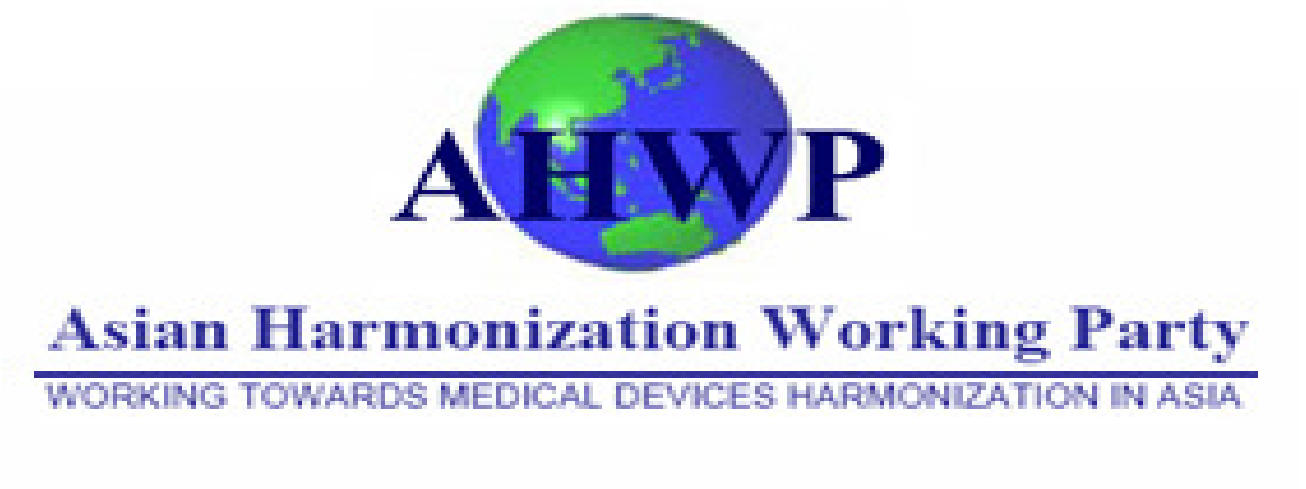


Asian Harmonization Working Party

WG 03
Work Items

Ali Al dalaan
Vice Chair AHWP –TC
Chair,WG3
Dir.,Technical support and Info Dept.,Saudi FDA
Hong kong 04-07 Nov.2009

AHWP WG03 Work Items

Team setup

- Request to AHWP member economy for nomination
- Select WG3: review CV
- First teleconference held on 24 Mar 2009
  - Finalized work plan for 2009-2011
  - Reviewed comments on N17 (SG3 guidance document)

AHWP WG03 Work Items

Team setup

Name	Country
Chair – Ali M. Al-Dalaan	Saudi Arabia
Co-Chair – Ronald Goon	Singapore
Senior Advisor – Prof. Tony C. Chan	USA
Mr. Jason Ho	Hong Kong
Ms. Jeong Jin Jo	Korea
Kulveen Singh Bali	India
Mr. Davey Han	People's Republic of China
Mr. Jizhong Jin	
Mr Huang Jin	People's Republic of China
Asok Kumar	
Mr. Darly Kuriakose	
Dr. Vincent Chee Choong Lam	Malaysia
Ee Bin Liew	Singapore
Mr. Tony Low	
Ms. Rani Malli	India
Mr. Tim Mission	
Yean Ting Ong	Malaysia
Doki Park	Korea
Mrs. L. G. Smitha	India
Mr. Bryan So	Hong Kong
Ms. Christine Tsai	Hong Kong
Ms. Carol Jirui Yan	People's Republic of China
Sateesh Yelisetti	India

AHWP WG03 Work Items

- Second teleconference held on 25 Aug 2009
  - Reviewed further comments on N17 (SG3 guidance document)
  - Reviewed draft of N18 rev 5 (SG3 guidance document on corrective action)
  - Reviewed proposed Corrigendum to ISO13485:2003
  - Discussed proposed new SG3 draft guidance N19 on classification of audit observations

AHWP WG03 Work Items

- ***Objectives and strategic plan***

- Liaison with GHTF

❖ Establish WG3 representative with GHTF SG3
❖ Chair WG3
❖ Vice chair
- GHTF SG3Chair, formal invitation
- Jun,2008
- February 2009

❖ GHTF SG3 Chair & Co-chair
❖Invited as members of WG3

AHWP WG03 Work Items

For example

- **GHTF - SG3 Participants List**

Limerick, Ireland, September 21-24, 2009
Limerick Strand Hotel, 6th Floor
Ennis Road, Limerick, Ireland.
T: +353 (0)61 421 800
F: +353 (0)61 421 866

Name	Country/ Region	Govt	Industry	Observer	Association	Attend SG3
Al Dalaan, Ali		**X**			**AHWP**	✓
Arglebe, Carlos	EU		X		COCIR	✓
Asai, Hideki			X		JFMDA	✓
Cobbold, Egan	CAN	X			HC	✓
Devereux, Emmett	EU		X		EUCOMED	✓
Dorman-Smith, Victor	EU		X		EUCOMED	✓
Goon, Ronald			**X**		**AHWP**	✓
Gurney, Laila			X		MEDEC	✓
Hashimoto, Tokiko		X			MHLW	✓
Kopesky, Ken			X		AdvaMed	✓
Makino, Tsutomu		X			PMDA	✓
Nakamura, Munehiro			X		JFMDA	✓
Smith, Keith		X			TGA	✓
Sardeson, Scott			X		AdvaMed	✓
Trautman, Kim		X			FDA	✓
Wetzel, Dirk	EU	X			BfArM	✓
Observers						
Seppanen, Holly			X	X	Tech Expert	✓
McRoberts, Steve	EU		X	X	UL / Tech Expert	✓
Hokao, Hidetaka		X		X	Govt	✓
Kimmelman, Ed	US			X	Chair TC210/WG1	✓
Regrets						
Frey, Gunter			X		NEMA	No
Miyamoto, Yuichi		X		X	PMDA	No
Nicol, Ken			X		MTAA	No

AHWP WG03 Work Items

- **Objectives and strategic plan continue:**
  - Harmonization between WG3 & SG3
    - » Chair of WG3 & the chair SG3 discussed in general terms the value and benefits of the AHWP & GHTF enhancing their work together on common projects related to MD Regulation
    - » One or more members of the AHWP WG3 join the GHTF SG3 as permanent member.
    - » Enable WG3 members to participate their opinion and comments in the development of SG3 guidance documents and ISO developed medical device quality management system standards.
    - » Encourage increased understanding on the benefits of harmonization
    - » Facilitate a linkage with the Global Harmonization Task Force (GHTF)
  - Forge a common direction for the harmonization of medical device regulation in AHWP
  - Provide a forum for discussion and training, facilitate information exchange and initiate projects relating to GHTF harmonization among regulators and industry groups in AHWP
  - Seek to establish AHWP as a formal regional grouping within GHTF

AHWP WG03 Work Items

Participated and REVIEW OF GHTF SG3 documents

- N17 Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers
- N18 management system – Medical Devices – Guidance on corrective action and preventive action
- SG3 New Work Item Proposal N19

AHWP WG03 Work Items

- WG3 Chair and Co-chair participated in GHTF SG3 meeting to develop and review guidance documents N17, N18 and N19
- WG3 members reviewed and provided their comments for previous documents

AHWP WG03 Work Items

Setup comments format

AHWP WG3: Quality Management System

Document number: GHTF/SG3/N17:2008

& Title: Quality Management System – Medical Devices –

Guidance on the Control of Products and Services Obtained from Suppliers

Submitted by (name): Jin Huang Economy Member / Industry: China / Shenzhen Association of Medical Devices On: 25/02/2009

Comment Number	Economy Member / Industry (e.g. SFDA)	Page / Section / Line	Editorial or Technical	Comment	Proposed revised text	WG3 Decision (& date)
1	/ Shenzhen Association of Medical Device	Page 5 / Section 1.0 / Line 14~16	Technical	Internal audit scope should not be only criterion to identify whether the supplier operates under a separate quality management system. The reason is as following: For example, some organization has several manufacturing sites (might be in different countries). But they are under same quality management system. One of manufacturing sites might be chose as the manufacturer of some medical devices, and the other manufacturing sites provide sub-assembling to the manufacturer. If the management review scope of this organization includes all of these manufacturing sites or external audit scope includes all of these manufacturing sites, all of these manufacturing sites should be considered under the same quality management system.	Change the line 14~ Page 5 to: For example, if the supplier is neither a part of the manufacturer's internal and external audit scope nor within a same management review scope, then the supplier is under a separate quality management system and is considered an internal supplier.	
2	/ Shenzhen Association of Medical Device	Page 14 / Section / Line 10	Technical	Regarding "intellectual property", the controls should not only include "Protection of intellectual property", but also manufacturer should ask the supplier to disclose requested information to regulatory authorities for approval of medical devices for commercial sale and distribution. Usually this kind of requirements could be clearly defined in a contractual agreement.	Add the following information under Line Page 14. ●Disclose requested information to regulatory authorities for approval of medical devices for commercial sale and distribution	

AHWP WG03 Work Items

- **Setup Agenda Format**

Agenda
AHWP WG3 Teleconference
March 24, 2009
10:00 – 11:20 Australia

Item		Topic	Support Documents
	10:00 am	**Start**	
1	5 min	Welcome •Introductions •Opening Remarks	
2	15 min	Members introduction	
3	15 min	Work plan 2009-2011	
4	30 min	Review comments on received GHTF SG3 N17	 Commentstemplate (2) - ee bin comments
5	10 min	Election and appointment of WG3 secretary	
6	5 min	Next and Future Teleconference	
	11:20 am	End	

AHWP WG03 Work Items

Teleconference Meeting

AGENDA
AHWP WG3 Teleconference
August 25, 2009
2.00pm – 3.00pm (Singapore time)

Item		Topic	Support Documents
	2:00 pm	Start	
1	10 min	•Welcome •New members' introductions •Confirmation of WG3 Secretary	
2	15 min	•Finalise comments on GHTF SG3 N17	WG3Commentstempl ate (2) - ee bin comm Commentstemplate-J in H.DOC
3	10 min	•GHTF SG3 N18	7.6 N18-Toronto-day3 nn
4	15 min	•ISO 13485:2003 Corrigendum Update	Corrigendum for ISO13485_2003 082 Observations on the comments on the Cor
5	5 mins	•Comments on GHTF guidance documents •Adoption of GHTF guidance documents by AHWP member economies	
6	5 mins	•Next WG3 Meeting – Hong Kong	
	3.00pm	CLOSE	

AHWP WG03 Work Items

Over view of N17 Contents

1. Scope
2. Definitions.
3. General Principles
4. Planning

AHWP WG03 Work Items

❑ 1. Scope

- ❑ provides guidance for medical device manufacturers on the control of products and services obtained from suppliers.
- ❑ For the purposes of this document:
  - ❖ a product or service is one.
  - ❖ a supplier is anyone that is independent from the manufacturer's quality management system.
    - ➢ **example,** if the supplier is not a part of the manufacturer's internal audit scope, then the supplier is under a separate quality management system and is considered an internal supplier.
- ❑ Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same quality management system.
- ❑ Manufacturers are required to define and document the type and extent of controls applied to suppliers and to maintain objective evidence that products and services meet predefined specifications.
- ❑ Applicable to combination products

AHWP WG03 Work Items

2. Definitions

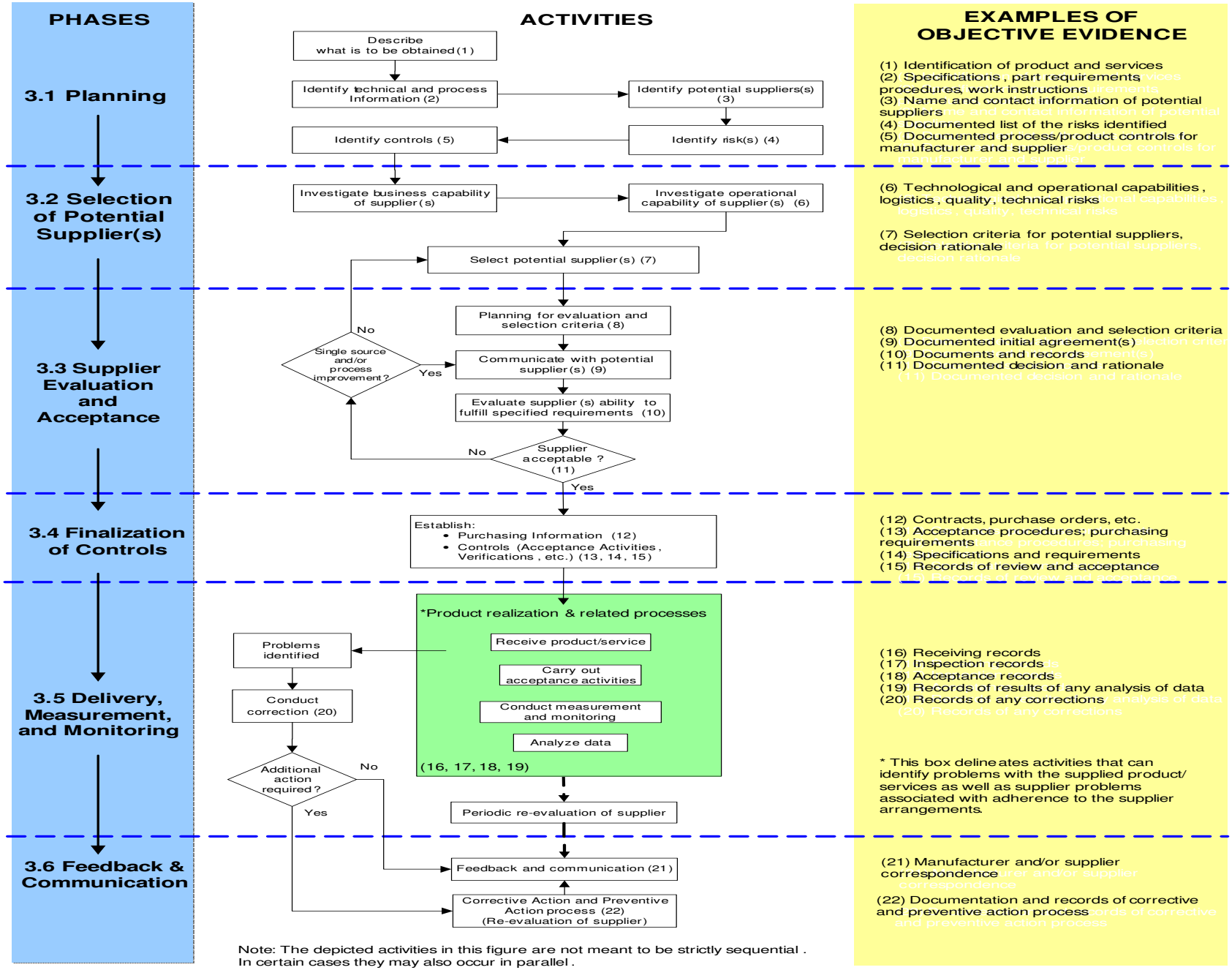
- ❑ Supplier
- ❑ Product
- ❑ Process
- ❑ Objective evidence
- ❑ Manufacturer

AHWP WG03 Work Items

3. General Principles

The process of establishing controls for products and services obtained from suppliers typically comprises six phases, which include:

- ❑ Planning
- ❑ Selection of potential supplier(s)
- ❑ Delivery, measurement and monitoring
- ❑ Supplier evaluation and acceptance
- ❑ Finalization of controls
- ❑ Delivery, measurement and monitoring
- ❑ Feedback and communication, including Corrective Action and Preventive Action process


PHASES
3.1 Planning
3.2 Selection of Potential Supplier(s)
3.3 Supplier Evaluation and Acceptance
3.4 Finalization of Controls
3.5 Delivery, Measurement, and Monitoring
3.6 Feedback & Communication
ACTIVITIES
Describe what is to be obtained (1)
Identify technical and process Information (2)
Identify potential suppliers(s) (3)
Identify risk(s) (4)
Identify controls (5)
Investigate business capability of supplier(s)
Investigate operational capability of supplier(s) (6)
Select potential supplier(s) (7)
Planning for evaluation and selection criteria (8)
Single source and/or process improvement?
No
Yes
Communicate with potential supplier(s) (9)
Evaluate supplier(s) ability to fulfill specified requirements (10)
Supplier acceptable ? (11)
No
Yes
Establish:
• Purchasing Information (12)
• Controls (Acceptance Activities, Verifications, etc.) (13, 14, 15)
*Product realization & related processes
Receive product/service
Carry out acceptance activities
Conduct measurement and monitoring
Analyze data
(16, 17, 18, 19)
Problems identified
Conduct correction (20)
Additional action required?
No
Yes
Periodic re-evaluation of supplier
Feedback and communication (21)
Corrective Action and Preventive Action process (22)
(Re-evaluation of supplier)
EXAMPLES OF OBJECTIVE EVIDENCE
(1) Identification of product and services
(2) Specifications, part requirements, procedures, work instructions
(3) Name and contact information of potential suppliers
(4) Documented list of the risks identified
(5) Documented process/product controls for manufacturer and supplier
(6) Technological and operational capabilities, logistics, quality, technical risks
(7) Selection criteria for potential suppliers, decision rationale
(8) Documented evaluation and selection criteria
(9) Documented initial agreement(s)
(10) Documents and records
(11) Documented decision and rationale
(12) Contracts, purchase orders, etc.
(13) Acceptance procedures; purchasing requirements
(14) Specifications and requirements
(15) Records of review and acceptance
(16) Receiving records
(17) Inspection records
(18) Acceptance records
(19) Records of results of any analysis of data
(20) Records of any corrections
* This box delineates activities that can identify problems with the supplied product/ services as well as supplier problems associated with adherence to the supplier arrangements.
(21) Manufacturer and/or supplier correspondence
(22) Documentation and records of corrective and preventive action process
Note: The depicted activities in this figure are not meant to be strictly sequential. In certain cases they may also occur in parallel.

AHWP WG03 Work Items

3. General Principles

3.1 planning

- ✓ Product or service to be obtained from supplier.
- ✓ Technical and process information.
- ✓ Identification of potential supplier(s).
- ✓ Identification of risk(s).
- ✓ Identification of controls.

AHWP WG03 Work Items

3. General Principles

3.2 Selection of potential suppliers

- ✓ Supplier business capability
- ✓ Supplier operational capability
- ✓ Selection of potential supplier

AHWP WG03 Work Items

3. General Principles

3.3 Supplier evaluation and acceptance

- ✓ Planning for evaluation and selection criteria.
- ✓ Communicate with potential suppliers
- ✓ Evaluation of potential supplier’s ability to meet selection criteria
- ✓ Supplier acceptance

AHWP WG03 Work Items

3. General Principles

3.4 **Finalization of Controls**

The list below shows other typical areas that should be considered for finalizing the agreement between the manufacturer and its supplier.

- ✓ Acceptance and verification activities
- ✓ Complaint handling
- ✓ Root cause analysis
- ✓ Corrective action and preventive action
- ✓ Product risk management
- ✓ Design
- ✓ Labelling/traceability requirements
- ✓ Technical documentation (of the supply)
- ✓ Handling of non-conformities
- ✓ Change control requirements
- ✓ Creation and retention of documents and records
- ✓ Supplier audits
- ✓ Product recall
- ✓ Periodic evaluation or re-evaluation (supplier's product, service and/or data)

AHWP WG03 Work Items

3. General Principles

3.5 Delivery, measurement and monitoring

consist of:

- ✓ Receiving product/service
- ✓ Carrying out acceptance activities (e.g. inspection or test, review certificates of conformity/analysis)
- ✓ Conducting measurement and monitoring
- ✓ Analyzing data using valid statistical techniques

AHWP WG03 Work Items

3. General Principles

3.5 Feedback and communication

a) Provisions for CAPA related activities performed by suppliers are defined in the manufacturer's QMS.

b) Based on the products provided by a supplier, all CAPA specific activities to be performed and data/information to be provided by that supplier are identified (e.g. related to the extent of control necessary at the supplier).

c) The supplier's obligations related to CAPA activities are communicated to the supplier and clearly defined in a contractual agreement (e.g. in the contract itself or a quality assurance agreement).

d) The supplier fulfils his contractual obligations in relation to the CAPA activities (e.g. timely processing of corrections).

e) Documentation and records related to a supplier's CAPA activities are controlled and readily available.

AHWP WG03 Work Items

Over view N18 Contents

1. Scope
2. Definitions.
3. Overview
4. Phases

AHWP WG03 Work Items

1. Scope

- This document provides guidance for establishing adequate processes for measurement, analysis and improvement within the QMS as related to correction and/or corrective action for nonconformities or preventive action for potential nonconformities of systems, processes or products.

AHWP WG03 Work Items

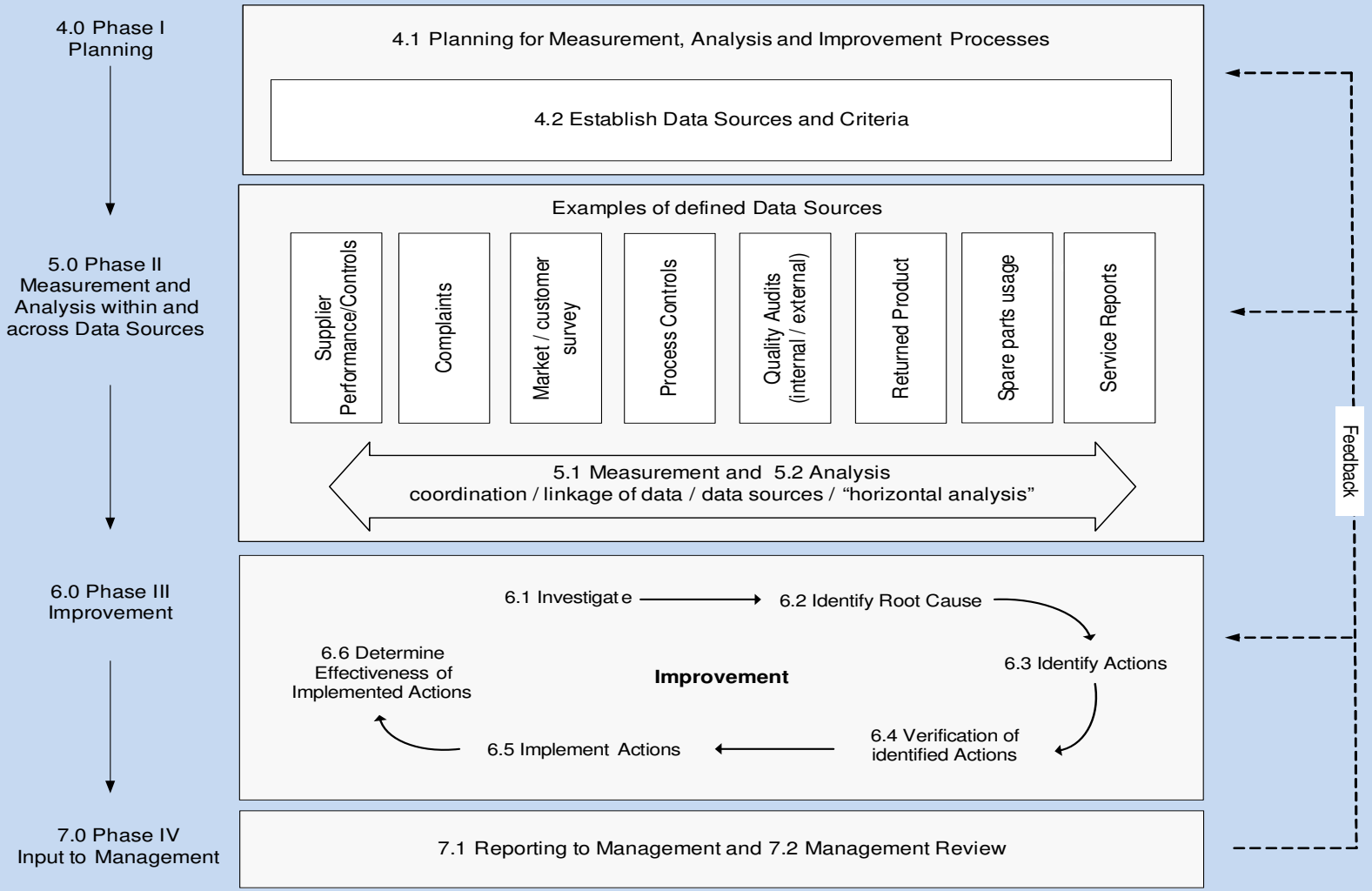
2. Definitions

- ❑ Correction
- ❑ Corrective action
- ❑ Data Source
- ❑ Concession
- ❑ Preventive action
- ❑ Nonconformity
- ❑ Verification
- ❑ Validation

AHWP WG03 Work Items

3. Overview

The graph below Illustrates typical Phases to be considered when planning, implementing and maintaining effective processes for measurement, analysis, improvement and providing input to management.



AHWP WG03 Work Items

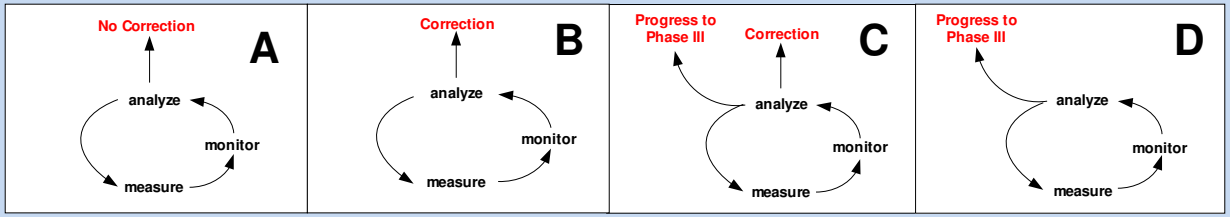
4. Phases

- Phase I: Planning
- Phase II: Measurement and Analysis within and across Data Sources
- Phase III: Improvement
- Phase IV: Input to Management

AHWP WG03 Work Items

4. Phases

- Phase I: Planning
    - Planning for Measurement, Analysis and Improvement Processes
    - Establish Data Sources and Criteria
- Phase II: Measurement and Analysis within and across Data Sources=
    - Measurement
    - Analysis

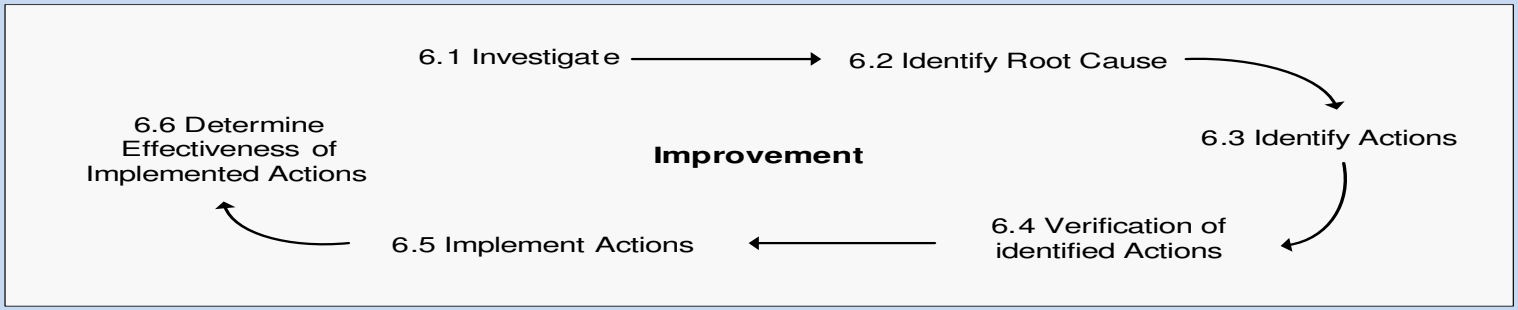


This figure show that the outcomes of measurement and analysis

AHWP WG03 Work Items

4. Phases

Phase III: Improvement



- Investigate
- Identify Root Cause
- Identify Actions
- Verification of identified actions
- Implement Actions
- Determine Effectiveness of Implemented Actions

Phase IV: Input to Management

- Reporting to Management
- Management Review

AHWP WG03 Work Items

- SG3 New Work Item ProposalN19
- Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies.

THANK YOU