Building QCP & Assessing it

Najwa Adlan, CPHQ
Medical Laboratory supervisor, POCT
Department Of Pathology & Laboratory Medicine
King Faisal specialist Hospital & Research Center

Agenda

What is QCP

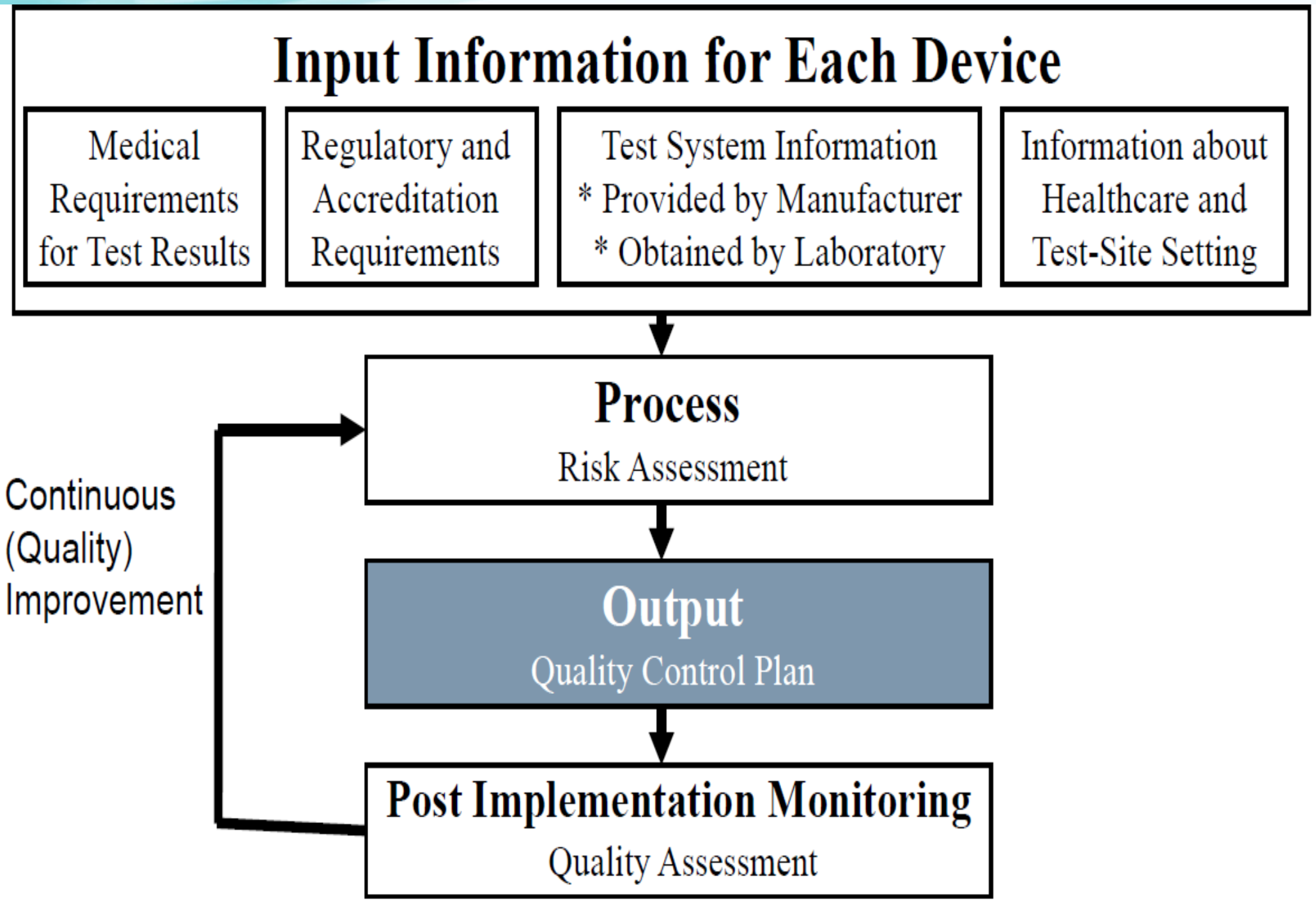
Information needed

Elements of the QCP

Quality Assessment

Quality Control Plan (QCP)

- Quality Control Plan (QCP) describes practices, procedures and resources needed by your laboratory to ensure the quality of a testing process.
- The QCP includes measures to assure the accuracy and reliability of test results, and that the quality of testing is adequate for patient care.
- It must provide an immediate detection of errors that can occur from any part of the testing
- Amount of QC is considered based on frequency and volume of patient testing



Adapted from: EP23-A Workbook. www.clsi.org; CMS memo, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf.pdf

Needed Information

- Hazard Identification Analyses
- Risk estimation Potential frequency of problem
- Risk evaluation Criticality of problem
- Risk Control Mitigations in place or to be implemented

Procedures to consider for QCP

- Liquid Quality control
- Equipment maintenance
- Electronic controls
- Internal controls
- Personnel training and competency assessment
- Equipment calibration
- Other specified quality control activities

Elements of the QCP

- Type of the QC
- Number of levels
- Frequency
- Criteria of acceptability

1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)

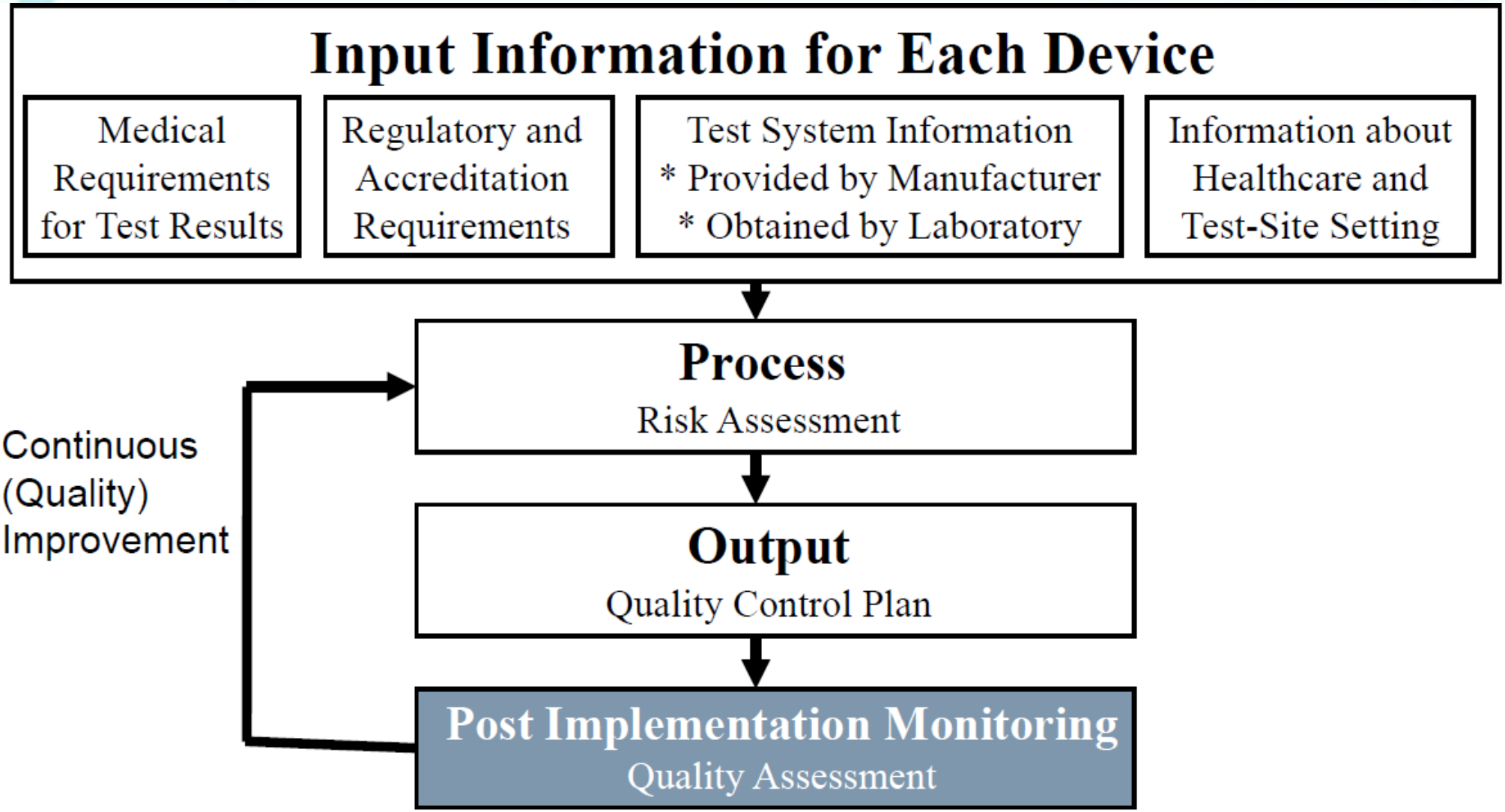
Developing the QCP

- Responsibility: Development & Implementation of QCP has to be delegated to a qualified individual by the medical director.
- The evidences of creating , implementing must be approved and signed by the lab direct

5 Items to be addressed in the final draft of the QCP

- **Provide** immediate detection of the error
- **Specify**: number, Type and frequency
- **Contain:** The evidences of creating , implementing must be approved and signed by the lab director
- **Require:** Frequency not less than Manufacture
- **Indicate:** Director Reviewable, signature and dated.

Quality Assessment



Adapted from: EP23-A Workbook. www.clsi.org; CMS memo, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf.pdf

What Information you need for QA

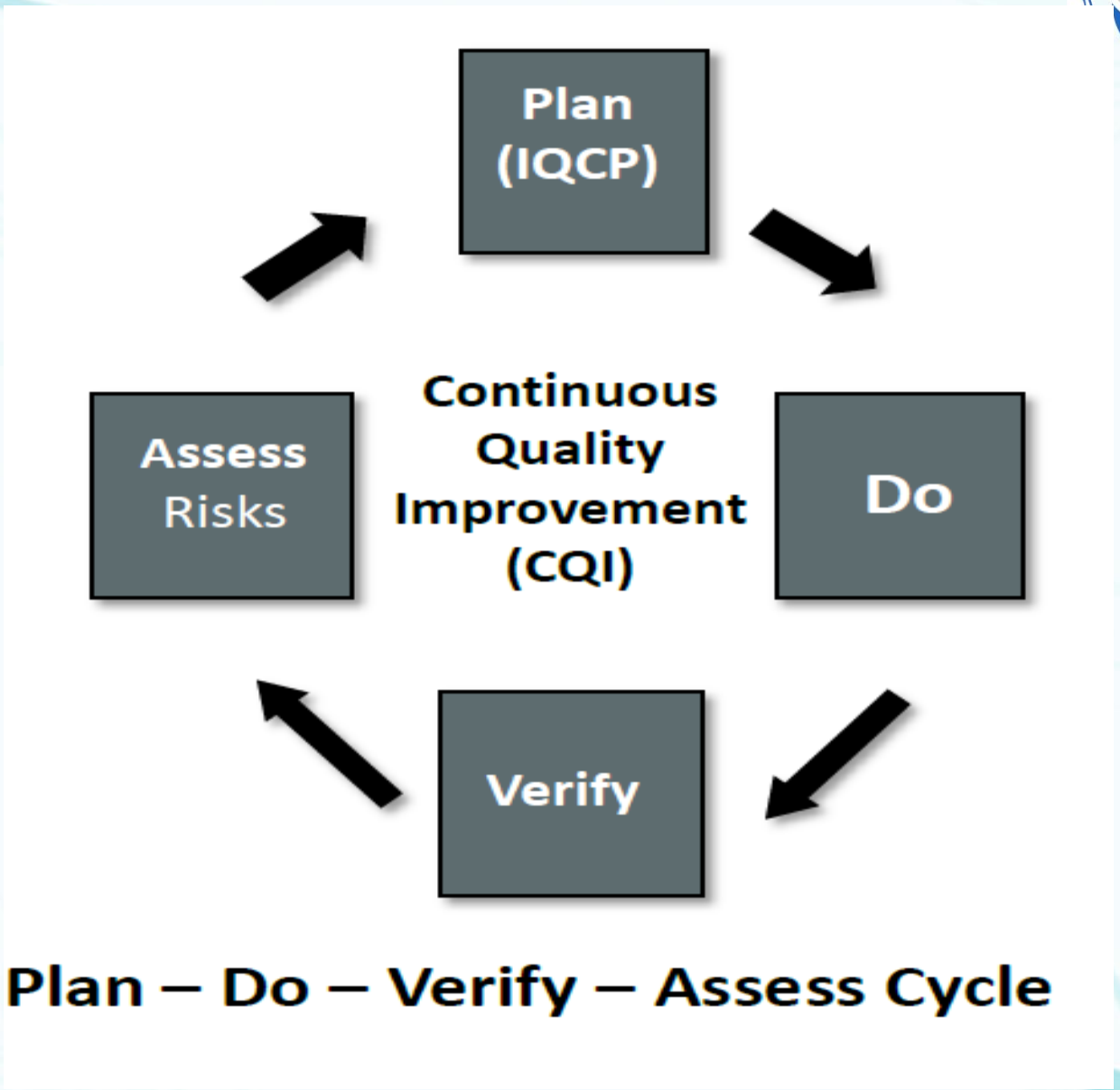
- All the data and reports form your QCP (QC records, PT, Calibration etc)
- Incidents and Complains
- Feedbacks

WHAT HAPPENS WHEN WE FAIL?

What if Failure Persist

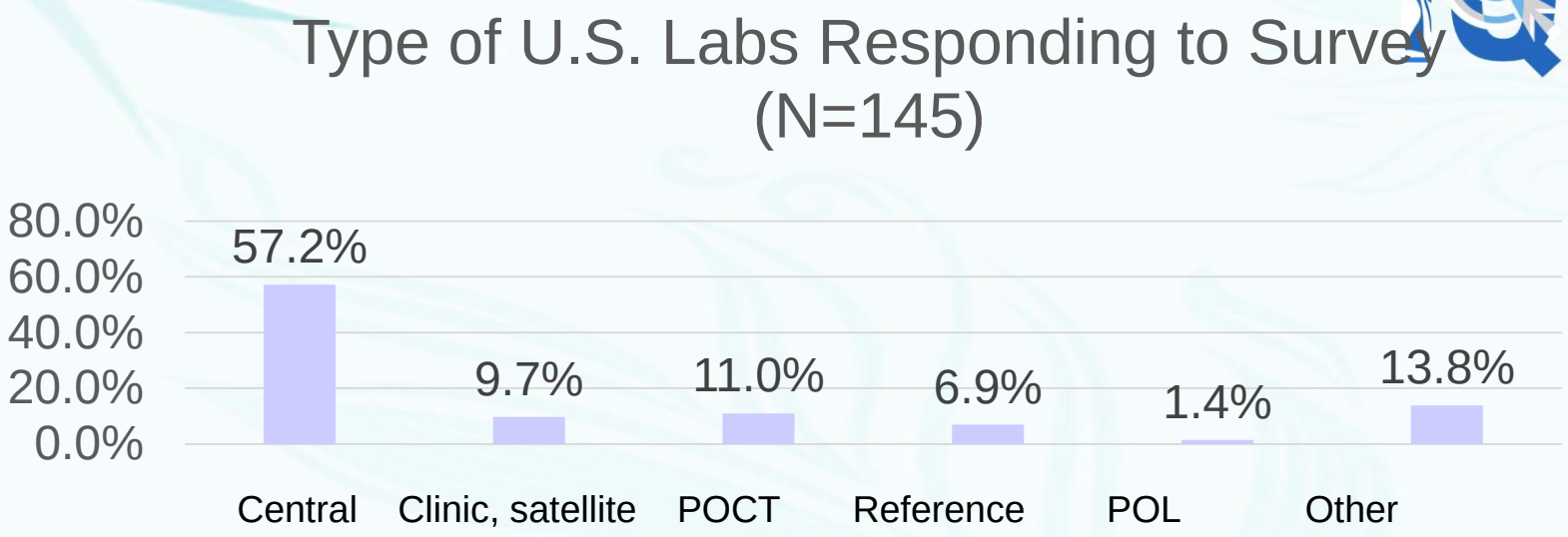
Quality Assessment (QA)

- Assure that the Quality control Plan is working according to defined lab policy
- Laboratory Personnel must establish a review system for the ongoing operation and monitor effectiveness.
- Corrective actions effectiveness
- Clear frequency
- Updates are documented approved and signed

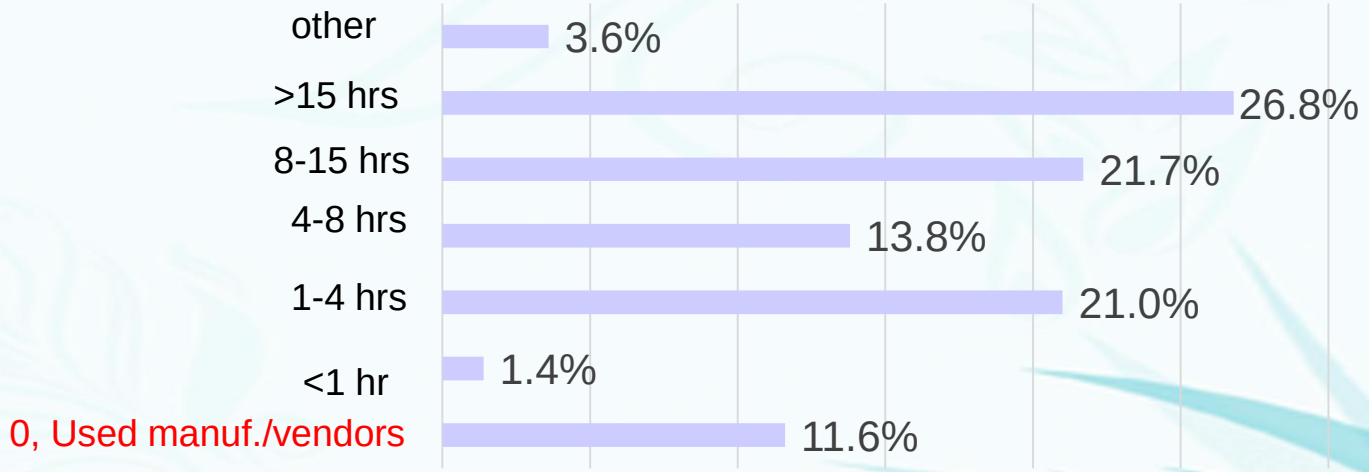


Plan – Do – Verify – Assess Cycle

2016 IQCP User Survey Findings

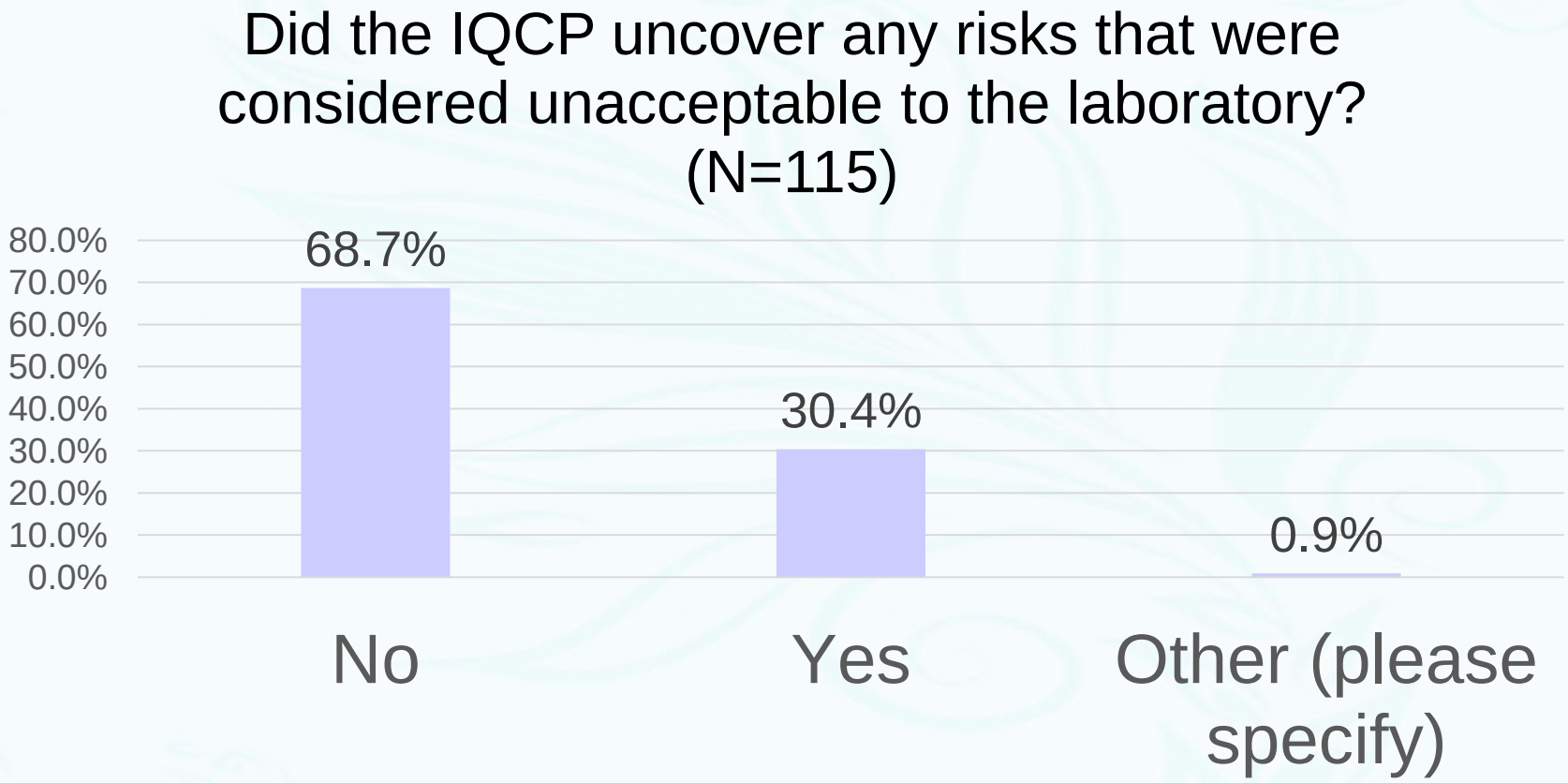


Time to generate (1) IQCP (N = 138)



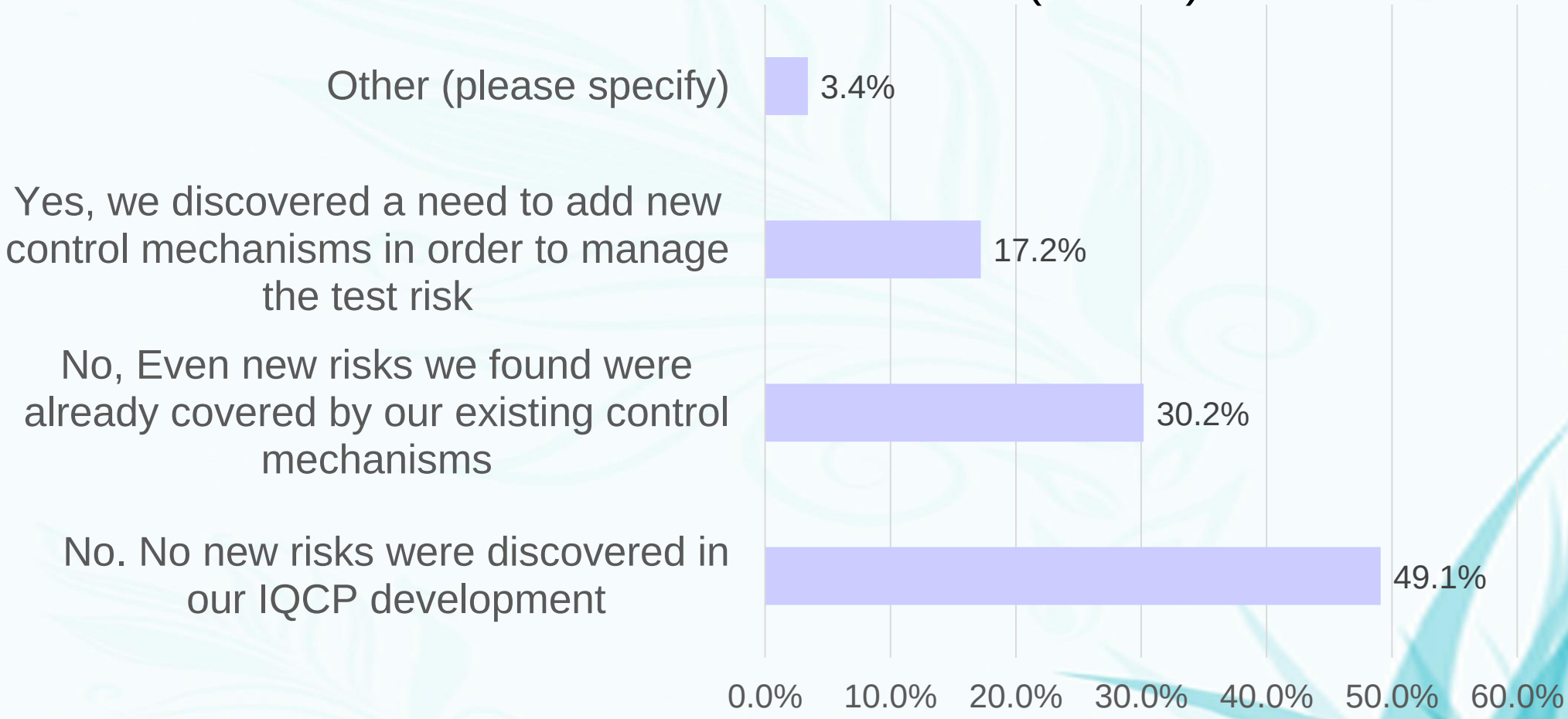
http://www.westgard.com/iqcp-user-survey.htm

2016 IQCP User Survey Findings



http://www.westgard.com/iqcp-user-survey.htm

Did the IQCP process require adding new control mechanisms to address risks (N=116)



For the tests where an IQCP was developed, how often is QC being run? (N=115)

Build A IQCP

Non-Waived
Have EQC
CLIA Requirement 3 times a day
Manufacture (with Each new lot number)