable competing technologies.

(b) Encouraging development of inherently safe reactors. Congress could encourage the movement toward advanced reactor development by lending support (both verbal and in terms of R&D funding) to reactor design characteristics now viewed as desirable. These characteristics were recently set forth in an issue of the Federal Register as follows:

-- Designs that require few supplemental safety features to ensure safety, and/or designs that provide longer time constants to allow for more diagnosis and management prior to reaching safety systems challenge.

-- Simplified safety systems which require the fewest operator actions, the least equipment (especially equipment subjected to severe environmental conditions), and the minimum number of components needed for maintaining safe shutdown conditions, thereby facilitating operator comprehension and reliable system function. Such simplification can also reduce the uncertainties associated with deterministic engineering judgment and probabilistic risk analyses.

-- Designs that (1) minimize the potential for severe accidents and their consequences by providing sufficient inherent safety, reliability, redundancy, diversity and independence in safety systems; (2) provide reliable equipment in the rest of the plant, thereby reducing the number of challenges to the safety systems; (3) provide easily maintainable equipment and components; and (4) reduce potential radiation exposures to plant personnel.

-- Increased standardization and shop fabrication to minimize the potential for field construction errors without creating new difficulties in factory-to-field transport, installation and maintenance.

-- Design features that can be proven by citation of existing technology or which can be satisfactorily established by commitment to a suitable technology development program.

(c) Legislating safety criteria. Congress could establish quantitative performance goals that new reactors would be required to meet as a condition for future licensing. The performance goals could be based upon PRA covering the estimated frequency of core melt accidents; or alternatively they might be based on time-dependent technical estimates of passive safety features. In either case, it might be useful to establish institutes or centers specifically devoted to assessing the technical merits of new reactors (apart from the NRC).

Option (c) above would constitute the strongest Congressional response, and is the most direct means of reconciling public and private interests in regulatory reform. The establishment of quantitative performance goals by Congress would go well beyond the institution's straightforward "oversight" responsibilities. Yet, Congress has, in the case of automobile and environmental regulation, performed a standard-setting role. Perhaps the most interesting example of standard setting has been Congress' establishment of automobile mileage standards, with quantitative goals being set at increasingly higher levels over time. A similar approach could be used for nuclear power.

3. A Workshop on New Approaches to Regulatory Reform. Given the uncertainties in the role of NRC resulting from the nuclear moratorium, and the bleak outlook for passage of nuclear regulatory reform legislation, we believe that a workshop on new approaches to nuclear regulatory reform might be useful. At such a workshop one would hope ideas other than the traditional ones are put forward. Participants might be drawn from IEA, ORNL, NRC, DOE, the private sector, Congress, and public interest groups.The summary of the workshop proceedings could serve as the basis for further discussion of possible directions for regulatory reform.

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FROM PRESCRIPTIVE TO PERFORMANCE-BASED REGULATION OF NUCLEAR POWER

FROM PRESCRIPTIVE TO PERFORMANCE-BASED REGULATION OF NUCLEAR POWER

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Though the two papers, "Improving the Regulation of Nuclear Power," by S. David Freeman, and "An Alternative Regulatory Approach," by Jack Barkenbus differ in many details, they agree in one essential point: that the Nuclear Regulatory Commission (NRC) must establish recognizable, publicly acceptable safety goals, and that all new reactors must meet these safety goals--indeed, the NRC is committed to license any reactor that meets its safety goals. Thus the vendor is not required to meet the safety goals in a manner prescribed by NRC; he is given full freedom to meet the goals in whatever way he likes, provided that he can demonstrate to the NRC that his design actually meets the safety goal established by NRC.

The two papers differ in respect to what the safety goals should be. Barkenbus simply rejects probabilistic risk assessment (PRA) as a tool for establishing safety goals, and insists that safety must be inherent; Freeman, though recommending strongly the acceptance of inherently safe reactors, is less dogmatic than Barkenbus: he accepts the use of probabilistic risk assessment as a means of comparing reactors of generally similar type.

My own inclination is toward Barkenbus' hard-line approach--that is, to require that all <u>new</u> reactors built in the United States must be inherently safe. However, as a practical matter, I recognize the great obstacles in the way of implementing such a policy and so, as a practical expedient, I would recommend adoption of Freeman's less restrictive position--that new reactors must meet safety standards established by PRA.

Exactly what these standards should be is, of course, the ultimate issue. As Freeman points out, the standards <u>must</u> be acceptable, and understandable, to the public. He therefore suggests that the promulgation of such standards must be made a major public issue, with full participation by the public, and equally important, by Congress. Indeed, I would urge most serious consideration of establishing these standards by law.

At first sight this may seem bizarre and unrealistic. But in many ways such a procedure may have advantages. We list them as follows:

(1) Were the safety standards established by Act of Congress, they would receive the most intense public scrutiny. Indeed, once they were settled by passage of such a law, the public sanction and mandate for nuclear power itself will have been re-established. So to speak, the law of the land would now say safe nuclear power is acceptable--and the law in effect defines "safe."

(2) Were such a law in place, much of the pressure for reform of NRC may be relaxed--since, as far as new reactors are concerned (which is what the law would be aimed at), NRC's task is to certify that a reactor meets the standard, and that the operation remains competent.

(3) Numerical standards of the sort here contemplated have already been incorporated into law--the CAFE automobile standard being the most notable.

What Should the Safety Standards Be?

If one accepts the principle of incorporating safety standards into law, we are faced with the question of what the standards should be. The current safety standard promulgated by NRC amounts to a mean core melt probability, (CMP) as determined by PRA, of 10^{-4} per reactor-year. This means that with a fleet of 120 reactors in the United States, the a priori probability of a core melt by the year 2000 somewhere in the United States is around 20 percent; since the PRA estimate may be high or low by, say, a factor of 10, the estimated likelihood of a core melt in that time actually lies between 2 percent and 86 percent.

I would therefore suggest a more stringent standard; moreover, as was done with the CAFE standards, the core melt probabilities should be reduced as time passes. Such a schedule might be the following:

For reactors to be licensed between	CMP
1985-1995	10^{-4}/RY
1995-2005	10^{-5}/RY
2005--	10^{-6}/RY

To be sure, the core melt probability for the entire fleet of reactors will continue to be dominated by the CMP of the older reactors as long as their CMP remains around 10^{-4} per reactor year. Most of these reactors will reach their 30-year lifetime by 2015; if the reactors actually retire by then, this problem will gradually fade. Another way of dealing with the problem would be to require old reactors to meet the more stringent CMP standards before they can be re-licensed, once their original license expires. Of course, the older reactors will have had an aggregate of some 3000 reactor years of operation before any of their licenses expire. During this time, data on precursor events, of the sort amassed by Kukielka and Minarick, should show whether or not the CMPs estimated by PRA are too high or too low. I should think that as operators become better trained, the trend will be downward, and many of the old reactors might meet the 10^{-5} per reactor year standard without requiring backfits.

On the Possible Utility of PRA as a Regulatory Instrument

At present the uncertainties in PRA (estimated by Rasmussen to be a factor of 10 either way!) are so great as to all but obviate PRA as a mechanism for determining how safe is safe enough. Yet, as argued in all of IEA's working papers, a reliable PRA--say PRA whose uncertainty is not more than a factor of 3, could be a key element of a rationalized regulatory apparatus. Is there any hope of reaching this level of certainty for PRA?

The usual answer by those versed in the art is a resounding no--that PRA for reactor systems is so intrinsically unscientific and possesses so many arbitrary elements as to forever be beyond use as the underpinning for a strict regulatory or legislative regime based on PRA. I would argue, however, that this may be an unnecessarily pessimistic assessment--that eventually the uncertainties in PRA might be reducible to the point where it can be used as a regulatory standard. Here I shall examine possible approaches to reducing the uncertainty in PRA.

Experience Annihilates Uncertainty

If the mean probability of a core melt accident is k per reactor year, than the probability that no core melt will occur in T reactor years is exp - kT. We define the confidence interval with which we can say $k \leq k_o$ to be the probability that a core melt will occur in the time T, i.e., $(1 - \exp - k_oT)$. Then Table 1 gives the confidence interval for various T and k_o.

Table 1. Confidence interval in % for a priori mean core melt probability

T (reactor years)	Mean core melt probability, k_o					
	$k_o = 10^{-6}$/RY	10^{-5}	10^{-4}	5×10^{-4}	10^{-3}	5×10^{-3}
500	.05(%)	.5(%)	5(%)	25(%)	31(%)	92(%)
1,000	.1	1.0	10	41	63	99
2,000	.2	2.0	19	63	86	100
5,000	.5	5.0	31	92	99	100
10,000	1.0	10.0	63	99	100	100

From this table we see that with the world's total LWR experience of 2000 reactor years since Three Mile Island without a core melt, we can say with 86 percent confidence that the core melt probability is not greater than 10^{-3} per reactor year. By the end of the century, with $T \sim 5000$ reactor years worldwide, if no core melt occurs we can say that with 99 percent confidence, $k \leq 10^{-3}$ per reactor year; with 92 percent confidence, no higher than 5×10^{-4} per reactor year; and with 31 percent confidence that it is no higher than 10^{-4} per reactor year. In another 10 years, i.e., by 2010, we can say with 86 percent confidence that k does not exceed 2×10^{-4} per reactor year. Thus by 2010, if there is no core melt, we can say with good confidence that the probability of core melt is no higher than twice the proposed NRC guideline. It is in this sense that time annihilates uncertainty in PRA.

Does time annihilate uncertainty fast enough? Probably not, unless the nuclear moratorium in the United States persists until 2010, and the world's fleet of reactors numbers 500 or more. In that event, the experience with reactors will be sufficient so that one can say without elaborate calculation that the mean core melt probability is of the order of 10^{-4} per reactor year or less provided there is no core melt. This can be seen easily since, by 2010 the world's commercial reactors will have accumulated about 10,000 reactor years (assuming 500 reactors). If no core melt has occurred in this time, then the mean core melt probability can hardly be much greater than 1/10,000 per reactor year. The more accurate calculation shows that there is only a 10 percent chance that the mean core melt probability is as high as 2×10^{-4} per reactor year.

The foregoing general argument suggests that the unreliability of PRA, which militates against its use as a regulatory or licensing standard, may be a temporary thing. Should the present moratorium last long enough, and should we survive this period without another core melt, we would be justified in accepting as valid PRAs that reproduced the actual observations. Of course, by that time one could argue that reactors similar to the ones which have exhibited such long-term integrity would prima facie be regarded as adequately safe without the necessity of invoking PRA to justify this conclusion.

Minarick-type Analysis

Minarick's analysis goes beyond a comparison of observed core melts and predicted (by PRA) core melts since he in effect compares predicted and observed partial sequences. Can one improve the reliability of PRA by comparing predicted partial sequences with observed partial sequences explicitly, without, as Minarick does, estimating the likelihood of hypothetical events that would convert a partial sequence into a core melt? Thus we probably have enough data on hand now to estimate quite reliably the probability of

- Diesel generator failure
- PORV failure to re-seat
- Scram-rod failure
- Station blackout
- Steam generator tube rupture
- Loss of load

to mention a few. Each of these incidents enters into PRA; one would hope that a systematic inventory of these events could eventually lead to better estimates of component failure rates, which are the basic input data for PRAs.

The Ritter Bill

Can PRA be so systematized and the procedures so standardized that the technique can be given legal status? Though this may go beyond what is fully practical, some effort in this direction is embodied in Congressman Ritter's H.R. 4192, which calls for the establishment of a Central Board of Scientific Risk Analysis under the National Academy of Sciences, and is mandated by Congress. Such a Central Board of Scientific Risk Analysis presumably would be able to certify that PRAs, or at least the NRC-approved PRA methodology, conformed to the highest standards allowed by the state of the art; it would further the science of risk analysis; and perhaps most importantly, it might serve as an unbiased entity to whom the public and Congress could turn for evaluating risk analysis and PRAs.

The Ritter Bill in effect injects Congress into the analysis of risk. Though it falls short of requiring Congress to decide how safe is safe enough, it begins to move in that direction. A well established and recognized Central Board of Scientific Risk Analysis, acting in concert with NRC, could judge "how safe"; Congress would then have to decide whether this is "safe enough," rather than having to decide both matters--"How safe" and "Is this safe enough?"

The NRC's Job in PRA

Although, were the moratorium to continue, there would be little call to judge the safety of new reactors, I should think that NRC would have the strongest incentive to improve the reliability of PRA. This would require a systematic, and I fear laborious, analysis of data on component failure rates; and sensitivity analysis from which one can judge how uncertainties in failure rates affect estimates of core melt probabilities. For this purpose data ought to be drawn from the world's fleet of reactors, rather than from only the U.S. reactors. The aim ought to be to reduce the uncertainty in PRA estimates of core melt probability from the current level of a factor of 10 either way to, say, a factor of three either way. Were this possible, and once it had been achieved, I should think the objection to using PRA as Congressionally legislated, or NRC-mandated performance standards would be much less cogent than it now appears to be.

Despite these possibilities both for improving the reliability of PRA and of incorporating the PRA process into licensing or even legislation, one must be aware of the difficulties:

-- PRA will always remain inscrutable to the public; the public, if it accepts PRA, will be depending on experts, a posture that is now in general disfavor.

-- The results of PRA can never be as transparent and definite as are the results of a gas mileage test. Congress, in mandating performance standards based even on improved PRA, would still fall short of capturing the degree of uncertainty incorporated in CAFE standards.

In summary, I am very optimistic about improving PRA, less optimistic about using PRA as a performance standard. Perhaps the main thrust of these considerations is to urge again the great importance, and possible high payoff, of a major and consistent campaign to improve PRA.

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NUCLEAR REGULATORY REFORM: A TECHNOLOGY-FORCING APPROACH

NUCLEAR REGULATORY REFORM: A TECHNOLOGY-FORCING APPROACH

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The Nuclear Regulatory Commission (NRC) today has few staunch defenders. The nuclear industry is quick to identify NRC policies and regulations as key culprits in the fate that has befallen nuclear power in this country.[1] At the same time, critics of nuclear power claim that the NRC relationship with industry is far too cozy, and that industry's interests are frequently placed before public safety interests.[2] Efforts to reconcile these two visions have not been successful to date. More regulations and tougher enforcement policies have not mollified nuclear critics, but they have antagonized industry and, even more important, produced disillusioned customers (the electric utilities) who have unofficially forsworn further orders of reactors for the rest of this decade at least.

There is no magic regulatory elixir that can rally the unqualified support of all interested parties and the public at large. There may be opportunities yet unexplored, however, for significantly restructuring the nature of regulation such that the endless cycle of accusations and recriminations is broken, and for providing greater assurance that nuclear power will have a long-term future. The key element in this regulatory restructuring is the creation of a technology-forcing approach that builds upon technical advances that are being made in reactor safety. Such an approach would produce a shift from prescriptive, open-ended regulation to a more performance-directed, bounded regulation; in other words, a fixed goal-oriented regulation, rather than the current, limitless and means-oriented regulation.

Section I, that follows, will illustrate the problems that have arisen with prescriptive nuclear power regulation, and will provide some examples of how some countries have avoided U.S. regulatory practices. Section II will deal with recent industry efforts to supplant prescriptive regulation, with reactor standardization and a type of regulation pursued by the Federal Aviation Administration (FAA). Section III will argue that in terms of nuclear power's long-term future, and in order to convince a skeptical public, it may be desirable to borrow practices not from the FAA, but from performance-based automobile regulation in this country. In the case of automobile regulation, the Congress and regulators established clear performance goals or standards, and then left the means of attainment to industry's discretion. The concluding section will summarize the arguments raised earlier and place the suggested reform in larger perspective.

I.

PRESCRIPTIVE REGULATION

A textbook illustration of regulation in America will frequently portray officials from a government agency peering discretely over the shoulder of corporate decision-makers, seeking to ascertain whether the decisions made by corporate executives ensure the public's health and safety. A more realistic portrayal today, however, would picture the government official and corporate executives sitting at the same boardroom table--and frequently it would be the corporate executive who would be listening. The intrusion of government into the boardrooms of America is widely recognized, but hardly accepted with equanimity. While the legitimacy of regulation is generally accepted in most large-scale endeavors, the lengths to which regulators sometimes go to ensure the achievement of their objectives, certainly are not.

An early 1980s survey of 300 business executives in numerous regulated industries, revealed considerable dissatisfaction with the nature of regulation. Their complaints centered on six separate points:[3]

1. Overlap and confict among agencies.
2. Overextension of the agency mandate--a concern with means as well as goals, leading agencies to dictate how goals will be met.
3. Overregulation without regard to costs or efficiency.
4. Adversarial attitudes toward business.
5. Delays in exercising mandated authority.
6. Duplicative and unnecessary reporting requirements.

All of these problems have been noted at one time or another by nuclear industry spokesmen. Of most interest to us in this paper is number 2, the overextension of the regulatory mandate to encompass not only the goals of regulation but the means--something frequently termed "prescriptive" regulation. Complaining of prescriptive regulation in the study noted above, an industry official regulated by the Food and Drug Administration (FDA) states, "Far better for the agency to state the objective it wants achieved, provide some incentive to the industries involved to devise their preferable means of achieving the goal, and to audit periodically to determine compliance."[4] Nuclear industry spokesmen have been equally adamant. Donald Edwards of Yankee Atomic Electric in 1982 called for a fundamental change at NRC to a "performance goal-setting and monitoring organization" from the "prescriptive semi-design organization it has become."[5]

No one will deny that the NRC has become increasingly prescriptive over the years. In 1965 an industry-supported inquiry (the "Mitchell Report") protested the absence of regulatory guidance in meeting licensing requirements. This complaint has been eliminated by the tidal wave of regulations that have evolved since then. Today applicants are handed approximately 1500 pages of detailed criteria found in the Standard Review Plan. Similarly, whereas in 1970 the AEC had 4 regulatory guides setting forth statutory and regulatory requirements, by 1978 the NRC had 130 guides, 110 separate revisions to the guides, and another 64 technical positions.[6] These prescriptions, moreover, are valid only on the day they are issued. New, additional rules and regulations can be issued at any time, even after the plant has gone into service. Since the Three Mile Island (TMI) accident, numerous additional requirements in such areas as pipe restraint design for seismic and pipe whip phenomena, security and sabotage staffing, fire protection, quality assurance, and operator training, have been forthcoming. As a result, safety has increasingly become what the NRC says it is, and regulation "by the book" has become commonplace. Hence, regulation has, to a large extent, shaped industry decision-making, going well beyond the classical model of regulation whereby the regulator simply ensures that industry externalities are accounted for.

The first and major problem with prescriptive regulation was stated succinctly by the Kemeny Commission, formed in the aftermath of the TMI accident: "The existence of a vast body of regulations by NRC tends to focus industry attention narrowly on the meeting of regulations rather than a systematic concern for safety."[7] In other words, industry becomes attuned to <u>accountability</u> rather than <u>responsibility</u>. Regulators and industry officials gradually come to view conformity or compliance with the rules rather than actual performance indicators as the measure of safety.[8] So much time and attention are devoted to these surrogate measures of safety ("complying with the regulations") that the larger goal of such regulation is frequently neglected. New industry-based safety initiatives are not brought forward either because the sense of responsibility has shifted or because industry fears that these initiatives will simply be added to (not subtracted from) the requirements that the NRC already imposes.

Second, the shift in responsibility to the regulator can have serious safety implications because a central bureaucracy, no matter how capable, cannot adequately regulate a diverse and varied industry at the level of detail involved in NRC standards. Diverse capabilities and circumstances require a flexible approach to safety management; and a central bureaucracy by its very nature is not capable of that flexibility.

Third, this mode of regulation can have a devastating impact upon industry morale and devotion to duty. Constant oversight and punitive action in the event of noncompliance with the rules produce an unhealthy spirit of skepticism and resistance toward all regulation.

The vast body of regulation requires that the NRC hire an army of inspectors to determine whether regulations are being met. In addition to NRC resident inspectors, the NRC, and other groups, carry out a host of audits at nuclear power plants. The accompanying chart reveals the number of audits conducted annually at Tennessee Valley Authority (TVA) nuclear power plants. It is quite likely that at this stage we have reached a level of diminishing marginal returns with respect to additional audits.

The impetus for this type of detailed, open-ended regulation is quite clear. Public concerns over the safety of nuclear plants, and the existence of poor or inadequate management at some nuclear power facilities, have led to political pressures for "tougher" regulation. The NRC can hardly ignore the widespread and deep public apprehensions over the management of this technology. Their response to calls for "tougher" regulation has been to promulgate even more prescriptive regulations, provide additional oversight at nuclear power plants, and issue more fines for discovered instances of regulatory noncompliance. While the enhancement of public safety through this "tougher" regulatory stance is questionable, one result is clear and predictable: an unwillingness of utilities to invest further in nuclear power. If we as a society, therefore, are to obtain the enormous potential benefits from this form of energy, we must reconcile the public desire for more stringent regulation with the industry need for predictable and bounded

SUMMARY OF REVIEW AND AUDIT ACTIVITIES AT NUCLEAR POWER PLANTS

TVA REVIEW AND AUDIT

Reviews and Audits Within Line Organizations

- Review by Supervision/Management
- QC Inspections
- Plant Operations Review Committee (PORC)
- Nuclear Safety Review Board (Operations)
- Special Investigating Committees

Office of Quality Assurance (OQA)

- Periodic Audits
- Surveillance
- Reviews

Nuclear Safety Review Staff (NSRS)

- Management Reviews
- Special Reviews
- Investigations

EXTERNAL REVIEWS AND AUDITS

NRC

- NRR - Technical Reviews in Licensing Proces
- I&E - Reviews/Audits/Inspections
  Operating, Construction Phase
- SALP - Annual Assessment of Performance
- PAT - Performance Appraisal - Operations
- CAT - Performance Appraisal - Construction

INPO

- Periodic Review of Operations
- Initiating Programs for Review of Construction

Special Reviews

- Outside Review by Consultants - Fire Protection
- Nuclear Insurers

Source: Newt Culver, Tennessee Valley Authority, March 15, 1983.

regulation. While these goals may strike many as contradictory and irreconcilable, they need not be. The balance of this paper details the basis for this assertion. We look first to foreign experience in the regulation of nuclear power.

FOREIGN REGULATION

The prescriptive nature of U.S. nuclear power regulation is by no means the norm followed throughout the globe. In fact, one can cite numerous examples of how U.S. regulation stands apart from the norm. Walter Marshall, chairman of Britain's Central Electricity Generating Board, has stated that there are only 45 pages of safety guidelines that UK nuclear operators are obliged to follow, as opposed to 3,300 pages of prescriptive regulations in the United States. He has commented, "In Britain we concentrate on the question, 'Is the reactor safe?,' rather than on the question, "Have the regulations been satisfied?'"[9]

Canada's Jon Jennekens has also noted the difference between Canadian and U.S. nuclear power regulation. Jennekens has stated, "The Canadian approach to nuclear safety has been to establish a set of fundamental principles and basic criteria.... Primary responsibiity is then placed upon the proponent to develop the competence required to show that the proposed plant will not pose unacceptable or public health and safety risks."[10] In a veiled reference to U.S. practices, Jennekens continues, "Under no circumstances will this program of documenting regulatory criteria, principles and basic requirements be carried to the point of imposing a 'design by regulation' approach. The primary responsibilty for safe design and operation rests with the licensee, and every effort must be made to guard against destroying his initiative and ingenuity."[11]

Still another example is in Sweden where officials have noted "the small [regulatory] staff reflects the philosophy to avoid detailed regulation. The main task is to set goals, review their proposed technical solutions, and audit the quality of performance."[12]

For those of us who have grown accustomed to the prescriptive nuclear regulation in this country, the regulatory philosophies expressed above, at first, appear hopelessly naive and feeble. How can so much decision-making fall within the discretion of corporate management, when the public stakes in these decisions are so enormous? Aren't the public regulatory bodies in these countries simply abdicating their responsibilities?

A more careful reading and examination of these philosophies, however, provides yet another impression. Their regulatory styles, though different from that in the U.S., may be appropriate, given the nature of the nuclear industry in these countries. Specifically, the nuclear industry is a good deal more consolidated in these countries, than in the U.S. and therefore, the level of performance is less varied, and more consistent. Even more important, however, when we look at the content of regulation we find that several countries require higher safety design standards than those in the U.S. In other words, in many cases the design performance standards or requirements for reactor safety are a good deal stiffer.

In Germany and Belgium, for example, containment and reactor pressure vessels are required to withstand the impact of an aircraft crash directly on the buildings. As a result, containments are stronger than those found in the United States. New German and Belgium reactors are also required to have a dedicated, bunkered, heat removal system as a second line of defense--another feature not required at American reactors. Sweden, in addition to Belgium and West Germany, has adopted a series of additional performance criteria not found in the U.S.: e.g., (1) the "30-minute" criterion that stipulates no operator interference should be required in the first 30 minutes of a reactor upset; (2) the "N-2 criterion" stipulating that the reactor must be safe during an upset condition even though one safety system is out for maintenance and another is incapacitated.

The result of the requirement for greater safety margins in the design of nuclear reactors, is a less intrusive regulation in day-to-day operations. Once regulators verify that reactors have been built to design standards, less oversight is required to ensure public safety. This implies greater regulatory input in the beginning (construction stage), and less thereafter (operational stage). One reviewer has noted "the one situation where foreign regulatory requirements typically exceeds those of the United States is in the area of technical review and approvals of the engineering design prior to construction."[13] Putting this situation in slightly different terms, the U.K.'s Marshall has stated that British regulators "are much nastier to us before we get the license and much nicer to us after we get the license."[14]

It is true, therefore, that United States and foreign regulatory practices differ in important respects. It is not accurate, however, to label one "tougher" than the other. Greater levels of engineered safety allow for less regulatory intrusion once the reactors are operating. This is a trade-off with interesting implications for the U.S. nuclear industry and one that will be explored in the subsequent sections of this paper.

II.

STANDARDIZATION

The nuclear industry in this country appears to believe, in principle at least, that standardization of its product is the key to reducing regulatory interference. It is often noted that nuclear plants in this country have been built in a "one-of-a-kind" manner. For the most part, this has resulted from the diversified and independent nature of the nuclear industry--namely four nuclear steam supply system (NSSS) vendors, each with its own preferred light water reactor variant; roughly 12 independent architect-engineers (A-E) responsible for producing the balance of plant; and approximately 50 separate utilities charged with operating the plants. The results of this institutional smorgasbord, therefore, have been nuclear power plants that differ quite substantially from one another, with each reflecting the desires and predilections of the particular combination of NSSS, A-E, and utility. This heterogeneity requires independent and sometimes lengthy review requirements on the part of the safety regulator. Nor has the timeliness of this review been facilitated by the "design as you go" approach often taken by the industry. The absence of complete designs at the licensing review stage invites greater regulatory prescription.

Lester has stated, "The main barrier to increased standardization stems not from technical problems but from the current structure and organization of the industry."[15] In other words, the numerous companies within the industry have, up to this time, been unwilling to sacrifice their own perceived competitive advantages for the sake of standardization. As stated previously, the NSSS vendors have their own respective preferred light water variants, individual A-Es approach plant construction differently, and utilities frequently seek to influence design on the basis of unique meteorological, seismic, and hydrological conditions at the site. Lester goes on to say that what is needed within the industry is the formation of consortia including specific NSSS vendors, and A-E and component manufacturers, for the design and engineering of the entire safety related plant (or through an A-E taking a stronger and more comprehensive role in reactor design). It would also require that utilities be willing to purchase a reactor essentially as if it were a stock item ordered through a catalogue.

THE FAA MODEL

Assuming that the nuclear industry itself is willing today to move seriously to standardization, and anti-trust barriers can be overcome, benefits would only accrue if regulatory practices were to take cognizance of this development and change accordingly. The change anticipated and desired would be a movement to reactor "certification," whereby the NRC would give its approval to certain reactor designs even prior to application for construction. By placing its "seal of approval" or certifying standardized designs, the NRC would be foreclosing, except in the case of major new developments, further design prescriptions in the course of actual licensing and operation.

Reactor certification could function in a manner similar to aircraft certification carried out by the Federal Aviation Administration (FAA). The FAA, after its own review of new aircraft designs, awards "airworthiness" certificates. This certification allows the aircraft to be built as designed, in accordance with the regulations and procedures valid at the time of certification. Constantly changing regulatory requirements imposed during construction, and even operation of the aircraft, therefore, are ruled out except when exceptional operating experiences indicate the need for change (e.g., the DC-10 experience). Because of this policy, the public flies on airplanes of differing vintage and safety standards--DC-3s as well as Boeing 767s. DC-3s are considered safe, and Boeing 767s even safer.

The nuclear industry today is in effect seeking a "power-worthiness" certificate from the NRC equivalent to the FAA's "airworthiness" certificate. In the most recent NRC-sponsored licensing bill before Congress, the NRC is asking for authority to certify approval of standardized reactor designs. After certification, the NRC would be prohibited, for a period of 10 years, from requiring modifications unless "a modification is required to protect the public health and safety or the common defense and security and that the modification proposed will substantially enhance the public health and safety or the common defense and security by improving overall safety or security of facility operations."[16] Through this legislative authority, a much heavier burden of proof would be placed upon the NRC than currently exists to justify the imposition of design modifications.

With a "power-worthiness" certificate in hand, the licensing period for nuclear reactors would, presumably, be reduced substantially. During the actual licensing period, the NRC would be able to restrict its review to site-specific and compliance concerns, since the reactor design review would have been handled previously in a generic review setting. Reducing licensing time (and thereby money) and enhanced regulatory predictability would be the primary benefits derived from certification through standardization. There could also be safety benefits resulting from shorter learning curves and the easy transfer of operating experience from one reactor to another.

The NRC and nuclear vendors have traveled part of the way down the certification and standardization path during the 1980s. Three of the four NSSS vendors have produced standard reference models or designs of the reactors they currently offer, for NRC pre-application approval.* The NRC has reviewed these models to determine whether they should receive a final design approval (FDA). The issuance of an FDA would allow the licensing applicant to dispense with construction licensing reviews and hearings devoted to the safety of the nuclear steam supply system. Operating licensing reviews of the system would be limited to determining whether the system had been built as designed.

Whether the issuance of FDAs will result in significant savings, remains to be seen. There have been no utility orders of FDA reactor designs, so it is impossible to form a judgment based on experience. Savings could also be contingent upon the scope and detail of plant standardization, with greater savings accruing to the more detailed designs and to those integrated with balance-of-plant designs. Moreover, the FDA is not quite the equivalent of a "power-worthiness" certificate, as it does not specifically preclude the imposition of backfits.

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*The current reactor design reports submitted for NRC approval are RESAR-90 (Westinghouse), GESSAR II (General Electric), and CESSAR (Combustion Engineering).

THE EPRI INITIATIVE

Whereas the NSSS vendors still hold out hope for the FDA certification process, when combined with licensing reform, the utilities are far less optimistic that nuclear power's problems can be resolved in this manner. The seven-year absence of utility orders for nuclear power plants can be attributed to several factors (e.g., a surplus of electrical generating capacity, severe cash flow problems), but certainly one prominent factor is disillusionment with the technology and its regulation as they now exist.

A study of utility perceptions of existing reactor technology carried out by the Electric Power Research Institute (EPRI) in 1982 revealed that utility managers had plenty to criticize.[17] They indicated that nuclear plants had become too large, complicated, and unnecessarily difficult to operate. They pointed out that existing nuclear reactor designs were patched together through years of accumulated regulations. While they were satisfied that light water reactor concepts were sound, they listed many areas where the designs could be improved. The flaws in reactor design combined with never-ending regulations that pushed the price tag to levels never anticipated, produced a strong aversion to further nuclear investments.

Faced with this gloomy prognosis, EPRI recently initiated a five-year, $20 million program it calls the Advanced Standardized LWR Industry Program. This program is devoted to redesigning, standardizing, and simplifying the light water reactor, such that, when combined with regulatory reform, nuclear power can once again become a viable energy option. It is interesting to note that it is the customers, the utilities, that are taking the lead in this program. EPRI's John Taylor has stated, "We believe that utilities should stipulate in detail their requirements for a nuclear plant on the basis of their own extensive construction and operating experience rather than relying primarily on the suppliers."[18] Reactor vendors and A-Es have agreed to participate in the program, but it is EPRI that will provide its direction.

The major goals of the EPRI project are to derive conceptual designs for a light water reactor that will: (1) be economically competitive with coal-fired power stations; (2) have a construction cost of $1600/kw and a required construction time of 6 years or less; (3) be simpler, and easier to maintain and operate; (4) gain NRC approval by 1989. Clearly, the electric utility industry is not content to see the nuclear option wither or to sit back and let others shape the nature of the choices open to them. Questions remain, however, over how or whether EPRI's program recommendations will become integrated within the reactor designs of NSSS vendors. Will the designs produced through this exercise find enthusiasm among the reactor vendors and A-Es? Moreover, what impact will NRC approval of an advanced, simplified light water reactor conceptual design have upon the actual licensing of reactors? These questions will remain unanswered for the time-being.

The basic purpose of the EPRI initiative should be kept in mind. It is intended to produce a reactor design that can be licensed and deployed in the 1990s, when possible electricity shortages loom. Exclusive reliance upon LWR designs, therefore, is explained by the relatively short time perspective adopted by the investigation. No major innovations in the technology, or in the regulation, can be expected if short-term concerns are dominant.

A regulatory system patterned after the FAA certification model seems appropriate when viewed in this time frame. The modified and simplified LWR design would be brought before the NRC to receive its review and ultimate blessing. Upon attaining its FDA or "power-worthiness" certification, the design would presumably be exempt from further review and modification (over a period of a decade, at least), except for extraordinary circumstances derived from operating experience. This approach, based upon the maxim, "industry proposes and the regulator disposes," would be consistent with FAA practice, and with how the nuclear industry views the proper industry-regulator relationship.

If, however, one takes a longer view of the nuclear future than EPRI, say one spanning decades rather than a single decade, the FAA regulatory model seems less appropriate. The essentially reactive or passive FAA regulatory role may be appropriate for aircraft technology at this time, but appears less germane to nuclear technologies in the long run. The basis for this judgment is given in the following paragraphs.

ACTIVE REGULATION

Certain similarities between aircraft and nuclear power technologies have attracted many within the nuclear industry to seek parallel regulatory regimes as well. Both the aircraft and nuclear power industries deal with a complex technology whose failure could lead to catastrophic human consequences. Public safety is, therefore, of paramount concern in both. Each airplane or reactor constitutes a sizable capital investment, requiring that the technology function well over an extended time period.

Despite these similarities, there is a crucial difference relating not to the technologies themselves but to public reaction to them. Specifically, the vast majority of the public now finds the risks incurred in airline travel acceptable. They perceive clear benefits associated with airline travel that cannot be duplicated through any other form of transportation. No controversy exists, therefore, over the need for large-scale passenger air service. Public acceptance of nuclear power, however, is far more limited and conditional. A substantial portion of the population feels that the risks associated with nuclear power are excessive relative to the benefits (electricity) that can be derived through other, albeit imperfect, technologies. Widespread public fears of nuclear power may be exaggerated or overblown relative to actual risks but no one should question their pervasiveness or their depth. Slovic, et al. have documented the intensity of nuclear power fears in their public surveys, revealing how nuclear power ranks high across several dimensions.[19]

If long-term public acceptability is the goal sought, then, FAA-type regulation may not constitute a sufficient regulatory response. The FAA deals with a technology well accepted by the public and hence does not need to advance safety standards or requirements with the vigor of the NRC. In fact, the FAA still retains a promotional role along with its safety responsibilities--a role the NRC was explicitly required to forgo at its founding in 1974. Not all FAA observers have been happy with its reactive regulatory role. Miller has stated "...modern safety has been implemented in civilian aviation only as much as the manufacturers or operators chose to do so.... The FAA has followed, not led in the safety engineering and management field, if, indeed, they have even been in the parade at all."[20] Poole has concurred, stating that airworthiness Federal Air Regulation (FAR) design standards frequently lag behind the technological state-of-the-art, and constitute only a minimum safety standard.[21]

The EPRI and NSSS standardization efforts, based upon the FAA certification approach, fail as long-term approaches to nuclear power since their driving force is economic savings rather than greater safety margins. When utilities speak of risk, they normally refer to economic or investment risk, not public safety risk. What EPRI is seeking is a simpler and cheaper LWR with no degradation in current levels of safety. While EPRI's emphasis on modifications in existing technology is understandable, and even desirable in light of possible electricity shortfalls looming a decade from now, it is not a sufficient response to the long-term public acceptance problem. If nuclear power is to have a long-term significant impact as an energy source in this country, it must gain the acceptance of a broader spectrum of the public. Certification by the NRC of an industry-sponsored design is unlikely to accomplish this task. Over the long-term, therefore, enhanced safety must be addressed directly and not derivatively.

The NRC must take a more active role in the design of nuclear reactors than the FAA has with respect to commercial aircraft--active not in a prescriptive sense, but in setting forth performance objectives or goals for the industry to achieve. An example of a more active regulatory role can be found in the experience of another regulated industry--the automobile industry. A brief review of automobile regulation and its relevance to nuclear power will be the focus of the next section.

AUTOMOBILE REGULATION

Prior to the mid-1960s, the auto industry was essentially free of federal regulatory controls. This situation changed abruptly in 1966 when Congress passed the National Traffic and Motor Vehicle Safety Act. The origins of the 1966 Act can be found in the successful crusading of Ralph Nader (publication of his book, Unsafe At Any Speed), and the mass public approval that it evoked. Prior to Nader's crusade, calls for greater levels of automobile safety focused primarily on altering driver behavior. Nader, realizing the difficulties in changing individual behavior, called instead for technical changes in the automobile.

The 1966 Act called for higher safety performance standards in automobiles. The emphasis Congress placed upon performance standards, as opposed to design standards was deliberate. Mills has pointed out that the legislative history of the Act clearly calls for the setting of performance standards as follows:

> Unlike the General Services Administration's procurement standards, which are primarily design specifications, both the interim [safety] standards, and the new and revised [safety] standards are expected to be performance standards, specifying the required minimum safe performance of vehicles but not the manner in which the manufacturer is to achieve the specified performance.
>
> The Secretary [of Commerce] would thus be concerned with the measurable performance of a braking system, but not its design details. Such standards will be analogous to a building code which specifies the minimum load-carrying characteristics of the structural members of a building wall, but leaves the builder free to choose his own materials and design. Such safe performance standards are thus not intended or likely to stifle innovation in automotive design.[22]

In the Act, Congress gave authority to the executive branch to set safety performance standards that were "practical." The National Highway Safety Transportation Administration was created for this purpose, and the subsequent regulation of these standards.

Despite the admonition that performance standards be "practical," Congress clearly sought to push the auto industry to higher than existing safety levels. Its intent is even clearer in subsequent automobile legislation, particularly in the areas of air emissions and fuel economy. In 1970 Amendments to the Clean Air Act, Congress even wrote the performance standards into the law--requiring a 90 percent reduction in automobile tailpipe emissions (of the 3 major pollutants, carbon monoxide, hydrocarbons, and nitrogen oxides) by the year 1975. In the Energy Policy and Conservation Act of 1975, Congress prescribed fuel economy standards that automobile fleets would have to meet, the last being a standard of 27.5 miles/gallon by the year 1985. In each of these cases, Congress was forcing innovation by calling for automakers to achieve standards not then attainable by existing technologies. Performance standards, therefore, were combined with a "technology-forcing" strategy.

The designation of fuel economy and emission performance standards presented no technical problem since they could be identified in units easily grasped by the public and subject to measurement. These units were miles/gallon consumed for fuel economy measurement and gram of pollutant emitted/mile for emission standards. Unfortunately, there was no equivalent unit of measure that could be used to calibrate and measure safety performance standards for the vehicle as a whole. While we do find performance standards used in certain sections of the car (e.g., the "crashworthiness" of automobile bumpers), prescribed design or equipment standards have been far more prevalent--leading to such post-1970 safety requirements as seatbelts, an energy absorbing steering column, and dual braking systems.

The establishment of precise performance standards where applicable, and equipment standards where not, has certainly not led to any diminution in automobile regulatory controversy. The industry-regulator relationship is clearly adversarial. Mills has stated that when performance-based regulation supplants prescription-based regulation, controversy does not go away; rather it simply shifts from one arena to another.[23] He states that while fuel economy performance standards can be stated in a brief paragraph, the testing procedures promulgated by the Environmental Protection Agency to measure actual performance run approximately 200 pages in the Federal Register. Measurement of performance, therefore, is not always a straightforward matter.

Much of industry's discontent, of course, stems from the "technology-forcing" nature of the regulation. The automakers claim that too much has been expected of them within a relatively short time span. Automakers were clearly not able to meet emission standards during the 1970s. Despite much protestation, they have been relatively successful in meeting scheduled fuel economy standards. Automakers have successfully resisted the imposition of air bags in automobiles for over 15 years. Though some automaker opposition to this regulation is based upon the fundamental belief that government should not "meddle" in the affairs of markets, much opposition is simply more pragmatic; i.e., a feeling that the industry is being pushed too far, too fast. Presumably, much of the opposition to the "technology-forcing" regulation would be relaxed if the deadlines for conformance with the regulations were pushed back a decade or more.

It may be useful at this time to briefly summarize the two regulatory paths set forth as possible models for future nuclear power regulation. The first path is based upon the airline regulatory model and has found increasing favor within the nuclear industry. This might be termed a "certification" or "reactive" approach whereby industry takes the design initiative and presents a standardized design to the regulatory body which then rules upon its adequacy. The industry is the initiator and the regulatory body the reviewer ("industry proposes, and the regulator disposes"). The second path, based upon the automobile regulation model, envisions a much more active and technology-forcing role on the part of the regulator. The regulator (or Congress) sets design goals, and industry determines how these goals can best be achieved. To the extent possible, the regulator avoids telling industry how to achieve the goals or standards, but rather devotes its efforts to assessing whether the stated goals are indeed being achieved.

The standardized reactors now being designed by the nuclear industry itself for NRC certification are unlikely to put public fears to rest. Active government direction and a more technology-forcing approach stand a better change of gaining public legitimization for nuclear power than the industry-preferred approach. Thoughts on how to achieve or implement a technology-forcing policy are provided in the following section.

III.

TECHNOLOGY-FORCING REGULATION

As noted previously, it proved impossible for automobile regulators to set an overall quantitative safety standard that would apply to the entire vehicle. Lacking an easily calculated unit of measure (comparable to auto emissions or fuel economy) for safety, regulators were forced to compromise their desire for pure performance standards, and rely upon the promulgation of required equipment standards. Much of the adversarial relationship that exists between the regulator and automaker is accounted for by disputes over prescriptive requirements (e.g., airbags).

Regulation of nuclear power plants runs a similar risk. There is no transparent, easily calculable, unit of measure relating to overall nuclear power safety performance. Hence it is not possible for regulators to set a comprehensive quantitative safety goal that the industry must achieve at some time in the future and expect to be able to measure the attainment (or lack thereof) of the goals. Finding an appropriate balance or compromise between performance and prescription must be an issue of high priority.

Much discussion in recent years has focused upon the use of probabilistic risk assessment (PRA) in the measurement of safety goals. PRA is a computer based technique utilizing "event tree" or "fault tree" analysis to derive calculable probabilities for accident sequences. The analyst either hypothesizes an event taking place in a reactor and subsequently calculates the probability of it producing consequences; or assumes a fault (consequence) and works backward to see how the fault could arise. The calculations are based upon computer codes containing a host of assumptions regarding failure rates for both human and mechanical components.

Virtually everyone agrees that PRA has played an important role in advancing nuclear safety. Through its disciplined and methodical approach to safety, PRA has proved a welcome supplement to conventional engineering judgment. PRA can provide valuable guidance in plant design by identifying those areas of the plant in most need of shoring up. Phung has stated, "There has been evidence that PRAs have been useful in increasing the understanding of how the various systems hang together, where the weak links are, and the costs and benefits of strengthening these weak links."[24] As a regulatory tool, PRA has proved useful in setting regulatory priorities, particularly with regard to outstanding generic issues before the NRC, and identifying high payoff research areas.

A potentially larger role for PRA was implied in the promulgation of preliminary safety goals by the NRC in 1982. The NRC set forth preliminary qualitative and quantitative goals or guidelines for the industry to achieve. A plant performance guideline was proposed to cover large-scale core meltdowns as follows: "The likelihood of a nuclear reactor accident that results in a large-scale core melt should normally be less than one in 10,000 (10^{-4}) per year of reactor operation." Despite the use of this quantitative measure, the NRC document itself cautioned against using PRA estimates in lieu of existing regulation, stating:

> Because of the sizable uncertainties still present in the methods and the gaps in the data base--essential elements needed to guage whether the guidelines have been achieved--the quantitative guidelines should be viewed as aiming points or numerical benchmarks which are subject to revision as further improvements are made in probabilistic-risk assessment. In particular, because of the present limitations in the state-of-the-art of quantitatively estimating risks, the numerical guidelines are not substitutions for existing regulations.[25]

Despite this caveat, some within the nuclear community hold out the hope that licensing on the basis of PRA analysis can eventually lead to the elimination of prescriptive regulation. PRAs covering existing reactors indicate little (if any) new technical ingenuity is required to meet the stated NRC performance guideline of 10^{-4}.

A significant segment of the nuclear community (and virtually all of the anti-nuclear community), however, has urged restraint in the use of PRA as a licensing tool.[26] The absence of empirical validation for many of the codes that comprise a PRA analysis, is perhaps the most serious objection. This means that levels of uncertainty in the analysis are particularly high and cannot be reasonably bounded by precise confidence intervals. Moreover, the calculations themselves are of such complexity that replicability of results is often not possible and never easy. In other words, the inscrutibility of the technique or methodology, particularly in view of general public standards, means that verification of industry or regulatory PRA results will be particularly difficult. Given the low credibility ranking of the industry and its regulator, the absence of methodological transparency will seriously harm the chances for any proposed regulatory changes based upon PRA. The problem, then, is not with the level at which safety goals are set, either with regard to public consequences or core-melt accidents. It does not matter whether a goal of 10^{-4} is established or 10^{-6}. The problem resides in the inability to clearly establish that the selected goal is being attained and the unwillingness of a skeptical public to accept "expert" assurances that it is being met. Budnitz has stated the technical problem as follows:

> There is a broad consensus in the technical community that the analytical methods available for determining whether such broad aggregated goals were achieved are highly uncertain in their results; they are not well enough advanced for this application. Phrased another way, it appears that there is not now an adequate technical means to calculate accurately enough whether the safety goals would be met, in the form in which they have recently been proposed by the Commissioners.[27]

Starr has captured the political/institutional dimension by stating, "Public acceptance of any risk is more dependent on public confidence in risk management than on the quantitative estimates of risk consequences, probabilities, and magnitudes."[28]

Does this mean that prescriptive nuclear regulation is inevitable? Or that a reactive certification approach is the only alternative to existing regulation? I think not. It does mean that regulations cannot be purely prescriptive or performance-based. The outline of a useful regulatory balance is described in the following pages.

GENERAL DESIGN CRITERIA

General design criteria covering light water reactors were devised in the 1950s and 1960s in order to provide regulatory guidance, and they cover virtually all aspects of reactor system design. The general design criteria became codified in 1971 when 64 separate criteria were published in the Code of Regulations (Appendix A of 10 CFR 50). Now may be the time to revisit these general design principles or criteria to evaluate their applicability to future regulatory requirements.

Specifically, it may be useful to incorporate three new principles or criteria that, on the basis of LWR experience, now appear essential to embody in future reactor design. There is growing consensus as to the importance of the following principles:

1. Public safety should be assured through the use of passive safety systems that enlist the laws of nature to eliminate risk to the general public.
2. Safety should not depend upon prompt and taxing operator response.
3. A premium should be placed on simplicity, avoiding instruments with multiple functions, cross connections, and interaction between primary and secondary systems.

While these characteristics are widely recognized as desirable in future reactor design, industry and government officials have stopped short of requiring their inclusion in future designs. What is suggested here is that the embodiment of these principles as general design criteria would provide the necessary direction the industry needs as it looks to the long-term future. In other words, it is suggested that these principles form the basis of any 21st century reactor standardization effort.

In order to provide sufficient regulatory guidance or direction, the principles listed above will have to be expressed at a lower level of generality. It is in the expression of these principles that performance-based goals should be set forth, to the extent possible. One can anticipate the absence of necessary operator intervention being expressed in such units as hours, for example; or the ability of passive safety systems to protect the reactor may be expressed in days. It may be somewhat more difficult to express the principle of simplicity in performance terms.

The important point in this approach is that the regulators (or Congress) would be establishing safety (performance) goals that are clear and demonstrable to the general public. Vendors seeking a license would no doubt have to conduct safety demonstrations to convince both regulators and the public that the performance goals would be achieved. Nothing short of a demonstration would be necessary to convince a skeptical public.

What is being suggested, therefore, is a technology-forcing regulatory approach, not unlike that practiced in the automobile industry. Regulators or Congress would provide performance goals for the industry to achieve, but would not, to the extent feasible, tell the industry how to achieve these goals. The problems that have afflicted automobile regulation relate primarily to the time frame within which significant design changes were required. Congress clearly required auto emission changes in an unreasonable time frame. The requirement for immediate safety design changes in the 1960s meant reliance upon then state-of-the-art technologies.[29] The antidote to this problem is not to discard the technology-forcing approach altogether, but to simply allow more time for its implementation. The NRC might, for example, adopt a policy setting forth performance goals as suggested above, and require their incorporation in licensing approval after the year 2005. This would provide vendors with both direction and time to meet new regulatory requirements.

The distinction in time should be made clear. The EPRI "certification" approach based upon modest changes in existing light water reactor technology is an adequate short-term approach to meeting electricity needs through nuclear power. It is unrealistic to expect the industry to embark upon promising but untested and radical departures from conventional reactors when the possibility of electricity shortages in the 1990s exists. A short-term approach, however, should not preclude a more fundamental long-term industry/regulatory effort. Several reactor concepts have been identified that have the potential of being demonstrably safe, constituting virtually no risk to the general public.[30] Time is required, however, to both confirm these safety claims and to demonstrate economic feasibility. By setting desired and required performance standards well in advance, industry and regulators will have the time to implement ambitious, but necessary, goals. Setting regulatory requirements twenty years into the future may strike some as operating within an excessively long-term perspective. Yet when viewed in terms of nuclear power's promise of a virtually inexhaustible energy source, twenty years is but a moment. Steps must be taken today to ensure that long-term future.

IV.

CONCLUSION

Current and past regulatory and licensing reform efforts have been flawed since they have addressed only the concerns of industry, and neglected the concerns of a general public worried about nuclear power's safety. Efforts to "streamline" the licensing process for industry--involving measures such as one-step licensing, pre-licensed sites, and a prohibition on backfitting--have failed to garner Congressional support because they deal with only part of the problem. Yet many of the industry's complaints about the prescriptiveness and open-endedness of nuclear regulation today are legitimate and need to be resolved before further plant orders will be forthcoming. In order to convince Congress to act it must be shown that industry and larger public concerns can be reconciled in a common approach.

The basis for such an approach may rest in a tradeoff between the requirement for higher design or performance standards in new reactors (satisfying public concerns) and a prohibtion against the intrusive and prescriptive regulation of these reactors (satisfying industry concerns). This tradeoff, to a limited extent, is already embodied in the nuclear regulatory policies of some European countries. It is time for either Congress or the NRC to establish clear and ambitious performance standards ("safety goals") for the licensing of future reactors--safety standards that would make reactors virtually immune from a core-meltdown accident and would constitute no risk to the general public.

A mixture of performance and prescriptive standards for new reactors would be based upon the criteria of passive safety, operator flexibility, and reactor simplicity. The practical expression of these criteria as standards should be undertaken with great care and in consultation with industry and public representatives. Much future controversy can be forgone if special attention is also devoted to the means that will be used to measure the fulfillment of selected performance standards.

This technology-forcing approach must be placed within the proper time frame. While a number of "inherently safe" reactor designs have already been identified, it will take considerable time and expense to adequately test and develop incipient reactors for both safety and economic performance characteristics. Adequate and meaningful demonstrations must be part of this testing period. The introduction of ambitious licensing requirements, therefore, should be phased in over time.

Technical fixes should not be viewed as capable of resolving all the issues facing nuclear power today. Outstanding operation and management of existing reactors is essential. Nuclear wastes must be managed expeditiously. If used judiciously, however, technical fixes can be a central element in an effort to restore the health and vigor of this valuable energy option.

FOOTNOTES

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IMPROVING THE REGULATION OF NUCLEAR POWER

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The NRC has achieved a unique distinction among governmental regulatory agencies. It is being accused of simultaneously over-regulating and under-regulating nuclear power. Usually such charges are evidence that the agency is taking a middle course and simply not satisfying either extreme. But there is mounting evidence that with the NRC there may be some truth in both charges.

The nuclear option is certainly in deep trouble. The Three Mile Island (TMI) accident shattered the general public's confidence in the safety of nuclear plants. And in the aftermath of that accident the design and operation charges to improve safety have combined with other factors to send the cost of nuclear plants through the ceiling. As a result, utility executives, financial institutions and the consuming public have all lost confidence in the economics of nuclear power. And there is a growing perception that no more new nuclear plants will be ordered in the U.S. for a long, long time--perhaps never.

A THRESHOLD QUESTION

Why Should the Nation Preserve the Nuclear Option?

A threshold question that must be addressed before considering a program to reform the nuclear option is "Why bother?". In light of the concerns about nuclear safety, waste disposal, proliferation, and the cost overruns that are creating rate shock, the burden of proof falls pretty heavily on anyone suggesting that the public would be well served by rescuing the nuclear option. Why not let it die and let oil, natural gas, coal, renewables and conservation supply our energy in the future?

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These questions require a persuasive answer. Such answers exist but, unfortunately, the pro-nuclear advocates of regulatory reform are not making them. In essence, I believe the public interest reasons for a reform package are as follows:

1. In this pre-solar age, which will certainly last many more decades, the economic and national security problems from continued reliance on oil imports, the damage caused to the environment by acid rain and other forms of air pollution from burning fossil fuels as well as the CO_2 buildup all combine to make it prudent to preserve a safer nuclear option.

2. Reactor concepts that are much safer and economic can probably be developed if the nation decides to make the necessary investment.

No one wishes to build new nuclear plants on the basis of the current reactor designs in the U.S. because of concerns about safety, extensive backfits, and cost overruns that destroy the economics of nuclear power. A better nuclear product is both necessary and technically feasible if the dangers posed by fossil fuels are to be alleviated.

The Second Nuclear Era, recently published by the Institute for Energy Analysis in Oak Ridge, Tennessee, documents the opportunities for developing advanced reactors that incorporate the lessons learned about the need to design more safety and simplicity into the reactors. The argument for regulatory reform, in my opinion, can be persuasive only if there is a parallel commitment to the development of a far safer and more economic nuclear product than the existing reactors. Only with the prospect of such a product does the nuclear power option appear attractive enough to be worth preserving.

Air Pollution

One of the best public interest reasons for rescuing nuclear power is the air pollution concerns with the fossil fuels that would otherwise be used, especially coal. Unfortunately, the utilities are not making this argument very forcefully since they are still trying to persuade the public that the coal they burn doesn't cause acid rain (and if it does, it is too expensive to clean up). They are opposing legislation to reduce sulphur oxide emissions.

The acid rain problem and other forms of air pollution from the burning coal are quite serious. The prevailing scientific opinion is that emission of SO_2 needs to be cut in half as promptly as possible. Certainly much safer, economic nuclear power offers a large part of the answer to that worrisome problem in the years ahead.

America today faces dying lakes and forests due to air pollution. Even the most determined opponent of acid rain legislation must concede that some form of air polluiton is the villain. To the extent a combination of conservation, solar energy, and nuclear power can be substituted for fossil fuels, we will have cleaner air. And the American people in every poll voice their overwhelming support for cleaner air.

One of the fundamental advantages of nuclear power is that it produces virtually no air pollution. If the concerns over safety and disposal of wastes can be satisfied--and the technical solutions are there if they are pursued--then nuclear power can be advanced as a relatively clean alternative to help in the fight for clean air.

Nuclear power is also a solution to a more remote but potentially disastrous problem--the prospect of climatic changes due to the buildup of CO_2 in the air. It is a fact that the buildup is taking place. In theory it could result in a warming of the earth that might, over time, melt the polar ice caps and thus flood vast coastal areas or change climate sufficiently to play "russian roulette" with agriculture and living species. Thus far, no such effects have been observed and scientists doubt that disaster is imminent; some doubt it will ever come. But if the build-up continues there is a scientific basis for fearing that the worst might happen. The truth is that the worst could happen and no one knows whether it will or not. It would therefore seem prudent to moderate the growth in fossil fuel consumption. To do so will require the fullest possible use of renewables and nuclear as well as a strong conservation ethic.

National Security

America has gone back to sleep on the energy issue, forgetting that about one-third of its oil is still imported. Our deep involvement in the Middle East--including loss of life in Lebanon--is linked to oil dependency. The U.S. and its allies are so dependent on Middle East oil that we are committed to go to war to keep the oil flowing.

Yet there is a false perception in the land that the energy crisis is over--that we won "that war." The facts are different. We import about 4 million barrels of oil a day, the same 30 percent of total as a decade ago. And at least as much comes from outside the Western Hemisphere as a decade ago.

It is true that the U.S. is somewhat less vulnerable to an embargo because we have built up an oil stockpile and are importing less from the Arab nations. But in 1974 and again in 1979 we learned that the greatest threat from oil imports is not an embargo but a sharp increase in price. A small shortage in the world market has and can cause prices to skyrocket and our economy to take a nose dive. And in the event of a shortage, we know that all the oil producers, whether they are members of OPEC or not, will charge us those sharply escalated prices.

As the world's economies recover from the deep recession of recent years, demand for oil could, within a decade, again begin to outstrip production. We are becoming vulnerable to a sudden cutback by any major producer. Sudden, sharp price increases and resulting recession-inducing oil shocks are possible in the years ahead.

Whatever one's view about the risk may be, no one should doubt that our oil dependency poses a grave threat to world peace. The U.S. policy initiated by President Carter and reiterated by President Reagan is to use military force to keep the oil lifeline open. And we have recently made it clear in Lebanon and in the Persian Gulf that America will stand by that commitment.

Surely the national interest would be served by limiting U.S. dependence so that it would not be a cause of war or economic ruin. Nuclear power could play an important role in achieving greater self-sufficiency as nuclear-powered electricity replaces petroleum in more and more industrial applications. Perhaps some day electric vehicles can replace gasoline-powered cars. But electricity is substitutable today for at least 30 percent of the oil that is imported. As we proceed with the further mechanization and computerization of America, electricity becomes a key to productivity. Thus replacing petroleum can solve a national security problem while also facilitating economic prosperity.

There is little doubt that America could reduce oil imports if there were a national policy to phase down imports over the next few years to a very small amount that poses no economic or national security threat. Such a policy would require a reasonably safe and economic alternative. Nuclear power could be perfected to help fill the gap, not instead of conservation or renewables but simply to replace oil without adding to air pollution from coal.

Savings to Consumers

In light of the cost of overruns recently incurred by nuclear plants, it may be presumptuous or even foolish to suggest that one reason to save the nuclear option may be to save consumers money. But there is good reason to believe that new nuclear plants designed for safety, simplicity and economy in the years ahead could produce electricity below the cost of fossil-fueled plants, especially over the life cycle of the plant. If coal is forced to carry the whole load, economical supplies will be fully utilized and the price of coal will escalate rapidly as new mines are developed. Nuclear power from "better" reactors could be competitive with coal by the turn of the century, and could save consumers billions of dollars and also avoid a lot of environmental damage in the decades that follow.

An Overview of Nuclear Power Regulation

The much discussed shortcomings of the NRC regulatory process--which is the subject of this paper--are but part of a vast array of concerns about nuclear power. In addition to plant safety and economics, there is widespread concern about the proper disposal of nuclear wastes. Some people fear that the proliferation of nuclear weapons is facilitated by nuclear power plants that produce weapons-usable material in their waste products. Some oppose nuclear power because the centralized controls and surveillance of people required for its safety is contrary to the more decentralized, independent society they prefer.

A perfect NRC would help a lot but most of these concerns would persist. Regulatory reform is therefore not the magic wand that would automatically restore the attractiveness which nuclear power once had nor would it bring forth a rush of orders for new nuclear plants.

It may be fair to state that the NRC regulatory process largely reflects the real problems with the product itself that the accident at Three Mile Island (TMI) so dramatically revealed. No one seriously doubts that some of the additional engineered safeguards the NRC has mandated were needed to correct the deficiencies revealed by TMI. Nor is there any doubt about the need for upgrading the skills of plant personnel. With the benefit of hindsight it is now clear that before 1979 the utilities and the NRC gave insufficient attention to safety. The flood of the new regulatory requirements by the NRC since then has been a reaction to very real shortcomings in the nuclear product itself.

Nevertheless, the problems with the regulatory process appear to be a serious, central concern, even if they are but part of a larger picture. Making a public judgment that nuclear plants are safe enough is the NRC's job. Yet the public has thus far been presented with no persuasive evidence or judgments by the NRC that could convince concerned citizens that nuclear plants are "safe," or even that the deficiencies revealed by TMI have been corrected. The only group telling the public that nuclear plants are "safe" are the utilities and the nuclear industry. Their advertising campaign is at best unconvincing. It is contradicted by a seemingly never-ending series of media reports of nuclear plant incidents and infractions of NRC rules and resulting fines. A casual observer could easily conclude that another big accident might occur at any time. Indeed, there is a wide range between the best and worst plants with regard to safety, and the poor performers may well still constitute more of a risk than is acceptable or necessary.

Previous discussions of regulatory reform have centered around steps to shorten the licensing process for new plants. But utility executives and the public alike are not likely to support new plants--even of a better design--unless we can do a better job with the nuclear plants already built. And serious shortcomings exist in the regulation of existing plants--shortcomings that are contrary to the nation's interest in maximizing the safety and the economy of operation. This paper will therefore deal with the basic reforms I feel are important to improve the functioning of the NRC with respect to existing plants as well as new ones.

While the public perceives that the NRC is too soft on the nuclear plants, the utilities perceive the NRC as the prime villain mandating a seemingly endless array of backfits and detailed rules and regulations that increase costs and actually reduce safety. As a result no one knows how much a nuclear plant will cost except that it will be high and take a very long time to complete.

There are new designs for nuclear plants that could dramatically improve safety and the economics as well. But the utilities do not believe that the regulatory process will reflect the improvements in the safety of the nuclear product and permit these reduced costs. Until the regulatory process is reformed to provide assurance that these reduced costs can be achieved, new plants incorporating those improvements are not likely to be ordered.

The utilities raise similar questions about whether the NRC's current approach to regulation will achieve the greatest safety over time. The NRC is requiring workers and managers to respond to a great many very detailed rules and regulations. In effect, the NRC tells the utility how to run its plant. The detailed rules, and not overall safety, are the focal point and get all the attention.

The NRC, in effect, regulates by prescribing a "cookbook" and appears to care more about how the "meal" is prepared rather than how it finally turns out. The alternative in most other nations is to lay down performance standards to assure safety and let the utility suggest the detailed procedures for meeting those standards in their own way.

Plant personnel at U.S. nuclear stations spend much of their time reacting and responding to the NRC's detailed rules and regulations. In many plants they are so busy complying with the "cookbook," they have little time left over for discovering and correcting safety-related deficiencies on their own, which may well be more significant than concerns identified by the NRC.

The regulatory failures, both real and perceived, are certainly not the beginning or the end of nuclear power's troubles. But it is clear that if the views of either side in the regulatory debate are correct, we face either an end to nuclear power, grave risks of a nuclear accident, or a waste of billions of dollars in unnecessary investments and downtime (or all of the above). It is obvious that the concerns about NRC regulation expressed by both sides of the debate must be examined and the regulatory process reformed as necessary to alleviate these concerns.

PROBLEMS WITH NRC REGULATION

The NRC Has Not Assured the Public That Nuclear Power is Safe Enough

TMI exposed the NRC as an agency in 1979 that had not done enough to prevent an accident which frightened the nation, inflicted huge financial damage to utilities and their customers, and underscored to investors the financial risks in nuclear power. And while the NRC's response has been energetic, the public has little or no basis to conclude that enough has been done to ensure that the public will not be harmed.

The NRC has not established any standard of how safe is safe enough, at least not in any definitive manner that has been presented to the public. Thus no nuclear plant has been found to be "OK" insofar as TMI issues are concerned. And there are still a number of safety issues that the NRC considers unresolved. Presumably these issues do not pose serious safety risks. Yet how can one be sure?

What has been occurring is a steady flow of news stories about relatively small accidents in nuclear plants, fines by the NRC for violation of NRC regulations, failure to complete the cleanup at TMI, concerns about the quality of construction at numerous plants, questions about the competence of the management at several plants, and massive cost overruns and plant cancellations. The press has been doing what comes naturally in the wake of TMI, writing about items that are news--bad news, that is. It is not news when a nuclear plant is routinely and economically grinding out the kilowatt hours. It is only news when somethings goes wrong.

A concerned citizen following the issue of nuclear power in the general media would have good reason to conclude that nuclear power was still dangerous and was uneconomic as well. And while polls on the subject differ, they show at least 40 percent of the American people now believe nuclear power is dangerous and oppose the construction of more nuclear plants.

It is important to evaluate the difference between the understandable public perception of the NRC as not doing enough and what has in fact happened since TMI. On existing plants (no new plants have been ordered), several points can be made:

1. The NRC has not yet defined an overall safety standard for each plant with a timetable and program for meeting it.

2. The NRC has, in fact, mandated an imposing number of additional engineered safeguards that in large part have already been backfitted into existing nuclear units. Investments may well average around $100 million per reactor. Analysis suggests they have reduced the risk of a TMI-type accident by a considerable margin.

3. The skills of power plant operators have been improved considerably by extensive retraining of existing operators and much more intensive requirements and training for new operators.

4. The formation of INPO is enabling the utilities to learn from each other and begin to do more self-policing.

This information on plant improvement has not been brought home to the public by any creditable source. Indeed, while most plants have become safer since TMI, public opinion has been moving steadily in the opposite direction so that at present more people are opposed to new nuclear plants than were opposed in 1979 right after TMI.

A major reason for this trend may be that the concern over safety has been merged into a growing concern that nuclear power has become uneconomic. Recently the issue of "rate shock"--huge rate increases caused when nuclear plants that cost several times as much as their estimates go into the rate base--is giving nuclear power more of a "black eye" than safety concerns. These cost overruns are by no means isolated--they are pervasive. And the most acute cases in Washington, Michigan, New Hampshire, and Long Island are plunging the finances of utility owners onto the brink of bankruptcy.

The economic cloud over nuclear power merges with the safety concern since some, but by no means all, of the cost overruns were induced by the backfits and delays caused by inadequate concern for safety in the initial design--as revealed by TMI. The added safety features and delays needed to make existing designs safe enough have thus made them uneconomic. This does not necessarily mean that the technology is fatally flawed. But it does strongly suggest that new designs are vital for new plants--designs that build more safety into the plant on the front end and thus eliminate the need for the expensive add-ons that plague the existing designs.

Until a much safer and economic design for a nuclear plant is developed and presented to the public, the "economic cloud" will continue to merge with the "safety cloud" and cast its shadow over the nuclear option. Economics is vital, as is safety, because no conceivable reform of NRC regulation will persuade a utility executive to order a new plant that does not offer the prospect of saving money over available alternatives.

THE KEY ISSUE - HOW SAFE IS SAFE ENOUGH?

Since TMI, one of the central concerns that haunts concerned citizens is, can it happen again? What are the risks, and are they acceptable to the public?

The NRC has effectively avoided facing up to this issue in any definitive way. When confronted with such issues at specific plants--such as Indian Point and TMI Unit I--years go by with no clear NRC decision. It can be argued that the test under existing law is "as safe as possible," regardless of the cost. Perhaps so, but the NRC has not adopted such a test, and in fact, in the past year, has been applying a cost-benefit test to many decisions concerning backfits without much public input.

To be sure, if a clear and present danger of a big accident were perceived, the NRC would order a plant shutdown. But before TMI, that accident was considered an "incredible event" by the NRC. The public has a right to wonder whether the plants are yet safe enough to avoid an accident that will harm them. And the utilities have no standard to tell them whether they measure up.

Nuclear power is on the horns of a dilemma. Anything that does not violate the laws of nature can happen, so it is impossible to say that nuclear power is absolutely safe. And the NRC has not said how safe is safe enough so there is no opportunity to assess the risk and decide whether it is acceptable. Uncertainty thus dominates the scene.

The issue of how safe is safe enough is admittedly difficult. It requires an informed judgment. Whatever the standard, it will be criticized. But it just happens to be the essence of the NRC's responsibility. It borders on the unbelievable that after a quarter century of licensing and 6 years after TMI, the NRC has not yet squarely decided this central issue.

Resolving the issue of how safe is safe enough is central to reforming the regulatory process. For new plants it is quite clear that the reactors can be designed to be much safer than the best of the existing designs. Many of these possibilities were documented in the IEA's Second Nuclear Era study.

The risk of a major accident can be reduced by a factor of 100, at least, and thus be brought down to risks so low that the public can be expected to accept them. And in the future the so-called inherently-safer reactors, the PIUS and gas-cooled modular units can reduce the risks of a disastrous accident even further, down to the range that can fairly be called *de minimus*. What is not so clear is whether such plants can be economical and reliable. Federal funding for R&D must be keyed to achieving both safety goals and competitive costs.

The Utilities Claim That the NRC is the Problem

The utilities operating nuclear power plants feel very strongly that the NRC is destroying the economics of nuclear power and actually impairing safety. I believe it is useful to set forth their views which are based on interviews I conducted with plant managers and workers. The utilities' complaints can be summarized in the following categories.

1. An Overload of Backfits. The utilities major complaint is about the flood of mandated additions to nuclear plants that have been ordered since TMI in 1979. They claim the NRC focus has not been on improving the overall safety of the plant but rather on making a lot of "improvements." The utilities concede that some backfits were needed but argue that all backfits do not improve safety equally, some may not provide enough improvement to warrant their expense, and that the cumulative impact of all of them may actually impair safety.

The point they make is that there can be so many safety features crowded into a limited space that in an accident, the operator can be overwhelmed. And they claim the added workload on operating personnel of maintaining and operating so many add-ons may result in increasing the risk of neglect of more important safety systems.

The utilities contend that safe operation of a nuclear plant depends vitally on the operators and the entire work force in the plant. These people constitute a limited resource that is severely overtaxed by the vast array of *ad hoc* backfits required to be installed on an urgent basis. The utilities complain that in these circumstances the quality of the work suffers as does the ability to carry out routine operation and maintenance which is the backbone of a safety-first policy.

The utilities that have the most NRC violations have backlogs of as many as a thousand items they have discovered that they believe need fixing--many of them safety-related--which they have not had time to fix. Thus some of the plants that are among the poorer performers are being forced to spend most of their time carrying out NRC orders and explaining violations. They claim they do not have the time or the incentive to look for more things that need fixing or to fix what they believe is "broke." The people in the plant are really the mainline of defense against accidents. The NRC cannot hope to perform that role. But the situation that has developed makes many plant people feel they do not count.

The mandating of additional backfits has abated, but the utilities are quite uncertain about the future. They fear the worst based on past experience and therefore assume an order for a new reactor would undergo the same delay and backfit experience, and that its cost and completion date would be uncertain.

The current utility attitude was succinctly expressed by an Assistant Secretary of Energy for Nuclear Energy, who is quoted as saying that in today's regulatory environment if a utility executive ordered a nuclear power plant, "it's time to send for the guy with the net." The agenda for his successor, he says, will consist of three main items--"Licensing reform, licensing reform, licensing reform" (Energy Daily, August 23, 1984).

There can be no doubt that the nuclear industry sees the NRC licensing process as the heart of the problem. And just as with the public's concerns, their perception is itself a reality that must be faced.

2. Chaotic Decision-Making: The situation which exists at the NRC in 1985 appears fundamentally unchanged from that described by the Kemeny Commission in 1979:

> The NRC Commissioners have largely isolated themselves from the licensing process . . . . The Commissioners have also isolated themselves from the overall management of the NRC. (p. 51)

Both the citizen groups concerned about safety and the utilities complain that the NRC is not making timely decisions on critical matters. And while individual commissioners work hard and grapple with the issues, there is general agreement that the Commission does not provide a sense of direction that effectively controls staff actions. To the outside world, the staff is not only free of Commission direction, it consists of various independent fiefdoms. There is no effective guidance from the top so in a sense every group marches to its own drumbeat.

The crux of the complaints centers on NRC's decision-making process, or rather the absence of any process. There is no one in the NRC responsible for and in command of all the different NRC groups reviewing a particular plant. There are resident inspectors, regional office people, and Washington NRC staff that can impose requirements. But there is no decision-making process by which a utility can get a timely decision that says "Yes--what you're doing is OK." The utilities complain that regulation is uneven and in some cases "nit picking." What the utilities perceive is a "contest" between the various NRC groups to see which can find more items in violation of their regulations.

The NRC does not have a process that approves or disapproves of a licensee's actions during the construction period. Individual staff groups may say that "it looks OK," but they do not bind the NRC. The NRC reserves the right to second-guess any action later on when an operating license is considered. This means that utilities build and operate plants in an environment of uncertainty as to whether anything they do is "right."

3. Cookbook Regulation: A fundamental problem advanced by the utilities is the prescriptive approach to regulation which NRC practices. It is highlighted by the massive number of NRC rules and regulations which detail the manner in which a plant must be operated. Even the regulatory guides are in reality prescriptions, since no one wants to risk a violation or fine for failing to follow the guidance. The utilities feel that "the lawyers and distant bureaucrats" are largely running their plants on the basis of requirements designed to satisfy concerns about the very poorest performers. As one plant manager put it, "My engineers are in the office writing explanations to the NRC instead of out in the plant finding out what's wrong and fixing it."

NRC's enforcement scheme appears to the utility to emphasize strict, blind obedience with little or no room for utility discretion. Every deviation is assumed to pose a risk to safety even if it is just another way of doing the job that is different from the way the NRC inspector wants it done. And in contrast to the FAA, for example, most NRC staff have not had experience operating a nuclear plant.

For example, the NRC regulations require that back-up equipment for use only in an emergency, such as a diesel power generator, be started up once a week. Periodic testing is obviously necessary but the considered judgment of plant operators is that operating them that often is itself a safety hazard because it prematurely degrades the equipment and introduces unnecessary opportunity for human error. In addition, it diverts the limited workforce in the plant away from the backlog of safety-related work that needs attention.

Yet the NRC rules are the law. They are obeyed. But the plant people feel frustrated because many rules make no sense to them and contiually remind them that they are really not in charge of their plant.

Another example is that if there is an honest error of judgment as to whether an incident is safety-related and it is not reported, the utility is fined twice, once for the infraction and again for failing to report. The work force in many plants feel oppressed and demoralized by the system.

One can say that a utility can remedy this by "overreporting," but the effect of this approach is to make the people in the plant feel they have no discretion at all.

LESSONS FROM OTHER NATIONS

It may be instructive to note that while the United States first developed nuclear power technology a number of European nations and Japan at the moment appear to be having greater success with their nuclear programs than the U.S. The reasons for their superior performance on safety as well as economics involve different institutional arrangements and management skills, but the differences in the regulatory process are important and instructive as to reforms in the U.S. that might be helpful.

A fundamental point is that more stringent safety requirements were imposed on the original design of the light water reactors built in West Germany, Sweden, and the one proposed in Great Britain. As a result, these nations have largely avoided the flood of backfits after TMI that were mandated in the U.S. For example, the pressurized water reactor being proposed in Great Britain at Sizewell requires about 20 percent greater investment to meet more stringent safety criteria but the owner boasts that the risk of a major accident is reduced to one in a million reactor years. The West German and Swedish regulatory authorities have imposed a so-called "n + 2" rule which requires a plant to be designed to always be at least 2 malfunctions away from real trouble. A 1,000 MW reactor being completed in Sweden (Oskarsham III) this year reflects an advanced design that does in fact achieve greater safety and economy than the reactors in the U.S. The reactor required no backfitting because superior safety was built in on the front end.

In every nation other than the U.S., the regulatory agency specifies broad standards of performance rather than detailed rules and regulations. The difference is fundamental, despite the fact that most nations follow the basic NRC technical guidance. In other nations guidance is really guidance. As a result, the utility shoulders the responsibility for safety in fact as well as by law.

In Sweden, for example, the regulatory authority has a much smaller staff (on a comparable basis), but the staff is made up of people with experience in nuclear plants. They specify performance objectives but do not tell the utilities "what to do" to achieve those objectives. The relationship is more consultative. No one doubts the regulatory agency's authority to close down a plant or to order whatever changes are needed for safety. It is just that the authority is exercised with an understanding that the utility and its workforce are competent, and do not need to be given detailed instruction.

It is true that greater scope for intervention by third parties and review in the courts are present in the U.S. than in other nuclear power nations. Intervenors cause delays that are well publicized by the industry. But a less emotional and more factual analysis reveals that it is the failure to build enough safety into the U.S. plants at the front end and the detailed, prescriptive nature of regulation that has caused most of the problems that plague nuclear power in the U.S. today.

It is often stated that Sweden (and the others) are small nations with a few highly competent utilities that are safety conscious and thus can be trusted. The argument is that a performance-oriented approach would not work in the U.S. because of the uneven quality of the numerous nuclear utilities in the U.S.

The point is valid and fundamental. There well may be utilities in the U.S. that are just not competent to operate such a demanding technology as nuclear power.

But the solution to an incompetent operator is not a cookbook. The answer is to upgrade the quality of the operator and then treat that person with respect. We have learned that treating workers with respect is necessary in building relatively simple items like automobiles. It is crucial in operating as demanding an item as nuclear power plants.

Another significant difference that accounts for the better performance overseas is the greater attention paid to operator training and working conditions. The Japanese especially have concentrated on these people-oriented concerns in recognition that plant safety and productivity depend heavily in the quality of the workforce.

Before TMI, neither the utilities nor the NRC gave operator training enough serious attention. The utilities, being reactive, reflected the absence of NRC regulatory requirements on operator training before TMI and did not give that crucial matter much attention. This points up a fundamental deficiency of the "cookbook" approach to regulation. When the NRC overlooks a vital concern, so do the utilities. Yet there is no way that a regulatory agency can gain the firsthand knowledge of what is really needed to design, build, or operate a technology as demanding as nuclear power.

REGULATORY REFORM LEGISLATION PREVIOUSLY PROPOSED

Reform of nuclear power regulation is not a new subject. It is as old as the regulatory program itself. Arthur W. Murphy, Professor of Law at Columbia University, aptly summarized the situation in 1976 (well before TMI) in the following language:

> Although no one has ever seriously questioned the need for extensive regulation of the nuclear power industry, the administration of the regulatory program has been the subject of constant controversy for the twenty-odd years of its existence. Those subject to regulation complained that the regulation was oppressive; others that it was inadequate. There has been at least some justice in both positions.[1]

From 1954 to 1974 the regulation of nuclear power was in the hands of the Atomic Energy Commission, the agency charged with promoting the development of nuclear power. The AEC stressed the promotion of atomic

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[1] The Nuclear Power Controversy, Arthur W. Murphy, Prentice-Hall, Inc. (1976), p. 109.

energy over the kind of objective, tough-minded approach to safety that the EPA has shown in enforcing the air quality laws.

It is useful also to recall that a Joint Committee on Atomic Energy existed in these years. It exerted great influence and saw to it that concerns about safety were effectively swept under the rug. For example, in 1963 the Joint Committee on Atomic Energy ordered former AEC Chairman David E. Lilienthal to appear before them and greeted him with hostile questions because he dared to criticize in public the construction of a large nuclear power plant within the borough of Queens in New York City! Public opposition forced the plant to be shelved but the attitude of the Joint Committee and the AEC was that any criticism by a member of the nuclear community was little short of treason.

The principal focus of regulatory reform in the early 1970s was to end this rather obvious conflict of interest. The creation of the NRC as a separate agency removed the conflict of interest issue and shifted the focus of regulatory reform to the licensing process in general and to means for streamlining that process in particular. Thus the principal advocates of regulatory reform shifted from the opponents of nuclear power and became the nuclear industry itself.

Suggestions for shortening the licensing process go back to 1965. The package advanced consisted of measures to reduce the time required for a utility to obtain a license. Key ingredients were early site approval, limitations on issues intervenors can raise, and one-step licensing. The same set of proposals have been repeatedly presented to the Congress by successive administrations (in 1975, 1978, and 1982). The major addition to the package proposed by the Reagan administration is to place limitations on mandating more backfitting changes on existing plants.

Congress has shown very little interest in these reforms, advocated by the utilities and the nuclear industry. The reason is that, at least since the TMI accident in 1979, this package of regulatory reforms run almost directly counter to the trend of public opinion. The Congress correctly senses that the public is still concerned about whether the nuclear plants are safe enough and oppose cutting back on the opportunities for the NRC and the intervenors to "add more safety" to the plants.

Indeed one of the central problems with the regulatory process at the moment is that the general public--the "man in the street," nearly half of whom appear to oppose new nuclear plants--do not feel they are being heard in the NRC licensing process. Regulatory reform must provide the public with more of a feeling that their concerns--indeed their fears--are being considered if nuclear power is to regain public acceptance. The industry needs to understand that easier public access to the licensing process is in their interest, and such access need not mean unnecessary delay if it occurs before construction begins. as it would. It is counter-productive to advocate changes in the law to shield the reactors from public scrutiny--that simply heightens fears.

It is quite obvious that unless a regulatory reform package offers elements that appeal to those concerned with the issue of safety, as well as to those interested in reducing costs, it will meet stiff opposition in the Congress.

The focus has been on new legislation, but in my view it is entirely possible that a high percentage of the changes needed to serve the public interest could be achieved by the NRC on its own initiative without new legislation. But unless the reforms are balanced and satisfy concern about safety as well as economy, Congressional intervention and public opposition could frustrate the initiative. One way or another public opinion on this issue will be felt in the shaping of a workable reform package.

CONCLUSIONS

1. <u>The NRC Should Establish Stringent Safety Standards and Then Let the Utility Run the Plant.</u>

There is a fundamental flaw in the prescriptive approach to regulation which assumes that plant managers and workers are not competent. As the Kemeny Commission observed,

> "The existence of a vast body of regulations by NRC tends to focus industry attention narrowly on the meeting of regulations rather than in a systematic concern for safety." [p. 20]

People in some parts of the U.S. will say we need an NRC "cookbook" to tell our utility how to operate the plant because we can not trust our utilities to be safety conscious. And it is true that some of the utilities may not be competent enough to operate a nuclear plant or to be trusted to put safety first. But the answer would not appear to lie in detailed rules of "how to do it" because no rule book can prevent human error or anticipate every accident.

The answer lies in reforming the management and the work force at those plants or turning the plant over to a competent operator. Safety ultimately rests on competent people in the plant who feel responsible. Continuing a system that treats everyone as incompetent and relieves managers of incentives to shoulder the responsibility for safety is a threat to safety and a great waste of money.

Any system of regulation requires, of course, a checkup system. Today each nuclear plant has a resident NRC inspector on the job full-time. In addition, auditors come from both the regional office and Washington. This is understandable and useful. But in addition there are INPO, insurance companies, state agencies, EPA, internal quality assurance, occupational health and safety, radiation health, and inhouse nuclear safety people. At TVA's Browns Ferry plant there were 38 audits in a recent 19-week period, and each required follow-up reports, etc.

Obviously a certain amount of auditing is essential, but we may well have passed the point of diminishing returns leaving the management little time to manage. They certainly feel that they only have an opportunity to react.

It is true that violations of NRC regulations often reflect real failures to be safety conscious. And the NRC does concentrate on the plants they perceive to be in trouble. But all plants are subjected to the same detailed requirements and this results in the better plants wasting time and money on unnecessary red tape.

Performance, not a rule book, should be the focus of regulation.

The industrial world is moving toward more democracy in the work place to achieve quality and productivity. Only in America where nuclear power is in such peril is such a dictatorial system imposed on the work force operating a technology that everyone concedes is vitally dependent on operators who can think and understand during an emergency.

2. The Management of Poor Performing Plants Must be Upgraded or Replaced.

A failure of equal or perhaps greater magnitude has been the reluctance of the NRC to assure that nuclear power plants are licensed only to highly competent utilities. There is no substitute for operating a nuclear plant with management and people that the public can trust.

It is widely believed that there are some nuclear utilities that simply do not possess the technical or management skills to operate nuclear power plants. There is also a growing belief that safety and productivity could be vastly improved if a smaller number of highly competent companies operated the nation's nuclear plants rather than the 60 separate organizations now in the business. The industry is just not that rich in management talent. While there are exceptions to any rule, any entity that operates several nuclear plants is generally better able to cope with daily technical problems and emergencies.

There is a strong economic incentive, as well as safety reasons, for shifting operating control of the poorer performing nuclear plants to more competent managers. There is a correlation between good safety performance and good productivity. And the cost of the additional kilowatt hours that competent management can produce from a nuclear plant is less than one cent per kilowatt hour--since plant investment and the people to run it are present regardless of the plant load-factor.

There should therefore be a strong interest on the part of stockholders and consumers of the utilities with "problem plants" in bringing stronger management or perhaps transferring management and control to nuclear management with a record of competence.

There are, of course, a number of difficult legal and operational issues that need to be resolved to make such changes. The service company concept is one option but by no means the only one. But service companies do exist. And they can operate several power plants. And utilities do operate plants owned by others. The problems are by no means insuperable.

Facing up to the "people oriented" deficiencies is the most urgent requirement for improving the safety of nuclear plants. It does not require legislation--but it does require the NRC, INPO, and the industry leaders to agree that decisive action is needed to move the operation of nuclear power into the hands of trustworthy entities.

The NRC can play a key role in this basic reform by ruling that such highly competent, safety-conscious operators will not be regulated by a "cookbook" and exerting pressure on the other operators to make themselves eligible for similar treatment.

3. The NRC Must Set Safety Standards.

The engineered backfits and upgrading of personnel constitute a healthy reaction to TMI. But they are not a substitute for an analysis of the safety of each plant with an emphasis on overall plant safety rather than particular concerns and pieces of hardware. One technique that can assist in such an analysis is probabilistic risk assessment (PRA). Such assessments are most useful for making comparisons among plants and making qualitative judgments--less weight should be placed on the quantitative results they produce.

The NRC has a duty to concentrate on a plant-by-plant assessment of whether each plant is "safe enough" by examining operating experience, the proximity to population, and other relevant factors.

The NRC needs to face up to its responsibility to make a basic judgment on the safety of each plant in the aftermath of TMI. That is the essence of its job. If additional backfits are needed to protect the public, then they should be installed on a plant-by-plant basis to meet overall safety goals.

The utilities have implemented an extensive number of backfitting improvements since 1979. I do not believe that any cost-benefit test should be used to judge backfits. However, the work force available in a nuclear power plant constitutes a finite resource that is rather fully occupied. Additional backfits will displace other work and add to the scope of an operator's duties. There needs to be a judgment on a plant-by-plant basis as to whether they are really needed in the interest of safety.

As stated earlier, it is time to focus on overall plant safety. Additional backfits should be ordered only if needed to meet the overall safety requirements specified above. Meeting overall safety goals requires improvement in the skills of the operators and managers, instilling a sense of responsibility for safety in the management and work force in the plant, and installing backfits in an orderly manner that reflects a priority for overall plant safety.

The public has not been adequately informed of the efforts since the 1979 TMI accident to make extensive improvements in the safety of existing reactors. A report pulling the facts together about plant and personnel improvements should be prepared by a credible organization (such as the GAO or OTA) with the ability to attract attention.

4. The NRC Should Make Timely, Binding Decisions.

The NRC should establish a decision-making process so that utilities get a timely, binding ruling on issues while a plant or modification is being built. It is inefficient and demoralizing for the NRC to keep the utilities in the dark as to whether they have complied with NRC standards while they build a plant and then come along years later and tell them they have built it wrong and need to make very expensive and time-consuming changes.

There should be one NRC person who is responsible for all NRC staff decisions at each nuclear plant. And he or she should be delegated the authority to bind the NRC. Any decisions that require Commission approval should be promptly referred to the Commission and decided.

The NRC badly needs more people with experience in operating nuclear plants. It also needs a management structure that brings order and a sense of direction to its work. As it moves away from the cookbook toward performance, it can and should greatly reduce the size of its staff and at the same time bring in 20 or 30 top notch people with operating experience.

LICENSING REFORM FOR NEW PLANTS

Regulatory reform requires the development of a program that will improve both the safety and the economics of new plants. The basic ingredients of such a program for new plants are as follows.

Reforms to Strengthen Safety Requirements

The first step is for the NRC to establish a standard for new plants designed to satisfy the public's concern about a core meltdown type accident. In my view the standard should require a reactor that is either an inherently-safer concept such as the PIUS or a substantially improved version of existing light-water reactor designs with a dedicated shutdown and heat removal system that is independent, simple to operate, and reliable. The risk of widespread harm to the public should be virtually eliminated.

This standard should encourage the development of the PIUS and perhaps other inherently-safer concepts but permit licensing of vastly improved PWRs such as the Sizewell B design and the safer BWRs being designed by GE and ASEA-ATOM.

This standard should be adopted only after extensive public discussion and input that goes well beyond the ordinary Federal Register notice and rulemaking procedures. Key Congressional committees should be consulted and opinion leaders, beyond the limited number that follow technical NRC issues, should be asked for their views on the question of how safe is safe enough?

The Commission has plans for the adoption of such improved reactors by rule so that it can be licensed without delay. The rule would approve the reactor concept and a complete design. The rule should require that a complete design be submitted before a permit will be issued to commence construction. This requirement is vital to enabling all interested persons and the NRC to pass judgment on the design, and equally vital to enabling the utility to proceed with construction without delay and without backfitting changes during the construction period.

In addition to stringent safety criteria for the reactor, the reform package must include strict criteria for the operator of the plant and also for the qualifications of designer-builder. These criteria should be developed in cooperation with INPO and, of course, after comment from all interested persons. I believe that past performance, rather than good intentions, should be the primary basis.

A clear signal should be sent through these criteria that new nuclear plants should be designed, built, and operated only by those organizations that have achieved good safety-first performances.

If America can be assured that new nuclear plants will be designed to be virtually immune from a core meltdown accident, and built and operated by highly competent, safety-conscious designers, builders, and utilities, then I believe that nuclear power will regain the public acceptance which is now so badly eroded.

Streamlining the Regulation of the New Safer Plant

By requiring a very safe and complete design and a competent operator, the licensing process can reflect these improvements and be designed to assure that unnecessary delay and expense are avoided.

With a complete design there is every reason to complete the review before construction commences. In those circumstances, the design of the plant would be frozen during the construction period (except for modifications proposed by the licensee and approved by the NRC). The construction permit hearing would be the central hearing. Obviously, the NRC would audit the construction and should reform its process to give approval of items as they are built. The procedures which Georgia Power and the NRC are trying out at the Vogtle plant could provide a useful benchmark. Final sign-off will occur at completion of each of the various phases of construction.

It is wasteful and contrary to the interests of safety to put off addressing questions about the construction of a plant until just before a plant is completed. The operating license should not be an occasion for a hearing to review questions that need to be settled as the plant is built. A hearing would appear to be unnecessary at the operating license stage under this procedure.

There is no good reason to restrict the rights of intervenors to raise issues about nuclear power plants. Indeed, as mentioned earlier, it is important that steps be taken to assure that more widespread representation of the general public's concerns be reflected in the licensing process. Toward that end, it would be useful if NRC staff were assigned the responsibility of seeking out public opinion and views of concerned and informed citizens and reflecting those views in the licensing process. Their role should be to represent the public, not the utility applicant, although hopefully in the future there will not be as much friction between the two as in the past.

While the public needs to be heard, those views need to be presented in a timely fashion. The time to raise issues about the nuclear plants is before they are built. The proposed approach, which would require a complete design that complies with rigid safety standards, will afford everyone a chance to be heard in a timely fashion. This would eliminate any unnecessary delay by confining the adversary proceedings to the hearing before construction commences.

It is not necessary or desirable to outlaw all changes in a nuclear plant. One cannot and should not outlaw new knowledge. It is appropriate to guarantee that no backfits would be mandated during the construction period, but thereafter the public safety requires that the NRC be able to order changes needed to maintain the basic safety standard.

Procedures should also assure that once a new plant that meets standards is approved, duplicates of that plant would be reviewed only for local conditions and any changes proposed by the applicant or required on the basis of new knowledge. The rule the NRC proposes to adopt for new plant design would accomplish this purpose.

The regulatory process for operating the nuclear plants of the future should also be reformed. With superior safety built into the plant and an operator with a proven record of safety-first performance, the NRC should specify performance standards and not impose a "cookbook" of rules and regulations that specify how the operator shall run the plant. The regulatory process for all new plants should follow the pattern in other nations by stressing performance. The NRC staff for auditing new plants should be made up of people with experience in power plants, people who can recognize and respect the judgment of people in the plants, and yet come down hard when performance really is inimical to safety.

SUMMARY

The ideas advanced here are not intended to be a blueprint, but rather to focus the debate on what I perceive to be the essential elements of a reform package. These reforms deal with the concerns of the nuclear power opponents as well as those of the proponents.

The present system of regulation is a failure. It is inadequate from a safety viewpoint. It is wasting billions of dollars. I consider the essential reform required is a basic change in the NRC's way of doing business. They should prescribe performance standards that focus on overall safety goals. Utility management should be held responsible and those that do not shape up must be removed one way or another.

To respond to the fears of those concerned about nuclear safety, I have proposed:

1. A standard design for new plants that requires and encourages development of a reactor that virtually eliminates the risk of widespread harm to the public.

2. Upgrading the competence of nuclear plant operations by requiring a proven record of safety-conscious management. This means some utilities that have not measured up will be required to turn over management of their nuclear plant to a service company or another utility with a record of competence.

3. Requiring the NRC to face up to the issue of how safe is safe enough and to make a plant-by-plant judgment on the basis of overall safety analysis.

4. Broadening the opportunity for public participation in NRC licensing by placing on NRC staff the responsibility for soliciting and presenting views of the public generally.

To respond to the legitimate industry complaints of overregulation, I have proposed:

1. The elimination of the "cookbook" mode of regulation and substituting a relationship between the NRC and industry based on performance standards.

2. Requiring final approval of the design of new plants before construction begins. This would mean no backfits during construction and resolution of all design issues at a construction permit hearing. Construction issues are to be decided in stages as phases of construction are completed.

3. Eliminate all additional backfits on existing plants or those under construction unless needed to meet the overall safety standard.

4. Require the NRC to establish a decision-making process for its staff, under Commission direction, that will provide the utilities with timely, definitive decisions. One staff person should be designated to be in charge of all staff decisions for each nuclear plant.

Legislation should not be necessary; however, it is important that Congress and the public, the NRC and the industry reach a consensus that these basic reforms should be made. If adopted, they would improve the safety and efficiency of existing plants and provide the incentive and process for new plants that are much safer as well as more economical.

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SCIENCE AND ITS LIMITS: THE REGULATORS' DILEMMA

SCIENCE AND ITS LIMITS: THE REGULATORS' DILEMMA*

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William Ruckelshaus in his beautiful essay, Risk, Science and Democracy, has expressed very clearly what I shall call "The Regulators' Dilemma." "During the past 15 years, there has been a shift in public emphasis from visible and demonstrable problems such as smog from automobiles and raw sewage, to potential and largely invisible problems, such as the effects of low concentrations of toxic pollutants on human health. This shift is notable for two reasons. First, it has changed the way in which science is applied to practical questions of public health protection and environmental regulation. Second, it has raised difficult questions as to how to manage chronic risks within the context of free and democratic institutions."[1]

When the concerns were patent and obvious--like smog in Los Angeles--science could and did give unequivocal answers: for example, smog comes from liquid hydrocarbons and the answer to smog lay in controlling emissions of these substances. The regulators' course was rather straightforward because the science upon which the regulator based his judgment was operating well within its power. But when the concern was subtle--how much cancer is caused by 10 percent of background radiation--science was being asked a question that lay beyond its power; the question was trans-scientific. Yet the regulator, by law, was expected to regulate even though science could hardly help him: this is the Regulators' Dilemma.

Though my essay is entitled The Regulators' Dilemma, many of the same issues arise in the adjudication of disputes over who is to blame, and who is to be compensated, for damages allegedly caused by rare events. The Regulator's Dilemma is faced also by the toxic tort judge--indeed the Regulator's Dilemma could equally be called the "toxic tort dilemma."

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This symposium, concerned with Hazards: Technology and Fairness, must come to grips with the Regulator's Dilemma. If my car injures a pedestrian, I am liable to be sued--but what is at issue is not whether or not I have injured the pedestrian. It is whether or not I am at fault in running into him. If the lead from my car's exhaust is alleged to cause bodily harm, the issue is not whether my car emitted lead but whether the lead actually caused the alleged harm. The two situations are quite different: in the first, the relation between cause and injury is not at issue; in the second, it is the issue.

In this paper, therefore, I shall try to delineate more precisely those limits to science that give rise to the Regulator's Dilemma; I shall speculate on how these intrinsic limits to science seem to have catalyzed a profound attack on science by some sociologists and public-interest activists; and I shall offer a few ideas that might help the harried regulators finesse these trans-scientific limits of science.

Science and Rare Events

Science deals with regularities in our experience; art deals with singularities. It is no wonder that science tends to lose its predictive or even explanatory power, when the phenomena it deals with are singular, unreproducible, and one of a kind--i.e., "rare"--rather than regular, reproducible, and with many instances. Though science can often analyze a rare event after the fact (say, the Cretaceous-Tertiary extinction) it has great difficulty predicting when such an uncommon event will occur.

I shall distinguish between two sorts of "rare" events--"accidents" and "low-level sports." "Accidents" are large-scale malfunctions whose etiology is not in doubt, but whose a priori likelihood is very small. Three Mile Island, or Bhopal, are examples of "accidents." The precursors to these events, and the way in which the accidents unfolded are well understood. Estimates of the likelihood of the particular sequence of malfunctions is on less solid ground. As the number of individual accidents increases, prediction of their probability becomes more and more reliable. We can predict very well how many automobile fatalities will occur in 1986; we can hardly claim the same degree of reliability in predicting the number of serious reactor accidents in 1986.

"Low-level sports" are rare in a rather different sense than are "accidents." We know that about 100 rads of radiation will double the mutation rate in a large population of exposed mice. How many mutations will occur in a population of mice exposed to 100 mr of radiation? Here the mutation, if induced at all by such low levels of exposure, are so rare that, to unequivocally demonstrate an effect with 95 percent confidence would require the examination of many million mice. Though in principle, this is not impossible, in practice it is. Moreover, even if we could perform so heroic a mouse experiment, the extrapolation of such findings to humans would still be fraught with uncertainty. Thus the effects of very low-level insult in man are rare events whose frequency again is beyond the ability of science to predict with accuracy.

When dealing with events of this sort, science resorts to the language of probability--i.e., instead of saying that this accident will happen on that date, or that a particular person exposed to a low-level insult will suffer a particular fate, it tries to assign probabilities for such occurrences. Of course, where the number of instances are very large, or the underlying mechanisms are fully understood, the probabilities are themselves perfectly reliable. In quantum mechanics, there is no uncertainty as to the probability distributions. But in the class of phenomena we are speaking of here, even though the likelihood of an event happening, or of a disease being caused by a specific exposure, is given as a probability, the probability itself is very uncertain. One can think of a somewhat fuzzy demarcation between what I've called science and trans-science: the domain of science covers phenomena that are deterministic, or the probability of whose occurrence can itself be stated precisely; trans-science, the domain of events whose probability of occurrence is itself highly uncertain.

"Scientific" Approaches to Rare Events

Despite the difficulties, science has devised mechanisms for estimating, however imperfectly, the probability of rare events. For accidents, the technique is probabilistic risk assessment (PRA); for low-level sports, a variety of empirical and theoretical approaches have been used.

Probabilistic Risk Assessment (PRA). Though probabilistic risk assessment had been used in the aerospace industry for a long time, it first sprang into public prominence with Professor Rasmussen's Reactor Safety Study, WASH-1400, which first appeared in 1975.[2]

Probabilistic risk assessment seeks to identify all sequences of subsystem failures that may lead to a failure of the overall system; it then tries to estimate the consequences of each system failure so identified. The output of a PRA is a probability distribution, P(C); i.e., the probability, P, per reactor year, of consequence having magnitude C. Consequences include both material damage and health effects. Usually, the probability of accidents having large consequences is less than the probability of accidents having small consequences.

A probabilistic risk assessment for a reactor requires two separate estimates: first, an estimate of the probability of each accident sequence, and second an estimate of the consequences--particularly the damage to human health--caused by the uncontrolled effluents released in the accident. An accident sequence is a series of equipment or human malfunctions: a pump that fails to start, a valve that does not close, an operator confusing an "on" with an "off" signal. For many of these individual events, we have statistical data--i.e., enough valves have operated for enough years so that at least in principle we can make pretty good estimates of the probability of failure. Uncertainties still remain since we can never be certain that we have identified every relevant sequence. Proof of the adequacy of PRA must therefore await the accumulation of operating experience. For example, the median probability of a core melt in an LWR, according to the original Rasmussen report, was 5×10^{-5}/RY; the core melt at TMI-2 occurred after only 700 reactor-years. However, TMI-2 differed from the reactors treated by Rasmussen, and in retrospect, one could rationalize most of the discrepancy between the Rasmussen estimate and the seemingly premature occurrence at TMI-2.[3] Since TMI-2, the world's LWRs have accumulated some 1500 years of reactor operation without a core melt. This performance places an upper limit on the a priori estimate of the core-melt probability. Thus if this probability were as high as 10^{-3}/RY (as had been suggested by D. Okrent),[4] then the likelihood of surviving 1500 reactor years would not be more than 22 percent; otherwise put, we can say with 78 percent confidence that the core-melt probability is not as high as 1 in 1000 reactor years. With 500 LWRs on line in the world, should we survive until 2000 without another core melt, we could then say with 95 percent confidence that the core-melt probability is not higher than 1 in 3000 reactor years. In the absence of such experience, one is left with rather subjective judgments. Although the Lewis critique of Rasmussen's study[5] asserted that it could not place a bound on the uncertainty of PRA, Rasmussen has argued that his estimate of core-melt probability might be in error by about a factor of 10--that is, the probability may be as high as 1 in 2000 reactor-years or as low as 1 in 200,000/RY. As we see, we can, after 1500 reactor years of operation without a core melt, say with about 78 percent confidence that Rasmussen's upper limit (1 in 2000/RY) is not too optimistic. And if we survive to 2000 without a core melt, the confidence level with which we can make this assertion rises to 95 percent. Our confidence in probabilistic risk analysis can eventually be tested against actual, observable experience; but until this experience has been accumulated, we must concede that any probability we predict must be highly uncertain. To this degree our science is incapable of dealing with rare accidents, but time--so to speak--annihilates uncertainty in estimates of accident probability.

Unfortunately time does not annihilate uncertainties over consequences as unequivocally as it does frequency of accidents. A large reactor or chemical plant accident, can cause both immediate, acute health effects, and delayed, chronic effects. If the exposure either to radiation or to methyl isocyanate is high enough, the effect on health is quite certain. For example, a single exposure of about 400 rads will cause about half of those exposed to die. On the other hand, in a large accident there will also be many who are exposed to smaller doses, indeed to doses so low that the dose response is practically indeterminate. At Bhopal, 200,000 people were exposed to MIC and recovered. We cannot say positively whether or not they will suffer some chronic disability.

The very worst accident envisaged in the Rasmussen study, with a probability of 10^{-9}/RY, led to an estimated 3300 early fatalities, 45,000 early illnesses, and 1500 per year delayed cancers among 10^7 exposed people. Almost all of the estimated delayed cancers are attributed to exposures of less than 1000 milliroentgens per year--a level at which we are very hard put to estimate the risk of inducing cancer. Similarly, the American Physical Society's critique[6] of the Rasmussen Study attributed an additional 10,000 deaths over 30 years among 10 million people exposed to Cs^{135} laid down in a very large accident. The average exposure in this case was 250 millirem per year, again a level at which our estimates of dose-response are extremely uncertain.

Has the nuclear community, particularly its regulators, figuratively shot itself in the foot by trying to estimate the number of delayed casualties as a result of these low-level exposures? In retrospect, I think the Rasmussen study would have been on more solid ground had it confined its estimates only to those health effects that resulted from exposures at higher levels, where science makes reliable estimates; for the lower exposures the consequences could have been stated simply as the number of man-rems of exposure of individuals whose total exposure did not exceed, say, 5000 mr, without trying to convert this number into numbers of latent cancers. Thus health consequence would be reported in two categories: for highly exposed individuals, the number of health effects; for slightly exposed individuals, the total man-rems or even the distribution of exposures accrued by the large number of individuals so exposed. Perhaps some scheme such as this could be adopted in reporting the results of future probabilistic risk assessments: it at least has the virtue of being more faithful to the state of scientific knowledge than does the present convention.

Low-level Exposure

In both of my examples of accidents (Bhopal and reactors) many people are exposed to low level insult; the uncertainties inherent in estimating the effects of such low-level exposure are heaped on top of uncertainties in estimating the probability of the accident that might lead to the exposure in the first place.

Science has exerted great effort to ascertain the shape of the dose-response curve at low doses--but very little, if anything, can be said with certainty about the low dose response. Thus to quote the 1980 report

(BEIR-III) of the National Academy of Sciences, The Effects on Populations of Exposure to Low Levels of Ionizing Radiation, "The Committee does not know whether dose rates of gamma or x-rays of about 100 mrads/yr are detrimental to man.... It is unlikely that carcinogenic and teratogenic effects of doses of low-LET radiation administered at this dose rate will be demonstrable in the foreseeable future." All of which prompted President Handler to comment in his letter of transmittal to EPA, "It is not unusual for scientists to disagree...(and)...the sparser and less reliable the data base, the more opportunity for disagreement.... The report has been delayed...to permit time...to display all of the valid opinions rather than distribute a report that might create the false impression of a clear consensus where none exists."[7]

This forthright admission that science can say little about low-level insults I find admirable. It represents an improvement over the unjustified assertion in the BEIR-II report of 1972 that 170 millirems per year over 30 years, if imposed on the entire U.S. population would cause between 3,000 and 15,000 cancer deaths per year.[8] I do not quarrel with the estimated upper limit--which amounts to 1 cancer per 2500 man-rems; I regard the lower limit different from zero as being unjustified--and as having caused great harm. The proper statement should have been, at 170 mr/yr, we estimate the upper limit for the number of cancers to be 15,000/yr; and the lower limit might be zero.

Since the appearance of the BEIR reports, two other developments have added to the burden of those who must judge the carcinogenic hazard of low level insults: (1) natural carcinogens, and (2) ambiguous carcinogens.

Natural carcinogens. Is cancer "environmental" in the sense of being caused by technology's effluents, or is cancer a natural consequence of aging? In the past few years I believe we have seen a remarkable shift in viewpoint: whereas 15 years ago most cancer experts would have accepted a primarily environmental etiology for cancer, today the view that natural carcinogens are far more important than are manmade ones has gained many converts. Bruce Ames, in his famous Science article which was illustrated by Robert Indiana's modern painting, Eat-Die, marshalled powerful evidence that many of our most common foods contain carcinogens.[9] Indeed, John Totter, supported by the late Philip Handler, has offered epidemiological evidence for the oxygen radical theory of carcinogenesis: that we grow older and eventually get cancer because we metabolize oxygen; and oxygen radicals can play havoc with our DNA.[10] As such views of the etiology of cancer acquire scientific support, I should think that the transcientific question, How much cancer is caused by a tiny chemical or physical insult, will be recognized as irrelevant. One doesn't swat gnats in the face of a stampeding elephant.

Ambiguous carcinogens. To further complicate the cancer picture, I call your attention to evidence that some agents, such as dioxin, various dyes, and even moderate levels of radiation, seem to diminish the incidence of some cancers at the same time they increase the incidence of others--so that the lifespan of the treated animals on average exceeds that of the untreated ones.[11] A most striking example given by Haseman, is yellow dye #14 given to leukemia-prone female F344 rats, which completely suppresses leukemia (which is always fatal) but causes liver tumors, most of which are benign.

I mention these two findings--or perhaps points of view--to stress my underlying point, that where we are concerned with low-level insult to human beings, we can say very little about the cancer dose-response curve. Saying that so many cancers will be caused by so much low-level exposure to so many people, a practice that terrifies many people, goes far beyond what science actually can say.

How Science Reacts to Intrinsic Uncertainty

Does the scientific community accept the notion that there are intrinsic limits to what it can say about rare events: that as events become rarer, the uncertainty in the probability of occurrence of a rare event is bound to grow? Perhaps a better way of framing this question is--Of what use can we put the tools of scientific investigation of rare events--say, probabilistic risk analysis and large-scale animal experiment as surrogates for epidemiological inquiry--if we concede that we can never get definitive answers?

For probabilistic risk analysis, I should say that an uncertainty as high as a factor of ten is often useful, especially if one uses the PRA for comparing risks. For example, the 1500 reactor years already experienced since TMI suggests that a reactor core melt probability is likely to be less than 10^{-3}/yr and may well be as low as PRA predicts, less than 10^{-4}/yr. This is to be compared with dam failures whose probability, based on many hundreds of thousands of dam years (and where time has annihilated uncertainty), is around 10^{-4}/yr. Even with this uncertainty, we can judge roughly how safe reactors are compared to dams.

When one compares the relative intrinsic safety of two very similar devices--like two water-moderated reactors--PRA is on much more solid ground. Here one is not asking for absolute estimates of risk, but rather estimates of relative safety. If the reactors, A & B, differ in only a few details--say reactor A has two auxiliary feed water trains whereas B has only one--the ratio of core-melt probabilities ought to be much more reliable than their absolute values, since the ratio requires an estimate of failure of a single subsystem, in this case, the extra AFW on reactor A.

Not only can one say with reasonable assurance how much safer Reactor A is than Reactor B, one can, as a result of the detailed analysis, identify the subsystems which contribute most to the estimated failure rate. Even if PRA is inaccurate, it is very useful in unearthing deficiencies: one can hardly deny that a reactor in which deficiencies revealed by PRA have been corrected is safer than one in which they have not been corrected, even if one is unwilling to say how much safer.

Somewhat the same considerations apply to low-level insult. An agent that does not shorten lifespan at higher dose will not shorten lifespan at lower dose. An agent that is a very powerful carcinogen at high dose is more likely to be a carcinogen at low dose than one that is a less powerful high-dose carcinogen. Thus animal experiments surely are useful in deciding which agents to worry about, which not to worry about. And of course the Ames test has made at least some preliminary screening of carcinogens more feasible. The difficulty today seems to be not so much identifying agents that at high dose may be carcinogens, as it is prohibiting exposures far below levels at which no effect can be, or ever will be, demonstrated. The regulator and the concerned citizen is inclined to lean over backward so far as to approve the Delaney amendment, which forbids in interstate commerce any carcinogenic agent in food, without ever saying anything about allowable levels or relative risks of, say, cancer induction by nitrosoamines and digestive disorders caused by meat untreated with nitrites!

The Delaney Amendment is the worst example of how a disregard of an intrinsic limit of science can lead to bad policy by overenthusiastic politicians. Harvey Brooks has often pointed out that one can never prove the impossibility of an event that is not forbidden by a law of nature. Most will agree that a perpetuum mobile is impossible because it violates the laws of thermodynamics. That one molecule of PCB may cause a cancer in humans is a proposition that violates no law of nature: hence many, even within the scientific community, seem willing to believe that this possibility is something to worry about! It was this error that led to the Delaney Amendment.

The Attack on Science from the Sociology of Knowledge

When is an event so rare that the prediction of its occurrence forever lies outside the domain of science, i.e., within the domain of trans-science? Clearly we cannot say, and perhaps as science progresses, this boundary between science and trans-science recedes towards events of lower frequency. But at any stage, the boundary is fuzzy, and much scientific controversy boils over deciding where that boundary lies. One need only read the violent exchange between Professors Radford and Rossi over the risk of cancer from low levels of radiation to recognize that, where the facts are obscure, argument--even ad hominem argument--blossoms. Indeed Alice Whittemore in her "Facts and Values in Risk Analysis for Environmental Toxicants,"[12] has pointed out that at this "rare event" boundary between science and trans-science, facts and values are always intermingled. A scientist who believes that nuclear energy is evil because it inevitably leads to proliferation of nuclear weapons (which is a common basis for opposition to nuclear energy) is likely to judge the data on induction of leukemia from low-level exposures at Nagasaki differently than is a scientist whose whole career has been devoted to making nuclear power work. Cognitive dissonance is all but unavoidable when the data are ambiguous and the social and political stakes are high.

No one would dispute that judgments of scientific truth are much affected by the scientists' value system when the issues are at or close to the boundary between science and trans-science. On the other hand, as the matter under dispute moves away from that border into the domain of science, most would claim that the scientist's extra-scientific values intrude less and less. Soviet scientists and American scientists may disagree on the effectiveness of a Ballistic Missile Defense, but they agree on the cross-section of U^{235} or the lifetime of the pi-meson.

This all seems obvious, even trite. Yet in the past decade or so, a school of Sociology of Knowledge has sprung up in the United Kingdom which claims that "scientific views are determined by social ("external") conditions, rather than by the internal logic of scientific tradition and inherent characteristics of the phenomenal world,"[13] or "...all knowledge and knowledge claims are to be treated as being socially constructed: genesis, acceptance, and rejection of knowledge (is) sought in the domain of the Social World rather than...the Natural World."[14]

The attack here is not on science at the border, in particular, the prediction of the frequency of rare events. At least the more extreme of the sociologists of knowledge claim that the traditional ways of establishing scientific truth--by appealing to nature in a disciplined manner--is not how science really works even in situations very far from the science/trans-science border. Scientists are seen as competitors for prestige, for pay, for power, and it is the interplay between these conflicting aspirations, not the working of some underlying scientific ethic, that defines scientific "truth." To be sure, these attitudes towards science are not widely held by practicing scientists at the center of scientific activity; however, they are taken seriously by many political activists who, though not in the mainstream of science nevertheless exert important influence on other institutions--the press, the media, the courts--which ultimately influence public attitudes toward science and its technologies.

If one takes such a caricature of science seriously, how can one trust an expert? If scientific truth, even at the core of science, is decided by negotiation between individuals in conflict because they hold different non-scientific beliefs, how can one say that this scientist's opinion is preferred to that one's? And if the matter at issue moves across the science/trans-science boundary, where all we can say with certainty is that uncertainties are very large, how much less able are we to distinguish between the expert and the charlatan, between the scientists who tries to adhere to the usual norms of scientific behavior, and the scientist who suppresses facts that conflict with his political or social or moral preconceptions.

I don't think it will do to define a new branch of science, "regulatory science," in which the norms of scientific proof are less demanding than are the norms in ordinary science. I should think that a far more honest and straightforward way of dealing with the intrinsic inability of science to predict the occurrence of rare events is to concede this limitation, and not to ask of science or scientists more than they are capable of providing. Regulators instead of asking science for answers to unanswerable questions, ought to be content with less far-reaching answers; where uncertainty bands can be established, regulate on the basis of uncertainty; where uncertainty bands are so wide as to be meaningless, recast the question so that regulation does not depend on answers to the unanswerable. And, since these same limits apply to litigation the legal system ought, much more explicitly than it has heretofore, to recognize that science and scientists often have little to say, probably much less than some scientific activists would admit.

The bona fides of scientific adversaries often is at the heart of litigation over personal injury alleged to be caused by subtle, low-level exposures. Each side presents witnesses whose scientific credentials are regarded as impeccable by the side the witnesses are supporting. Since the issues themselves tend to be trans-scientific, one can hardly decide the validity of the "scientific" assertions of either side's witnesses. Under the circumstances, I suppose one is justified in regarding a scientific witness no differently than any other witness: his credibility is judged by his past record, behavior, and general demeanor, as well as the self-consistency of his testimony. Such, at least, was the way in which Judge Patrick Kelley settled the Johnston vs. United States case, by impugning, on grounds no different from those one would invoke in an ordinary lawsuit, the competence if not the integrity of one side's scientific witnesses.

Finessing Uncertainty

Various approaches for finessing uncertainty can be identified. I shall briefly describe two of these--the Technological Fix and De Minimis--without claiming that these are the most important, let alone the only ones.

Technological Fix. Science cannot predict exactly the probability of a serious accident in a light water reactor, or the likelihood that a radioactive waste canister in a depository will dissolve and release activity to the environment. Can one design reactors or waste cans for which the probability of such occurrences is zero--or at least which depend, to prevent such mishaps, on immutable laws of nature that can never fail rather than on incompletely reliable intervention of electromechanical devices? Surprisingly, this approach to nuclear safety has come into prominence only in the past 5 years. K. Hannerz[15] in Sweden and G.H. Lohnert[16] in Germany have each proposed reactor systems, PIUS and the modular High Temperature Gas Cooled Reactor, whose safety does not depend on active interventions, but rather on passive, inherent characteristics. Though one cannot say that the probability of mischance has been reduced to zero, there is little doubt that the probabilities are several, perhaps three, orders of magnitude lower than the probabilities of mischance for existing reactors. To the extent that such reactors embody the principle of inherent safety, their adoption would avoid much of the hassle over reactor safety, Price-Anderson, repetition of Three Mile Island, etc. In short, such a technical fix enables one largely to ignore the uncertainties in any prediction of core melt probabilities.

The idea of incorporating inherent or passive safety in the design of chemical plants had been proposed, unbeknownst to the nuclear community, by Professor Theodore Kletz of the Loughborough University of Technology in 1974,[17] shortly after the disaster at the Flixborough cyclohexane plant, which killed 28 people. I should think that one of the main consequences of the Bhopal disaster will be incorporation of inherent safety into new chemical plants; again, a way of finessing uncertainty in predicting failure probabilities.

De Minimis. A perfect technical fix, such as a totally safe reactor, or a crash-proof car, is usually not available, at least at an affordable cost. Some low levels of exposure to materials that are toxic at high levels are inevitable, even though we can never accurately establish the risk of such exposures. One way of dealing with this situation is to invoke the principle of de minimis. This principle, as exposed by H. Adler and A. Weinberg,[18] argues that for insults that occur naturally and to which the biosphere has always been exposed, and presumably to which it has adapted, one should not worry about any additional manmade exposure as long as the manmade exposure is small compared to the natural exposure. The basic idea here is that the natural level of a ubiquitous exposure (like cosmic radiation), if it is deleterious, cannot have been very deleterious since in spite of its ubiquity, the race has survived. Moreover, we concede that we do not know and can never know, what the residual effect of natural exposure really is. An additional exposure that is small compared to the natural background ought to be acceptable; at the very least, its deleterious effect if any, can never be determined.

Adler suggested that for radiation whose natural background is well known, one might choose a de minimis level as the standard deviation of the natural background. This turns out to be around 20 percent of the mean background, around 20 mr/yr, and this value has been used as the EPA standard for exposure to the entire radiochemical fuel cycle.

We know more about the natural incidence and about the biological effects of radiation than we do for any other agent. It would be natural therefore to use the standard established for radiation as a standard for other agents. This approach has been used by Professor Westermark of Sweden, who has suggested that for naturally-occurring carcinogens such as arsenic, chromium and beryllium, one might choose a de minimis to be, say, 10 percent of the natural background.[19]

Clearly, a de minimis level will always be somewhat arbitrary. Nevertheless, it seems to me that unless such a level is established, we shall forever be involved in fruitless arguments, the only beneficiary of which will be the toxic tort lawyers. Could the principle of de minimis be applied in litigation in much the same way it might be applied to regulation--i.e., if the exposure is below de minimis, then the blame is intrinsically unprovable and cannot be litigated? I would imagine that the legal de minimis might be set higher than the regulatory de minimis; for example, the legal de minimis for radiation might be the background (since the BEIR-III concedes there is no way of knowing whether or not such levels are deleterious). The regulatory de minimis could justifiably be lower, simply on grounds of erring on the side of safety.

One approach might be to concede that there is some level of exposure that is "beyond demonstrable effect" (BDE). This defines a "trans-scientific" threshold. A de minimis level might then be established at some fraction, say 1/10, of this BDE level. For example, if we take the previously quoted value of 100 mr/yr of low LET radiation as the BDE level for somatic effects, then a de minimis for low LET might be set at 10 mr/yr. Of course such a procedure would evoke much controversy as to what is the BDE level, or whether 10 is an ample safety factor. This example demonstrates, however, that at least in the case of low level radiation, a scientific committee was able to agree on a BDE level. As for the safety factor of 10, this cannot be adjudicated on scientific grounds. The most one can say is that tradition often supports a safety factor of 10--for example, the old standard for public exposure (500 mr/yr) was set at 1/10 of the tolerance level for workers (5000 mr/yr).

Can a principle of de minimis be applied to accidents? What I have in mind is the notion that accidents that are sufficiently rare might be regarded somehow in the same category as Acts-of-God, and compensated accordingly. We already recognize that natural disasters should be compensated by the society as a whole. One can argue that an accident whose occurrence requires an exceedingly unlikely sequence of untoward events might also be regarded as an Act of God. Thus the Price-Anderson Act might be modified so that, quite explicitly, accidents whose consequences exceeded a certain level, and whose probability as estimated by PRA would be less than, say, 10^{-9}/yr, would be treated as Acts of God. Compensation in excess of the amount stipulated in the revised act would be the responsibility of Congress. The cut-off for compensation, or for probabiliites, would be negotiable, and perhaps would be revised every 10 years or so. One not entirely fanciful suggestion might be to set any probability of the order of 10^{-7} to 10^{-8} per year to be a de minimis cut-off, this being the frequency at which the earth may have been visited by the cometary asteroids which may have caused the geologic extinctions.

Conclusions

The reader must be aware that, as in most such questions, identifying and characterizing the problem is easier than solving it. That the regulators' and the toxic torts dilemma is rooted in science's inability to predict rare events cannot be denied. How to get the regulator and the toxic tort judge off the horns of the dilemma is far from easy, and my two suggestions are offered tentatively and with diffidence.

Equally obvious is the intrinsic social dimension of the issue. In an open, litigious democracy such as ours, any regulation, any judicial decision can be appealed, and if the courts offer no redress, in principle, Congress can; but these mechanisms are ponderous. The result seems to me to be a gradual slowing of our technological-social engine--enmeshed more and more in fruitless argument over irresolvable questions.

Western society was debilitated once before by such fruitless tilting with Don Quixotian windmills. I refer of course to the devastating campaign against witches of the 14th to the early 17th centuries. As William Clark has put it so vividly, in this period society took for granted that death, disease, and crop failure could be caused by witches.[20] To avoid such catastrophes one had to burn the witches responsible for them--and some million innocent witches were burned as a result. Finally in 1610, the Spanish Inquisitor Alonzo Salazar y Frias realized there was no demonstrated connection between catastrophe and witches. Though he did not prohibit their burning, he did prohibit use of torture to extract confessions. The burning of witches, and witch-hunting generally declined precipitously.

I have recounted this story many times by now. Yet it still seems to me to capture the essence of our dilemma: the connection between low-level insult and bodily harm is probably as difficult to prove as is the connection between witches and failed crops. That our society nevertheless has allowed this issue to emerge as a serious social concern, I regard as an aberration, which in the modern context, is hardly less fatuous than were the witch hunts of the Middle Age. That dark phase in Western society died out only after several centuries. I hope our open, democratic society can regain its sense of proportion far sooner and can get on with managing the many real problems we always will face rather than waste our energies on essentially insoluble, and by comparison, intrinsically unimportant, problems.

AMW:bc
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