Functioning of Regional Training Centre under MvPI

1.0 OBJECTIVE

1.1 To lay down a procedure to ensure the functioning of Regional Training Centre (RTC) under National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI).

2.0 SCOPE

2.1 This document shall be applicable to NCC-MvPI and all RTCs under MvPI.

3.0 PROCEDURE

3.1 Based on the number of Medical Device Adverse Event Monitoring Centre(s) (MDMC) within a particular region, a RTC may be inducted for smooth functioning of MvPI activities. The consent of MDMC Coordinator/Deputy Coordinator will be required to accept the additional responsibility as RTC.

3.2 The proposed MDMC to be designated as RTC should be active in terms of Medical Device Adverse Event (MDAE) reporting (quality & quantity wise), conducting materiovigilance sensitization awareness programme and public outreach activities.

3.3 If the performance of RTC is not found satisfactory, the RTC status may be withdrawn and shifted to well performing MDMCs.

3.4 NCC-MvPI shall maintain the list of RTC as per Annexure I.

3.5 NCC-MvPI shall maintain the list of RTC & States/Union Territory (UT) under their purview as per Annexure II.

3.1 The RTC shall fulfill its responsibilities as MDMC as per Standard Operating Procedure (SOP) - Ensuring the functioning of MDMCs, and shall also provide training and technical support to MDMCs of their respective region (Available on www.ipc.gov.in).

3.2 The Coordinator/Deputy Coordinator and Materiovigilance Associate (MvA) at RTC shall fulfill their responsibilities as per SOP - Roles & Responsibilities of Technical Staff at MDMC/NCC (Available on www.ipc.gov.in).

3.6 RTC shall engage in the MvPI expansion activities and encourage institutions/hospitals to get enrolled under MvPI as new MDMC. RTC shall also assist NCC-MvPI for identifying and evaluating proposal for new MDMCs as and when required.

3.7 RTC shall ensure implementation of materiovigilance system at MDMCs in all states/UT under their purview.

3.8 RTC shall coordinate with Central Drugs Standard Control Organization (CDSCO)/ State Regulatory Authorities/IPC zonal offices for further support/assistance.

3.9 RTC shall organize periodic MDMC review meetings with Coordinator and MvA to review the performance of MDMCs under their jurisdiction (at least twice in a year), to improve functioning of MDMC and report shall be sent for information to NCC-MvPI.

3.10 RTC shall convene periodic interactive review meetings (preferably twice in a year or as and when required) with the poor or non-performing MDMCs to encourage them to report MDAE.

3.11 RTC shall develop promotional materials like pamphlets/poster/resource material/radio jingles/television promotions to sensitize consumer and Healthcare Professionals (HCPs) in regional language.

3.12 RTC shall conduct regular sensitization/awareness programmes for HCPs (doctors, nurses, pharmacists, medical & pharmacy students and others), consumers (patients, care-givers and general public) at MDMC or peripheral centres.

3.13 RTC shall organize regular community level consumer awareness programmes to sensitize general public about reporting of MDAE under MvPI.

3.3 RTC shall conduct at least one Continuing Medical Education (CME)/Advance Level Training (ALT) per year with prior approval from NCC-MvPI as per SOP - Conducting sensitization/Continuing Medical Education (CME)/Advanced Level Training (ALT) and extending financial support to MDMC/RTC under MvPI (Available on www.ipc.gov.in).

3.14 RTC shall coordinate with different public health programme officials of their respective region and ensure submission of suspected MDAEs for medical devices used under different public health programme.

3.15 If any personnel are interested to participate in the unplanned training of Materiovigilance they shall approach to the RTC of their respective region.

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

6.1	RTC	:	Regional Training Centre
6.2	IPC	:	Indian Pharmacopoeia Commission
6.3	SOP	:	Standard Operating Procedure
6.4	MvPI	:	Materiovigilance Programme of India
6.5	NCC	:	National Coordination Centre
6.6	MvA	:	Materiovigilance Associate
6.7	MDMC	:	Medical Device Adverse Event Monitoring Centre
6.8	MDAE	:	Medical Device Adverse Event
6.9	CDSCO	:	Central Drugs Standard Control Organization
6.10	HCP	:	Healthcare Professional
6.11	ALT	:	Advance Level Training
6.12	CME	:	Continuing Medical Education
6.13	UT	:	Union Territory

7.0 ANNEXURE(s)

7.1 Annexure I : List of Regional Training Centres

7.2 Annexure II : List of RTC & States/Union Territory (UT) under their purview

REVISION LOG

Version	Description of Change	Release Date
00	New document for posting on IPC's website	03-FEB-2026