



Quality Control for the Future: Risk Assessment in Laboratory Practice

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BIO-RAD

American Statistical Association (ASA) T-Shirt



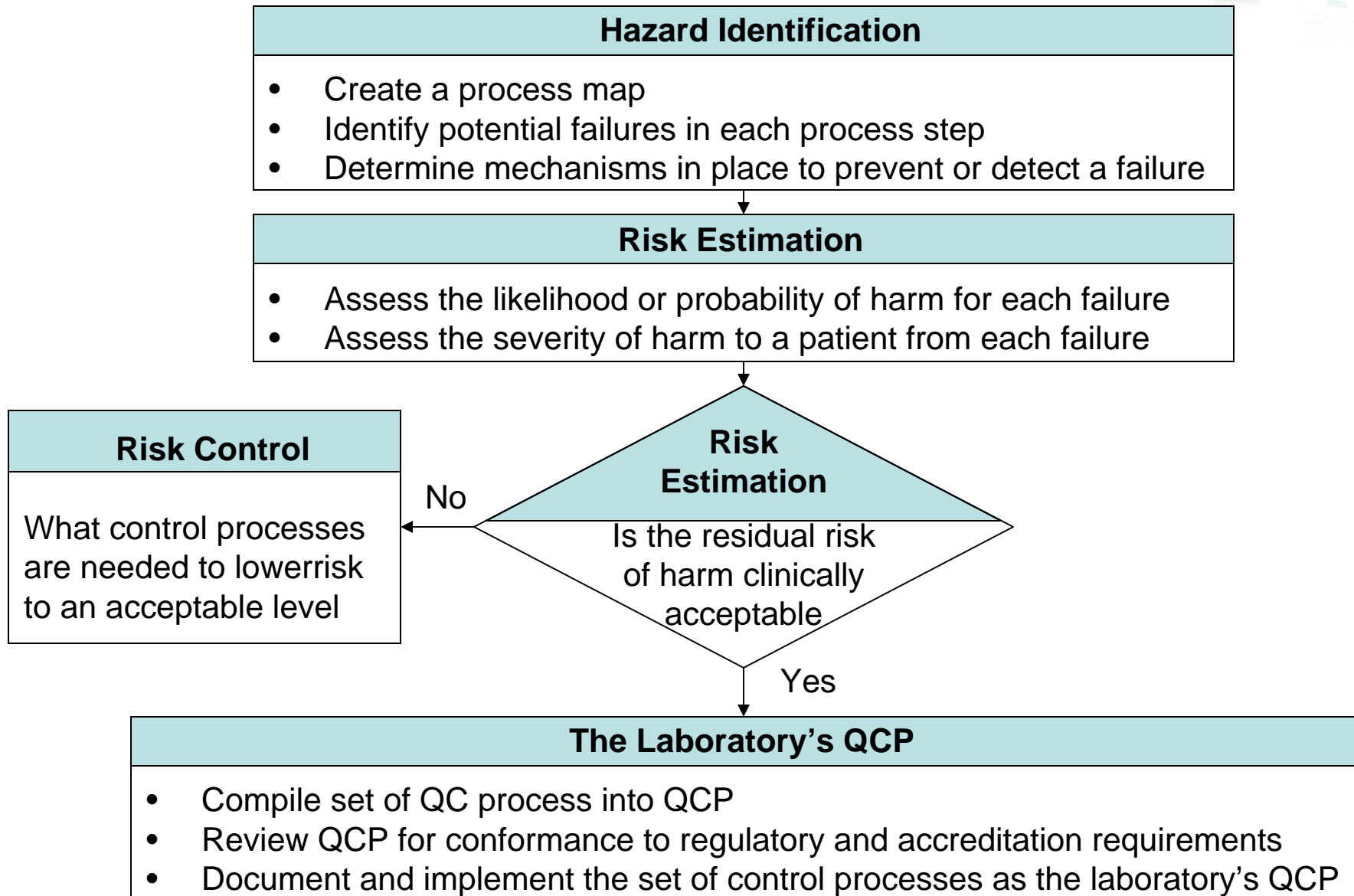
Statistics
*is never
having to say
you're certain. . . .*

BIO-RAD Another ASA T-Shirt

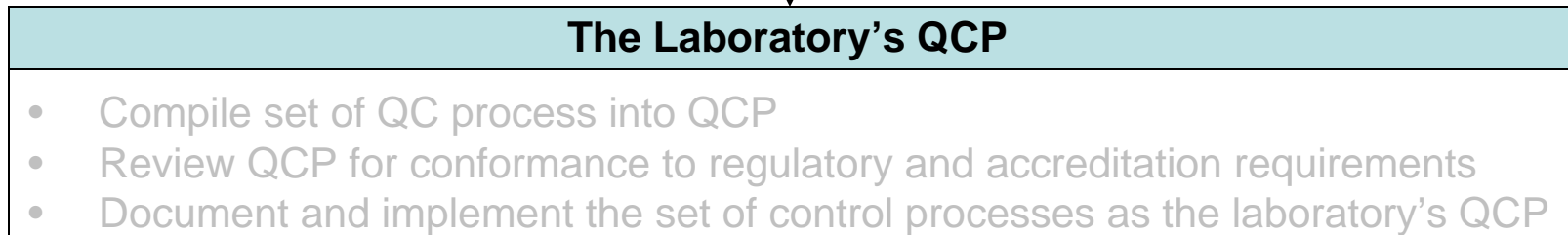
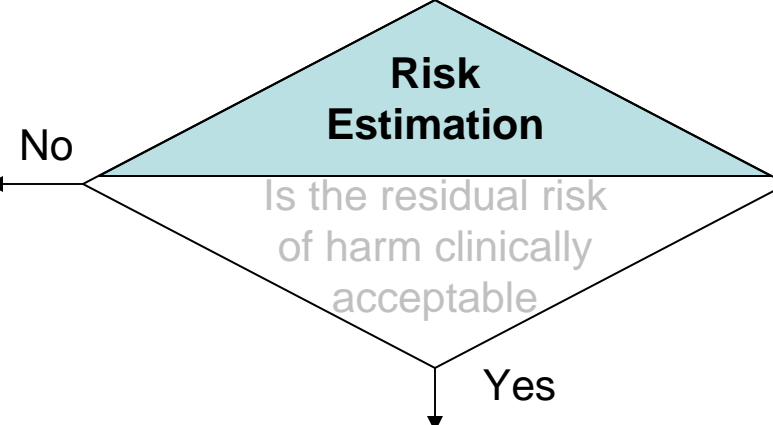
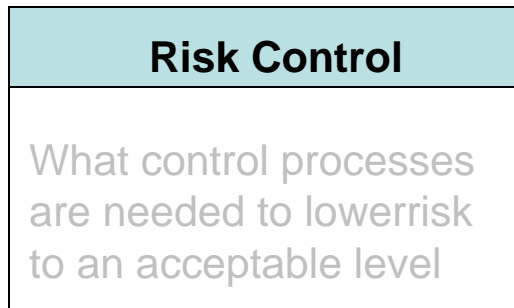
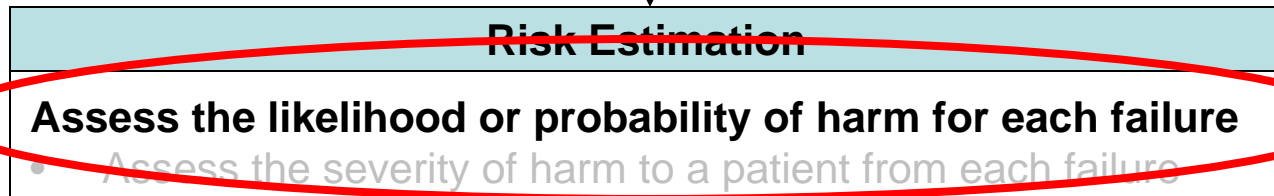
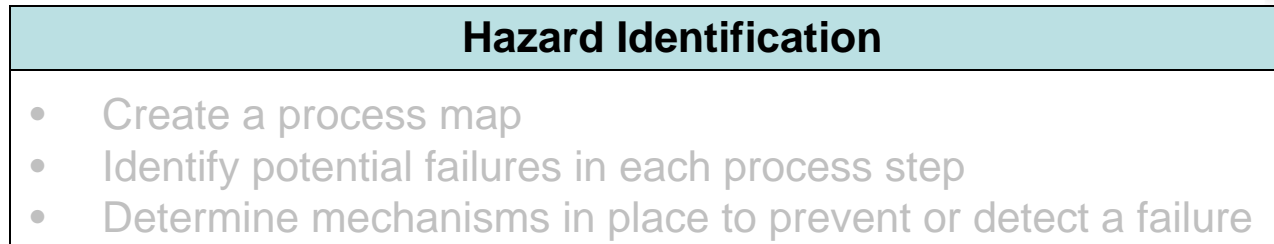


*In God We Trust...
All Others Bring Data.*

EP23: Figure 5. Risk Assessment

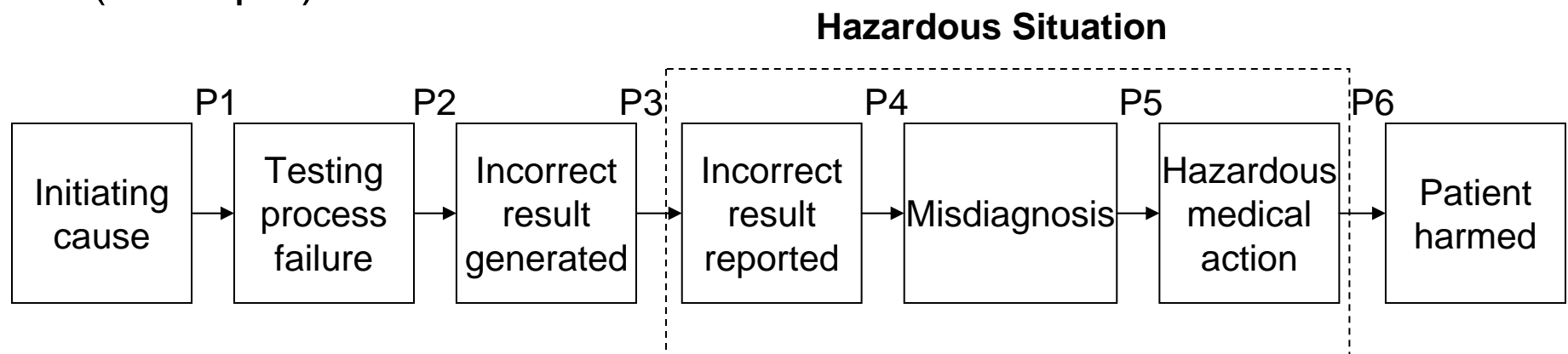


EP23: Figure 5. Risk Assessment





- Sequence of Events Creating Risk of Harm for a Patient (Example)



EP23-A, Figure 6

- EP23 states;
 - quantitative estimates of the probabilities in the sequence leading to patient harm are desirable,
 - but may not be easily quantifiable.



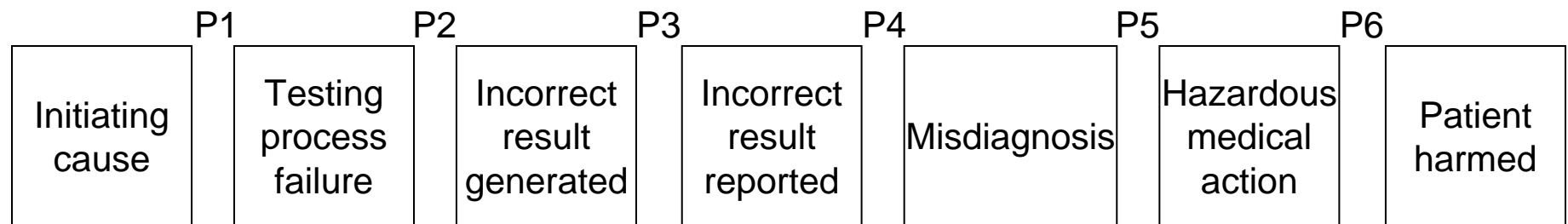
- If probability estimates are not easily quantifiable, EP23 suggests using descriptive categories such as

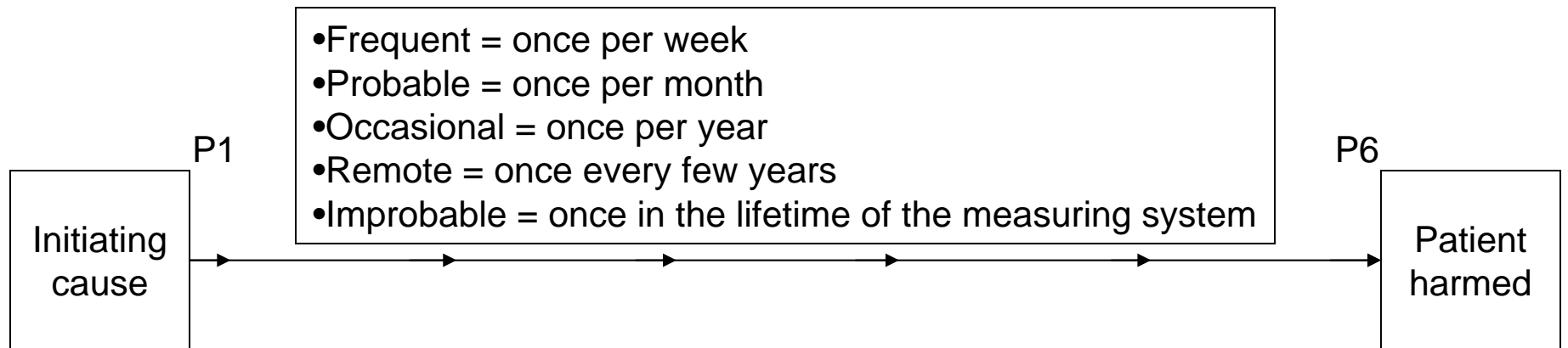
- Frequent = once per week
- Probable = once per month
- Occasional = once per year
- Remote = once every few years
- Improbable = once in the life of the measuring system

EP23-A 7.2.1

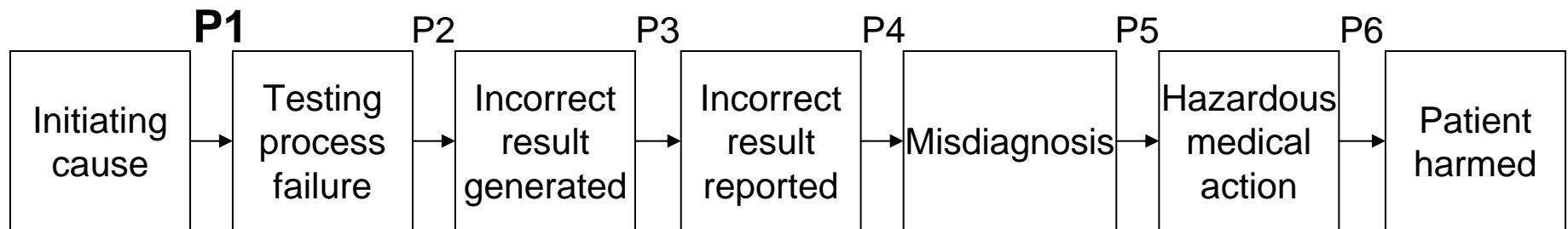
- *Note, these are rates of occurrence not probabilities*

Estimating Probability of Harm





Is this the best we can do?

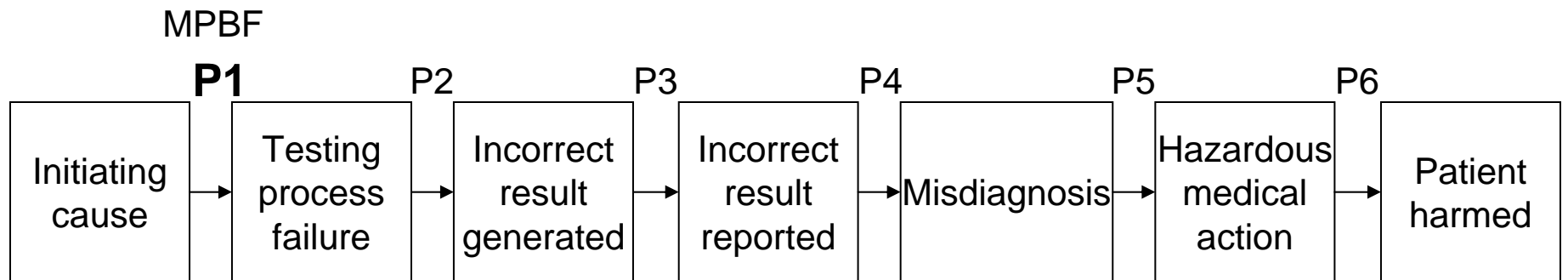


- P1: The probability that a testing process failure occurs

P1: Probability of a Failure Mode



- P1 = how likely is a given failure mode going to occur
- *or more commonly*
- P1 can be the mean time between failures (MTBF)
Information regarding MTBF may come from
 - Manufacturer
 - Historical failure data
 - Literature
- MTBF can be converted to mean number of patient results between failures (MPBF)
 - $MTBF = 30$ days
 - 150 patient results examined per day (on average)
 - $MPBF = 30 * 150 = 4500$ patient results



- P2: The probability that a testing process failure generates incorrect patient results

P2: Probability of Producing an Incorrect (Unreliable) Result

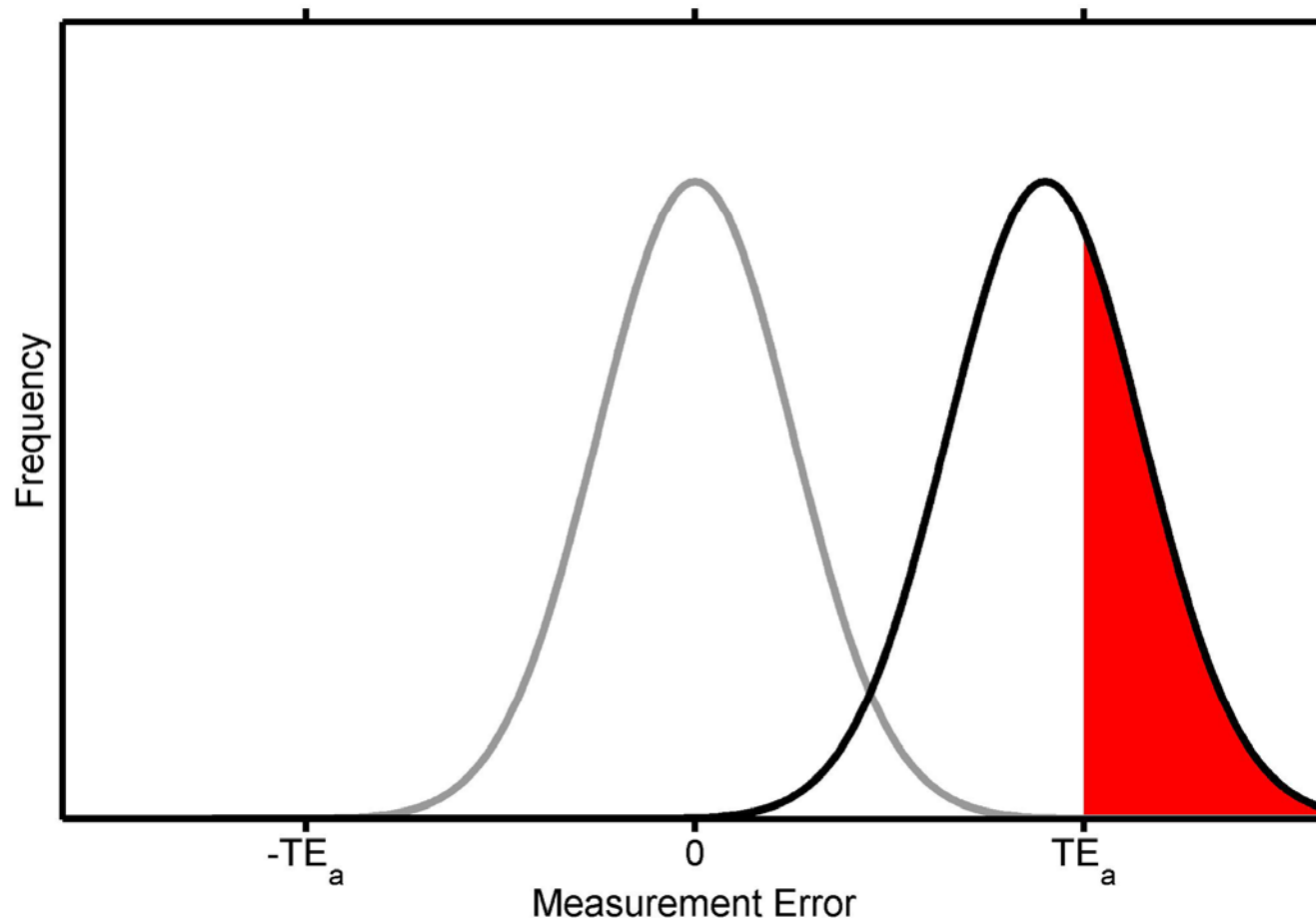


- The number of unreliable patient results produced during the existence of an out-of-control condition depends on
 - The quality required for patient results
 - The type and magnitude of the out-of-control condition
 - The power to detect the out-of-control condition
 - When (how often) QC evaluations are performed
- An out-of-control condition may result in many unreliable patient results being produced



- ISO 15189 Clause 5.6.1: *Laboratory QC should assure that patient results meet the quality required for their intended use*
- The quality of a patient result depends on the difference between the correct value and the value reported.
- If the error in a patient's result exceeds the allowable total error (TE_a)
 - The result is considered unreliable (or incorrect).
 - It creates a hazardous situation for the patient.

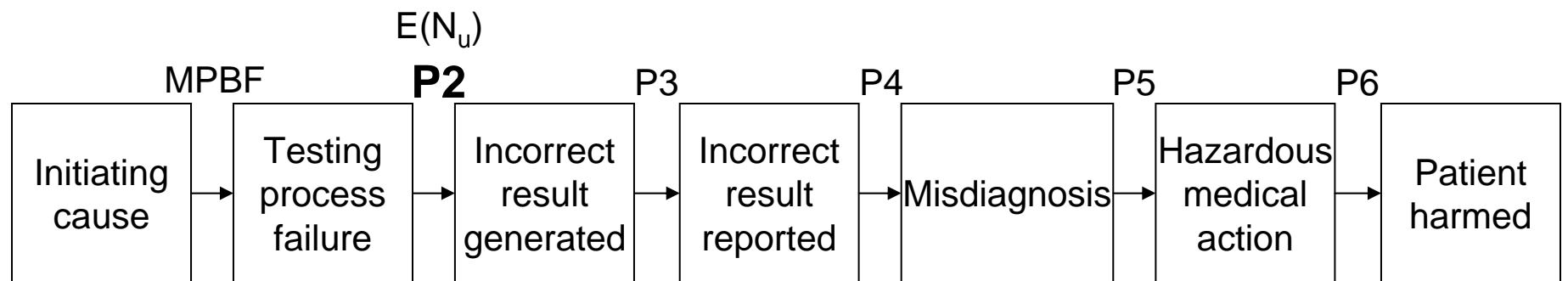
Probability of an Unreliable Result Due to a Systematic Error Condition



Expected Number of Unreliable Patient Results Produced: $E(N_U)$



- The number of unreliable patient results produced during an out-of-control condition (red asterisks) will depend on
 - The magnitude of the out-of-control condition
 - The power of the QC rule – **Detection**
 - The number of patient specimens between QC events
- $E(N_U)$ = Expected number of unreliable patient results generated during an out-of-control condition



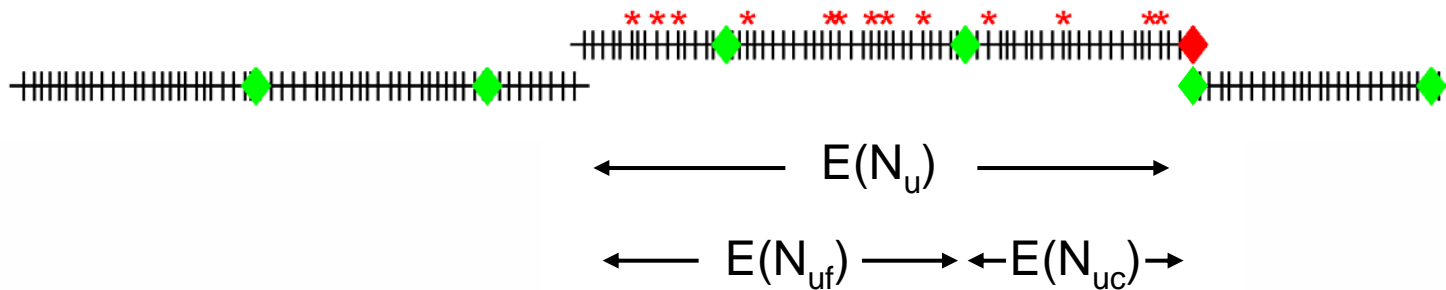
- P3: The probability that incorrect results that are generated will be reported

P3: Probability of Reporting an Unreliable Patient Result

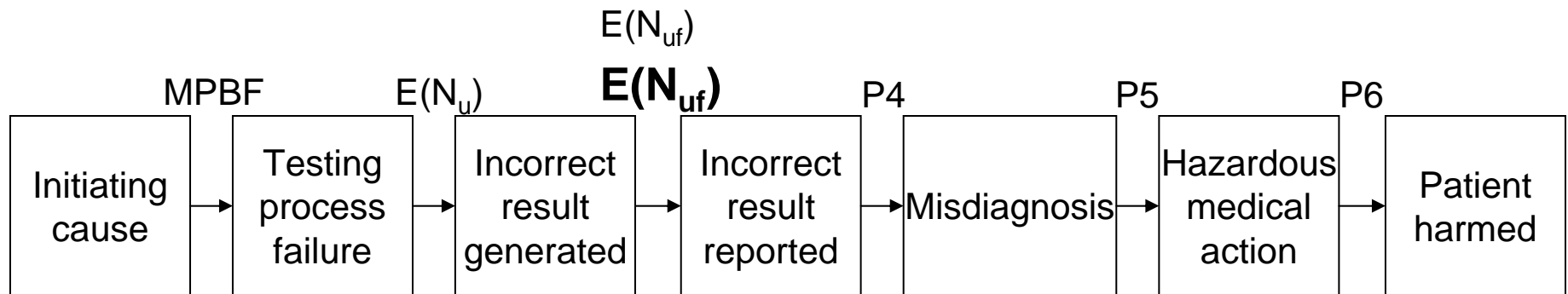


- The probability of reporting an unreliable result that leads to an incorrect action depends on
 - The number of unreliable results produced because of an out-of-control condition
 - How and when results are reported
 - The likelihood of identifying and correcting a reported unreliable result before an incorrect action is taken

Expected Number of Unreliable Patient Results Reported



- The patient results produced during an out-of-control condition can be divided into
 - Results prior to the last accepted QC event (Pre)
 - Results since the last accepted QC event (Post)
 - Bracketed QC: results aren't reported
 - Immediate reporting: results should be repeated and updated in a timely fashion
- $E(N_{uf})$ = Expected number of unreliable “final” results
- $E(N_{uc})$ = Expected number of unreliable “correctable” results



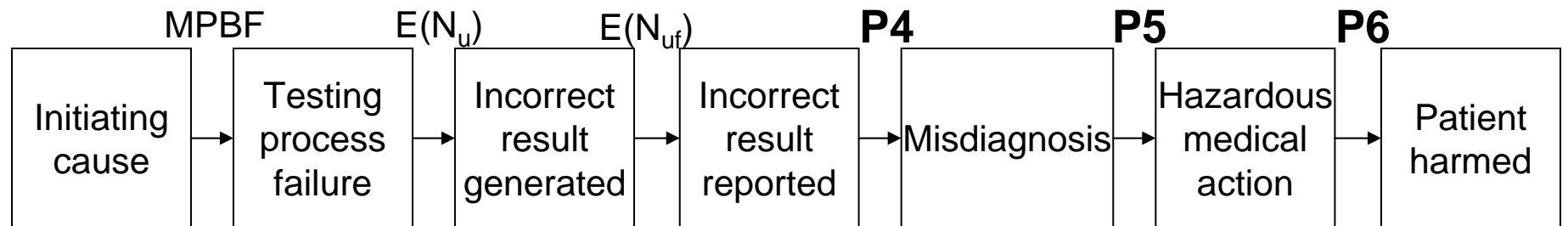
- P4: The probability that an incorrect result leads to a misdiagnosis
- P5: The probability that a misdiagnosis leads to a hazardous medical action
- P6: The probability that a hazardous medical action leads to patient harm
- $P4 * P5 * P6$: The probability that an incorrect result leads to patient harm

Probability of Patient Harm from an Unreliable Patient Result

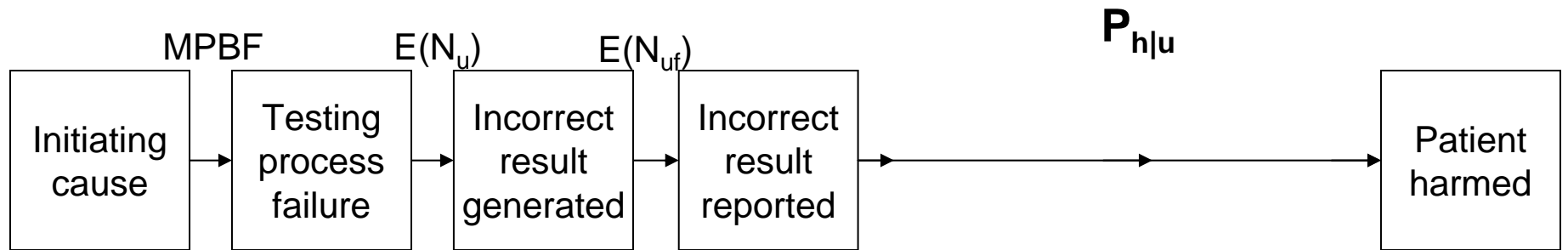


- The probabilities (P4, P5, P6) are associated with activities outside the laboratory
- Their product equals the probability of patient harm *given* that an unreliable result has been reported
 - $P_{h|u} = P4 * P5 * P6$
- EP23 says;
 - “medical judgment is used to estimate the overall probability of harm due to receiving an incorrect result”
 - Medical literature
 - Consultation

Estimating Probability of Harm



Estimating Probability of Harm

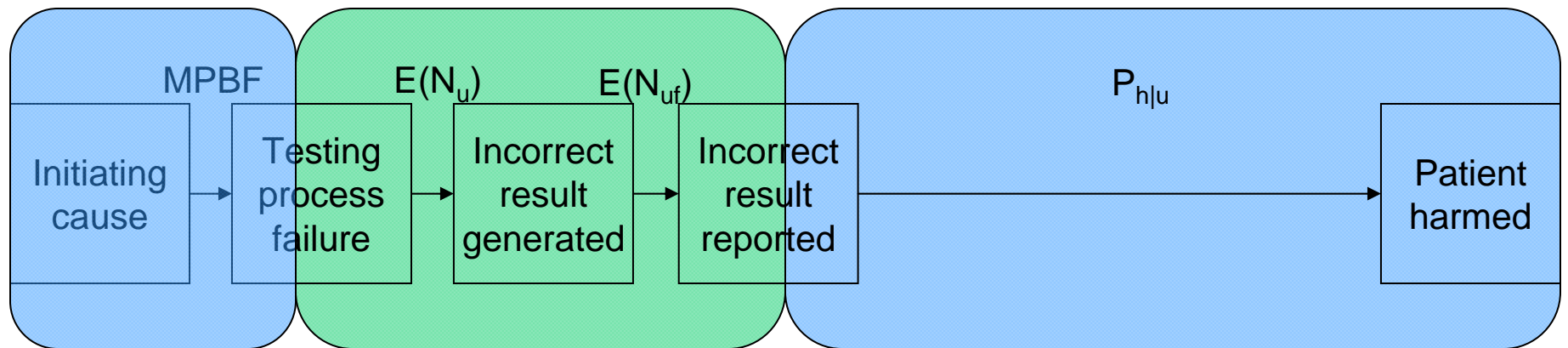


Estimating Probability of Harm: Risk Management + Statistical QC

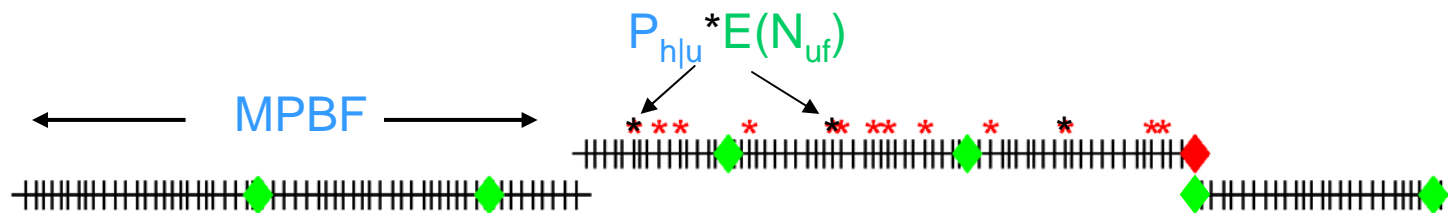


Risk Management

Statistical QC



Harmed Patients from Failure Mode Occurrence



- Probability of patient harm is
 - The expected number of patients harmed due to incorrect results from a failure mode: $P_{h|u} * E(N_{uf})$
 - Divided by the average number of patient results examined between failure mode occurrences: MPBF

$$\text{Probability of Harm} = P_{h|u} * E(N_{uf}) / \text{MPBF}$$



- A quantitative assessment of the probability of harm can be obtained by combining:
 - Risk Management activities
 - the rate of occurrence of identified failure modes
 - the probability of harm from a incorrect reported result
 - Statistical QC design
 - the expected number of incorrect results reported due to the occurrence of a failure mode



	Estimate Risk	Reduce Risk
Rate of Occurrence of Failure Modes	Yes: manufacturer info, technical bulletins, product alerts	Some: lab environment/processes training Very little: Medical devices
Number of Incorrect Results Reported	Yes: Statistical QC design & evaluation	A lot: Detection in analytical phase A little: Detection in pre- and post-analytical phases
Probability of Harm from an Incorrect Result	Yes: Medical literature, medical judgment, consultation	Very little: Report formatting, education



- The laboratory has two main mechanisms to estimate and reduce the risk of patient harm:
 1. Identify as many potential failure modes as possible and seek ways to reduce occurrences of the identified failure modes

Risk management

2. Implement QC strategies that minimize the number of incorrect patient results that are reported when a failure mode does occur

Statistical QC

- The combination enables a laboratory to address the full spectrum of patient risk implications for their operations



THANK YOU!