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BITE THE APPLE, GET DRIVEN OUT OF THE GARDEN: A RISKY STORY TELLING AT THE ASME TOWN MEETING*

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STORY IN SHORT— ABSTRACT

Risk, the all-encompassing four-letter word became a widely used household cliché and an institutional mantra in the nineties. Risk analysis models from the Garden of Eden to the Capitol Hill lawn have made a number of sharp paradigm shifts to evolve itself as a decision-making tool from individual risk perception to societal risk-based regulatory media. Risk always coexists with benefit and is arbitrated by costs. Risk-benefit analysis has been in use in business and industry in economic ventures for a long time. Only recently risk management in its current state of development, evolved as a regulatory tool for controlling large technological systems that have potential impacts on the health and safety of the public and on the sustainability of the ecology and the environment.

This paper summarizes the evolution of the risk management concepts and models in industry and the regulatory agencies in the U.S. over the last three decades. It also discusses the benefits and limitations of this evolving discipline as it is applied to high-risk technologies from the nuclear power plant and petrochemical industry, etc. to nuclear weapons technology.

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1.0 TO BITE OR NOT TO BITE! — INTRODUCTION TO THE EPISODE OF RISKY TECHNOLOGIES

Every rational human activity is goal oriented towards achieving a benefit or satisfaction to an individual, organization, institution or the Society as a whole. But experience shows no benefit is risk free. Therefore, a significant conscious human effort is always invested in the minimization of risk and the maximization of benefit. But this min-max seesaw process is associated with a cost that is limited by resources of all kinds, both physical and societal, such as time, material, energy, economics, expertise, knowledge, etc.. Thus, a realistic human activity involves a 3-D problem solving chore in the benefit-risk-cost dimensions.

From the prototypical human of the primordial jungle (the Garden) to the terminal man of the Silicon Culture everyone has been constantly solving this 3-D equation in his/her head for their individual well-being. In the societal level, business organizations have been solving the same equation in a more formal way for the optimization of their financial returns for a long time. Only lately, for the last several decades the largest institutions like the government and regulatory agencies are involved in the development of risk-based quantitative methodologies for decision-making and regulation of large technical systems, which have significant impacts on public health and safety, and on the sustain-ability of the ecology, environment and the national economy.

Formal risk-based methodologies and concepts are evolving as a discipline called Risk Management in the nineties. Risk Management is a trans-science, which goes beyond the methodologies of hard physical and biological sciences/engineering and the soft sciences like decision theory, psychology, sociology, political science, economics, to the realm of value disciplines like expert judgment, law, ethics, political ideology, policy making, public opinion and communication; which belong to the arts. That is why it is called trans-science or post-normal science[1].

In this paper a brief description is presented on this new discipline, its strong points, limitations and future prospects. This description is a personal reflection of the author and has no institutional position. The reader should treat this as a story or description of an evolving discipline that is trying to imprint a new image in our collective psyche, which may be called the societal risk consciousness.

2.0 HOW MUCH ALAR* IS USED IN THE BIG APPLE? — DIMENSIONS OF RISKS IN HIGH RISK TECHNOLOGIES

The extent of the chemical revolution that happened over the last half century is of enormous dimension[2]. From 1930 to 1990 production of chemicals increased from one million tons to 500 million tons at an estimated doubling period of seven to eight years. The total number of chemicals discovered or created by humankind so far is about 7 million according to United Nations' statistics. The number of chemicals in common use in significant quantities is about 80,000. According to one estimate, 7,000 known

* Alar: A chemical used on apples as an insecticide and an agent for making the appearance fresh (a cosmetic role).

chemicals have been tested for carcinogenicity. California State EPA has identified 371 chemicals as potential carcinogens. The number of commercial and industrial sources of hazardous waste in the United States is 650,000. Ninety-nine percent of this hazardous waste comes from two percent of the sources. Sixty-four percent of all hazardous wastes are managed at only ten regulated facilities. Sixty-six percent of all hazardous waste comes from chemical manufacturing, twenty-three percent comes from the production of metals and machinery, three percent from petroleum refining waste and the remaining eight percent comes from hundreds of other small categories of wastes.

Nuclear wastes also make another significant component of wastes in terms of its high toxicity and presence of long-lived radioisotopes in the biosphere, in large quantities.

Another significant waste form is of the biological origin, e.g., sewage and medical infectious wastes. Recently, they are growing at an exponential rate because of localized concentration of human habitation in urban centers (the megalopolis). In the United States alone, 2·3 trillion gallons of municipal effluents per year are discharged to the coastal water system threatening the ecosystem. About 5 billion gallons of industrial waste water per year are also discharged into the coastal water system. Impact of these large amounts of manmade chemical, nuclear, and biological wastes is found to cause irreversible damage to the environment and detrimental consequences to the public health and safety.

2.1 WRATHS OF TECHNOLOGY

Modern scientific and technological revolution gave man an enormous capability to thrive in nature and improve his quality of life. But, the story is not all success and glory. It also involves high risks and liabilities. Tables 1 and 2 list some of the recent technological disasters and major problems associated with the legacy of the cold war, respectively.

2.2 SPECULATION ON THE CAUSAL RELATION OF SOCIETAL RISK CONSCIOUSNESS TO THE WRATHS OF TECHNOLOGY

These representative examples of the impacts of technology on society bring to focus the negative aspects of technological impact on society. In addition there have been ample positive evidences of increased cancer incidence in the general public, deteriorating effects on health and well-being of the general population, ecology and the environment.

Table 1
Some Examples of Recent Technological Disasters of Very High Societal Consequence

Accident	Year	Consequence
1. TMI	1979	Minimal Public Health Consequence, Public Faith in Technology Eroded Significantly
2. Bhopal	1984	3,000 dead, 10,000 disabled, $470 Million Settlement
3. Chernobyl	1986	Very Large Consequence; $100 Billion Estimated; 50,000 local residents exposed to large doses; 100,000 clean-up workers exposed to very high doses; contamination of large areas of Eastern Europe and Scandinavia
4. Challenger	1986	7 deaths, large public impact
5. Valdez	1989	$3.5 billion cleanup cost; $5 billion fine imposed

These led to a social consciousness about the risks of large technological systems that accelerated the global environmental movement which was initiated since Rachel Carson's "Silent Spring" (1962). British historian, Arnold Toynbee, saw the evolutionary dynamics in human civilization in terms of challenge and response[3]. Perhaps the response is currently operative in our society through the risk-based regulatory activities to the challenge of the assaulting power of technology to the biosphere. Man's evolution from a ferocious predator to an ambitious analyst claiming to control all catastrophes, both natural and man-made gives a false sense of supreme power. The new analytical capability of risk assessment and the associated risk management efforts are some new toys that are thought to be the panacea of solutions of all the problems of high risk technologies. But if this new toy or the technique is not used with judgment recognizing its advantages and limitations, it may cause more problems than solutions. If realistic decisions are not made in the application of this technique, the process may suffer from "paralysis-by-analysis" syndrome. If judiciously used, this analytical, logical technique excels other methods in developing insights and decisions about the vulnerabilities of the systems and processes by a rational method and model, which are superior to gut-feeling type of decision making. Perhaps this is the reason Risk Management became an institutional mantra at the government policy making apparatus. However, critics like the analytic philosophers against methods may maintain that the ambitious analysts lured the institutional child to this new toy at the *Toys-R-Us of Science*. Who knows? Only time will tell. Let us proceed with the story in the meantime.

Table 2
Legacy of the Cold War

1. Contamination due to Military Facilities Accidents/Operations in the Former Soviet Union (FSU)
   a) Mayak Nuclear Facility (near Ozyorsk, former Secret City of Chelyabinsk)
   b) Explosion of nuclear material at Kyshtyn
   c) Dumping of HL nuclear waste into Lake Karachai and the Techa River, near Chelyabinsk
   d) Contamination of the Barents and Kara seas by dumping low-level waste and the nuclear submarines abandoned at Novaya Zembya
   e) Continued practice of sea dumping of low-level waste due to absence of storage facility on land.
   f) 6000 tons of spent nuclear fuel stored in the FSU
   g) Tens of thousands of fuel assemblies in Russian Nuclear Submarines.

2. U.S. Weapons Complex
   a) Great public concern over contamination at Hanford and Rocky Flats.
   b) Expected time for cleanup - 30 years.
   c) Estimated Total Cost Range: $258 B (min)
$678 B (max)

3.0 HOW MUCH IS ALLOWABLE? — RISK-BASED REGULATIONS: A SHORT HISTORICAL PERSPECTIVE OF RISK MANAGEMENT

Probabilistic Risk Assessment (PRA) in the technical field was initiated first in the nuclear power industry in the 1960's. F.R. Farmer[4] of UK AEC introduced the Probabilistic Siting Criteria of nuclear plants in 1967 by postulating a "risk line" based on the equation $P \times C^{\alpha}$; product of the probability of accident and the consequence by the release of the amount of I^{131} from the reactor core. The exponent, α determines the slope of this "risk line" on a log-log plot. In 1969 Chauncey Starr[5] in the U.S. showed a probabilistic relation between the acceptance of risk from larger technological system and the benefits in relative financial terms as a framework for a risk management range in large technological systems. In this relation, he identified three regions of risk levels: Excessive, Management range, and Deminimis range or Below Regulatory Concern (BRC). These initial efforts by the pioneers in the field established the ground work of risk assessment/risk management concepts in the regulation of large technological system in the societal context.

In the early 1970's the methodology for the quantitative PRA was established by the pioneering WASH-1400 study by Professor Norman Rasmussen[6] under the sponsorship of the U.S. Nuclear Regulatory Commission. Since late 1980's through the present the methodology has been improved by further regulatory research and studies and PRA is being used in support of regulation and licensing of nuclear power plants. Other government agencies have also started evolving risk-based regulatory processes since late 1960's, first using a qualitative approach method, then into quantitative method since the

1980's. In this regard, Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), and other agencies developed their quantitative safety goals for the implementation of the risk-based regulation. National Aeronautics and Space Administration (NASA) started using quantitative risk assessment technique since the Challenger disaster (1986). NASA's policy NMI8070.4 on risk management established the frame work for integrative and quantitative risk analysis. Chemical industry has been performing safety and reliability analysis for more than two decades by using qualitative Hazard and Operability (HAZOP) analysis.[7] Table 3 summarizes the evolution of risk-based regulations at U.S. NRC and Table 4 shows the milestones of the EPA and other regulatory agencies' efforts over the last three decades to regulate chemical risks. All these agencies base their risks in terms of number of additional cancer deaths due to nuclear radiation and/or carcinogenic chemicals above that due to natural background level. Table 5 compares the probabilistic safety goals of various agencies.

Table 3
Highlights of Nuclear Regulatory Commission (NRC)
Risk-Based Regulatory History

- 1967 Reactor Siting Criteria - Farmer's Paradigm - Risk Line
- 1975 Wash - 1400 (Methodology for Risk Assessment)
- 1986 Safety Goals for the Operation of Nuclear Power Plants
- 1988 Generic Letter - IPE (Individual Plant Examination)
- 1989 NUREG - 1150 - Severe Accidents Risks: An Assessment for Five U.S. Nuclear Power Plants
- 1991 NUREG - 1407 - IPEEE (Individual Plant External Events Examination)
- 1992 Advanced Reactor - Risk Assessment - Ch. 19 of the Safety Analysis Report

Table 4
Highlights of Other Regulatory Agency's Risk-Based Regulatory History
(e.g., EPA, FDA, etc.)

- 1969 National Environmental Policy Act (NEPA)
- Mid-70's Pesticide Residue Issue
  Zero Risk Requirement
  (Delaney Clause - Zero Tolerance in Food Additive)
- 1976 First Environmental Health Risk Characterization (Qualitative), Cancer Risk, Use of Categories
- 1976-83 Slow Growth in Quantitative Risk Assessment
  National Academy of Science Paradigm
- 1983 Established the Foundation for Health Risk Analysis and the Paradigm for Risk-Based Regulation at EPA
- 1986 EPA Guidelines for Risk Assessment and Management
- 1983-94 Evolving Risk-Based Regulation and Policy

Table 5
Safety Goals Proposed by Various Agencies
(Probabilistic Additional Cancer Risk)

Organization/ Agency	Source of Risk	Nature of Risk	Safety Goal (per year)
FDA	Toxic Chemical (Food additive)	Incremental life time cancer risk	1×10^{-6}/yr.
OSHA	Exposure to carcinogenic chemical	Lifetime incremental cancer risk	1×10^{-3} (significant) 1×10^{-9} trivial (B.R.C.)
EPA	Abandoned hazardous waste sites (Superfund Program)	Lifetime incremental cancer risk	$>1 \times 10^{-6}$ (significant)
NRC	NPP Accident - Nuclear Radiation	1. Prompt Fatality 2. Lifetime incremental cancer risk	0.1% of all other causes 0.1% of all other causes (latent cancer)
DOE	Hazardous Facility - Nuclear Radiation Hazards	1. Prompt Fatality 2. Lifetime incremental cancer risk	Same as above Same as above

4.0 ASTRONOMICAL LAUNDRY BILL! — COST OF REGULATION

To regulate the high-risk technologies costs enormous amount of money. One estimate for the cost per life-year saved (1990 dollars) by the lifesaving regulatory program of the routine radiation control at nuclear power plants is given as $164,875,379.[8] Annual environmental risk reduction costs $150 billion/year. Clean Air Act Amendment of 1990 costs $25 billion/year (additional). EPA's proposed regulation of pulp and paper industry costs $880 million/year. One estimate[9] gives the costs of chemical clean up of 420,000 sites, having various waste categories range from a maximum of $678 billion to a minimum of $258 billion. The cost variation is dependent on the degree of clean up. Cleaning up the first 90% costs less than the last 10% because the difficulty increases exponentially. The cost of clean up or containment of contamination at the U.S. military sites (for example, Rocky Flats and Hanford) is expected to be $150—250 billion and will take about 30 years.[10] Estimated cleanup cost for the Nevada Test Site ranges from 1 to 45 billion dollars depending on the level of cleanup concentration (pCi/g).[11] This shows the magnitude of the cost of clean up, which will cause severe strain on the federal financial health as it did to the nuclear power industry in the eighties. A familiar echo of the eighties to the issue of *"how safe is safe enough"* in the nuclear industry is being reverberated in the government agencies in the issue of *"how clean is clean enough"* in the nineties. This astronomical laundry bill may bankrupt the federal exchequer.

5.0 IN SEARCH OF A PARADIGM — A STRUCTURE IN CHAOS?

Although the risk assessment methodologies and applications have been evolving since the early part of 1970, the concept of risk management as an integrated approach for regulation and decision process did not come into existence before the middle of the 1980's. The Study of the National Academy of Science in 1983, for the first time came up with a paradigm for risk management,[12] which illustrated the separate, but interactive relation between risk assessment and risk management activities and functions (Figure 1). This paradigm is used by the Environmental Protection Agency for its risk-based regulatory activities.[13] It provides a good model of the complex multidisciplinary process involved in risk management. It depicts basic differences between the two-culture aspects of this new science which has been baptized by Weinberg as a trans-science[14]. It is appropriately called trans-science or post normal science because only the risk assessment part follows the Scientific Methodologies whereas the risk management part addresses societal, political, ethical, legal issues which belong to value disciplines and the arts. There is no question about the usefulness of this kind of paradigm or model. It delineates the basic functions of the dual nature of the discipline and gives a structural basis for organizational responsibilities and component activities. A ponderable structure is born out of chaotic confusion associated with the roles of risk assessment and risk management activities.

Although this paradigm is definitely a useful and valuable model for describing the various components of the risk management activities, it does not include all aspects of risk management as applied currently in risk-based regulatory process. Inclusion of other dimensions to the model by adding the concept of comparative risk for the evaluation and communication of risk has been proposed. It is also proposed to add another component as Science policy or the institutional aspect of risk to the front end of risk assessment segment in the paradigm. In addition, to show the interactive flow of information between the various components of risk management an interactive loop may be introduced in the paradigm which will allow the provision for improvement from the learning process of the risk assessment/risk management applications. Figure 2 depicts such an interactive paradigm.

Figure 1. Risk Assessment/Risk Management Paradigm —
NATIONAL ACADEMY OF SCIENCE VERSION

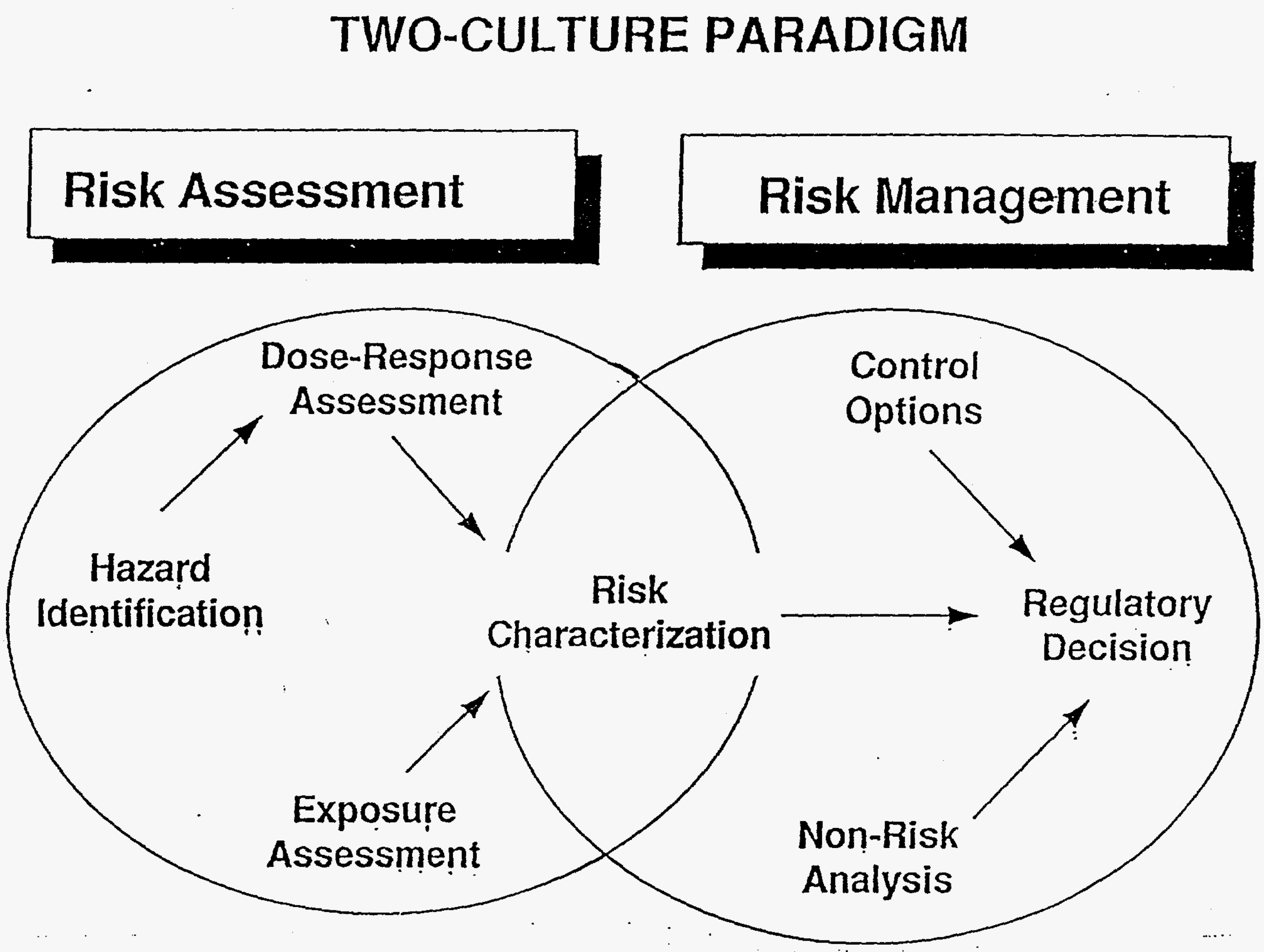
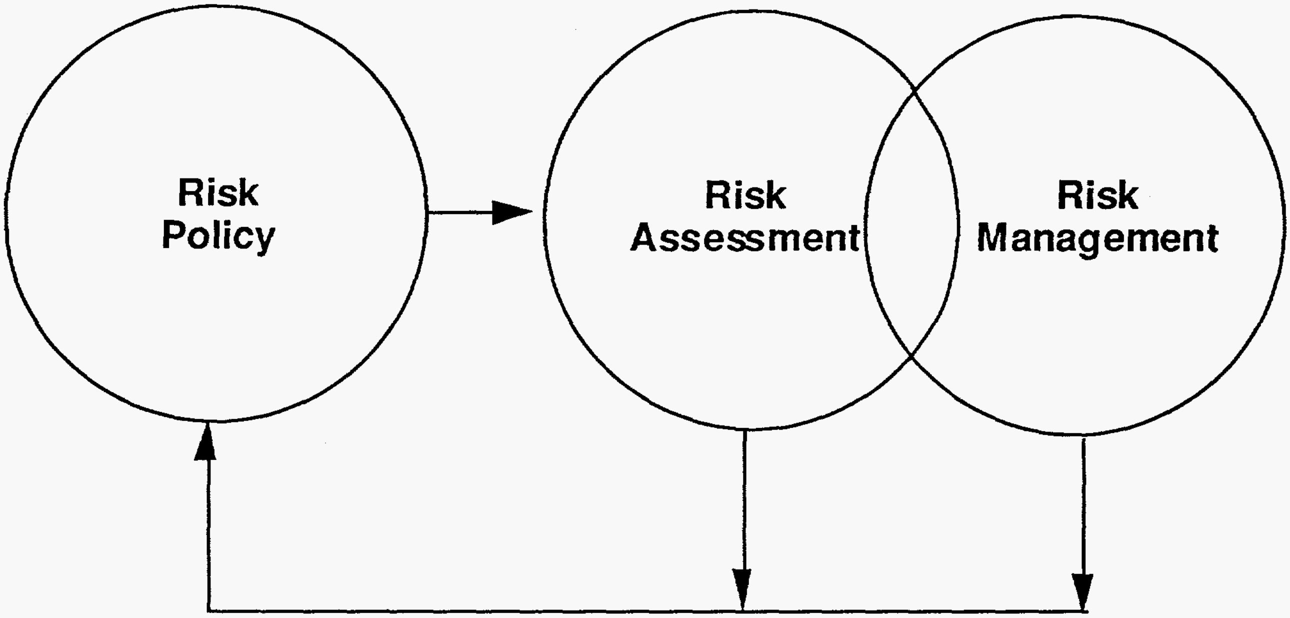


Figure 2. An Interactive Risk Management Paradigm — Another Mutation of the National Academy of Science Version



6.0 DUELS OF THE EXPERTS - NORMAL ACCIDENT VS. HIGH RELIABILITY ORGANIZATION THEORY

Risk assessment and risk management paradigm brought up a rational framework for the risk-based regulation in terms of its scope and responsibility definition. However, there remains an unresolved controversy over how to control the modern high-risk technologies like the nuclear power, nuclear weapons, complex chemical and petrochemical technologies, recombinant DNA technology, large dams, hazardous material transportation technologies, etc. These technologies have large economic benefits and also catastrophic impacts on the society if they fail. Strategies and limits for regulating such high-risk technologies are being debated along two competing theory lines: the "Normal Accident Theory" and the "High Reliability Organization Theory".

The "Normal Accident" School has the premise that severe accidents are inevitable over time in spite of all rational measures. Its premise is based on the conviction that the great complexity and the tightly coupled nature of the systems in high-risk technologies are inherently prone to accidents because of the high degrees of both interactive complexity and tight coupling.[15] The other School postulates that by building redundancy into design, operation, procedure, having safety-conscious organizational culture and learning from trial and error a high-reliability organizational system can be developed and operated without high consequence accidents.[16]

Evaluation of test cases from the existing high-risk technologies have been performed by both Schools. However, gathered evidence leans more towards the conviction of the Normal Accident School.[17] These two Schools replicate the age-old controversy of the inherent vulnerability of human condition vs. the control of destiny by human free will and rationality.

7.0 LIVED HALF-HEARTEDLY EVER AFTER — CONCLUSION OF A CONFUSION!

In the spirit of story telling, the following concocted parable of homo-fabricator may be endured.

Since that first severe accident, LOHA (the Loss of Heaven Accident), man, the Homo Habilis became Homo-Fabre (the tool maker). Technology was born and transformed him into Homo-Sapien. Escalation of technology released an enormous conquering and harnessing power of man on nature. Perhaps this is an over-correcting mitigative effect of that primordial accident. Complex technologies did build a dream of recreated heaven on earth. But as is already evidenced, the story is not of unmixed blessing and not even an equitable ratio of benefit to risk. Analytic philosophers, competent sociologists, eminent scientists/technologists and enlightened political scientists all are wrestling with the same old 3-D problem solving of the risk-benefit-cost continuum of high-risk technologies. There are serious disagreements among them on the level of regulatory controls of these technologies, since there are uncertainties in all levels of analysis, individual and collective biases, and downright arrogance and ignorance leading to a chaotic decision process for establishing policy for regulatory control. The only bright spot on this chaotic situation is that, in spite of all analytic and social limitations a science-based risk policy can nurture a culture that will ultimately make the technology-based society safer than it is currently predicted or it is realized that there is no free lunch. Therefore, let us have "peace of mind" with the realization that technology has its own limits and let us live half-heartedly ever after! We may not quite live that peacefully when we hear the warning of an eminent social scientist against the risk assessment profession which is engaged in assisting to regulate the risks of new high-risk technologies. Charles Perrow[17] warns us:

" ... The new risks have produced a new breed of shamans, called risk assessors. As with the shamans and the physicians of old, it might be more dangerous to go to them for advice than to suffer unattended. ... The dangers of this new alchemy where body counting replaces social and cultural values and excludes us from participating in decisions about the risks that a few have decided the many cannot do without. The issue is not risk, but power."

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