QUALITY CONTROL BASED ON RISK MANAGEMENT

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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, EVALUATING ,CONTROLING AND MONITORING RISK (ISO 14971)**

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

CLIA 88…1992

CLINICAL LABORATORY IMPROVEMENT AMENDMENT

EQUIVALENT QUALITY CONTROL(EQC) 2003

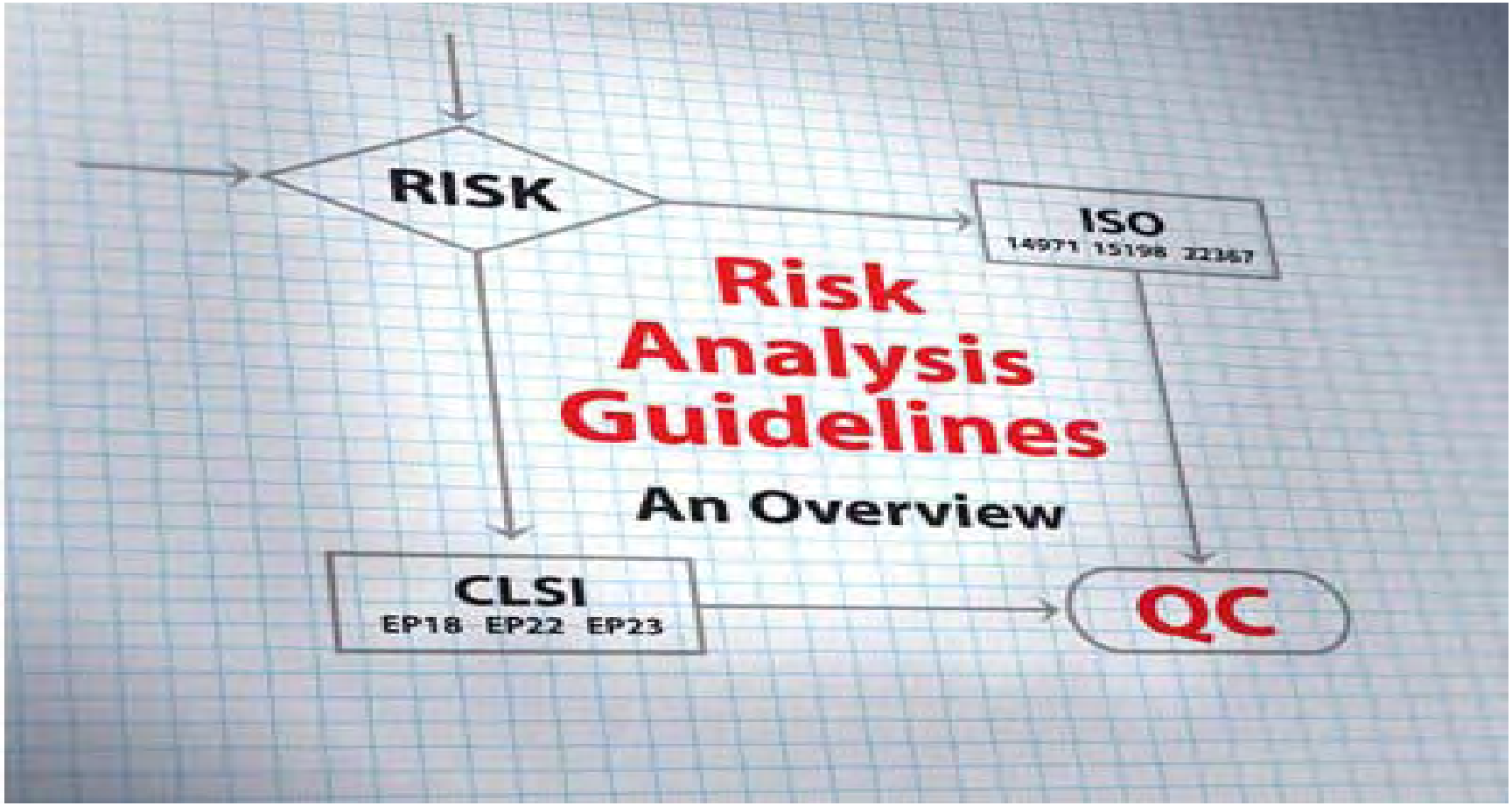
CLINICAL AND LABORATORY STANDARD INSTITUDE(CLSI)

CENTER OF MEDICARE AND MEDICADE SERVICES (CMS)

IN 2005 CMS COLABORATED WITH CLSI AND PROFESSIONAL ORGANIZATIONS ,LABORATORIES, INDUSTRIES AND OTHERS

TO SOLICIT NEW IDEAS FOR QC FOR THE FUTURE

CLSI AND ISO


RISK
ISO
14971 15198 22367
Risk
Analysis
Guidelines
An Overview
CLSI
EP18 EP22 EP23
QC

TOW MAJOR CONCLUSIONS

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 PROTHOCOL

EP 18: RISK MANAGEMET TECHNIQUES TO IDENTIFY AND CONTROL LABORATORY ERROR SOURCES

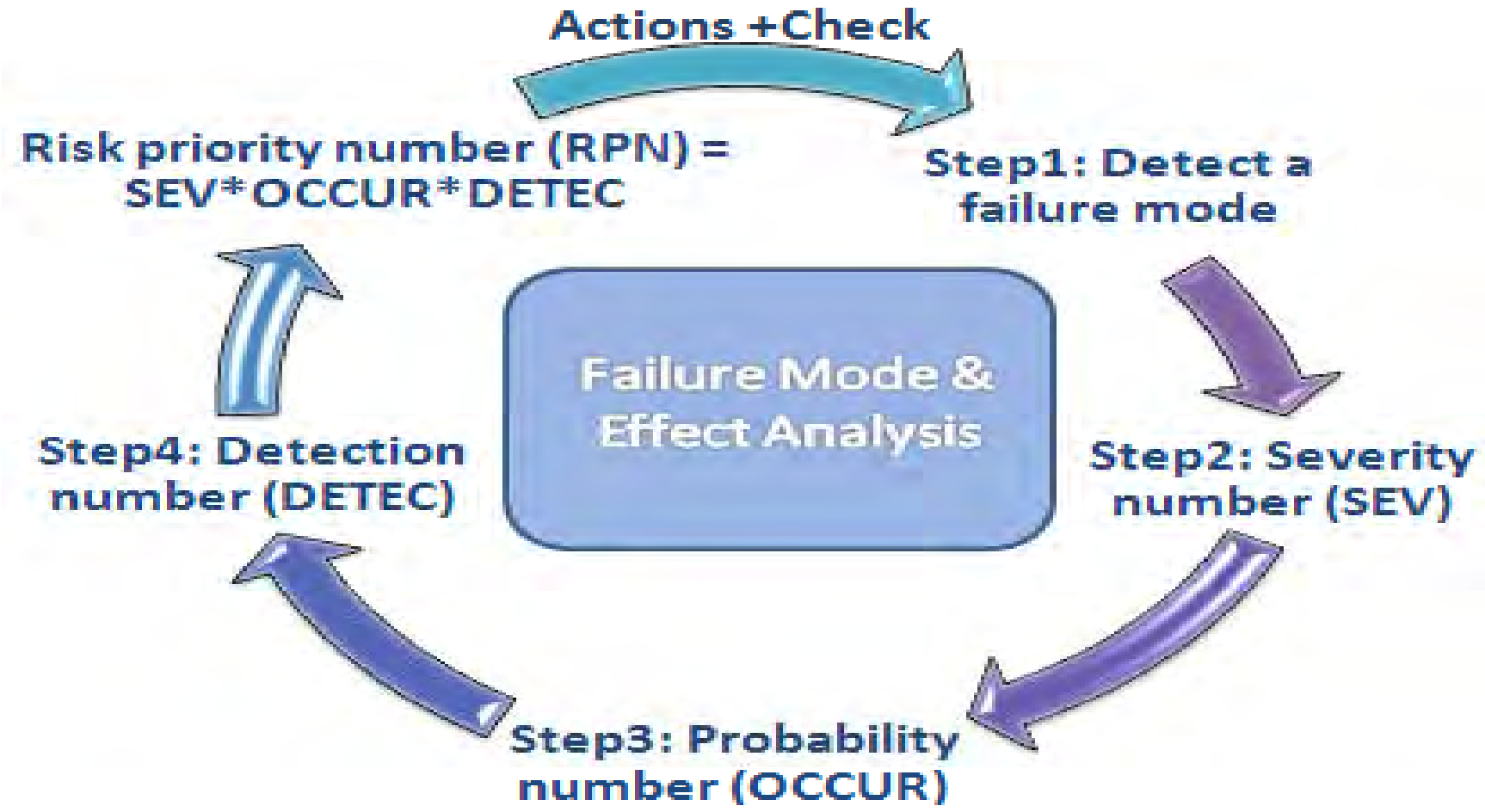
EP 22: PRESENTATION OF MANUFACTURER'S RISK MITIGATION FOR USERS OF IN VITRO DIAGNOSTIC DEVICES.

PE 23: LABORATORY QUALITY CONTROL BASED ON RISK MANAGEMENT.

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 CYCLE


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

GENERIC RANKING FOR RISK ASSESSMENT

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

RPN CALCULATION

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

- **O**ccurrence **S**everity **D**etection

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)

- Inadequate sample introduction
- Stop the device if the results of QC is out
- Barcode reading errors
- Test panel reading errors
- Device has integrated quality checks as intra QC system
- Has program to calculate RCV and K values

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

RISK MANAEMENT