

# Assessing Scheduled Support of Medical Equipment

*Presented by:*

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# Who is ECRI?

Nonprofit, international health services research agency promoting the highest standards of *safety*, *quality* and *cost effectiveness* in healthcare since 1969

- What do our resources include?
  - Membership-based access to Web resources, databases, research reports, guides, directories
  - Consultation services and special projects
- Around the world, who relies on ECRI's services?
  - Hospitals, health systems, health plans, and insurers
  - Government agencies, legal and regulatory professionals

# Alternative Presentation Titles . . .

- To PM or Not to PM . . .
- How Often is Enough?
- Recommendations ? For All Devices in All Facilities???
- Recommendations or Requirements?



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# How safe is “safe”?



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# In the Beginning . . .

- The electrical safety “scare”
- 1,500 US hospital electrocutions/year-1970
- Monthly inspections of defibrillators
- Quarterly inspections of monitors
- *Health Devices* Volume 1 Number 1 addresses the isolated power controversy
- The birth of clinical engineering



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# Initial Observations

Equipment management is essentially risk management

*Nothing* can be 100% safe or 100% reliable!

Inspect something today and it can fail tomorrow . . .



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# Initial Observations

Technology has become more reliable ?

- Better designed and frequently double insulated
- Devices have self diagnostics and error/event logs
- Significant failures rarely identified during inspections
- The need for preventive maintenance is declining
- ECRI has no evidence of injury or death attributable to the lack of inspection or preventive maintenance



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# Initial Observations

- Many “PM” programs are outdated ? electrical safety and risk continue to be overemphasized
- Manufacturer recommendations have not changed
- Regulatory agencies continue to translate those recommendations into requirements



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# What is Scheduled Support?

- Inspection – verification of performance and safety
- Preventive maintenance – periodic procedures to minimize risk of failure and to ensure continued proper operation
- **Scheduled support** = inspection *and/or* preventive maintenance
- Relatively few devices require true preventive maintenance – “PM” should not be equated with inspection



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# Overview

- Is there value in performing periodic inspection?
- If so, do what and how often?
- How to determine, document and *sustain* the decision?
- Are manufacturer recommendations for preventive maintenance justified?



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# What reasons are given for performing periodic inspections?

- To reduce the risk of injury (to patients, staff, visitors)
- To reduce the risk of significant adverse impact on patient care (e.g., due to downtime)
- To comply with codes, standards, and regulations



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# What is Risk?

## *Risk*

“Combination of the probability of occurrence of harm and the severity of that harm.”

ANSI/AAMI/ISO 14971:2000



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# What is Risk?

## *Risk*

“the chance of something happening that will have an impact upon objectives. It is measured in terms of consequences *and likelihood.*”

AS/NZS 4360:1999



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# Assessing Equipment Risk

- High-risk devices
- Medium-risk devices
- Low-risk devices



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# High-risk devices

Life-support, key resuscitation, critical monitoring and other likely devices whose failure or misuse is *reasonably likely to seriously injure patients or staff*

- Ventilators
- Defibrillators
- Anesthesia units

# Medium-risk devices

Devices, including many diagnostic instruments, whose misuse, failure or absence (e.g. out of service with no replacement available) would have a significant impact on patient care, but *would not be likely to cause direct serious injury*

- Clinical laboratory equipment
- Ultrasound scanners
- Electrocardiographs



# Low-risk devices

Devices whose failure or misuse is *unlikely to result in serious consequences*

- Ophthalmoscopes
- Electronic thermometers
- Cast cutters

# Defining *versus* Predicting

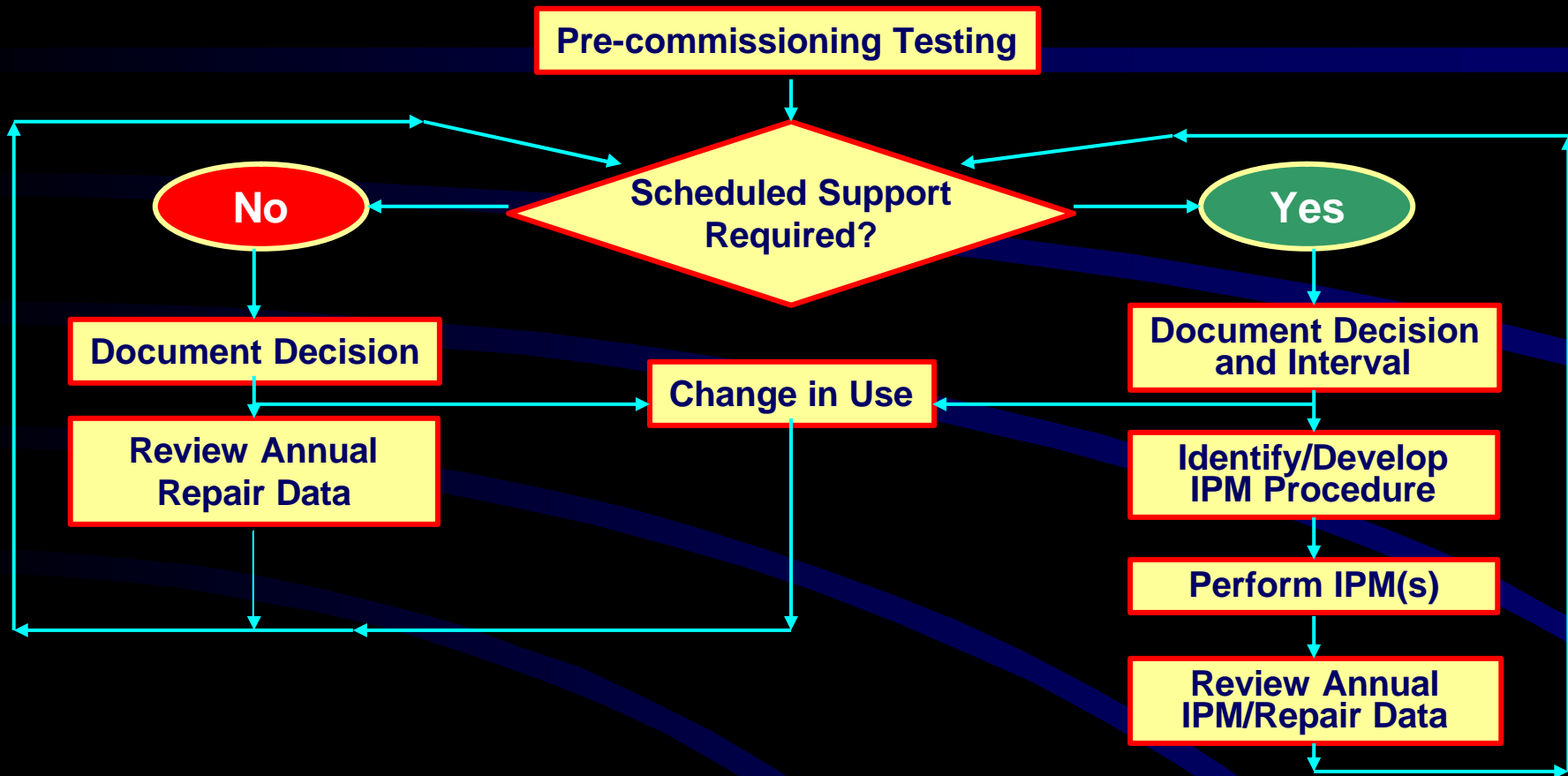
- Risk level can vary with device use
- Risk level definitions don't predict probability or nature of failure
- Risk level *should* be used to prioritize the completion of scheduled inspections

# Low-risk devices

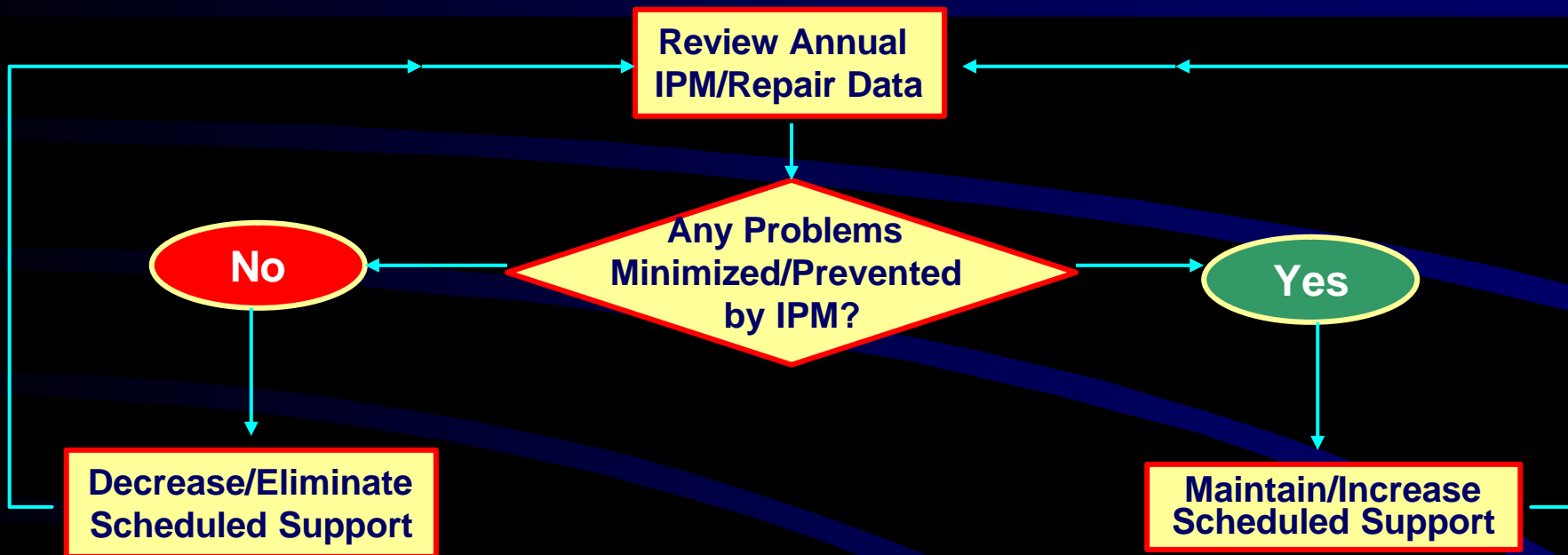
If failure of a device is *unlikely to result in serious consequences . . .*

then there is little or no value in inspecting many low risk devices

# Is Scheduled Support Required?



# Annual Review of IPM / Repair Data



# Assessing the Need for Inspection

Start with manufacturer recommendations but consider that they were developed:

- before reliability data was available
- for the device in every type of facility, anywhere over its expected life (i.e., a worst-case use scenario)

Also consider device's self-test capability



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# Scheduled Support Data

Review findings from inspections and repairs:

- were any failures not detected by users?
- could any failures have been prevented?
- were any failures due to user abuse?



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# Determining and Documenting Scheduled Support Decisions

- Need to switch emphasis from equipment risk to failure mode analysis (*not* FMEA)
- Need to identify differences in use/environment (per yesterday's legal speaker)
- Need to document these issues have been considered





# Numeric/Formulaic Assessment Tools

- Can these tools produce an objective determination?
- Can they produce consistent results?
- They typically emphasize failure effects rather than failure data

# Hypothetical Scheduled Support Assessment Scheme

Severity of Failure (1–4)

multiplied by

Likelihood of Occurrence (1–4) =

Risk Score



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# Hypothetical Scheduled Support Assessment Scheme

Risk Score  $\geq 8$ : Device is *likely* to need inspection

How can factoring 2 *subjective* decisions

- identify *worst case* failure
- estimate likelihood of such a failure

Produce an objective, definitive determination?



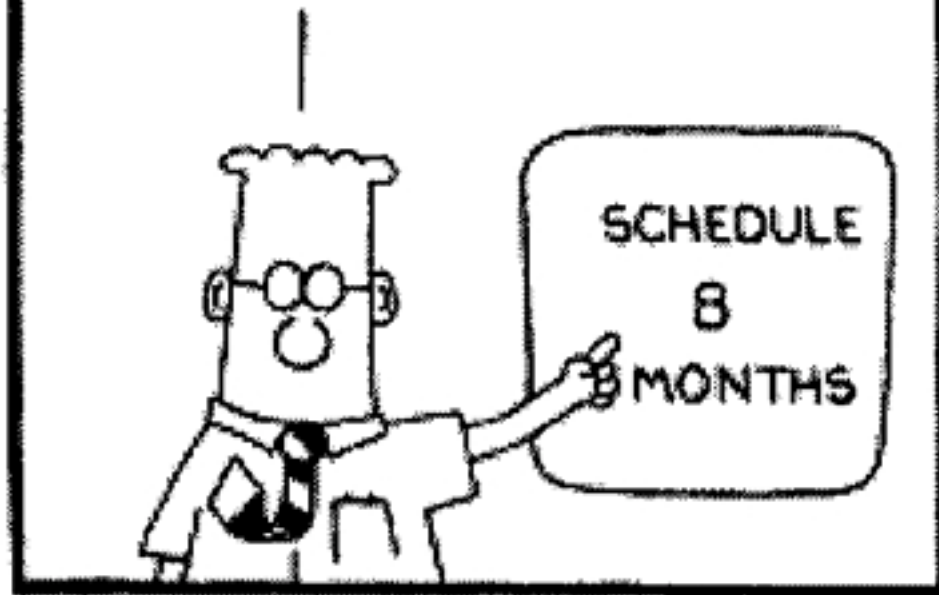
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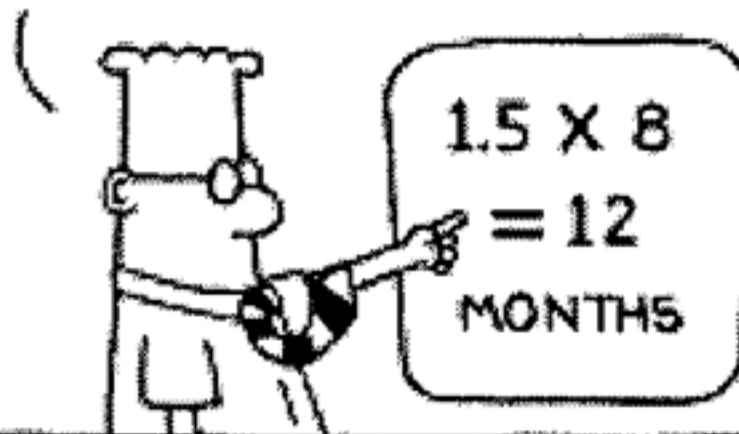


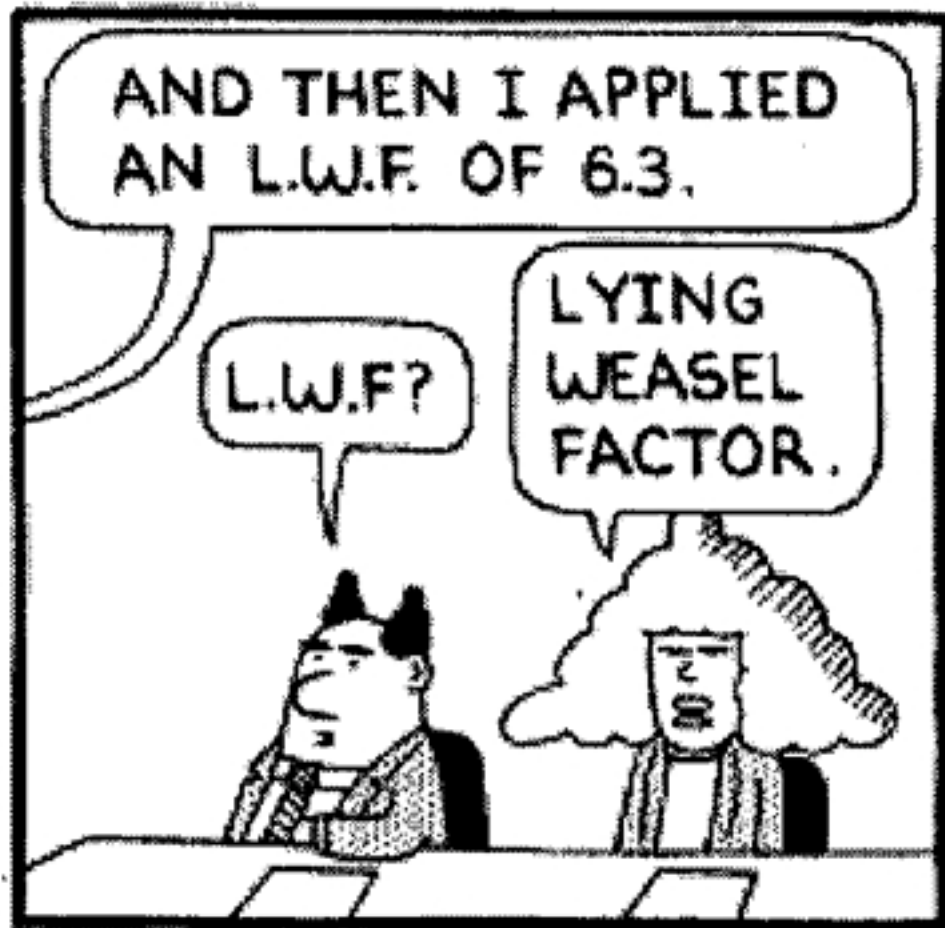
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IN A PERFECT WORLD  
THE PROJECT WOULD  
TAKE EIGHT MONTHS.



BUT BASED ON PAST  
PROJECTS IN THIS  
COMPANY, I APPLIED  
A 1.5 INCOMPETENCE  
MULTIPLIER.





# Sources of Information/Evidence

## Internal

- Maintenance management system – Failure Data!
- Use/environment considerations

## External

- Equipment manufacturers
- Official bodies (TGA, MHRA, FDA, IEC)
- Independent bodies (ECRI)
- Other equipment users



# ECRI's Scheduled Support Assessment Form

- Equipment history – failure data
- Use issues
  - portable device/battery power?
  - heavy or infrequent use?
- Routine user performance verification or pre-use check?





# Scheduled Support Alternatives to “Ritualistic PMs”

- User training
- Pre-use check/User performance verification
- “Walk through” inspections
- Minor, abbreviated inspection
- Inspect a sample of the devices
- Do nothing, but monitor repair data



# Inspecting Infusion Pumps: How Often Is Enough?

“Many hospitals have a large number of general-purpose infusion pumps in their inventory. Therefore, the frequency at which these facilities schedule routine inspection of these pumps can have a major impact on their workforce utilization and costs. . .

ECRI believes that, for most pumps in most facilities, inspection need not be scheduled for more than once a year, *and that in many cases even this frequency is unnecessary.*” (*Health Devices* 1998)



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# Case Study: Infusion Pumps

- They are high-risk devices
- They have mechanical parts and are used for many years
- A comparatively high number of adverse incidents are associated with pumps

# Why pumps may not require periodic testing!

- Flow accuracy does not significantly deteriorate over time (5-10 years)
- No reports of insidious or preventable failures
- When they do fail, they fail “safe” (stop and alarm rather than over- or under-infusing)
- Event logs show primary cause of adverse incidents is operator error
- Survey: 3% have stopped scheduling inspection

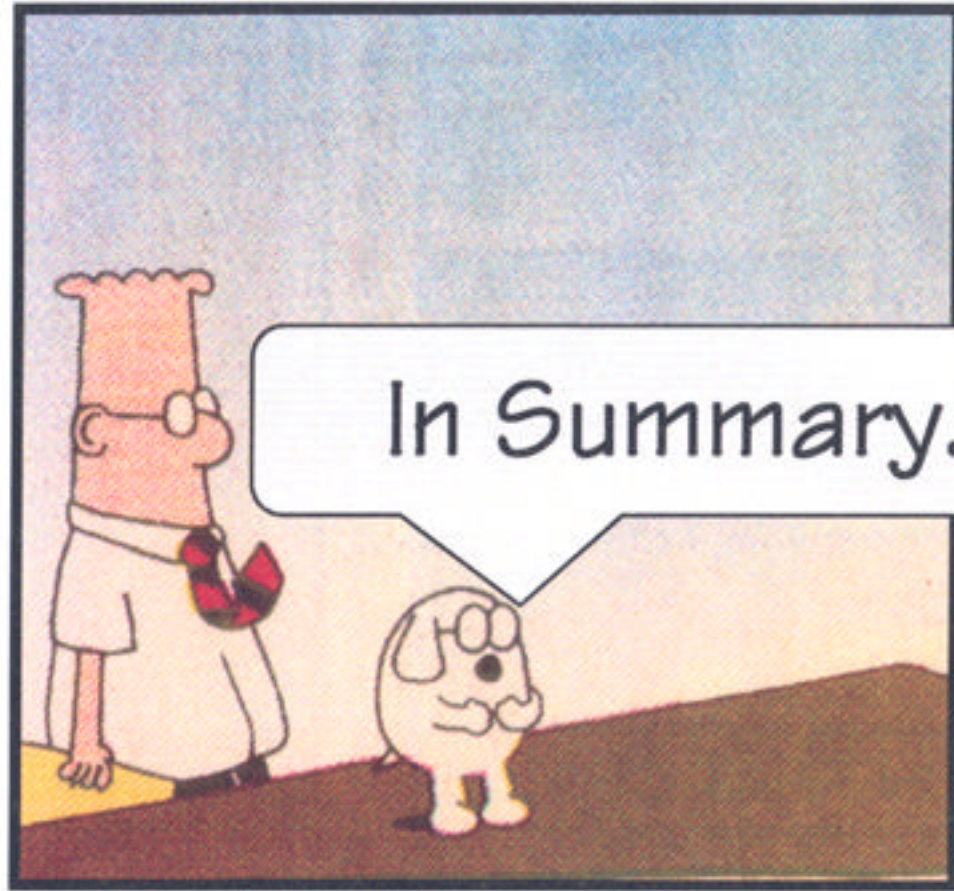


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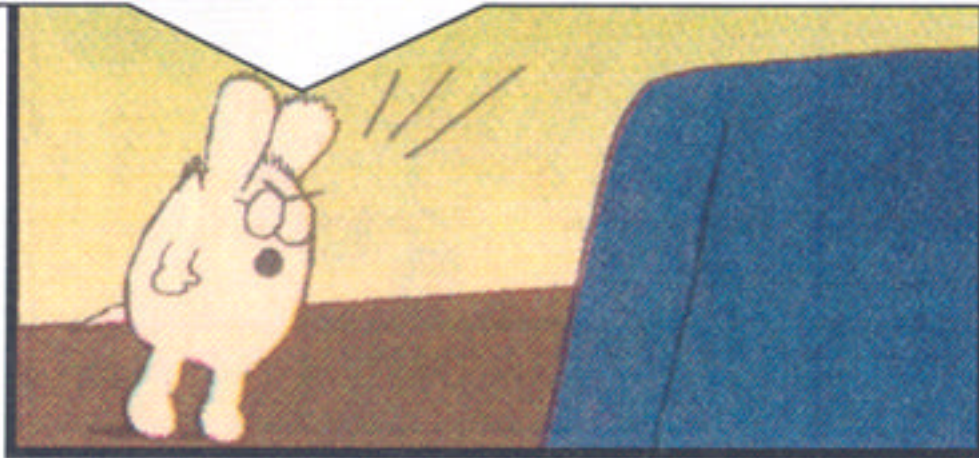


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In Summary...

NEVER Question  
an Engineer's Opinion,  
You Thundering Moron!



# In Summary

- Consider manufacturer recommendations but also equipment experience and use environment
- Determine appropriate inspection procedure and inspection interval
- Eliminate unnecessary inspections particularly on low-risk devices
- De-emphasize electrical safety testing

# In Summary

- Document your decisions (ESSA form)
- **Present conclusions to hospital's safety/quality committee for approval**
- Modify inspection intervals based on ongoing repair experience and changes in device use





# Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

- OK not to schedule IPM – but document decision
- OK for different schedules for same device based on differences in use
- **Hospitals may modify manufacturer protocols based on their experience (2005)**
- Support decisions with records that identify issues related to reliability, failures, and misuse



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# An Interesting Study

## Global Failure Rate: A Promising Medical Equipment Management Outcome Benchmark

Journal of Clinical Engineering July/September 2006

Binseng Wang et al. present failure data from 3 independent service organizations

Data is presented as *Failures/Device/Year*

Failure = # completed repair work orders



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# What is a Failure?

“The device doesn’t operate”

“Repair or calibration had to be performed”

“Shouldn’t include work orders for user abuse/error”

“Shouldn’t include cosmetic repairs”

# Failure: Proposed Definition

“The condition of not meeting intended function or safety requirements and not attributable to user abuse or user error.

A failure is corrected by repair and/or calibration.”

# Definition Challenges

It may be difficult to determine when user abuse or user error is the cause of a failure.

Similarly, environmental conditions (e.g., temperature, electrostatic discharge, line voltage spikes) beyond manufacturer specifications would ideally be excluded but are often not easily identified.



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# Mining Failure Data

Failure data will be extremely helpful in assessing the need for scheduled support (and also for comparing model reliability)

Every effort should be made to determine and track any ***failures that were/would not have been recognized by a clinician*** and also those that ***could have been prevented***



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# Strategies for Change

- Process needs to become driven by relevant failure data ? start by reviewing experience with pumps and monitors
- ECRI can facilitate a global equipment failure database
- If in doubt, perform inspections on a sample
- Stop referring to periodic inspections as "PMs", planned preventive maintenance, calibration

# Strategies for Change

- Lobby manufacturers to be more flexible with maintenance recommendations (. . .“or in accord with hospital experience”)
- Request a customized statement of scheduled support requirements in equipment RFPs
- Forward replies of excessive requirements to ECRI
- Educate governmental agencies and accreditation groups by **demonstrating relevant failure data**



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# Questions?

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