1.0 OBJECTIVE

1.1 To lay down a procedure for roles & responsibilities of technical staff at Medical Device Adverse Event Monitoring Centre (MDMC)/ National Coordination Centre (NCC).

2.0 SCOPE

2.1 This document shall be applicable for the technical staff at MDMC/ NCC under Materiovigilance Programme of India (MvPI).

3.0 PROCEDURE

3.1 **Roles and responsibilities of technical staff at NCC:**

3.1.1 Conducting quality review of Individual Case Safety Report (ICSR) and signal detection;

3.1.2 Preparing the MvPI Monthly Progress Report (MPR), annual reports of NCC-MvPI and submit it to IP commission;

3.1.3 Coordinating/ communicating with other government organizations & stakeholders to implement the programme throughout all over India;

3.1.4 Organizing induction trainings for internship trainees and newly enrolled MDMC centres in every 3 months;

3.1.5 Preparing the resource materials such as NCC-MvPI newsletters, guidance documents, e-media and other communications;

3.1.6 Guiding student trainees about MvPI and Medical Device Adverse Event (MDAE) reporting whenever assigned;

3.1.7 Other activities as assigned by the competent authority, from time to time.

3.2 **Role & Responsibilities of the MDMC Coordinator:**

3.2.1 Ensuring the active participation and capacity building of MDMC and assuring the logistics & infrastructural facilities for smooth functioning of the NCC-MvPI activities;

3.2.2 Ensuring awareness is being created to healthcare professionals and patients about medical device safety alerts and signals issued from NCC-MvPI to promote patient/ user safety;

3.2.3 Meeting commitments and responding to the requests from competent authorities/ NCC-MvPI for furnishing correct and complete information;

3.2.4 Ensuring timely and effective communication with NCC-MvPI;

3.2.5 Ensuring the quality and correctness of materiovigilance data submitted to the NCC-MvPI;

3.2.6 Ensuring formation of Materiovigilance Expert Committee (MEC) and conducting timely meetings as per SOP: Functioning of MDMC;

3.2.7 Maintaining the data related to the training/ CME/ awareness/ sensitization programmes on materiovigilance conducted at MDMC as per SOP- 'Conducting Training Programmes' and providing the same to the NCC- MvPI upon request for the MPR;

3.2.8 Continuous monitoring and guiding the Materiovigilance associates/ MvPI internship trainees (if appointed) to perform the assigned duties of NCC-MvPI;

3.2.9 Maintaining the confidentiality of the communications/ correspondence to and from NCC-MvPI such as Medical Device Adverse Event (MDAE) reports, safety alerts, etc.;

3.2.10 Establishing a mechanism to enable the traceability and follow-up of MDAE reports and causality assessment and to ensure that the reports are handled and stored properly so as to allow availability of the same for verification of the said information, whenever required by NCC-MvPI/ competent authorities.

3.3 **Role and responsibilities of the Deputy Coordinator:**

3.3.1 Assisting and supporting the Coordinator of the MDMC in all his assigned activities;

3.3.2 To work as Coordinator of the MDMC during the absence of the Coordinator and carry out all the duties and responsibilities of the Coordinator.

3.4 **Roles and responsibilities of Materiovigilance Associate at MDMC:**

3.4.1 Materiovigilance associate shall daily visit each department of the MDMC (like cardiology, surgery and radiology etc.) and Out Patient Department (OPD) of the MDMC for collection of MDAE reports;

3.4.2 Ensuring the completeness of reported cases by taking necessary follow-ups at the MDMC in response to any incomplete MDAE reports or queries raised by NCC-MvPI;

3.4.3 Analyzing the primary root cause(s) of the event or incident based on technical training provided time to time;

3.4.4 Creating awareness among the healthcare professionals/ patients about the importance of MvPI and the reasons why reporting adverse events related to medical devices are important or necessary;

3.4.5 Conducting MvPI sensitization/ awareness programs in hospitals/ medical colleges or institutions by circulating newsletters/ posters issued by the NCC-MvPI;

3.4.6 Conducting baseline study on medical devices based on global corrective action/ recalls/ safety alerts and submitting the same to the NCC-MvPI;

3.4.7 To submit weekly reports to the NCC-MvPI. In the absence of any adverse event reports, a valid justification must be provided to the NCC-MvPI;

3.4.8 Maintaining all relevant records and the steps taken to report an adverse event or problem with a medical device in hospital;

3.4.9 Arranging meetings to interact with staffs, doctors, nurses, medical device manufactures to sort out the problems regarding MDAE reporting & management, if any;

3.4.10 Guiding student trainees about MvPI and MDAE reporting whenever assigned by NCC-MvPI;

3.4.11 Other activities as assigned by the competent authority, from time to time.

3.5 Roles & Responsibilities of the Materiovigilance Expert Committee (MEC) at MDMC:

3.5.1 The committee shall be responsible for planning, implementing and monitoring of various activities of the Materiovigilance Programme of India (MvPI) in the MDMC;

3.5.2 Reviewing and analyzing adverse events to evaluate and assess MDAE reports to identify risks and trends;

3.5.3 Conducting root cause analysis of adverse events related to suspected medical device reported to NCC-MvPI, IPC in order to determine their causal relation to the device and identify any other potential contributing factors unrelated to the device;

3.5.4 Assessing and managing risks based on the adverse event analysis;

3.5.5 Recommending and tracking corrective and preventive actions for safety issues;

3.5.6 Contributing continuously in improving materiovigilance processes;

3.5.7 Analyzing post-market data to identify emerging risks;

3.5.8 Engaging with other external experts for complex safety assessments, if required;

3.5.9 Conducting regular reviews of product safety and recommend necessary actions.

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

CDSCO	:	Central Drug Standard Control Organization
ICSR	:	Individual Case Safety Report
IPC	:	Indian Pharmacopoeia Commission
MDAE	:	Medical Device Adverse Event
MDMC	:	Medical Device Adverse Event Monitoring Centre
MEC	:	Materiovigilance Expert Committee

MPR	:	Monthly Progress Report
MvA	:	Materiovigilance Associate
NA	:	Not Applicable
NCC	:	National Coordination Centre
OPD	:	Outpatient Department
QA	:	Quality Assurance
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