### **RISK FACTOR RESOLUTION IN THE REGULATORY PROCESS**

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## ABSTRACT

The successful siting and licensing of controversial projects such as nuclear power plants and hazardous waste disposal facilities have been found to require not only a finding of compliance with the objective standards established by the regulatory and licensing bodies but also substantial public acceptance of the risks. To achieve that public acceptance, some observers have suggested that it may be necessary to address certain non-technical risks, the values-related risks ("VRRs"), which have been identified in some studies in risk communication. Although these VRRs do not lend themselves to formal resolution in the technical regulatory and licensing processes, those processes may indirectly address and resolve the VRRs. Under those circumstances, it is suggested that an appropriate forum should be found for officially and definitively crediting the resolution of the VRRs so as to reach closure on them and avoid their duplicative consideration in inappropriate forums.

## INTRODUCTION

Experience shows that the successful licensing of facilities which the public views as potentially risky to health and safety—including nuclear power plants and hazardous waste facilities—requires substantial public acceptance of those risks. One element of public acceptance is a demonstration of compliance with the objective scientific standards and licensing criteria that are established by the agencies which are authorized to license and regulate those facilities. However, such demonstrations of compliance have not always sufficed for public acceptance. Some observers believe it is because the compliance findings do not address all of the risks which the public considers significant.

Some studies in risk assessment and risk communication have shown that the public's *perception* of risk includes several so-called value-related risks ("VRRs"), i.e. qualitative factors about risk such as the voluntariness of exposure to the risk or its potential for catastrophic impacts, which are generally not included in conventional probabilistic calculations of consequences due to risk. (1) Although research does not generally show that these perceptions are translated into *actions*, there are, for example, no reports of a mass exodus from the vicinity of a nuclear power plant after it begins to operate, there is a continuing belief that the exclusion of VRRs from formal consideration results in decisions which the public finds incomplete and, thus, possibly unacceptable. If this belief is correct, the official, definitive resolution of VRRs in an appropriate forum would support a technically supportable licensing decision in favor of a controversial facility.

The need for a separate forum for addressing VRRs appropriately is clear from several aspects of their nature. First, VRRs are claimed to be based, in part, on non-technical perceptions of fundamental notions such as freedom and fairness. Therefore, an attempt to address VRRs in a forum which is designed to deal with only the technically accurate quantitative evaluations of impacts, such as a licensing process which focuses on quantitative environmental impacts, would not be expected to result in a consideration of VRRs in a manner which fully addresses their particular nature. VRRs should, therefore, be addressed in a forum which is appropriate to their non-technical nature.

Second, the effective consideration and resolution of VRRs also requires the use of an appropriate process. For the process to be effective, experience shows that it must provide for effective communication through the two-way exchange of information between the concerned members of the public and the decisionmakers. One-way communication in which experts try to educate the public about the technical errors of their ways has generally been found to be ineffective. (2)

Third, because VRRs tend to involve strong emotions, presentations of those issues tend not to be logically structured in a dispassionate manner. Although the emotional aspects of these VRRs cannot be eliminated, the emotions can be channeled by appropriately structuring the process for considering VRRs. Thus, these risks should be considered in an official forum which provides for public participation in a structured but not stifling manner and also provides for closure of the risk issues through the acceptance of measures that have been determined to be appropriate for addressing those risks.

Finally, because concerns about the VRRs is not corroborated by public actions, the burden of going forward to demonstrate the existence of VRRs in a particular situation should be carried by the proponents of such claimed concerns. Moreover, where the VRRs which have been identified in general can be shown to apply in a particular case and appear to have been resolved favorably elsewhere, the process for considering the VRRs in that later case should be structured to incorporate those earlier findings. In particular, the favorable resolution of VRRs elsewhere should create a rebuttable presumption, with the rebuttal to be carried by the proponents of a different conclusion.

To further discuss how these principles could be applied, the following aspects of VRRs are discussed below. First, the VRRs which have been identified to be of general concern are reviewed. Second, it is shown that in many cases, as a general matter, these VRRs will have been implicitly addressed by the formal considerations of the technical risks which are currently included for evaluation in most regulatory processes. Third and finally, it is suggested that an appropriate, formal process, independent of any licensing or regulatory process, should be considered for development as a method for converting the informal resolution of VRRs into a formal, final resolution of them.

## **TYPES OF RISKS**

Risk and risk assessment are intrinsic to potentially hazardous activities. But risk evaluation is not a new concept associated with recent technological advances. As early as 1947, Judge Learned Hand applied the quantification of risk as the product of probability of occurrence of an event times the impact of that event. (3) Today, that formula still applies and is the basis of the probabilistic risk assessments.

For quite some time it has also been recognized that technical experts and non-technical members of the public view risks differently. As early as 1980, Chauncey Starr recognized the differences between what we here call VRRs and the exclusive use of scientific studies which quantified impacts related to risks as the only technically valid method for evaluating risk. (4) The public's concern with VRRs was acknowledged but given no weight in technical decisionmaking.

Continuing experience with public interactions over risk evaluation has shown that the impacts of VRRs on public opinion, but not action, can be substantial. The refusal by a segment of the public to accept technical calculations of impacts as definitive has led to further research into the details of the public's perception of risk. That research has resulted in the identification of a number of VRRs which the non-technical public finds generally important. Covello (5) has found the following VRRs to be significant:

Value-Related Risk Factor	Public Evaluation of Value-Related Risk Factor
	Cause of Direction of Perception of Impact of Risk Factor
catastrophic potential	increases with extent to which fatalities and injuries
	would be grouped in space and time
familiarity	increases with unfamiliarity
understanding	decreases with increase in understanding of the
	mechanisms or processes responsible for risks
personal controllability	decreases with increase in personal controllability
voluntariness of exposure	decreases with increase in voluntariness of exposure
effects on children	increases with specificity of impact on children
timing of manifestation	increase with delay in appearance of effects
effects on future generations	increases with impact of effects on future generations
victim identity	increases with identifiability of individuals affected
accident history	increases with previous major and minor accidents
equity	increases with unequal distribution of risks and benefits
dread	increases with dread of effects
trust in institutions	increases with decreasing trust in responsible institution
media attention	increases with extent of media attention
reversibility	increases with irreversibility of the consequences
origin	increases with result due to human and not natural action

## CURRENT GENERAL CONSIDERATIONS OF RISK

All of the technically cognizable risks that are associated with a project like a nuclear power plant or a hazardous waste facility are fully considered in the current regulatory and licensing processes for such facilities. Risks related to possible exposures to hazards related to either normal operation or unlikely accidents are considered as intrinsic elements of the formal aspects of the licensing process. By contrast, risks related to values are generally limited to presentations during any informal hearings which may be conducted at various points in the regulatory processes for the development and licensing of such projects. They may also be raised in comments on proposed rules but may be dismissed as irrelevant to the legally recognized issues in a rulemaking. Because of the limited official responses to such issues, members of the public use other available political and public relation avenues for pursuing their concerns regarding VRRs.

#### Formal Considerations of Risks

Regulatory standards and licensing criteria are based on well-known technical principles, including the well-established relationships between exposures to hazards and their consequences, the so-called dose-response relationships which convert such exposures into probabilities of observable impacts. Depending on the particular statutory direction to the regulatory and/or licensing agencies, the exposure standards and licensing criteria are generally designed to provide an acceptable level of protection but not an absolutely risk-free environment. An acceptable level of protection is generally defined with the help of national and international standard setting bodies. In many instances, either federal or state law also requires the regulatory and licensing agencies to consider risks as part of an environmental impact statement. These formal aspects of the consideration of risk may incidentally also be applicable to the resolution of the VRRs which are generally acknowledged to be of concern to the non-scientific public

#### Legal Exclusion of Certain VRRs

At least one VRR, dread or fear of risk from an accident, has been determined by the Supreme Court to be legally excludable from consideration at the federal level under the National Environmental Policy Act ("NEPA"). (6) The case involved a challenge to the restart of the nuclear power plant Three Mile Island, Unit 1, the sister plant to Three Mile Island, Unit 2. Opponents to the plant's restart contended that the NRC's Final Environmental Statement was incomplete because it did not include consideration of the possible psychological disturbances that might be experienced by the public which lived in the vicinity of the plant and would dread the potential for another accident.

The Supreme Court dismissed those fears as too attenuated to be required to be considered. The Supreme Court limited the scope of NEPA to effects on the physical environment. It found that the steps: (1) from restart of the plant; (2) through the risk of accident; and (3) to the resulting psychological impacts, had lengthened the chain of

causation from restart to dread too far for the purposes of NEPA. Accordingly, the Supreme Court held that the NRC was not required by NEPA to include consideration of those fears in the Final Environmental Statement.

Although this legal precedent arose in the course of restarting a nuclear power plant, it logically applies equally to any situation in which the fear of an accident is similarly attenuated. In particular, the Supreme Court's decision clearly applies to any claim of fear from a passive facility because such a facility is inherently low-energy and, thus, does not present the risks associated with the higher energy of an active facility like a nuclear power plant. Because any psychological impacts related to fear from an off-normal event are related to the intensity of that event, i.e. the rapidity of its ability to seriously affect large numbers of people, if there is no legal requirement to consider the fear of a possible significant event at an active, energetic nuclear power plant, the generally applicable principle that the greater includes the lesser, leads to the conclusion that there is clearly no legal basis for considering such fear for the inherently less intense, consequences due to an off-normal event at a passive facility like a hazardous waste site. This comparison implies that the technical compliance findings which would be made for a passive facility would implicitly show there is no basis for a claim of dread due to that facility. Thus, the consideration of the VRR of dread in an appropriate forum could result in its explicit resolution based on the logical consequences of its implicit consideration in the technical evaluation process.

#### Informal Considerations of VRRs

VRRs may be introduced into public hearings which the regulatory agencies conduct for facilities either under statutory direction or in their discretion. Because such hearings are legislative in nature, they are open to all observations about the subject facility. For example, hearings about the siting of a facility often involves questions about the proximity of the proposed facility site to population centers or recreation facilities.

Official agency responses to these VRRs have generally relied on scientific estimates of risk to address these concerns. Such responses are legally adequate because they are rational and there are no legal requirements on how the regulatory agencies need to respond to comments raised at informal public hearings. However, such agency reliance on objective measures of risks have been shown not to be considered responsive by the segment of the public which supports consideration of VRR concerns.

VRRs also are sometimes raised in public comments on rules proposed by the regulatory and licensing agencies. Comments in proposed rules are subject to treatment by the agencies in accordance with either the federal Administrative Procedure Act ("APA"), or its state equivalents, and the extensive case-law which has interpreted the statutory provisions. Under the APA, for example, an agency must respond to all substantial comments on a proposed rule. Agencies often comply with this requirement conservatively by responding to all comments, whether or not they are significant. Agency responses to comments which involve VRRs may be dismissed as legally irrelevant. Such a claim of irrelevance is consistent with the view that only quantitative estimates of risks are relevant to public health and safety.

#### Unofficial Alternatives for Considering VRRs

Because opportunities to raise VRRs in the official regulatory forums have been limited, members of the public who share these VRRs express them through other available means. These means include the political process and the media. For example, legislators often reflect the concerns of their constituencies and oppose the siting of certain facilities which their constituencies consider to be unacceptable.

Similarly, media coverage of such projects also has been negative to the extent that it reflects the views of project opponents. The media may publish opponents' views, in part, because they make better copy and, therefore, sell more newspapers. But if these views sell more newspapers it could be because the opponents' views address the VRRs which are of concern to some percentage of media consumers.

Alternative forums will continue to be used by concerned citizens and project opponents to promote their views about VRRs as long as the VRRs are not definitively addressed in an official process which provides for finality. These forums also will be continue to be used by project opponents even if the VRRs are fully addressed in an official process. However, those concerned citizens who are not unalterably opposed to a project as a philosophical matter may find the official consideration of the VRRs adequate.

# CURRENT OFFICIAL CONSIDERATIONS OF VRRs

VRRs are generally not considered by the licensing and technical agencies. Because those concerns are not strictly technical, they have been considered to be outside the agencies' jurisdictions and, thus, not legally cognizable. In some cases, this exclusion of VRRs from agency consideration is reinforced by a statutory direction to rely on recognized expert opinion for the establishment of regulatory and licensing criteria. For example, in Illinois, the Illinois Department of Nuclear Safety, which regulates certain aspects of nuclear power plants in Illinois, is required to adopt into Illinois' regulatory standards for those plants, to the extent practicable, the Boiler and Pressure Vessel code promulgated by the American Society of Mechanical Engineers.

# POSSIBLE EXPLICIT CONSIDERATION OF VRRs

As discussed above, VRRs are perceived risks to a portion of the public. Experience shows that this portion of the public will support the consideration of VRRs as part of any decisionmaking process. Studies on VRRs have focused on how to improve communications about them but have not resulted in a comparable expansion of the scope of the decisionmaking process to include resolutions of VRRs as elements of a decision. Accordingly, consideration could be given to the development of an official process for the conduct of an official, objective review and definitive resolution of VRRs.

In exploring how VRRs might be definitively considered, it is useful to understand the current limitations on their inclusion in a formal licensing process. Consider the NRC's licensing process. Its strength is the formality of the process which enables regulatory issues to be considered as they relate to they licensing criteria.

The NRC's licensing process is a formal adjudication on the record. It is comparable to trial in civil court. As such, the NRC process is required to strictly limit the issues which the NRC can consider in a licensing proceeding. Experience with the NRC's application of the adjudicatory process to the licensing of nuclear power plants shows that it would not be amenable to the consideration of VRRs. Because these risks are not clearly related to the licensing criteria which have been established by the NRC, efforts to include considerations of those risks in the formal adjudicatory licensing process will fail because the decision criteria are not applicable. Therefore, even if the NRC were to apply its substantial legal discretion to modify its licensing process, (7), the consideration of VRRs would be inappropriate in an adjudicatory proceeding.

This brief review of the current limitations on the formal considerations of VRRs suggests that an process for considering VRRs needs to be developed. One possibility is a legislative-style proceeding. It might be appropriate for addressing VRRs because it would create a structured, but not rigid forum for interchange between the decisionmaker and the public.

Whatever process is adopted, it should also reflect the uncertainty in the existence of VRRs. Moreover, it should reflect that in many cases, especially those which involve passive facilities, the technical evaluations of the legally cognizable risks and the demonstrations that those risks are acceptable, have, as an implicit byproduct, the result of showing that the VRRs also are resolved in an acceptable manner, as indicated in the table below. Accordingly, the official process which is adopted to resolve VRRs should be structured to recognize in an explicit, legally conclusive way the implicit favorable resolution of VRRs in another proceeding.

Value-Related Risk Factor	Likely Resolutions of Value-Related Risk Concerns
catastrophic potential related	calculations and analyses should show that no credible
to the risk	accident will result in fatalities and injuries that are
	significantly grouped in either space or time
familiarity of risk	reviews of the risks should show that they are comparable
	to similar risks that have been dealt with for many years
understanding of the risk	descriptions of how the particular facility will work should
	overcome any claimed difficulty in understanding the risks
personal controllability over	personal controllability of exposure to the risk should be
the risk	supported by a determination that its chronic character
	gives individuals time to take mitigating measures
voluntariness of exposure to	concern about the involuntary nature of exposure to the
the risk	risk should be addressed adequately by a showing that its

	chronic nature provides time to take mitigating actions,
	including removal from the source of risk
effects of the risk on	discussions of the risks should definitively demonstrate
children	that there is no disproportionate impact of risk on children
timing of manifestations	concerns based on the length of the latent period for the
related to the risk	appearance of health consequences should be overcome
	by showing that monitoring of the facility, and not the
	appearances of health effects, will be relied for
	determining the effectiveness of safety measures
effects of the risk on future	concerns about inter-generational inequities should be
generations	alleviated by showing that the facility will not affect future
	generations adversely and estimates of the long-term
	benefits of the current related activities
identity of victims of the	the identifiability of individuals should be adequately
risk	addressed by the acceptability of the exposure limits and
	the availability of the option to move away
accident history	this concern should be addressed by showing how the
	history of other facilities has been factored into
	performance criteria for the current facility
equity of the risk	a concern about the inequality of distribution of risks and
	benefits should be addressed by a showing that the
	benefits have been broadly realized and the risks have
	been irreversibly committed to

Value-Related Risk Factor	Likely Resolutions of Value-Related Risk Concerns
dread of the risk	any dread due to fear of the risk should be addressed by a generally accepted, well-supported determination that any
	credible realizable risk is too low to support that lear
trust in institutions	any concern about the lack of trust in responsible
responsible for managing	institutions should be addressed by the history of longevity
the risk	of important societal institutions
media attention to the risk	involvement of the media in a VRR resolution process
	could result in positive media attention
reversibility of the risk	any concern about the irreversibility of the consequences
	should be addressed by a showing that their chronic nature
	provides enough time to take timely mitigating measures
origin of the risk	concern about accidents resulting from human activity
	should be addressed adequately by showing that the
	facility has sufficient defense-in-depth to accommodate
	human activity without significant adverse results

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- (3) *United States v. Carroll Towing Company*, 159 F.2d 169, 173 (2d Cir. 1947) (The burden of adequate precaution must be undertaken if it is less than the product of probability of occurrence times the gravity of resulting injury.)
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- (6) *Metropolitan Edison Company v. People Against Nuclear Energy*, 460 U.S. 766 (1983).
- (7) Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U. S. 519 (1978)