RISK MANAGEMENT IN CLINICAL LABRATORIES: THE FUTURE OF QC

A.MALEKPOUR,
Pharm.Dr,PhD,NRCT,DABCC,FACB

RISK MANAGEMENT

Risk Management is a new approach in medical laboratories, but it has been a long history of use in other industries

RISK MANAGEMENT DEFINITION

- SYSTEMATIC APPLICATION OF MANAGEMENT POLICIES, PROCEDURES AND PRACTICES TO THE TASK OF ANALYZING, EVALATING, CONTROLING AND MONITORING RISK (ISO 14971)

HARMONIZING LABORATORIES STANDARS AROUND THE WORLD

Many countries around the world have one or more organizations responsible for accreditation of their laboratories. Adaption of ISO and CLSI Risk management will help all laboratories employ a uniform approach in determining and to adapt internationally accepted medical laboratories practices

WHAT IS THE RISK?

RISK IS : THE FUNCTION OF THREE FACTORS:

OCCURANCE: Probability or frequently of failure

DETECTION: Probability that failure will be detected before harm

SEVERITY: Consequence of harm

THE PERSON WHO RISK NOTHING,DOES NOTHING, HAS NOTHING AND BECAME NOTHING.

CLINICAL LABORATORY IMPROVEMENT AMENDMENT(CLIA 88)

- - IN 1988 CMS PASSED CLIA FOR CLINICAL LABORATORISE OF THE USA.(CLIA 88):
- -WAIVED TEST, MODERATE COMPLEXITY TEST,
- PROVIDER-PERFORMANCE MICROSCOPY
- HIGH COMLEXITY TESTS
- EQUIVALENT QUALITY CONTROL2004
- NEW INSTUMENT WITH INTENAL QUALITY-ASSESSMENT SYSTEM
- EQC, DEPEND ON ABILITY OF INSTRUMENT AND LAB DIRECTOR

CENTER FOR MEDICARE AND MEDICADE SERVICES (CMS) CLINICAL AND LABORATORY STANDARD INSTITUDE (CLSI)

IN 2005 CMS COLABORATED WITH CLSI AND PROFESSIONAL ORGANIZATIONS ,LABORATORIES, INDUSTRIES AND OTHERS TO SOLICIT NEW IDEAS FOR QC FOR THE FUTURE

TOW MAJOR CONCLUSIONS CLSI AND CMS

1- ONE- SIZE-FIT-ALL QC IS NOT APPROPRIATE ANY LONGER DUE TO NEW TECHNOLOGIES NOW EAVAIABLE FOR LABORATORIES.

2- MANUFACTURERS DO NOT PROVIDE SUFFICIENT INFORMATIONS ABOUT WHAT PROBLEMS/LIMITATIONS EXIST IN THEIR TEST SYSTEM AND HOW TO MITIGATE THEM.

CLINICAL AND LABORATORY STANDARD INSTITUDE (CLSI)

EP- EVALUATION PROTHOCOLS

EP-18 RISK MANAGEMENT TECHNIDUES TO IDENTFY AND CONTROL LABORATORY ERREORS

EP-22 PRSENTATION OF MANUFACTURER,S RISK MITIGATION FOR USERS OF IN VITRO DIAGNOSTIC DEVICES

EP-23 LABORATORY QUALITY CONTROL BASED ON RISK MANAGEMENT.

EP 18
STATISTICAL QC

STATISTIC IS NEVER
TO SAY YOU ARE CERTAI

EVALUATION PROTOCOL-18
EP 18

- **-EP 18 (Evaluation Protocol): USING**
- Failure Mode and Effects Analysis, **(FMEA)** and Failure Reporting ,Analysis, and Corrective Action System**(FRACAS)**.
- **FMEA** AND **FRACAS** ARE GUIDELINE FOR RISK MANAGEMENT

FMEA

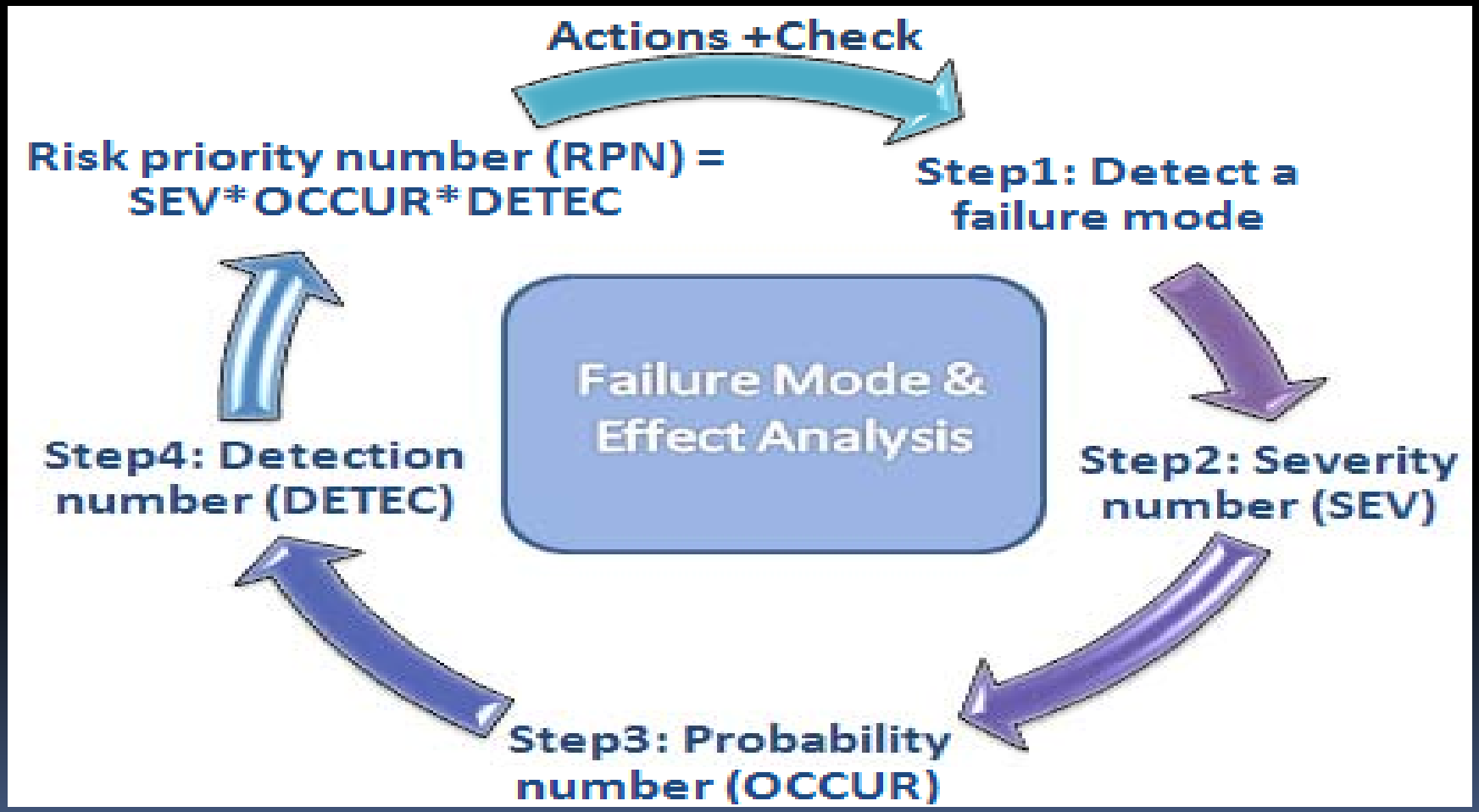
FAILURE MODES AND EFFECT ANALYSIS

- **FMEA** IS A PROCEDURE IN PRODUCT DEVELOPMENT AND OPERATION MANAGEMENT FOR ANLYSIS OF POTENTIAL FAILURE MODES WHITIN THE SYSTEM FOR CLASSIFICATION, SEVERITY AND LIKELIHOOD OF THE FAILURES
- Us armed force 1949, NASA 1960, auto industry 1970

Table of Ranking Severity, Occurrence and Detection

RANKING	SEVERITY	OCCURRENCE	DETECTION
10	Highly Hazardous	Very high	Non-detectable
9	Hazardous	Very high	Very improbable
8	Very high	High	Improbable
7	High	High	Very low
6	Moderate	Moderate	Low
5	Low	Moderate	Moderate
4	Very low	Moderate	Moderately high
3	Minor	Low	High
2	Very minor	Very low	Very high
1	None	Remote	Highly detectable

FMEA CYCLE


Actions +Check
Risk priority number (RPN) = SEV*OCCUR*DETEC
Step1: Detect a failure mode
Failure Mode & Effect Analysis
Step4: Detection number (DETEC)
Step2: Severity number (SEV)
Step3: Probability number (OCCUR)

RPN CALCULATION

S	x	O	x	D	=	RPN
10		2		2		40
3		10		2		60
2		5		10		100

FAILURE REPORTING,ANALYSIS AND CORRECTIVE ACTION SYSTEM

FRACA

FRACA is a process for reporting , classifying analyzing failures and planning corrective action in response to those failures.

FRACA PROCESS IS CLOSED LOOP FAILURE REPOTING,ANALYSIS AND CORRECTIVE ACTION

EVALUATION PROTOCOLS
EP 22(1)

- **MANUFACTURERS CAN IDENTIFY THE VARIOUS SIGNIFICANT RISKS:**

- Too high or too low storage temperature for cartilage/reagent
- Too high or low operating temperature when test is perform..
- Undetected hemolysis in serum or plasma
- Inappropriate changes in calibration setting
- Reagent degradation after calibration
- Calibration degradation
- Can detect the interference compound in samples and control

EVALUATION PROTOCOLS EP22 (2)

- Stop the device if the results of QC is out
- Barcode reading errors
- Test panel reading errors
- Inadequate sample introduction
- Device has integrated quality checks as intra QC system

ABBOTT ARCITECHT c16000

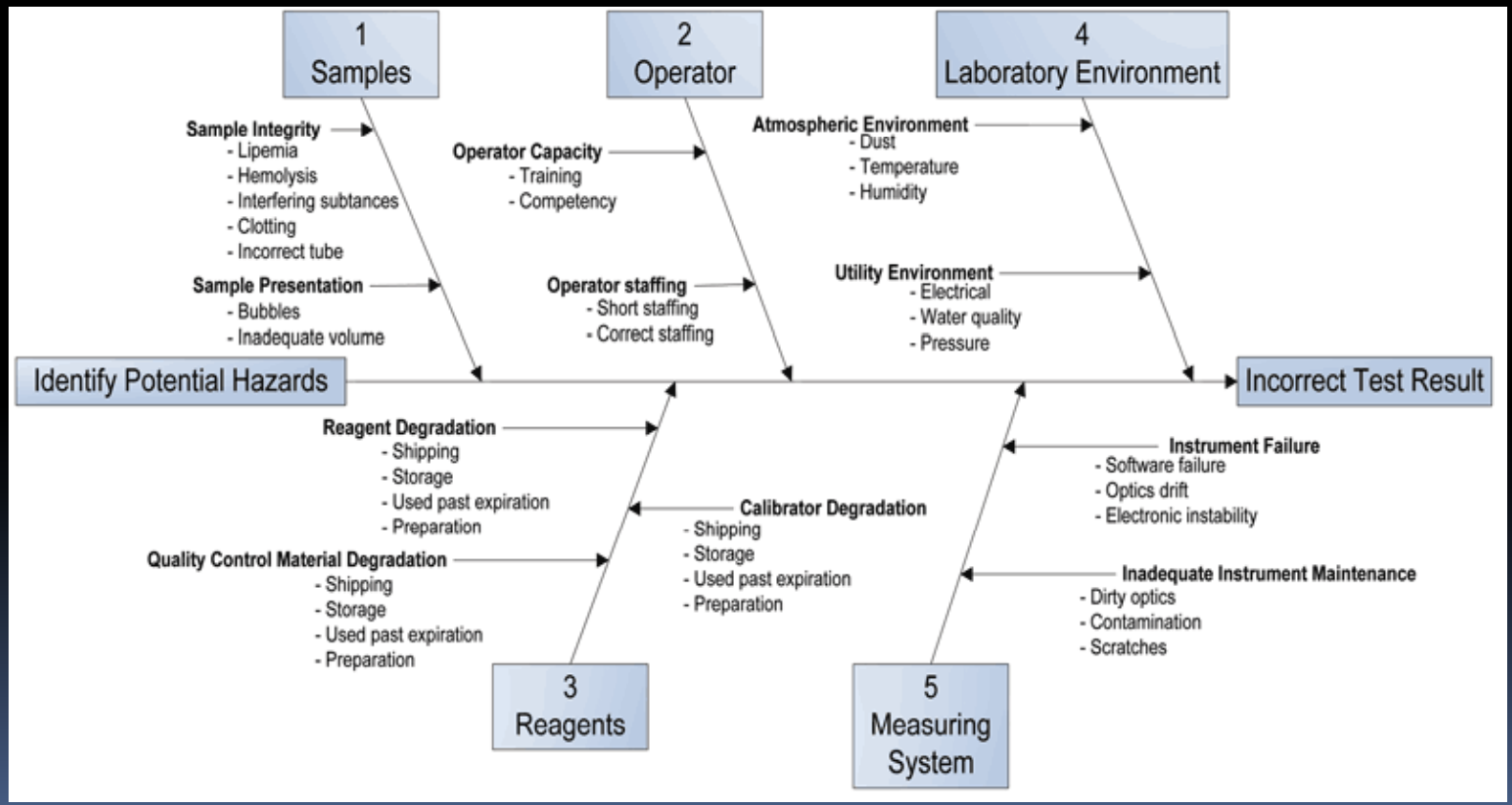
ABBOTT ARCHITECTc16000

- -200 samples on board
- -145 tests: chem, EIA,ISE.
- -Throughput : 1800 test/hr.
- -Minimum sample volume: 2 ul
- -Daily maintenance: 15 min.
- -Short, Icteric, hemolyzed samples: detected
- -OTHERS.

EP 23

- **EP 23 :** Laboratory QC based on risk management - provides guidance based on risk management for laboratories develop quality control plans to the particular combination of measuring system, laboratory setting and clinical application of the tests

HAZARD IDENTIFICATION PHASE OF RISK MANAGEMENT



SELECTION AND EVALUATION A METHOD

- SELECTION A METHOD OR ANALYZER:
- EVIDENCE BASED MEDICAL LAB
- a-IFCC , AACC, EFCC, PUBMED .....
- b-EXTERNAL QC OR PEER GROUP PROGRAM

EVALUATION OF A METHOD

1-SD , CV, ALLOWABLE TOTAL ERRORS.

2-LINEARITY VRIFICATION.

3-CALIBRATION AND CAL. VERFICATION.

4-DETECTION LIMIT (3 TYPES).

5-REFRENCE RANGE.

6-SELECTION NO.OF QC , QC PROGRAM BY USING POWER FUNCTION GRAPH AND PROBABILITY OF FALSE REJCTION(Pfr) AND ERROR DETECTION(Ped).

EVALUATION A METHOD (2)

- 7-OPERATIONAL PROCESS SPICIFICATION OPSpecs.
- 8- CONFIRM EVALUTION BY USING - 6-SIGMA.
- 9- DELTA CHECK.
- 10- REFERENCE CHANGE VALUE (RCV)
- 11- Anion Gap

RISK MANAEMENT

LIFE CYCLE RISK MANAGEMENT PROCESS