



Reducing Risk in the Clinical Laboratory

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Professor, Chair

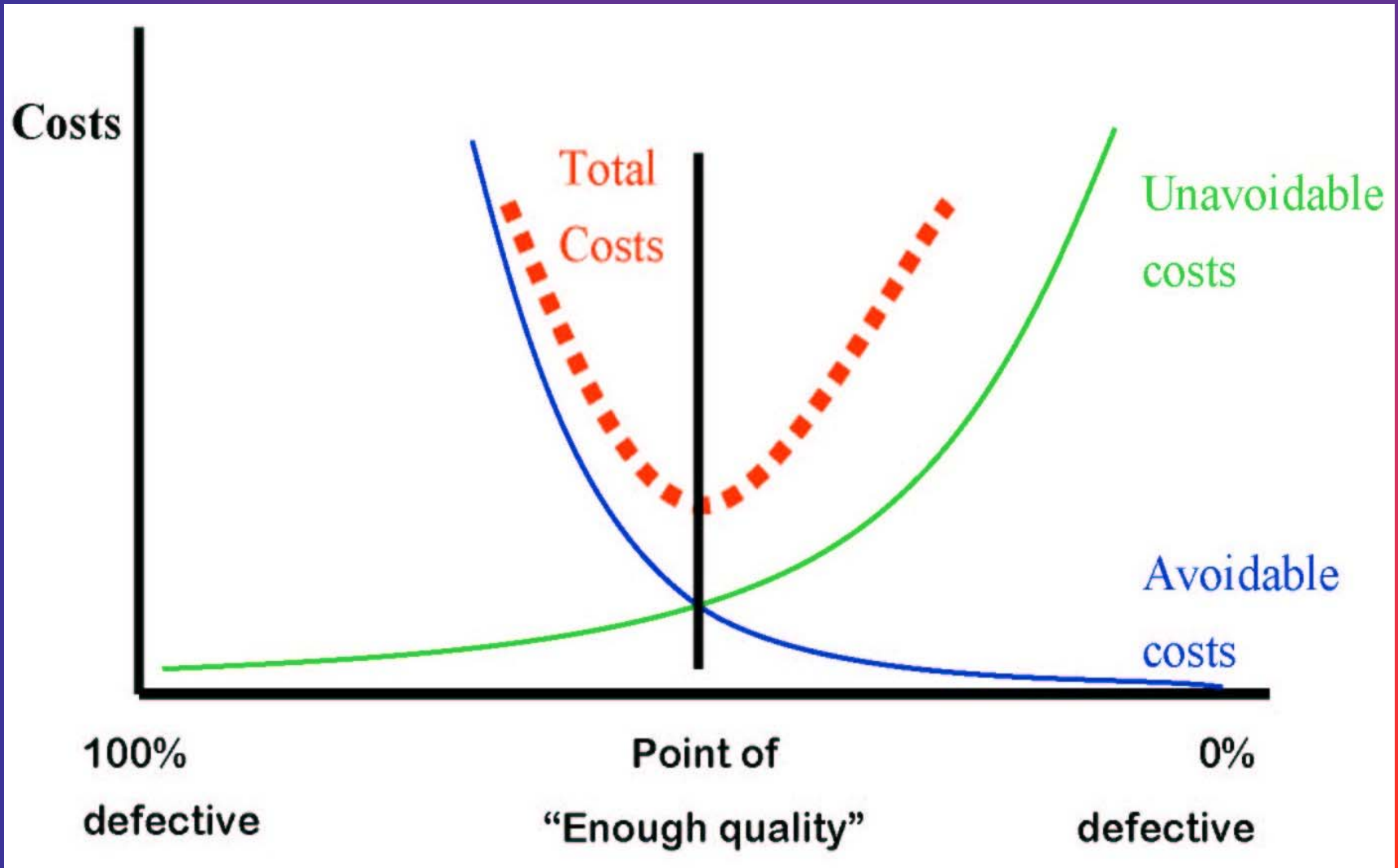
Program Office for Laboratory Quality Management

University of British Columbia

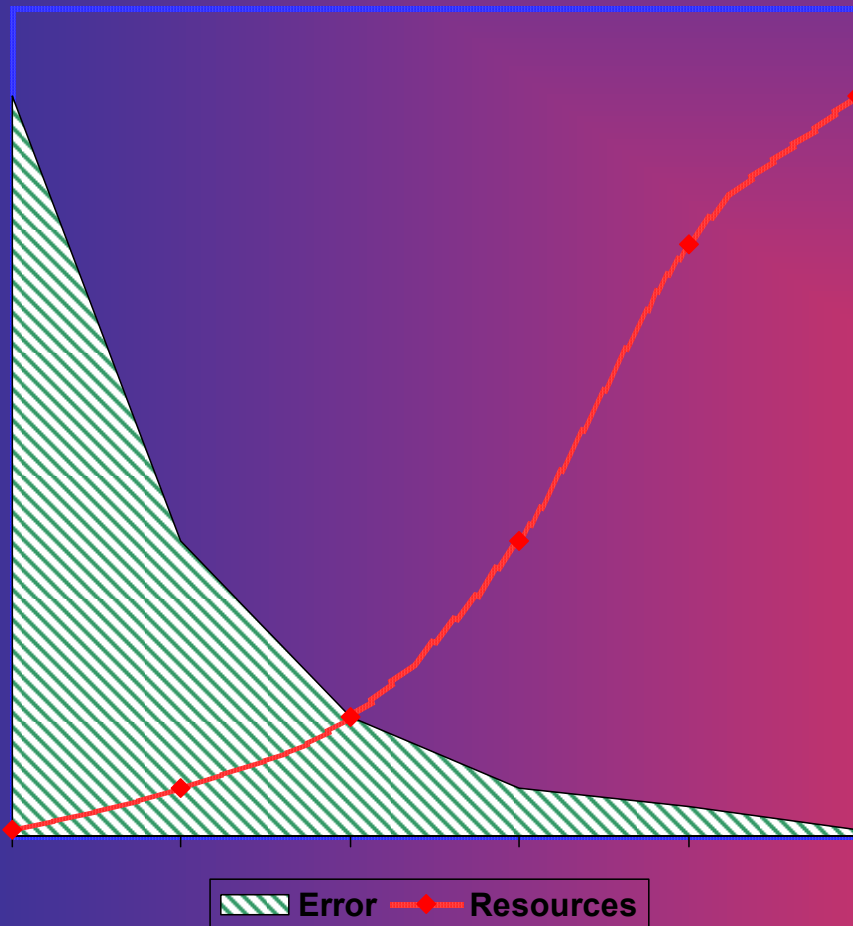
Vancouver BC Canada

Cost of Quality

Joseph M. Juran



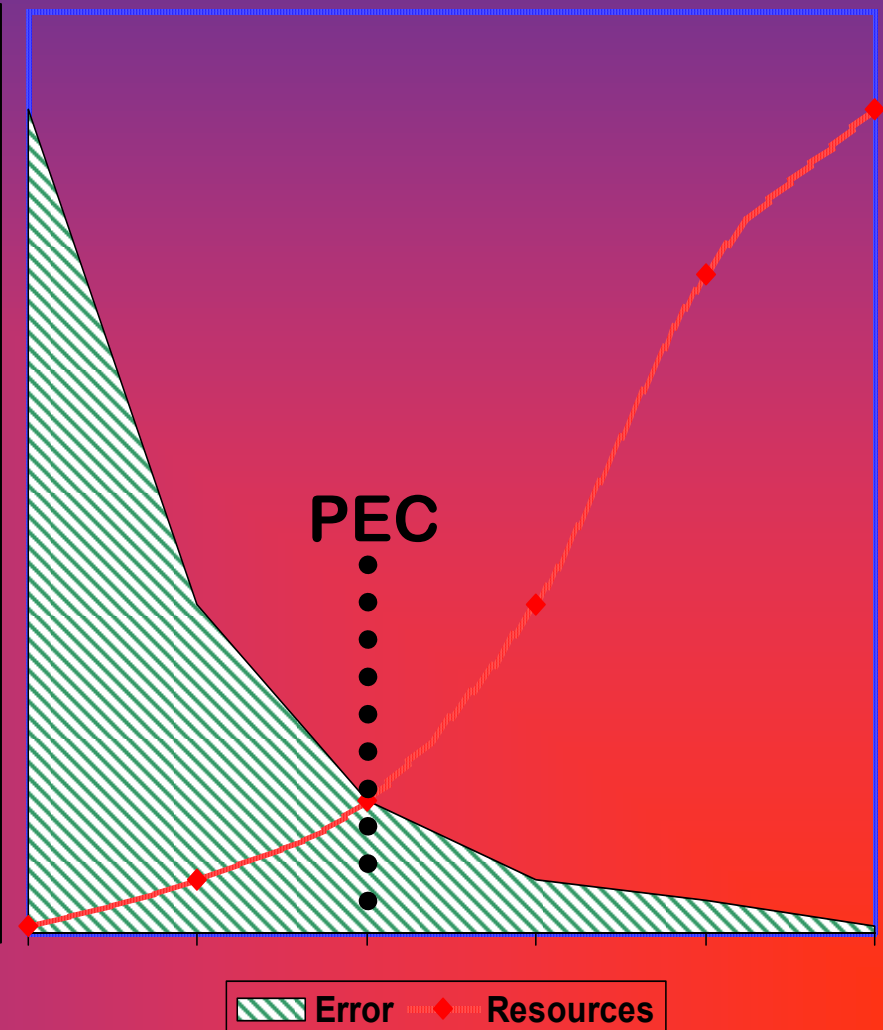
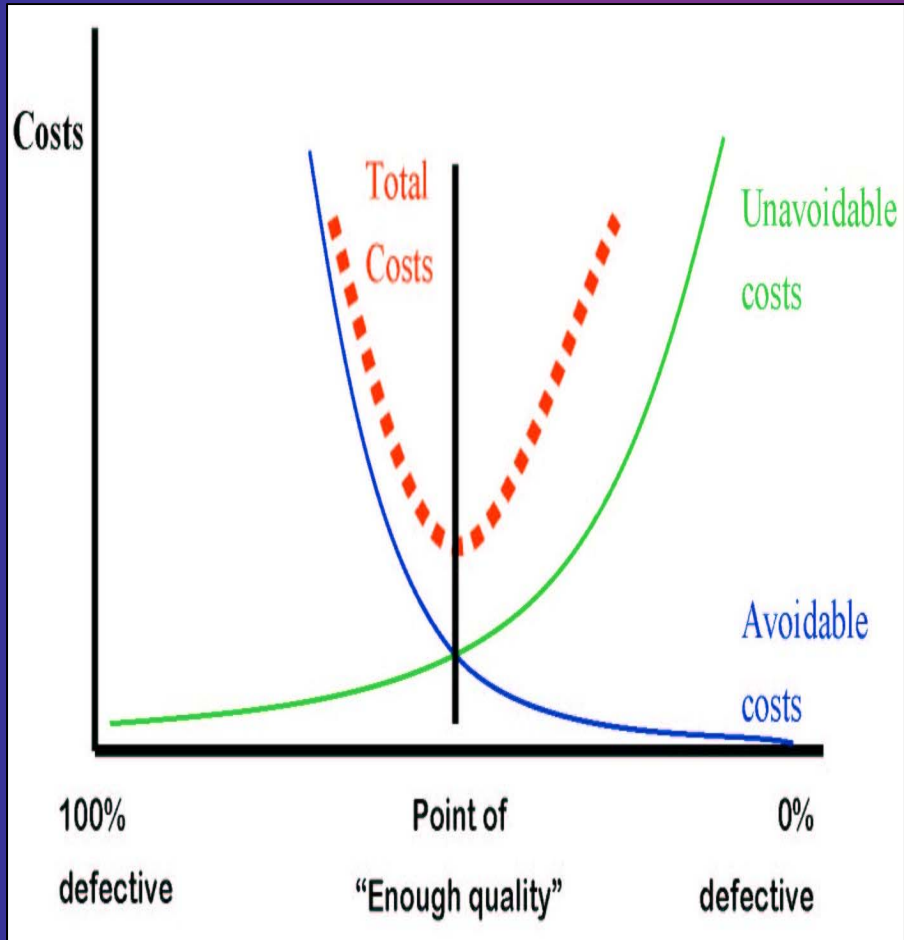
Risk Reduction Resource Requirement



Large initial change
requires relatively small
amounts of resources.

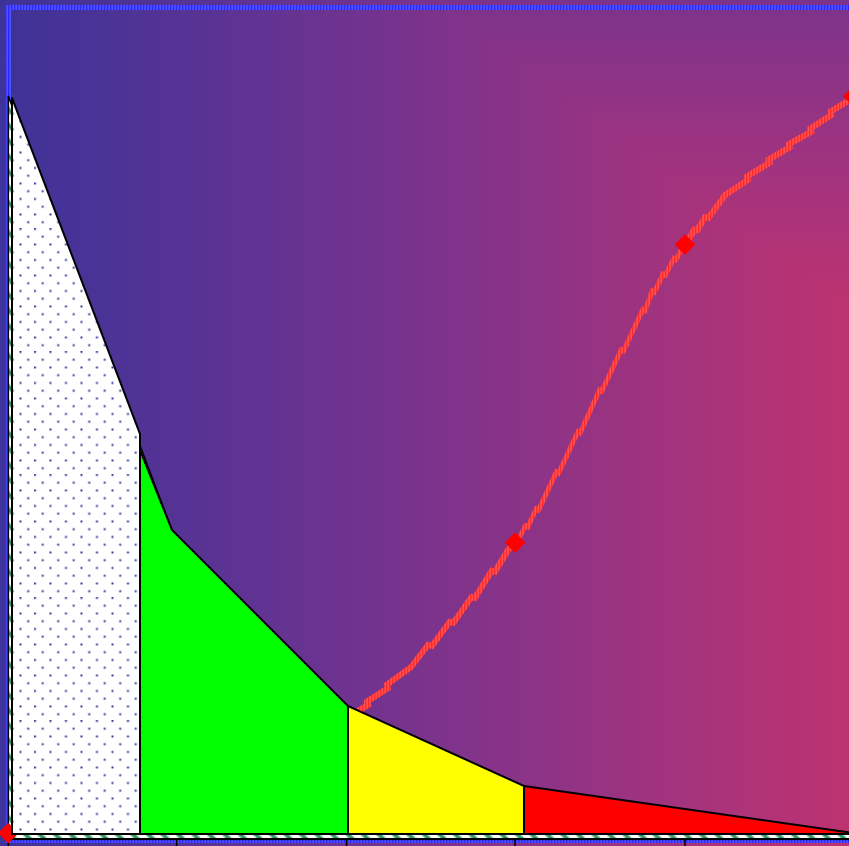
Residual change becomes
increasingly more
expensive

Saying the same things about Quality and Cost



Risk Reduction

Reducing Laboratory Accidents



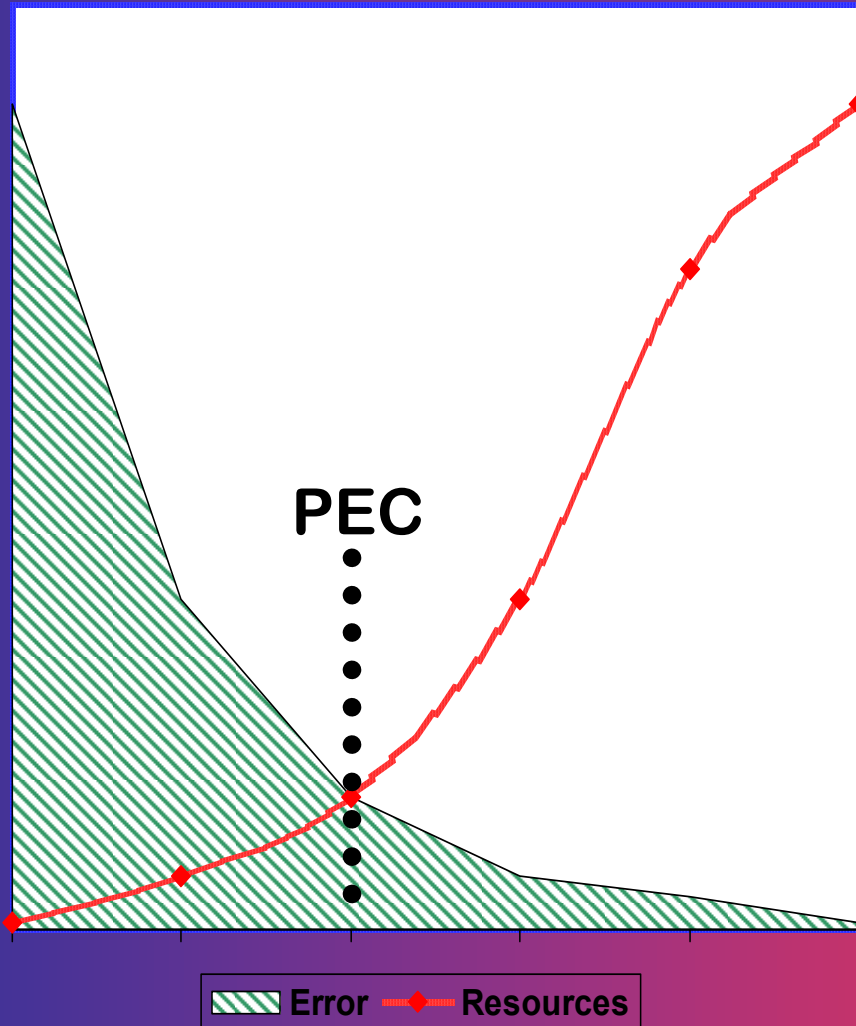
Reduce clutter

Increase awareness

Gloves, Gown, Masks

Cabinets, Ventilation

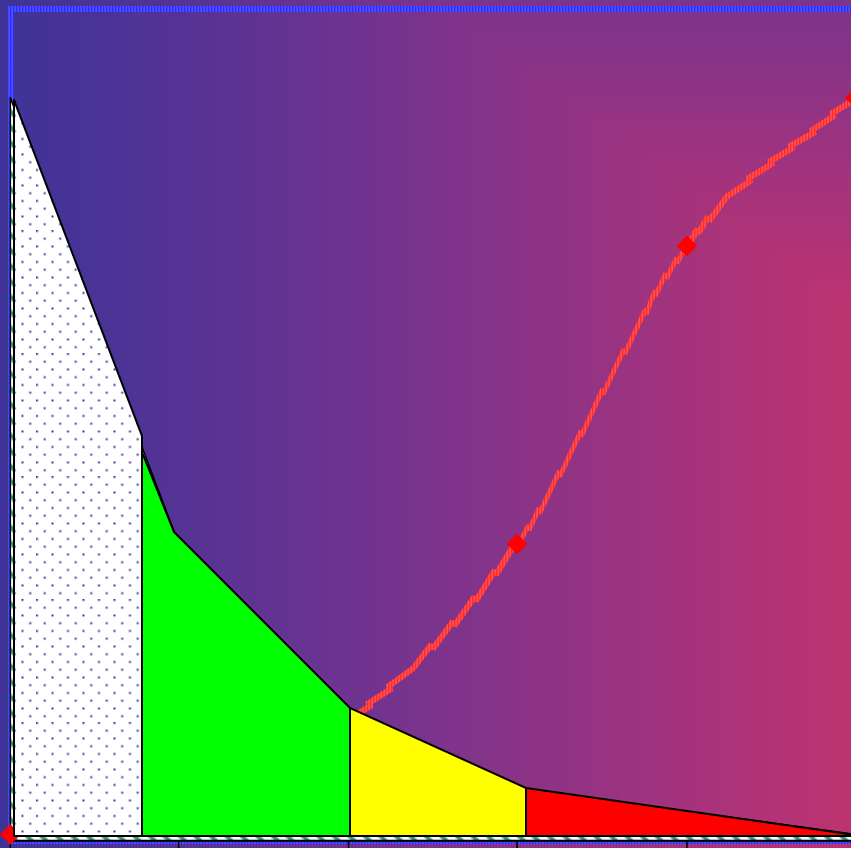
Change and its Impact on Resources



- Quality
- Safety
- Risk

Risk Reduction

Reducing Laboratory Error



Quality Control

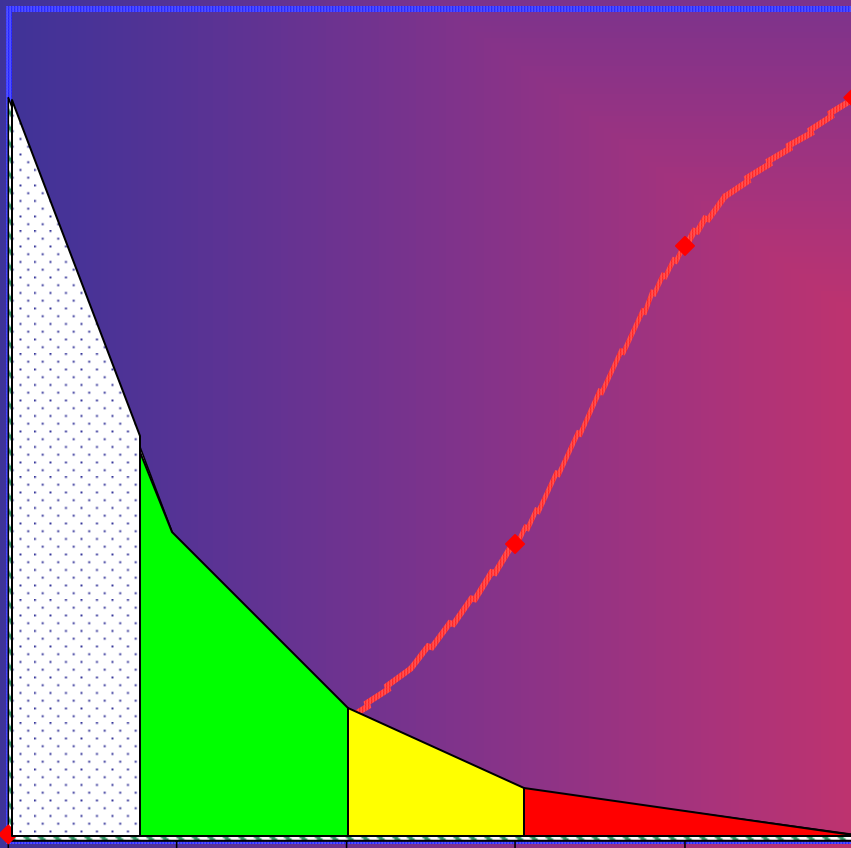
Internal Audit Program

EQA - PT

External Consultant

Risk Reduction

Reducing Identification Errors



Verbal Confirmation

Bracelet Confirmation

Requisition Confirmation

Bar Code Confirmation

Risk and the Clinical Laboratory

Clinical laboratories are engaged in the process of risk reduction all the time, but characterize it with different vocabulary.

Safety

Error Reduction

Prevention Programs

Process Improvement

- Worker risk
 - Safety
 - Responsibility
- Patient risk
 - Patient Identification
 - Specimen Identification
 - Information
 - Analytic sensitivity and specificity
 - Report interpretation
- Laboratory risk
 - Financial
 - Liability
 - Safety

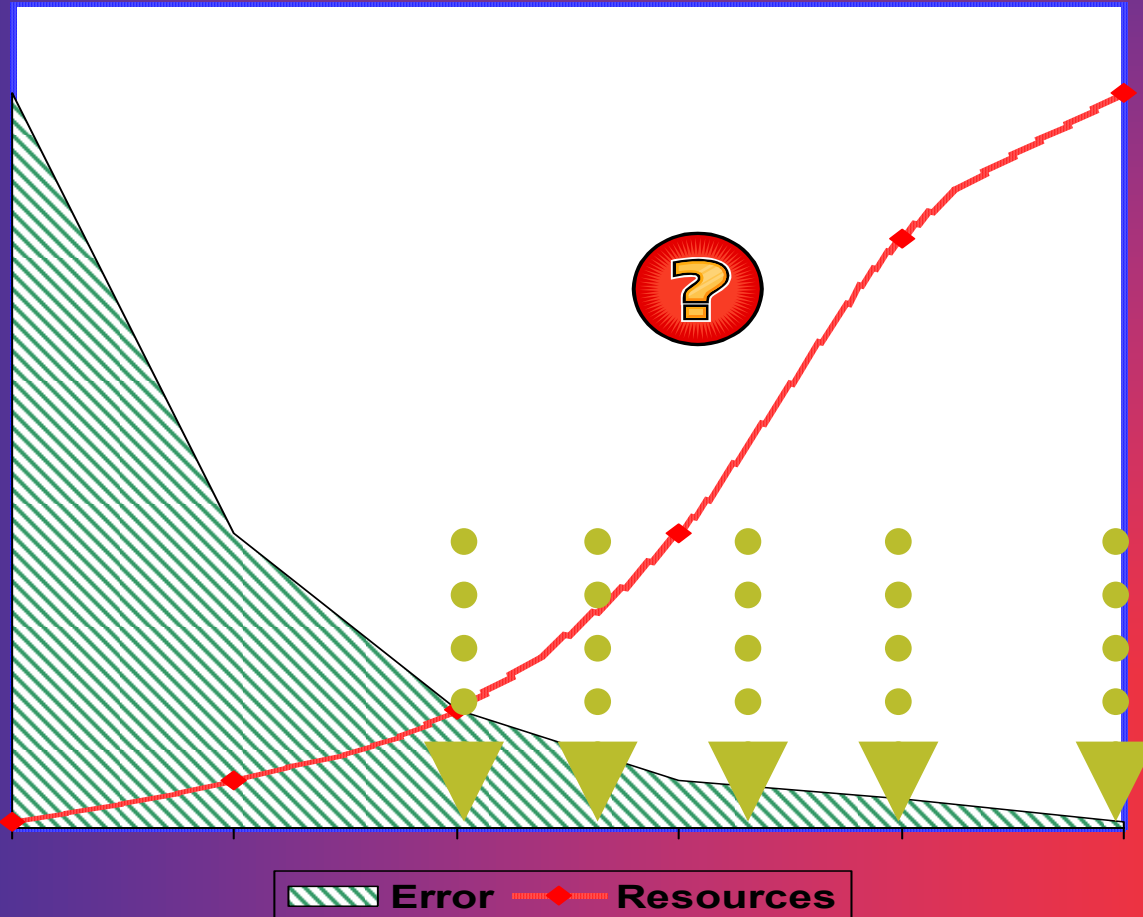
What is Reasonable Risk Reduction



Risk tolerance
ALARP
Risk aversion

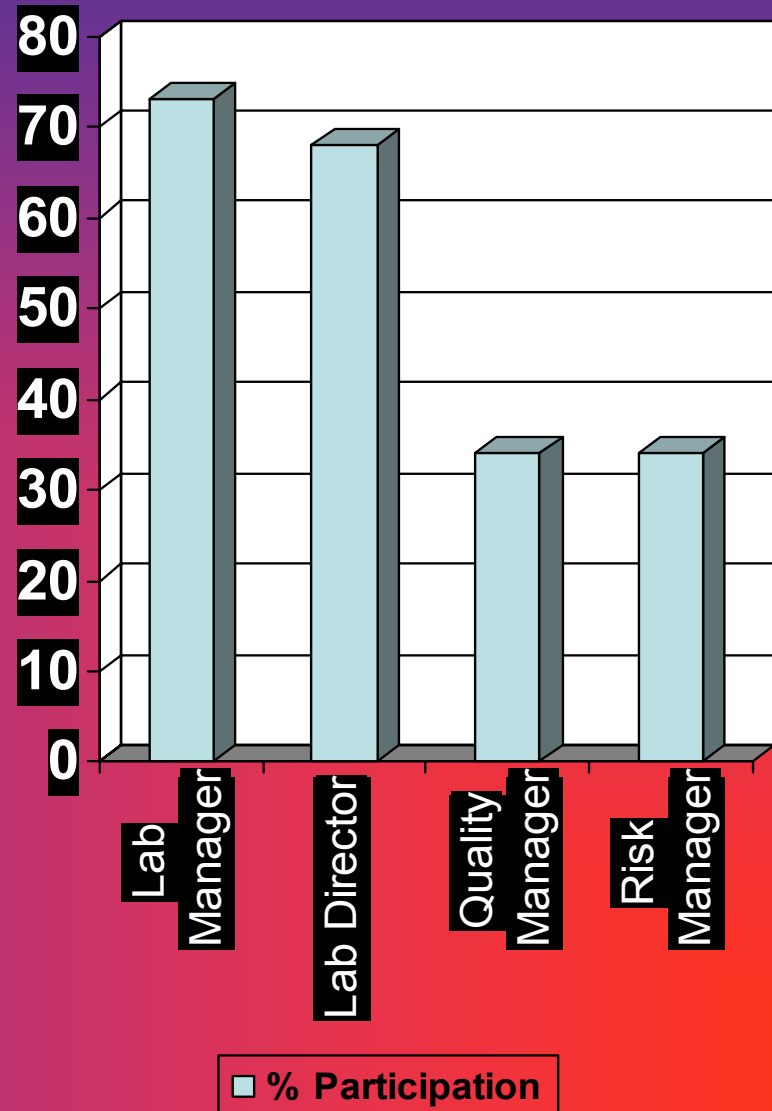


What is “Enough Risk Reduction”?



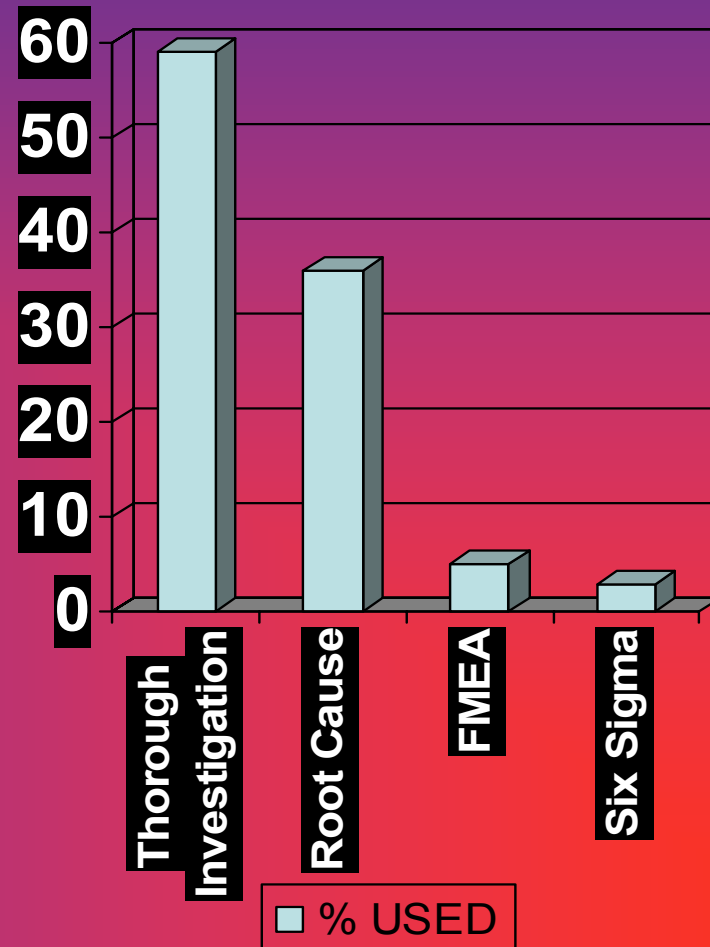
Participation of Risk Management in Clinical Laboratories

- Who is typically involved in investigation of adverse events?



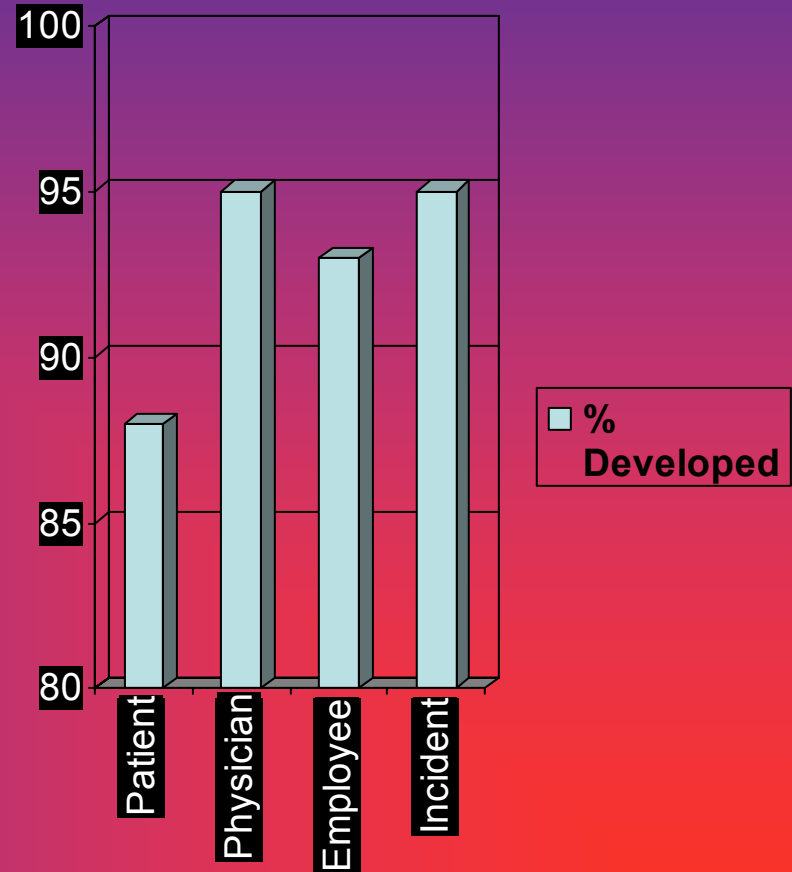
Participation of Risk Management in Clinical Laboratories

- What Quality Management tools are used in conjunction with investigation of adverse events?

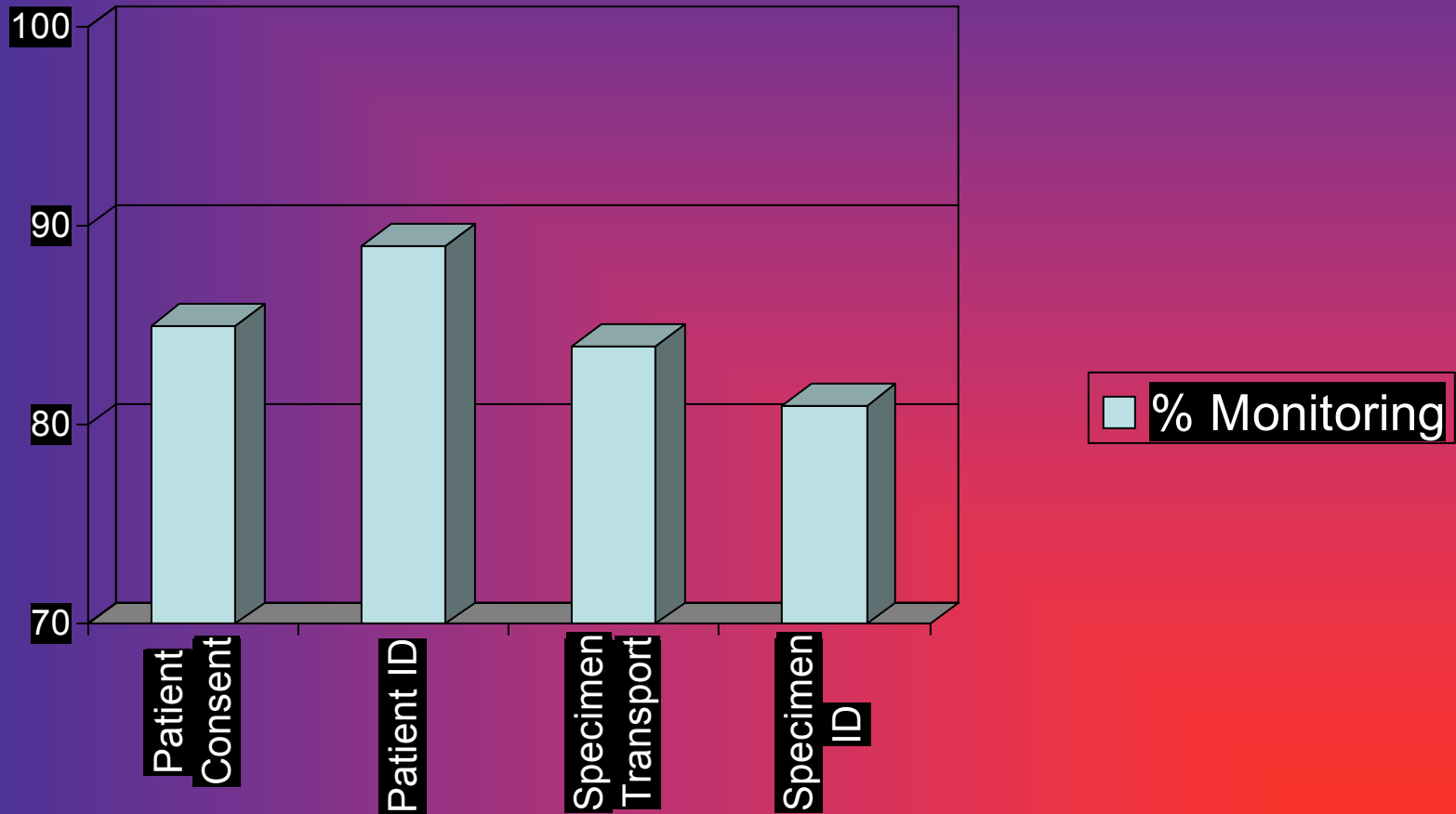


Participation of Risk Management in Clinical Laboratories

- Are preventive actions and corrective actions developed during the investigation of the following complaints?



Monitored Pre-Analytic Activity in Clinical Laboratories



Major Determinant in Risk Reduction





Reasons to Reduce Risk



- Risk Comments heard in the laboratory on a daily basis

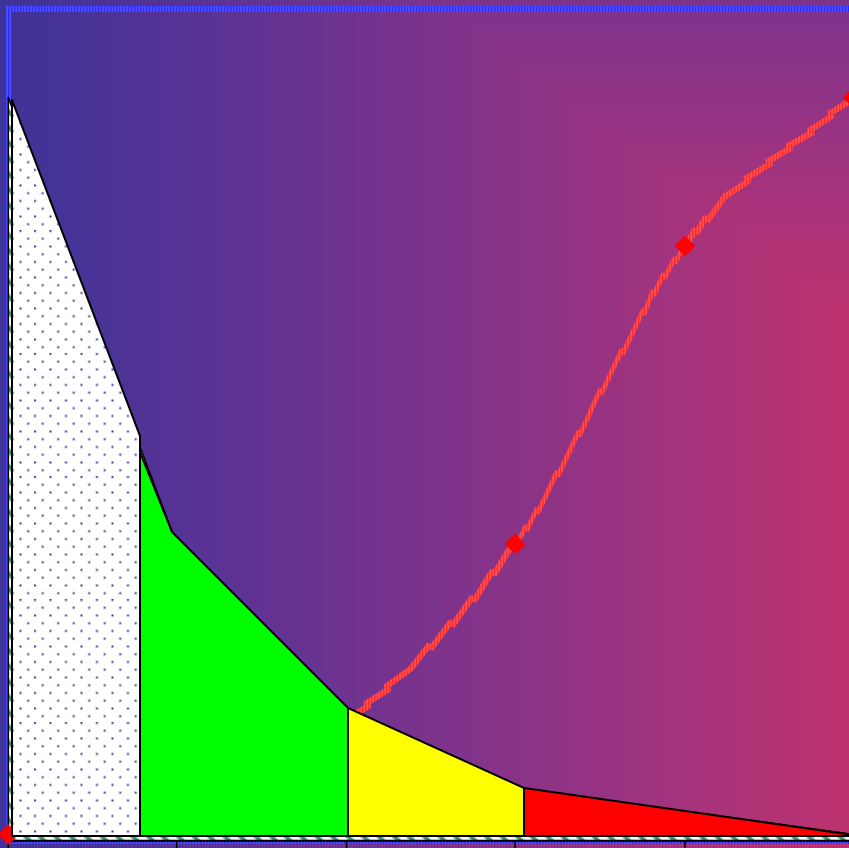
- What would you do if it was your mothers sample?

What would you do if the patient was a lawyer?

Imagine you are standing in the courtroom trying to justify what you just did!

Risk Reduction

Reducing Nosocomial Infections



Frontline Involvement

Handwashing

Special Education

Routine Surveillance

Risk Reduction through Quality Systems and Improvement

ISO 15189: 2003 ISO 9001:2000 CLSI GP26: A3

- External Audits and EQA
- Internal Audits
- Preventive Actions
- Opportunities for Improvement
- Corrective Actions

Published examples of FMEA in the Medical Laboratory

- FMEA and Patient ID Errors
 - Nichols J. 2004
 - Clin Leadersh Manag Rev; 18:328
- FMEA and
 - Capuno M. 2004
 - Clin Leadersh Manag Rev; 18:37.
- FMEA and Specimen Labeling
 - Dock B. 2005
 - Clin Lab Sci;18:210

FMEA and Medical Care

- **Medication Error**
 - Adachi W, Lodolce AE
 - Am J Health Syst Pharm. 2005 May 1;62(9):917-20.
- **Injury Reduction**
 - Marx DA, Slonim AD.
 - Qual Saf Health Care. 2003 Dec;12 Suppl 2:ii33-8.
- **Artificial Heart**
 - Zapanta CM, Snyder AJ, et al.
 - ASAIO J. 2005 May-Jun;51(3):214-23.
- **Invasive Diagnostic Devices**
 - Bramstedt KA.
 - ASAIO J. 2002 May-Jun;48(3):293-5.
- **Infant Abductions**
 - Hosp Peer Rev. 2004 Jun;29(6):77-8.
- **Transfusion**
 - Burgmeier J.
 - Jt Comm J Qual Improv. 2002 Jun;28(6):331-9

ISO 22367

- While there are some examples of the use of risk reduction methods in health care, there are few examples of the use of risk procedures and their application in the clinical laboratory. As such it is premature to establish a standard to dictate requirement.

Possible applications of Risk Management Procedures in the Medical Laboratory

- Patient Identification Errors
- Accession Errors
- Provision of new tests and services

In Summary...

- Quality Management systems require application of preventive actions to reduce the opportunity for significant error.
 - Tools established for assessing potential opportunities for risk would appear to fit preventive action needs.
 - Laboratories can develop strategies to incorporate Risk Management techniques within the Quality Management system to prevent error.

Conclusion...

- Clinical laboratories perform many activities to reduce the risk of error
- Most are done as “reactive” preventive activity
- Most do not use the tools found helpful in risk management
- Most do not incorporate the time and skills of risk managers in incident investigation.