Ministry of Health and Family Welfare
Government of India

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

National Quality Assurance Standards for AEFI Surveillance Program (2016)

Ministry of Health & Family Welfare
Government of India

2016

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सत्यमेव जयते

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Government of India
Ministry of Health & Family Welfare
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MESSAGE

India aims to reduce childhood and material mortality substantially in the coming years. Increasing the reach and access to healthcare is a strategy towards that goal. India has also introduced newer vaccines and booster doses, targeting morbidity and mortality due to vaccine preventable diseases through the Universal Immunization Programme (UIP), which is the largest in the world targeting almost 27 million newborns and 30 million pregnant women through 9 million sessions each year.

Vaccines used in the country are safe and effective. However, like other pharmaceutical products, vaccines are not entirely risk free and adverse events may occasionally follow vaccination. The Adverse Events Following Immunization (AEFI) Surveillance programme indicates the Government's intent to ensure the quality and safety of vaccines administered in the country.

The Government has increased investment to improve the AEFI surveillance in the country. One of the strategies to improve the AEFI system is to establish a Quality Management System (QMS) for AEFI surveillance system. A QMS helps in incremental improvements which is self-sustaining and integral to the system being improved. Quality assurance systems in the health sector has largely been limited to hospitals and health facilities. The QMS for AEFI surveillance is probably the only example of use of quality management in a public health programme.

National Quality Assurance Standards for Quality Assessment in AEFI Surveillance Programme will help the stakeholders to self-assess and also for external assessors to conduct regular assessments of AEFI surveillance at all levels. I am thankful to all experts who contributed to the development of this Assessors' Guidebook. I hope this guidebook will be used to improve the AEFI surveillance across the country and achieve the surveillance programme objectives.

(Arun Kumar Panda)

New Delhi
2nd September, 2016

Healthy Village, Healthy Nation

एड्स - जानकारी ही बचाव है
Talking about AIDS is taking care of each other

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MESSAGE

India has the largest immunization programme in the world. Through 9 million sessions a year, with around 28000 cold chain points, more than 500 million vaccine doses are administered to 27 million children and 30 million pregnant women. It is important to have a strong AEFI surveillance system to ensure that vaccines under UIP are safe.

India is not only one of the largest consumers of vaccines but also manufactures and exports vaccines to many countries. Therefore, it is expected that we should have a strong AEFI surveillance system. The National Regulatory Assessment conducted in 2012 recommended that AEFI surveillance be improved. Of the many activities since undertaken to improve AEFI surveillance in the country, establishing a Quality Management System (QMS) for AEFI surveillance system has been given priority. Accordingly, the MOHFW requested the National Health Systems Resource Centre, New Delhi to help develop the QMS for AEFI surveillance. The National Quality Assurance Standards for AEFI Surveillance Programme (2016) has been developed jointly by the NHSRC and AEFI Secretariat within ITSU as part of the QMS. In addition to the standards recommended for the surveillance system, there are checklists to assess the system at different levels, identify gaps and recommend improvements to close the gaps.

I am confident that if the standards and checklists are utilized properly at all levels (national, state, district and session sites), India's AEFI surveillance system will be among the best in the world.

(Vandana Gurnani)

New Delhi
05th September, 2016

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FOREWORD

The Ministry of Health and Family Welfare, Government of India has intensified efforts in the last few years to improve immunization coverage and quality of immunization services being provided to children and pregnant women. While new vaccines and booster doses have been introduced, it has become necessary to increase demand for vaccines for better acceptance and improved coverage levels.

While vaccines undergo stringent clinical trials before being introduced into the programme, a strong post marketing surveillance will ensure that quality of vaccines is maintained. More than 90% of the vaccines administered in the country are through the public health system. Therefore, having a strong AEFI surveillance system is important.

In the last few years, a lot of initiatives have been taken to strengthen the AEFI surveillance system. The National AEFI Committee has been made more representative and meets regularly. The national AEFI guidelines have been revised in 2015 and disseminated. Zonal AEFI Consultants to support states to improve surveillance have been placed with the AEFI Secretariat which has been set up within ITSU. The National AEFI Technical Collaborating Centre has been set up in a leading medical college in Delhi. The SMOs of NPSP-WHO are now involved in AEFI surveillance. A pool of experts at the national level to conduct causality assessments and special investigations has been created. State AEFI Committees are being made functional and capacity built to improve surveillance, investigate and causally assess cases. Almost all districts have AEFI committees and they are being trained to manage AEFI cases, report and investigate cases. Trainings of medical officers and health workers in AEFI are also being conducted in many states.

One of the suggestions to improve AEFI surveillance is to set up a Quality Management System (QMS) for AEFI. Together with the National Health Systems Resource Centre, the AEFI Secretariat was asked to develop the QMS. Towards this, standards and indicators for processes at national, state, district and session sites have been developed along with checklists for each level to measure the status against the standards. These have been brought together in this book – National Quality Assurance

Standards for AEFI Surveillance Programme (2016) - which can be used to frequently assess the status, identify gaps and track progress in activities to close gaps to improve quality.

It is expected that using the checklists will help to not only improve AEFI surveillance indicators and also bring about some improvement in quality of service delivery which is perceptible in the field. This will require a lot of commitment and change in attitude amongst all stakeholders (including health workers, medical officers, their supervisors and immunization programme managers and partners at all levels).

This is probably the first time that a QMS system is being adapted to improve a public health programme. If this endeavor is a success, it can be probably expanded to other health programmes starting with the larger UIP programme.

I would like to acknowledge and appreciate the contributions of the Quality Improvement Division of NHSRC, the AEFI Secretariat at ITSU and the National AEFI Technical Collaborating Centre at LHMC, New Delhi working together to bring out these standards. I hope this brings about sustainable improvement in the AEFI surveillance system and enhance vaccine safety in the country.

(Pradeep Haldar)

New Delhi
12th September, 2016

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PREFACE

One of the recommendations of the international assessment of the National Regulatory Authority of India conducted by the WHO in 2012 was to set up a Quality Management System for an AEFI surveillance system. Quality Management Systems have been traditionally developed for industrial systems, factories and for closed, stand-alone organizations with limited and specific objectives and workforce. Even in the health sector, it is usually the pharmaceutical industries, laboratories and lately hospitals and health facilities who have adopted QMS for improvement. There is hardly any evidence of QMS being adapted for a public health programme such as AEFI surveillance, in which lakhs of health workers, tens of thousands of medical officers, hundreds of immunization programme managers are core stakeholders. In addition to these, AEFI surveillance also brings together academicians belonging to various specialists from medical colleges, Pharmacovigilance partners, professional associations (IAP, IMA, TNAI, others), epidemiologists and public health professionals, researchers, etc. to contribute in AEFI reporting, investigations and causality assessments at national, state and district levels.

A deliberate decision was taken to approach the Quality Improvement Division of National Health Systems Resource Centre to help in developing the QMS. A National Quality Assurance Committee for AEFI Surveillance headed by Dr. Sanjiv Kumar Dixit, ED, NHSRC, was constituted in 2013 to guide the development of the QMS. Its members included experts from the quality improvement sectors, programme managers from different levels, AEFI domain experts with clinical as well as field experience, etc. Three working groups were formed, one of which was the independent working group for development of standards and certification criteria in AEFI surveillance. The working group was headed by Dr. Satinder Aneja, Director-Professor, Department of Pediatrics, LHMC, New Delhi. The large group met thrice and there were also many meetings of smaller groups to develop the standards and the checklist for different levels to assess

elements for each standard. Part 3 explains the assessment methodology and the scoring system. Part 4 tells us the "how to" of implementing the Quality Assurance system. Part 5 has four checklists for use at the session site, district, state and national level to assess quality of the surveillance system.

I am sure that this book of Standards will be used by the stakeholders at all levels for self-assessment once every quarter and implement activities to close the gaps observed, thereby improving sustainable improvements in AEFI surveillance. Annual external audits at each level will help in unbiased assessments which will also be more objective and candid and should be taken seriously.

Once again I would like to congratulate the working group which brought this together. I hope the State and District Quality Assurance Teams of the NHSRC who are working currently on health facility accreditation and certification will also join the public health teams to implement the QMS at all levels ultimately bringing in the desired change in AEFI surveillance.

(M K Aggarwal)

New Delhi
06th September, 2016

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National Health Systems Resource Centre
Technical Support Institution with
National Health Mission
Ministry of Health and Family Welfare,
Government of India

Foreword

India runs one of the world largest immunization program. There have been major achievements in last few years including India was declared polio free and eliminated maternal and neonatal tetanus. Now government is introducing new vaccines and vaccine delivery methods including pentavalent, IPV and Rotavirus. Government also investing resources in campaign and promotions, with aim to make country free of vaccine preventable diseases.This is possible only if community has confidence in vaccines and immunization program. Adverse Event Following Immunization (AEFI) is rare but critical incidents that can tarnish the image of immunization program and prevent it from reaching the desired objectives. This is also important as India is the major supplier of vaccines to developing world.

Quality is the next big initiative in Public Health. In the last three years India has seen interest of both policy makers as well as from service providers to improve the quality of services of Public Health Facilities. Government of India has launched National Quality Assurance Program for Public Health Facilities. The program defines the quality standards for different level of facilities and mechanism of assessment and quality certification.

Though Quality systems for hospitals are quite developed and practiccdworldwidc, public health programmes are lagging behind. With current burden of communicable and non-communicable diseases the preventive public health programs would be critical to ensure healthy population. It is vitalto strengthen public health programs not only terms of coverage but also quality. These quality standards for AEFI surveillance isa path breaking work in this regard and will show the way for establishing quality management system in public health program.

I congratulate the members of Standard Formulation Committee for this pioneering work and hope that these standards will help in improving the quality of Immunization Program in India.

Sanjiv Kumar

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List of Abbreviations

ADR	:	Adverse Drug Reaction
AEFI	:	Adverse Event Following Immunization
ANM	:	Auxiliary Nurse Midwife
CDSCO	:	Central Drugs Standard Control Organization
CRF	:	Case Reporting Format
DC	:	Deputy Commissioner
DIO	:	District Immunization Officer
DCGI	:	Drug Controller General of India
FCIF	:	Final case investigation form
HMIS	:	Health Management Information system
ICSR	:	Individual Case Summary Report
ISO	:	International Organization for Standardization
ITSU	:	Immunization Technical Support Unit
IPC	:	Indian Pharmacopeia Commission
IAP	:	Indian Academy of Paediatrics
IMA	:	Indian Medical Association
LRF	:	Laboratory Reporting Form
MO	:	Medical officer
MOHFW	:	Ministry of Health and Family Welfare
ME	:	Measurable Elements
NABH	:	National Accreditation Board of Hospitals
NHM	:	National Health Mission
NHSRC	:	National Health Systems Resource Center
OB	:	Observation
PCIF	:	Preliminary Case Investigation Form
PI	:	Parents Interview
PHC	:	Primary Health Centre
PSUR	:	Periodic Safety Update Report
RR	:	Record Review
SEPIO	:	State Expanded Programme of Immunization Officer
SI	:	Staff Interview
UIP	:	Universal Immunization Programme
VHND	:	Village Health and Nutrition Day
WHO	:	World Health Organization

Table of Contents

Part I

Introduction to Quality Assurance

I. Introduction to Quality Standards for AEFI Surveillance Program

The Government of India's Universal Immunization Programme (UIP) is one of the largest in the world and protects children from more than seven vaccine preventable diseases. While vaccines are safe, there are rare chances of occurrence of Adverse Events Following Immunization (AEFI). An AEFI occurring in the field may lead to a situation which, if not handled well could result in decline in confidence of the community in the UIP programme, leading to poor vaccination rates. This will eventually cause an increase in vaccine preventable diseases and subsequent increase in preventable mortality & morbidity in children. An AEFI surveillance system has been in place for the past many years to ensure reporting of all suspected AEFIs so that each case is properly investigated and causality assessment done. Standard guidelines for reporting, investigating and conducting causality assessment of AEFIs have been disseminated to the medical officers and health workers in the field. However, there are problems with the actual implementation of the guidelines mainly because of competing priorities, sensitization, training and monitoring issues. In many cases, the personnel do not have clarity on their roles and responsibilities and what exact steps need to be taken when an AEFI is reported. This affects the quality of reporting and investigation of AEFI cases.

The MOHFW revised the AEFI Surveillance and Response Operational Guidelines in 2015. In order to ensure quality of operationalization of the Guidelines, it was felt that a Quality Management System for AEFI Surveillance should be developed for use at all levels and by all personnel.

Creating benchmarks of quality (standards) will be the first step towards preparing a Quality Management System. Once the personnel are aware of the standards and the measurable indicators for each standard, it will be easy for them to try and improve the quality of the AEFI surveillance system incrementally in their geographic area and at their levels. As quality improves slowly but constantly at different levels and areas, there will be a sustained improvement in quality of AEFI surveillance at the national level. The standards are related not only to the core AEFI surveillance processes of reporting and investigation, but also cover areas such as communication, capacity building, etc. so that it is developed as a system and not just a stand-alone, one-time activity.

"Quality Standards for AEFI Surveillance Programme" will be applicable at all levels of the health system starting from the session sites up to the MOHFW. Specific health cadres (SEPIOs, DIOs, MOs, and ANMs) have been addressed in the Standard.

II. The Quality Measurement System

Measuring quality in healthcare has been a challenge for quality practitioners. Most of the existing quality standards which are part of the quality measurement systems nationally and internationally focus on measurement of quality of care in healthcare settings like hospitals and health centers. Not much has been done to develop standards and tools that enable measuring quality of public health programmes. The fundamental challenge posed in this endeavor is to decide the unit of assessment. Contrary to hospital based standards where quality assessment is focused within a geographically confined and functionally and physically closely interrelated activities, measuring of quality in a program may require assessment of multiple sites and outreach activities. Measuring the processes related to one of the world's largest immunization programmes poses even great challenges in terms of scalability and sustainability. Extensive literature search has not thrown up any published quality standards on the AEFI surveillance programme.

Scope

The primary objective of these standards is to measure the quality of AEFI surveillance programme. These standards cover all aspects of the programme from notification and reporting, to investigation, causality

assessment, communication, operational management, etc. AEFI surveillance is a part of the UIP programme with the objective of improving vaccine safety and maintaining the confidence of the community in the immunization programme. At the point of delivery (session site) and at other levels, there are other processes happening simultaneously and the processes relevant to AEFI surveillance quality cannot be seen separately. Therefore, standards on notification of AEFI also cover counselling of the mother at the time of immunization and availability of processes to ensure availability of infrastructure and other arrangements for treating/ managing any immediate reaction following immunization. Since the scope of these standards is limited to AEFI surveillance processes, other aspects of the immunization programme such as logistics, cold chain management, immunization protocols, immunization schedule, skills of the vaccinator, specific treatment of patients with suspected AEFI, etc. have not been included. In future, these standards may be developed further to cover all processes of immunization.

Following are the attributes of the quality measurement system for the AEFI surveillance programme:

1. **Comprehensiveness –** The proposed system is all-inclusive and captures all aspects of AEFI surveillance. There are eight broad Areas of Concern ranging from notification to communication and causality assessment, with 40 standards which are assessed at four levels (session site, district, state and national). This provides a reasonable matrix to capture all related processes.

2. **Contextual –** The standards have been defined taking into consideration the current processes and priorities of the AEFI surveillance programme in India. Peculiarities and specific quality issues prevalent in the programme have been addressed and given due consideration in consultation with programme managers and domain experts in AEFI surveillance.

3. **Aspirational –** While the standards have incorporated current practices and guidelines related to AEFI surveillance, an attempt has been made to include desirable objectives that may be achieved in the near future. The intention is to not only ensure the quality of the current process, but also to trigger quality improvement by raising the bar to a higher level. For example, currently causality assessment of all cases is done at the national level. The standards aspires that causality assessment process be done at the state level for all cases, and the national level would verify only a few cases for quality control in the future.

4. **User Friendly –** It has been the endeavor of the team to avoid complex language and jargon, so that the system remains user-friendly for easy understanding and implementation by the service providers. The scoring system has been made simple with uniform scoring rules and weightage. Additionally, a formula fitted excel sheet tool has been provided for convenience, and also to minimize calculation errors.

5. **Evidence based –** The standards and measurable elements draws their requirements primarily from the current technical guidelines released by MOHFW, which are in line with the current global AEFI guidelines.

6. **Objectivity –** The assessment criteria needs to be explicit to measure quality in an extensive program such as AEFI surveillance to reduce assessor variability and requirement of training. The 40 standards have been further divided into 235 tangible measurable elements for objective assessment. Each measurable element is accompanied by an assessment method and means of verification to aid unbiased measurement of requirements. Compliance to each measurable element is registered as a score. These scores are then presented as score cards depicting the quality of different aspects of the programme.

7. **Balanced –** Various activities within the AEFI surveillance programme have been given due weightage according to their importance in the programme. These weightages have been adjusted by increasing or decreasing the number of measurable elements in respective standards.

National Quality Assurance Standards for AEFI Surveillance Programme

The quality assurance standards for AEFI surveillance programme given in this book are in line with the "Surveillance and Response Operational Guidelines for Adverse Event Following Immunization - (AEFI), MOHFW, 2015". There are forty standards, categorized into 8 areas of concern. Each standard further has specific Measurable Elements (in total 239 ME). These standards and MEs are assessed using checklists at four levels. Completed checklists would generate scorecards for a level, area of concern, and department/ programme, as shown in figure 4.1.

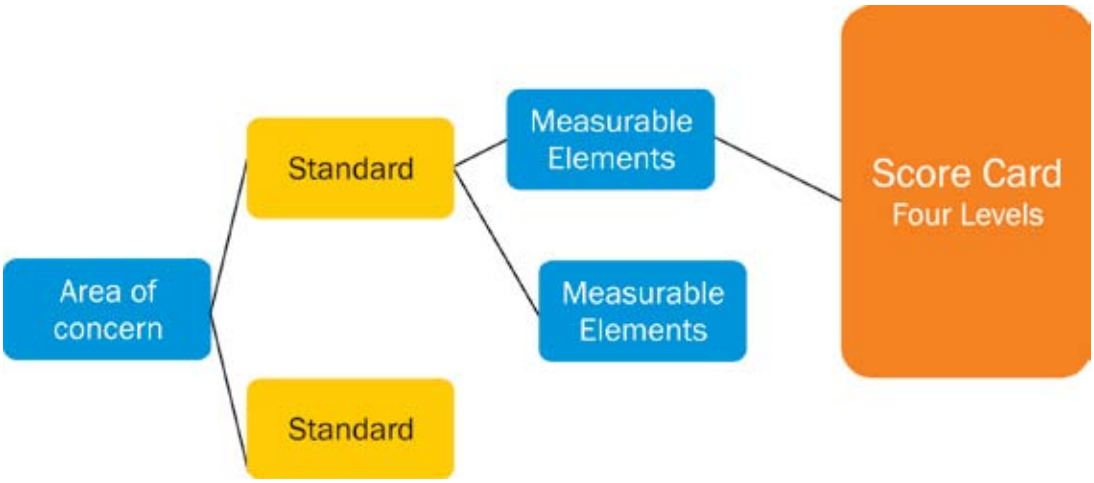


Figure 4.1 Relationship between Standard, Measurable Elements and Levels checklists

Areas of concern

Following is a brief outline of Areas of Concern, under which quality standards for the AEFI Surveillance Programme are presented in this manual :-

A. Notification and Reporting – Notification of AEFI is the first and most critical process for AEFI surveillance. Immunization services are provided at different locations ranging from VHNDs at an anganwadi center to public and private tertiary care hospitals Vaccinators at all immunization points should be able to identify an AEFI and know how to report it. Under this Area of Concern, there are five standards related measurable elements which set the norms for immediate notification as well as routine reporting of AEFI cases from the point of vaccination to the national level through a prescribed well defined channel. This area of concern also assesses the reporting of AEFI from the private sector, using a dedicated standard for this.

B. Investigation – Investigation of AEFI cases is done by the DIO or the District AEFI committee once an AEFI case reported. The five standards in this area of concern looks into the processes of preliminary and final investigation as well as special investigation if required in specific cases. There is also a specific standard on collection of samples for lab investigation.

C. Causality Assessment - This area of concern has five standards which measure the process of causality assessment done by the state or national AEFI committees for reported cases along with investigation reports. The standards in this area of concern looks at how cases are selected for causality assessment, defining causality question, and conducting causality assessment using predetermined tools and algorithms. A dedicated standard also sets norms for operational and managerial aspects of causality assessment activities.

D. **Operational Management –** There are a total of five standards in this area of concern. These standards are related to constitution and functioning of AEFI Committees at district, state and national level. This area of concern also assesses the training and capacity building activities for the AEFI surveillance programme. There is a dedicated standard for assessing preparedness at immunization sites for preventing and managing AEFIs.

E. **Communication –** Communication has been recognized as an important aspect of AEFI and the overall immunization programme and is a separate area of concern with five standards which looks into the strategy and process of communication in routine as well as AEFI crisis. There is a dedicated standard for management of information on social media.

F. **Convergence –** Multiple stakeholders are involved in the AEFI surveillance programme including state and central health departments, drug regulatory authorities, development partners and academic/research institutions. This area of concern has five standards which looks into the convergence activities with partner agencies, drug regulatory authorities, pharmacovigilance programme, professional associations, academic institutions and collaborating centres, as well as civil administration and law enforcement agencies.

G. **Monitoring and Feedback –** There are five standards under this area of concern which measures the key performance indicators for the AEFI programme: procedures for scanning of different sources to identify unreported AEFI cases, procedure for providing feedback on reports submitted, timeliness, feedback to the states regarding outcome of findings, causality assessments, trend analysis and follow up with non-reporting states and districts.

H. **Quality Management System -** The five standards of this area of concern measure the awareness of the AEFI surveillance quality policy and objectives, availability and adequacy of SOPs, work instructions to process owners, procedures for internal assessment, improvement plans and availability of risk management action plans.

Level Checklists: There are checklists available for four levels - Immunization site, district, state and National, which are briefly described below:

1. **Site Level -** This checklist is applicable to any site that provides immunization services. It may be an outreach session or a sub centre; a primary health care facility, or an immunization clinic in a public or private secondary or tertiary hospital. The immunization clinic/session is the place where the vaccine recipient, vaccinator, vaccines come together and a lot of key processes occur which are crucial for AEFI notification, reporting and investigations. A checklist with relevant standards and measurable elements looks into these processes of notification and reporting, competencies of staff in identifying AEFIs and also processes for preventing and treating AEFI at immunization sites.
2. **District Level** - All immunization services delivered in immunization session sites are managed and monitored by personnel at PHCs and at the district level. AEFI reporting is the primary responsibility of health workers and medical officers. The health staff identifies and reports the serious, severe and minor AEFIs. The district official confirms the serious/severe cases, verifies the Case Reporting Format and sends it to state and national levels. At the district level, the DIO is the member-secretary of the AEFI Committee and ensures its functionality. The reported cases are investigated by the Committee and the Case Investigation Form is submitted to the state and national levels. Apart from these, the district officials coordinate with the medical colleges, private practitioners and other stake holders. The district committee reviews and analyses AEFI data and plans the necessary actions/activities to be undertaken. It also prepares plans to handle the media in routine as well as crisis situations.

3. **State Level -** The State Immunization Officer coordinates and leads the AEFI activities in the state. The State AEFI Committee reviews and analyses the AEFI cases reported by the districts. The state also collaborates with medical colleges, ADR monitoring centres, municipal corporations, private practitioners and other partners involved in immunization activities. The committee also conducts causality assessment of each reported case at the state level within 100 days of case notification. The state immunization officer ensures that the state communication plan is established to handle crisis situations related to AEFI. The state also provides support to the districts in investigation of AEFIs and helps to improve reporting of cases from districts.

4. **National Level -** At the national level, the AEFI Secretariat supports the Immunization Division in strengthening AEFI surveillance. The national AEFI committee reviews the overall pattern of reports and investigations. A national database of serious and severe AEFIs is maintained at the national level and feedback is provided to the states. The periodic review of AEFI surveillance activities is conducted at the national level. Members of the National AEFI Committee meet on a regular basis as per the calendar and discuss the issues related to AEFI. The National AEFI Secretariat provides support and assistance to the states and districts in AEFI surveillance, investigation and causality assessment.

Part II

National Quality Assurance Standards for AEFI Surveillance Programmme

I. Programme Overview

In India, AEFI surveillance has been in place since 1988. Intensive efforts have been put in by the Government of India for strengthening surveillance and to improve monitoring of AEFI in the country. The National AEFI Guidelines have been revised in 2005 and 2010 and recently in 2015. In 2011, Standard Operating Procedures (SOPs) for reporting AEFI were prepared and disseminated across the country. Considering the need to further strengthen AEFI surveillance, the National AEFI Secretariat was established at the Immunization Technical Support Unit (ITSU) of the Ministry of Health and Family Welfare (MoHFW), India in 2012.

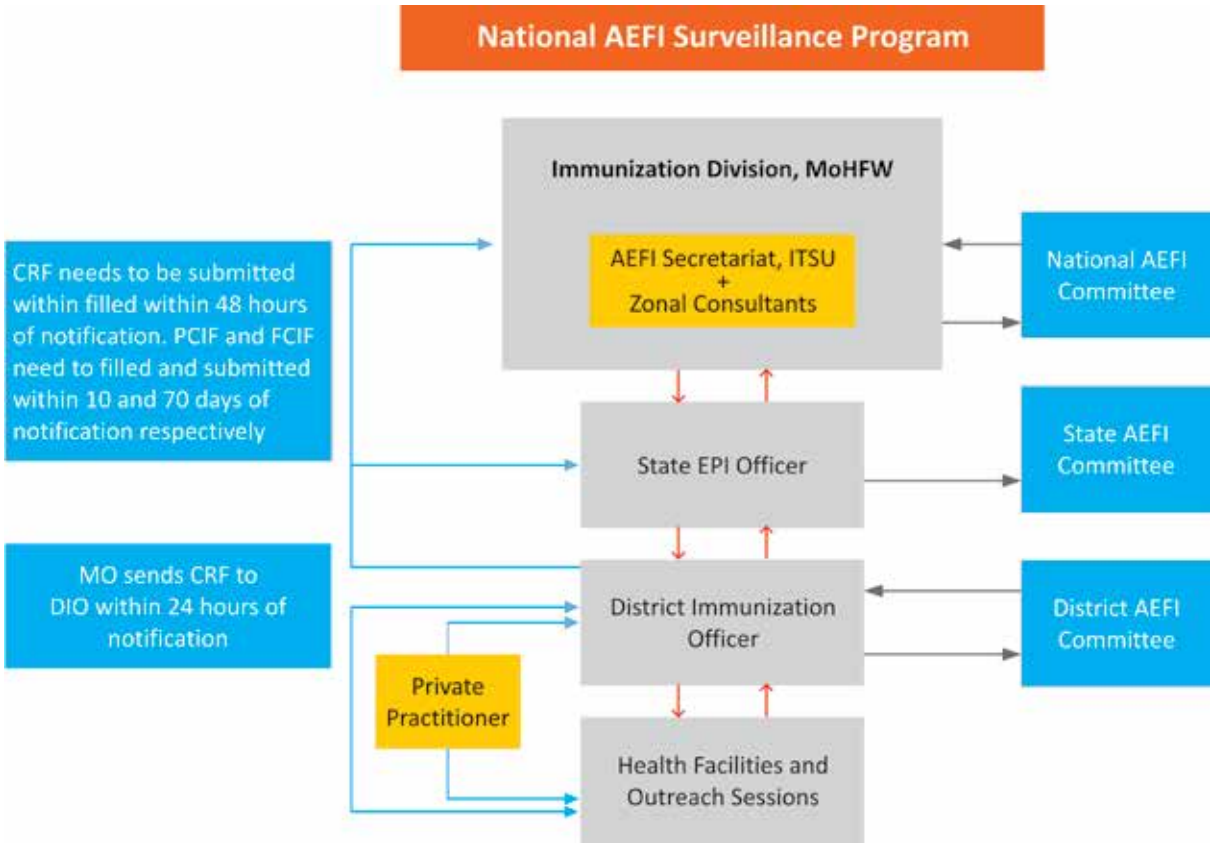


Figure 2: Reporting flow in National AEFI Surveillance Programme

Since then, several initiatives have been undertaken to streamline the AEFI Surveillance programme at the national level and to undertake capacity building of state and district level workers/officials/taskforce to ensure timely AEFI reporting and investigation:

- The Secretariat coordinates a meeting calendar of three meetings every year for the National AEFI Committee.
- Four zonal AEFI consultants have been put in place to work with the AEFI Secretariat and support the states in investigation and assessment of serious AEFIs.
- For technical oversight and support to the National AEFI Secretariat, a collaboration has been set in place with Lady Hardinge Medical College as the National AEFI Technical Collaborating Centre.
- Regular Causality Assessment meetings have been conducted by the Secretariat in the National AEFI Technical Collaborating Centre to ensure that all reported cases are causally assessed.

II. Intent of Quality Assurance Standards for AEFI Surveillance Programme

Area of Concern- A: Notification and Reporting

AEFI surveillance is an important component of the Universal Immunization Programme. For strengthening AEFI surveillance, vigilance by health care providers is of utmost importance. Notification and reporting of an AEFI case is the first crucial step in the AEFI surveillance system. The completeness and timeliness of reporting are the major factors determining quality of the programme. It is essential that the health staff be able to identify and report all severe, serious and minor AEFIs.

Following are the five standards in this area of concern:

Standard A1 – The primary responsibility for notifying AEFI cases is defined and communicated at each level	All serious, severe AEFIs are to be immediately notified by the first person who identifies the event. The ANM, ASHA, Medical Officers and Private Practitioners are the key personnel involved in notification. The Medical Officer or District Immunization Officer is responsible for reporting the case through the Case Reporting Form (CRF).
Standard A2- There is an established procedure for routine reporting of AEFI cases	All serious, severe and minor AEFIs are reported from the level of occurrence (field) of the AEFI, upto the national level through monthly progress reports or CRF. An AEFI register is maintained at the PHC to list all notified AEFIs by name, and based on this register, weekly reporting of all serious and severe cases is done to DIO in VPD-H002 format.
Standard A3- There is an established procedure for immediate reporting of serious/severe AEFI cases	All serious/severe AEFIs are to be immediately notified by the first person who identifies the event. The notification should be done to the nearest government PHC/CHC and/or the DIO by the quickest means of communication (telephone, messenger etc.). The medical officer, PHC fill the CRF for all serious and severe AEFIs notified to him and sends it to the DIO within 24 hours of notification. The DIO after confirming the case, sends the filled and verified CRF within 48 hours of notification to the state and national level simultaneously. Line lists of reported cases through CRF are maintained by DIO, State Immunization Officer and Immunization Division/ AEFI Secretariat at the national level.
Standard A4- Preliminary and final case investigation formats are reported as per defined protocol	The preliminary and final case investigation forms capture in-depth information regarding the event required for causality assessment of the cases. The DIO sends the PCIF to the State Immunization Officer and AEFI Secretariat, MOHFW as early as possible or within 10 days of case notification. The FCIF along with all relevant documents should be sent within 70 days of notification to the SEPIO and Immunization division, MOHFW
Standard A5- There is an established procedure to ensure recording and reporting of AEFI cases from the private sector	A private practitioner shall notify the MO/ DIO regarding a serious/severe AEFI. This will also be reported through the CRF to the state and national level. The case notified by any private health facility or private practitioner is investigated by the district health authorities as per the national AEFI guidelines.

Area of Concern - B: Investigation

The ultimate goal of a case investigation is to arrive at a clinical diagnosis based on the chronology of medical events, detailed medical history and other evidences such as laboratory investigations. Once a probable diagnosis is available, it will help in finding the cause of the AEFI and to undertake appropriate response for action. The investigations should identify any immunization error-related or vaccine quality defect -related reactions because these are preventable. In case of co-incidental events, it is important to document and communicate because this maintains public confidence in the immunization programme.

Following are the five standards in this area of concern:

Standard B1 – Criteria for AEFI cases to be investigated is defined and communicated	The reported AEFI must be investigated if it: • Appears to be a serious event (as defined by WHO) of known or unknown cause, • Belongs to a cluster AEFI, • Is a suspected immunization error, • Appears on the list of events defined for AEFI surveillance (known adverse event reported following vaccination with a specific vaccine) • Causes significant parental or public concern, • Cases identified by state and national level which require immediate intervention for investigation • Cases (not previously known to be associated with a newly introduced vaccine) which the notifier/reporter thinks could be an adverse event with a newly introduced vaccine
Standard B2- Preliminary investigation of cases is done as per guidelines	DIO along with district AEFI committee should use the Preliminary Case Investigation Form (PCIF) as a guide to investigate the case (collect data about the patient, vaccine, immunization services etc.) and collect specimens wherever applicable and conclude the investigation by framing provisional clinical diagnosis within 10 days of notification.
Standard B3- Final case investigation report is prepared as per guidelines	The DIO will fill the Final Case Investigation Form (FCIF) which is a summary of the case with outcome, findings of investigation with all available documents e.g. hospital records, postmortem report, vaccine testing report etc. and send it to the State Immunization Officer and the Deputy Commissioner (UIP) MOHFW within 70 days of case notification.
Standard B4- A standard procedure is followed for special investigation	A special investigation may be necessary in the following scenarios with defined timelines for all activities in case of : • Cluster events • Requested by state government or MOHFW/AEFI secretariat • Media reports on AEFIs causing concern in the community • Serious AEFIs reported after new vaccine introduction of significant concern
Standard B5- There is established procedure for collection of samples for lab investigation	When appropriate, specimen in the correct quantity as per specimen collection guidelines required for the investigation should be collected. Laboratory specimens should be accompanied by clear supporting documents (LRF, CRF, PCIF and other relevant documents), reasons for specimen collection and any specific additional request for information by the investigators.

Area of Concern - C: Causality Assessment

Causality assessment is the systematic review of the information obtained about an AEFI case, to determine the likelihood of the event having been caused by the vaccine(s) received. This does not necessarily establish whether or not a definite relationship exists between an event and immunization, but generally only ascertains a degree of association of the event with the vaccine/vaccination. It is a critical part of AEFI surveillance and enhances confidence in the national immunization programme.

Causality assessment may provide a more descriptive explanation of the event, which may help to understand what caused the event. If a manufacturing defect or a programme error is suspected to be the cause of the event, specific steps can be taken to ensure prevention of further errors. If events are coincidental, it reassures the community and stakeholders that the vaccines are safe. In essence, whether an AEFI might be attributable or not to the vaccine or vaccination determines what steps need to be taken to address the event.

Following are the five standards in this area of concern:

Standard C1 – Case selection for AEFI causality assessment is done as per established criteria	All serious and severe AEFI cases that may have been caused by immunization error, significant events of unexplained cause occurring within 30 days after a vaccination, events causing significant parental or community concern and signals generated as a result of an unusual individual case or cluster case should be reported, and after complete investigation undergo causality assessment after satisfying the minimum criteria for eligibility causality assessments will be done by the state AEFI committee and the national AEFI committee.
Standard C2- Causality question is defined as per protocol	Causality assessment is started with framing a causality assessment question which includes the name of the vaccine(s) suspected of causing the event and the valid diagnosis for the event. e.g. “Has the vaccine A caused Hepatomegaly?” As far as possible, the valid diagnosis should meet a standard case definition.
Standard C3- Causality assessment is done using predefined tools and algorithms	After the causality question is framed, causality assessment is done using a standard checklist following which an algorithm is used to arrive at the conclusion.
Standard C4- There is an established procedure for organizing causality assessment as per defined timelines	Causality assessment of AEFI cases is done by a group of trained personnel belonging to different specialties at state and national level. Causality assessment is done at the state level by members of state AEFI committee each case is reviewed by the chair, state AEFI committee to ensure correct processes have been followed (framing causality questions, fillings standard checklist, following the algorithm for final classification) Finally each case is collectively approved by the state AEFI committee. This process should be completed within 70 days of case notification and communicated to the immunization division. At the national level, a CA subcommittee will conduct the causality of each case the chair of the CA subcommittee will review the cases to ensure all processes were correctly followed before sending them to the national AEFI committee for approval. The timelines for causality assessment at the national level will follow the current timelines as determined by the CA sub-committee and endorsed by the National AEFI Committee.
Standard C5- There is an established procedure for taking appropriate action on outcome of causality assessment	Findings should be promptly and clearly communicated: Messages should be clear on any next steps to be taken, including communicating reassurance or the need to take action within the programme such as training, research, modifying systems, refining tools etc. to minimize or avoid recurrences.

Area of Concern - D: Operational Management

Following are the five standards in the area of concern:

Standard D1 – AEFI committees at district, state and national levels are constituted and functional	Every state and district should have an AEFI Committee with membership as detailed in the AEFI Surveillance and Response Operational Guidelines – 2015. Once constituted, the members of the Committees should meet at least once a quarter or as and when necessary to discuss the status of the AEFI surveillance system, to monitor and to suggest activities to improve it. Minutes of the meetings should be maintained and shared with the higher level. The committee will help DIO/SEPIO in case investigations, media management, etc. as and when necessary. State AEFI Committee members will conduct causality assessment of the cases reported from the districts.
Standard D2 – There is an established procedure for functioning of national AEFI committee	The National AEFI Committee advises and assists the MoHFW on matters related to AEFI surveillance. The AEFI Secretariat facilitates the work of the National AEFI Committee by coordinating meetings and implementing the recommendations of the Committee. This standard concerns the established procedures for the functioning of the National AEFI Committee, starting with formal constitution with fixed TORs, adequate representation, conducting meetings as and when required (at least four times a year), etc. There are four sub- committees under the National AEFI Committee - causality assessment, media, investigation and laboratory. There is also a panel comprising of the Chairs of National Committee and the four-sub committees which discusses special cases. The AEFI Secretariat ensures regular updation and analysis of AEFI surveillance data, shares information regularly with AEFI and pharmacovigilance partners and states. It maintains data securely.
Standard D3 – Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated	Various personnel/health cadre in districts and states (frontline workers, multipurpose workers, health supervisors, medical officers, DIOs and SEPIOs) and at the national level (Deputy Commissioner and technical staff at the AEFI Secretariat) have specific roles and responsibilities with timelines as per the AEFI Surveillance and Response Operational Guidelines – 2015. It is important for each person to be aware of his/her role in reporting, investigating and conducting the causality assessment of each AEFI case. Trainings, feedback during meetings and in writing, are some of the ways to ensure communication of roles and responsibilities to health personnel so that AEFI surveillance indicators are improved and maintained.
Standard D4 – There are established procedures for training and capacity building of personnel involved in AEFI surveillance	It is necessary for all the personnel involved in AEFI surveillance to be trained properly so that they can follow the guidelines and complete their activities in a timely manner and also maintain quality. Immediately after the AEFI guidelines are revised, state level functionaries are trained on the revised guidelines on the programme and causality assessment. District level functionaries are trained for reporting and investigation. In addition to these specific AEFI trainings, sessions on AEFI management, reporting and investigations are part of the three days' training on immunization for MOs and two days' training on immunization for health workers. State AEFI Committee members are trained and supported by national experts in conducting causality assessments.

Standard D5 - Immunization sites are prepared for preventing and treating any adverse event following immunization	Following the prescribed guidelines for conducting immunization sessions will ensure: 1) Prevention of AEFIs due to programme errors 2) To manage all types of AEFIs in the periphery. Guidelines recommend that the parents/caregivers are informed of the following four key messages: 1) Which vaccines were administered 2) The diseases prevented by them 3) What could be the possible minor side effects 4) How these can be managed. For fever and pain, ¼ of a tablet of paracetamol is given to every caregiver. Each vaccine recipient is to be kept under observation after vaccination for 30 minutes. The vaccinator should have access to the emergency drug tray so that if an AEFI such as anaphylaxis is suspected, treatment can be started immediately. The vaccinator is aware of what type of AEFIs can occur, how to identify them and what to do to ensure prompt treatment to the patient. She should also be aware of how programme errors occur and how to prevent them from occurring.

Area of Concern - E: Communication

Effective communication around vaccine safety, including management of public reactions, requires serious investment of resources and efforts towards strategic communication for immunization. In order to have a sustainable impact on the behavior of individual or groups on a larger scale, communication efforts need to be strategic, participatory, evidence-based, well-funded and a result-oriented process. Regular communication with the community and the media will improve relations between health providers and communities, It will encourage community involvement which will prevent the community from losing confidence in vaccinations and reduce the fear of AEFIs.

This area of concern measures the procedures for regular communication to maintain confidence in the immunization programme, procedures for communication in case of serious AEFI events, established strategy for media management at district, state and national level, defined procedures for management of information on social media and also for capacity building of key personnel responsible for communication at each level of administration.

Following are the five standards in this area of concern:

Standard E1 - There are established procedures for regular communication to build confidence of universal immunization program in the community	This standard pertains to a system of regular communication and also measures the process through which vaccinators deliver four key messages to parents, communicate benefits of RI at VHND sessions and immunization benefits to the community. It also deals with the process of dissemination of the messages through Mid and Mass media by the health administration.
Standard E2- There are established procedures for communication in case of serious AEFI event	The AEFI response protocol for media and communication guidelines has been disseminated. The standards measure the availability of protocol with the designated staff /official to interact with parent, community and news media when the event has occurred.

Standard E3- **There is a defined strategy for media management at district, state and national levels**	There is a standard procedure for communicating with media for routine and crisis situation and also for validation of media reports, articles and editorials in newspapers, and this is being followed. Database of contact details of the reporters is maintained, and regular media interaction (formal and informal) is done. Availability of media plan, crisis communication, operational plan and identification of spokesperson is ensured.
Standard E4- **There are defined procedures for management of information on social media**	This standard pertains to use of social media for managing information. Social media is regularly scanned for negative reports and rumours. Routine immunization messages are regularly communicated through social media and there is a planned strategy to counter rumours and misinformation on social media.
Standard E5- **There is an established procedure for capacity building of key personnel responsible for communication at each level of administration**	This standard deals with the verification of training, workshop records and identified list of spokesperson/officials for communication trained on the media management and the requirement for further trainings.

Area of Concern - F: Convergence

All stakeholders in AEFI surveillance are routinely communicating and coordinating with each other to avoid information gaps and take timely & appropriate action. Convergence among all stakeholders is maintained at such levels that any safe vaccine continues to be in use and any unsafe vaccine is withdrawn immediately, and action taken for prevention of similar errors.

Following are the five standards in this area of concern:

Standard F1 – **There are established procedures for coordination with partner agencies**	Regular meetings (monthly/once in two months) of partner agencies (ITSU, WHO, UNICEF etc.) for regular coordination and communication shall be held. Review of ongoing/completed activities, decisions made during the previous meetings will be undertaken and future activities will be planned to further strengthen the programme.
Standard F2- **There are established procedures for coordination with drug regulatory authorities**	Regular meetings (monthly/once in two months) and information sharing with regulatory bodies (CDSCO, IPC) are held. CDSCO will take regulatory decisions on the basis of analysis of AEFI data collected and assessed by experts and recommended to the MOHFW.
Standard F3- **There are established procedures for coordination with the Pharmacovigilance Programme**	Regular meetings (monthly/once in two months), are held and real time information sharing between Indian Pharmacopoeia Commission (IPC) and MoHFW should be done for all serious AEFIs reported by ADR Monitoring Centres. Coordination and communication shall be done at national, state (representative of ADR monitoring center and state AEFI committee) and district levels (Representatives of ADR monitoring center and district AEFI committee) to avoid information gaps and take timely actions.
Standard F4- **There are established procedures for coordination with professional associations , academic institutions and collaborating centres**	Regular quarterly meetings of professional associations (IAP, IMA etc.), academic institutions (representative specialists from medical colleges),collaborating centers (representatives from technical collaborating centers) at national, state and district levels as part of AEFI committee meetings with respective programme managers should be held. Communication and coordination with professional organizations and academic institutions shall be ensured to improve reporting from all sectors and providing technical guidance to the programme at all levels.

Standard F5- There are established procedures for coordination with civil administration and law enforcement agencies	Regular sensitization of civil administration and law enforcement agencies during regular immunization task force meetings at all levels should be done. AEFI committees shall be encouraged to invite the civil administration and law enforcement agencies to participate in the AEFI investigation planning meetings, visiting sites together for investigations and jointly collect specimens as far as possible.

Area of Concern - G: Monitoring & Feedback

Following are the five standards in this area of concern:

Standard G1 – Key performance indicators for AEFI programme are defined, monitored and analyzed	The AEFI guidelines have a list of indicators which measures the performance of the AEFI surveillance programme in districts, states and the country. The AEFI surveillance line list is the basis for analyzing the indicators. The analysis should be presented and discussed in the AEFI committee meetings at all levels to look for gaps, areas for improvement, and activities to improve surveillance.
Standard G2 – There are established procedures for scanning of different sources for identifying signals for AEFI cases	Most of the adverse events are notified by the health workers, while some are notified by the private practitioners (directly to the MO/DIO or through IDsurv portal of Indian Academy of Paediatrics) or by the media. The AEFI surveillance system through the District and State Immunization Officers reports and investigates all adverse events in their jurisdiction. Some AEFIs are reported by Adverse Drug Reaction Monitoring Centres of the Pharmacovigilance Programme of India under the Indian Pharmacopeia Commission. Occasionally, manufacturers report events through Periodic Safety Update Reports to the regulatory authority (Central Drugs Standards Control Organization). The system of categorizing cases is different for the AEFI surveillance system, PSURs and ICSRs. The results of causality from these three sources need to be analyzed regularly to look for signals. If a signal is detected, the MoHFW will inform the CDSCO to take appropriate action.
Standard G3 – There is an established procedure for providing timely feedback on reports submitted	When a case is reported to the state/MoHFW, the reports are analyzed and feedback given to the reporter state on completeness and any missing information within 72 hours using a checklist. A revised report or clarification is expected, based on the feedback. Phone calls are made for cases in which the corrected format is not received or the information sought is not received. A list of pending documents for each case is also shared with the states and districts.
Standard G4 – There is an established procedures for providing feedback to the states regarding outcome of findings in causality assessments and trend analysis	Feedback to states and districts on the causality assessments done at the national level should be shared regularly so that remedial actions can be taken wherever needed. Analysis of the AEFI surveillance status should be shared with the states and districts regularly for taking action to improve surveillance.
Standard G5 – There is an established procedure to follow up with non-reporting states and districts	Regular analysis is needed to find out non-reporting and under-reporting states and districts, and this should be communicated frequently to the states and districts. Analysis should include the root cause analysis, recommending specific steps for improvement.

Area of Concern - H: Quality Management System

A quality management system consists of a set of interrelated activities that assure quality of services according to the standards set, and strive to improve upon it through systematic planning, implementation, checking and acting upon the compliances. The standards in this area of concern are opportunities for improvement to enhance quality of services and strengthening the AEFI programme.

Following are the five standards in this area of concern:

Standard H1 – Quality policy and objectives are defined and disseminated	This standard is concerned with establishment and dissemination of quality policy and objectives in the AEFI surveillance programme. The staff may be interviewed to know assess awareness of quality policy and objectives. Review of records should be done for assessing that quality objectives meet SMART criteria and have been reviewed periodically.
Standard H2- Standard Operating Procedures are defined, documented and established at each level	This standard is concerned with availability and adequacy of standard operating procedures and work instructions with the respective process owners.
Standard H3- There are established procedures for internal assessment and periodic reviews	This standard pertains to the processes of internal assessment at a defined periodicity. Review of internal assessment and audit records may reveal their adequacy and periodicity.
Standard H4- Continual Quality Improvement is practiced at each level of AEFI surveillance programme	This standard is concerned with implementation of quality management system at all levels and the use of checklists, records, and a system to measure satisfaction of stakeholders & employees, analysis of the feedback and the action plan. The assessor should review the records pertaining to performance indicators and analysis of key indicators.
Standard H5- There is an established procedure to identify and mitigate risks in relation to AEFI programme	This standard pertains to risk management framework at AEFI surveillance programme. Assessors should check the plan & processes to manage the risks, list of identified risks and their analysis with the action taken. Record review should be done for the actions taken and system for measuring the effectiveness of action taken.

III. Measurable Elements for AEFI Quality Assurance Standards

Area of Concern - A Notification and Reporting	
Standard A1	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**
ME A1.1	Vaccinator is aware of categories of AEFI
ME A1.2	Person responsible for notifying the AEFI is identified
ME A1.3	Person responsible for reporting the AEFI is identified
ME A1.4	Identified person is aware of the categories of AEFI to be notified
ME A1.5	Reporting authority and route is communicated
Standard A2	**There is an established procedure for routine reporting of AEFI cases**
ME A2.1	Weekly reporting of AEFI cases is ensured by ANM/Nodal person for reporting AEFI
ME A2.2	AEFI register is maintained at the block or Primary Health Centre
ME A2.3	Weekly reporting of all serious/severe cases is submitted to District Immunization Officer
ME A2.4	AEFI cases are reported in HMIS on monthly basis
Standard A3	**There is an established procedure for immediate reporting of serious/severe AEFI cases**
ME A3.1	The service provider is aware of the AEFI events required to be immediately notified/ reported
ME A3.2	List of severe/serious AEFIs with case definition are available with the service provider
ME A3.3	AEFI case reporting format is available with the medical officer
ME A3.4	Route and timelines of reporting of CRF are communicated
ME A3.5	Duly filled CRF is reported by medical officer to DIO within 24 hours of notification
ME A3.6	EPID number for each case is assigned by DIO
ME A3.7	Completed CRF is forwarded by DIO to state immunization officer and national level within 48 hours of AEFI case notification
MEA3.8	CRFs are collated and line listed by DIO
ME A3.9	CRFs are collated and line listed by State Immunization Officer
ME A3.10	CRFs are collated, line listed and reported at national level as per defined protocol
Standard A4	**Preliminary and Final case investigation formats are reported as per defined protocol**
ME A4.1	Hard copies of blank formats for PCIF and FCIF are available with the DIO
ME A4.2	Preliminary case investigation report in requisite format is submitted as per defined route and time line
ME A4.3	Final case investigation report in requisite format is submitted as per defined route and time line
ME A4.4	Investigation reports are collated and reported to state & national level as per defined protocol
Standard A5	**There is an established procedure to ensure recording and reporting of AEFI cases from the private sector**
ME A5.1	Key private facilities providing immunization services are identified
ME A5.2	Private service providers have been effectively communicated regarding reporting channel and procedures with contact details
ME A5.3	Primary and secondary care hospitals are involved in reporting of AEFI cases
ME A5.4	District immunization authorities are receiving notification/ reports from the private sector

Area of Concern - B Investigation	
Standard B1	**Criteria for AEFI cases to be investigated is defined and communicated**
ME B1.1	Lists of cases/events that require initiation of investigation are available
ME B1.2	Criteria for case selection for investigation have been effectively disseminated
ME B1.3	Criteria for case selection for investigation are followed by District AEFI committee
ME B1.4	State immunization officer identifies the cases requiring immediate intervention from state level in the form of special investigation
ME B1.5	Cases requiring immediate intervention for investigation from national level are identified
Standard B2	**Preliminary Investigation of cases is done as per guidelines**
ME B2.1	Reporting medical officer prepares the list of evidences which will be required for investigation in consultation with DIO
ME B2.2	Possible source of information has been mapped and listed before starting the investigation
ME B2.3	Used vaccine vials and other material related to AEFI incident is preserved in cold chain
ME B2.4	Demographic information has been recorded in PCIF
ME B2.5	Information regarding the vaccine and immunization session related to the AEFI is recorded
ME B2.6	History of events in chronological order is recorded
ME B2.7	Previous medical history of the patient is recorded
ME B2.8	Details of first examination of reported AEFI case are recorded
ME B2.9	Details of immunization processes and practices including any probable immunization error are recorded
ME B2.10	Cold chain and transport details are recorded in PCIF
ME B2.11	Information gathered from parents and community is recorded
ME B2.12	Case investigation report is reviewed and approved by district AEFI committee
ME B2.13	Appropriate decision is taken regarding lab investigation of vaccine vials and syringes
ME B2.14	Provisional clinical diagnosis is framed
ME B2.15	Available documents related to the event/investigation are sent with the PCIF within 10 days of notification
Standard B3	**Final case investigation report is prepared as per guidelines**
ME B3.1	Patient clinical records have been attached
ME B3.2	Lab findings of vaccines sent are recorded
ME B3.3	Updated information regarding patient clinical history and examination are recorded
ME B3.4	A probable diagnosis is arrived at and recorded in final investigation report
ME B3.5	The final outcome of the patient is recorded
ME B3.6	Final investigation report is reviewed and approved by District AEFI committee
Standard B4	**A standard procedure is followed for special investigation**
ME B4.1	Case / events requiring special investigations are defined
ME B4.2	Timelines and authority for initiating the special investigation are defined and practiced
ME B4.3	Special investigation team has representation of relevant domain experts
ME B4.4	Team ensures that all relevant documents, records and information is available before commencing the investigation
ME B4.5	Cluster events and sudden unexplained deaths are investigated as per protocol
ME B4.6	Field visit is undertaken as per protocol
ME B4.7	Clinical and epidemiological investigation is done as per protocol
ME B4.8	Lab findings of vaccine sent for testing are recorded

ME B4.9	Provisional conclusion is arrived at in final report
ME B4.10	Submitted report is adequate
ME B4.11	Submitted report is time-bound
Standard B5	**There is an established procedure for collection of samples for lab investigation**
ME B5.1	Biological and autopsy samples are taken as per protocol
ME B5.2	Health officials are aware of correct quantity of vaccine samples to be collected
ME B5.3	Packing of samples is done as per protocol
ME B5.4	Documentation of samples is done as per protocol
ME B5.5	There is provision of storing used vials related with the AEFI event in cold chain
ME B5.6	Local drug regulatory authorities are involved at all steps of lab testing of vaccines
Area of Concern - C Causality Assessment	
Standard C1	**Case selection for AEFI causality assessment is done as per established criteria**
ME C1.1	Case selection criteria for causality assessment is defined
ME C1.2	Causality assessment team is aware of case selection criteria for causality assessment
ME C1.3	It is ensured that case records and relevant information are available before commencing the causality assessment
ME C1.4	Responsible officials/ committee has screened the reported AEFI cases for causality assessment
ME C1.5	All eligible AEFI cases have been subjected to causality assessment
Standard C2	**Causality question is defined as per protocol**
ME C2.1	Implicated vaccine is identified provisionally
ME C2.2	A valid diagnosis is arrived at based on information provided
ME C2.3	Dedicated causality question is defined for each implicated vaccine
ME C2.4	Objective causality question/s are defined based on available case information
Standard C3	**Causality assessment is done using predefined tools and algorithms**
ME C3.1	Standard causality assessment report format is available
ME C3.2	Standard causality assessment report format is used for each case
ME C3.3	Causality assessment algorithm is effectively communicated to the trained experts/ individuals
ME C3.4	There is a system for verification of filled checklist, algorithm and classification
ME C3.5	Causes other than those defined in the investigation reports are considered and consensus reached to accept or reject the association
ME C3.6	Vaccine Product related causal association is considered and consensus reached to accept or reject the association
ME C3.7	Immunization error related causal association is considered and consensus reached to accept or reject the association
ME C3.8	Immunization anxiety related causal association is considered and consensus reached to accept or reject the association
ME C3.9	Time window for the reported event following administration of the implicated vaccine is considered for causal association
ME C3.10	Evidence against the causal association is considered and consensus reached to accept or reject the evidence
ME C3.11	Other qualifying factors for classification is considered and consensus reached to accept or reject the qualifying factors
ME C3.12	Final outcome of causality assessment is classified as per defined categories
ME C3.13	Quality review feedback report is available for completed causality assessment
ME C3.14	Final causality assessment report has been signed by the team members

Standard C4	**There is an established procedure for organizing causality assessment as per defined timelines.**
ME C4.1	Causality assessment is done by a team of trained experts
ME C4.2	Timeliness and turnaround time for completing different steps of causality assessment are defined
ME C4.3	Timeliness and turnaround time for completing different steps of causality assessment are adhered to
ME C4.4	There is an established system for tracking and monitoring of cases submitted for causality assessment
ME C4.5	Causality assessment reports and other relevant records along with the cases are indexed as per defined protocol
ME C4.6	Causality assessment reports are securely stored and status updated
ME C4.7	There is an established procedure for finalizing date of causality assessment meeting and circulation of meeting notice
ME C4.8	There is an established procedure for training experts for conducting causality assessment
ME C4.9	Reviewed and verified CA cases are submitted to the relevant authority at State and National level
Standard C5	**There is an established procedure for taking appropriate action on outcome of causality assessment**
ME C5.1	Findings of causality assessment are shared with relevant stakeholders
ME C5.2	Follow up actions are taken for vaccine product related reactions
ME C5.3	Follow-up actions are taken for immunization errors related errors
ME C5.4	Follow-up actions are taken for anxiety error related reactions
ME C5.5	Coincidental cases are effectively communicated
Area of Concern - D Operational Management	
Standard D1	**AEFI committees at district, state and national level are constituted and functional**
ME D1.1	District AEFI committee has been formally constituted and updated in last three years.
ME D1.2	District AEFI committee has adequate representations of stakeholders and experts with names and designations
ME D1.3	Terms of reference and responsibilities of members have been effectively communicated
ME D1.4	District AEFI committee meets at least once in a quarter and minutes are recorded
ME D1.5	District AEFI committee members are actively involved in surveillance activities, investigation and review of case investigation reports
ME D1.6	State AEFI committee has been formally constituted and updated at least once in last three years.
ME D1.7	State AEFI committee has adequate representation of all stakeholders and experts with name and designations
ME D1.8	State AEFI committee meets at least once in a quarter and minutes are recorded
ME D1.9	Terms of reference and responsibilities of members have been effectively communicated
ME D1.10	State AEFI committee members are actively involved in surveillance activities, case investigations and review of reports
ME D1.11	State AEFI committee members regularly meet to review AEFI case investigation reports
ME D1.12	State AEFI Committee members conduct causality assessments of all received eligible cases from districts
ME D1.13	National AEFI committee has been formally constituted and updated at least once in last three years
ME D1.14	National AEFI committee has adequate representation of all stakeholders and experts with names and designations

ME D1.15	National AEFI committee meets at least once in a quarter and minutes are recorded
ME D1.16	Terms of reference and responsibilities of members have been effectively communicated
ME D1.17	National AEFI committee members are actively involved in surveillance activities, investigation and review of reports
ME D1.18	The four national subcommittees are active in ensuring timeliness of deliverables
ME D1.19	Special cases vaccine product related, vaccine quality defect related and immunization error related deaths are discussed by the Chairperson of National AEFI Committee and Chairpersons of four sub-committees
Standard D2	**There is an established procedure for functioning of National AEFI Secretariat**
ME D2.1	There is a procedure for sharing of AEFI data received at the national level
ME D2.2	Documented procedures exist for storing and retrieving of data
ME D2.3	There is a designated person for documenting and entering received data
ME D2.4	Procedures exist for maintaining confidentiality, security and integrity of records, data and information
ME D2.5	Procedures exist for retention and disposal of AEFI records
ME D2.6	There is a system for monitoring internal processes of the national AEFI secretariat
ME D2.7	There is an established procedure for entertaining requests under RTI
Standard D3	**Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated**
ME D3.1	Front line worker is aware of her role and responsibilities in AEFI surveillance programme
ME D3.2	Health Supervisor is aware of his/her role and responsibility for AEFI surveillance programme
ME D3.3	Medical Officer is aware of his/her role and responsibility for AEFI surveillance programme
ME D3.4	DIO is aware of his/her role and responsibility for AEFI surveillance programme
ME D3.5	State Immunization Officer is aware of his/her role and responsibility for AEFI surveillance programme0
ME D3.6	Deputy Commissioner (UIP) is aware of his/her role and responsibility for AEFI surveillance programme
ME D3.7	Technical Staff at National AEFI Secretariat are aware of their role and responsibilities for AEFI surveillance programme
Standard D4	**There are established procedures for training and capacity building of personnel involved in AEFI Surveillance**
ME D4.1	AEFI guidelines are available with key stake holders at all levels
ME D4.2	Training and skill needs assessment has been done for AEFI surveillance programme at all levels
ME D4.3	Training calendar has been prepared as per training needs
ME D4.4	Training has been provided to stakeholders as per schedule
ME D4.5	There is a system to take training feedback
ME D4.6	There is a system to measure training effectiveness
Standard D5	**Immunization sites are prepared for preventing and treating any adverse event following immunization**
ME D5.1	Parents are counselled for informing about any untoward event or concern following vaccination
ME D5.2	Antipyretic drugs are provided wherever required
ME D5.3	Beneficiaries are observed for 30 minutes after immunization
ME D5.4	Emergency drug tray is available at site of immunization

ME D5.5	Protocols/ instructions regarding preventing, identifying, managing AEFI are displayed at the immunization sites
ME D5.6	Vaccinator is aware of what to do in case of any immediate serious reaction/ anaphylaxis
ME D5.7	Vaccinator is aware of how to prevent immunization error-related reactions
Area of Concern - E Communication	
Standard E1	**There are established procedures for regular communication to build and maintain confidence in the Universal Immunization Programme in community**
ME E1.1	Key personnel for community engagement have been identified and authorized
ME E1.2	Vaccinators and extension workers deliver the four key messages to parents after each vaccination
ME E1.3	Vaccinators and extension workers communicate the benefits of RI at VHND sessions
ME E1.4	Advocacy with community Influencers for giving key messages on benefits of immunization is been done
ME E1.5	The Health administration regularly disseminates messages through Mid & Mass media regarding benefits of RI
Standard E2	**There are established procedures for communication in case of serious AEFI event**
ME E2.1	Protocol for media response is available
ME E2.2	Officials are designated to interact with parents and community when an event occurs
ME E2.3	Designated spokespersons to interact with media in timely and appropriate manner when an event occurs
ME E2.4	Specific scanning of media reports is done for the reported AEFI
ME E2.5	Follow up of media reports is done on daily basis
Standard E3	**There is a defined strategy for media management at district, state and national level**
ME E3.1	Scanning of media reports is done on a regular basis
ME E3.2	List of media contact persons is available with immunization officers
ME E3.3	There is a system of regular liaison with media houses and journalists at state and national level
ME E3.4	Designated official knows which information should not be prematurely shared with the media
Standard E4	**There are defined procedures for management of information on social media**
ME E4.1	There is a formal and authorized social media account for disseminating messages on routine immunization
ME E4.2	There is a designated official for addressing the social media
ME E4.3	Social media is regularly scanned for negative reports and rumours
ME E4.4	Routine immunization messages are regularly communicated through social media
ME E4.5	There is a planned strategy to counter rumours and misinformation on social media
Standard E5	**There is an established procedure for capacity building of key personnel responsible for communication at each level of administration**
ME E5.1	Key personnel for media management have been identified and authorized
ME E5.2	Formal training for communicating with the community and influencers has been provided
ME E5.3	Formal training for communicating with media has been provided
ME E5.4	Capacity building has been undertaken for media management
ME E5.5	Capacity building for social mobilization and advocacy is undertaken for community engagement

Area of Concern - F Convergence	
Standard F1	**There are established procedures for coordination with partner agencies**
ME F1.1	Partner agencies have been identified at each level
ME F1.2	There is an established channel for sharing bilateral information with partner agencies
Standard F2	**There are established procedures for coordination with drug regulatory authorities**
ME F2.1	Drug regularity authorities are involved at all levels of AEFI surveillance
ME F2.2	There is an established channel for sharing bilateral information with drug authorities
Standard F3	**There are established procedures for coordination with Pharmacovigilance Programme**
ME F3.1	Pharmacovigilance authorities are involved at all levels of AEFI surveillance
ME F3.2	There is an established channel for sharing bilateral information with Pharmacovigilance programme
Standard F4	**There are established procedures for coordination with professional associations, academic institutions and collaborating centres**
ME F4.1	List of representatives of professional bodies are available at each level of programme
ME F4.2	There is a system of regular interaction and information sharing with professional bodies
ME F4.3	Institutions and organizations working in similar domains are identified and collaborated
Standard F5	**There are established procedures for coordination with civil administration and law enforcement agencies**
ME F5.1	Key officials in civil administration and police department are identified at each level
ME F5.2	Civil administration is regularly updated regarding immunization programme
ME F5.3	There is an established procedure for seeking help of civil administration in case of crisis
Area of Concern - G Monitoring and Feedback	
Standard G1	**Key performance indicators for AEFI programme are defined, monitored and analyzed**
ME G1.1	Key performance indicators are defined at each level
ME G1.2	There is a system to gather and update data for generation of indicators on weekly, monthly and quarterly basis
ME G1.3	The indicators are being regularly analyzed at each level
ME G1.4	The quality of data received at all levels is verified regularly
ME G1.5	Benchmarks and control limits have been defined for key performance indicators
ME G1.6	There is a system to effectively communicate feedback on AEFI surveillance indicators to the lower levels on monthly basis
Standard G2	**There are established procedures for scanning of different sources for identifying signals for AEFI cases**
ME G2.1	There is a system to analyze data and trends to identify potential signals
ME G2.2	There is a system for identifying, documenting and communicating a signal to relevant stakeholders
ME G2.3	There is a system to take action on identified signals
Standard G3	**There is an established procedure for providing timely feedback on reports submitted**
ME G3.1	There is a defined criteria and checklist to assess completeness and quality of submitted investigation reports
ME G3.2	Turnaround time for giving feedback on investigations is defined and adhered to
ME G3.3	Follow-up is done on given feedback in stipulated time

Standard G4	**There is an established procedure for providing feedback to the states regarding outcome of findings of causality assessments and trend analysis**
ME G4.1	Periodic feedback is given to states on trend analysis of key performance indicators
ME G4.2	State ensures that relevant feedback has been communicated to stakeholders at district and facility level
Standard G5	**There is an established procedure to follow up with non-reporting states and districts**
ME G5.1	Non-reporting districts and states are identified periodically
ME G5.2	Under-reporting districts and states are identified periodically
ME G5.3	Root cause analysis is done for non-reporting/under-reporting districts and states
ME G5.4	Feedback on non-/under-reporting districts is given to states
ME G5.5	Follow up action is taken over feed back
Area of Concern - H Quality Management System	
Standard H1	**Quality policy and objectives are defined and disseminated**
ME H1.1	Quality team for AEFI surveillance programme is in place & it reviews the quality at periodic intervals
ME H1.2	Quality policy for AEFI surveillance programme is defined
ME H1.3	Quality objective for AEFI surveillance is defined
ME H1.4	Progress towards achieving quality objectives is monitored periodically
Standard H2	**Standard Operating Procedures are defined, documented and established at each level**
ME H2.1	Standard operating procedures for key processes are prepared, approved & updated
ME H2.2	Standard operating procedures are available at point of use
ME H2.3	Standard operating procedures adequately describes processes& procedures
ME H2.4	Staff is trained & aware of procedures written in SOPs
Standard H3	**There are established procedures for internal assessment and periodic reviews**
ME H3.1	Periodic internal assessments are conducted at various levels at defined intervals
ME H3.2	Non-compliances are enumerated & recorded adequately
ME H3.3	Action plans are made on gaps found during the assessment process
ME H3.4	Corrective actions are taken to address the issues observed in the assessment
ME H3.5	There is a mechanism for validation and analysis of quality indicators to facilitate quality improvement
Standard H4	**Continuous Quality Improvement is practiced at each level of AEFI surveillance programme**
ME H4.1	Stakeholder satisfaction surveys are conducted & analyzed at periodic intervals
ME H4.2	Action plans are prepared for the lowest performing areas in stakeholder survey
ME H4.3	Internal quality assurance programme for its key processes are in place
ME H4.4	The QMS is communicated and coordinated amongst all the staff involved in the AEFI surveillance programme through an appropriate training mechanism
ME H4.5	The quality improvement programme identifies opportunities for improvement based on pre-defined intervals
Standard H5	**There is an established procedure to identify and mitigate risks in relation to AEFI programme**
ME H5.1	Risk management framework is in place for the AEFI surveillance programme
ME H5.2	Risk & opportunities for improvement in all critical processes are identified, analyzed & prioritized
ME H5.3	There is a system in place to take actions to eliminate, avoid & mitigate risks
ME H5.4	There is a system in place to check effectiveness of actions taken.

Part III

Assessment Protocols

I. Assessment Methodology

1. General Principles

Assessments need to be carried out based on adherence to general principles of assessment which are a prerequisite to achieving the objectives of the assessment and arriving at unbiased conclusions which are useful to the service providers as well as to other stake holders, such as officials at district and state levels and also at national levels. Following are the key principles of the assessment:

a) Integrity – Assessors and persons managing assessment programs should

- Perform their work with honesty, diligence and responsibility
- Demonstrate their competence while conducting the assessment
- Make assessment in an impartial manner
- Remain fair and unbiased in their findings
- Be sensitive to any influence that may be exerted while carrying out assessment

b) **Fair Presentation** – Assessment findings should truthfully and accurately represent the assessment activities. Any unresolved diverging opinion between assessors and assessed should be brought out. Communication should be truthful, accurate, objective, timely, clear and complete.

c) **Confidentiality** – Assessors should ensure that information acquired by them during the assessment is kept confidential and should not be shared with un-authorized personnel. The information must not be used for personal gain.

d) **Independence** – Assessors should be independent of the activity they are assessing and should in all cases act in a manner that is free from biases and conflict of interest. For internal assessment, an assessor should not assess his or her own department and processes.

e) **Evidence-based approach** – Conclusions should be based on evidence which is verifiable and reproducible.

2. Planning Assessment Activities

The following assessment activities are undertaken at different levels:

a) Internal Assessment – A continuous process of assessment within the facility by internal assessors

b) External Assessment – Assessment by quality assurance unit

c) Assessment for certification – Assessment by assessor deputed by the Ministry of Health and Family Welfare or an organization on behalf of the MOHFW

Internal Assessment– Internal assessment is a continuous process and forms an integral part of a quality assurance programme. Internal assessments need to be done not only at national, state and district levels but also at the session sites. Internal assessments will be done in the offices of the programme managers (DIOs, SEPIOs and Immunization Division), by the AEFI Committees at all levels and also the Technical Collaborating Centres at national and state levels. The session sites (health facility and outreach) will also conduct their own internal audit. A quality teamwhich will do the audit will be formed at each level. States, districts and session sites in which surveillance indicators are poor and are a cause of concern can be prioritized for internal audits. Certain areas within AEFI surveillance requiring specific improvements can be audited on priority.

For internal assessments, a nodal person may be designated as the coordinator, whose main responsibilities are given below:

1. Prepare assessment plan and schedule
2. Constitute the assessment team for internal assessment
3. Arrange stationary for internal assessment
4. Maintain and keep assessment records safely
5. Communicate and coordinate with departments
6. Monitor and review the internal assessment programme
7. Disseminate the findings of internal assessment
8. Prepare action plan in coordination with quality team and respective departments

External Assessment– External assessors are responsible for undertaking an independent quality assessment of the programme at a particular level. States and districts with poor quality surveillance indicators would have priority in the assessment programme. Visits for assessment also provide opportunity for state/district level capacity of quality assurance and handholding. It needs to be ensured that all levels are assessed frequently as mandated.

3. Constituting the assessment team

Assessment team should be constituted according to the level of assessment. The assessment team should comprise of technical experts on immunization and AEFI surveillance. These may be immunization officers, technical experts from partner agencies and program managers. At least one of the member should be a trained assessor for National Quality Assurance Standards.

4. Preparing Assessment Schedule

The assessment schedule is a micro plan for assessment. It consists of details regarding levels of assessment, dates, timings, etc. The Assessment schedule should be prepared beforehand and shared with respective departments.

5. Conducting the Assessment

i. Pre-assessment preparation – The leader of the assessment team should ensure that the assessment schedule has been communicated to all concerned staff of the programme. Stationary for the assessment including the checklist should be available in adequate quantity. The team leader should assign responsibility according to the assessment schedule and competence of different team members.

ii. Opening meeting – A short opening meeting with the staff should be conducted for introduction, informing about aims and objective of the assessment as well as role clarity.

6. Communication during Assessment

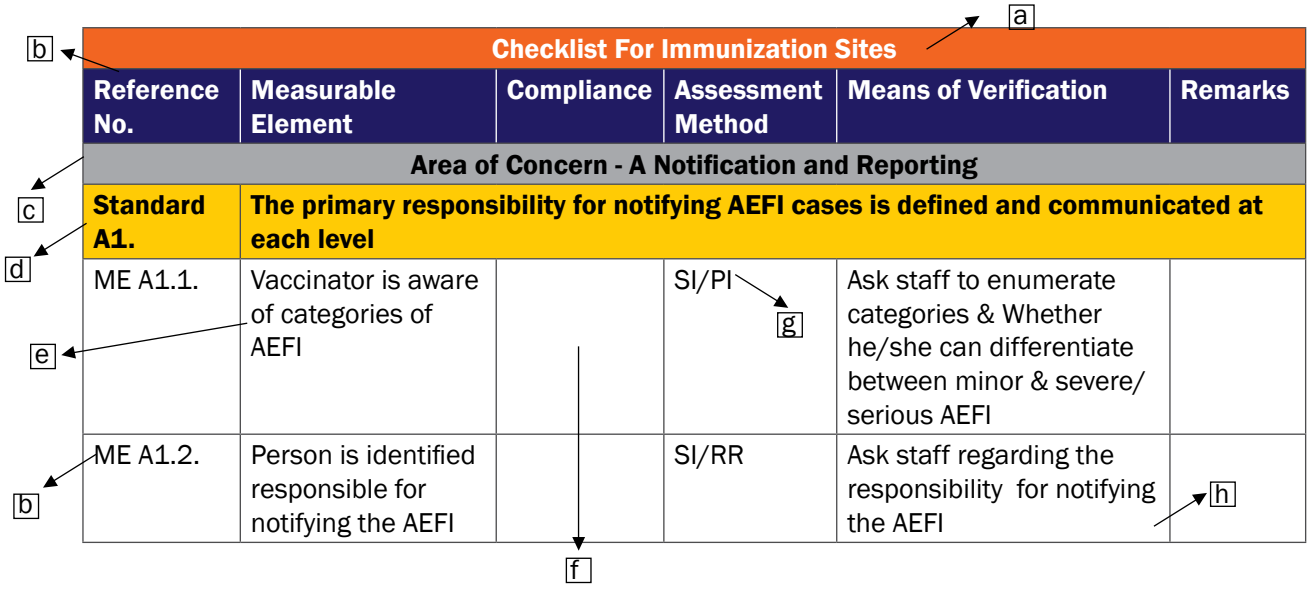
Behavior and communication of the assessors should be polite and empathetic. Assessment should be a fact finding exercise and not a fault finding exercise. All type of conflict should be avoided. In event of conflict, the head or assessment coordinator should be contacted to mediate and resolve the conflict.

7. Using the checklist for assessment

The checklist is the main tool for assessment. Assessors should familiarize themselves with the checklist beforehand. Layout of the checklists in the manual is given below:

a) The title of the checklist denotes the name of the level for which the checklist is intended.

b) Extreme left column of checklist contains the reference number of the standard and Measurable Elements. The reference number helps in identification and traceability of a standard.



Checklist For Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Notification and Reporting					
Standard A1.	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**				
ME A1.1.	Vaccinator is aware of categories of AEFI		SI/PI	Ask staff to enumerate categories & Whether he/she can differentiate between minor & severe/ serious AEFI	
ME A1.2.	Person is identified responsible for notifying the AEFI		SI/RR	Ask staff regarding the responsibility for notifying the AEFI	

c) The in grey colour contains the name of the area of concern under which the standards are listed.

d) The row in yellow colour horizontal bar has statement describing the standard which is being measured. There are a total of forty standards, only relevant standard will be included in each level checklist, to all each levels. Only the relevant standards for the level.

e) The second column contains text of the measurable elements for the respective standard. Only applicable measurable elements of a standard are shown in a checklist. You may not find all measurable elements under a standard in a level checklist. They have been excluded because they are not relevant to that level.

f) A blank column to the right of the measurable element is the space to record findings of assessment in terms of compliance, partial and non-compliance.

g) The column to the right of the blank compliance column is the assessment method column. It explains the 'HOW TO' to gather the information.

The Assessor should read measurable elements try to gather evidence and information to assess the compliance to the requirement of the measurable elements generally. Information can be gathered by four methods:

Observation (OB) – The compliance of many of the measurable elements can be assessed by directly observing the processes and surrounding environment. An example is a Display of work instructions and other important information on a board/job aid in the office.

Record Review (RR) – For most processes (especially reporting and notification), a review of records may generate more objective evidences. Many such evidences can be used to pinpoint the findings of an observation.

Staff Interview (SI)– Interaction with staff will help in assessing the knowledge levels required for performing certain jobs/functions:

a) Competency Testing – Asking staff how do they perform certain procedures

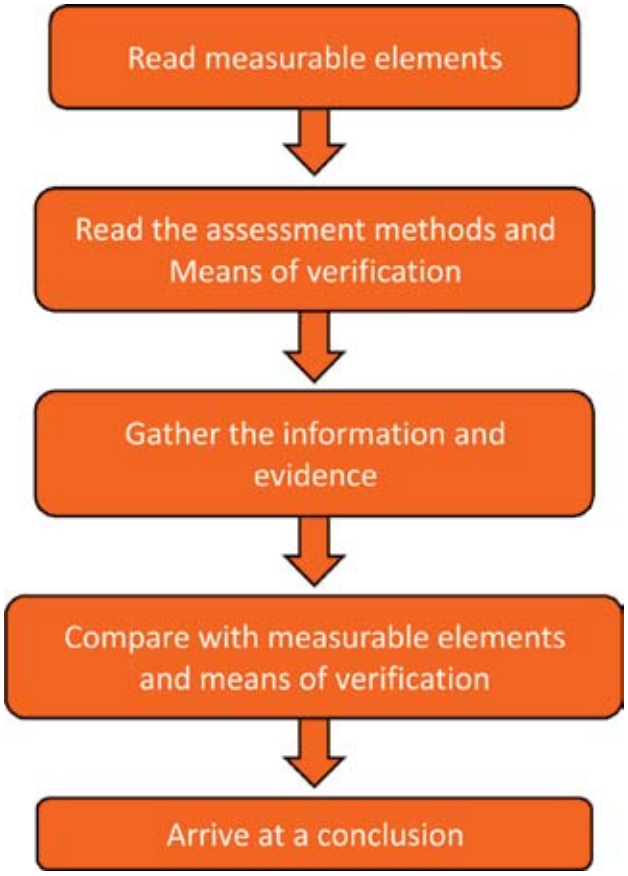
b) Demonstration – Asking staff to demonstrate certain activities

c) Awareness- Asking staff about awareness of quality policy

Parent Interview (PI) – Interaction with beneficiary and relatives may be useful in getting information about quality of services and their experience at the facility. It should include feedback on quality of services, staff behavior, counselling procedures, reporting, notification, feedback, etc.

h) The column next to the assessment method column lists the means of verification. It denotes what to look for in a particular measurable element. It may be a procedure to be observed, or an example of a question to be asked to the interviewee or a benchmark which could be used for comparison or a reference to some other guidance and legal document. It may be left blank or self-explanatory in some cases.

Fig. 3: Flow diagram of gathering information during assessment is given below:



8. Assessment Conclusion –

After gathering information and evidence for measurable elements, an assessor is expected to decide the level of compliance (full compliance, partial compliance or non-compliance) for each of the Measurable elements.

II. Scoring System

After assessing all the measurable elements, marking the compliance, scores of the levels (session site, districts, states, and national) can be calculated.

Rules of Scoring

- 2 marks for a full compliance
- 1 mark for a partial compliance
- 0 Marks for a non-compliance
- All measurable elements have equal weightage to keep scoring simple.

Once scores have been assigned to each ME, level wise and standard wise scores can be calculated by adding the individual scores for each ME. The final score should be given in percentage, so that it can be compared with other session sites/districts/states.

Calculation of percentage is as follows:

$$\frac{\text{Score obtained X 100}}{\text{No. of ME in checklist X 2}}$$

Scores can be calculated manually or scores can be entered into the excel sheet given to get scores and dash boards.

The assessment scores can be presented in as a score card depicting quality scores and area of concern wise score. An example is given below:

Score card				
Level Immunization site/district/state/national				
	Area of concern	**Maximum Score**	**Score received**	**Percentage**
A.	Notification & Reporting			
B.	Investigation			
C.	Causality Assessment			
D.	Operational Management			
E.	Communication			
F.	Convergence			
G.	Monitoring and Feedback			
H.	Quality Management system			

Part IV

Implementing Quality Assurance for AEFI Surveillance Programme

Step by Step Approach for Quality Management System

Quality Assurance is systemic approach which consists of defining the standards, assessing activities against defined standards and then closing the gaps to meet the defined standards. This is a continuous process which ultimately lead to quality improvement. This approach has been tried and tested in many industries including healthcare. Quality assurance in an vast program such as the Universal Immunization Programme of India may have peculiarities that needs to be factored in due course.

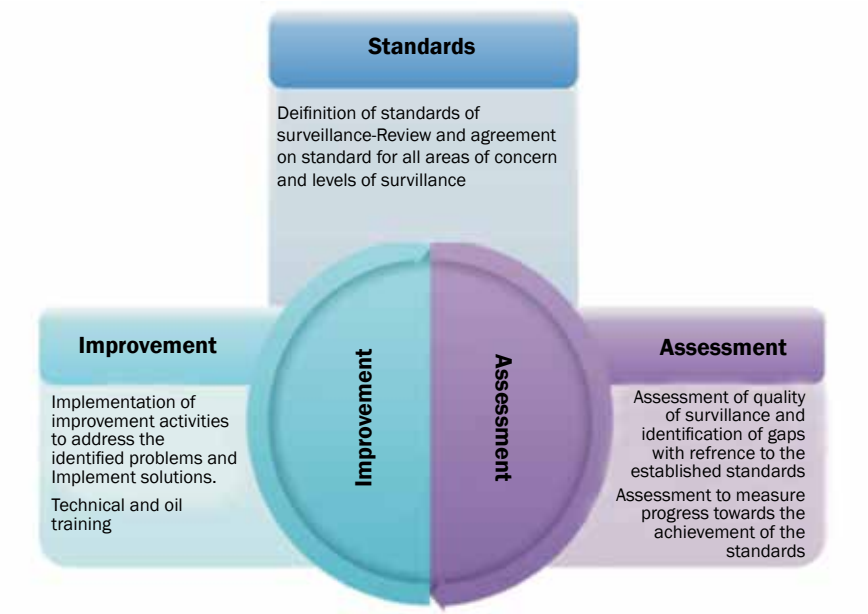


Fig. 4: Approach to Ensuring Quality (WHO- Regional Framework for Quality of Care)

Step 1 – Defining and disseminating Quality Standards for AEFI Surveillance

The first step to implement any quality system would be defining the standards of care/services. Through this publication Quality Standards for AEFI Surveillance programme has been defined based on prevalent national and international protocols and existing evidence. These standards should become guiding principles and performance benchmark for measuring and improving policies and processes of AEFI surveillance programme. Also equally important is to effectively disseminate these standards to all stakeholders. This could be done by sharing the standards as well as formal trainings on quality assurance. The stakeholders include program officers at state and district level as well partner agencies such as drug control officers, Pharmacovigilance Program and International agencies. A national level event may be organized to disseminate the quality standards. As standards are dynamic and may change because of change in polices or evidence, these should be reviewed periodically. The standards must be reviewed at least once in three years. The scope of these standards may be extended to the whole immunization programme based on learning from implementing standards for AEFI surveillance programme.

Step 2- Setting up Institutional Framework

Sustaining quality assurance activity would require an institutional framework for planning, implementing and monitoring quality assurance related activities. At national level “National Quality Assurance Committee for AEFI surveillance programme” has been constituted by Ministry of Health & Family Welfare to oversee the quality related activities. Under the National Quality Assurance Programme, Quality Assurance Committee s have been constituted at state and district level across all states of India. It would be prudent to utilize the existing framework rather than creating a parallel structure. The State Quality Assurance Committee will

be overall responsible for implementing the standards and monitoring the quality management system for AEFI surveillance programme. For focused activities of this programme a Quality Team can be formed under state AEFI surveillance committee designating two or three members. At the district level the District AEFI committee will be responsible for the AEFI quality assurance related activities in coordination with District Quality Assurance Committee.

Step 3

1. **Periodic Assessment:** Assessment Tools (Checklists) are available for each level of AEFI surveillance programme. Assessment should be carried out using these checklists once in a quarter.
2. **Baseline Assessment/Internal Assessment:** Baseline assessment of Quality Management system of AEFI surveillance programme would be coordinated by the District Immunization Officer at district level, by State Immunization Officer at state level and AEFI secretariat at national level. The same team would also conduct internal assessments (followed by action planning for further improvement of the system) at fixed intervals (at least half yearly)
3. **Peer Assessment:** Peer assessment would be done at least once in a year.

(1) Peer assessment of AEFI Secretariat would be done by NHSRC

(2) Peer assessment of state level AEFI surveillance programme would be done by State Immunization Officer of some other state/AEFI Secretariat

(3) Peer assessment of district level AEFI surveillance programme would be done by District Immunization Officer of an other district in same state.

Step 4 - Action Planning & Prioritizing

Level of support required	Severity ranking
a) Gaps that could be observed at facility level	a) High gaps affecting the surveillance programme care directly
b) Gaps requiring support from district authorities	b) Medium gaps indirectly affecting the surveillance programme
c) Gaps requiring state support	c) Low gaps not affecting the surveillance programme but quality of services
d) Gaps requiring national support	

Based on the findings of baseline assessment, the gaps can be identified & enumerated for each department. These gaps can be categorized on the basis of severity of gap and level of support required, as given below:

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

Step 5- Setting Quality Policy and Quality Objectives

Quality Policy needs to be framed by the process owner in consultation with the staff and other stakeholders. At the national level, these would be PVPI, CDSCO, WHO, etc. 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. Quality policy is a broad statement that describes what & how the surveillance intends to improve the quality of its services. Quality policy should always acknowledge user satisfaction as key component of its policy. It should be formulated in local language and displayed at critical places for better understanding.

Quality objective are tangible short term goals that all levels 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.

Step 6 - 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 having multiple stakeholders and complex proceeds requires standardization of processes and clear delineation of responsibilities. Standards Operating Procedures should be prepared and implemented by the District, State & National AEFI surveillance Committees. National Level SOPs has already been prepared and are in the process of implementation. Template SOPs for State and District AEFI committee are under process of development, and will be disseminated from the National level. These SOPs should be adapted by state and district AEFI committees and implemented at local level. Updated & Controlled copies of following SOPS should be available at their respective level-

Level	SOPs
Immunization Sites	Notification & Reporting Investigation Operational Management Communication Convergence Quality Management System
District AEFI Committee	Notification & Reporting Investigation Operational Management Communication Convergence Monitoring & Feedback Quality Management System
State AEFI Committee	Notification & Reporting Investigation Causality Assessment Operational Management Communication Convergence Monitoring & Feedback Quality Management System
National AEFI Committee	Data Management & Analysis Investigation including special investigation Causality Assessment Operational Management Communication Convergence Monitoring & Feedback Quality Management System

Step 7 Certification

External Certification of Quality Management system of AEFI surveillance programme would be done for 3 levels:

(4) National Level AEFI secretariat

(5) State Level AEFI surveillance Programme

(6) District Level AEFI surveillance Programme

External Assessment Team for National Level, state level &district Level:

(1) Domain expert with minimum experience of 5 Years as program manager/ technical expert in immunization.

(2) Expert working with WHO/ development partners/International NGOs.

(3) Trained National level External assessor for NQAS.

Make sure, there is no conflict of interest while constituting team for the External assessment.

Certification Criteria:

(1) National Level AEFI secretariat: AEFI Secretariat is eligible for certification only if it get at least 70% scores during external assessment.

(2) State Level AEFI surveillance Programme: State level AEFI surveillance programme is eligible for certification only it get at least 70% scores during external assessment as well as 60% score for 2/3 district during peer assessment.

(3) District Level AEFI surveillance Programme: District level AEFI surveillance programme is eligible for certification only if it get at least 70% scores during external assessment.

National level certification would be given by Central Quality Supervisory Committee of MOHFW, Govt. of India.

Part V

Level Checklists

National Quality Assurance Standards for AEFI Surveillance Programme

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Notification and Reporting					
Standard A1	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**				
ME A1.1	Vaccinator is aware of categories of AEFI		SI/PI	Ask staff to enumerate categories & whether he/ she can differentiate between minor & severe/ serious AEFI	
ME A1.2	Person responsible for notifying the AEFI is identified		SI/RR	Ask staff regarding the responsibility for notifying the AEFI	
ME A1.3	Person responsible for reporting the AEFI is identified		SI/RR	Ask staff regarding the responsibility for reporting the AEFI	
ME A1.4	Identified person is aware of the categories of AEFI to be notified		RR/SI	Ask staff to enumerate categories & whether he/ she can differentiate between minor & severe/ serious AEFI	
ME A1.5	Reporting authority and route is communicated		RR/SI	Ask staff to whom are the cases reported and how	
Standard A2	**There is an established procedure for routine reporting of AEFI cases**				
ME A2.1	Weekly reporting of AEFI cases is ensured by ANM/ Nodal person for reporting AEFI		RR	In case no AEFI case is reported during the week, a nil report is submitted	
ME A2.2	AEFI register is maintained at the block Primary Health Centre		RR	Verify whether the register is available	
ME A2.3	Weekly report of all serious / severe cases is submitted to District Immunization Officer		RR	Verify weekly reports of AEFI cases	
ME A2.4	AEFI cases are reported in HMIS on monthly basis		RR/SI	Verify HMIS reports for previous months	

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard A3	**There is an established procedure for immediate reporting of serious/severe AEFI cases**				
ME A3.1	The service provider is aware of the AEFI events required to be immediately notified and reported		SI	Ask staff which AEFIs need to be reported immediately	
ME A3.2	List of severe / serious AEFI with case definition are available with service provider		SI/RR	Verify availability of case definition list	
ME A3.3	AEFI case reporting format is available with the designated medical officer		RR	Check availability of printed CRF format	
ME A3.4	Route and timelines of reporting of CRF are communicated		SI	Ask staff whom to report AEFI cases and how	
ME A3.5	Duly filled CRF is reported by medical officer to DIO within 24 hours of notification		RR/SI	Check timeliness of reporting of serious AEFI cases. If no case has been reported, ask the MO if he is aware of the timeline for sending CRF to DIO.	
Standard A5	**There is an established procedure to ensure recording and reporting of AEFI cases from the private sector**				
ME A5.1	Key private facilities providing immunization services are identified		RR	Verify whether the list of private facilities exists in the facility/level	
ME A5.2	Private service providers have been effectively communicated the reporting channel and procedures with contact details		RR/SI	Verify with private service providers and also if documentation is available (letters, meeting minutes, etc.)	
ME A5.3	Primary and secondary care hospitals are involved in reporting of AEFI cases		SI	Verify number of cases reported	

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - B Investigation					
Standard B2	**Preliminary investigation of cases is done as per guidelines**				
ME B2.1	Reporting Medical Officer prepares the list of evidences which will be required for investigation in consultation with DIO		SI/RR	Relevant registers, ANM diaries, session tally sheets, indent records, used and unused vial, diluents, syringes etc. Ask MO/DIO for items to be included in the list of evidence.	
Area of Concern – D Operational Management					
Standard D3	**Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated**				
ME D3.1	Front line worker is aware of her role and responsibilities for AEFI surveillance programme		SI	Ask ANM, ASHA and AWW if they are aware of what to do if there is an AEFI	
ME D3.2	Health Supervisor is aware of his/ her role and responsibility for AEFI surveillance programme		SI	Ask the Health Supervisor regarding his/her role and responsibility in the AEFI surveillance programme. Verify with the current AEFI guideline	
ME D3.3	Medical Officer is aware of his/ her role and responsibility for AEFI surveillance programme		SI	Ask MO and verify with the current AEFI guideline	
Standard D4	**There are established procedures for training and capacity building of personnel involved in AEFI Surveillance**				
ME D4.1	AEFI guidelines are available with key stake holders at all levels		RR/SI	Verify availability of copies of the AEFI guidelines with committee members at all levels: BMO, DIO, SEPIO, others.	
ME D4.2	Training and skill needs assessment has been done for AEFI surveillance programme at all levels		RR/SI	Verify whether the TNA report exists	
ME D4.4	Training has been provided to stakeholders as per schedule		RR	Verify training records	

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard D5	**Immunization sites are prepared for preventing and treating any adverse event following immunization**				
ME D5.1	Parents are counselled for informing about any untoward event of concern following vaccination		OB	Observe interaction at session site and interview parents/ caregivers	
ME D5.2	Antipyretic drugs are provided wherever required		OB, PI	Observe session site and interview parents/caregivers	
ME D5.3	Beneficiaries are observed for 30 minutes after immunization		OB, PI	Observe session site and interview parents/caregivers	
ME D5.4	Emergency drug tray is available at the site of immunization		OB/RR/SI	Verify the emergency tray with the updated available list as per recommendation	
ME D5.5	Protocols and Instructions regarding preventing, identifying, managing AEFI are displayed at the immunization sites		OB	Verify whether the materials are displayed at the session site	
ME D5.6	Vaccinator is aware of what to do in case of any immediate serious reaction/ anaphylaxis		SI	Ask the vaccinator what steps to take in case of a serious reaction/ anaphylaxis	
ME D5.7	Vaccinator is aware of how to prevent immunization error related reactions		SI	Ask the vaccinator how to prevent immunization error related reactions from occurring	

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern – E Communication					
Standard E1	**There are established procedures for regular communication to build and maintain confidence in the Universal Immunization Programme in the community**				
ME E1.1	Key personnel for community engagement have been identified and authorized		SI	List of designated staff	
ME E1.2	Vaccinators and extension workers deliver the four key messages to parents after each vaccination		OB	Observe ANM and ask parents/caregivers the four key messages	
ME E1.3	Vaccinators and extension workers communicate the benefits of RI at VHND sessions		OB	Observe sessions and interactions	
ME E1.4	Advocacy with community Influencers for giving key messages on benefits of immunization		OB/SI/PI	Meeting with VHSNC members, District Medical DMEIO and block panchayati raj members	
Standard E5	**There are established procedures for capacity building of key personnel responsible for communication at each level of administration**				
ME E5.5	Capacity building for social mobilization and advocacy is undertaken for community engagement		SI/PI	Verify by interacting with volunteers, chosen advocates and community	
Area of Concern – F Convergence					
Standard F5	**There are established procedures for coordination with civil administration and law enforcement agencies**				
ME F5.3	There is an established procedure for seeking help of civil administration in case of crisis		RR	Ask for meeting minutes or SOPs or directives or evidences of previous events in which help was sought from civil administration or police	

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - H Quality Management System					
Standard H1	**Quality policy and objectives are defined and disseminated**				
ME H1.2	Quality policy for AEFI surveillance programme is defined		OB/RR/SI	Check quality policy is displayed & staff is aware of quality policy	
ME H1.3	Quality objective for AEFI surveillance is defined		OB/RR/SI	Check quality objectives are displayed. Also check staff is aware of quality objectives	
ME H1.4	Progress in achieving quality objectives is monitored periodically		RR	Check quality objectives are reviewed at periodic intervals	
Standard H2	**Standard Operating Procedures are defined, documented and established at each level**				
ME H2.1	Standard operating procedures for key processes are prepared, approved & updated		RR	Covers following areas: notification & reporting, investigation, causality assessment, operation management, communication, convergence, monitoring & feedback & QMS. Check current version of SOP is available	
ME H2.2	Standard operating procedures are available at point of use		RR/SI	Check relevant part of SOP is available with its process owner	
ME H2.3	Standard operating procedure adequately describe processes & procedures		OB/RR/SI	Check work instructions are displayed	
ME H2.4	Staff is trained & aware of procedures written in SOPs		RR/SI	Verify with the training records and staff interview	
Standard H3	**There are established procedures for internal assessment and periodic reviews**				
ME H3.1	Periodic internal assessments are conducted at various levels at defined intervals		RR	Check whether internal assessment plan & schedule is prepared, internal assessors are identified & trained, records of internal assessment are maintained & person identified to coordinate activities.	

Checklist for Immunization Sites					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME H3.2	Non compliances are enumerated & recorded adequately		RR	Check records are maintained	
ME H3.3	Action plans are made on gaps found during assessment process		RR	Check action plan is reviewed periodically	
ME H3.4	Corrective actions are taken to address the issues, observed in the assessment		RR	Check system is in place to ensure that corrective actions are taken timely	
Standard H4	**Continual Quality Improvement is practiced at each level of AEFI surveillance programme**				
ME H4.2	Action plans are prepared for the low performing areas in stakeholder survey		RR	Check records are available & maintained	
ME H4.3	Internal quality assurance programme for its key processes are in place		RR	Check availability & use of checklist for investigations, causality assessment, communication, monitoring & feedback etc.	
Standard H5	**There is an established procedure to identify and mitigate risks in relation to AEFI programme**				
ME H5.1	Risk management framework is in place for AEFI surveillance Programme		RR	Check availability of risk management framework with commitment to manage risk. Also check availability of plans, relationships, accountabilities, resources, processes and activities to manage all types of risks	
ME H5.2	Risks & opportunities for improvement in all critical processes are identified, analyzed & prioritized		RR/SI	Check whether risks and opportunities are clearly defined including what is acceptable & what is unacceptable, how to eliminate, avoid & mitigate specific risks	
ME H5.3	There is a system in place to take actions to eliminate, avoid & mitigate the risks		RR	Verify risk register	
ME H5.4	There is a system in place to check effectiveness of the actions taken.		RR	Verify risk register	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Notification and Reporting					
Standard A1	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**				
ME A1.3	Person responsible for reporting the AEFI is identified		SI/RR	Ask staff who is responsible for notifying an AEFI	
ME A1.4	Identified person is aware of the categories of AEFI to be notified		RR/SI	Ask staff whether the identified person is aware of the categories of AEFI to be notified	
ME A1.5	Reporting authority and route is communicated		RR/SI	Ask staff whether the identified persons responsible for notification of AEFIs knows whom to notify and how to notify an AEFI	
Standard A3	**There is an established procedure for immediate reporting of serious/severe AEFI cases**				
ME A3.2	List of severe / serious AEFI with case definitions are available with the service provider		SI/RR	Verify whether list of case definitions is available with the service provider	
ME A3.4	Route and timelines of reporting of CRF are communicated		SI	Ask staff whether the identified persons responsible for notification of AEFIs knows whom to notify and how to notify an AEFI	
ME A3.6	EPID number for each case is assigned by District Immunization Officer		SI/RR	Similar to AFP cases in following format: IND-ST-DIS-YR-NUM	
ME A3.7	Completed CRF is forwarded by DIO to State Immunization Officer and National level within 48 hours of AEFI case notification		RR/SI	Verify from CRFs. If there are no CRFs, ask staff	
ME A3.8	CRF are collated and line listed by District Immunization Officer		RR/SI	Verify existence of line list at district level	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard A4	**Preliminary and final case investigation formats are reported as per defined protocol**				
ME A4.1	Formats for PCIF and FCIF are available with the DIO		RR	Verify availability of blank formats of PCIF and FCIF	
ME A4.2	Preliminary Case Investigation form is submitted as per defined route and time line		RR/SI	Verify with the reports submitted	
ME A4.3	Final Case Investigation form is submitted as per defined route and time line		RR/SI	Verify reports submitted	
Standard A5	**There is an established procedure to ensure recording and reporting of AEFI cases from the private sector**				
ME A5.1	Key private facilities providing immunization services are identified		RR	Verify list of private facilities	
ME A5.2	Private service providers have been effectively communicated the reporting channel and procedures with contact details		RR/SI	Verify using letters, meeting minutes, training workshop reports, etc. and interviews	
ME A5.3	Primary and secondary care hospitals are involved in reporting of AEFI cases		SI/RR	Verify records of cases reported/line listed	
ME A5.4	District Immunization authorities are receiving notification/ reports from private sector		RR/SI	Verify records of cases reported/line listed	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - B Investigation					
Standard B1	**Criteria for AEFI cases to be investigated is defined and communicated**				
ME B1.1	List of cases/ events requiring initiation of investigation are available		RR	Check if any list or criteria for cases to be initiated for investigation is available with DIO	
ME B1.2	Criteria for case selection for investigation has been effectively disseminated		SI	DIO is aware of criteria for case selection for investigation: Serious AEFI, Cluster AEFI, suspected immunization error, significant public concern etc.	
ME B1.3	Criteria for case selection for investigation followed by District AEFI Committee		RR	District AEFI Committee is able to demonstrate that it uses criteria for case selection and investigation	
Standard B2	**Preliminary investigation of cases is done as per guidelines**				
ME B2.1	Reporting Medical Officer prepares the list of evidences which will be required for investigation in consultation with DIO		SI/RR	Relevant registers, ANM Diaries, session tally sheets, indent records, used and unused vial, diluent syringes etc. Ask MO/DIO items to be included in the list of evidences	
ME B2.2	Possible sources of information has been mapped and listed before starting the investigation		RR	Check if any list or criteria for cases to be initiated for investigation is available with DIO	
ME B2.3	Used vaccine vials and other material related to AEFI incident is preserved in cold chain		RR/SI	Used vaccine vials and other material related to AEFI incident is preserved at the nearest cold chain point	
ME B2.4	Demographic information has been recorded in PCIF		RR	Patient's name, father's name, mother's name, complete address, gender, address of place of vaccination, type of session, details of investigators (section A - basic details in PCIF)	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME B2.5	Information regarding the vaccine and immunization session related to the AEFI is recorded		RR	Date & time of vaccination, date of first notification, source of notification, details of vaccine received including name of vaccine, dose no., name of manufacturer, batch/ lot no., expiry date, date and time of opening of vial and no. of children vaccinated with the same vial.	
ME B2.6	History of events in chronological order is recorded		RR	Date and time of first symptom, date and time of key symptom, time of hospitalization, date and time of death if occurred and whether post-mortem done or not	
ME B2.7	Previous medical history of the patient is recorded		RR	Past history of similar events, adverse events after previous vaccination, allergy, pre-existing illness, congenital disorder, previous hospitalization history, drug history, family history of any disease, and details of birth including complication (if any) (Section B)	
ME B2.8	Details of first examination of reported AEFI case are recorded		RR	Source of information, signs and symptoms, physical examination, treatment provided and provisional diagnosis (Section C)	
ME B2.9	Details of Immunization processes and practices including any probable immunization error are recorded		RR	Details regarding when patient got immunized, physical condition and sterility of vaccine, reconstitution and handling, and any error in administering the vaccine, type of syringe used, etc. (Section D and E)	
ME B2.10	Cold chain and transport details are recorded in PCIF		RR	Monitoring of temperature, correct storage, use of refrigerator for purposes other than storing vaccines, storage of partially used vaccines and unusable vaccines and diluents in refrigerator/ freezer	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME B2.11	Information gathered from parents and community is recorded		SI	Information regarding and similar cases occurring in the neighborhood / locality /village	
ME B2.12	Case investigation report is reviewed and approved by district AEFI committee		RR/SI	Details of meetings conducted and name and signatures of district AEFI Committee members are recorded in the PCIF	
ME B2.13	Appropriate decision is taken regarding lab investigation of vaccine vials and syringes		RR/SI	Lab investigation is advisable in cluster cases, immunization error and whenever vaccine quality is suspected	
ME B2.14	Provisional clinical diagnosis is framed		RR/SI		
ME B2.15	Available documents related to the event/ investigation are sent with the PCIF within 10 days of notification		RR		
Standard B3	**Final case investigation report is prepared as per guidelines**				
ME B3.1	Patient clinical records have been attached		RR	Copies of patient records including case sheet, discharge summary notes, laboratory and autopsy reports should be attached with FCIF. In case of death occurring at home, verbal autopsy report should be attached.	
ME B3.2	Lab findings of vaccines sent are recorded		RR/SI	Vaccine/diluent sample test reports from CDL Kasauli and test reports for syringes / needles from CDL Kolkata are attached and their findings are recorded in FCIF. In case no samples have been sent for testing, verify awareness of the protocol through staff interview.	
ME B3.3	Updated information regarding patients clinical history and examination are recorded		RR		

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME B3.4	A probable diagnosis is arrived and recorded in final investigation report		RR		
ME B3.5	A final outcome of the patient is recorded		RR		
ME B3.6	Final investigation report is reviewed and approved by District AEFI committee		RR	Details of meeting conducted and names and signatures of district AEFI committee members are recorded in the PCIF	
Standard B4	**A standard is followed for special investigation**				
ME B4.5	Cluster events and sudden unexplained deaths are investigated as per protocol		RR	Line listing of cases, verbal autopsy	
Standard B5	**There is an established procedure for collection of samples for lab investigation**				
ME B5.1	Biological and autopsy samples are taken as per protocol		RR	Appropriate collection of samples, preservation and forwarding to concerned laboratories with adequate documentation.	
ME B5.2	Health officials are aware of correct quantity of vaccine samples to be collected		SI	One set sent to lab, one set to be stored at facility and two sets preserved by Drug Inspector	
ME B5.3	Packing of samples done as per protocol		SI	The cold chain in the form of frozen but conditioned ice packs should be maintained. There should be no adhesive tape on label. There should be appropriate identification details including EPID no. marked on the packet with the official seal of CMO or drug inspector.	
ME B5.4	Documentation of samples done as per protocol		RR	Availability and use of Lab Requisition Form	
ME B5.5	There is provision of storing used vial related with AEFI event in cold chain		SI	Verify at the cold chain point	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME B5.6	Local drug regulatory authorities are involved at all steps of lab testing of vaccines		RR	Decision making, collection, packing, sealing, transportation, feedback on laboratory results	
Area of Concern - D Operational Management					
Standard D1.	**AEFI committees at district, state and national level are constituted and functional**				
ME D1.1	District AEFI Committee has been formally constituted and updated at least once in last 3 years		RR	Verify with the formal letter with names and designations of the members	
ME D1.2	District AEFI committee has adequate representation of stakeholders and experts with names and designations		RR	Verify with the formal letter with names, designations of all stakeholders -representatives of IAP, IMA, municipal corporation, specialists from medical colleges, district hospital and partner agencies	
ME D1.3	Terms of reference and responsibilities of members have been effectively communicated		RR	Verify the copy of TOR	
ME D1.4	District AEFI committee meets at least once in a quarter and minutes are recorded		RR	Verify minutes of meetings	
ME D1.5	District AEFI committee members are actively involved in surveillance activities, case investigation and review of case investigation reports		RR/SI	Verify attendance from PCIF and meeting minutes	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard D3	**Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated**				
ME D3.4	DIO is aware of his/her role and responsibilities for AEFI surveillance programme		RR/SI	Compare role and responsibilities of DIO in current AEFI guidelines	
Standard D4	**There are established procedures for training and capacity building of personnel involved in AEFI surveillance**				
ME D4.1	AEFI guidelines are available with key stake holders at all levels		RR/SI	Verify availability of copy of AEFI Guidelines with all committee members at all levels and with DIO and BMOs.	
ME D4.2	Training and skill needs assessment has been done for AEFI surveillance programme at all levels		RR/SI	Verify using Training Needs Assessment report	
ME D4.3	Training calendar has been prepared as per training needs		RR/SI	Ask for the training calendar at district level and at bloc levels	
ME D4.4	Training has been provided to stakeholders as per schedule		RR	Verify using training records	
ME D4.5	There is a system to take training feedback		RR/SI	Verify training reports for availability of pre and post training evaluation and feedback	
ME D4.6	There is a system to measure training effectiveness		SI	Verify records to check if staff has been interviewed to assess training effectiveness	
Area of Concern - E Communication					
Standard E1	**There are established procedures for regular communication to build and maintain confidence in the Universal Immunization Program in community**				
ME E1.4	Advocacy with community Influencers for giving key messages on benefits of immunization		OB/SI/PI	Meeting with VHSNC, DMEIO members and block panchayati raj members.	
ME E1.5	Health administration regularly disseminates messages through Mid & Mass media regarding benefits of RI		RR	Banners/poster, hoardings, folk media performances, media plan, logbook	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard E2	**There are established procedures for communication in case of serious AEFI event**				
ME E2.1	Protocol for media response is available		SI	Verify with the designated officials	
ME E2.2	Officials are designated to interact with parents and community when an event occurs		RR	Verify name of the designated official interacting with the community	
ME E2.3	Designated spokespersons are identify to interact with media in timely and appropriate manner when an event has occurs		RR	Verify using newspaper cuttings/other sources that the designated spokesperson's version was recorded on the same day and the message was appropriate as per the protocol	
ME E2.4	Specific scanning of media reports is done for the reported AEFI event		RR	Verify documents, IEC officer, district officer	
ME E2.5	Follow up of media reports is done on a daily basis		RR	Verify news records	
Standard E3	**There is a defined strategy for media management at district, state and national level**				
ME E3.1	Scanning media reports is done on a regular basis		RR	Verify media reports	
ME E3.2	List of media contact persons is available with immunization officers		RR	Details of reporters with contact numbers and names	
ME E3.3	There is a system of regular liaison with media houses and journalists at state and national level		SI	Formal and informal media interaction	
ME E3.4	Designated official knows which information should not be prematurely shared with the media		SI	Name and details of the designated spokesperson is available	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard E5	**There is an established procedure for capacity building of key personnel responsible for communication at each level of administration**				
ME E5.1	Key personnel for media management have been identified and authorized		RR	Verify list of key personnel at district, state & national level	
ME E5.2	Formal training for communicating with the community and influencers has been provided		RR	Verify training records, reports of media sensitization workshop	
ME E5.3	Formal training for communicating with media has been provided		RR	Verify using training records	
ME E5.4	Capacity building undertaken for media management		RR	Verify availability of tools, minutes of meeting, workshop, training records	
Area of Concern - F Convergence					
Standard F1	**There are established procedures for coordination with partner agencies**				
ME F1.1	Partner agencies have been identified at each level		RR	Ask for list of AEFI committee members for adequate representation of partner agencies	
ME F1.2	There is an established channel for sharing bilateral information with partner agencies		RR	Verify minutes of coordination meeting with the partner agencies	
Standard F2	**There are established procedures for coordination with drug regulatory authorities**				
ME F2.1	Drug regularity authorities are involved at all levels of AEFI surveillance		RR	Verify list of AEFI committee members for involvement of drug inspector	
ME F2.2	There is an established channel for sharing bilateral information with drug authorities		RR	Ask for shared documents like line lists, cases reported and letters, and minutes of the coordination meeting	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard F3	**There are established procedures for coordination with Pharmacovigilance Programme**				
ME F3.1	Pharmacovigilance authorities are involved at all levels of AEFI surveillance		RR	Verify the list of AEFI committee members for involvement of PVPI	
ME F3.2	There is an established channel for sharing bilateral information with Pharmacovigilance Programme		RR	Verify the list of cases reported through PVPI are shared and investigated through direct reporting system	
Standard F4	**There are established procedures for coordination with professional associations, academic institutions and collaborating centres**				
ME F4.1	List of representatives of professional bodies are available at each level of programme		RR	Verify membership of District AEFI Committee for names and designations from professional bodies	
ME F4.2	There is a system of regular interaction and information sharing with professional bodies		RR	Verify for evidence from records of formal communication and meeting minutes.	
Standard F5	**There are established procedures for coordination with civil administration and law enforcement agencies**				
ME F5.1	Key officials in civil administration and police department are identified at each level		RR/SI	Verify the existence of list of identified officials with contact details	
ME F5.2	Civil administration is regularly updated regarding immunization programme		RR	Verify using records of district task force meeting	
ME F5.3	There is an established procedure for seeking help of civil administration in case of crisis		RR/SI	Verify with the develop protocol, SOP	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - G Monitoring and Feedback					
Standard G1	**Key performance indicators for AEFI program are defined, monitored and analyzed**				
ME G1.1	Key performance indicators are defined at each level		RR	Verify availability of current AEFI Surveillance guidelines with the immunization officer	
ME G1.2	There is a system to gather and update data for generation of indicators on weekly, monthly and quarterly basis		RR	Ask for weekly reports- VPD-H002 and VPD-D001 - and line list of AEFI cases, monthly HMIS reports and quarterly AEFI surveillance analysis reports	
ME G1.3	The indicators are being regularly analyzed at each level		RR	Verify from meeting minutes and other supporting records	
ME G1.4	The quality of data received at all levels is verified regularly		RR	Numbers of serious and severe cases line listed match with the number reported in weekly reporting forms; Number of units reporting serious and severe AEFI match with the total number of reporting units	
ME G1.5	Benchmarks and control limits have been defined for key performance indicators		RR	Verify the availability of current AEFI surveillance guidelines	
Area of Concern - H Quality Management System					
Standard H1	**Quality policy and objectives are defined and disseminated**				
ME H1.2	Quality policy for AEFI surveillance programme is defined		OB/RR/SI	Check Quality Policy is displayed & staff is aware of Quality Policy	
ME H1.3	Quality objective for AEFI surveillance is defined		OB/RR/SI	Check Quality objectives are defined & SMART. Also check staff is aware of Quality objectives	
ME H1.4	Progress toward achieving Quality objectives is monitored periodically		RR	Check Quality objectives are reviewed at periodic intervals	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard H2	**Standard Operating Procedures are defined, documented and established at each level**				
ME H2.1	Standard operating procedures for key processes are prepared, approved & updated		RR	Notification & Reporting, investigation, operation management, communication, convergence, monitoring & feedback & QMS. Check current version of SOP is available	
ME H2.2	Standard operating procedures are available at point of use		RR/SI	Check relevant part of SOP is available with its process owner	
ME H2.3	Standard operating procedures adequately describe processes & procedures		OB/RR/SI	Check work instructions are displayed	
ME H2.4	Staff is trained & aware of procedures written in SOPs		RR/SI	Verify with the training records and staff interview	
Standard H3	**There are established procedures for internal assessment and periodic reviews**				
ME H3.1	Periodic internal assessments are conducted at various levels at defined intervals		RR	Check internal assessment plan & schedule is prepared, internal assessors are identified & trained, records of internal assessment is maintained & person is identified to coordinate activities.	
ME H3.2	Non compliances are enumerated & recorded adequately		RR	Check records are maintained	
ME H3.3	Action plans are made on gaps found during the assessment process		RR	Check action plan is reviewed periodically	
ME H3.4	Corrective actions are taken to address the issues, observed in the assessment		RR	Check system is in place to ensure that corrective actions are taken timely	

Checklist for District Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard H4	**Continual quality improvement is practiced at each level of AEFI surveillance programme**				
ME H4.1	Stakeholder satisfaction surveys are conducted & analyzed at periodic intervals		RR	Check feedback is taken from stakeholders at periodic intervals & it is analyzed	
ME H4.2	Action plans are prepared for the low performing areas in stakeholder survey		RR	Check records are available & maintained	
ME H4.3	Internal quality assurance programme for its key processes are in place		RR	Check availability & use of checklist for investigations, causality assessment, communication, monitoring & feedback etc.	
Standard H5	**There is an established procedure to identify and mitigate risks in relation to AEFI program**				
ME H5.1	Risk management framework is in place for AEFI surveillance programme		RR	Check that risk management framework is available with commitment to manage risk. Also check availability of plans, relationships, accountabilities, resources, processes and activities to manage all types of risks	
ME H5.2	Risks & opportunities for improvement in all critical processes are identified, analyzed & prioritized		RR/SI	Check risk management framework clearly defines what is acceptable & what is unacceptable, how to eliminate, avoid & mitigate the risks	
ME H5.3	There is a system in place to take actions to eliminate, avoid & mitigate the risks		RR	Verify risk register	
ME H5.4	There is a system in place to check effectiveness of the actions taken.		RR	Verify risk register	

National Quality Assurance Standards for AEFI Surveillance Programme

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Notification and Reporting					
Standard A1	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**				
ME A1.3	Person responsible for reporting the AEFI is identified		SI/RR	Ask staff regarding who is responsible for notifying serious AEFIs	
ME A1.4	Identified person is aware of the categories of AEFI to be notified		RR/SI	Ask staff regarding the responsibility for notifying the AEFI	
ME A1.5	Reporting authority and route is communicated		RR/SI	Ask staff whether the identified persons responsible for notification of AEFIs knows whom to notify and how to notify an AEFI	
Standard A3	**There is an established procedure for immediate reporting of serious/severe AEFI cases**				
ME A3.4	Route and timelines of reporting of CRF are communicated		SI		
ME A3.9	CRFs are collated and line listed by State Immunization Officer		RR/SI	Verify availability of line list	
Standard A4	**Preliminary and final case investigation formats are reported as defined protocol**				
ME A4.4	Investigation reports are collated and reported to state & national level as per defined protocol		RR/SI	Verify reports submitted	
Area of Concern - B Investigation					
Standard B1	**Criteria for AEFI cases to be investigated is defined and communicated**				
ME B1.1	List of cases/ events that require initiation of investigation are available		RR	Check if any list or criteria for cases to be initiated for investigation is available with SEPIO/DIO	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME B1.4	State Immunization Officer identifies cases requiring immediate intervention from state level in the form of special investigation		SI/RR	Ask state immunization officer about what type of cases require immediate intervention from State AEFI committee in the form of investigation	
Standard B4	**A standard procedure is followed for special investigation**				
ME B4.5	Cluster events and sudden unexplained deaths are investigated as per protocol		RR	Line listing of cases, verbal autopsy, filled reporting formats	
Area of Concern - C Causality Assessment					
Standard C1	**Case selection for AEFI causality assessment is done as per established criteria**				
ME C1.1	Case selection criteria for Causality Assessment is defined		RR	Verify current AEFI guidelines	
ME C1.2	Causality assessment team is aware of case selection criteria for causality assessment		SI	Selected serious and severe AEFI cases, cases which may be due to immunization error, significant events occurring within 30 days of vaccination, cases causing community or parental concerns, unusual signals	
ME C1.3	Ensure that case records and relevant information are available before commencing the causality assessment		RR/SI	Reporting formats, lab Investigation reports, patient case records, postmortem reports and any other information	
ME C1.4	Responsible officials/ committee have screened the reported AEFI cases for causality assessment		RR	Screening of line list of reported AEFI cases and scanning case records for eligibility for causality assessment to be done at state level	
ME C1.5	All eligible AEFI cases have been subjected to causality assessment		RR	All AEFI cases have been causally assessed by state AEFI committee, verify using line list	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard C2	**Causality question is defined as per protocol**				
ME C2.1	Implicated vaccine is identified provisionally		RR	Verify causality assessment reports	
ME C2.2	A valid diagnosis arrived at based on information provided		RR	Verify causality assessment reports	
ME C2.3	Dedicated causality question is defined for each implicated vaccine		RR	Verify causality assessment reports	
ME C2.4	Objective Causality questions are defined based on the case information		RR	Verify causality assessment reports	
Standard C3	**Causality assessment is done using predefined tools and algorithms**				
ME C3.1	Standard causality assessment report format is available		RR	Verify availability of format in checklist	
ME C3.2	Standard causality assessment report format is used for each case		RR	Verify filled checklist or algorithm	
ME C3.3	Causality assessment algorithm is effectively communicated to the trained experts/ individual		SI	Interview trained experts for awareness of algorithm	
ME C3.4	There is a system for verification of filled checklist, algorithm and classification		SI		
ME C3.5	Causes other than those defined in the investigation reports are considered and consensus reached to accept or reject the association		RR	Verify section 1 of the causality assessment checklist	
ME C3.6	Vaccine Product related causal association is considered and consensus reached to accept or reject the association		RR	Causal association in reference to vaccine product in question is explored with available standard literature	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME C3.7	Immunization error related causal association is considered and consensus reached to accept or reject the association		RR	Any indication regarding probable immunization error is searched in the available investigation report- PCIF	
ME C3.8	Immunization anxiety related causal association is considered and consensus reached to accept or reject the association		RR	Any indication regarding probable immunization anxiety is searched in the available investigation report- PCIF	
ME C3.9	Time window for the reported event following administration of implicated vaccine is considered for causal association		RR	Verify the checklist section 2	
ME C3.10	Evidence against the causal association is considered and consensus reached to accept or reject the evidence of qualifying factors		RR	Verify the checklist section 3	
ME C3.11	Other qualifying factors for classification is considered and consensus reached to accept or reject the evidence of qualifying factors		RR	Verify the checklist section 4	
ME C3.12	Final outcome of causality assessment is classified as per defined categories		RR	As per guidelines.	
ME C3.13	Quality review feedback report is available for completed causality assessment		RR	Verify with the quality review feedback report	
ME C3.14	Final causality assessment report has been signed by the team members		RR	Verify the causality assessment report	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard C4	**There is an established procedure for organizing causality assessment as per defined timelines.**				
ME C4.1	Causality assessment is done by a team of trained experts		RR	Verify with the list of members attending meeting	
ME C4.2	Timeliness and turnaround time for completing different steps of causality assessment are defined		RR/SI	Verify all steps starting from screening of cases for eligibility and completion, selection of complete and eligible cases, preparing a list of cases shortlisted for CA, formation of groups of experts, subjecting the cases to causality assessment, quality review, analysis of classified cases and feedback to all levels.	
ME C4.3	Timeliness and turnaround time for completing different steps of causality assessment are adhered to		RR/SI	Verify that the processes are being followed as per defined steps and timeline	
ME C4.4	There is an established system for tracking and monitoring of cases submitted for causality assessment		RR	Verify using tracking and monitoring sheet	
ME C4.5	Causality assessment reports and other relevant records along with the cases are indexed as per defined protocol		RR	Verify that processes are being followed as per defined protocol in the SOPs	
ME C4.6	Causality assessment reports are securely stored and status updated		OB/RR		
ME C4.7	There is an established procedure for finalizing date of causality assessment meeting and circulation of meeting notice		RR	Verify causality assessment documents	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME C4.8	There is established procedure for training experts for conducting causality assessment		RR	Verify the training records	
ME C4.9	Reviewed and verified CA cases are submitted to the relevant authority at state and national level		RR	Verify the list of approved cases	
Standard C5	**There is an established procedure for taking appropriate action on outcome of causality assessment**				
ME C5.1	Findings of causality assessment are shared with relevant stakeholders		RR/SI	State, DIO, Drug Regulatory authorities, Pharmacovigilance	
ME C5.2	Follow up actions are taken for vaccine product related reactions		RR	CDSCO, PVPI and States, check the evidence with emails, records, minutes	
ME C5.3	Follow-up actions are taken for immunization error related reactions		RR	Check records, minutes of meeting.	
ME C5.4	Follow-up actions are taken for anxiety error related reactions		RR	Check records, minutes of meeting.	
ME C5.5	Coincidental cases are effectively communicated		RR/SI	Check records, minutes of meeting.	
Area of Concern - D Operational Management					
Standard D1	**AEFI committees at district, state and national level are constituted and functional**				
ME D1.6	State AEFI committee has been formally constituted and updated at least once in last three years		RR	Verify formal letter with names and designations of the members	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME D1.7	State AEFI committee has adequate representation of all stakeholders and experts with names and designations		RR	Verify formal letter with names, designations of all stakeholders -representatives of IAP, IMA, specialists from medical colleges and partner agencies	
ME D1.8	State AEFI committee meets at least once in a quarter and minutes are recorded		RR	Verify minutes of meeting	
ME D1.9	Terms of reference and responsibilities of members have been effectively communicated		SI	Verify using AEFI guidelines.	
ME D1.10	State AEFI committee members are actively involved in surveillance activities, case investigations and review of reports		RR	Verify attendance sheet and minutes of meeting	
ME D1.11	State AEFI committee members regularly meet to review AEFI case investigation reports		RR	Verify minutes of the meeting	
ME D1.12	State AEFI committee members conduct causality assessments of all received cases from district		RR	Verify the state causality assessment reports to assess the timeliness of causality assessment of severe and serious AEFIs, to be completed within 100 days of case notification	
Standard D3	**Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated**				
ME D3.5	State immunization Officer is aware of his/her role and responsibility for AEFI surveillance programme		SI	Roles and responsibilities of SEPIO to be compared with those listed in current AEFI guideline	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard D4	**There are established procedures for training and capacity building of personnel involved in AEFI Surveillance**				
ME D4.1	AEFI guidelines are available with key stake holders at all levels		RR/SI	All state AEFI committee members and experts, consultants at all levels: BMO, DIO, SEPIO verify the copy	
ME D4.2	Training and skill needs assessment has been done for AEFI surveillance programme at all levels		RR/SI	Ask for Training Needs Assessment report	
ME D4.3	Training calendar has been prepared as per training needs		RR/SI	Verify using training calendar at state level	
ME D4.4	Training has been provided to stakeholders as per schedule		RR	Verify training records	
ME D4.5	There is a system to take training feedback		RR/SI	Verify that the training reports include pre and post training evaluation and feedback	
ME D4.6	There is a system to measure training effectiveness		SI	Verify records to check if staff has been interviewed to assess training effectiveness	
Area of Concern - E Communication					
Standard E1	**There are established procedures for regular communication to build and maintain confidence in the Universal Immunization Program in community**				
ME E1.5	Health administration regularly disseminates messages through Mid &Mass media regarding benefits of RI		RR/SI	Banners/Poster, hoardings, folk media performances	
Standard E2	**There are established procedures for communication in case of serious AEFI event**				
ME E2.1	Protocol for media response is available		RR	Verify availability of approved protocol with the designated officials	
ME E2.2	Officials are designated to interact with parents and community when an event has occurrs		RR	Verify the list of designated officials	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME E2.3	Designated spokespersons are identify to interact with media in timely and appropriate manner when an event occurs		RR	Verify news records that the designated spokespersons' version was reported the same day or the following day and appropriate message carried as per protocol	
ME E2.4	Specific scanning of media reports is done for the reported AEFI event		RR/SI	Verify scanned media records	
ME E2.5	Follow up of media reports is done on a daily basis		RR	Verify using newspaper cuttings and other records	
Standard E3	**There is a defined strategy for media management at district, state and national level**				
ME E3.1	Scanning of media reports is done on a regular basis		RR	Verify with media report	
ME E3.2	List of media contact persons is available with immunization officers		RR	Details of reporters with contact numbers with and names	
ME E3.3	There is a system of regular liaison with media houses and journalist at state and national level		SI	Formal and Informal media interaction	
ME E3.4	Designated official knows which information should not be prematurely shared with the media		SI		
Standard E4	**There are defined procedures for management of information on social media**				
ME E4.1	There is a formal and authorized social media account for disseminating messages on routine immunization		RR/SI	Verify the social media account	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME E4.2	There is a designated official for addressing social media		RR/SI		
ME E4.3	Social media is regularly scanned for negative reports and rumours		RR	Verify with the reports	
ME E4.4	Routine immunization messages are regularly communicated through social media		RR/SI		
ME E4.5	There is a planned strategy to counter rumours and misinformation on social media		RR	Verify availability of planned strategy	
Standard E5	**There is an established procedure for capacity building of key personnel responsible for communication at each level of administration**				
ME E5.1	Key personnel for media management have been identified and authorized		RR	Verify the list of key personal at state level	
ME E5.3	Formal training for communicating with media has been provided		RR	Verify training records	
ME E5.4	Capacity building has been undertaken for media management		RR	Verify the filled and updated formats as per the media checklist	
Area of Concern - F Convergence					
Standard F1	**There are established procedures for coordination with partner agencies**				
ME F1.1	Partner agencies have been identified at each level		RR	Verify list of AEFI committee members for involvement of partner agencies and adequate representation	
ME F1.2	There is an established channel for sharing bilateral information with partner agencies		RR	Verify minutes of the coordination meeting with the partner agencies	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard F2.	**There are established procedures for coordination with drug regulatory authorities**				
ME F2.1	Drug regularity authorities are involved at all level of AEFI surveillance		RR	Verify list of AEFI committee for involvement of State Drug Controller in meetings	
ME F2.2	There is an established channel for sharing bilateral information with drug authorities		RR	Verify shared documents such as line list, cases reported and letters, minutes of coordination meeting	
Standard F3	**There are established procedures for coordination with Pharmacovigilance program**				
ME F3.1	Pharmacovigilance authorities are involved at all levels of AEFI surveillance		RR	Verify the list of AEFI committee for involvement of PVPI	
ME F3.2	There is an established channel for sharing bilateral information with the Pharmacovigilance Programme		RR	Verify the list of cases reported through PVPI are shared and investigated through direct reporting system	
Standard F4	**There are established procedures for coordination with professional associations, academic institutions and collaborating centres**				
ME F4.1	List of representatives of professional bodies are available at each level of programme		RR	Verify list of state AEFI committee for involvement of PVPI	
ME F4.2	There is a system of regular interaction and information sharing with professional bodies		RR	Verify evidence and records of formal communication	
ME F4.3	Institutions and organizations working in similar domains are identified and collaborated		RR	Verify list of collaborating institutions	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard F5	**There are established procedures for coordination with civil administration and law enforcement agencies**				
ME F5.1	Key officials in civil administration and police department are identified at each level		RR/SI	Verify list of officials with the contact details	
ME F5.2	Civil administration is regularly updated regarding immunization programme		RR	Verify with the records of task force meeting	
ME F5.3	There is an established procedure for seeking help of civil administration in case of crisis		RR/SI		
Area of Concern - G Monitoring and Feedback					
Standard G1	**Key performance indicators for AEFI programme are defined, monitored and analyzed**				
ME G1.1	Key performance indicators are defined at each level		RR	Verify availability of current AEFI Surveillance guidelines with the immunization officer	
ME G1.2	There is a system to gather and update data for generation of indicators on weekly, monthly and quarterly basis		RR	Check for weekly VPD-D001 and VPD-S001, updated line lists, monthly HMIS reports and quarterly AEFI surveillance analysis presentation/report	
ME G1.3	The indicators are being regularly analyzed at each level		RR	Verify from meeting minutes and other supporting records	
ME G1.4	The quality of data received at all levels is verified regularly		RR	Numbers of serious and severe cases linelisted match with the number reported in weekly reporting forms; number of units reporting serious and severe AEFI match with the total number of reporting units	
ME G1.5	Benchmarks and control limits have been defined for key performance indicators		RR	Verify the availability of current AEFI surveillance guidelines	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME G1.6	There is a system to effectively communicate feedback on AEFI surveillance indicator to the lower level on a monthly basis		RR	Verify availability of feedback in the form of letters, presentations and meeting minutes.	
Standard G3	**There is an established procedure for providing timely feedback on reports submitted**				
ME G3.1	There is a defined criteria and checklist to assess completeness and quality of submitted investigation reports		RR	Verify records such as pending documents list, feedback report and checklist	
ME G3.2	Turnaround time for giving feedback on investigation is defined and adhered to		RR	Verify records	
ME G3.3	Follow-up is done on given feedback in stipulated time		RR	Verify with the feedback analysis reports	
Standard G4	**There is an established procedure for providing feedback to the states regarding outcome of findings causality assessments and trend analysis**				
ME G4.2	State ensures that relevant feedback has been communicated to stakeholders at district and facility level		RR	Verify records for communication of feedback in the form of reports, letters, meeting minutes, etc.	
Standard G5	**There is an established procedure to follow up with non-reporting states and districts**				
ME G5.1	Non reporting districts and states are identified periodically		RR	Verify analysis reports which include performance of the states and districts	
ME G5.2	Under reporting districts and states are identified periodically		RR	Verify letters and analysis reports	
ME G5.3	Root cause analysis is done for non-reporting/under reporting district and states		RR	Verify analysis reports	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME G5.5	Follow up action is taken over feed back		RR		
Area of Concern - H Quality Management System					
Standard H1	**Quality policy and objectives are defined and disseminated**				
ME H1.1	Quality team for AEFI surveillance programme is in place & it reviews quality at periodic intervals		RR	Check office order for constitution of Quality team with specified frequency of meetings to review quality of its services	
ME H1.2	Quality policy for AEFI surveillance programme is defined		RR/SI	Check Quality policy is displayed & staff is aware of Quality Policy	
ME H1.3	Quality objective for AEFI surveillance is defined		RR/SI	Check Quality objectives are defined & SMART. Also check whether staff is aware of Quality objectives	
ME H1.4	Progress toward achieving Quality objectives is monitored periodically		RR	Check Quality objectives are reviewed at periodic intervals	
Standard H2	**Standard Operating Procedures are defined , documented and established at each level**				
ME H2.1	Standard operating procedures for key processes are prepared, approved & updated		RR	SOPs are for following areas: notification &reporting, investigation, causality assessment, operations management, communication, convergence, monitoring & feedback & QMS. Check current version of SOP is available	
ME H2.2	Standard operating procedures are available at point of use		RR/SI	Check relevant part of SOP is available with its process owner	
ME H2.3	Standard operating procedures adequately describe processes & procedures			Check work instructions are displayed	
ME H2.4	Staff is trained & aware of procedures written in SOPs		RR/SI	Verify training records and interview staff	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard H3	**There are established procedures for internal assessment and periodic reviews**				
ME H3.1	Periodic internal assessments are conducted at various levels at defined intervals		RR	Check internal assessment plan & schedule is prepared, list of internal assessors identified & trained, records of internal assessment is maintained & person to coordinate activities is identified.	
ME H3.2	Non compliances are enumerated & recorded adequately		RR	Check records are maintained	
ME H3.3	Action plans are made on gaps found during the assessment process		RR	Check action plan is reviewed periodically	
ME H3.4	Corrective actions are taken to address the issues, observed in the assessment		RR	Check system is in place to ensure that corrective actions are taken timely	
ME H3.5	There is a mechanism for validation and analysis of quality indicators to facilitate quality improvement		RR	Verify availability of listed quality indicators and their analysis report	
Standard H4	**Continuous Quality Improvement is practiced at each level of AEFI surveillance programme**				
ME H4.1	Stakeholder satisfaction surveys are conducted & analyzed at periodic intervals		RR	Check feedback is taken from stakeholders at periodic intervals & it is analyzed	
ME H4.2	Action plans are prepared for the low performing areas in stakeholder survey		RR	Check records are available & maintained	
ME H4.3	Internal quality assurance programme for its key processes are in place		RR	Check availability & use of checklist for investigations, causality assessment, communication, monitoring & feedback etc.	

Checklist for State Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME H4.4	The QMS is communicated and coordinated amongst all the staff involved in the AEFI surveillance programme through an appropriate training mechanism		RR/SI	Verify training records and staff interview	
ME H4.5	The quality improvement programme identifies opportunities for improvement based on pre- defined intervals		RR/SI	The frequency of review is defined in the quality manual. However, a review is to be done at least once in four months and should include process indicators, performance indicators and analysis of key surveillance indicators. Check minutes of the review meetings.	
Standard H5	**There is an established procedure to identify and mitigates risks in relation to AEFI programme**				
ME H5.1	Risk management framework is in place for AEFI surveillance Programme		RR	Check that risk management framework is available with commitment to manage risk. Also check availability of plans, relationships, accountabilities, resources, processes and activities to manage all type of risks	
ME H5.2	Risks & opportunities for improvement in all critical processes are identified, analyzed & prioritized		RR/SI	Check that risk management framework clearly defines what is acceptable & what is an unacceptable risk, how to eliminate, avoid & mitigate the risks	
ME H5.3	There is a system in place to take actions to eliminate, avoid & mitigate the risks		RR	Verify risk registers	
ME H5.4	There is a system in place to check effectiveness of the actions taken.		RR	Verify risk registers	

National Quality Assurance Standards for AEFI Surveillance Programme

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Notification and Reporting					
Standard A1	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**				
ME A1.5	Reporting authority and route is communicated		RR/SI	Ask programme manager and staff	
Standard A3	**There is an established procedure for immediate reporting of serious/severe AEFI cases**				
ME A3.10	CRFs are collated, line listed and reported at national level as per defined protocol		RR/SI	Verify line list along with the submission letter/email	
Standard A4	**Preliminary and final case investigation formats are reported as defined protocol**				
ME A4.4	Investigation reports are collated and reported at state & national level as per defined protocol		RR/SI	Verify with the reports submitted	
Area of Concern - B Investigation					
Standard B1	**Criteria for AEFI cases to be investigated is defined and communicated**				
ME B1.1	List of cases/ events that require initiation of investigation are available		RR	Check if any list or criteria for cases to be initiated for investigation is available with programme manager and staff	
ME B1.5	Cases requiring immediate intervention in investigation at national level are identified.		SI/RR	National AEFI secretariat should have list of criteria to identify cases requiring immediate attention in form of investigation by national experts (Immunization Division, National AEFI Committee, DCG(I))	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard B4	**A standard procedure is followed for special investigation**				
ME B4.1	Case / events requiring special investigation are defined		RR/SI	Clusters, request from state, media attention through reports, serious AEFI reported after new vaccine introduction (for national level) and in cases recommended by national experts (Immunization Division/Technical Collaborating Centre/National AEFI Committee)	
ME B4.2	Timelines and authority for initiating special investigation are defined and practiced		RR/SI	Decision is taken by DC (UIP), Technical Collaborating Centre, National AEFI Committee members, and Secretariat staff. Team is formed and send for investigation within predefined days of receipt of request/notification.	
ME B4.3	Special investigation team has representation of relevant domain experts		RR	The investigation team should have experts from the national level (including drug regulators) and State AEFI Committee. The SEPIO should be a member. The team should have a paediatrician, epidemiologist and a programme officer.	
ME B4.4	Team ensures that all relevant documents, records and information is available before commencing the investigation		SI	Available reports, patients records, map of area , media reports , analysis of AEFI in the event area and similar events reported through other sources like IDSP	
ME B4.5	Cluster events and sudden unexplained deaths are investigated as per protocol		RR	Check line list and investigation reports	
ME B4.6	Field visit is done as per protocol		SI	Visit to session site, onsite observation, assessment of cold chain during storage and transportation, interview with service providers, health officials and community/ parents	
ME B4.7	Clinical and epidemiological investigation is done as per protocol		RR/SI	Review of patient records, lab reports and epidemiological data	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME B4.8	Lab findings of vaccines sent for testing are recorded		RR	Report from CDL Kasauli for syringes /diluent and syringes / needles from CDL Kolkata are attached and their findings are recorded in FCIF. If no samples have been sent for lab investigations verify that the staff is familiar with the procedure	
ME B4.9	Provisional conclusions is arrived in final report of special investigation		RR	Verify the final report	
ME B4.10	Submitted report is adequate		RR	Should have all the required sections with details, such as team composition, background and reason for special investigation, details of individual cases (including clinical details), cold chain examination, assessment of injection safety practices, epidemiological investigation, clinical records review, probable clinical diagnosis, conclusion and recommendations as per the Protocol for Special Case Investigations.	
ME B4.11	Submitted report is time bound		RR	As per current protocol	
Area of Concern - C Causality Assessment					
Standard C1	**Case selection for AEFI causality assessment is done as per established criteria**				
ME C1.1	Case selection criteria for Causality Assessment is defined		RR	Verify with the current AEFI guidelines	
ME C1.2	Causality assessment team is aware of case selection criteria for causality assessment		SI	All reported and investigated serious and severe AEFI cases are eligible for causality assessment with all completed investigation reports and other supporting documents such as hospital records, verbal autopsy forms and post mortem reports.	
ME C1.3	Ensure that case records and relevant information are available before commencing causality assessment		RR/SI	Reporting formats, lab Investigation reports, patient case records, Postmortem reports, etc.	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME C1.4	Responsible officials/ committee has screened the reported AEFI cases for causality assessment		RR	The line lists and reporting/ investigation formats are screened for missing pages and information. Attempts are made to get the missing reports/information. Then the cases are considered for eligibility for causality assessment.	
ME C1.5	All eligible AEFI cases have been subjected to causality assessment		RR	The State AEFI Committees causally assess all reported and investigated cases. The National AEFI Committee will assess only a certain proportion of the cases causally assessed by the State Committees.	
Standard C2	**Causality question is defined as per protocol**				
ME C2.1	Implicated vaccine is identified provisionally		RR	Verify causality assessment report	
ME C2.2	A valid diagnosis is arrived at based on information provided		RR	Verify causality assessment report	
ME C2.3	Dedicated causality questions is defined for each implicated vaccine		RR	Verify causality assessment report	
ME C2.4	Objective causality questions are defined based on the case information		RR	Verify causality assessment report	
Standard C3	**Causality assessment is done using predefined tools and algorithms**				
ME C3.1	Standard causality assessment report format is available		RR	Verify causality assessment report receive from state and also availability of blank formats for preparation for Causality assessment meetings.	
ME C3.2	Standard causality assessment report format is used for each case		RR	Verify causality assessment records for filled checklist, algorithm	
ME C3.3	Causality assessment algorithm is effectively communicated to the trained experts/ individuals		SI	Interview trained experts for awareness of algorithm	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME C3.4	There is a system for verification of filled checklist, algorithm and classification		SI		
ME C3.5	Causes other than those defined in the investigation reports are considered and consensus reached to accept or reject the association		RR	Verify section 1 of the causality assessment checklist	
ME C3.6	Vaccine Product related causal association is considered and consensus reached to accept or reject the association		RR	Causal association in reference to vaccine product in question is explored with available standard literature	
ME C3.7	Immunization error related causal association is considered and consensus reached to accept or reject the association		RR	Any indication regarding probable immunization error is searched in the available investigation report- PCIF	
ME C3.8	Immunization anxiety related causal association is considered and consensus reached to accept or reject the association		RR	Any indication regarding probable immunization anxiety is searched in the available investigation report PCIF	
ME C3.9	Time window for the reported event following administration of the implicated vaccine is considered for causal association		RR	Verify the checklist section 2	
ME C3.10	Evidence against the causal association is considered and consensus reached to accept or reject the evidence		RR	Verify the checklist section 3	
ME C3.11	Other qualifying factors for classification is considered and consensus reached to accept or reject the qualifying factors		RR	Verify the checklist section 4	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME C3.12	Final outcome of causality assessment is classified as per defined categories		RR	Consistent causal association (A1, A2, A3, A4), Indeterminate (B1, B2), Inconsistent causal association (C) and unclassifiable (D)	
ME C3.13	Quality review feedback report is available for completed causality assessment		RR	Verify availability of quality review feedback report	
ME C3.14	Final causality assessment report has been signed by the team members		RR	Verify causality assessment report for signatures	
Standard C4	**There is an established procedure for organizing causality assessment as per defined timelines.**				
ME C4.1	Causality assessment is done by a team of trained experts		RR	Verify list of experts who have attended previous meetings	
ME C4.2	Timeliness and turnaround time for completing different steps of causality assessment are defined		RR/SI	Verify for all steps from records, line lists and other records	
ME C4.3	Timeliness and turnaround time for completing different steps of causality assessment are adhered to		RR/SI	Verify the processes are being followed for all steps as per defined timeline	
ME C4.4	There is an established system for tracking and monitoring of cases submitted for causality assessment		RR	Verify using the tracking and monitoring sheet	
ME C4.5	Causality assessment reports and other relevant records along with the cases are indexed as per defined protocol		RR	Verify the process are being followed as per defined protocol in the SOPs	
ME C4.6	Causality assessment reports are securely stored and status updated		RR		

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME C4.7	There is an established procedure for finalizing date of causality assessment meeting and circulation of meeting notice		RR	Verify causality assessment documents	
ME C4.8	There is an established procedure for training experts for conducting causality assessment		RR	Verify the training records	
ME C4.9	Reviewed and verified CA cases submitted to the relevant authority at National level AEFI committee for approval		RR	Verify list of approved cases	
Standard C5	**There is an established procedure for taking appropriate action on outcome of causality assessment**				
ME C5.1	Findings of causality assessment are shared with relevant stakeholders		RR/SI	Ask for communication regarding results of causality to states, drug regulators, pharmacovigilance partners	
ME C5.2	Follow up actions are taken for vaccine product related reactions		RR	Check evidence in form of letters / emails, etc.	
ME C5.3	Follow-up actions are taken for immunization errors related reaction		RR	Check evidence in form of letters / emails, etc.	
ME C5.4	Follow-up actions are taken for anxiety error related reactions		RR	Check evidence in form of letters / emails, etc.	
ME C5.5	Coincidental cases are effectively communicated		RR/SI	Check evidence in form of letters / emails, etc.	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - D Operational Management					
Standard D1	**AEFI committees at district, state and national level are constituted and functional**				
ME D1.13	National AEFI committee has been formally constituted and updated atleast once in last 3 years		RR	Ask for formal letter with name and designation of the members	
ME D1.14	National AEFI committee has adequate representation of stakeholders and experts with names and designations		RR	Check the list of committee members	
ME D1.15	National AEFI committee meets at least once in a quarter and minutes are recorded		RR	Verify meeting minutes	
ME D1.16	Terms of reference and responsibilities of members have been effectively communicated		SI	Verify order for TORs	
ME D1.17	National AEFI committee members are actively involved in surveillance activities , investigation and review of reports		RR	Verify attendance and meeting minutes	
ME D1.18	The four subcommittees are active in ensuring timeliness of deliverables		SI	Verify the records	
ME D1.19	Special cases, vaccine product related, vaccine quality defect related and immunization error related death are discussed by the Chairperson of the National AEFI committee and Chairperson of four sub committees		RR	Verify meeting minutes	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard D2	**There is an established procedure for functioning of the National AEFI committee secretariat**				
ME D2.1	There is a procedure for sharing of AEFI data received at the national level		RR	Verify the protocol	
ME D2.2	Documented procedures exist for storing and retrieving of data		RR/SI	Verify the electronic database and the hardcopy data base	
ME D2.3	There is a designated person for documenting and entering received data		SI		
ME D2.4	Procedure exists for maintaining confidentiality, security and integrity of records, data and information		RR	Verify the records	
ME D2.5	Procedure exists for retention and disposal of AEFI records		RR	Verify the procedure by record review	
ME D2.6	There is a system for monitoring internal processes of the national AEFI secretariat		RR/SI	Verify the monitoring sheet and checklist	
ME D2.7	There is an established procedure for entertaining requests under RTI		RR		
Standard D3	**Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated**				
ME D3.6	DC (Immunization) is aware of his/ her role and responsibilities for AEFI surveillance programme		SI	Verify using current AEFI guidelines	
ME D3.7	Technical staff at National AEFI Secretariat are aware of their roles and responsibilities for the AEFI surveillance programme		SI/RR	Verify Roles and responsibilities of technical staff at the AEFI Secretariat using current AEFI guidelines and SOPs	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard D4	**There are established procedures for training and capacity building of personnel involved in AEFI Surveillance**				
ME D4.1	AEFI guidelines are available with key stake holders at all levels		RR/SI	Check availability of AEFI guidelines with DC (Immunization), national experts, members of Technical Collaborating Centre and national AEFI committee and staff of Secretariat.	
ME D4.2	Training and skill needs assessment has been done for AEFI surveillance programme at all levels		RR/SI	Check TNA report	
ME D4.3	Training calendar has been prepared as per training needs		RR/SI	Ask for training calendar at national level.	
ME D4.4	Training has been provided to stakeholders as per schedule		RR	Verify training records	
ME D4.5	There is a system to take training feedback		RR/SI	Verify that the training reports include pre and post training evaluation and feedback	
ME D4.6	There is a system to measure training effectiveness		SI	Ask for plans for assessing training effectiveness	
Area of Concern - E Communication					
Standard E1	**There are established procedures for regular communication to build and maintain confidence in the Universal Immunization Programme in community**				
ME E1.4	Health administration regularly disseminates messages through Mid & Mass media regarding benefits of RI			Banners/posters, hoardings, folk media performances, media plan, logbook	
Standard E2	**There are established procedures for communication in case of a serious AEFI event**				
ME E2.1	Protocol for media response is available			Verify with the designated officials	
ME E2.3	Designated spokespersons are identified to interact with media in timely and appropriate manner when an event has occurs			Verify news cuttings to see if designated spokesperson's version was reported the same day and appropriate message was given and carried as per protocol	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME E2.4	Specific scanning of media reports is done for the reported AEFI			Verify documents and talk to IEC/communication officers, etc.	
ME E2.5	Follow up of media reports is done on a daily basis			Verify newspaper cuttings	
Standard E3	**There is a defined strategy for media management at district, state and national level**				
ME E3.1	Scanning of media reports is done on a regular basis			Check newspaper cuttings and other records	
ME E3.2	List of media contact persons is available with immunization officers			Ask for list of reporters with contact details	
ME E3.3	There is a system of regular liaison with media houses and journalists at state and national level		SI	Ask for evidence of regular formal/informal media interactions	
ME E3.4	Designated official knows which information should not be prematurely shared with the media		SI	Name and details of the designated spokesperson/s is available	
Standard E4	**There are defined procedures for management of information on social media**				
ME E4.1	There is formal and authorized social media account for disseminating messages on routine immunization		RR/SI	Verify the social media account	
ME E4.2	There is a designated official for addressing social media		RR/SI		
ME E4.3	Social media is regularly scanned for negative reports and rumours		RR	Verify with the reports	
ME E4.4	Routine immunization messages are regularly communicated through social media		RR/SI		

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME E4.5	There is a planned strategy to counter rumours and misinformation on social media			Verify availability of planned strategy	
Standard E5	**There is an established procedure for capacity building of key personnel responsible for communication at each level of administration**				
ME E5.2	Key personnel for media management have been identified and authorized			Check the availability of the list of key personal at national level	
ME E5.3	Formal training for communicating with media has been provided			Verify training records	
ME E5.4	Capacity building has been undertaken for media management			Verify tools available as well as training and workshop records	
Area of Concern - F Convergence					
Standard F1	**There are established procedures for coordination with partner agencies**				
ME F1.1	Partner agencies have been identified at each level		RR	Verify using list of AEFI committee members for involvement of partner agencies and adequate representation	
ME F1.2	There is an established channel for sharing bilateral information with partner agencies		RR	Verify the minutes of coordination meeting with the partner agencies	
Standard F2	**There are established procedures for coordination with drug regulatory authorities**				
ME F2.1	Drug regularity authorities are involved at all levels of AEFI surveillance		RR	Verify using list of AEFI committee members for involvement of drug regulators (CDSCO/DCGI/PVPI)	
ME F2.2	There is an established channel for sharing bilateral information with drug authorities		RR	Ask for online file sharing mechanism, cover letters of case reports sent to DCGI every fortnight, line list with results of causality assessment with vaccine details, etc. and minutes of partners coordination meetings	
Standard F3	**There are established procedures for coordination with Pharmacovigilance Programme**				
ME F3.1	Pharmacovigilance authorities are involved at all levels of AEFI surveillance		RR	Verify AEFI committee membership for involvement of PVPI	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME F3.2	There is an established channel for sharing bilateral information with pharmacovigilance programme		RR	Verify emails informing AEFI cases reported through PVPI and list of cases, online file sharing platform, minutes of partners meeting, etc.	
Standard F4	**There are established procedures for coordination with professional associations , academic institutions and collaborating centres**				
ME F4.1	List of representatives of professional bodies are available at each level of the programme		RR	Verify list of committee members for representation from professional bodies	
ME F4.2	There is a system of regular interaction and information sharing with professional bodies		RR	Ask for evidence and records of formal communication	
ME F4.3	Institutions and organizations working in similar domains are identified for collaborated		RR	Ask for list of collaborating institutions	
Standard F5	**There are established procedures for coordination with civil administration and law enforcement agencies**				
ME F5.1	Key officials in civil administration and police department are identified at each level		RR/SI	Verify the list of identified officials with the contact details	
ME F5.3	There is an established procedure for seeking help of civil administration in case of crisis				
Area of Concern - G Monitoring and Feedback					
Standard G1	**Key performance indicators for AEFI program me are defined, monitored and analyzed**				
ME G1.1	Key performance indicators are defined at each level		RR	Verify using current AEFI Surveillance guidelines with the immunization manager and other staff	
ME G1.2	There is a system to gather and update data for generation of indicators on weekly, monthly and quarterly basis		RR	Weekly reports- VPD-S001, line lists; Monthly HMIS reports and Quarterly AEFI surveillance analysis reports and presentations	
ME G1.3	The indicators are being regularly analyzed at each level		RR	Verify from meeting minutes and other supporting records	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME G1.4	The quality of data received at all levels is verified weekly regularly		RR	Numbers of serious and severe cases line listed match with the numbers reported in weekly reporting forms; number of units reporting serious and severe AEFI match with the total number of reporting units	
ME G1.5	Benchmarks and control limits have been defined for key performance indicators		RR	Verify from current AEFI surveillance guidelines	
ME G1.6	There is a system to effectively communicate feedback on AEFI surveillance indicators to the lower levels on a monthly basis		RR	Ask for letters/emails and other records	
Standard G2	**There are established procedures for scanning of different sources for identifying signals for AEFI cases**				
ME G2.1	There is a system to analyze data and trends to identify potential signals		SI/RR	Ask for weekly updates and reviews, monthly review meetings and reports	
ME G2.2	There is a system for identifying, documenting and communicating signals to relevant stakeholders		SI/RR	Ask for AEFI Secretariat staff regarding the process of signal detection and communication	
ME G2.3	There is a system to take action on identified signals		SI/RR	Ask Secretariat staff regarding the signal detection and communication	
Standard G3	**There is an established procedure for providing timely feedback on reports submitted**				
ME G3.1	There is a defined criteria and checklist to assess completeness and quality of submitted investigation reports		RR	Verify records/emails, letters to states and districts for incomplete reports, incorrect entries, pending documents and investigation reports	
ME G3.2	Turnaround time for giving feedback on investigation is defined and adhered to		RR	Verify records	
ME G3.3	Follow-up is done on given feedback in stipulated time		RR	Verify using feedback analysis reports	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard G4	**There is an established procedure for providing feedback to the states regarding outcome of findings causality assessments and trend analysis**				
ME G4.1	Periodic feedback is given to states on trend analysis of key performance indicators		RR	Ask for analysis reports shared with states or state performance presentation	
Standard G5	**There is an established procedure for follow up with non-reporting states and districts**				
ME G5.1	Non reporting districts and states are identified periodically		RR	Verify analysis reports with state-wise and district-wise performance	
ME G5.2	Underreporting districts and states are identified periodically		RR	Verify letters with analysis reports	
ME G5.3	Root cause analysis is done for non-reporting/under reporting districts/ states		RR	Verify analysis reports and presentations	
ME G5.4	Feedback on non/ under reporting district is given to states		RR	Verify letters/emails/meeting minutes in which feedback has been sent to states	
ME G5.5	Follow up action is taken over feed back		RR	Check records for correspondence	
Area of Concern - H Quality Management System					
Standard H1	**Quality policy and objectives are defined and disseminated**				
ME H1.1	Quality team for AEFI surveillance programme is in place & it reviews the quality at periodic intervals		RR	Check office order for constitution of Quality team & team meets at defined intervals to review quality of its services	
ME H1.2	Quality policy for AEFI surveillance Programme is defined		RR/SI	Check quality policy is displayed & staff is aware of quality policy	
ME H1.3	Quality objective for AEFI surveillance is defined		RR/SI	Check quality objectives are defined & SMART. Also check staff is aware of quality objectives	
ME H1.4	Progress towards achieving quality objectives is monitored periodically		RR	Check quality objectives are reviewed at periodic intervals	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard H2	**Standard Operating Procedures are defined, documented and established at each level**				
ME H2.1	Standard operating Procedures for key processes are prepared, approved & updated		RR	Ask for current version of SOPs: notification &reporting, investigation, causality assessment, operation management, communication, convergence, monitoring & feedback & QMS.	
ME H2.2	Standard operating procedures are available at point of use		RR/SI	Check that relevant part of SOP is available with its process owner	
ME H2.3	Standard operating procedure adequately describes processes& procedures			Check work instructions are displayed	
ME H2.4	Staff is trained & aware of procedures written in SOPs		RR/SI	Verify though training records and staff interviews	
Standard H3	**There are established procedures for internal assessment and periodic reviews**				
ME H3.1	Periodic internal assessments are conducted at various levels at defined intervals		RR	Check availability of internal assessment plan and see if schedule is prepared, internal assessors are identified & trained, records of internal assessment are maintained & a person is identified to coordinate activities.	
ME H3.2	Non compliances are enumerated & recorded adequately		RR	Check records are maintained	
ME H3.3	Action plans are made on gaps found during the assessment process		RR	Check action plan is reviewed periodically	
ME H3.4	Corrective actions are taken to address the issues observed in the assessment		RR	Check system is inplace to ensure that corrective actions are taken timely	
ME H3.5	There is a mechanism for validation and analysis of quality indicators to facilitate quality improvement		RR	Verify the listed quality indicators and analysis reports	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Standard H4	**Continuous Quality Improvement is practiced at each level of AEFI surveillance program**				
ME H4.1	Stakeholder satisfaction surveys are conducted & analyzed at periodic intervals		RR	Check feedback is taken from stakeholders at periodic intervals & it is analyzed	
ME H4.2	Action plans are prepared for the low performing areas in stakeholder surveys		RR	Check records are available & maintained	
ME H4.3	Internal quality assurance programme for its key processes are in place		RR	Check availability & use of checklist for investigations, causality assessment, communication, monitoring & feedback etc.	
ME H4.4	The QMS is communicated and coordinated amongst all the staff involved in the AEFI surveillance programme through an appropriate training mechanism		RR/SI	Verify training records and interview staff	
ME H4.5	The quality improvement programme identifies opportunities for improvement based on pre- defined intervals		RR/SI	As quality improvement is a dynamic process, it needs to be reviewed at regular pre-defined intervals, as defined by the organization in the quality improvement manual but at least once in four months, The review shall include the performance indicators, analysis of key indicators as identified and determined, including the mandatory indicators, and minutes of the review meeting that are recorded and maintained	
Standard H5	**There is an established procedure to identify and mitigate risks in relation to the AEFI programme**				
ME H5.1	Risk management framework is in place for AEFI surveillance programme		RR	Check risk management framework and whether it has plans, relationships, accountabilities, resources, processes and activities to manage all types of risks	
ME H5.2	Risk & opportunities for improvement in all critical processes are identified, analyzed & prioritized		RR/SI	Check that the risk management framework clearly defines what are acceptable & what are unacceptable risks and how to eliminate, avoid & mitigate risks	

Checklist for National Level					
Reference No.	**Measurable Element**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
ME H5.3	There is a system in place to take actions to eliminate, avoid & mitigate risks		RR	Verify the risk registers	
ME H5.4	There is a system in place to check effectiveness of actions taken.		RR	Verify the risk registers	

Annexures

Assessment Report

A. Score Card

Score card				
Level Immunization site/district/state/national				
	Area of concern	**Maximum Score**	**Score received**	**Percentage**
A.	Notification & Reporting			
B.	Investigation			
C.	Causality Assessment			
D.	Operational Management			
E.	Communication			
F.	Convergence			
G.	Monitoring and Feedback			
H.	Quality Management system			

B. MAJOR GAPS OBSERVED

1.....

2.....

3.....

4.....

C. STRENGTHS/BEST PRACTICES

1.....

2.....

3.....

D.RECOMMENDATIONS/OPPORTUNITIES FOR IMPROVEMENT

1.....

2.....

3.....

Names and Signature of Assessors

Date-

Key Performance Indicators

S.No	Indicator	State	National
1	Number of serious/severe AEFI cases reported annually	✓	✓
2	Percentage of districts reporting serious/severe cases in a year	✓	✓
3	Percentage of serious/severe AEFIs with CRF shared with state/centre on time	✓	✓
4	Percentage of serious/severe AEFIs with PCIF reported on time	✓	✓
5	Percentage of serious/severe AEFIs with FCIF reported on time	✓	✓
6	No of Cases With Complete Document (FIR/PIR/DIR)	✓	✓
7	Percentage of serious/severe AEFI cases causally classified by the National AEFI committee	✓	✓
8	Percentage of states conducting at least three state AEFI committee meetings in a year	✓	✓
9	Number of districts having AEFI committees	✓	✓
10	Number of cases for which feedback on CRF has been sent to state/district	✓	✓
11	Percentage of death cases in which post mortem has been done and preliminary report received	✓	✓
12	Number of cases notified by private sector (through private practitioners/ IDsurv/) reported	✓	✓
13	Number of cases notified by ADR Monitoring Centres / PvPI reported	✓	✓
14	Percentage of CRF feedback sent on time	×	✓
15	Percentage of Case with errors occurring in line list during entry	×	✓
16	Percentage of revised CRF received	×	✓

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