2) Risk assessment: History and perspective

a) Ideas of Risk

i) Risk is a construct – Before risk there was fate


ii) As originally formulated, risk is

(1) Statistically based

(a) Originated from questions of how to avoid losing games of chance (a then unrecognized question of economic risk)

(b) Girolamo Cardano (1500 - 1571) – The Renaissance Gambler – wrote *Liber de Ludo Aleae (Book on Games of Chance)*, the first serious effort to develop statistical principles of probability (Bernstein pp. 47-54).

(c) Blaise Pascal and Pierre de Fermat (1654) solve Paccioli’s puzzle and create the theory of probability (Bernstein, pp. 60 - 70).

(2) Epidemological/Actuarial

(a) John Graunt (1662) – *Natural and Political Observations made upon the Bills of Mortality* – compilation of births and deaths in London from 1604 to 1661

(3) Thus, risk is a probability (of an unwanted event)

iii) As the concept has evolved, risk has morphed

(1) Risk (science-based)

(a) *The likelihood of harm to be manifested under relevant conditions*

(2) Risk (broadly)

(a) *Risk is a function of knowledge, trust, and perception*
(3) Risk (relativistic, revisionist)

(a) Risk is perception

(4) The goal of the risk analyst is to maximize knowledge and trust through science-based assessments that minimize relativism in risk-based decision-making.


b) Risk Analysis and Policy: Use and Frameworks

i) “[Risk and] policy analysis is analytical activity undertaken in direct support of specific public or private sector decision makers who are faced with a decision that must be made or a problem that must be resolved.”


ii) Risk as we address it in this course is focused on considerations of human, animal, and ecological risk

(1) Harm arising from the effect of a stressor

*stressor* — any physical, chemical, or biological entity that can induce an adverse response (synonymous with agent)
iii) risk analysis from this standpoint is recent (1970’s) and has its basis in regulatory decision-making

(1) Redbook Paradigm


**Red Book Paradigm**

Under the Red Book paradigm, risk assessment is largely a science-driven process that quantitatively evaluates the probability of risk. As such, risk assessment is largely, but not entirely, removed from emotive factors that influence risk perception. Risk assessment flows in a logical, stepwise fashion from problem formulation through characterization of effect (toxicity or hazard), exposure, and risk. It culminates in a risk conclusion. The characterization process is recursive; when risk characterization shows concerns, new science is brought forward and mitigation options are considered in the refinement of the risk assessment. This process of recursive characterization mostly focuses on exposure refinement and proceeds by tiers. Lower tiers use extremely conservative assumptions to screen out negligible risk concerns. Emphasis is placed on increased scientific scrutiny of issues of concern in higher, more scientifically exacting tiers of assessment. Key to the assessment of risk is the understanding and treatment...
of variable and uncertain assumptions in the assessment. Conservative assumptions within tiers of assessment, coupled with refinement and mitigation, largely determine how the risk will eventually be managed and communicated. Risk analysis, under the Red Book paradigm, does not consider science to occur in a vacuum. Risk managers bring forward social, cultural, economic, and political concerns in the process of problem formulation and also monitor the risk assessment throughout its various stages. Additionally, the risk manager formulates the risk assessment conclusions along with social, cultural, economic, and political concerns in making and implementing policy.*

(2) Orangebook Paradigm


The emergence of the Orange Book paradigm for risk analysis (NRC, 1996) represents the ascendancy of the policy specialist as the driver in risk determinations. This paradigm shifts risk characterization from a science-driven enterprise to an “analytic-deliberative” process where analytical characterization of risk and uncertainty (the science part) is augmented with deliberation among all interested parties to determine how uncertainties are to be addressed. This approach to risk analysis, where all stakeholders are
simultaneously engaged in the characterization of risk, ostensibly increases transparency and, therefore, heightens knowledge and trust by the public. The current vogue for such an approach to risk analysis is an indictment of the ability of scientists to effectively engage interested parties in problem formulation and to communicate risk in a way understandable to both risk managers and the public.*


c) Challenges for the risk assessor


ii) Parsing variance and uncertainty

(1) Variance: “objective uncertainty”

an *statistically-based measurement of the heterogeneity present in experimental measurements*

(2) Uncertainty: a best guess

an *estimate of inputs that are not measured and/or are not measurable*

(3) In the face of uncertainties scientists seek to measure variance, whereas, the risk assessor will use estimates and sensitivities

*i.e., What is the effect on the outcome when an estimate varies over three orders of magnitude?*

iii) Maintaining integrity of the risk assessment

- formalism
- transparency
- iterative approach
- delineation of known and unknown
- parsing of heterogeneity from lack-of-knowledge
- quantitative (probabilistic)
risk assessment … scientific, but not science *per se*

<table>
<thead>
<tr>
<th>Science</th>
<th>Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ empirically driven</td>
<td>□ limited empirical data</td>
</tr>
<tr>
<td>□ fully documented</td>
<td>□ incomplete documentation</td>
</tr>
<tr>
<td>□ reports heterogeneities</td>
<td>□ reports lack of knowledge</td>
</tr>
<tr>
<td>□ peer review</td>
<td>□ peer review is arduous</td>
</tr>
<tr>
<td>□ full and open debate</td>
<td>□ nature of process hinders debate</td>
</tr>
</tbody>
</table>

**Ten Commandments for the Risk Assessor** (after Morgan & Henrion)

1) Do your homework with literature, experts, and users.
2) Let the problem drive the analysis.
3) Make the analysis as simple as possible, but no simpler.
4) Identify all significant assumptions.
5) Be explicit about decision criteria and policy strategies.
6) Be explicit about uncertainties.
7) Perform systematic sensitivity and uncertainty analysis.
8) Iteratively refine the problem statement and analysis.
9) Document clearly and completely.
10) Expose the work to peer review.
iv) Adjusting to alternative decision-making criteria
Frequently reflected in regulatory policies and guidance

**Utility-based criteria**
- Deterministic benefit-cost
- Cost effectiveness
- Bounded cost
- Maximize multi-attribute utility
- Minimize chance of worst possible outcome

**Rights-based criteria**
- Zero risk
- Approval/compensation
- Approved process

**Technology-based criteria**
- Best available technology

**Hybrid criteria**