

Suggested BioMed Equipment Safety Inspection & Testing Strategy Worksheet - Rating system for risk-based inspections

Criteria: Choose one rating from each category	Weight Score	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	
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	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	
While common device failure modes are not very predictable, device history indicates that testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	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	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	
There are requirements for testing independent of a numerical rating system 2	2	
Total Score:		
A combined score of 13 or more is justification for semiannual testing.		
A combined score of 9-12 is justification for annual testing.		
A combined score of 8 or less is justification for less than annual testing (either bi-annual or no scheduled testing, depending on clinical application).		

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