

- FMS.25.5 The hospital ensures that all maintenance works are conducted by qualified and trained staff.
- FMS.25.6 Equipment maintenance and repairs are documented to help in the decision making for replacement.
- FMS.25.7 Investigation procedures conform to manufacturer's instructions.
- FMS.25.8 There is an equipment recall system that is implemented.
- FMS.25.9 Each department has a back-up or alternative for each critical equipment to cover for prolonged downtime.
- FMS.25.10 Preventative Maintenance data are used for upgrading/replacing of equipment.
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**Standard Intent:**

To ensure that medical equipment are safe to use through regularly inspection, maintenance and testing, a medical equipment management program must be implemented. Such a program needs to include:

1. Availability of a valid medical equipment management plan.
2. Inventory of medical equipment's that covers at least (Equipment name, its manufacturer, model, serial number, location, organization number and maintenance history).
3. Availability of a system for medical equipment's alerts and recalls monitoring through SFDA and manufacturer notifications and reporting medical equipment failures in a death, serious injury or illness to SFDA.
4. Availability of necessary service and operation manual whether hardcopy or softcopy to refer to when needed.
5. Availability of calibrated necessary test and calibration equipment's.

Since medical equipment's failures are expected, the hospital needs to develop a risk-assessment based back up plan for failed medical equipment's through provision of a stand-by medical equipment or shifting to an equal medical intervention alternative.

The program needs to be run by qualified biomedical engineers through education, experience and training.

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