1.0 OBJECTIVE

1.1 To lay down a procedure to ensure the functioning of Medical Device Adverse Event Monitoring Centre(s) (MDMC) under Materiovigilance Programme of India (MvPI).

2.0 SCOPE

2.1 This document shall be applicable to all Medical Device Adverse Event Monitoring Centre(s) under Materiovigilance Programme of India.

3.0 PROCEDURE

3.1 The MDMCs shall be responsible for the continuous monitoring, systematic collection, and timely reporting of Medical Device Adverse Events (MDAEs).

3.2 MDMC's shall create a Materiovigilance Expert Committee (MEC) to analyze these reports.

3.3 The MEC should be constituted with the following members (including, but not limited to):

S.NO.	DESIGNATION	ROLE IN MEC
1	Head of Institution/ Medical Superintendent/ Dean/ Head of Department	Chairman
2	Coordinator/ Deputy Coordinator of MDMC	Member Secretary
3	Procurement/ Administration Officer	Member
4	Subject Experts from different clinical departments including Pharmacology	Member
5	Biomedical Engineer	Member
6	Technician (based on medical device in question)	Member
7	Nursing In Charge	Member
8	Clinical Pharmacist	Member

3.4 The MEC shall be approved by the Head of the Institution. The same shall be intimated to NCC-MvPI and it should be displayed on the official website of the institution.

3.5 The objectives, roles, and responsibilities of the members of the MEC shall be clearly defined by MDMC, incorporating the basic roles and responsibilities assigned by NCC-MvPI as per Standard Operating Procedure – 'Roles and responsibilities of technical staff at MDMC-NCC', with the option to include additional responsibilities as determined by the organization.

3.6 A decision taken by the MEC shall be considered final if it is approved by the 2/3rd of the committee members.

3.7 The MEC shall convene at least once every month, at a time mutually convenient to all members, to deliberate on matters outlined in the SOP – 'Roles and responsibilities of technical staff at MDMC-NCC'.

3.8 The Coordinator and Deputy Coordinator of the MDMC, along with the members of the MEC, shall diligently carry out their respective roles and responsibilities in accordance with the guidelines outlined in the SOP – 'Roles and responsibilities of technical staff at MDMC-NCC'.

3.9 The MDMC shall organize basic and/ or advanced-level awareness programs on a monthly basis, either within the institute or in collaboration with nearby peripheral healthcare facilities and submit the report as per SOP – 'Conducting Training Programmes'.

3.10 The MDMC shall monitor, collect the Medical Device Adverse Events as per SOP – 'Collection of MDAE reports at MDMC' and report it through ADRMS within the specified timeline as per SOP – 'Capture and record the information in MDAE reporting form on ADRMS'.

4.0 SAFETY AND PRECAUTIONS

4.1 Do not use any SOP if it is not signed and issued by competent personnel or the authorized signatories.

4.2 Do not use adhesive tape or whitener on SOP.

4.3 Do not share the SOP information outside the organization.

5.0 REFERENCES

In-House

6.0 ABBREVIATIONS

ADRMS	:	Adverse Drug Reactions Monitoring System
IPC	:	Indian Pharmacopoeia Commission
MDAE	:	Medical Device Adverse Event
MDMC	:	Medical Device Adverse Event Monitoring Centre
MEC	:	Materiovigilance Expert Committee
MvPI	:	Materiovigilance Programme of India
NCC	:	National Coordination Centre
SOP	:	Standard Operating Procedure

7.0 ANNEXURE(s):

NA

REVISION LOG

Version	Description of Change	Release Date
00	New document for posting on IPC's website	21-JULY-2025