PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes

Authoring Group: Study Group 3

Date: 22nd September 2009

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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Introduction

This guidance document is intended for medical device manufacturers and regulatory authorities. It is intended for educational purposes and is not intended to be used to assess or audit compliance with regulatory requirements. It is expected that the reader is familiar with regulatory Quality Management System (QMS) requirements within the medical devices sector.

For the purposes of this document it is assumed that the medical device manufacturer has a QMS which requires the manufacturer to have documented processes to ensure that medical devices placed on the market are safe and effective. For example ISO13485 Medical Devices – Quality Management Systems – Requirements for regulatory purposes, Japanese Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and in vitro Diagnostics (MHLW[1] Ministerial Ordinance No. 169), and the FDA[2] Quality System Regulation 21 CFR Part 820.

For this purpose the manufacturer will establish processes and define appropriate controls for measurement and analysis to identify nonconformities and potential nonconformities. The manufacturer should have established processes defining when and how corrections, corrective actions, or preventive actions should be undertaken. These actions should be commensurate with the significance or risk of the nonconformity or potential nonconformity.

The acronym “CAPA” will not be used in this document because the concept of corrective action and preventive action has been incorrectly interpreted to assume that a preventive action is required for every corrective action. This document will discuss the escalation process from different “reactive” sources which will be corrective in nature and other “proactive” sources which will be preventive in nature. The manufacturer is required to account for both types of data sources whether they are of a corrective or preventive nature.

Regardless of the nature of the data source, if there is a decision to escalate the information to further evaluation and investigation, the steps of investigation, identification of root causes and actions needed, verification, implementation, and effectiveness checks will be similar.

This guidance document will describe measurement, analysis and improvement as complete and integrated processes.

1.0 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.

[1] Japanese Ministry of Health Labor and Welfare
[2] US Food and drug Administration

2.0 Definitions

The references to clauses in this section refer to ISO 9000:2005.

2.1 Correction

Action to eliminate a detected nonconformity (3.6.2)

Note 1 A correction can be made in conjunction with corrective action (3.6.5)

Note 2 Corrections can be, for example, rework (3.6.7) or re-grade (3.6.8)

2.2 Corrective action

Action to eliminate the cause of a detected nonconformity (3.6.2) or other undesirable situation

Note 1 There can be more than one cause for nonconformity

Note 2 Corrective action is taken to prevent recurrence whereas preventive action (3.6.4) is taken to prevent occurrence

Note 3 There is a distinction between correction (3.6.6) and corrective action

2.3 Data Sources

The processes within a Quality Management System that provide quality information that could be used to identify nonconformities, or potential nonconformities.

2.4 Concession

Permission to use or release a product that does not conform to specified requirements (3.6.11).

2.5 Preventive action

Action to eliminate the cause of a potential nonconformity (3.6.2) or other undesirable situation

Note 1 There can be more than one cause for nonconformity

Note 2 Preventive action is taken to prevent occurrence whereas corrective action (3.6.5) is taken to prevent recurrence

2.6 Nonconformity

Non fulfillment of a requirement (3.1.2)

2.7 Verification

Confirmation through provision of objective evidence (3.8.1) that specified requirements (3.1.2) have been fulfilled.

Note 1 The term “verified” is used to designate the corresponding status.
Note 2 Confirmation can comprise of activities such as:
- performing alternative calculations,
- comparing a new design specification (3.7.3) with a similar proven design specification, undertaking tests (3.8.3), performing demonstrations, and reviewing and approving documents prior to issue.

2.8 Validation

Confirmation through provision of objective evidence (3.8.1) that the requirements for a specific intended use or application have been fulfilled.

Note 1 The term “validated” is used to designate the corresponding status.
Note 2 The use conditions for validation can be real or simulated.

3.0 Overview

The Management of any medical device manufacturer is ultimately responsible for establishing adequate processes for measurement, analysis and improvement within the QMS as related to correction and/or corrective action (action to prevent the recurrence) of nonconformities or preventive action (action to prevent the occurrence) of potential nonconformities of product or processes.

A nonconformity as defined in 2.6 is a non fulfillment of a requirement. It is important to understand that requirements may relate to product, process or the QMS.

When a nonconformity is identified, the manufacturer will determine the significance, risk of the nonconformity and the potential for recurrence. Once these have been determined the manufacturer may decide the nonconformity has little associated risk or is unlikely to recur. In such cases the manufacturer may decide only to carry out a correction.

Should the nonconformity recur within the QMS, during manufacture or after the medical device has been delivered to a customer, it is an indication that improvement action is needed. In either case the QMS requires that corrective action should be carried out with the aim to prevent recurrence. The corrective action may be as simple as retraining, or as complex as redesigning the manufacturing process.

The manufacturer may encounter situations that have not actually caused a nonconformity, but may do so in the future. Such situations may call for preventive action. Examples include:

- Corrective actions are taken within a QMS to eliminate observed nonconformities (regardless of whether the actions are taken for more than one site or facility operating within that QMS). Similar actions applied in another QMS (regardless whether it is the same or a different manufacturer) that has not yet experienced these nonconformities, would be considered preventive actions.
- Production or acceptance testing trend data indicates that control limits are being approached and revision of product or production (process, equipment or facilities) requirements may be necessary. These revisions could constitute a preventive action. Preventive action would not include planned process adjustments intended to return process performance to nominal values from the edges of the process control range.

Figure 1 illustrates typical Phases to be considered when planning, implementing and maintaining effective processes for measurement, analysis, improvement and providing input to management.

The Management should ensure that measurement criteria are defined for identified data sources and communicated across the organization.

As a check on the effectiveness of the processes defined, management should regularly review the outputs of processes and make adjustments as needed.

Documented procedures, requirements and records should be maintained by the manufacturer to ensure and demonstrate the effective planning, operation and control of the processes. Documented evidence of decisions and actions taken will be a part of the QMS.

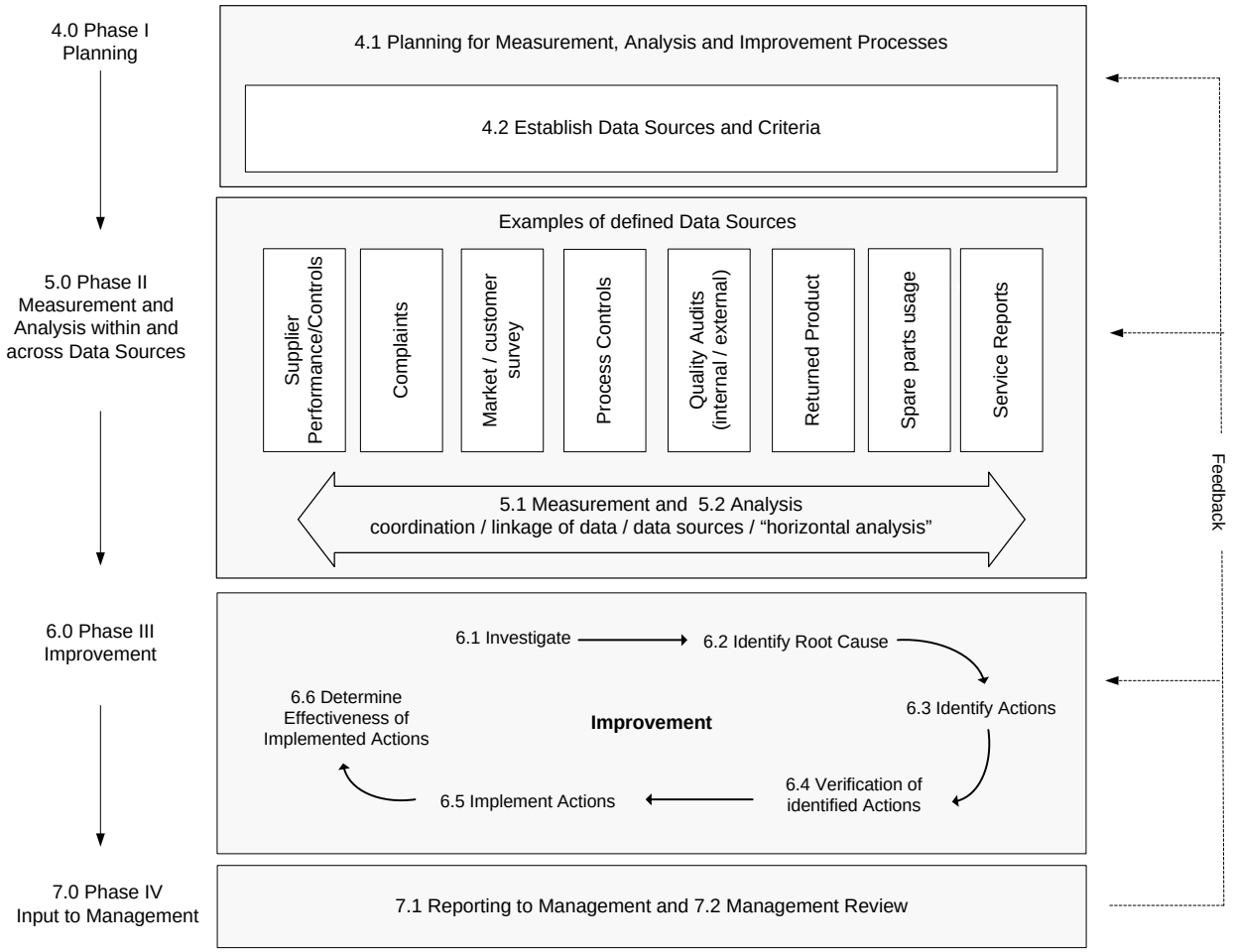

Figure 1: Processes for measurement, analysis and improvement

4.0 Phase I: Planning

The manufacturer is responsible for the implementation and maintenance of a QMS which enables their organization to provide safe and effective medical devices meeting customer and regulatory requirements.

Implementing and maintaining an effective QMS is a responsibility of top management in an organization. The involvement of management at appropriate levels of the organization (e.g. review, approval) in actions taken in response to a nonconformity or potential nonconformity should be established.

Risk Management activities are to include risk control and risk mitigation outputs should be considered throughout planning.

4.1 Planning for Measurement, Analysis and Improvement Processes

Factors to consider during this planning phase should be aligned with the manufacturer's overall business planning and as a minimum include the type of device being manufactured, intended markets and users, and regulatory requirements. As part of planning, management should review the processes critical to the operations with regard to quality and regulatory requirements and select relevant data sources to measure, analyze and facilitate improvement as necessary.

In the process of planning, measurement and analysis, a manufacturer needs to take into account data sources, the measurement of the data elements within each data source, the frequency of monitoring, and the analysis to be performed within a data source, or across data sources.

The measurement of data elements should be done in a way that ensures the organization will be effective in managing the operations and having an effective QMS. Each of the data elements should be planned and established with specific requirements for measurement that are monitored routinely.

The scope of the QMS and the scope of the measurement, analysis and improvement processes will provide the boundaries as to whether the data source is reactive/corrective or proactive/preventive.

The planning phase should ensure the following:

1. Identification of relevant internal and external data sources that are indicators of process and product performance.

2. Provision for adequate resources and establish responsibilities and authorities to enable the necessary actions. Resources may include technical experts, testing laboratories, data management, infrastructure, training, etc.

3. Definition of requirements for each identified data source, including limits, acceptance criteria, escalation criteria and mechanisms for reporting of nonconformities or potential nonconformities.

4. Analysis of data elements within data sources.

5. Coordination and analysis of data across data sources.

For each data element individual criteria should be defined, however criteria may be defined for a combination of data elements. Criteria should be quantitative whenever possible in order to maximize consistency and reproducibility for subsequent analysis. If the criteria and data are qualitative, subjectivity should be eliminated or minimized.

Acceptance criteria should be based on system, product and process specifications or requirements which are typically identified during design and development activities. This includes the design of the Quality Management System, development and maintenance of assembly processes, delivery processes, servicing and installation processes.

Escalation criteria used for the purpose of initiating the improvement process (see 6.0 Phase III: Improvement) may often be called action levels, trigger points, thresholds, etc. In particular, criteria should be established for immediate escalation. These criteria would be identified from risk management activities. For new technology and existing technologies with new intended uses/applications, initial escalation criteria may be difficult to define for the monitoring process. Therefore a manufacturer should plan for resources to analyze information in order to confirm initial assumptions and establish or revise escalation criteria.

Planning should provide for confirmation that the defined limits, acceptance criteria, escalation criteria and mechanisms for reporting of nonconformities or potential nonconformities for the original data sources and data elements are still appropriate. Where new data sources need to be established, confirm that they have been identified and their criteria defined.

4.2 Establish Data Sources and Criteria

The manufacturer should identify and document relevant data sources and their data elements, both internal and external to the organization. Data elements provide information regarding nonconformities, potential nonconformities and the effectiveness of the established processes within the data sources. Consideration should be given to the management review data and regulatory requirements.

Examples of data sources can be, but are not restricted to:

- Supplier
- Performance/Controls
- Complaint Handling
- Adverse Event Reporting
- Process Controls
- Finished Product
- Quality Audits (internal/external)
- Product Recall
- Spare Parts Usage
- Service Reports
- Returned Product
- Market/Customer Surveys
- Literature
- Management Review
- Product Realization (Design, Purchasing, Production and Service and Customer information)

For further examples of data elements see Annex A.

When action taken is limited to the specific area where the data has come from, correction of a significant situation may be delayed. It is important that the manufacturer reviews the information that is being identified across the organization. When the information is reviewed across

data sources it is clear what needs to be done. A manufacturer should look for common factors across the data sources. Doing so will lead to an effective corrective action.

5.0 Phase II: Measurement and Analysis within and across Data Sources

Once data sources, data elements and acceptance criteria have been specified, as part of the planning process, the manufacturer is required to perform measurement, monitoring and analysis processes to determine conformity or nonconformity.

Software used in measurement, monitoring and analysis, whether purchased (Off-The-Shelf) or custom developed, should be validated for its intended use.

5.1 Measurement

For the purposes of guidance, measurement is a set of operations to determine a value of a data element (i.e. quantity, quality).

Data collected from the measurement of product, process and QMS are acquired throughout the life-cycle of the product. The manufacturer should define for example frequency of the measurement, precision and accuracy of the data. The manufacturer should also ensure that the data collected is current and relevant.

Measurement data should be retained as a quality record. The manufacturer should maintain the data in a form that is retrievable, suitable for analysis and meets both QMS and regulatory requirements.

Monitoring is the systematic and regular collection of a measurement. The manufacturer should define during the planning phase what, when and how data should be monitored. The data should be defined such that it can be analyzed for further action. The monitoring of data may be continuous or periodic, depending on the type of data source and elements. The monitoring processes should be periodically reviewed for their continued suitability.

5.2 Analysis

For the purpose of this guidance Analysis is a systematic review and evaluation of data from measurements to derive a conclusion.

The manufacturer should have documented procedures for the analysis of data against the established criteria. Analysis is performed to identify nonconformity or potential nonconformity or identify areas where further investigation should be initiated (see 5.2 Analysis). In addition analysis is used to demonstrate the suitability and effectiveness of product, process and QMS. Analysis can be performed utilizing analytical tools, a team of experts, process owners or independent reviewers. The results of the analysis should be documented.

After it is determined what will be measured, statistical techniques used should be identified to help understand variability and thereby help the manufacturer to maintain or improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making. Statistical techniques assist in identifying, measuring, analyzing, interpreting and modeling variability.

For the analysis of nonconformity, appropriate statistical and non-statistical techniques can be applied. Statistical techniques are for example:

- Statistical Process Control (SPC) charts
- Pareto analysis
- Data trending
- Linear and non-linear regression analysis
- Experimental design (DOE – Design of Experiments) and analysis of variance
- Graphical methods (histograms, scatter plots, etc.)

Non-statistical techniques are for example:

- Management reviews
- Results from quality meetings
- Safety committees (internal or external)
- Failure Mode and Effect Analysis (FMEA)
- Fault Tree Analysis (FTA)

Analysis will likely occur at several different points (time and/or organizational level). For example, a certain amount of analysis and possible failure investigation (where there is evidence of a nonconformity) will occur for each data source.

In addition to the analysis within the data sources there should also be a level of analysis across data sources to determine the extent and significance of nonconformity or potential nonconformity. The linkage of data from different data sources will be referred to as “horizontal analysis”. The horizontal analysis may:

1. determine that the action proposed from the data source analysis is appropriate without further progress into Phase III (see 6.0); or,
2. provide additional information warranting progress into Phase III (see 6.0), regardless of whether the data source analysis escalated the nonconformity or potential nonconformity.

For example, the data source market/customer survey may indicate a general dissatisfaction with the performance of a kind of product. When investigated further and reviewed with other data sources such as complaints, returned product and if applicable, service reports, a significant nonconformity becomes evident in the product or family of products and for which corrective action is required. Thus, the necessary escalation to Phase III (see 6.0) for corrective action occurs. Integral to this escalation is the determination of the Scope of the investigation, including the determination of whether the nonconformity arises from a systemic issue.

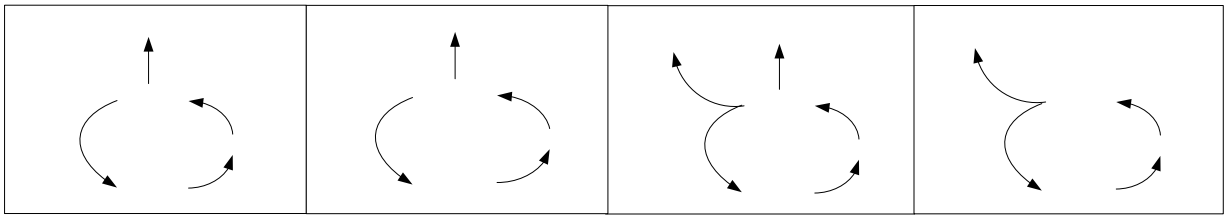

Figure 2: Outcomes of measurement and analysis

The outcome of the analysis would lead to one of the following decisions (see Figure 2):

A. No correction required, continue measurement and monitoring
The decision is made not to take any correction nor escalate the handling of the nonconformity to Phase III (see 6.0).

B. Correction required, continue measurement and monitoring
The decision is made to perform a correction but not to escalate the handling of the nonconformity to Phase III (see 6.0).

C. Correction and escalation to further investigation under the improvement process.
The decision is made to perform a correction and to escalate the handling of the nonconformity to Phase III (see 6.0).

D. Escalation for further investigation under the improvement process because there is not enough information at this time to determine the required action. In addition there may be predefined events that due to the significance of the risk will automatically be escalated to Phase III without an immediate correction.

   In the event a potential nonconformity is identified, it may be escalated into Phase III (see 6.0) for consideration of actions to prevent the occurrence of the potential nonconformity.

For Options A, B and C, both the data source analysis and the horizontal analysis, continue to occur on a monitoring basis to ensure risk and frequency assumptions remain valid.

For Options A and B the activities described in Phase III can be accomplished within certain processes (e.g. Change Management Process) if it is predefined and described in documented procedures. In addition there needs to be a process monitoring or analysis (i.e. trending) of the corrective actions to determine if additional escalation is necessary. Otherwise the activities in Phase III will be escalated as part of the improvement process.

When a nonconformity or potential nonconformity is escalated into Phase III (see 6.0), the nonconformity or potential nonconformity will undergo additional analysis and possible investigation.

Typically manufacturers have functional groups or processes surrounding some of their main data sources (e.g. Complaint Handling, handling of nonconformities, Material Review Boards, Change Management Process). Within these functional groups or processes certain activities described in Phase III (see 6.0 Phase III: Improvement) can implement immediate corrections.

These immediate corrections, or the decision to not implement an immediate correction, (described in Figure 2 - Options A, B and C) can occur without or before the escalation to Phase III as long as the functional groups or processes, and their documented procedures, clearly delineate and define the activities that can be accomplished without or before escalation to Phase III.

As discussed above, when no correction or immediate correction are taken within these functional groups or processes, there needs to be data source monitoring and analysis (trending) to determine if escalation to Phase III may be necessary from accumulated information. Whenever an issue is escalated to Phase III, any information gained within the defined activities of these functional groups or processes should be fed into the Phase III activities such as Investigation (see 6.1) or Identified Actions (see 6.3)

6.0 Phase III: Improvement

The improvement phase of a corrective action process or preventive action process is designed to eliminate or mitigate a nonconformity or potential nonconformity.

The improvement activities are tailored to the specific nonconformity or potential nonconformity. The amount of work in Phase III is therefore dependant upon the risk and significance of the nonconformity or potential nonconformity.

The improvement process and the activities described in Figure 3 shall be documented. Improvement generally involves the following activities that the manufacturer would take sequentially or sometimes simultaneously:

- A thorough investigation of the reported nonconformity;
- An in-depth root cause analysis;
- Identification of appropriate actions;
- Verification of identified actions;
- Implementation of actions; and
- Effectiveness check of implemented actions.

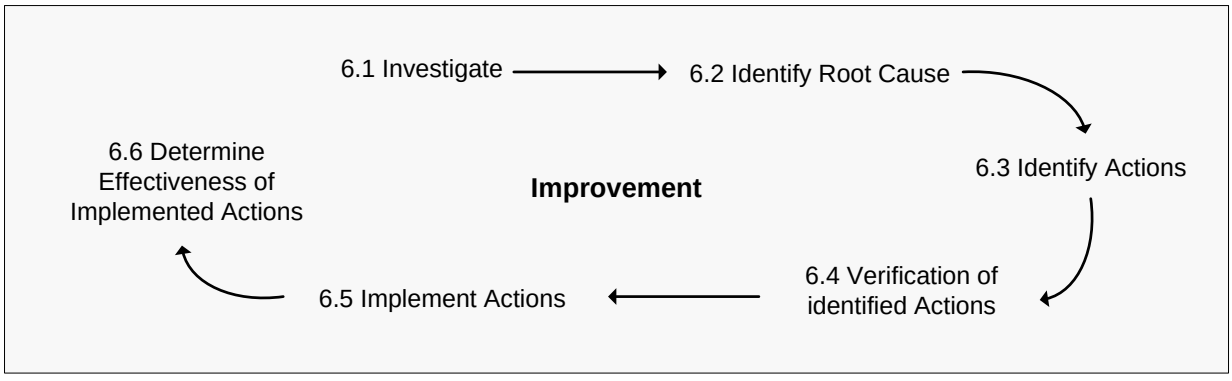

Figure 3: Phase III - Improvement

6.1 Investigate

The investigation documentation should include a statement of the nonconformity expressed as a problem statement. In addition the documentation should include the extent of the nonconformity or potential nonconformity, the conduct of the investigation, the method, resources, timeframe and records to be used and generated. From the information obtained throughout the process the problem statement should be reviewed and refined as appropriate.

The conduct of the investigation should:

- Determine the extent of the nonconformity or potential nonconformity;
- Acknowledge that there is likely to be several causes of an event, hence the investigation should not cease prematurely;
- Require that symptoms be distinguished from root causes and advocate the treatment of root causes rather than just the symptoms;
- Require that an end point be defined for the investigation. (An exhaustive investigation may unduly delay the correction of non-conformity or unnecessarily incur additional cost. For example; if removal of the causes identified so far will correct 80% of the effects then it is likely that the significant causes have been identified (Pareto rule))
- Take into account the output of relevant risk management activities;
- Agree on the form of evidence. For example, evidence should support:
  - the seriousness of the event;
  - the likelihood of occurrence of the event;
  - the significance of the consequences flowing from the event;

A recognized method for the investigation should include the collection of data and the organization of that data to allow analysis. The majority of time spent analyzing an event is spent in gathering data.

The investigation should build upon any analysis, evaluation and investigation that were previously performed (see 5.0). This will require the investigator to identify, define and further document the observed effects / non-conformity, or already determined causes, to ensure that the investigator understands the context and extent of the investigation. It may be necessary to:

- Review and clarify the information provided;
- Review any additional information available from an horizontal analysis;
- Consider whether this is a systemic issue/non-systemic issue.
- Gather additional evidence, if required;
- Interview process owners / operators or other parties involved;
- Review documents;
- Inspect facilities, or the environment of the event;

Previous investigations should be reviewed in order to determine if the event is a new problem or perhaps the recurrence of a previous problem where, for example, an ineffective solution was implemented. The following questions will assist in making the determination:

- Is the nonconformity from a single data source?
- Does the current nonconformity correlate with nonconformities from other data sources?
- Are multiple data sources identifying the same nonconformity?
- Do other nonconformities have an effect on the problem investigated here?

The systematic recording of observations, and the relationship between observations, will support a cause and effect analysis, and will assist to identify gaps in an understanding of the nonconformity.

Many of the tools used in investigations rely upon a cause and effect relationship between an event and a symptom of that event. To ensure that causes are identified, not symptoms, the following should be considered:

- There must be a clear description of a cause and its effect. The link between the root cause and the undesirable outcome needs to be described.
- Each description of a cause must also describe the combined conditions that contribute to the undesired effect.
- Each deviation from a procedure should have a reason. Therefore the reason for the deviation (root cause) should be identified, not just the symptom (occurrence of a deviation).
- A failure to act is only considered a cause if there was a pre-existing requirement to act. The requirement to act may arise from a procedure, or may also arise from regulations, standards or guidelines for practice, or other reasonably expected actions.

Some of the more common tools and techniques include:

- Cause and effect diagrams
- 5 whys
- Pareto Charting
- Fishbone cause and effect diagrams
- Change analysis
- Risk analysis techniques

The outcome of an investigation should include:

- Clearly defined problem statement
- What information was gathered, reviewed and/or evaluated
- Results of the reviews/evaluations of the information
- Identification of possible root causes of the nonconformity or potential nonconformity
- Possible solutions to address the causes

6.2 Identify Root Cause

Causes of detected nonconformity or potential nonconformity should promptly be identified so that corrective action can be taken to prevent recurrence, or preventive action taken to prevent occurrence. The process to identify the root cause should start with the output(s) of the investigation (see 6.1).

When assessing relevant data, the following should be considered:

- Systematic generation of cause and effect conclusions supported by documented evidence
- Evaluate significant or underlying causes and their relationship to the problem
- Ensure that all causes are identified, not the symptoms
- Check for more than one root cause (above processes if necessary)

Causes of nonconformities or potential nonconformities may include the following:

- Failure of, or malfunction of, incoming materials, processes, tools, equipment or facilities in which products are processed, stored or handled, including the equipment and systems therein;
- inadequate or non-existent procedures and documentation;
- non-compliance with procedures;
- inadequate process control;
- inadequate scheduling;
- lack of training;
- inadequate working conditions;
- inadequate resources (human or material);
- (inherent) process variability.

For further details on aspects to be considered when doing the root cause analysis see Annex B.

The output of the root cause analysis should be a clear statement of the cause(s) of the nonconformity.

6.3 Identify Actions

Once the root cause(s) has been determined, the manufacturer should identify and document the necessary corrections and/or corrective actions or preventive actions. These should be reviewed to ensure that all necessary actions are identified. This review may benefit from a cross functional approach.

The following outcomes are possible and should be documented:

1. No further action necessary.
   (provided that no safety issue exists and regulatory requirements are met)
   a. With continuous monitoring
   b. Acceptance under concession and continuance of monitoring

2. Corrections or additional corrections.
   It may be necessary to take immediate or short term corrections (e.g. containment, stop of shipment/supply, issuance of advisory notice) in order to address an immediate risk or safety issue. This may be necessary before investigation has been completed and root cause has been determined. However, after investigation and root cause determination, additional and/or possibly different corrections may become necessary.

3. Corrective Actions
   Corrective actions must encompass the need to correct the nonconformity and in addition address systemic problems. Changing and training of personnel to a new procedure may not, by itself, be appropriate or sufficient to address all identified root causes.

4. Preventive action

By its very nature preventive action can not follow a nonconformity.

As a result of this step, a list of action items to address the root cause(s) should be documented. These would typically include:

- Detail method of implementation;
- Applicable regulatory requirements;
- Identification of the responsibilities during execution;
- Identification of the necessary resources, including the human resources;
- Verification and/or validation protocols of the action(s) with acceptance criteria;
- Implementation schedule, including timelines.
- Method or data for the determination of effectiveness
- Identify the starting point of monitoring, and end point of correction and/or corrective action or preventive action as described above

6.4 Verification of identified actions

Before the implementation of action(s), a manufacturer should verify the identified action(s) and approve their implementation. In addition validation may be required where process validation or re-validation may be necessary, or where user needs or intended uses are changed and design validation will be required. The decision as to the necessity for validation is influenced, among other things, by the risk associated with the nonconformity, the complexity of the corrective or preventive action, and the costs associated with the implementation of the corrective or preventive action.

Verification activities are to ensure that all the elements of the proposed action (documentation, training etc) will satisfy the requirements of the proposed action (see 2.7). These activities should be performed by persons who are knowledgeable in the design or use of the product or process that is the subject of corrective or preventive action. Verification of a preventive action can be accomplished by introducing the conditions that would induce a nonconformity and confirming that the nonconformity does not occur.

Validation activities generate data and information that confirm the likelihood of the effectiveness of the corrective action to eliminate the nonconformity or proposed noncomformity.

Examples of items to be considered when planning the verification / validation activities include:

- Does the action(s) eliminate the determined root cause(s)?
- Does the action(s) cover all affected products/processes?
- Does the action(s) adversely affect the final products?
- Is it possible to finalize the actions timely in planned schedule (resources, materials/kits, logistics, communications, etc.)?
- Is the execution of the action commensurate with the degree of risk previously established?
- Are new risks or nonconformities derived from the action?

6.5 Implement Actions

The following items that may be considered at implementation should be documented:

- parties involved,
- materials,
- processes,
- training,
- communications,
- tools and
- timelines for the implementation of the approved action.

Verify that the implementation has been completed.

6.6 Determine Effectiveness of Implemented Actions

The manufacturer should gather data over a period of time related to the effectiveness of the implemented action. The manufacturer confirms that actions taken were effective as to the intended purpose of the action and did not introduce new issues or concerns.

If the manufacturer finds the actions are not effective, the manufacturer should re-initiate Phase III activities (see 6.0). If the manufacturer finds the actions create a new issue or a new nonconformity then the manufacturer needs to initiate Phase II (see 5.0) activities.

7.0 Phase IV: Input to Management

Management at different levels in the organization should be involved in each improvement action either through approval of the improvement steps or reporting. The Management Review is the overall mechanism for management to ensure that the Quality Management System as a whole is effective.

7.1 Reporting to Management

The manufacturer should have a mechanism/procedure that expeditiously raises safety related issues or other high risk issues to management. These issues can be identified in the data sources, the improvement process (see 6.0), or originate from other sources external to the Quality Management System. In addition to this expeditious escalation mechanism, the manufacturer should define the management responsibilities (i.e. process owner) of the measurement, analysis and improvement processes to ensure that the processes and the actions being implemented are effective. For this purpose there needs to be a mechanism for management at different levels to stay informed of the information or data from:

- the measurement and analysis activities from the individual data sources; and
- the investigations, actions, implementations, etc. from the improvement process

7.2 Management Review

The manufacturer has procedures for what is provided as input for the management review, including relevant information from the improvement process, such as improvement actions (corrective actions, or preventive actions) as well as important corrections.

The manufacturer needs to define what meaningful data is to be reported for a management review. Data should be specific to the quality objectives of the manufacturer and be reported regularly. Merely providing the number of improvement actions or the number of how many improvement actions are opened or closed to the management review process are not sufficient in assessing the effectiveness of the processes.

Included in this review would be an assessment of any opportunities for improvement of the device, manufacturing process, QMS or the organization itself.

An outcome of the review could be the allocation of funding or personnel to a particular area, project or device that the review has identified as not meeting customer and regulatory safety and effectiveness expectations.

8.0 Annex A

Examples of data sources and their data elements can be, but are not restricted to:

DATA SOURCES	DATA ELEMENTS
Supplier Performance/Controls	▪ Number of batches received ▪ Batch and/or shipment ▪ Inspection and test records ▪ Quantity of rejects or deviations ▪ Reason for rejection ▪ By supplier, if more than one supplier ▪ Use in which product or service ▪ Supplier problems
Complaint Handling	▪ Quantity ▪ By product family ▪ By customer (physician, healthcare facility, patient, etc.) ▪ Reason for complaint ▪ Complaint codes ▪ Severity ▪ Component involved
Adverse Event Reporting	▪ Event ▪ Quantity ▪ By product family ▪ By customer (physician, healthcare facility, patient, etc.) ▪ Type of event (death or serious injury, etc.) ▪ Component involved
Process Controls	▪ By product ▪ Operator ▪ Work shift ▪ Equipment and/or instruments used ▪ Inspection and test records ▪ In-process control results ▪ Process control parameters ▪ Inspection process ▪ Final acceptance ▪ Rejects ▪ Special process ▪ Validation study results ▪ Process monitoring observations
Finished Product	▪ Inspection and test records
Quality Audits (internal/external)	▪ Observations (number, category, corporate policy, regulatory requirements, significance, etc.) ▪ Repeat observations (indicative of effectiveness) ▪ Closure times ▪ Overall acceptability of contractor or supplier ▪ Compliance to audit schedule ▪ Audit personnel
Product Recall	▪ Recall report

DATA SOURCES	DATA ELEMENTS
Spare Parts Usage	▪ Frequency of replacement ▪ Batch number of spare part ▪ By supplier of spare part, if more than one supplier ▪ By customer ▪ By location or area of customer
Service Reports	▪ Installation ▪ First use of equipment ▪ Frequency of maintenance visits ▪ Types of repairs ▪ Frequency of repairs ▪ Usage frequency ▪ Parts replaced ▪ Service personnel
Returned Product	▪ Quantity ▪ Reason for returning product ▪ By customer ▪ Types of defects identified on returned product
Market/Customer Surveys	▪ Customer preferences ▪ Customer service response time ▪ Solicited information on new or modified products
Literature	▪ Published reports of failures of similar products
Management Review	▪ Management review output
Product Realization (Design, Purchasing, Production and Service and Customer information)	▪ Design and development review results ▪ Verification of design and development to ensure output meets input requirements ▪ Validation results ▪ Design and development changes (reason or cause for change) ▪ Where changes effective ▪ Note; each of the above has specific data that is generated from performing the activities as a result the data should be monitored and results reviewed on a regular basis to ensure the processes and the product are effective. ▪ Purchasing- Supplier controls ▪ Controls on purchased products or services (See above Supplier Performance/Controls) ▪ Verification results of purchased product ▪ Inspection and testing data of purchased product ▪ Production and Service processes- Cleaning operations of product and facilities ▪ Sterilization ▪ Installation results ▪ Servicing and Maintenance if required (See also: Service Reports) ▪ Verification and Validation results of processes used in production and service. Including approval of equipment and qualification of personnel ▪ Traceability Data ▪ Controls of monitoring and measuring devices ▪ Calibration and maintenance of equipment ▪ Customer Information- New or repeat customer ▪ Customer feedback maybe in other forms than complaints or returned product (Customer Service call data, repeat sales , delivery/distribution data)

9.0 Annex B

Checklist for aspects to be considered when doing the root cause analysis:

Materials

- Defective raw material (does material meet specification?)
- Batch related problem
- Design problem (wrong material for product, wrong specifications)
- Supplier problem (lack of control at supplier, alternative supplier)
- Lack of raw material.

Machine / Equipment

- Incorrect tool selection – suitability
- Inadequate maintenance or design – calibration?
- Equipment used as intended by the manufacturer?
- Defective equipment or tool
- End of life?
- Human error – inadequate training?

Environment

- Orderly workplace
- Properly controlled – temperature, pressure, particulate, cleanliness
- Job design / layout of work

Management

- Inadequate management involvement
- Stress demands
- Human factors
- Hazards not properly guarded
- Were management informed / did they take action?

Methods

- Procedures not adequately defined
- Practice does not follow written method
- Poor communications

Management system

- Training or education lacking
- Poor employee involvement
- Poor recognition of hazard
- Previous hazards not eliminated

Measurement, monitoring and improvement

- Inadequate measuring and improvement

10.0 Annex C

List of Activities corresponding to phases in the processes

The following is an outline / aid memoir of the main points described in SG3 N18. It is not intended as a "box ticking" exercise and should not be used as such, but used purely to summarise and align the steps in the process described in N18. The activity numbers do not imply sequential steps – some steps may take place in parallel.

Steps 20 to 22 are not described in N18 but are added as reminders of general management responsibilities in this area of the QMS.

PHASE	**ACTIVITIES**
1 Planning	1. Identify all data sources (internal & external) by product type (Clause 4.1) 2. Identify resources required and individual personnel responsibilities for measuring each data source (Clause 4.1) 3. Define the requirements for each data source and the data elements within each data source that will be measured, and analysed (Clause 4,1) 4. Define requirements for escalation to the Improvement process (Clause 4,1) 5. Define requirements for monitoring the measurements in the data sources (Clause 5.1 6. Establish data sources (Clause 4.2)
2 Measuring and Analysis	7. Measure and analyse all data sources for nonconformities and potential nonconformities (Clauses 5.0, 5.1 and 5.2) 8. Have reports of nonconformity or potential nonconformity come from more than one data source? 9. Is the nonconformity or potential nonconformity systemic?
3 Improvement	10. Determine scope and required outcome of investigation (Clause 6.1) 11. Investigate nonconformity or potential nonconformity (Clause 6.1) 12. Analyse nonconformity or potential nonconformity for root cause(s) (Clause 6.2) 13. Identify actions (correction, corrective

PHASE	ACTIVITIES
	action or preventive action) (Clause 6.3) 14. Verify proposed actions before implementation (Clause 6.4) 15. Implement proposed actions (Clause 6.5) 16. Determine effectiveness of actions (validate if possible) (Clause 6.6)
4 Management	17. Report investigation and outcome to management (Clause 7.1) 18. Review investigation, analysis and outcome and sign off (Clause 7.2) 19. If not satisfied return to step 10 20. If required, report to regulator (note: reporting may be required earlier depending on severity) 21. Audit system at determined intervals 22. If numbers of nonconformities or potential nonconformities exceeds targets, review all QMS processes

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