



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

FMS.05g.Policy on medical equipment related adverse events compliance and recalls

1. Policy Statement

Inodaya Hospital is committed to ensuring the safety, effectiveness, and reliability of all medical equipment used in patient care. The hospital shall establish and maintain a systematic process to identify, report, investigate, manage, and respond to medical equipment-related adverse events, ensure regulatory compliance, and promptly act upon manufacturer or regulatory recalls to prevent harm to patients, staff, and visitors.

2. Purpose

This policy aims to:

- Ensure timely identification and reporting of medical equipment-related adverse events
- Ensure compliance with regulatory, manufacturer, and accreditation requirements
- Establish a structured process for managing equipment recalls and safety alerts
- Prevent recurrence of equipment-related incidents
- Promote a culture of patient safety and continuous improvement

3. Scope

This policy applies to:

- All medical equipment and devices used in diagnosis, treatment, monitoring, and life support

Prepared by:	Verified by: 	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

- All hospital departments and clinical areas
- All staff involved in use, maintenance, procurement, and management of medical equipment
- Contracted service providers handling hospital equipment

4. Definitions

Medical Equipment / Medical Device:

Any instrument, apparatus, machine, implant, or related article used for diagnosis, prevention, monitoring, or treatment of disease or injury.

Adverse Event:

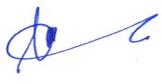
Any incident in which a medical device malfunction, failure, misuse, or inadequacy contributed or could have contributed to patient harm, staff injury, or near miss.

Near Miss:

An event involving medical equipment that did not result in harm but had the potential to cause harm.

Recall:

A corrective action taken by a manufacturer, supplier, or regulatory authority to remove, repair, replace, or modify a medical device due to safety, quality, or performance concerns.

Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

5. Responsibilities

- Hospital Management
- Biomedical Engineering Department
- Safety Officer / Quality Team
- Department Heads
- Users (Doctors, Nurses, Technicians)

6. Procedure: Medical Equipment–Related Adverse Events

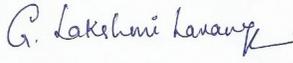
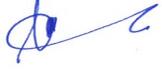
List of Medical Device Adverse Events (ADRs)

1. Device Malfunction–Related ADRs

- Device stops working during use
- Device fails to start or power on
- Unexpected shutdown of equipment
- Incorrect or unstable device performance
- Software malfunction or system crash
- Alarm failure or false alarms
- Display or monitor failure

2. Performance & Accuracy Issues

- Incorrect readings or measurements
- Delayed response or output
- Loss of calibration
- Inconsistent results
- Failure to maintain set parameters

Prepared by:	Verified by: 	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

3. Electrical & Mechanical Hazards

- Electric shock to patient or staff
- Short circuit or sparking
- Overheating of equipment
- Mechanical breakage or loose parts
- Moving parts causing injury

4. Patient Injury or Harm

- Burns from equipment
- Pressure injuries from devices
- Cuts or abrasions caused by device parts
- Allergic reactions to device materials
- Tissue damage due to device malfunction

5. Infection-Related ADRs

- Device-associated infections
- Improper sterilization or disinfection
- Contaminated reusable devices
- Failure of single-use device integrity

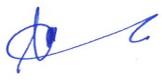
Procedure for Medical Device Adverse Event Handling

Medical Device Adverse Event Identified



Stop Using the Device Immediately



Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

Ensure Patient Safety and Provide Alternate Equipment



Disconnect and Isolate the Device Safely



Label Device as “DO NOT USE”



Inform Department Head



Inform Biomedical Engineering Department



Complete Incident / Adverse Event Report Form

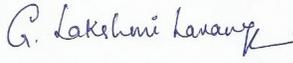
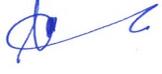


Submit Report to Quality / Safety Department



Preserve Device and Accessories (No Repair or Cleaning)



Prepared by: Ms.Chandrakala Biomedical Engineer	Verified by:  Mrs.G..Lakshmi Lavanya Accreditation Coordinator	Approved by:  Dr.G.Rammohan Managing Director
--	--	--



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

Biomedical Engineering Investigation



Review Maintenance Records and Usage History



Root Cause Analysis (if Serious / Repeated Event)



Identify Cause (Device / User / Maintenance / Environment)



Implement Corrective Actions (Repair / Replace / Withdraw)



Implement Preventive Actions (Training / SOP Update / PM Changes)



Manufacturer / Regulatory Reporting (If Required)



Recall Procedure Activated (If Applicable)



Prepared by: Ms.Chandrakala Biomedical Engineer	Verified by:  Mrs.G..Lakshmi Lavanya Accreditation Coordinator	Approved by:  Dr.G.Rammohan Managing Director
--	--	--



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

Documentation and Record Maintenance



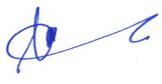
Staff Communication and Safety Learning



Periodic Review and Trend Analysis

Recall management in medical devices:

- Receipt of medical device recall notice from manufacturer, supplier, regulatory authority, or internal safety alert
- Verification of recall details including device name, model, batch or serial number, and reason for recall
- Identification of all affected devices using the hospital equipment inventory
- Classification of recall based on risk level (critical, moderate, or low risk)
- Immediate communication of recall information to concerned departments and users
- Prompt removal of affected devices from clinical use
- Clear labeling of recalled devices as “RECALLED – DO NOT USE”
- Safe isolation of recalled devices in a designated secure area

Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

- Arrangement of alternative equipment to ensure continuity of patient care
- Biomedical engineering evaluation of recalled devices
- Coordination with manufacturer or supplier for repair, modification, replacement, or return
- Implementation of manufacturer-recommended corrective actions
- Verification that recall actions have been completed effectively
- Documentation of affected devices, actions taken, and completion status
- Reporting of recall completion to hospital management and quality team
- Monitoring for any adverse events related to the recalled device
- Staff awareness and communication regarding recall outcomes
- Updating equipment inventory and maintenance records
- Retention of recall records as per hospital policy
- Periodic review of recall management effectiveness

MEDICAL DEVICE ADVERSE EVENT / ADR REPORTING FORM

Section A: Reporting Details

- Date of Reporting: _____
- Time of Reporting: _____
- Name of Reporter: _____
- Designation: _____
- Department / Unit: _____

Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by:
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

- Contact Number: _____

Section B: Patient Details

- Patient Name / Initials: _____
- UHID / MRN: _____
- Age: _____ Sex: Male Female Other
- Location (Ward / ICU / OT): _____

Section C: Medical Device Details

- Device Name: _____
- Manufacturer: _____
- Model Number: _____
- Serial / Batch / Lot Number: _____
- Type of Device: Implantable Non-implantable Disposable Reusable
- Date of Installation / First Use: _____
- Last Preventive Maintenance Date: _____

Section D: Description of Adverse Event

- Date and Time of Event: _____
- Type of Event:
 - Device Malfunction
 - Incorrect Output / Reading
 - Alarm Failure
 - Electrical / Mechanical Issue
 - Patient Injury
 - Near Miss
 - Other (Specify): _____
- Detailed Description of Event (What happened?):

Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by:
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

Section E: Outcome of the Event

- Patient Outcome:
 - No Harm
 - Temporary Harm
 - Serious Injury
 - Prolonged Hospitalization
 - Death
 - Not Applicable
- Was Emergency Intervention Required? Yes No

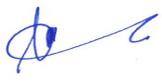
Section F: Immediate Actions Taken

- Device stopped from use: Yes No
- Device isolated and labeled "DO NOT USE": Yes No
- Alternative device provided: Yes No
- Biomedical Engineering informed: Yes No

Details of actions taken:

Section G: Preliminary Assessment

- Suspected Cause:
 - Device Failure
 - User Error

Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

FMS.05.g.Policy on medical equipment related adverse events compliance and recalls

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

- Maintenance Issue
- Environmental Factor
- Unknown
- Is this device under recall or safety alert? Yes No Not Known

Section H: Biomedical Engineering Review

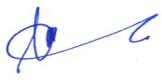
- Device inspected by: _____
- Date of Inspection: _____
- Findings:
- Action Taken:
 - Repaired
 - Replaced
 - Withdrawn from use
 - Sent to Manufacturer
 - No fault found

Section I: Reporting & Follow-up

- Manufacturer / Supplier Informed: Yes No
- Regulatory Reporting Done (if applicable): Yes No
- CAPA Initiated: Yes No

Section J: Signatures

- Reporter Signature & Date: _____
- Department Head Signature & Date: _____
- Biomedical Engineer Signature & Date: _____
- Quality / Safety Officer Signature & Date: _____

Prepared by:	Verified by: <i>G. Lakshmi Lavanya</i>	Approved by: 
Ms.Chandrakala	Mrs.G..Lakshmi Lavanya	Dr.G.Rammohan
Biomedical Engineer	Accreditation Coordinator	Managing Director



INODAYA Hospitals - Kakinada

Documentation code:

INH/FMS.Doc.No:15

**FMS.05.g.Policy on medical equipment related
adverse events compliance and recalls**

Prepared date:11/11/2025

Reference: FMS.5g. NABH Standards – 6th Edition

Issue Date:11/11/2025

Issue no: 01

Review No: 0

Review date: 11/11/2026

Prepared by:

Ms.Chandrakala

Biomedical Engineer

Verified by:

G. Lakshmi Lavanya

Mrs.G..Lakshmi Lavanya

Accreditation Coordinator

Approved by:

Dr.G.Rammohan

Managing Director