



Ministry of Health & Family Welfare  
Government of India



IMPLEMENTING  
GUIDEBOOK OF  
QUALITY  
MANAGEMENT  
SYSTEM FOR AEFI  
SURVEILLANCE  
IN STATES AND  
DISTRICTS



NATIONAL AEFI SECRETARIAT  
IMMUNIZATION TECHNICAL SUPPORT UNIT, MoHFW  
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# ABBREVIATIONS

AEFI	Adverse Event Following Immunization
ANM	Auxiliary Nurse Midwife
CDSCO	Central Drugs Standard Control Organization
DIO	District Immunization Officer
DQAU	District Quality Assurance Unit
HMIS	Health Management Information system
ITSU	Immunization Technical Support Unit
ME	Measurable Elements
MO	Medical officer
MOHFW	Ministry of Health and Family Welfare
NHM	National Health Mission
NHSRC	National Health Systems Resource Centre
NRA	National Regulatory Authority
OB	Observation
PHC	Primary Health Centre
PI	Parents Interview
RR	Record Review
SEPIO	State Expanded Programme of Immunization Officer
SI	Staff Interview
SQAU	State Quality Assurance Unit
UIP	Universal Immunization Programme
WHO	World Health Organization

## SCOPE AND OBJECTIVES

The objective of implementing the QMS in states, districts and session sites is to improve the quality and efficiency of AEFI surveillance at all levels, keeping in mind the necessity to ensure immunization safety for all vaccine recipients. This document has been prepared to help the state and district immunization programme officers to initiate QMS processes rapidly in the state and districts to attain certification as per NQAS for AEFI surveillance processes. The objectives of the guidance document are as follows:

1. To orient state and district programme officers and quality experts on the NQAS for AEFI surveillance programme & familiarize them with quality improvement methodologies.
2. To provide stepwise guidance for planning and implementation of NQAS at state-level and in districts.

### How to use this implementing guidebook?

The implementing guidebook is divided into three parts:

1. Part one: Introduction to Quality Management System for AEFI Surveillance Program: This section will help the immunization programme manager to gain an overall understanding of the processes involved in the implementation of QMS for AEFI surveillance at all levels. This part should be read in conjunction with the NQAS for AEFI surveillance. It gives a glimpse of the various components of the NQAS. The manager is introduced to the checklists which can be used to understand the basic activities and processes with respect to AEFI surveillance and conduct assessments at various levels such as state, district and immunization session site. This sections also enlists the roles and responsibilities of different stakeholders at different levels.
2. Part two: Implementing Quality Assurance for AEFI Surveillance programme: This section lists the institutional framework for implementation at different levels. This part helps programme managers to anticipate the next steps and plan in advance for them, gives an idea as to where the programme is heading and to gather the resources needed to implement the activities. This section also links the manager to some useful tools to help in planning and implementation of the programme.
3. Part three: Annexures: This section contains the tools and templates to help in the planning and implementation process.

PART  
**ONE**

**INTRODUCTION TO QUALITY  
MANAGEMENT SYSTEM FOR AEFI  
SURVEILLANCE PROGRAMME**



# INTRODUCTION TO QUALITY MANAGEMENT SYSTEM FOR AEFI SURVEILLANCE PROGRAMME

## Introduction

One of the strategies recommended to improve AEFI surveillance in districts and states is to set up and implement a Quality Management System (QMS). Implementation of QMS in a surveillance programme will help to focus on improving efficiency, quality, and safety and assure standardization of its processes, transparency, role clarity and accountability at levels of implementation.

Under NHM, a quality improvement programme for services provided in public health facilities is being implemented since 2014. Under the ambit of quality, district and state quality assurance committees/units, trained quality improvement officers, state empanelled assessors exist in all states/UTs. The endeavour is duly supported by MOHFW and Quality Improvement Division of its technical agency National Health Systems Resource Centre (NHSRC), New Delhi.

WHO assessors of India's National Regulatory Authority (NRA) in 2012 had recommended the establishment and implementation of QMS for AEFI surveillance. Accordingly, NHSRC has supported the development of National Quality Assurance Standards for AEFI surveillance programme. As required by the NRA, the national AEFI secretariat achieved quality certification in 2016 and its implementation has shown incremental, rapid and sustainable improvement in national level AEFI surveillance processes. A repeat assessment of the NRA in 2017 recommended that the QMS should be implemented in all state and districts to further improve AEFI surveillance in the country.

QMS for AEFI surveillance was piloted in two districts each in two states with support from the AEFI Secretariat, ITSU and Quality Division, NHSRC, New Delhi. Other states will implement QMS in phased manner in the coming years.

The NQAS for AEFI Surveillance programme is a compendium of standards with assessment tools, as well as key steps to be followed for its implementation at various levels, that is, national, state, district and session site levels. For details refer to National Quality Assessment Standards for AEFI Surveillance.

Under NQAS-AEFI, all levels will be externally validated and certified by national level NQAS and AEFI assessors. Systematic step by step approach will be followed to achieve national certification of a state following internal, peer and external assessments of all levels.

### Key steps for implementation of NQAS in AEFI at all levels:

- ❖ Develop quality team and define team's roles and frequency of its meetings
- ❖ Familiarise team with standards and assessment criteria
- ❖ Understand scoring methodology
- ❖ Conduct internal assessment and identify gaps
- ❖ Prepare an action plan for closing the gaps in stipulated time period
- ❖ Undertake beneficiary satisfaction survey
- ❖ Set up quality policy and quality objectives
- ❖ Develop and implement standard operating procedures (SOP)
- ❖ Undertake peer assessment, identify gaps and close the gaps
- ❖ Apply for external/ national assessment
- ❖ After certification, sustain the QMS through regular assessments
- ❖ External assessment for the state, district and PHC level activities would be done every three years.



Internal assessments are carried out at all levels once in three months. Gaps will be identified during the internal assessment and an action plan for their closure will be developed and implemented. Based on the scores obtained during internal assessments, peer assessment will be conducted at all levels. Following peer assessments, if the districts and state fulfil the prescribed criteria, the state will be eligible to apply for external assessment and certification. Criteria for assessments and certification is available at Annexure 1 in Part 3.

For activities to close gaps and implement other activities related to QMS at state, district and PHC / session site levels, a dedicated budget head (FMR B.13.3.2) has been created.

## 1. Roles and Responsibilities

### A. Roles & responsibilities – national level

The implementation of QMS will be coordinated by the AEFI Secretariat / Immunization Division and supported by the QI Division, NHSRC.

- » The AEFI Secretariat will facilitate preparation of resource package for NQAS for AEFI Surveillance and coordinate with states & UTs for smooth roll out of the initiative.
- » The QI Division, NHSRC would coordinate external assessment and certification activities under this initiative, undertake documentation of assessments at different levels, practices for cross learning and provide necessary support for successful implementation of the programme.

### B. Roles and Responsibilities - state level

The State Immunization Officer will be in charge of implementing the Quality Management System for AEFI Surveillance. He will be responsible for coordinating with the SQU cell to harness their expertise and support for planning, budgeting and implementing the QMS. He will ensure that the district immunization officers also coordinate with the district QA cell to implement the QA processes. Key responsibilities include:

- » Issuing notification regarding inclusion of quality assurance members in AEFI committees at state and district levels
- » Measurement, reporting and review of the key performance indicators
- » Finalization of SOP templates at state level and translate into local language, if required
- » Instructions for developing quality policy and quality objectives and dissemination (SOPs, checklists, etc.) with clarity on roles of different stakeholders in implementation process of QMS for AEFI surveillance.
- » Organize one day state level orientation of state level officials, DIO and district QA officials.
- » Dissemination of SOPs, quality policy and quality objective to districts before starting first internal assessments.
- » Allocation of budget to districts for QMS activities (district level training, SOPs at district level and PHC/Session site, mentoring and monitoring visits to PHCs, etc.)
- » Tracking of internal assessments, and facilitating peer assessments of districts and sub district level.

### C. Roles and Responsibilities - district level

At the district level, Quality Assurance cell and DIO will be responsible for implementing QMS-AEFI activities including tracking progress of assessments in all PHCs/sessions sites and district and monitoring activities required to be undertaken at PHC/session site levels.



The roles and responsibilities of each member should be defined. Main functions of the team are given below–

- » Defining the road-map for quality assurance for the PHC/session site.
- » Defining quality policy and quality objectives and periodic monitoring on them
- » Dissemination and orientation for quality standards & Standard Operating Procedures (SOP) among the PHC staff.
- » Performing internal as well as subsequent periodic quality assessment against defined standards with support from district immunization officer and quality assurance team.
- » Providing hands on training and guidance to PHC staff for meeting quality standards
- » Facilitating change ideas and focus interventions for quality improvement.
- » Mentoring and monitoring visits by district quality team to all PHC/ Sub centres

DIO and quality team should meet every month to review the progress on quality assurance. Minutes of meeting and action points should be recorded and shared with the state.

#### **D. Roles and Responsibility - PHC/Session site level**

At the PHC level, medical officer in consultation with quality assurance cell and DIO will be responsible for the implementation of activities at the PHC level. The responsibilities of medical officer of PHC will include:

- » Familiarising himself with the checklist and details of the SOPs. He should ensure that the ANMs and their supervisors are aware of the contents of the checklist, its utility during assessments, the structure of the gap action plan and details of the SOPs.
- » Checking the processes described in the SOPs, modifying them if needed to align them with the actual/expected practice before sharing and implementing the SOPs.
- » Conducting the first internal assessment of all selected subcentre session sites.
- » After every assessment (internal and peer), preparing a gap analysis and action plan of PHC and sub centre session sites.
- » Sharing internal assessment checklists and gap action plans to the district.
- » Sharing the gap action plan and other related information with the sub centre ANM and support implementation of the action plan.

PART  
**TWO**

# IMPLEMENTING QUALITY MANAGEMENT SYSTEM FOR AEFI SURVEILLANCE PROGRAMME



# 1. SETTING UP INSTITUTIONAL FRAMEWORK

Sustaining quality assurance activity would require an institutional framework at all levels for planning, implementing and monitoring quality assurance related activities. AEFI committees and quality assurance committees have been constituted at state and district level across all states of India. Two quality experts from the existing state and district quality assurance committees/units will be nominated as members of AEFI committees to guide and support the implementation of QMS. The state quality assurance committee also should have representation of the SEPIO/state AEFI committee for informing the status of implementation of standards and monitoring the quality management system for AEFI surveillance programme in the state.

## 1.1 Activities related to Quality Management System for AEFI surveillance at state, district and PHC/session site levels

### A. State level activities

The Quality Management System for AEFI Surveillance in a state will be implemented in a phased manner with different activities at the state, district and PHC/session site levels.

- » Quality assurance nodal officer and State EPI officer at the state level will be responsible for customization of SOPs templates and translation into local language as per state decision and provide sample quality policy and quality objectives for PHC/session sites.
- » Financial norms for activities related to Quality Management System for state, district and PHCs/session sites to be booked under budget head FMR code B.13.3.2 is given in **Annexure 2 (Approved financial norms for state, district and PHC/session site)**
- » One day sensitization workshop at state level for orientation of NQAS for AEFI including state level officials and district level officials will be organized. **Annexure 8 (Training workshop agenda for state level)**
- » Quality assurance cell will be responsible for dissemination of SOPs, quality policy and quality objective to districts.
- » State EPI officer will be responsible for allocation of budget to districts for all activities such as district level trainings, SOPs at district level and PHC/Session site, mentoring visits to PHCs, etc.
- » Quality assurance cell will the State EPI officer and district QA cells will prepare a plan for quarterly internal assessments and guide the preparation of gap action plans of the district and PHCs. **Annexure 7 (Sample gap action plan)**
- » QA cell and State EPI officer will be responsible for tracking internal assessments and facilitating peer assessments of districts.
- » QA nodal officer will conduct internal assessment of state level processes using state level checklist. An indicative list of documents which should be available at state level and may be inspected during assessment is in **Annexure 3 (List of records related to AEFI surveillance at state level)**.



## B. District level activities

- » Quality Management System for AEFI Surveillance will be implemented in all the districts in the state. Eligibility criteria for implementation at district level and at PHC/Session site level is available in **Annexure 1 (Eligibility criteria)**. The budget will also be required accordingly for implementation of the quality management system processes in the district and PHCs, so budget head FMR code **B.13.3.2** has been created under UIP to carry out QMS activities.
- » Budget for implementation of activities related to the quality management system for AEFI surveillance in the district and PHCs, may be booked under FMR code **B.13.3.2 (Quality Management System for AEFI surveillance under UIP)**. **Annexure 2 (Approved financial norms for state, district and PHC/session site)**
- » District immunization officers will ensure members of the district quality assurance unit are included as members of the District AEFI committee and attend AEFI committee meetings at least once a quarter to give a status report on the progress of QMS-AEFI in the PHCs/sessions sites and district level.
- » District immunization officer and quality assurance cell members will conduct a sensitization workshop in batches in the district. Training participants will be ANMs, their supervisors and PHC medical officers, etc. **Annexure 9(Training Workshop at District level)**
- » Quality assurance cell will be responsible for customization and dissemination of SOPs, quality policy and quality objective for PHCs and also provide training to the medical officer for implementation.
- » District immunization officer and quality assurance cell will be responsible for undertake quarterly internal assessment, preparation of gap action plans and support in implementation of the plan at the PHCs and district level. **Annexure 7 (Gap action plan)**
- » District immunization officer and quality assurance persons will undertake mentoring and monitoring visits to PHCs for handhold and support in implementation of SOPs and conducting the first internal assessment.
- » District immunization officer and quality assurance experts will facilitate and coordinate peer assessments of PHCs. District quality assurance experts will ensure that documentation related to AEFI activities and QMS for AEFI surveillance are as per requirement during internal assessments of PHCs and district levels. **Annexure 4(Documents required for NQAS for AEFI surveillance district level)**

## C. PHC level activities-

- » PHC medical officer will be overall responsible to provide orientation of supervisors and ANMs for using checklist and SOPs.
- » PHC medical officer will define and implement quality objective and quality policy in the PHC and will be responsible for conducting the first internal assessment of all subcentres and preparation of gap action plans with the help of the quality assurance expert.
- » As per eligibility criteria, QMS will be implemented in all PHC and subcentres. PHC medical officer will select subcentre for internal assessment and gap action plan.
- » Gap action plan and gap closure can be prepared in consultation with the Quality assurance expert. **Annexure 7 (Gap action plan)**
- » Gaps can be closed by conducting quality improvement activities such as training, capacity building of staff, implementation of SOPs and mentoring during field visit.
- » Medical officer will support ANMs to improve internal assessment scores and share the scores with district.

- » Medical officer will ensure appropriate documentation and filing system related to AEFI surveillance in PHC and also at subcentres (SOPs, risk register, beneficiary satisfaction survey form, training need assessment of the staff, last assessment checklist, and gap action plan) and produce them during peer assessments of PHC and subcentres. **Annexure 5(Documents required for NQAS for AEFI surveillance PHC level)**
- » Medical officer is responsible to collect and analyse beneficiary satisfaction survey form from ANMs and provide feedback of each attribute to the ANM in the subsequent meeting. **Annexure 10(Beneficiary attendant Satisfaction format)**

#### D. ANM activities-

- » ANMs will be responsible for implementing quality management system in their subcentre.
- » ANM will display quality policy and quality objective at a prominent place in the subcentre and will have an updated version of standard operating procedure (SOPs) available at subcentre during internal, peer and external assessments.
- » ANM will maintain all records of previous internal and peer assessment checklists, beneficiary satisfaction survey analysis reports, gap action plans, closure reports, etc. and produce them during assessments. **Annexure 7 (Gap action plan)**
- » ANM will maintain a risk register at the subcentre and will take suitable action to eliminate any risk assessed and recorded by the medical officer. **Annexure 6(format of risk register)**
- » Each ANM has to fill beneficiary satisfaction survey from the
- » ANM will fill a minimum of 10 beneficiary satisfaction surveys each month and hand them over to the medical officer at the end of the month for assessment and feedback. **Annexure 10 (Beneficiary Satisfaction format)**

#### E. Health supervisor activities-

- » Health supervisors will help ANMs to understand various QMS processes including implementing SOPs, quality policy and quality objective, risk register, beneficiary satisfaction survey, etc.
- » Health supervisor will help ANMs to prepare for internal and peer assessments and assist in gap closure processes after every assessment.
- » Health supervisors will also support medical officers of PHCs to conduct assessments.
- » Supervisors will monitor and ensure ANMs conduct sessions as per schedule, follow all guidelines to ensure safe vaccinations and recording and reporting of AEFIs as per AEFI guidelines and provide on job supervision.
- » Health supervisors will also support ANMs in management of crisis in case of suspected serious /severe AEFIs, analyse AEFI reports/registers and follow up when no AEFIs are recorded or reported.

PART  
**THREE**

**ANNEXURES**



# ANNEXURE 1

## Eligibility criteria for internal, peer and external assessments at PHC/immunization site, district and state levels

Eligibility criteria for assessment-QMS for surveillance					
S. No.	PHC/ Immunization Site	Internal assessment; eligibility for peer assessment	Peer assessment	External Assessment	Responsibility of Medical Officer/ District Immunization Officer/District Quality Team
1	<ul style="list-style-type: none"> <li>QMS will be implemented in all PHCs/ sub centre immunization sites.</li> <li>All PHCs/ sub centre immunization sites should have SOPs in place.</li> <li>Quality policy and quality objective are displayed in all PHCs/ sub centre immunization sites.</li> <li>Internal assessment scores and gap action plan are available at all PHC/ sub centre immunization sites.</li> </ul>	<ul style="list-style-type: none"> <li>Internal assessment should be done quarterly by Medical Officer of the PHC.</li> <li>PHC becomes eligible for peer assessment if 50% of the sub centre immunization sites score at least 70% in internal assessment (using PHC/ immunization site checklist).</li> </ul>	<ul style="list-style-type: none"> <li>Peer assessment of a PHC/ immunization site will be conducted by Medical Officer of another PHC of the same district / District Quality Assurance Team / District Immunization Officer.</li> <li>Peer assessment will be done for the PHC and for those sub centre immunization sites under the PHC which have scored at least 70% scores each in internal assessment.</li> </ul>	NA*	<ul style="list-style-type: none"> <li>Medical officer will review checklists and gap action plans following quarterly internal assessment of sub centre immunization sites and PHC and ensure implementation of action plans for gap closure.</li> <li>Medical officer, PHC will share internal assessment scores and gap improvement plans of the PHC and the sub centre immunization sites to the District Immunization Officer for each quarter.</li> <li>Peer assessment scores of a PHC and sub centre immunization sites will be shared by the assessor with the DIO/DRCHO.</li> </ul>

\*External Assessment will be done for select PHCs, if the district-level activities score at least 70% and 50% of PHCs in the district scores at least 70% in peer assessment.

### Eligibility criteria for assessment-QMS for surveillance

S. No.	District Level Assessment	Internal assessment and eligibility for peer assessment	Peer assessment	External Assessment	Responsibility of District Immunization Officer/District Quality Team
2	<ul style="list-style-type: none"> <li>■ QMS will be implemented at district level, all PHCs and sub centre immunization sites</li> <li>■ District level SOPs are available and implemented</li> <li>■ Quality Policy and Quality Objectives are displayed at district level</li> <li>■ District gap action plan for closure and internal assessment scores are available at the district for district level, all PHCs and sub centre immunization sites.</li> </ul>	<ul style="list-style-type: none"> <li>■ DIO/District Quality Assessment Team will conduct internal assessment for district level using district level checklist.</li> <li>■ District will be eligible for peer assessment when district level achieves at least 70% score in internal assessment and 50% of district PHCs score at least 70% in internal assessment.</li> </ul>	<ul style="list-style-type: none"> <li>■ Peer assessment of the district will be done by District Immunization Officer/ District Quality Assurance Team of another district.</li> <li>■ Peer assessor will validate internal assessment scores of district level and also validate two PHCs and one sub centre immunization site in each of the two PHCs scoring at least 70%.</li> </ul>	<ul style="list-style-type: none"> <li>■ External Assessment will be done for the district, if the district scores at least 70% during peer assessment using district level checklist and 50% of PHCs score at least 70% during peer assessment.</li> <li>■ External assessment will be done by certified external assessors from NHSRC, MOHFW.</li> </ul>	<ul style="list-style-type: none"> <li>■ District Immunization Officer/District Quality Team will conduct internal assessment for district level and collate and verify scores of internal and peer assessment of PHCs.</li> <li>■ Plans for peer assessment of PHCs/sub centre immunization site will be prepared and implemented by District Immunization Officer.</li> <li>■ Peer assessor from another district will share assessment report to state with copy to District Immunization Officer of the assessed district.</li> </ul>



### Eligibility criteria for assessment-QMS for surveillance

S. No.	State Level Assessment	Internal assessment and eligibility for peer assessment	Peer assessment	External Assessment for certification	Responsibility of State Immunization Officer/State Quality Team
3	<ul style="list-style-type: none"> <li>QMS is implemented at the state level</li> <li>SOPs will be developed, available and implemented for state level</li> <li>Quality policy and quality objectives are displayed.</li> <li>Prepare and implement action plan for gap closure for state level</li> <li>Prepare a line list of internal assessment of districts to track progress.</li> </ul>	<ul style="list-style-type: none"> <li>State Immunization Officer or State Quality Assurance cell will conduct the internal assessment of state.</li> <li>If state achieves at least 70% score in internal assessment and 50% of the districts in the state will get 70% score in peer assessment then the State will be eligible for peer assessment.</li> </ul>	<ul style="list-style-type: none"> <li>Peer assessment of the state will be done by State Immunization Officer/ State Quality Assurance Team of another state/AEFI Secretariat.</li> </ul>	<ul style="list-style-type: none"> <li>State will be eligible for external assessment if the state level scores at least 70% during peer assessment and 50% districts of the state scores at least 70% scores during peer assessment.</li> <li>External assessment will be done by external assessors certified by NHSRC MOHFW.</li> </ul>	<ul style="list-style-type: none"> <li>State Immunization Officer/ State Quality Assurance cell will collate and verify district level internal and peer assessment scores of all districts.</li> <li>State Immunization Officer/ State Quality Assurance Cell will plan and coordinate peer assessment of a district by another district.</li> </ul>

## ANNEXURE 2

### Approved financial norms for state, district and PHC/session site activities related to Quality Management System for AEFI surveillance under UIP (FMR B 13.3.2)

Quality Management System for AEFI surveillance will be implemented at state level, district level and PHC/session site levels. The activities are mainly divided into trainings, assessments and mentoring visits.

- 1. Assessments:** There are three types of assessments at state, district and PHC/session site – internal assessment, peer assessment and external assessment.

#### 1.1 Internal assessments

S. No.	Activity	Unit cost	Frequency/Unit of Allocation	Details
1.1.1	Internal Assessment of PHC (including for all subcenter session sites under PHC)	Rs. 500/-	1 per PHC in each quarter	Incidental cost for stationary, photocopying, printing reports, meetings for preparation of action plans, etc.
1.1.2	Internal Assessment of District level	Rs. 2000/-	1 per District in each quarter	Incidental cost for stationary, photocopying, printing reports, meetings for preparation of action plans, etc.
1.1.3	Internal Assessment of State level	Rs. 2000/-	1 per State in each quarter	Incidental cost for stationary, photocopying, printing reports, meetings for preparation of action plans, etc.

- 1.2 Peer assessments** will be done by officers and staff at the same level but from different facilities. Budget is allocated for this assessment as follows:

- 1.2.1 Peer assessment of PHC/session site – Rs. 5000/- per PHC (including subcenter session sites).** Peer assessment of PHC/Immunization Site will be done once a year for each PHC by another medical officer/district immunization officer of the same district.

Peer assessment of PHC/session site				
S. No.	Activity and level of activity	Unit cost	Frequency	Details
1.2.1	Peer Assessment PHC	5000/-	Once a year when at least 50% of subcentre session sites under this PHC achieves 70% scores in internal assessments	1 per PHC

### 1.2.2 Peer assessment of district\* level

Peer assessment of district level						
S. No.	Activity/Head	Unit cost	Number of participants	Days	Frequency/ year	Amount
1	Travel cost for Assessor Team (to and fro)/ Hiring of vehicle for the team (Reimbursement as per actual)	2500	2	1*	1*	5000
2	Honorarium for assessors	2000	2	1*	1*	4000
3	Boarding and lodging (if required)	2000	2	1*	1*	4000
	<b>Sub total</b>					<b>13000</b>
4	Contingency	3000				3000
<b>Total (for one district activity)</b>						<b>16000</b>

\* Peer assessment of district level and one subcenter session site in two PHCs will be done by two persons once a year for all eligible districts by district immunization officer or district quality assurance member of another district of same state.

### 1.2.3 Peer assessment of state\* level

Peer assessment of state level					
S. No.	Activity/Head	Unit cost	Number of assessors	Days	Amount
1	Travel cost for assessor (Train fare/Economy class air fare/taxi hiring as per actuals upto maximum of Rs.20000/-)	20000	2		40000
2	Honorarium for peer assessors (including one day's honorarium for travel day)	4000 for government assessors and 7000 for non-government assessors	2	2	28000 max.
3	Boarding and lodging	4000	2	2	16000
4	Local transport	2000	1	2	4000
5	Contingency (photocopies, printouts, etc.)	3000			3000
<b>Total</b>					<b>91000</b>

\* Peer assessment of State level processes will be done once a year by SEPIO/state quality assurance team of another state or the AEFI Secretariat.

**1.3 External assessment of state** will be done by certified assessors nominated by QA Division, NHSRC. States have been divided into large, medium, small and very small based on population. In addition to state level assessment, assessment of two districts (including PHC/session sites in each district) will be done in large and medium states. In small and very small states/UTs, assessment will be done at state level and one district (including PHC/session sites in that district).

External assessment of state level					
S. No.	Activity/Head	Unit cost	Number of assessors	Days	Amount
1	Travel cost for external assessor (Train fare/Economy class air fare/taxi hiring as per actuals up to Rs.20000/-)	20000	2		40000
2	Honorarium for external assessors (including honorarium for travel days as applicable)	4000 for government assessors and 7000 for non-government assessors	2	*3 (small, very small states/ UTs - state and one district)  *5 (large, medium states – state and two districts)	70000 max.
3	Boarding and lodging	4000	2	5	40000 max.
4	Local transport	2000	2	5	20000 max.
5	Contingency	10000			10000
<b>Total</b>					<b>180000</b>

\* In small states (Himachal Pradesh, Uttarakhand, Jammu & Kashmir, Delhi, Punjab, Kerala, Haryana) and very small states (Lakshadweep, A&N Island, Daman & Diu, D&N Haveli, Sikkim, Mizoram, Chandigarh, Goa, Puducherry, Arunachal Pradesh, Nagaland, Manipur, Tripura, Meghalaya), external assessors will assess state level processes on first day. On the second day, one external assessor will assess district level processes while the second assessor will assess two PHC/session sites.

\* In large states (Tamil Nadu, Karnataka, Gujarat, West Bengal, Rajasthan, Maharashtra, Madhya Pradesh, Bihar, Uttar Pradesh) and medium states (Chhattisgarh, Telangana, Assam, Odisha, Jharkhand, Andhra Pradesh), external assessors will jointly assess the state level processes on the first day and then travel to two districts for assessment of district and PHC/session site assessment (one district a day). One extra day for travel between two districts in the state and one day more to travel to state head-quarters is budgeted.

**2 Training on QMS in AEFI under UIP** – One day trainings will be conducted at state level and at district level.

**2.1 State level training (up to 40 participants per batch)** on QMS in AEFI for two persons from each district (DIO, DQAU member) and select state participants (state programme officer (QA), SQUA members, AEFI committee members, etc.) -once a year.

**Training at state level on QMS in AEFI surveillance for DIOs, DQAU members, state programme officers (QA), select AEFI committee members, etc.**

S. No.	Activity/Head	Unit cost	Number of assessors	Amount
1	Hiring of venue	10000		10000
2	Travel cost of participants	2000	40	80000
3	DA to participants	500	40	20000
4	Refreshment and Lunch	250	40	10000
5	Per diem to faculty	1000	2	2000
6	Incidental expenses for training (Training material, job aids, photo copying, LCD projector etc.) (Rate x Days of training x no. of trainees)	250	40	10000
7	Local Mobility support	2000		2000
	Contingency	10000		10000
<b>Total</b>				<b>144000</b>

**2.2 District level training (upto 50 participants) on QMS in AEFI for PHC Medical Officers, PHNs, ANM, supervisors, etc. (once a year).**

**Training (one day) at district level on QMS in AEFI surveillance for DIOs, DQAU members, state programme officers (QA), select AEFI committee members, etc.**

S. No.	Activity/Head	Unit cost	Number of assessors	Amount
1	Honorarium to District Trainers	600	2	1200
2	Refreshment and Lunch	250	50	12500
3	Incidental expenses (photocopy, job aids, etc.)	300	50	15000
<b>Total</b>				<b>28700</b>

**3 Mentoring cum monitoring visits by DIO/DQAU to PHCs/session sites for assessments and verifications**

**Mentoring/monitoring visits by DQAU members to PHC/session sites**

S. No.	Activity/Head	Unit cost	Number of assessors	Amount
1	Travel support (to and fro)/ Hiring of vehicle (Reimbursement as per actual)	1000	60	60000
2	DA	200	60	12000
<b>Total</b>				<b>72000</b>

## ANNEXURE 3

### 1. Step by step approach for Quality Assurance

#### 1.1 Sensitisation workshop on QMS for AEFI surveillance for ANMs, supervisors and medical officers

Quality can be achieved through collective efforts only. Therefore, it is important to ensure district officials and PHC staff are aware about their roles and responsibilities and the various activities which need to be implemented for improving the quality of AEFI surveillance through QMS processes. A one- day workshop should be organized at the state level, to orient the DIO, and representative from the district quality assurance team on the QMS for AEFI surveillance. Similar trainings are to be organised in the districts to orient MOs, health supervisors and ANMs on quality assurance programme, quality standards, assessment process. Participants may be encouraged to share their perception of quality and how the quality can be improved.

#### 1.2 Setting Quality Policy and Quality Objectives-

A quality policy is a broad statement which describes how the surveillance system intends to improve the quality of its functions. It should be formulated in local language and displayed at critical places for better understanding.

Quality objectives are tangible short-term goals that a level intends to achieve. The objective should be in sync with the quality policy. These objectives should be SMART, i.e. specific, measurable, attainable, reviewable and time-bound. Quality objectives should be set for each level.

Quality policy needs to be framed by the process owner in consultation with the staff and other stakeholders. At the state and district levels, these would be members of the AEFI committees, medical colleges which are technical collaborating centres, representatives of professional bodies, etc.



An example of a quality policy for the state level can be as follows:

*"We are committed to provide quality services in surveillance programme of **Adverse Event Following Immunization** in .....(state) and also to monitor the quality and safety of vaccines and the vaccination processes by working with other stakeholders.*

*We shall endeavour to constantly and actively collaborate with all immunization stakeholders to build confidence of community in vaccines and immunization programme.*

*.....(state) is committed to early detection, management, reporting, investigation and feedback on AEFIs to various stakeholders of immunization programme.*

The quality objectives for AEFI surveillance programme at the state level can be to:

1. Promptly detect, report and respond to AEFIs in the state.
2. Identify unusually high rates of AEFI related to a specific vaccine lot/brand.
3. Promptly address programmatic errors through implementation of corrective measures.
4. Conduct investigations and causality assessments within the recommended timelines.

States should draw up their own quality policy and objectives in consultation with relevant stakeholders and also support districts and PHCs to draft quality policies and objectives.

### An example of quality policy for PHCs can be -

*"In addition to the primary level of curative and preventive health services, we shall strive to provide immunization services to the beneficiaries / clients in the PHC/ Sub centre area. Our efforts will be focussed on providing a pleasant environment for vaccine administration and ensure immunization safety by administering correct vaccine at the correct site and using the correct technique. We will ensure that the immunization services provided by us are equitable, affordable, accountable and responsive to the need of the people, within limitation of its resources."*

## 1.3 Implementation of Standard Operating Procedures-

Quality is about doing things right, for the first time & every time, thereafter. To achieve this objective, all core and quality control processes should be standardized. Standard Operating Procedures (SOPs) are a tried and tested tool for standardizing the processes in various setups. The AEFI surveillance programme, with multiple stakeholders and complex procedures requires standardization of processes and clear delineation of responsibilities. Standards Operating Procedures should be prepared and implemented by the district and state AEFI surveillance committees. Template SOPs for states, districts and PHC levels have been developed as follows:

Levels	SOPS
Immunization Sites	<ul style="list-style-type: none"> <li>» Notification &amp; Reporting</li> <li>» Investigation</li> <li>» Operational Management</li> <li>» Communication</li> <li>» Convergence</li> <li>» Quality Management System</li> </ul>
District Level	<ul style="list-style-type: none"> <li>» Notification &amp; Reporting</li> <li>» Investigation</li> <li>» Operational Management</li> <li>» Communication</li> <li>» Convergence</li> <li>» Monitoring &amp; Feedback</li> <li>» Quality Management System</li> </ul>
State Level	<ul style="list-style-type: none"> <li>» Notification &amp; Reporting</li> <li>» Investigation</li> <li>» Causality Assessment</li> <li>» Operational Management</li> <li>» Communication</li> <li>» Convergence</li> <li>» Monitoring &amp; Feedback</li> <li>» Quality Management System</li> </ul>

## 1.4 Action Planning & Prioritising

Based on the findings of assessments, the gaps can be identified & enumerated for each area of concern in each health facility. These gaps can be categorized on the basis of severity as follows:

1. High severity gap which affects the surveillance programme directly.
2. Moderate severity gap which affects the surveillance programme indirectly.
3. Low severity gap which does not affect the surveillance programme but could affect the quality of services and results in dissatisfaction.

Gaps can also be categorised as gaps which can be resolved at the same level or which can be resolved at the next higher level or requiring intervention from the state or national levels.

For all the enumerated gaps, a time bound action-plan should be prepared in consultation with process owners and Medical Officer in charges. It may be possible that all the gaps could not be traversed in 'one-go'. Hence prioritisation of gaps is important to best value of the investment.

## 1.5 Beneficiary Satisfaction Survey

The first and foremost definition of quality is to meet the user's expectations. The best way to know the user's perception about the quality of services is to conduct regular periodic beneficiary satisfaction surveys at the session site, asking users to rate the services as per their experience. These surveys should be done at least quarterly. The feedback should be analysed to know the services or attributes of services with which the users are not satisfied. Results of the feedback can be then discussed in quality team meeting to decide on actions to be taken for enhancing beneficiary satisfaction.

## 1.6 Periodic assessments & improvements

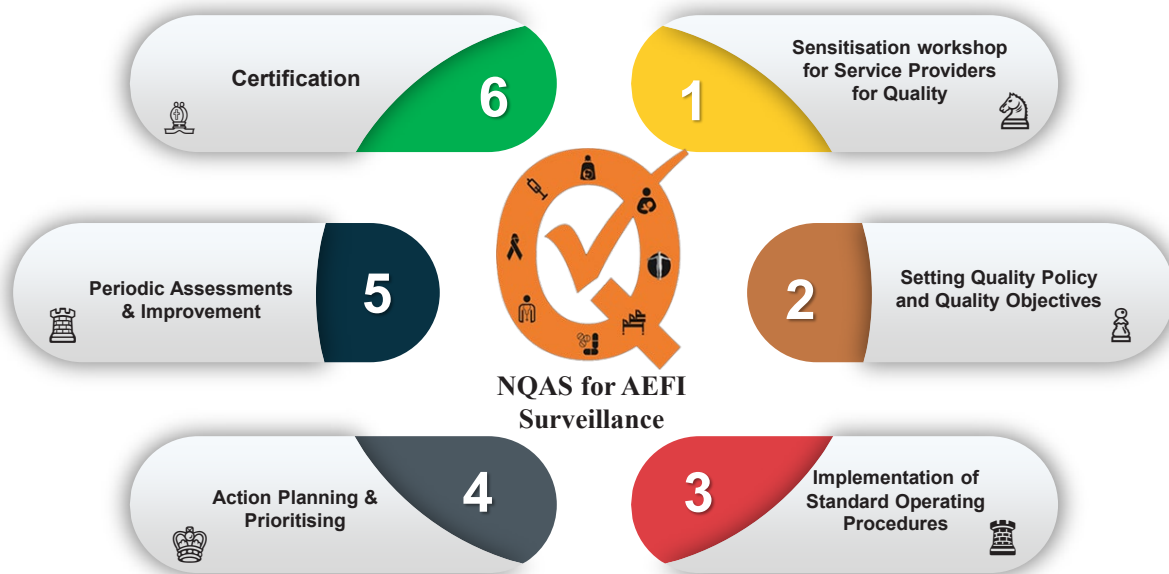
To check whether processes are in accordance to quality standards and SOPs, a system of periodic internal assessments should be implemented at the state, district and session site. Assessment should be carried out using the NQAS for AEFI surveillance checklists, at least once in a quarter. Findings of these assessment and audits should be compiled and discussed during the quality team meeting. The quality team with support of process owners should do the root cause analysis to identify the action points. Based on the action points a time bound action plan should be prepared. Follow-up on the action plan is meticulously done to traverse the gaps and improve the quality score of the facility. Quality team should ensure corrective & preventive actions are taken in time.

## 1.7 Certification

The internal assessments should be repeated till the subcentre achieves 70% score. Based on the criteria for peer assessment of a PHC, it should request the DIO/DQAU (District Quality Assurance Unit) for starting peer assessment process. Members of DQAU (District Quality Assurance Unit) verify the score by undertaking independent verification. If a PHC scores more than 70% in internal reviews and at least 50% of the PHCs of the district also achieve 70% scores and 50% of the districts complete peer assessments and achieve 70% district scores, the state can request an external assessment for certification.



## Steps by step approach for Quality certification



Reference: National Quality Assurance Standards for AEFI Surveillance Programme, MOHFW, Government of India

## ANNEXURE 4

### Documents required for NQAS for AEFI surveillance

#### State level

S. No	Updated document list	Yes/No	Remarks
1	State AEFI committee file ❖ List of committee members with letters notifying them as members with details of roles and responsibilities ❖ Meeting notices, attendance sheets and approved meeting minutes		
2	National AEFI guidelines (hard/soft copy)		
3	Line list of reported AEFI cases		
4	Records of cases with completed causality assessment (CRF, PCIF, FCIF, hospital records, Causality assessment format etc.)		
5	Feedback shared by email/letters with districts on causality assessment findings and follow up actions		
6	List of media house contact details Press releases New and visual media clippings Social media accounts (IDs) State media response templates (updated with last two months) and response protocols		
7	Key Performance Indicators (Monthly ppts, HMIS etc.)		
8	Follow up on Non-reporting/ silence districts		
9	Approved quality policy		
10	Quality objectives of last 03 months data		
11	Risk register (hard/soft copy bound)		
12	Standard Operating Procedures		
13	AEFI training records (attendance records, agenda, feedback and pre- and post-training test analysis of scores, etc.)		To be shared with districts also
14	Stakeholders satisfaction survey		

## ANNEXURE 5

### Documents required for NQAS for AEFI surveillance

#### District level

S.No	Updated document list	Yes/No	Remarks
1	Records of reported AEFI cases with filled formats (CRF, PCIF, FCIF, hospital records etc.)		
2	Line list at district		Format as per operational guidelines
3	List of private health providers providing vaccination		
4	AEFI cases reported in HMIS		Check HMIS report of last 03 months
5	List of severe/serious AEFI with case definitions		
6	List of mapped private health facilities providing vaccination		
7	AEFI guidelines in hard copy/soft copy		
8	Training Need Assessment		Check for format
9	District AEFI committee file 1. Notification letter to all members 2. Roles and responsibilities of SACM members. 3. Attendance sheet 4. Approved minutes of meetings		
10	List of media house contact details Press releases New and visual media clippings Social media accounts (IDs) District media response templates (updated with last two months) and response protocols		
11	Standard Operating procedures		07
12	Internal assessment scoresheets		
13	Gap action plan		Internal assessment score wise
14	Quality objectives		Score of last 03 months
15	Quality policy		Check whether displayed and staff aware of it
16	Risk registers (soft/hard copy)		Check whether it is available
17	Stakeholder satisfaction survey form		
18	List of key officials of civil administration and police dept. in district		Database of officials
19	Key Performance Indicators/ HMIS		Data of last 03 months

## ANNEXURE 6

### Documents required for NQAS for AEFI surveillance

#### PHC level

S. No.	Updated document list	Yes/No	Remarks
1	Case Reporting Forms (CRF) 1. Filled CRFs of reported cases 2. Blank CRFs (05 numbers)		Blank CRF is available in AEFI operational guidelines
2	Filled AEFI register		Format in operational guidelines in page number-
3	HMIS reports with monthly data of AEFI cases		Check HMIS report of last 03 months
5	List of severe/serious AEFI with case definitions		
6	List of mapped private health facilities providing vaccination		
7	AEFI guidelines in hard copy/soft copy		
8	Training Need Assessment		Check for format
9	Identified list of key personnel for community engagement		Check the list
10	Minutes of meeting of Mahila Arogya Samiti (MAS)		Check minutes of meeting
11	Standard Operating procedures		06
12	Internal assessment scoresheets		03 session per months ( last 03 months)
13	Gap action plan		Internal assessment score wise
14	Quality objectives		Score of last 03 months
15	Quality policy		Check whether displayed and staff aware of it
16	Risk register		Check whether it is available
17	Stakeholder and beneficiary satisfaction survey forms		Check whether survey forms are available @ 30 beneficiaries (10 per month) per subcentre



## ANNEXURE 8

### Gap Action Plan Format

Level: PHC/ sub centre/ district/state-	Name of session site/ facility:	PHC/ subcentre session site:	Assessment date:	Type of assessment:	
Gap Action Plan of Internal assessment (NQAS for AEFI surveillance programme)					
Gap ID	Gap Statement	Action to be taken	Responsible person	Timeline	Remarks

## ANNEXURE 9

### Training Workshop at State level on National Quality Assurance Standards (NQAS) for AEFI Surveillance

#### AGENDA

**Date:**

**Venue:**

**Objective: -**

1. Familiarise participants with the UIP and AEFI surveillance system at state, district and sub district levels.
2. Understand structures, tools (checklists, SOPs, etc.) and roles of different stakeholders in implementation process of QMS for AEFI surveillance.
3. Develop state implementation plan for QMS in AEFI surveillance.

Time	Topic	Methodology
09:30-09:45 AM	Introduction	Presentation
09:45-10:00 AM	Welcome remarks, training objectives	
10:00-10:15 AM	Pre-test	Handouts
10:15-11:15 AM	Basic concepts of UIP and AEFI surveillance	Presentation
11:15-11:30 AM	<b>Tea Break</b>	
11:30-01:00 PM	Overview of Quality Management System and familiarise with standards and assessment criteria for AEFI Surveillance	Presentation
01:00-2:00 PM	<b>Lunch break</b>	
02:00-03:00 PM	Discussion on NQAS checklist of session site level	Presentation
03:00-03:30 PM	Discussion on NQAS checklist of district level	Presentation
03:30-03:45 PM	<b>Tea Break</b>	
03:45-04:30 PM	Roles and responsibility of State QA cell; Planning for QMS implementation for certification	Presentation
04:30-04:45 PM	Post-test	Handouts
04:45-05:10 PM	Wrap Up: review of objectives and expected outcomes	Discussion

## ANNEXURE 10

### Training Workshop at District level on National Quality Assurance Standards (NQAS) for AEFI Surveillance

#### AGENDA

**Date:**

**Venue:**

#### DAY 1

1. Objective: Familiarise participants with the UIP and AEFI surveillance system at district and sub district levels.
2. Understand structures, tools (checklists, SOPs, etc.) and roles of different stakeholders in implementation process of QMS for AEFI surveillance.
3. Develop district implementation plan for QMS in AEFI surveillance.

Time	Topic	Methodology
09:30-09:45 AM	Introduction, Welcome remarks, training objectives	Presentation
09:45-10:00 AM	Pre-test	Handouts
10:00-10:30 AM	Basic concepts of AEFI surveillance	Presentation
10:30-11:15 AM	Overview of Quality Management System and familiarise with standards and assessment criteria for AEFI Surveillance	Presentation
11:15-11:30 AM	<b>Tea Break</b>	
11:30-12:15 PM	Discussion on Roles and responsibility of ANM (SOPs, Quality policy, Risk register, Beneficiary satisfaction survey, Gap action plan, Training need assessment)	Presentation
12:15–01:00PM	Discussion on NQAS checklist of Session site level	Presentation
01:00-2:00 PM	<b>Lunch break</b>	
02:00-03:00 PM	Discussion on NQAS checklist of district level	Presentation
03:00-03:30 PM	Roles and responsibility of District QA cell for assessment	Presentation
03:30-03:45 PM	<b>Tea Break</b>	
03:45-04:00 PM	Activities at PHC level for QMS in AEFI	Presentation
04:00-04:15 PM	Planning for QMS implementation	Group work
04:15-04:45 PM	Post-test	Handouts
04:45-05:00 PM	Wrap Up: review of objectives and expected outcomes	Discussion



# ANNEXURE 11

## Beneficiary attendant satisfaction survey format

Level: PHC/sub centre/district/state:		Month/Year_____				
S. No	Attributes	Highly Satisfied (05)	Satisfied (04)	Undecided (03)	Dissatisfied (02)	Highly dissatisfied (01)
1	Accessibility and visibility of immunization session					
2	Persuasiveness of ANM to ensure you waited for 30 min after immunization					
3	Comfortable ambience/ location of immunization session site					
4	Waiting time to receive the immunization services					
5	Availability and display of posters, banners for immunization					
6	Politeness and patience of ANM in providing all four key messages after immunization					
7	ANM communicates effectively and responds to fears and doubts regarding vaccines and vaccine safety					
8	Adequate time was given in advance regarding date, time and location of vaccination session					
9	Overall satisfaction regarding visit to immunization session					
What improvement would you like to see at immunization session site:						
Date:			Session:			

## ANNEXURE 12

### Beneficiary satisfaction survey analysis

PHC/sub centre/district/state :		Month/Year_____										
Beneficiary satisfaction survey analysis												
S. No	Attribute	1	2	3	4	5	6	7	8	9	10	Average
1	Accessibility and visibility of immunization session											
2	Persuasiveness of ANM to ensure you waited for 30 min after immunization											
3	Comfortable ambience/location of immunization session site											
4	Waiting time to receive the immunization services											
5	Availability and display of posters, banners for immunization											
6	Politeness and patience of ANM in providing all four key messages after immunization											
7	ANM communicates effectively and responds to fears and doubts regarding vaccines and vaccine safety											
8	Adequate time was given in advance regarding date, time and location of vaccination session											
9	Overall satisfaction regarding visit to immunization session											
Percentage Satisfaction												



