MEDICAL POLICY FORMULATION PROCESS AND TOOLS

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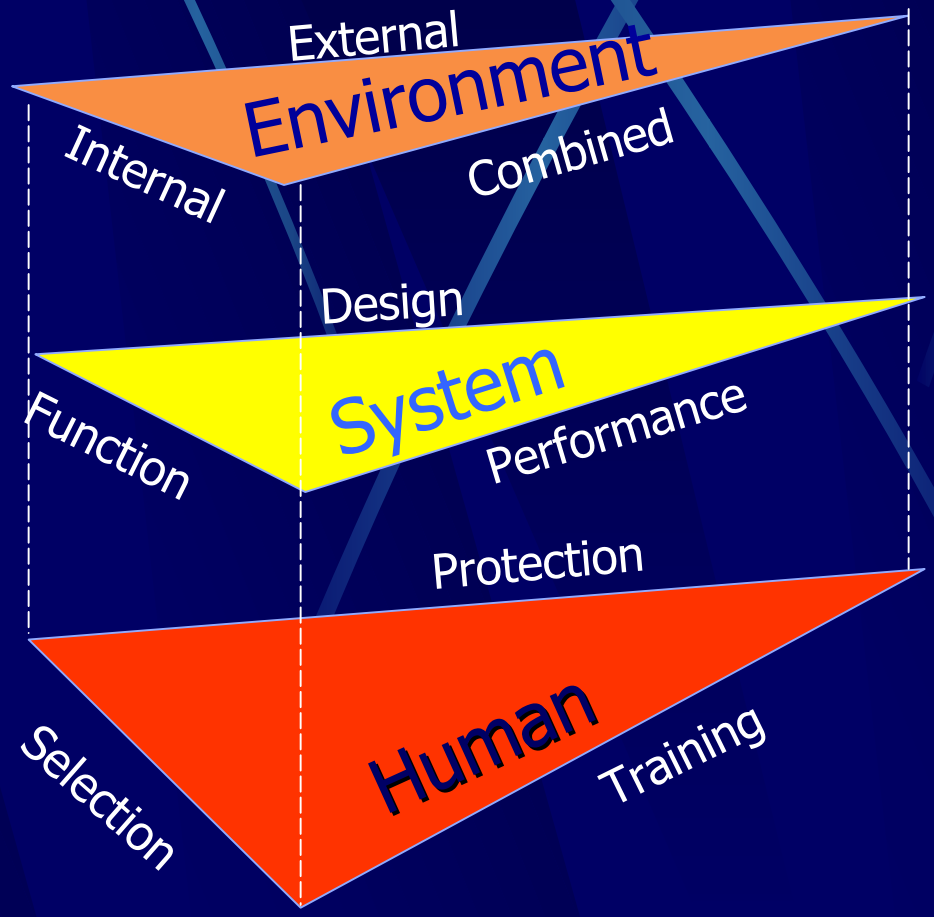
A Sequential Process

A 3-D Analytic Paradigm

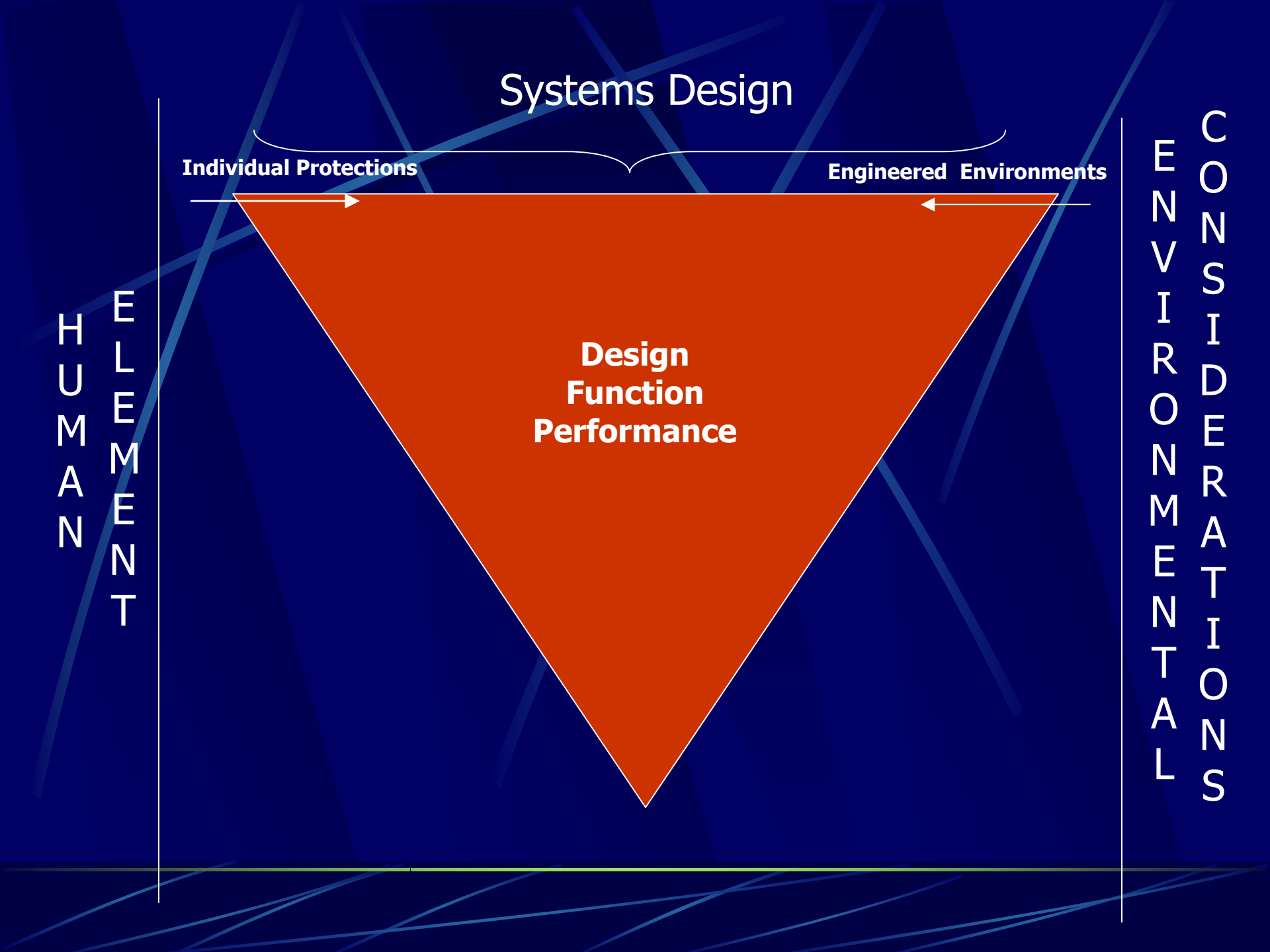

Stakeholders
Expedition/
Destination
Problems
Risks
Resources
Solutions/
Protection
Policy
Rx
POLICY
FORMULATION
PROCESS

Extreme Environments: Essential Elements of Policy



Adapted from Nicogossian 2001

Systems Design



Stakeholders

Stakeholders

- Persons with authority to make decisions
- Persons representing direct interests
  - Providers
  - Clients
  - Vendors
- Persons with opinions
- Persons with interests in outcomes

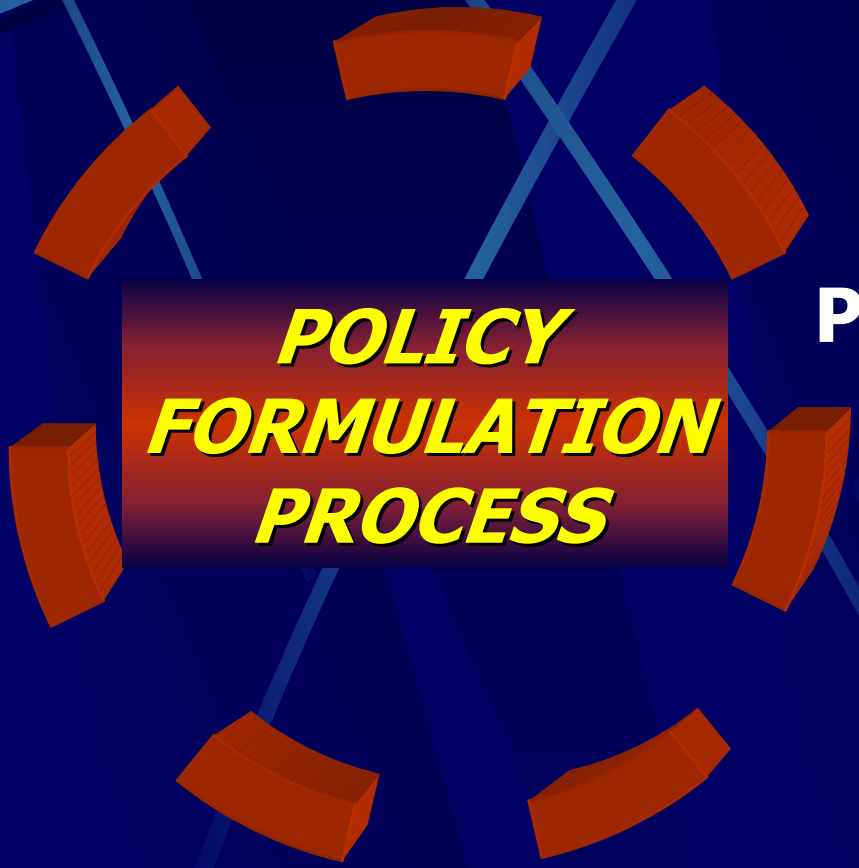
Methods of eliciting input

- Focus groups
- Commissions
- Consensus conferences
- In-depth groups—long term focus groups
- Stakeholder decision analysis
- Surveys and polling

Expedition/
destination

Expedition/destination

- Defines the:
  - Problems
  - Barriers
  - Resources
- Drives the:
  - Imperatives
  - Impact(s)
  - Outcome(s)



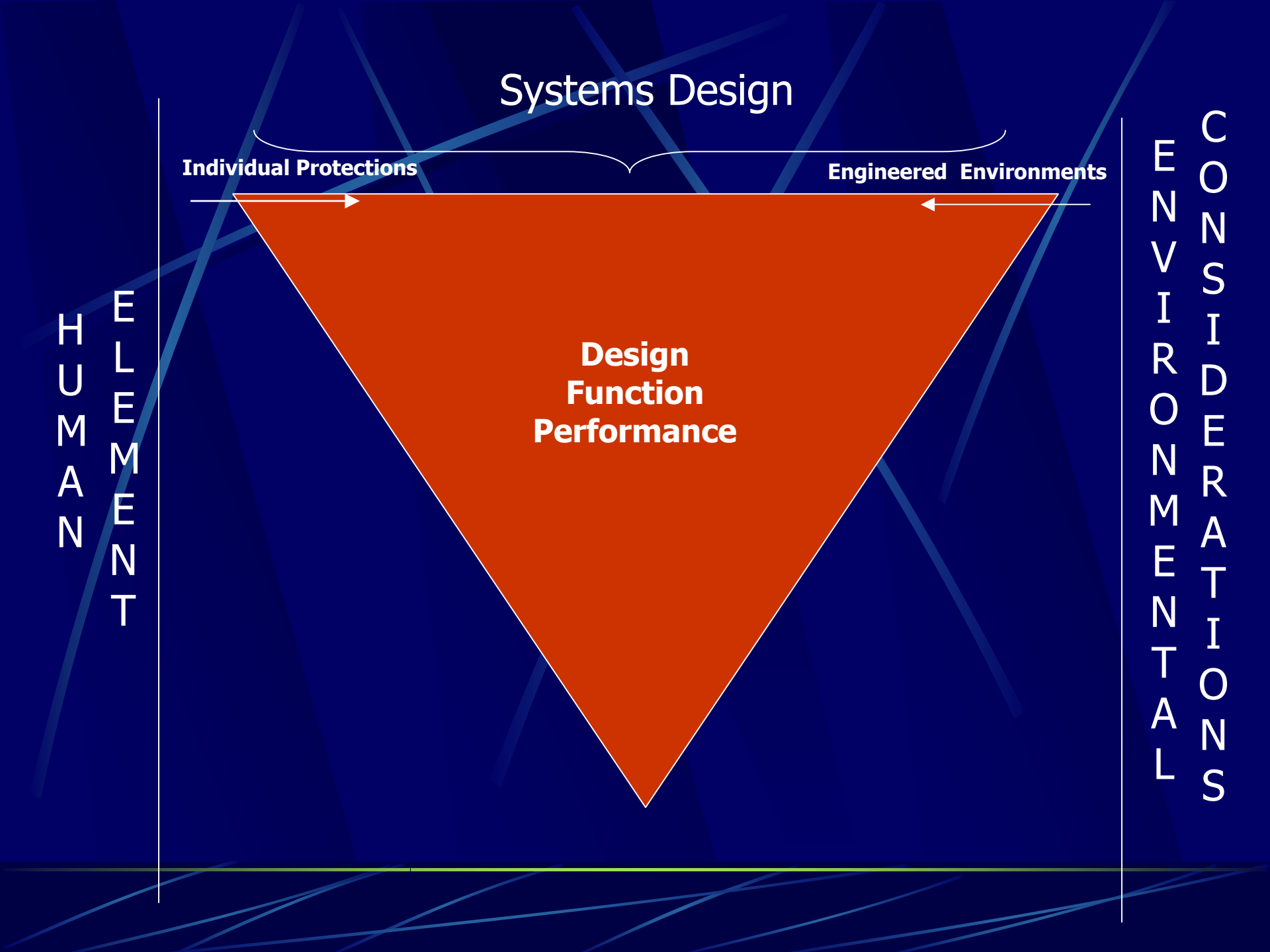
Problems

Problems:

- **Environment**
  - To destination
  - At destination
  - Return from destination
- **Human**
  - Is adaptation required?
  - Illness?
  - Injury?
- **Technology**
  - Logistics
  - Reliability
  - Level of protection
  - Health & safety

- Problems
- Barriers
- Resources

Systems Design



---proposed tool to log problems and risks

Environmental Considerations Assessment Inventory: Journer To/From					
Characteristic	**Problem**	**Risk Index**	**Long Term Health**		
Atmosphere					
Altitude/depth					
Temperature					
Water					
Nutrition					
Remoteness					
Isolation					
Confinement					
Communication					
Radiation					
Terrain					
Weather					
Infectious disease					
Predators					
Emergency Recovery					
Unknown Risk(s)					
Aggregated Risk Index					

---proposed tool to log problems and risks

Environmental Considerations Assessment Inventory: On Site

Characteristic	Problem	Risk Index	Long Term Health		
Atmosphere					
Altitude/depth					
Temperature					
Water					
Nutrition					
Remoteness					
Isolation					
Confinement					
Communication					
Radiation					
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Unknown Risk(s)					
Aggregated Risk Index					


POLICY
FORMULATION
PROCESS
Risks

Risks:

- Data envelope
- Categorization
- Qualifiers
- Time consideration

Categorization of Risks

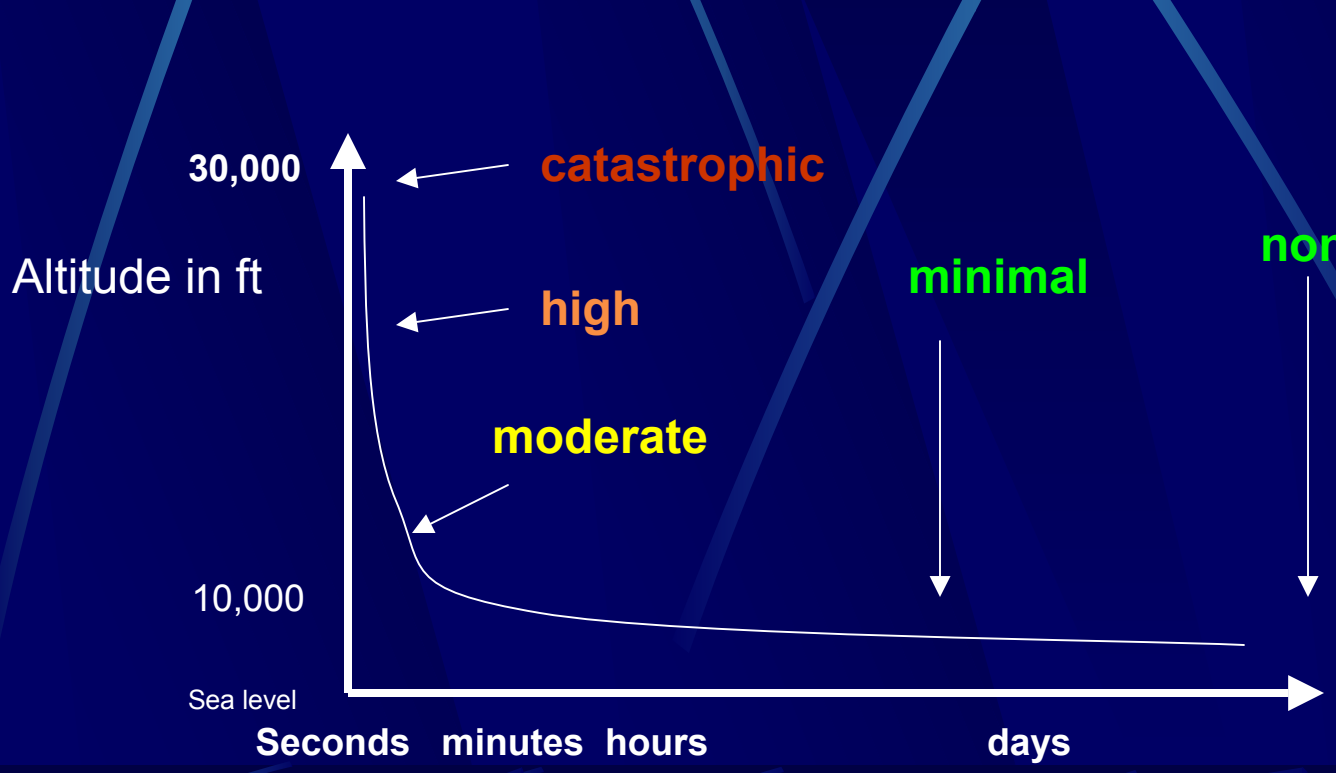
- None (0)
- Low (1)
- Moderate (2)
- High (3)
- Catastrophic (4)
- Unknown (5)

Definitions

- **None** : no known risks
- **Unknown**: unquantifiable risk which can range from 0 to ∞
- **Catastrophic**: loss of life or significant impairment with marked decrease of AQL
- **High**: significant probability of death, injury of disease
- **Medium**: probability of injury of disease which can be life threatening
- **Low** : small probability of life threatening events

Normative Data

Atmospheric Pressure, Hypoxia and Death (healthy individuals)



Determining

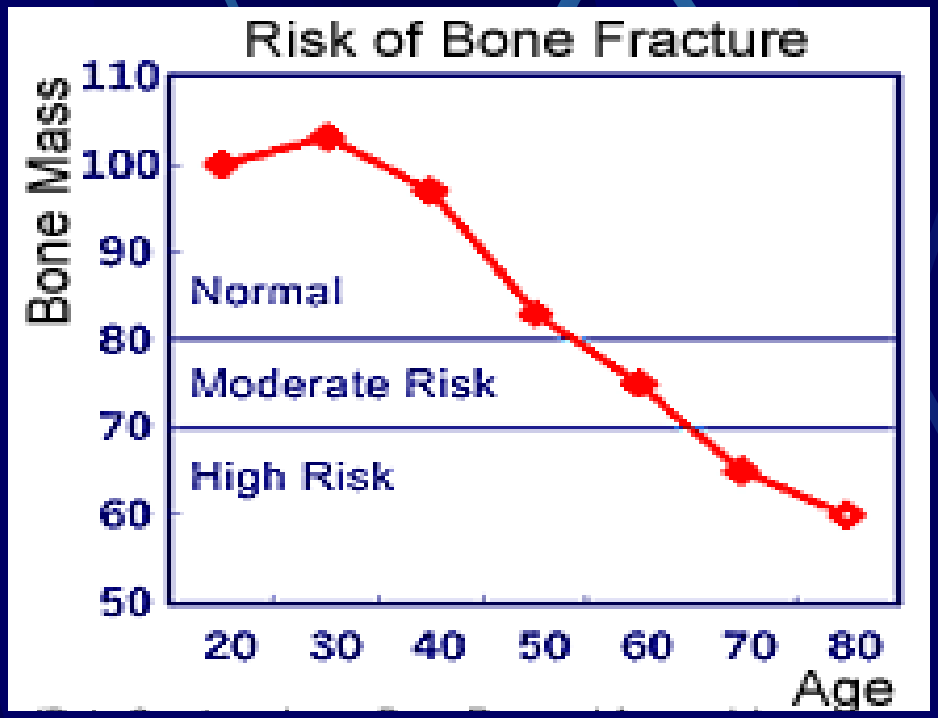
And

Communicating

Clinical

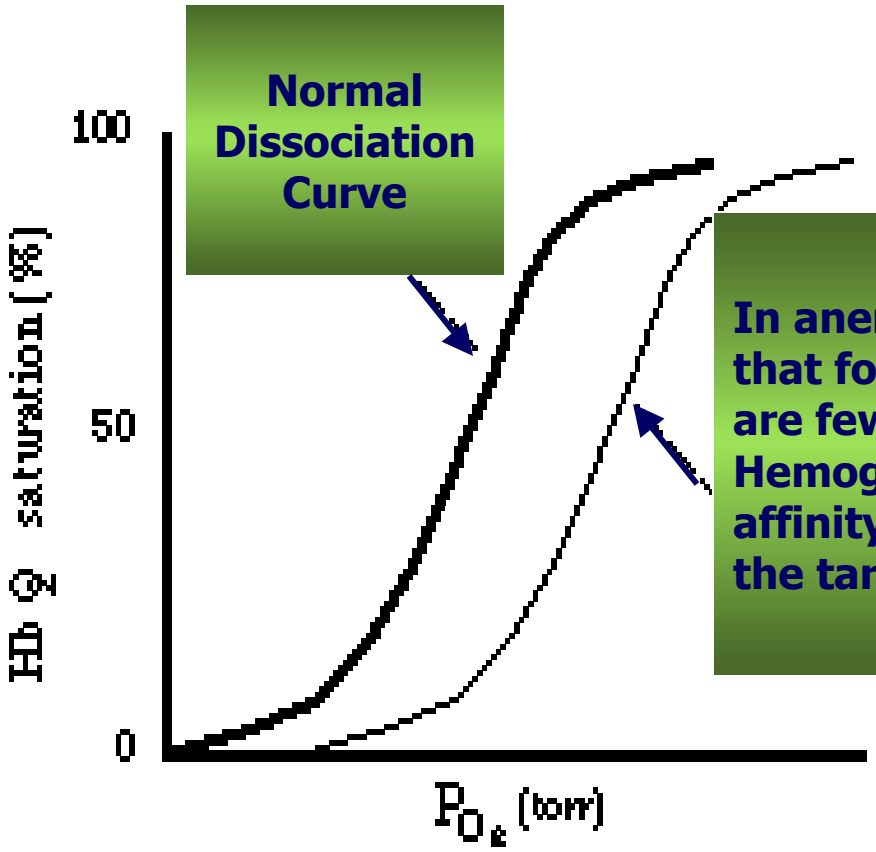
Significance

Bone Mass Loss and Risk of Fractures



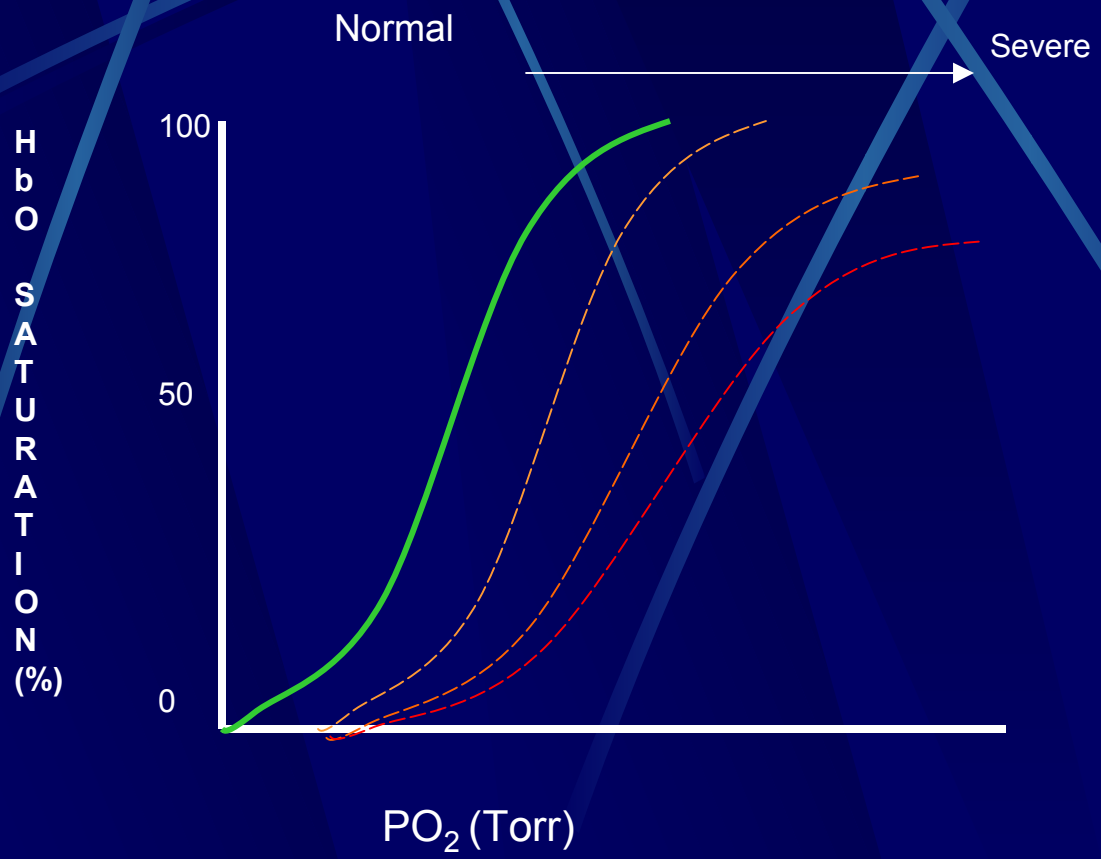
Adapted from the Japan Bone Renewal Academy

Anemia



In anemia, 2,3-DPG shifts curve to the right, so that for a given partial pressure of O_2 there are fewer O_2 molecules associated with the Hemoglobin—less saturation. This decreased affinity translates to better O_2 delivery to the target tissues.

Anemia



Radiation

RISK

Low

Medium

High

Catastrophic

Acute Whole-Body Radiation

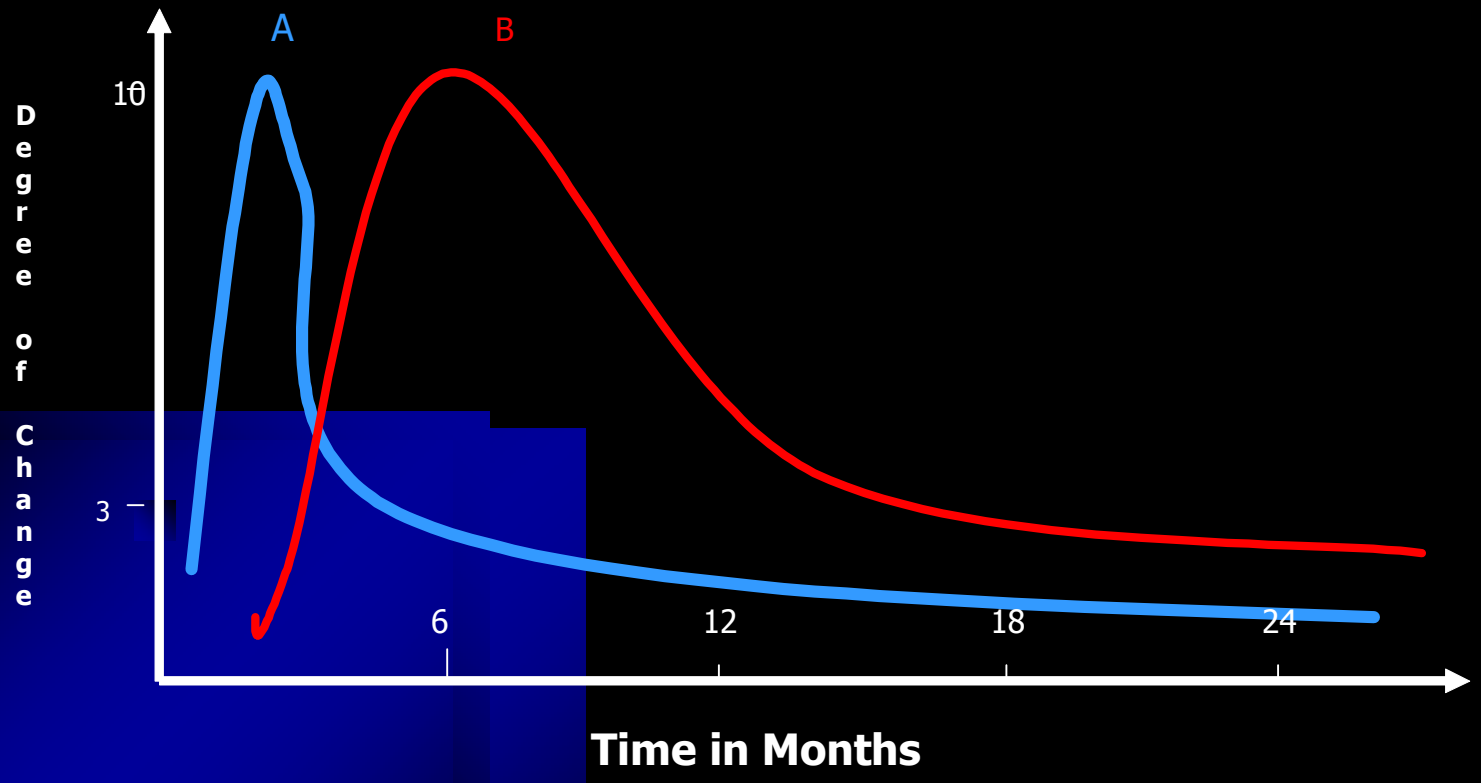
Dose (rem)	Probable Physiologic Effects
10-50	No obvious effects, except minor blood changes
50-100	5-10% nausea & vomiting for ~ 1 day; fatigue; slight reduction in lymphocytes & neutrophils; no deaths
100-200	25-50% nausea & vomiting for ~ 1 day; more symptoms; 50% reduction in lymphocytes & neutrophils; no deaths
200-350	Most have nausea & vomiting on first day; loss of appetite, diarrhea, some hemorrhage; up to 75% reduction in all circulating blood elements; death of 5 to 50%
350-550	Nearly all have nausea & vomiting on Day 1; hemorrhage, diarrhea, fever, emaciation; death of 50 to 90% by 6 weeks

Solar Particle Event can yield 100 - 500 rem in 1 day !

	more severe symptoms; death of up to 100%
750-1000	Severe nausea & vomiting may continue into the 3rd day; survival time less than 2.5 weeks
1000-2000	Nausea & vomiting within 1- 2 hours; all die within 2 weeks

Human Adaptation Profile

Adapted from A. Nicogossian 1984



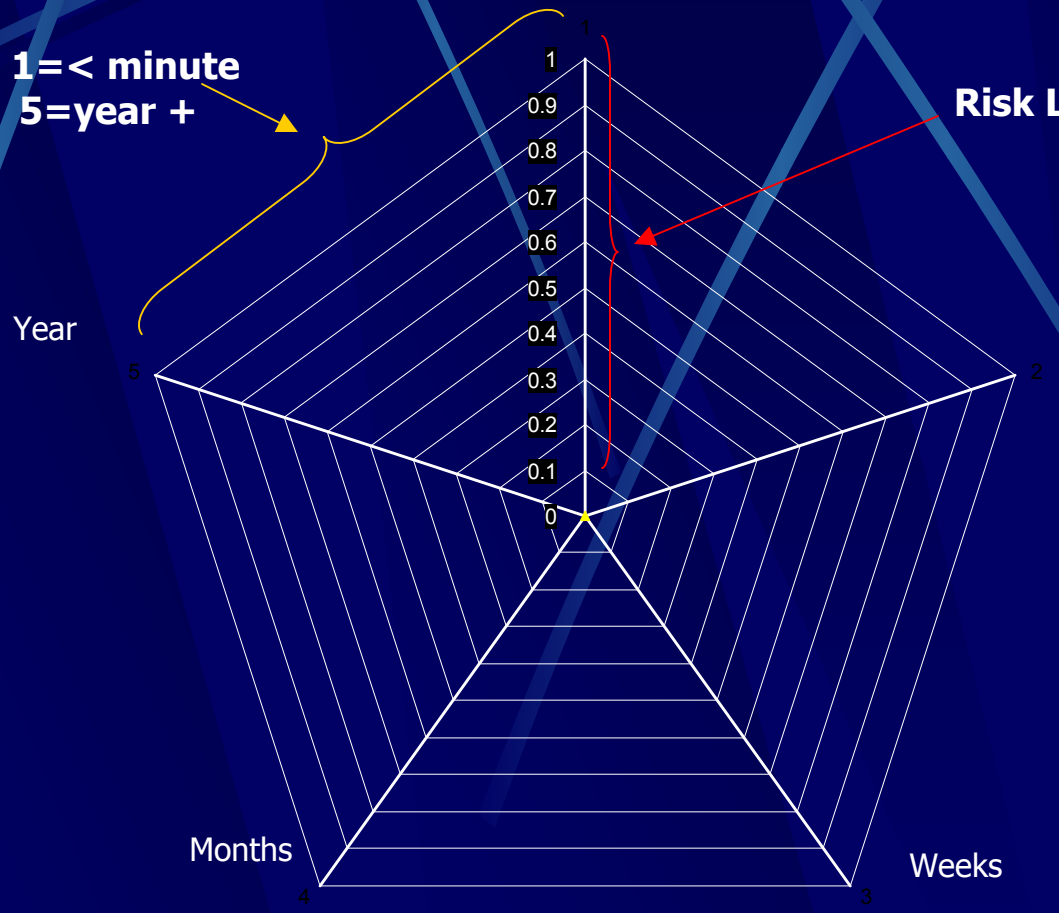
A = Acute adaptatation (usually complete) for Neuro Sensory and Motor, Cardiopulmonary,and to a lesser degree fluid and electrolyte systems

B = Chronic processes, sometimes patho-physiologic, occasionally reversible with countermeasures, for all other systems

---proposed tool to assist in assessing, calibrating and quantifying risk, illustrating relative risk, and communicating

Exposure Duration: 1=< minute 5=year +

Risk Level: 0=normal daily 1=catastrophic



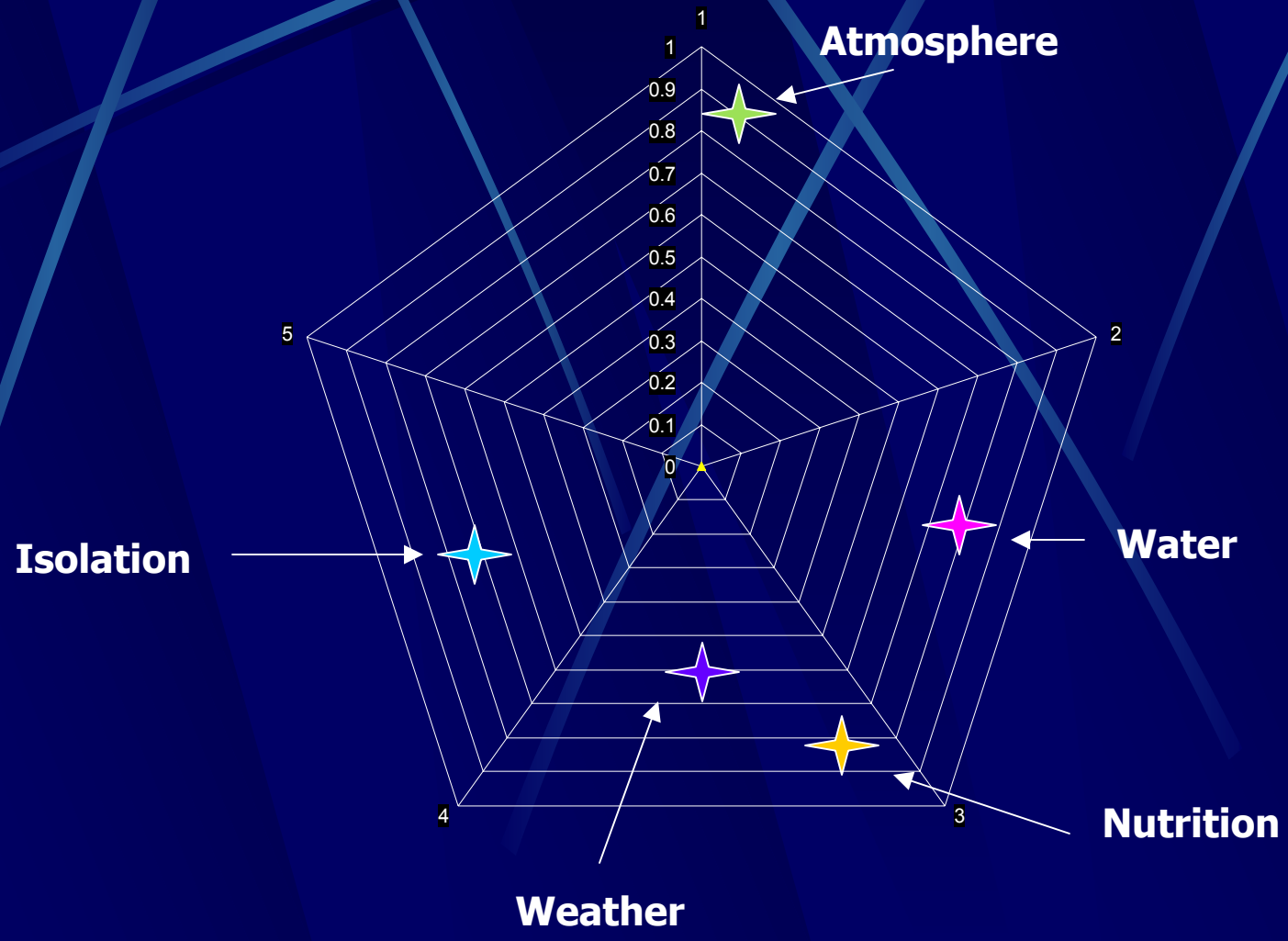
Risk Scoring Index

Example: Atmosphere on top Mount Everest=**1.8**

Matter of minutes

Level of risk

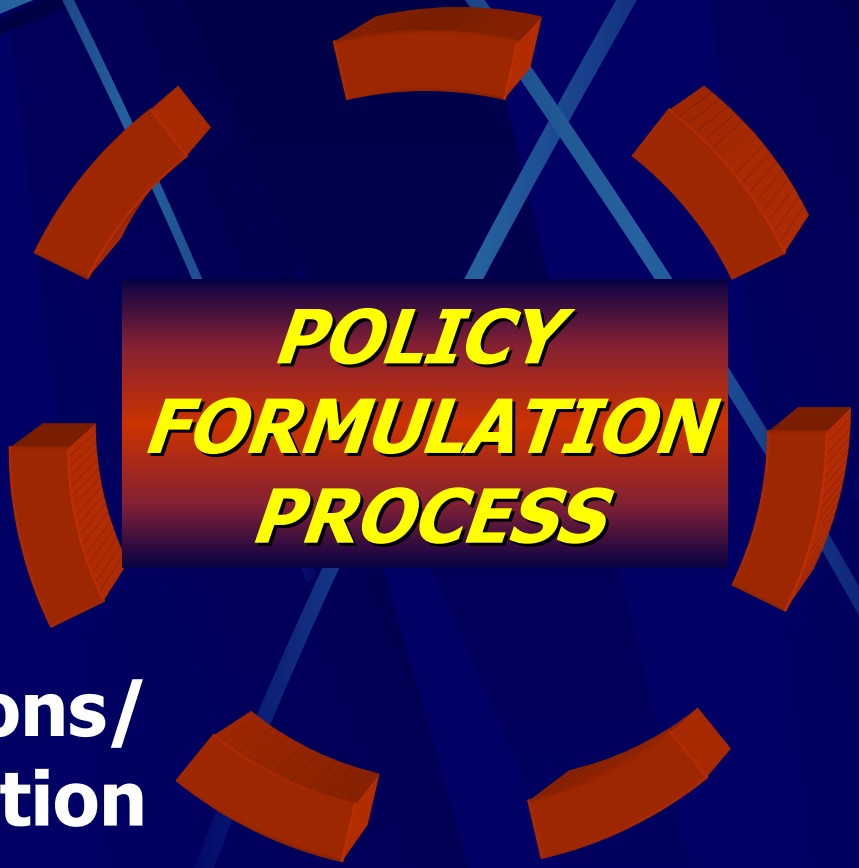
---Illustrative scatter plot of relative risks indices



Resources

Resources:

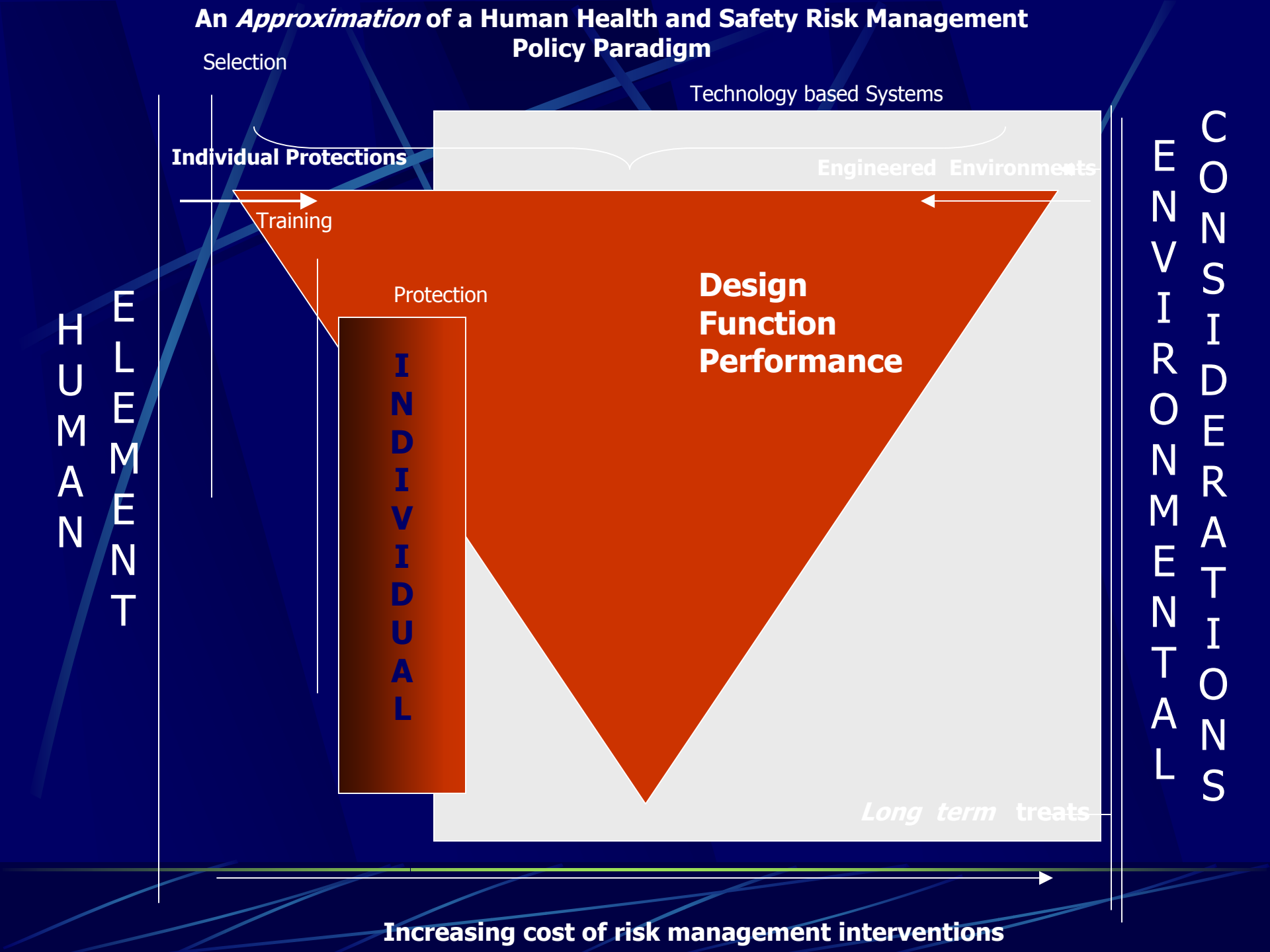
- Knowledge
- Technology
- Financial
- Logistics
- Time



Solutions/
Protection

Solutions/Protection:

- Primary
- Secondary
- Tertiary


An *Approximation* of a Human Health and Safety Risk Management Policy Paradigm
Selection
Technology based Systems
Individual Protections
Engineered Environments
Training
Protection
Design
Function
Performance
INDIVIDUAL
Long term treats
HUMAN ELEMENT
ENVIRONMENTAL CONSIDERATIONS
Increasing cost of risk management interventions

Risk Management Alternatives:

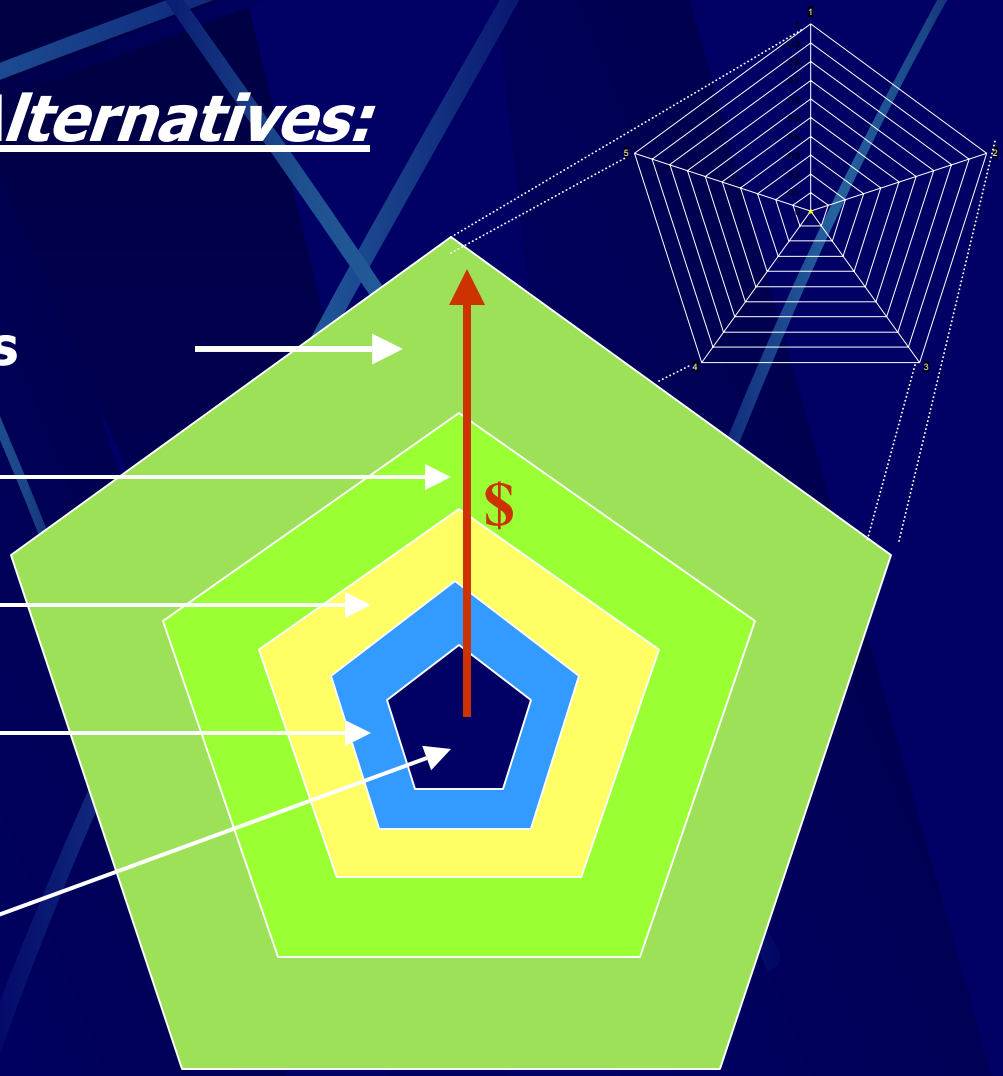
Engineered environments

Individual protections

Training

Selection

Zone of Minimal Risk=
Activities of Daily Living



---proposed tool for checklist and inventory of solutions and conclusions

Risks Management Inventory					
		Human Element			
Identifyied Environmental Risk	Knownledge Assessment	Selection	Training	Protection	Adaptive Systems

Policy
RX

Policy Recommendation:

- Cost benefit
- Directed to successful
- Outcome H & S

Qualifiers of Risks

- **Managed** : risk continuously monitored with the intent to intervene with administrative, financial or technical actions if the risks exceeds the set limits
- **Acceptable** : a risk which cannot be eliminated, politically and budgetary driven, and subject to either efficiency (Type II reliability) or effectiveness (Type I reliability) "Larry Hayman"
- **Tolerable**: a risk which can be eliminated, but at a significant cost and is subject to political opinions and decisions
- **ALARA:** what ever is technologically or scientifically achievable

Model for Evaluating Risks and Balancing Benefits: Extreme Environments

All values assigned on a 10 point scale

$\Sigma(\text{Benefits}) = B_1 + B_2 + B_3 + B_4 \ldots B_n$

Where B_1 = estimated contribution to knowledge
B_2 = estimated contribution to technology
B_3 = estimated political value
B_4 = estimated societal benefit/impact
B_n = other identified value(s)

$\Sigma(\text{Risk}) = X + R_1 + R_2 + R_3 + \ldots R_n$

Where R_1 = estimated physiological risk
R_2 = estimated environmental risk
B_3 = estimated psychological risk
B_n = other identified risk(s)
X = number of risk factors