

***MEDICAL POLICY
FORMULATION
PROCESS AND TOOLS***

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A Sequential Process

A 3-D Analytic Paradigm

Stakeholders

**Expedition/
Destination**

**Policy
Rx**

Problems

***POLICY
FORMULATION
PROCESS***

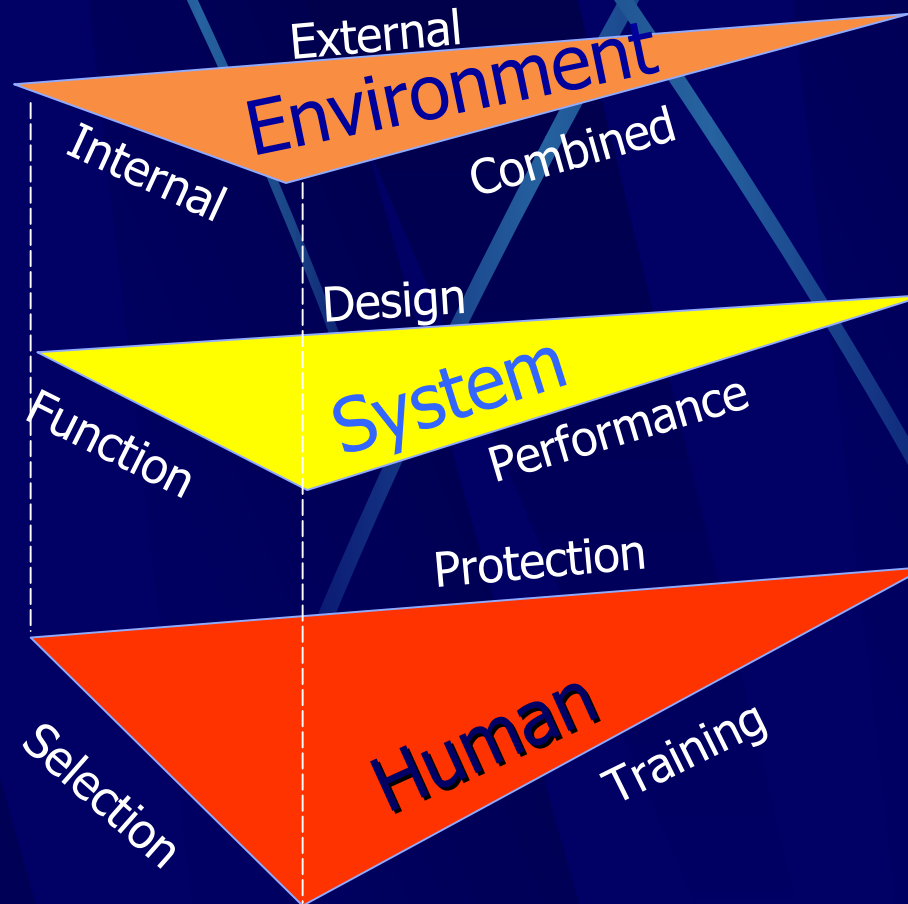
**Solutions/
Protection**

Risks

Resources



Extreme Environments: Essential Elements of Policy



Adapted from Nicogossian 2001

Systems Design

Individual Protections

Engineered Environments

Design
Function
Performance

HUMAN
ELEMENT

ENVIRONMENTAL
CONSIDERATIONS



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**

***POLICY
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Expedition/destination

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



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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

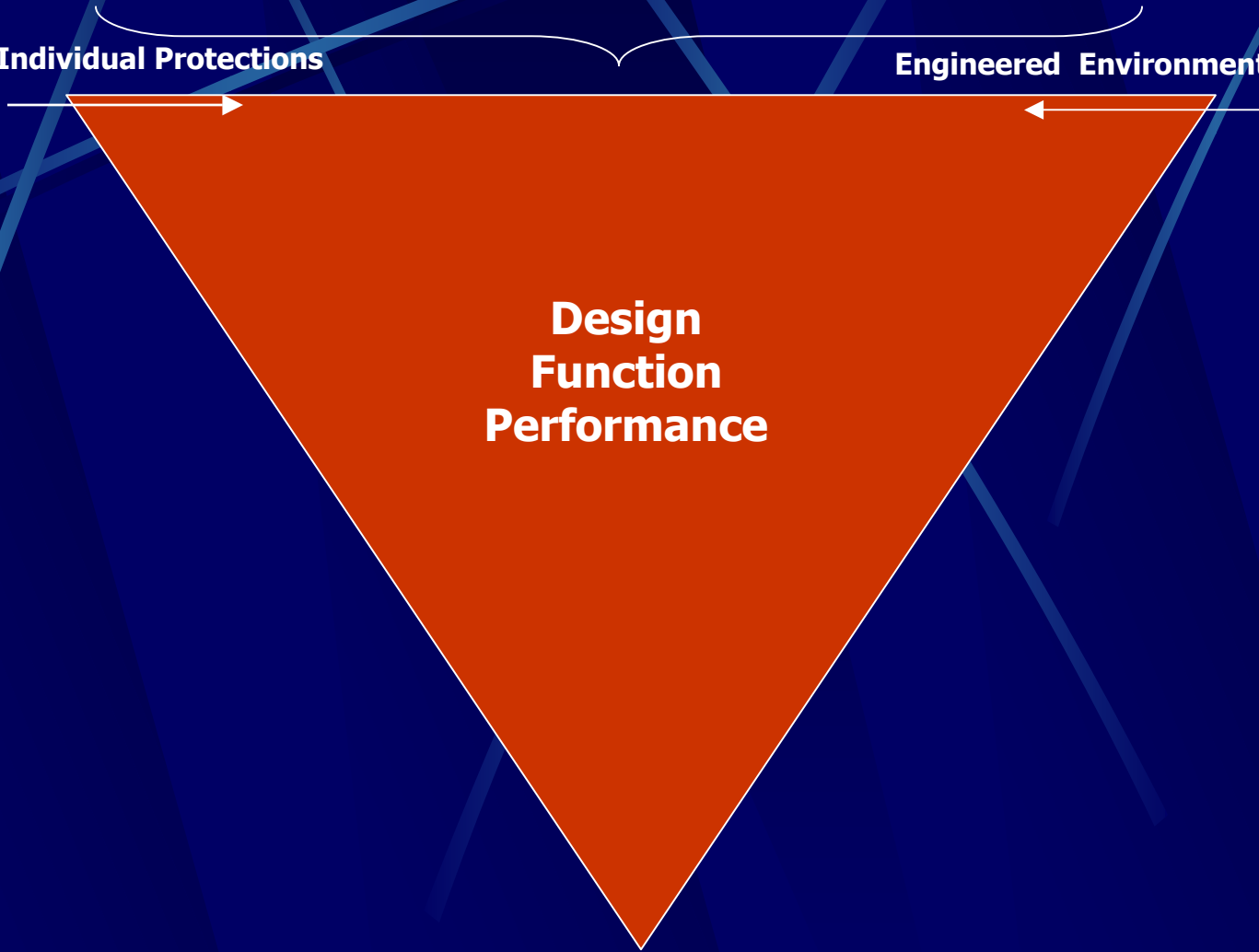
Individual Protections

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CONSIDERATIONS



---proposed tool to log problems and risks

Environmental Considerations Assessment Inventory: Journey 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)					
<i>Aggregated Risk Index</i>					

---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			
Terrain			
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Infectious disease			
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Unknown Risk(s)			
<i>Aggregated Risk Index</i>			



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Risks

Risks:

- **Data envelope**
- **Categorization**
- **Qualifiers**
- **Time consideration**

Categorization of Risks

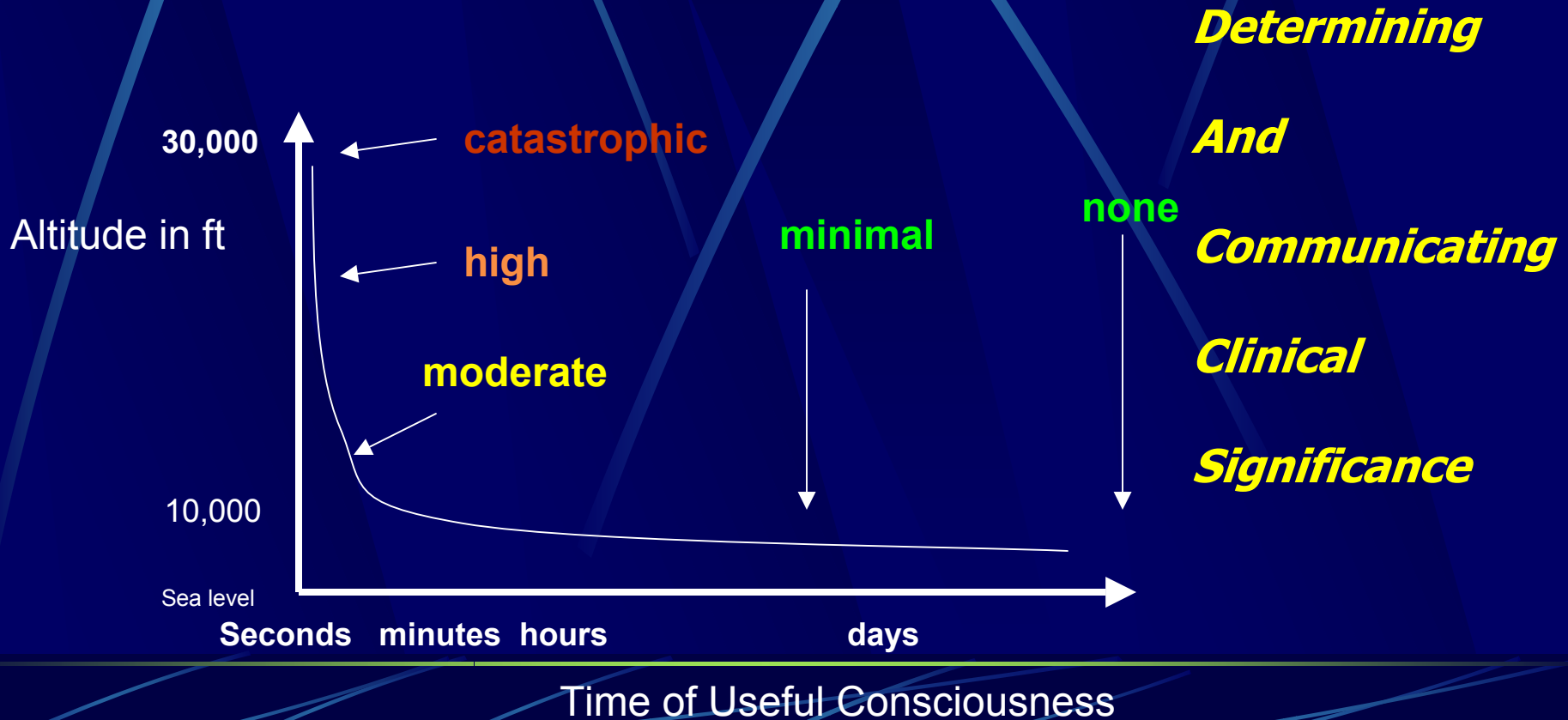
- None (0)
- Low (1)
- Moderate (2)
- High (3)
- Catastrophic (4)
- Unknown (5)

Definitions

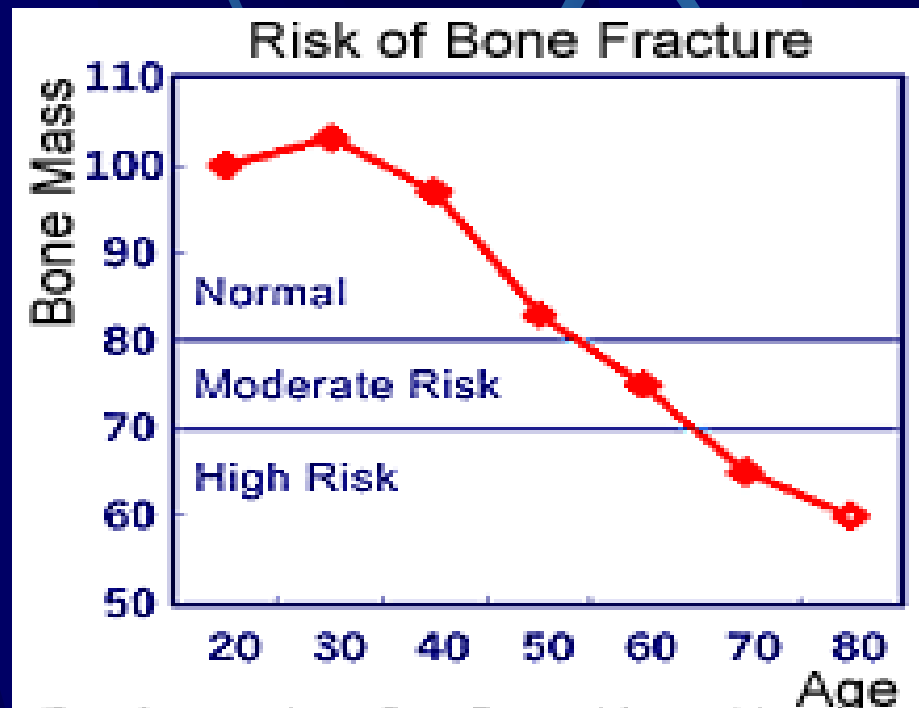
- **None** : no known risks
- **Unknown**: unquantifiable risk which can range from 0 to ∞
- **Catastrophic**: loss of life or significant impairment with marked decrease of AQL
- **High**: significant probability of death, injury of disease
- **Medium**: probability of injury of disease which can be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

Normative Data

Atmospheric Pressure, Hypoxia and Death (healthy individuals)

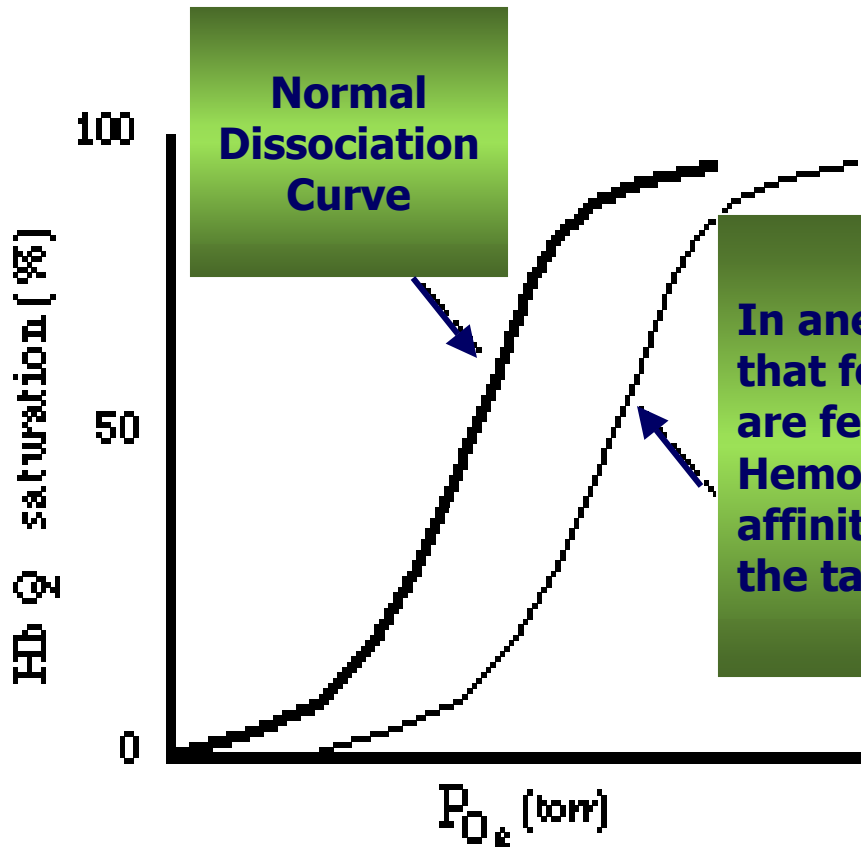


Bone Mass Loss and Risk of Fractures



Adapted from the Japan Bone Renewal Academy

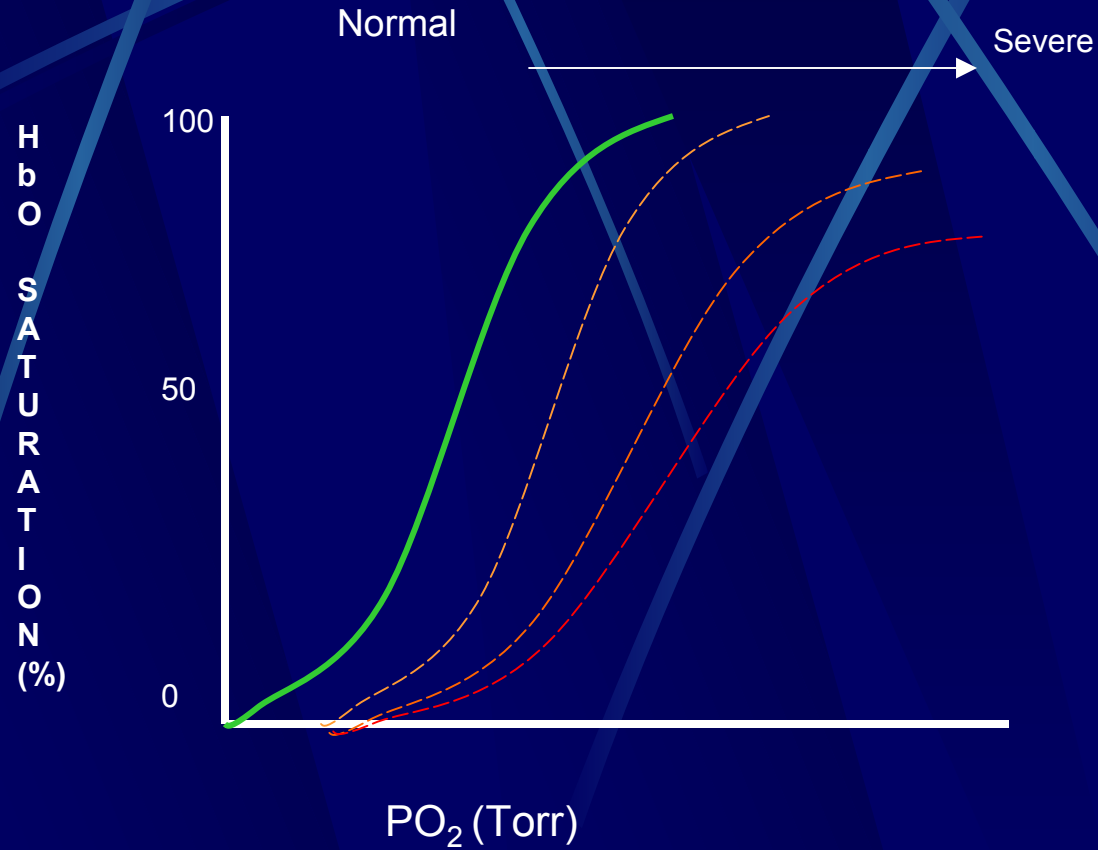
Anemia



Normal
Dissociation
Curve

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

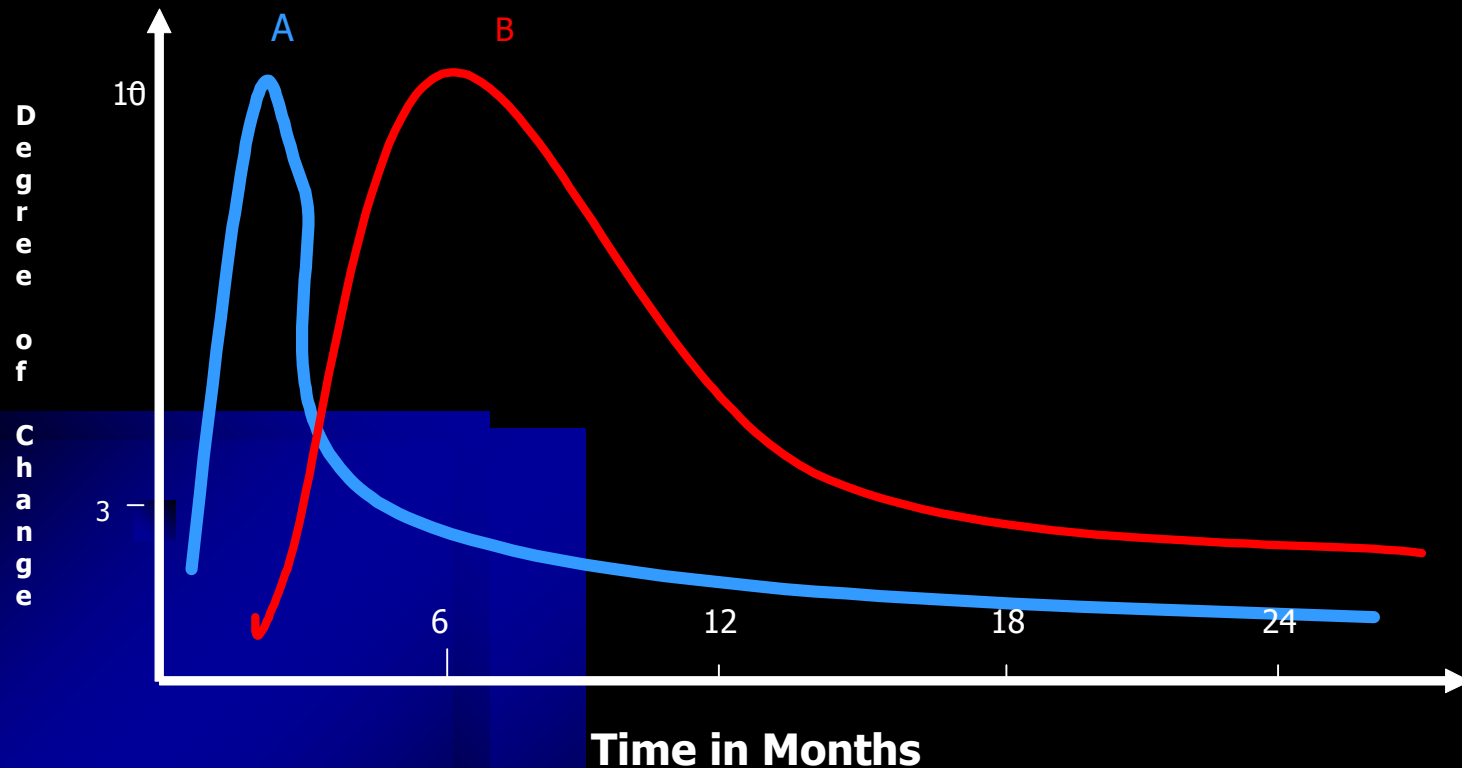
Catastrophic

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

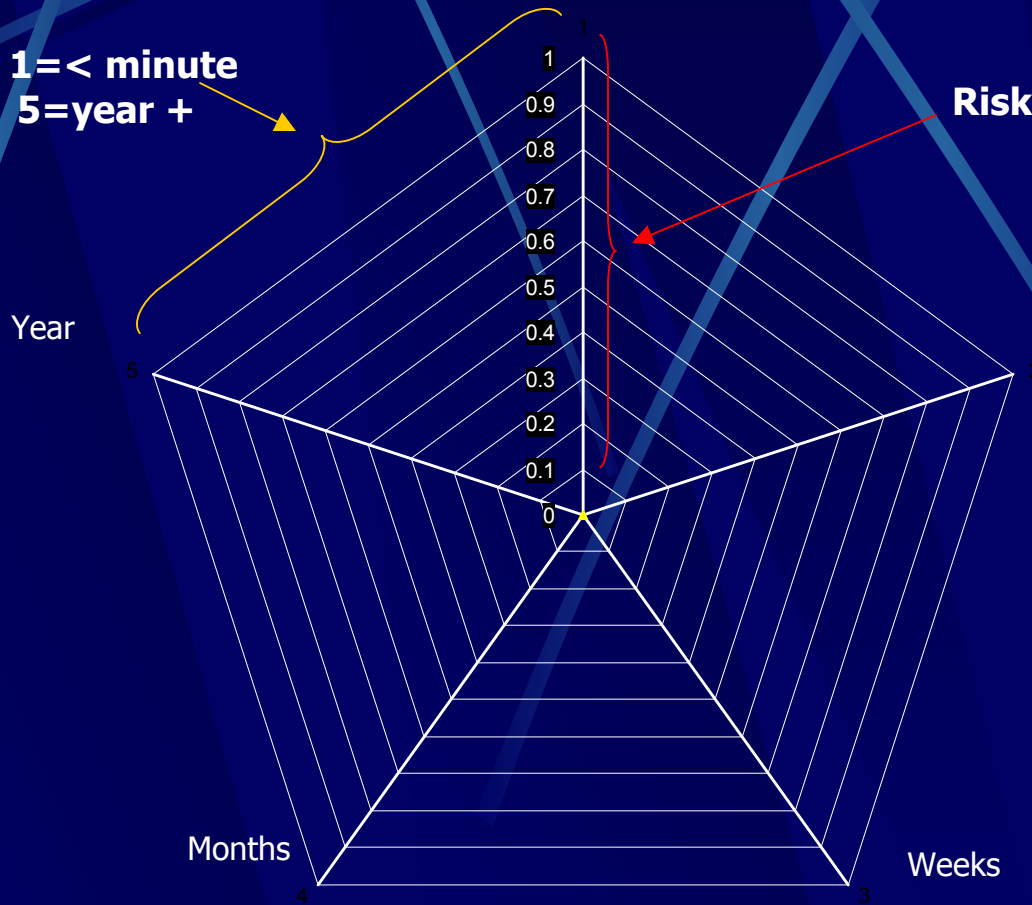


A = Acute adaptation (usually complete) for Neuro Sensory and Motor, Cardiopulmonary, and to a lesser degree fluid and electrolyte systems
B = Chronic processes, sometimes patho-physiologic, occasionally reversible with countermeasures, for all other systems

---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**

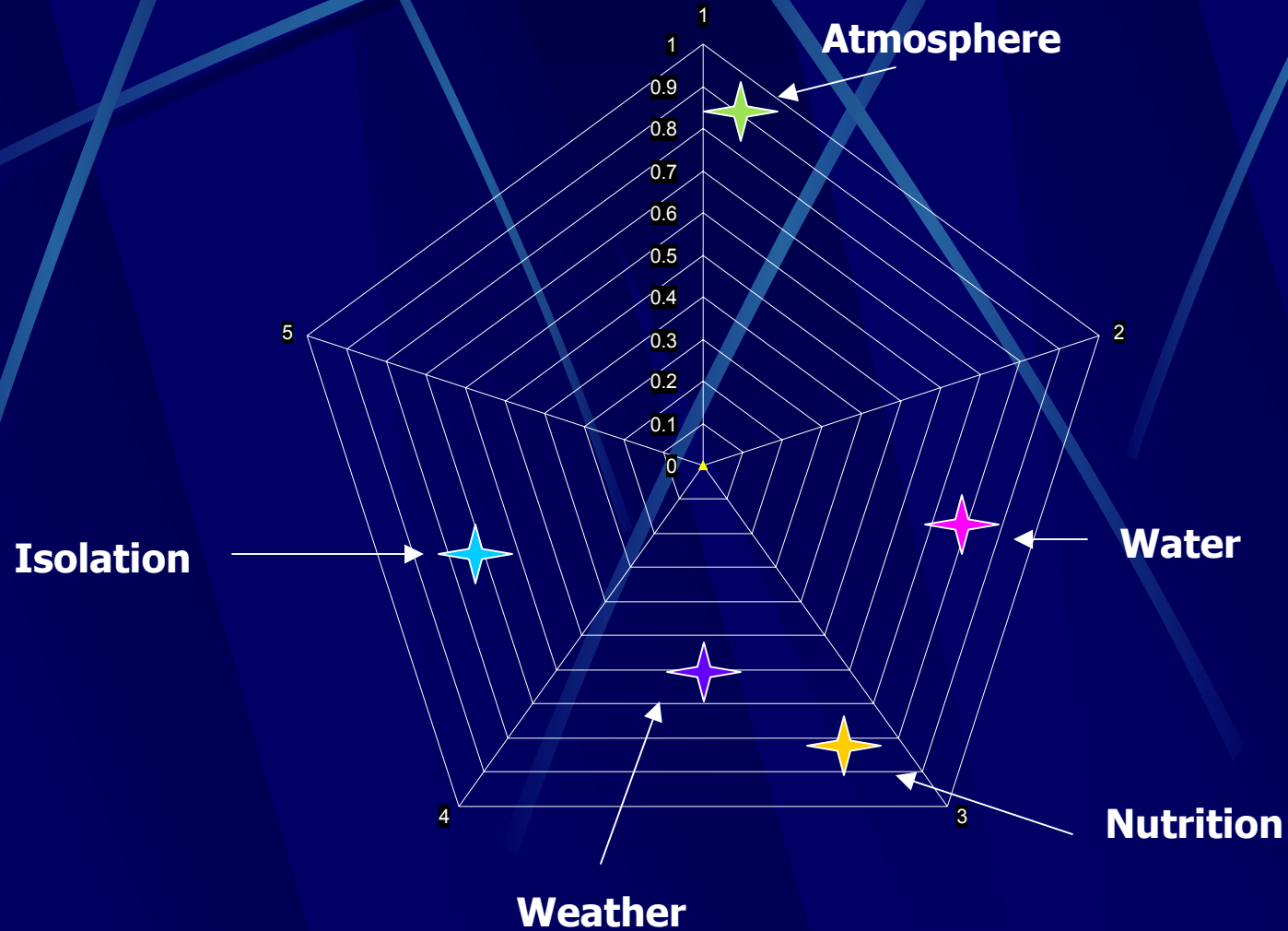
*Risk Scoring
Index*

Example: Atmosphere on top
Mount Everest → **1,8**

Matter of minutes

Level of risk

---Illustrative scatter plot of relative risks indices





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Resources

Resources:

- **Knowledge**
- **Technology**
- **Financial**
- **Logistics**
- **Time**



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**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**

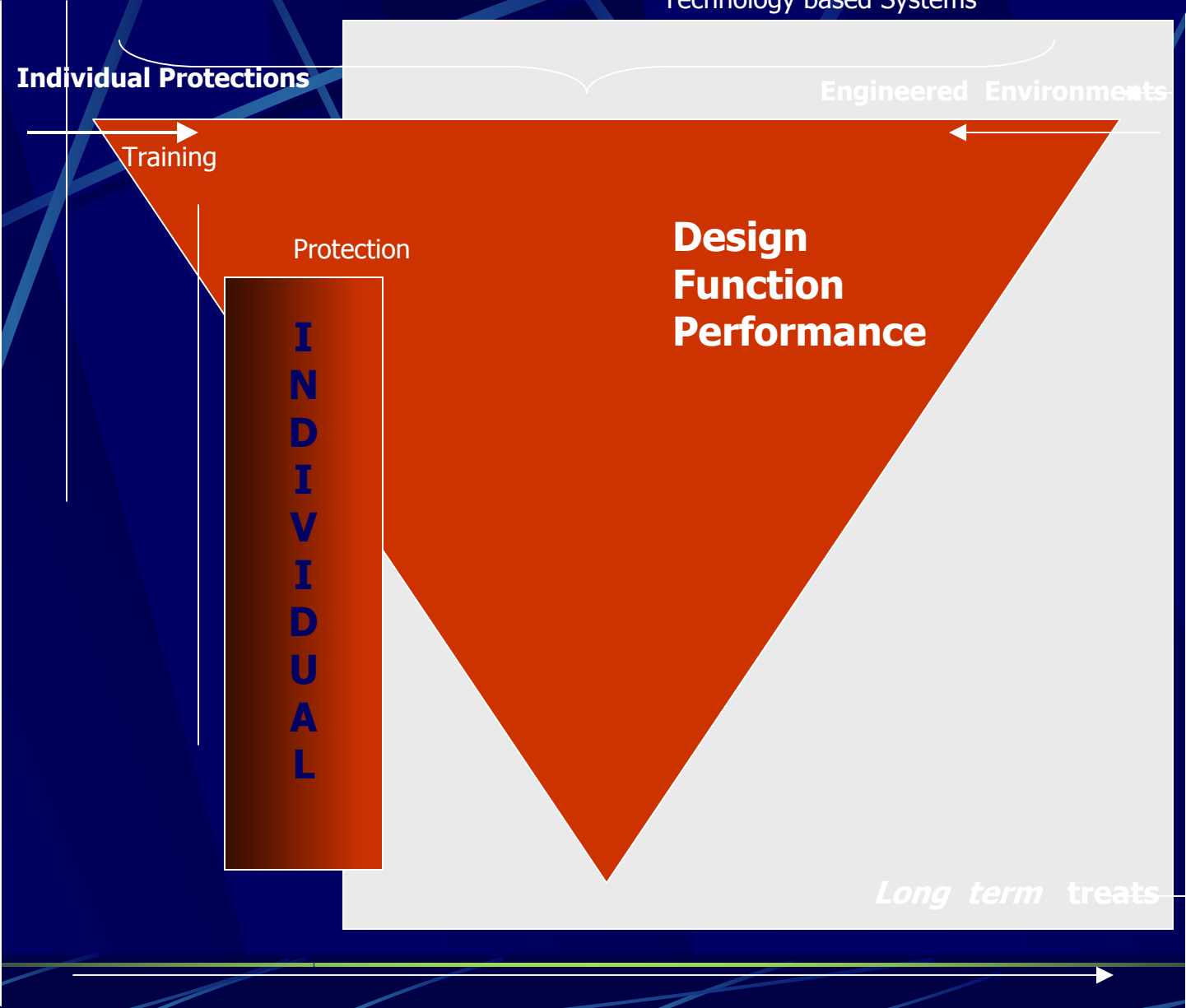
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Long term treats

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Increasing cost of risk management interventions



Risk Management Alternatives:

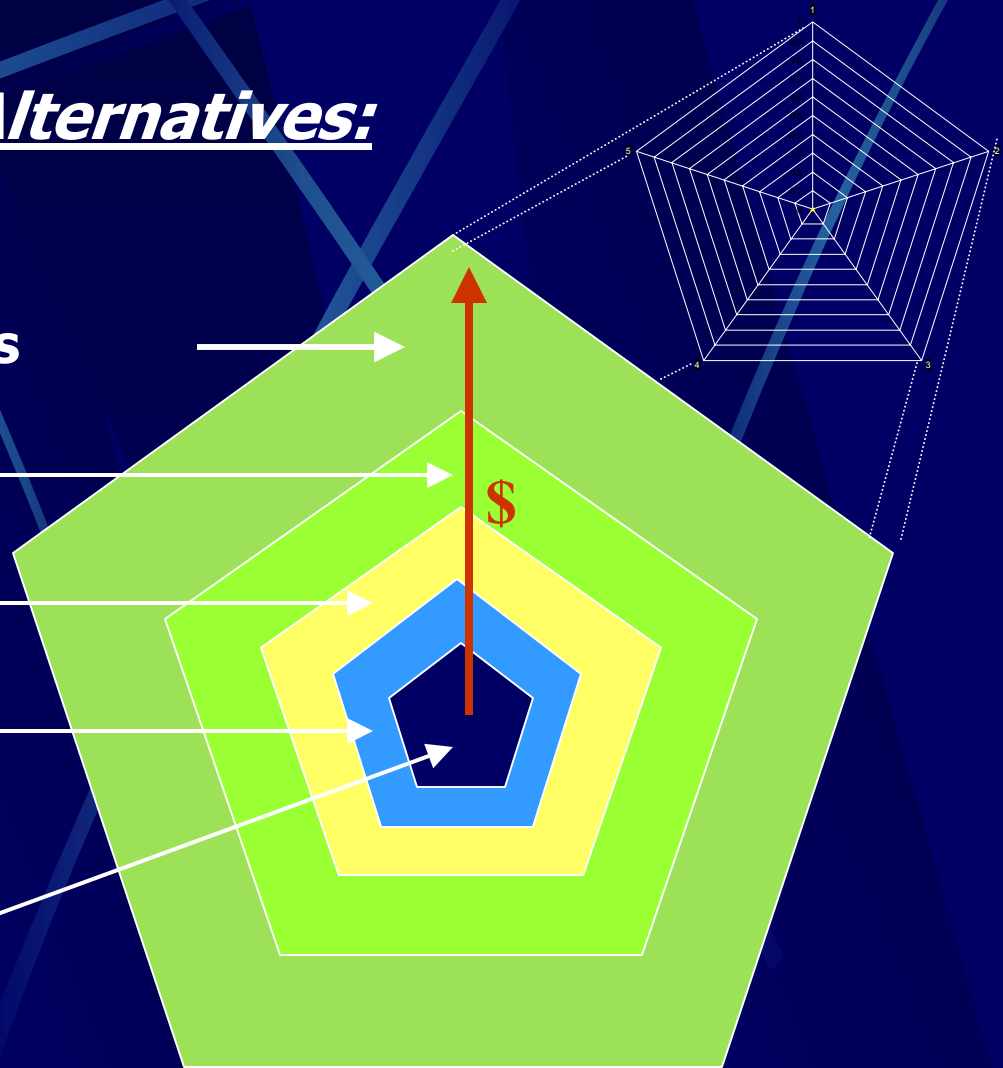
Engineered environments

Individual protections

Training

Selection

**Zone of Minimal Risk=
Activities of Daily Living**



**Policy
RX**

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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

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

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)

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

Where R_1 = estimated physiological risk

R_2 = estimated environmental risk

R_3 = estimated psychological risk

R_n = other identified risk(s)

X = number of risk factors