RISK AND THE MEDICAL LABORATORY

Michael A Noble MD FRCPC
Chair, Program Office for Laboratory Quality Management
University of British Columbia
Vancouver BC

OR

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Scenario 1

- A medical laboratory, acting in response to community demand introduces a new molecular test, but without functional validation.
- It becomes apparent there are many false positives and false negative results that lead to wrong diagnosis and poor treatment decisions and poor patient outcomes.
- The community becomes engaged which results in an official public enquiry.
- Millions of dollars are spent .
- Reputations are damaged.

Scenario 2

- A medical laboratory introduces a new test for sexually transmitted infection that is technically easier than the standard test.
- Despite the knowledge that the test has poor specificity, the test is used both for patient testing and patient screening.
- Many patients are incorrectly identified as having sexually transmitted infections. Unfortunately information is released and patient harm results.
- Patients seek redress through litigation.
- Community reputation is harmed.

Scenario 3
(speculation)

- A medical laboratory provides direct on-line access to results by patients.
- Unfortunately the medical laboratory information system is breached and the file of patient passwords compromised.
- Sensitive medical information on a person of note is made public.
- Reputations are damaged.

What these scenarios have in common

- Unhappy outcomes as a result of …

unrecognized or unmanaged RISK

It seemed like a good idea at the time

Lots of Very Useful Books on Risk

- Peter L. Bernstein
  - Against the Gods: The Remarkable Story of Risk
  - 1998
- James Reason
  - Managing the Risks of Organizational Accidents
  - 2000
- J. Davidson Frame
  - Managing Risk in Organizations
  - 2003
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  - Risk: Why we fear the things we shouldn't-and put ourselves in greater danger.
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  - Risk Management Handbook for Healthcare Organizations
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Published International Standards on Risk Management

- **ISO 14971:2007**
  Medical devices -- Application of risk management to medical devices
- **ISO/TS 22367:2008**
  Medical laboratories -- Reduction of error through risk management and continual improvement
- **ISO 31000:2009**
  Risk management -- Principles and guidelines
- **ISO/IEC 31010:2009**
  Risk management – Risk assessment techniques
- **MIL–STD–882D:2000**
  Department of Defence – Standard Practice: System Safety
- **ISO Guide 73**
  Risk management — Vocabulary
- **(CLSI EP23-A)**
  Laboratory Quality Control Based on Risk Management (2011)

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The Study of Risk

The word RISK is a derivative from Latin ***riscare*** (to dare). Risk Management became reality when humans realized that they could "dare the gods" and aspire to their own goals.

Peter L. Bernstein
Against the Gods: The Remarkable Story of Risk
1998

The concept of Risk is not NEW

- Gamblers and Investors
- Finance
- Manufacturing
- Service Sector
- Transportation
- Airlines

- Healthcare (1970s)
- Patient Safety Programs (2000)
- Medical Laboratories (2003)

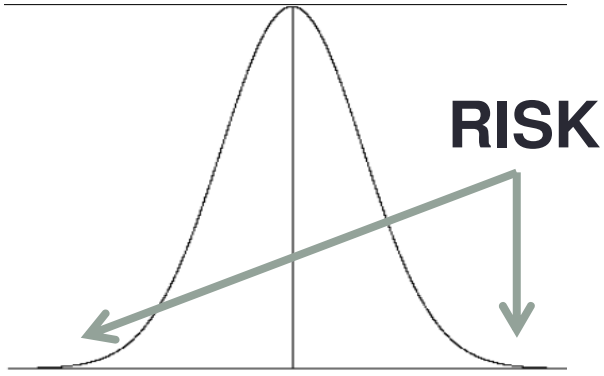
What is Risk?

***Risk* is:**

- the prospect of pain
- the potential for gain
- the likelihood and impact of some potential outcome
- ***the effect of uncertainty on objectives***
  - **ISO 31000:2009**
  - **Risk Management – Principles and guidelines**
    - an internationally recognised benchmark, providing sound principles for effective management and corporate governance.

Risk is a statistical dream…

- Risk Analysis is culmination of 300 years of statistical study
  - Bernoulli (1713)
    - The Law of the Big Numbers
    - Statistical Sampling
  - de Moivre (1754)
    - The Law of the Averages
    - Normal Distribution and Standard Deviation
  - Louis Bachelier (1900)
    - The Theory of Speculation
  - Harry Markowitz (1950)
    - Mathematical analysis of risk strategy



Risk is a Management Nightmare

Uncertainty includes:
Risk which is susceptible to measurement and another component which is not.

Calculated uncertainty is always incomplete.

Knight, F. H. (1921)
Risk, Uncertainty, and Profit. Boston,
Houghton Mifflin Company

Donald Rumsfeld said it better:

In 2002, when asked about the absence of evidence for terrorism, and WMDs

Donald Rumsfeld when addressing the risk calculations for WMDs (2002)

There are known knowns.
These are things we know that we know.
There are known unknowns.
That is to say, there are things that we know we don't know.
But there are also unknown unknowns.
There are things we don't know we don't know.

Modern Mathematics And Risk

- Game Theory and Chaos Theory

a. All events are cause and effect but often the cause is too obscure to be detected.
b. Commonly effects are separated from cause or causes and the greater the distance the less likely is detection.
c. It is impossible to know every factor that can or will influence an outcome and
d. Cause and outcome may be non-linear or non-proportional. [small causes may have big effects]

What Game and Chaos Theory Speak about Risk

a. *You can never completely predict a cause or an outcome.*
b. *Risk is not a fixed measurement; mutable by events and susceptible to change*
c. *Look to the best, but plan for the worst.*
d. *To the extent possible, reduce surprise by increasing information.*

Bad things happen…

- Organizational accidents are difficult events to understand and control. They occur very rarely and are hard to progress and foresee. To the people on the spot, they happen “out of the blue”.

- ***Difficult though they may be to model, we have to struggle to find some way of understanding their development to achieve gains in limiting their occurrence.***

James Reason
Managing the Risks of Organizational Accidents
1997

Why Risk Management is important for medical laboratories

- We analyze many samples from which we derive information.
- The information impacts upon decision making and health of others.
- Poor information can lead to poor outcomes.
- Our samples have some variables that we can control, and others that are difficult to control, and others that we can not control.
- ***Regardless of contributing events, the laboratory is usually viewed as the source of the problem.***

The Medical Laboratory Has a Wide Risk Footprint

The Risk Management Framework

- Plan for Risk
- Identify Risk
- Examine for Risk Impact
- Develop Risk Addressing Strategies
- Monitor and Control Risk Outcome

Managing Risk in Organizations
J. Davidson Frame
2003

Risk Management Framework

(The Risk – Quality Interface)

PLAN	**What do we do for High Risk? What do we do for Medium Risk? What do we do for Low Risk**
IDENTIFY POTENTIAL RISKS	**Are there events or variables that can affect us badly?**
EXAMINE FOR IMPACT	**Are bad things happening?**
DEVELOP A MITIGATION STRATEGY	**Can we reduce the likelihood of the variables impacting**
MONITOR OUTCOME	**Did our strategies have an effect?**

Working with Quality Partners can Help Reduce or Share Risk

Risk Management Tools

Risk Specific

- Severity Outcome Grid
- Failure Mode studies
  - Fishbone studies
  - Failure Mode Effects Analysis (FMEA)
  - Failure Mode Effects and Criticality Analysis (FMECA)
  - Hazard and operability study (HAZOP)
- SWOT Analysis
- Computer Modelling (Monte Carlo)

Quality Related

- Error Reduction through Monitoring, Detection, Remediation, Correction
- Internal Audit
- Preventive Action Exercises
  - Internal Audit Checklist.
- External Assessment

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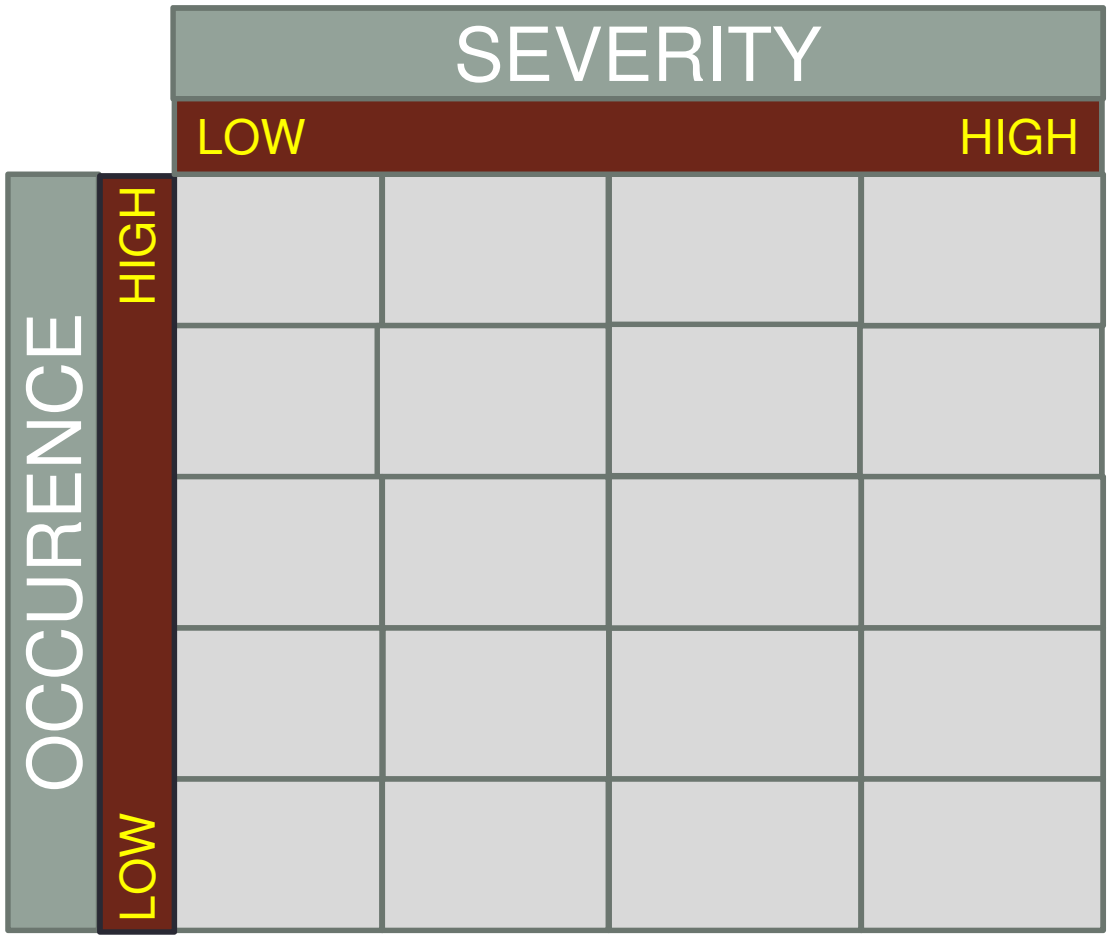
Severity – Occurrence Analysis

Strategy Table



(MIL–STD–882D:2000)
DEPARTMENT OF DEFENSE
STANDARD PRACTICE FOR SYSTEM SAFETY

Failure Occurrence Levels (MIL–STD–882D:2000)

Description	Level	Individual Item	Fleet
Frequent	A	Likely to occur through the life of the item	Continuously experienced
Probable	B	Will occur several times in the life of an item	Will occur frequently
Occasional	C	Likely to occur some time in the life of an item	Will occur several times
Remote	D	Unlikely but possible to occur in the life of an item	Unlikely, but can reasonably be expected to occur
Improbable	E	So unlikely, it can be assumed occurrence may not be experienced	Unlikely to occur, but possible

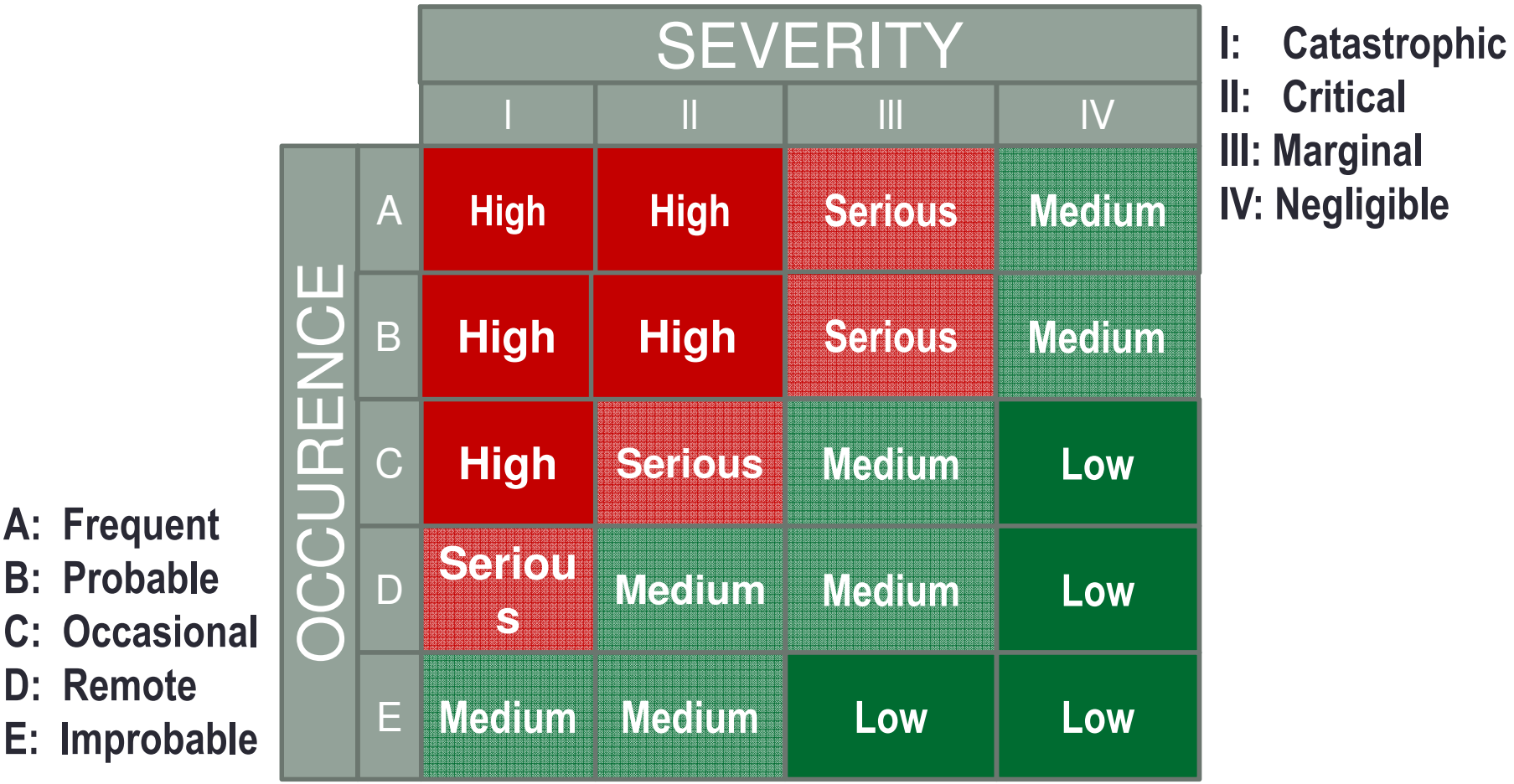
Mishap Severity Categories (MIL–STD–882D:2000)

Category	Description	Criteria
I	**Catastrophic**	Could result in death, permanent total disability, loss exceeding $1M, or irreversible severe environmental damage
II	**Critical**	Could result in permanent partial disability, injuries or occupational illness that may result in hospitalization of at least three personnel, loss exceeding $200K but less than $1M, or reversible environmental damage
III	**Marginal**	Could result in injury or occupational illness resulting in one or more lost work days(s), loss exceeding $10K but less than $200K, or mitigatible environmental damage.
IV	**Negligible**	Could result in injury or illness withouy a lost work day, loss exceeding $2K but less than $10K, or minimal environmental damage that does not violate laws.

Severity – Occurrence Analysis

Strategy Table

(MIL–STD–882D:2000)



Mishap Severity Categories (Proficiency Testing)

Category	Description	Criteria
I	**Catastrophic**	Mass laboratory contamination leading to staff illness/death Unremitting contaminations resulting in program shutdown Closure/Damage suit costs greater than 3 X annual revenue
II	**Critical**	Sample selection leading to multi-laboratory epidemic TDG related environmental/community contamination Contamination costs greater than 15% annual revenue
III	**Marginal**	Sample errors leading to multi-laboratory formal complaints Biosafety hazard leading to 24 hour shut-down Contamination costs greater than 2% annual revenue
IV	**Negligible**	Sample includes 1-log greater or lesser pathogen concentration than planned. Delay in sample transport not exceeding 24 hours. Sample cost over-run greater than $2,000, but less than $4,000

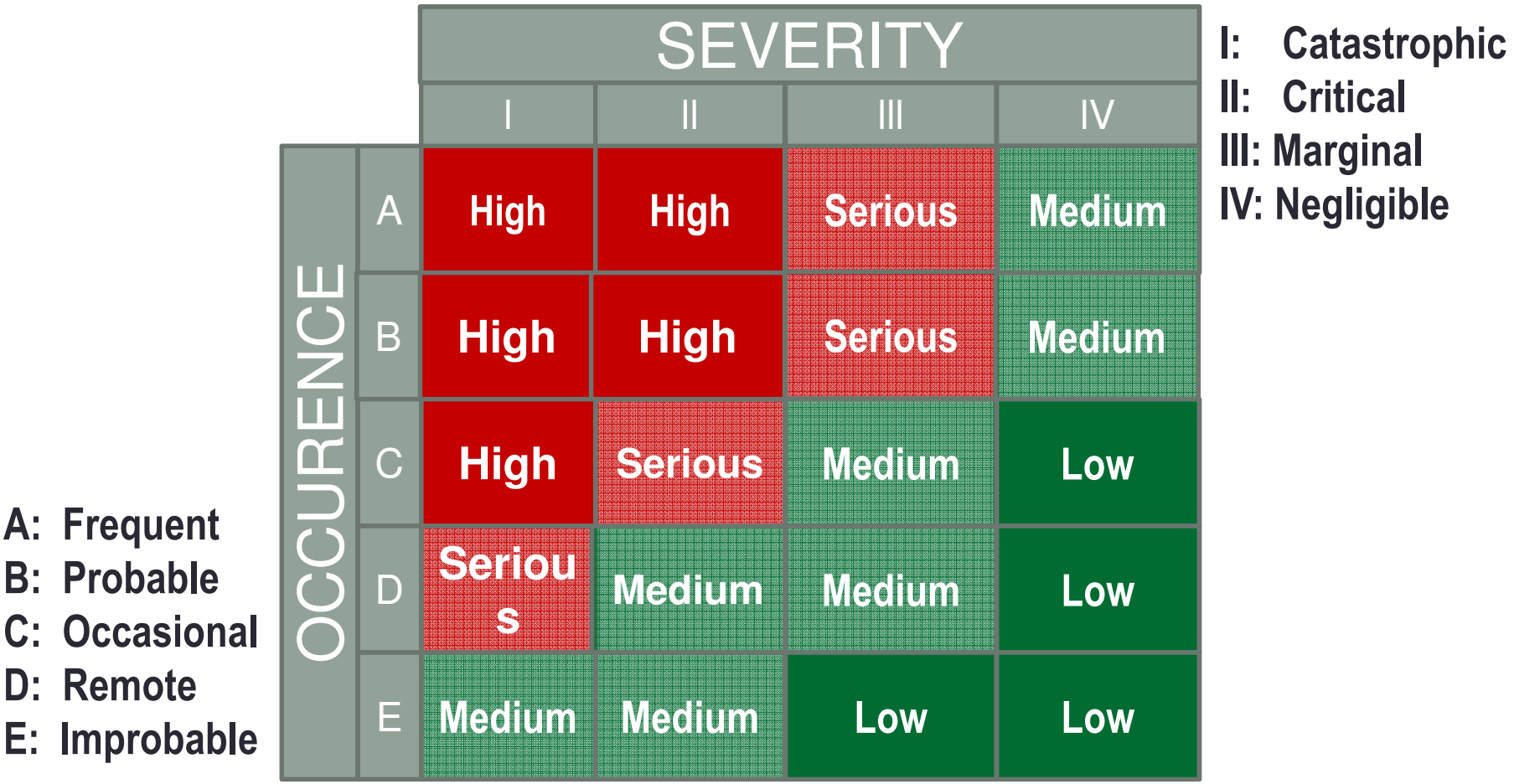
Mishap Severity Categories (Microbiology Laboratory)

Category	Description	Criteria
I	**Catastrophic**	Diagnostic false negative recurrent failure (>50) leading to missed nosocomial or community outbreak and laboratory closure. Environmental accident leading to laboratory closure
II	**Critical**	Diagnostic false-positive recurrent failure (>50) leading to reporting of pseudo-epidemic. Equipment/reagent failure leading to testing restrictions
III	**Marginal**	PT failure requiring review of a test performance. Recurrent delay in release of STAT sample reports requiring RCA review.
IV	**Negligible**	Recurrent delay in release of routine samples reports requiring RCA review

Severity – Occurrence Analysis

Strategy Table

(MIL–STD–882D:2000)



Risk Level and Decision Making

High Risk does not necessarily mean
Don't Do It

Low Risk does not necessarily mean
Forgetaboutit

Risk Level sets the Level of Responsibility for
RISK DECISION MAKING

Decision Making for Risk

The Higher the Risk Level, the higher the decision level.

The Lower the Risk Level, the more delegated the decision level.

Decision Making for Risk

Choices

Safety?

Cost?

Liability?

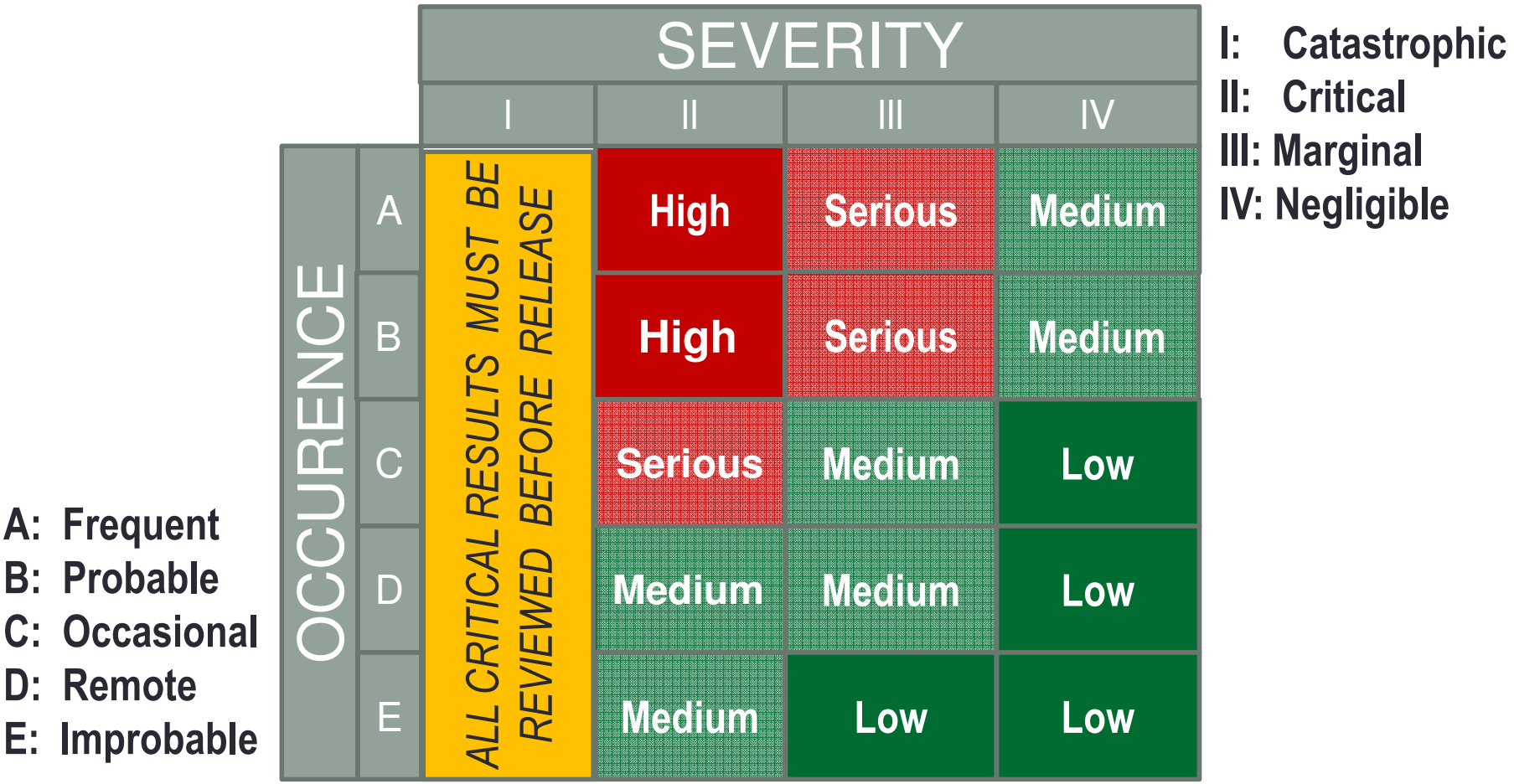
Reputation?

Who is at Risk?

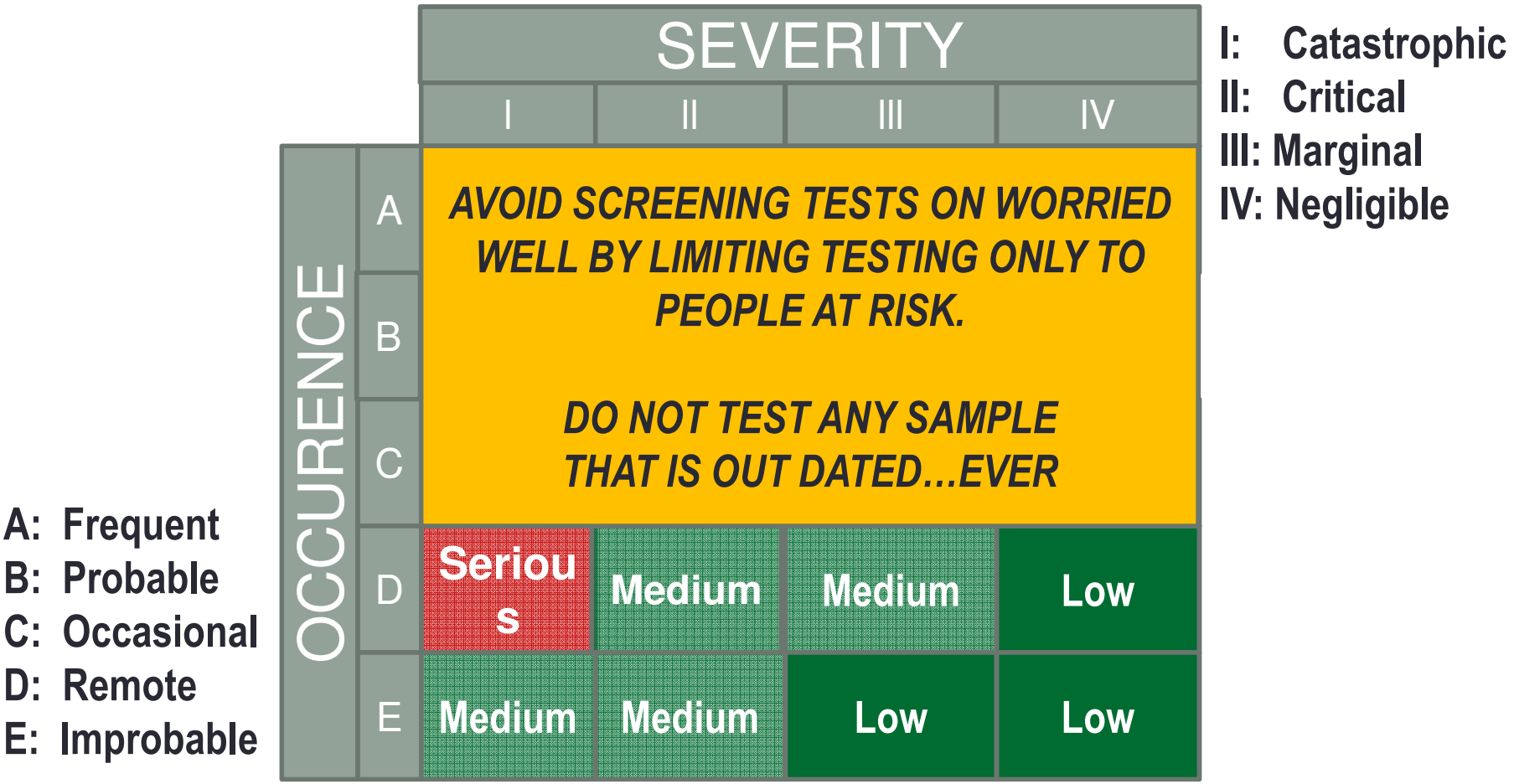
Can you Mitigate the Risk?

Can you Share the Risk?

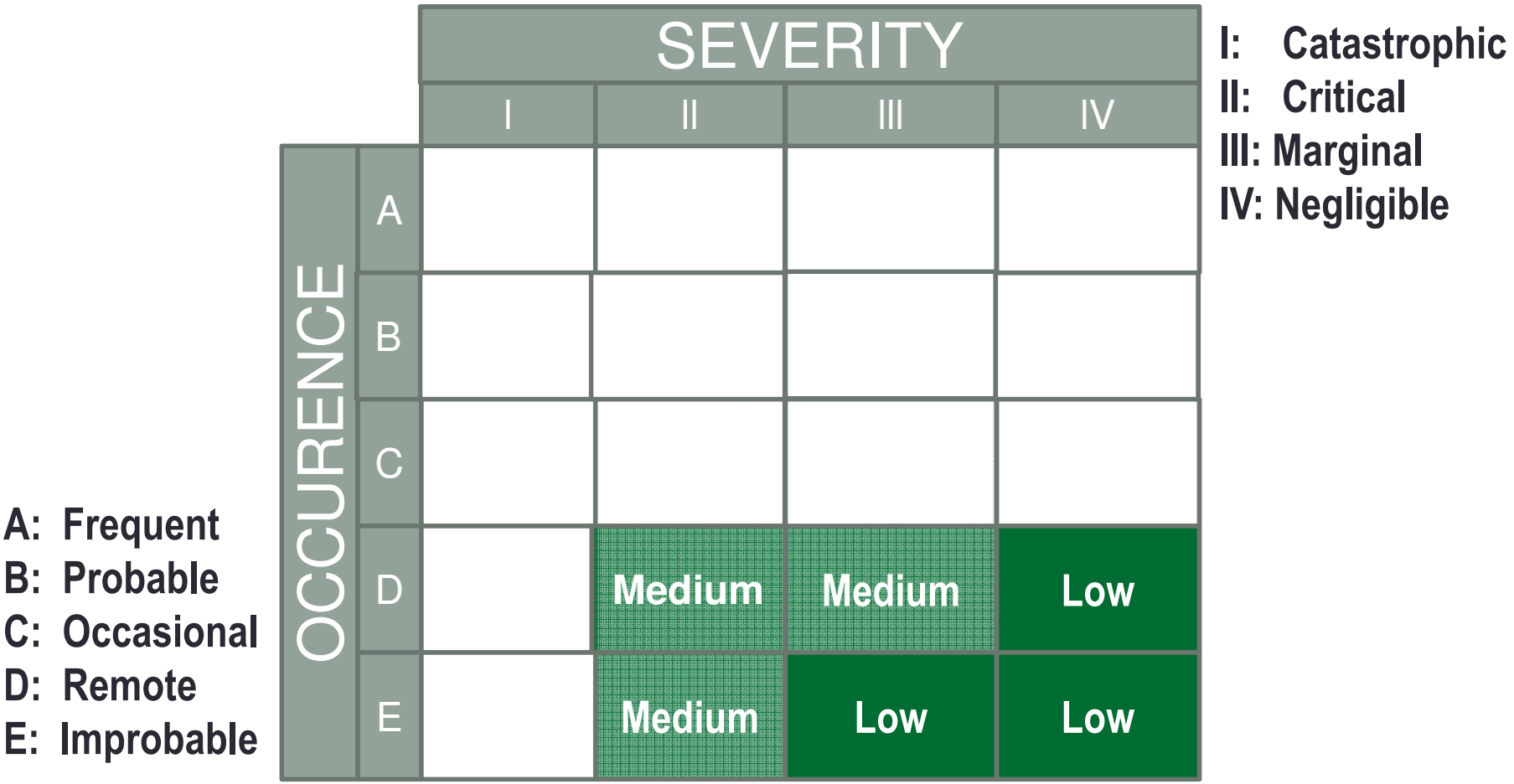
Severity – Occurrence Calculation
Mitigate Against Severity of Outcome



Severity – Occurrence Calculation
Mitigate Occurrence of Outcome



Severity – Occurrence Calculation
Mitigate Both Severity and Occurrence



In summary…

- Risk is the effect of uncertainty on outcomes
- Risk is a mathematical concept, but can not be solved by statistics.
- Modern mathematical theory indicates that the best strategies are those that reduce the opportunities for worst outcomes.
- Control the things you know, Learn more about the things you know you don't know, be diligent for those things that you didn't know that you didn't know.

in conclusion…

Hippocrates revisited

When it comes to managing Risk…

Be aware

Be sensible

Do No Harm

(including to yourself)

Assessing Risk with uncertain variables