

## Physical Plant: Biomedical/Preventive Maintenance

Name of Hospital: \_\_\_\_\_

Date: \_\_\_\_\_ Hospital Contact: \_\_\_\_\_

Always/  
Yes

Sometimes

Never/  
No

N/A

### General Information

- |                          |                          |                          |                          |  |
|--------------------------|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 1. Biomedical services are provided by employees of the hospital.  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2. If biomedical services are provided on a contract basis to the hospital, there is a copy of the contract on file in the department with a description of services. (The contract includes the type and frequency of equipment inspections and the type and frequency of reports.) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3. If the hospital's biomedical department provides services to other institutions, copies of the contracts and a description of services are available.   |

### Inspection System

- |                          |                          |                          |                          |  |
|--------------------------|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4. There is a list of biomedical equipment used in the hospital.   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5. There is a written maintenance schedule for all biomedical equipment.   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6. Testing is current according to the maintenance schedule.   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7. Permanent records are retained for testing the hospital equipment.  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | a. These records include maintenance performed by vendors (e.g., radiology and anesthesia equipment).  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8. Defibrillators are tested and maintained by the biomedical department according to manufacturer specifications.                               |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9. Biomedical department personnel participate in pre-purchase evaluations of equipment.   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10. Inspections are performed on all new equipment prior to use in the hospital.   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11. The hospital has a program for training staff on the use and maintenance of new equipment. (Suppliers or vendors may provide the education.) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. Inspection stickers are placed on each device noting when the piece of equipment was last tested and when it is due to be tested again.      |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 13. Staff members know how to determine if the equipment has been tested and when it is due to be tested.  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. Staff members know which devices have battery backup and how long the batteries will last in an emergency.                                   |

## Physical Plant: Biomedical/Preventive Maintenance

Always/ Yes	Sometimes	Never/ No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Summary reports are presented to the environment of care committee on user errors and recalls.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. If equipment is involved in a hospital-defined serious patient injury or death, it is inspected by an independent biomedical engineering firm and not returned to the manufacturer.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	a. Reports are submitted to the FDA according to the reporting provisions of the Safe Medical Devices Act of 1990 (SMDA).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17. The hospital has a policy that addresses patient-owned, loaner, or rental equipment.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	a. If patients are allowed to bring equipment to the hospital, the patient-owned or rental equipment is evaluated by the biomedical department prior to use.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18. Serial numbers of surgically implanted devices and patient information are reported to the manufacturer to comply with the tracking provisions of SMDA.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19. If the hospital sells or donates used biomedical equipment:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	a. Release forms are signed pertaining to the condition of the equipment.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	b. Equipment is sold “as is” without a warranty.

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*This interactive guide is not a standard of care. Any guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any action or treatment must be made by each healthcare practitioner in light of all circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.*