Don’t Roll the Dice on Medical Device Testing Programs:

The Importance of PMs

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Today's Speakers

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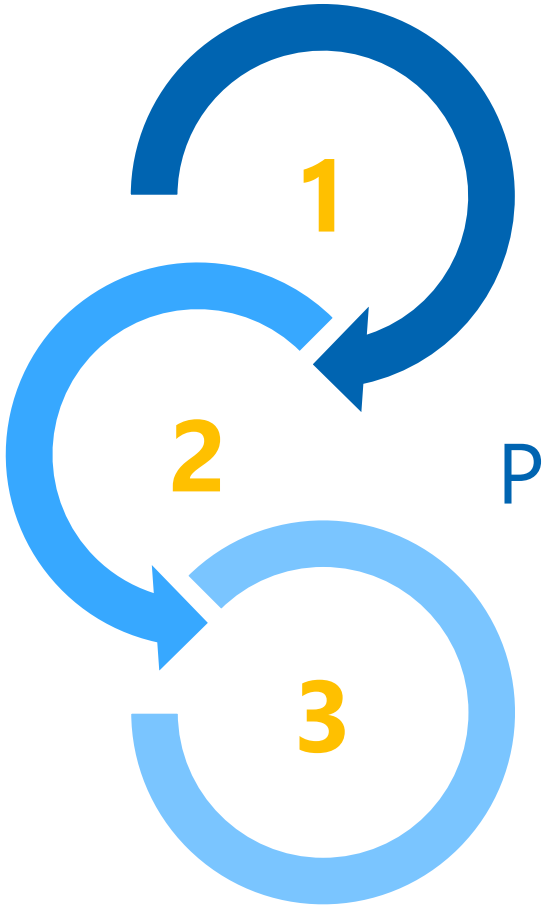
What we will cover today



1. Preventative Maintenance Pain Points
2. Procedure Management Best Practices
3. Workflow Automation Demonstration

Poll Question

Does your facility follow Preventative Maintenance (PMs) or Performance Inspection Procedures (PIPs)?

A Yes

B No

C I don’t know

What is a PIP?

- What is the difference between a Performance Inspection Procedure and Preventative Maintenance?
- When is each appropriate?
- What can your results from a PIP be used for?

Poll Question

Does your organization have clear, up-to-date preventative maintenance policies in place?

A Yes

B No

C Maybe

Challenges faced by biomed techs today

Preventative maintenance requirements

- Follow current up to date procedures
- Complete every step on every work order
- Capturing Data Verse Pass/Fail
- Record Accurate Results in a timely fashion,
- File results in a way they can be EASILY retrieved during an audit or for analysis
- Recorded calibration status of testing devices

Poll Question

Where do you get your test procedures?

A. OEM Service Manual

B. Hospital-specific checkout procedures

C. Online Forum

D. CMMS

E. 3rd Party Supplier (ECRI)

Procedure source

Get a quantitative assessment compared to:

- Manufacturer's specifications
- IEC, AAMI-ANSI, ECRI, or other global standards

Other Considerations:

- Alternative Equipment Maintenance (AEM) – who's verifying?
- Pass/Fail – is it enough?

Standardizing your test procedure results in tracking and predictive maintenance

Procedure version control

Version control should be managed

- Is taking the time worth the investment?
- How are alterations made and verified?
- Using workflow automation software enables quick and easy changes and standardization

Ensure the correct version is being used throughout your organization

Test frequency

What is your test frequency and how did you determine it?

- OEM
- AEM
- Use risk-based approach
- Use your organization's experience as well as the industry's experience with the medical device
- Repair only inventory

If the service manual is not available, inspection frequency must still be determined

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis, or direct monitoring	3	
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	5
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis, or loss of monitoring	3	
Device failure could result in severe injury to, or death of, patient or user	4	4
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device 1	1	
Common device failure modes are unpredictable or not very predictable 2	2	
While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	4
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	
A significant history of incidents exists	2	2
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	
There are requirements for testing independent of a numerical rating system	2	2
Total Score: 17		**17**
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		**2**

Sample risk assessment

Poll Question

When considering a change in your procedure process that may save you time, do you consider the potential risk involved?

A Yes

B No

C Maybe

Creating a new procedure

Determine maintenance status, PM, PIP, Repair Only

Build the procedure

- Team owns content control (notes, photos, etc.)

Review and Approve the procedure

Add procedure to the CMMS

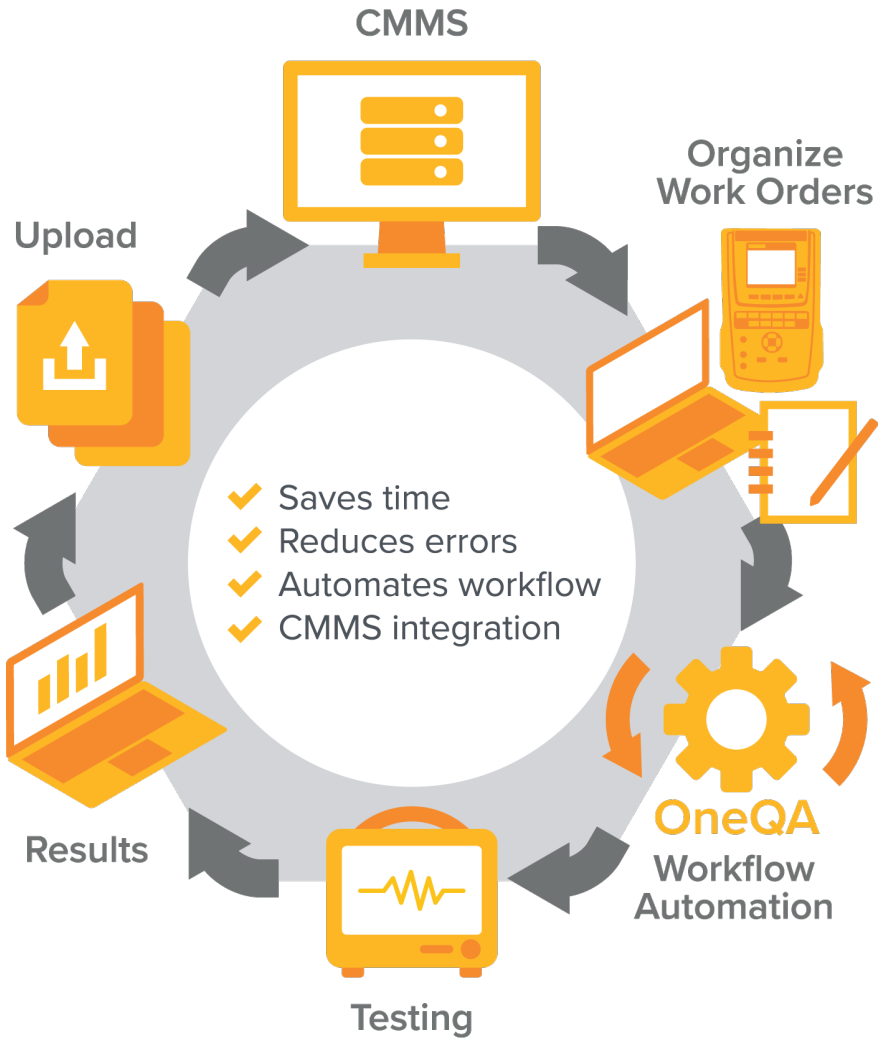
- Assign version control to the procedure

Every test should be able to be performed by Every Tech

Make procedure creation a team effort and Ensure It Gets Rolled Out Completely

Benefits of workflow automation

- Allows for multiple parameter settings at once
- Allows for multiple procedure creation and assignment by control number
- Redirects tech focus from how to PM to what are the readings and what do they mean/are they correct
- Allows for potentially valuable additional testing/data collection without adding additional workload to staff
- Allows for a more in-depth study/service at the same time of AEM
- Passing of knowledge
- Standardization



Value of workflow automation

Documentation becomes a powerful tool to help you do your job

You can focus on the medical device instead of . . .

- Searching for information
- Setting up procedures
- Taking notes
- Keeping your place

Improve quality

Use workflow automation to increase test accuracy

- Automatically have the correct procedure
- Have the correct tolerances for the correct test
- Improved recording accuracy
- No more missed steps

Save time

Use workflow automation to increase efficiency

- Automation is integrated into CMMS
- Procedures and work orders load automatically
- All associated documentation at your fingertips when you need it
- Test results captured in real-time
- Data is easily searchable

Live Workflow Automation

Demonstration

Q&A

Thank You!

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