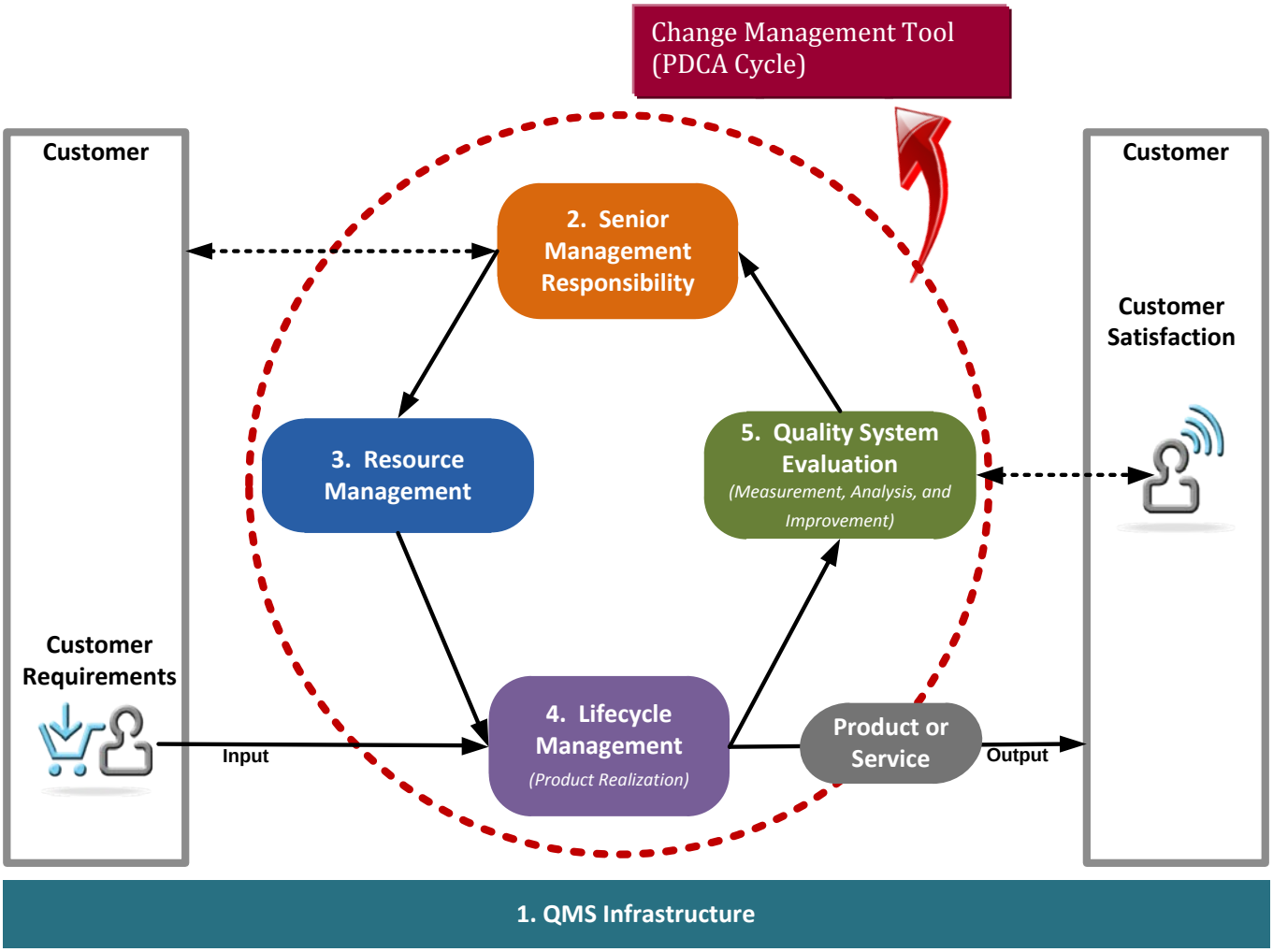
Center for Devices and Radiological Health

CDRH Quality Management Framework



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Introduction

"Quality is everyone's responsibility." W. Edwards Deming.

A quality management (QM) program[1] is an integral part of a dynamic, continually improving organization. The principles and practices described in this framework will facilitate the establishment of our quality management program. They include our quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis. While many at CDRH are already using these principles and practices, the process approach explained in this framework shows how these principles and practices work together, providing a clear roadmap towards quality management.

The framework is divided into five areas:

1. Infrastructure
2. Senior Management Responsibility
3. Resource Management
4. Lifecycle Management
5. Quality Management System Evaluation

Infrastructure is the foundation for the CDRH QM Framework. The section on Infrastructure explains our quality management policy and objectives, and describes our roles within the CDRH QM Program. The section on Senior Management Responsibility explains some of the ways by which management will provide evidence of their commitment to quality products and services. The section on Resource Management explains the support needed to establish an efficient and effective quality management program. The section on Lifecycle Management describes the processes for managing the quality our products or services throughout their lifecycle. Lastly, the section on Quality Management System Evaluation explains the measurement and monitoring activities needed to assess the quality of products and services, the effectiveness of the QM Program, and to achieve improvement.

This document is aspirational and represents the framework CDRH intends to develop over time. We expect that the full implementation of QM (as described in this framework) will take years to become fully operational, will require an ongoing effort, and is resource dependent. As we work together to establish the CDRH QM Program, this framework may be used as a guide. It is intended to help identify quality management system elements that may already exist, identify additional elements needed to implement a quality management program, and determine what is needed to establish a quality management program.

"It is not enough to do your best; you must know what to do, and then do your best."
W. Edwards Deming.

[1] As noted in FDA SMG 2020 a quality management system is "a set of formal and informal business practices and processes that focus on customer needs, leadership vision, employee involvement, continual improvement, informed decision making based on real-time data and mutually beneficial relationships with external business partners to achieve organizational outcomes."

Note to Reader

As CDRH works together to establish the CDRH QM Program and begins to bring processes into the QM Program, the Center will use this framework as a guide. This document is intended to help identify quality management elements that may already exist and additional elements needed to bring a process under the CDRH QM program.

This document is not intended and should not be used to select and audit CDRH processes to assess for compliance with the CDRH QM Program. CDRH does not intend for all Center processes to comply with this framework immediately upon the effective date of this document. Rather, the effective date of this document marks the beginning of a gradual implementation of the QM Program. CDRH plans to increase adherence with the QM principles and practices set forth by this document over time.

CDRH Quality Management Framework

1. Quality Management Infrastructure

1.0. General

The quality management infrastructure is the foundation for the Quality Management Framework for CDRH. The quality management infrastructure supports and interacts with all of the other four elements of the quality management system:

- Senior Management Responsibility
- Resource Management
- Lifecycle Management
- Quality Management Systems Evaluation

The quality policy, objectives, roles, and responsibilities are significant steps towards establishing a CDRH QM Program. They are components of the infrastructure need for a successful CDRH QM Program.

1.1. About the Center for Devices and Radiological Health

CRDH is a component of the U. S. Food and Drug Administration, Department of Health and Human Services. The concept of providing quality products and services underlies everything we do. The mission of CDRH is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S. We accomplish this by exercising the regulatory authorities granted to us by the Congress and delegated to us by the Secretary of Health and Human Services and the FDA Commissioner. A comprehensive statement of our mission, vision, and shared values is included in this framework by reference.

1.2. Quality Policy

CDRH is committed to continually improving the quality of our products and services. It is the responsibility of every CDRH manager, supervisor, and employee to pursue quality in the performance of our jobs. To do so, everyone at CDRH must understand what quality means to the center and how the choices we make affect quality.

The CDRH Quality Management Program will be a vehicle to fulfill our commitment to quality improvement. It will provide tools and resources, as available, to improve the consistency of our operations, help us make sound choices concerning quality, help measure our progress in meeting quality objectives, help us identify what is working or what is not working and assist in bringing identified issues to a satisfactory resolution.

1.3. Quality and Quality Management Systems

FDA SMG 2020 defines quality as a measure of a product's or service's ability to satisfy the customer's stated or implied needs. ISO 9000:2005 defines it as ability of a set of inherent characteristics of a product, system, or process to fulfill requirements of customers and other interested parties. Quality applies equally to products, systems, and services.[2] Since quality cannot be measured in a vacuum, determining the "quality" of our products means assessing the degree by which that product or service:

- satisfies stated or implied needs;
- conforms to established requirements; and
- fulfills stated customer expectations.

Every customer has a huge number of "needs and wants." Any given product is intended to satisfy a finite subset of needs and expectations. A quality management system aims to extract a reasonable set of requirements from the universe of all requirements, make them explicit by documenting them, and ensure that the resulting product or service consistently fulfills the documented requirements.

1.4. Quality Objectives

CDRH's quality objectives align with our quality policy and the strategic direction of CDRH and will evolve over time as our Quality Management (QM) Program matures. Initially, the objectives focus on establishment of the CDRH QM Program and developing baseline measures of quality.

Recognizing that implementation of the quality system will take time, the following six objectives focus on establishing the infrastructure for quality management, including significant components of the Quality Management elements identified in FDA SMG 2020 - FDA Quality System Framework for Internal Activities and ISO 9001:2008:

1.4.1 **Quality Management Framework.** Establish[3] a QM Framework consistent with the principles outlined in FDA SMG 2020 and "ISO 9001:2008 – Quality Management Systems – Requirements". Whenever possible, the framework should build upon existing procedures and practices.

1.4.2 **Quality Management Responsibilities and Resources.** Identify and define key roles, responsibilities, and resources, as available, needed to establish CDRH's QM Program.

1.4.3 **Quality Management Training.** Establish a Quality Management training program for all center staff, and a business process for training.

1.4.4 **Document Control.** Establish and maintain a document control procedure for Quality Management documents and forms, and a records management system for quality records.

1.4.5 **Corrective and Preventive Action (CAPA).** Establish a corrective and preventive action (CAPA) system at the level of the center and each office. The CAPA system shall include mechanisms for collecting and tracking quality issues.

1.4.6 **Quality Assessments/Audits.** Establish a procedure and schedules or criteria for conducting internal quality assessments and audits, and a procedure and schedule for

[2] A *product* is anything delivered to a customer, a *service* is an intangible product, and a *system* is a set of interrelated elements.

[3] *Establish* means define, document, and implement.

management review.

The following two objectives focus on applying the framework to selected key processes and services:

1.4.7 **Key Business Processes under Quality Management.** Identify and prioritize key business processes, aligned with center and office strategic priorities, to serve as the initial focus of quality procedure development activity.

1.4.8 **Key Business Process Evaluation.** For selected business processes, assess or audit existing procedures and practices to identify quality system elements that may already exist and identify additional elements needed to comply with the required framework elements.

As we gain experience with the Quality Management Program and continue to bring more CDRH processes and services into the QM Program, our objectives will shift toward satisfying the criteria for excellence as defined in the Baldrige Performance Excellence Program administered by the National Institute of Standards and Technology (NIST).

1.5. Quality Metrics

To track and assess the establishment of the CDRH QM Program, the center will develop quality metrics:

1.5.1 **Implementation metrics.** Institute metrics to track the progress for implementing the Quality Management elements listed above.

1.5.2 **CAPA/Complaint metrics.** Institute metrics to track the numbers of complaints and CAPAs, and to assess the impact (on public health, stakeholder needs, etc.) as well as the timeliness of the actions taken to address them.

1.5.3 **Business process metrics.** Institute metrics to assess and monitor the quality of key business processes under the Quality Management Program.[4]

1.5.4 **Stakeholder metrics.** Institute metrics to track the impact of organizational actions on our internal and external stakeholders.

1.6. Definitions

Terms throughout the SOP are defined in the Glossary (Appendix C). These definitions are taken from FDA SMG 2020 and are consistent with concepts and definitions used throughout the agency and regulated industry.

1.7. Quality Management Roles and Responsibilities

1.7.1 The **Quality Management Director** oversees the CDRH QM Program and chairs the CDRH Center Science Council (CSC) Quality Management Subcommittee.

1.7.2 The **CSC Quality Management (QM) Subcommittee** is comprised of representatives from each CDRH office. The CSC QM Subcommittee coordinates center-wide quality activities, provides direction in support of quality management activities, and monitors accountability within CDRH to improve the quality and transparency of CDRH decision making and critical management and administrative processes. Subcommittee responsibilities include, but are not limited to, those documented in

[4] For example, when addressing the business process for obtaining consults, a number of quality measures could be contemplated, such as reviewing CTS records to gauge timeliness of reviews, tracking the number of adverse findings uncovered by reviews, and instituting a procedure for periodic peer review of a random sample of consults.

this framework and in the CSC Quality Management Subcommittee charter.

1.7.3 **CDRH senior management** is responsible for assuring the quality management system is adhered to, from its development through completion of management reviews. CDRH senior management is responsible for prioritizing and approving center quality management activities, determining the need for audits, conducting management reviews (including review of CAPAs), and providing or prioritizing resources. CDRH senior management includes the Center Director, Deputy Center Directors, Associate Center Directors, and Office Directors.

1.7.4 **Office senior and middle management** are responsible for assuring the quality management system is adhered to, from its development through completion of management reviews, as explained in 1.7.3 above, for their offices. Office senior and middle line management includes division leadership.

1.7.5 The **Office Quality Management Representative** is responsible for planning and coordinating quality management programs in his/her office, and keeping communication open between the QM Subcommittee and their management.

1.7.6 **CDRH first-line management** is responsible for applying quality management concepts and principles and using the quality management tools (training, SOPs, checklists, etc.) to manage day-to-day work. First-line management includes branch chiefs and lab leaders.

1.7.7 **CDRH employees** are responsible for applying quality management concepts and principles in their daily activities and using quality management tools to produce quality products and services.

2. Senior Management Responsibility

2.0. General

Senior management is accountable for the quality of CDRH products and services. Therefore, the commitment of senior management is essential to developing, sustaining and improving the CDRH QM Program.

2.1. Senior Management Commitment

2.1.1 CDRH and office senior management are responsible for assuring the quality management system is adhered to, from its development through completion of management reviews.

2.1.2 CDRH senior management establishes quality policies and objectives, provides resources, as available, and demonstrates commitment to quality by their participation in quality activities.

2.2. CDRH Senior Management and Office Senior Management Prioritization

2.2.1 CDRH senior management is responsible for prioritizing and approving center quality management activities as well as for determining key center business processes under the CDRH QM Program.

2.2.2 Office senior management is responsible for prioritizing and approving office quality management activities as well as for determining key office business processes under the CDRH QM Program.

2.3. Management Review

2.3.1 At least once a year, CDRH senior management shall review and analyze the results of quality data, including relevant information on quality issues and corrective and preventive actions, to assure continued suitability, adequacy and effectiveness of products, services, and systems. The review shall also include an assessment of the quality policy and quality objectives.

2.3.2 At least once a year, office senior management shall review and analyze the results of office quality data, including relevant information on quality issues and corrective and preventive actions, to assure continued suitability, adequacy and effectiveness of products, services, and systems.

3. Resource Management

3.0. General

Resources and support are needed to establish an efficient and effective quality management program. The involvement and support of CDRH managers and employees will result in improving both organizational and quality management system effectiveness and efficiency.

3.1. Management of Resources

3.1.1 CDRH senior management is accountable for providing or reprograming resources, as available, to establish and maintain the CDRH QM Program and to fulfill CDRH quality objectives. (See 1.4)

3.1.2 Office senior management is accountable for prioritizing resources to accomplish work needed for their quality activities.

3.2. Competencies and Training

3.2.1 Staff shall be trained on activities under the CDRH QM Program.

3.2.2 Staff affected by the processes and procedures under the QM Program shall have an adequate level of understanding to carry out those processes and procedures.

4. Lifecycle Management

4.0. General

Lifecycle management integrates people, data, processes and business systems. This section describes the processes and related activities CDRH will use to assure the quality of products and services throughout their lifecycle.

4.1. Document Control

Appropriate process documentation (such as policies, processes, procedures, forms, templates, and work instructions) is required under a quality system. Documentation allows for a reference point whenever there is a question, and helps to identify which process and services are working, as well as those that may need to be re-examined.

Document control assures that appropriate quality management and key business process documentation are available to staff use; current versions are available for use by CDRH staff; and superseded versions are properly archived. The principles below apply to processes under the quality program.

4.1.1 Senior center and office management is responsible for selecting and prioritizing processes and establishing time frames for processes that will be brought under the quality program

4.1.2 Information needed to execute QM processes as well as center and office processes under the QM Program shall be documented. As needed, documentation may include documents outlining policies, processes, and procedures; forms; templates; and work instructions. A template for SOP-type documents is available in TRACTION.

4.1.3 Documents must be written to the level of those performing the work.

4.1.4 Offices and the center are responsible for creating, revising, and ensuring updated documents are used for all processes subject to the CDRH QM Program. They are also responsible for ensuring proper document distribution and removing obsolete documents.

4.1.5 As needed, training can be a valuable tool to assure staff understanding of the processes and practices described in a document.

Document Identification and Format

4.1.6 Document identification, including numbers or codes, shall be assigned to assure documentation can be appropriately indexed. The system shall be easy to understand, maintainable, and open to growth. Numbers, letters, prefixes and suffixes can all be used.

Document Review Clearance, and Approval

4.1.7 After writing a new document or revising an existing document, the initiator shall begin the clearance process. The document and the information shall be circulated to the appropriate management and individuals for review and clearance.

4.1.8 If not already established according to standard operating procedures, the clearance and approval process should be determined as part of the initial document development, and should be appropriate for the level of impact of the process described in the document and the type of process (e.g., a standard operating procedure impacting the immediate program area may need clearance by the appropriate management chain within that program area).

4.1.9 Each document shall be made effective by the approving official, given an effective date, and implemented. The approving official is the individual accountable for implementing the process described in the document.

Dissemination and Access

4.1.10 Documents for staff use shall be easy to find and available to all staff.

4.1.11 Documents related to processes and procedures under the QM Program shall be available to staff electronically. Offices and the center shall designate a central location from which staff can access their QM documents as well as documents related to processes and procedures under the QM Program.

4.1.12 Offices and the center shall determine where to house their original documents. Access to a document from locations other than the designated location shall be via hyperlink to that location.

4.1.13 Obsolete documents shall be archived, and access to obsolete documents shall be limited.

4.2. Corrective and Preventive Action (CAPA)

CAPA is critical to a quality management system. It provides the means by which systemic quality issues are addressed, remedied, and eliminated from happening again. Written procedures are required for a CAPA system.

CAPA focuses on the identification and systematic investigation of potential quality issues and observed discrepancies (failures and/or deviations) within a system or process. CAPA systems identify deviations from quality, correct the identified discrepancies, and prevent their occurrence or recurrence. To assure that corrective and preventive actions are effective, the systematic investigation and root cause analysis of quality issues is pivotal to help understand the causes and contributory factors. An abbreviated flowchart representation of the process outlined below is included in Appendix A.

Identifying and Collecting Quality Issues

4.2.1 Offices and the center shall develop a mechanism for identifying and collecting quality issues and concerns, including a mechanism for capturing quality concerns raised by employees. Examples of quality concerns include, but are not limited to:

- Negative audit or assessment findings; and
- Non-conformances

4.2.2 Offices and the center shall identify sources of quality data appropriate to their business processes, and establish procedures to collect and periodically review these data. Sources of quality data may include, but are not limited to, the following:

- Complaints;
- Databases;
- Assessments/Feedback indicating systemic problems; and
- Action Items/Inquiries

Evaluating Quality Concerns

4.2.3 **Office Quality Concerns.** Quality concerns that impact a single office shall be handled within that office.

- The office's Quality System Representative or designee shall assure timely and periodic review of data related to quality issues and concerns.
- Offices shall develop mechanisms to address office issues that do not rise to the level of CAPA investigations.

4.2.4 **Center Quality Concerns.** Quality concerns that impact multiple offices, or center-wide activities or programs shall be raised to the CSC Quality Management Subcommittee level.

- The Quality Management Subcommittee Chair shall meet periodically with the Quality Management Subcommittee to review and assess potential center-wide or cross-office quality problems, to recommend the appropriate course of action.
- The Quality Management Subcommittee shall develop a mechanism to address center issues that do not rise to the level of a CAPA investigation.

4.2.5 Not all quality issues need to be raised to the level of a CAPA investigation. Issues shall be addressed at the lowest possible organizational level and by the least burdensome means to obtain resolution. A rationale shall be provided when a decision to not address or defer an issue is made.

CAPA Investigation Determination – CAPA Issues vs. CAPA Investigation

4.2.6 CAPA issues require corrective and/or preventive actions, but may not require formal CAPA investigations if their causes are readily apparent and corrections as well as corrective, and/or preventive actions can be readily determined based on existing information.

4.2.7 Offices shall develop a mechanism to determine when to open a CAPA investigation to address quality issues related to specific business processes and established procedures for their office. The Quality Management Subcommittee shall develop a mechanism for determining when to recommend a CAPA investigation for cross-office and center-wide quality issues.

4.2.8 Offices shall determine the level of approval needed to open a CAPA, close a CAPA, or defer a decision; the Quality Management Subcommittee shall determine the level of approval needed to open, close, or defer a center CAPA.

4.2.9 If one or more of these characteristics is present, a CAPA investigation may be needed:

- The problem is not well understood;
- The root-cause is not clearly identifiable; or
- A solution is not apparent.

4.2.10 Offices shall establish a system for tracking, documenting and communicating their CAPA investigations and CAPA issues; the Quality Management Subcommittee shall establish a system for tracking and documenting center CAPA investigations and CAPA issues.

Initiating a CAPA Investigation

4.2.11 If a CAPA investigation is warranted, the following shall be considered when determining how and when to proceed:

- The potential adverse impact (e.g., urgency and severity);
- The scope and extent of the issue;
- Resource availability; and
- Regulatory authority.

4.2.12 The Office Director or designee shall assign office CAPA investigations within his/her office. CDRH senior management will determine to whom to assign a center or cross-office CAPA investigation.

4.2.13 The Quality Management Subcommittee shall monitor accountability in CAPA investigations.

4.2.14 It is recommended that those assigned a CAPA investigation follow these steps:

- Investigate the causes of nonconformities relating to product, processes, and/or the quality system.
- Identify action(s) needed to correct and prevent recurrence or occurrence of nonconforming products, or other quality problems.
- Make recommendations concerning corrective and preventive action(s) to the deciding Official or Committee, who shall make the final determination and assign responsibility for implementation.

Closing a CAPA

4.2.15 Offices and the center shall close a CAPA when all corrective and preventive actions have been completed.

4.2.16 Each office and the center shall review any related CAPAs because closure of one CAPA may result in the closure of a related CAPA requiring the same corrective and preventive actions.

Validation

4.2.17 Offices and/or the Quality Management Subcommittee shall monitor the effectiveness of corrective and preventive action(s). Each office and the center may consider the following when monitoring effectiveness:

- Periodically review quality data (including metrics) associated with the process or product;
- Introduce new measures and/or metrics to assess impact of implemented action(s);
- Obtain feedback from employees/customers who reported the quality problem;
- Conduct additional audits/assessments to validate action(s); and
- Review and analyze results during management review.

4.3. Continuous Process Improvement (CPI)

CPI is about making things better; it is simply a systematic way of looking at how we can do our work better.

Continuous Process Improvement (CPI) is a tool, or systematic approach, to improving the efficiency of our products and services. CPI efforts can be used to seek incremental improvements over time or breakthrough improvements all at once. As products and services are brought under the CDRH QM Program, areas of opportunity may be identified and CPI efforts initiated. Certain CDRH business practices already represent CPI efforts, such as some CDRH projects for FDA TRACK. Some CPI efforts could be used to assist in addressing a CAPA, while others may arise from strategic considerations. In all cases, the desired end result is a more effective and efficient way to produce the product or service. Among the most widely used tools for continuous improvement is the plan-do-check-act (PDCA) cycle, also known as the Deming Cycle or Shewhart Cycle:

- **Plan.** Identify an opportunity and plan for change. Identifying what needs to be done, by when, by whom and how.
- **Do.** Implement the change, i.e. carry out the plan, on a small scale.
- **Check.** Use data to analyze the results of the change and determine if the planned changed resulted in improvement.
- **Act.** If the change was successful, implement it on a wider scale and continuously assess results. If the change did not work, begin the cycle again.

4.3.1 CPI projects shall focus on the processes needed to realize the product or service.

4.3.2 CPI projects can be resource intensive, and shall be managed strategically by CDRH senior management.

4.3.3 When conducting a CPI project, consider using a continuous improvement tool such as PDCA, and carryout the following actions:

- Document the current ("as is") process[5]
- Document baseline performance
- Obtain the customer needs and expectations
- Establish process requirements
- Establish process measures (metrics for success)
- Identify process performance gaps
- Modify or standardize process
- Monitor changes via test or pilot implementation projects
- Assess impact of improvements (audit)

[5] These steps are only required for the first cycle.

5. Quality Management System Evaluation

5.0. General

Evaluation refers to a periodic process of gathering data, and the subsequent analysis or organization of the data, in such a way that the resulting information can be used to determine whether the program or service is effectively carrying out planned activities, and the extent to which it is achieving its stated objectives and anticipated results.

Metrics will allow CDRH to evaluate the QM Program. They will inform on the progress of establishing the QM Program. Metrics will also be used to evaluate key business processes under the CDRH QM Program. Results from metrics can lead to CAPAs and CPIs.

5.1. Measuring and Monitoring

5.1.1 CDRH shall plan and establish tools and methods to monitor, measure, and analyze their processes.

5.1.2 These tools and methods shall be used to:

- demonstrate fulfillment of product/service requirements; and/or
- assure adequacy of the quality management system, and continually improve its effectiveness; and/or
- assure adequacy of center processes, and provide data to support continuous improvement; and/or
- assess fulfillment of customer requirements and customer perception.

Measuring

5.1.3 The following steps are recommended when identifying needed metrics:

- **Identify the process, output or outcome to be measured.** Understand the key goals and objectives of the process and service as well as those of CDRH and the program under which the process or services falls. Process flowcharts and diagrams may help at this step.
- **Identify the customers.** Determine critical customer needs/requirements.
- **Develop the metrics.** We recommend using the SMART method described in 5.1.4 below. If measuring a step in a process (sub-process), make sure that sub-process metrics do not adversely affect the parent process.

5.1.4 The "SMART method" describes a set of criteria that a metric should have:

- "S" or "specific" metrics are specific to the target that is to be measured.
- "M" or "measurable" means that collected data is quantifiable, accurate and complete.
- "A" or "actionable" metrics are clear, i.e. the metric makes it easy to understand when further action is needed.
- "R" or "relevant" metrics address what is important, i.e. they avoid measuring for the sake of measuring; and
- "T" or "timely" means that data can be obtained when needed, i.e. when one can make the best use of them.

5.1.5 After metrics have been developed, the following questions will help determine if the set of metrics fulfill their intended purpose:

- Do they make sense to those directly involved in the affected product, service or process?
- How do they compare with existing metrics?
- Do they form a complete set (e.g., covered the areas of time, quality, cost, and customer satisfaction)?
- Do they reinforce the desired behavior?

Data Collection, Monitoring and Analysis

See 4. Lifecycle Management for additional information of monitoring and measuring QM activities.

5.1.6 CDRH shall identify and collect data on the performance of the quality management system and its processes, as well as for the products and services they provide.

5.1.7 Data shall be systematically collected using appropriate information systems. Examples of data that can be collected include:

- metric related information;
- non-conformances and corrective or preventive actions;
- satisfaction surveys; and
- results of audits.

5.1.8 CDRH shall monitor the data identified in 5.1.6, establish appropriate methods for acting upon the findings, and communicate to interested parties the methods and tools used as well as the results.

5.1.9 CDRH shall establish a documented procedure indicating:

- mechanisms to detect a nonconforming product/service
- tools for the identification of the nonconforming product/service;
- actions to correct the nonconforming product/service; and
- controls to prevent the non-intentional use or provision of the nonconforming product/service.

5.1.10 Data analyses shall include determination of applicable methods, including statistical techniques, internal audits, and the extent of their use.

5.1.11 Data collection methods and analyses shall be validated to assure they support a continual improvement process.

5.1.12 Information monitored shall be periodically collected and analyzed. The results from data analyses shall be periodically reviewed and corrective and preventive actions shall be taken when planned results and/or customer requirements are not met.

5.2. Assessments, Audits, and Program Evaluations

Assessments, audits, and program evaluations are mechanisms to review an organizational component, system, process, enterprise, project, product, or program. Assessments, audits, and program evaluations are performed within CDRH. Examples are included in Appendix B.

5.2.1 Center senior management is responsible for determining the need for center level assessments/audits, e.g. CDRH consult program. Office level audits/assessments are determined by the offices.

5.2.2 Offices or the center will conduct assessments and audits at planned intervals to determine whether the quality management system, including key business processes: are consistent with FDA SMG 2020 and ISO 9001:2008 and are being followed and are achieving stated objectives.

- An assessment is often an initial appraisal of a system, product, process, or service. The objective of an assessment is to characterize the "current state."
- Audit addresses implementation and effectiveness of a system, process, or service based on defined procedures. Specifically, the purpose of this activity is to verify that quality activities and products conform to established requirements. It also measures the adequacy and the effectiveness of implementing systems, processes and procedures and how they assist in achieving the established goals.
- A program evaluation utilizes some of the same tools as an assessment or audit. The objective is to determine the degree to which a program is meeting stated goals, objectives, or purpose.

5.2.3 A documented procedure shall be established to define the responsibilities, requirements, and schedules for planning and conducting audits, establishing records and reporting results.

- The procedure shall take into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.
- The audit criteria, scope, frequency and methods shall be defined.
- The audits shall be carried out by independent and qualified personnel to assure objectivity and impartiality of the audit process.
- Guidelines shall exist for the selection and training of the auditors and to assure the maintenance of their competence.

5.2.4 Following an internal assessment, audit or program evaluation results shall be analyzed, findings summarized and documented and, if needed, actions recommended to senior management. If corrective actions are recommended, see section 4.2 CAPA for next steps. If CPI is recommended, see section 4.3 Continuous Process Improvements for next steps.

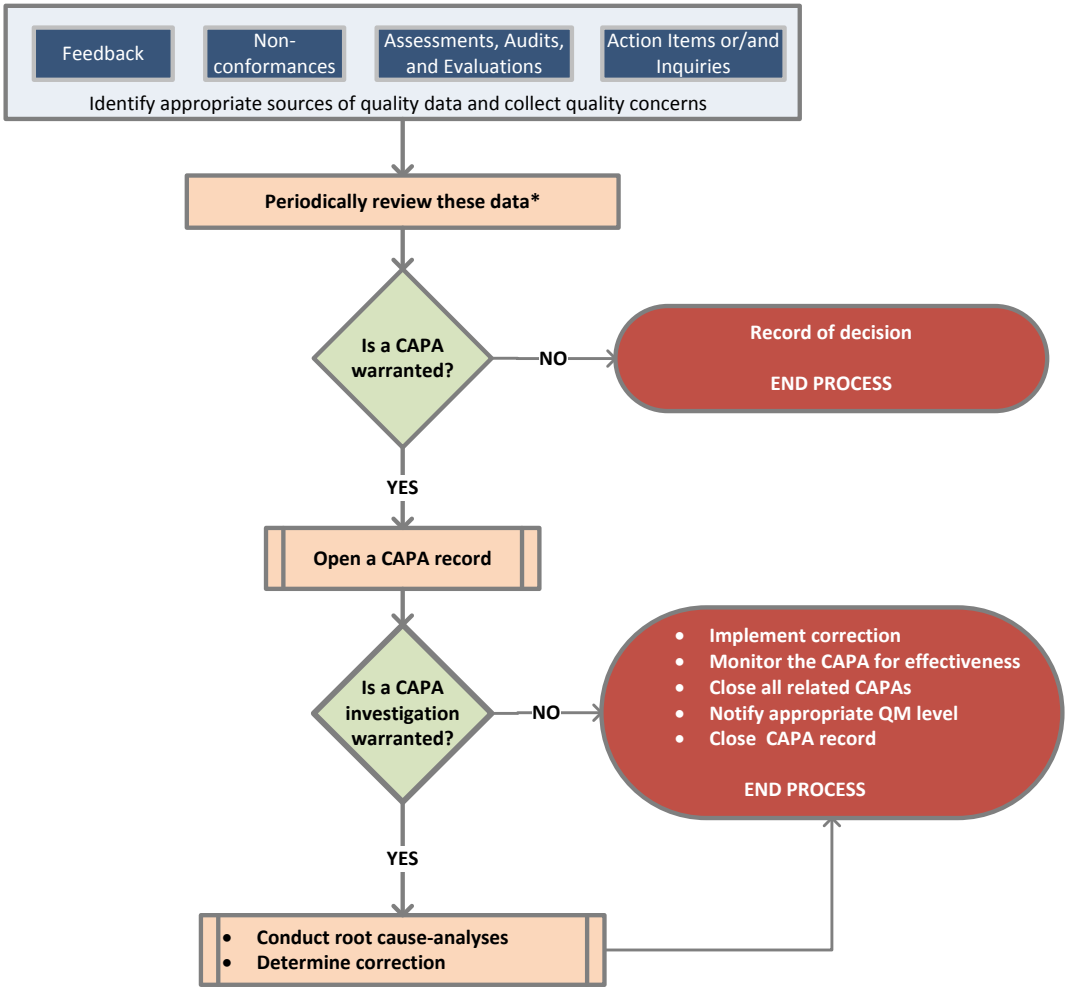
6. Effective Date

This document is not intended and should not be used to select and audit CDRH processes to assess for compliance with the CDRH QM Program. *CDRH does not intend for all Center processes to comply with this framework upon the effective date of this document. Rather, the effective date of this document marks the beginning of a gradual implementation of the QM Program. CDRH plans to increase adherence with the QM principles and practices set forth by this document over time.*

CHANGE CONTROL TABLE

VERSION #	REASON FOR CHANGE	EFFECTIVE DATE	APPROVING OFFICIAL (NAME/TITLE)
1.0	Original Document	January 24, 2013	/s/ William H. Maisel, MD, MPH CDRH Deputy Center Director for Science
			/s/ Nancy C. Braier, PHD Acting, Chair, CDRH Quality Management Subcommittee

Appendix A – CAPA Investigation Decision Flowchart



* Quality concerns that impact a single Office shall be handled within that Office. Quality concerns that impact multiple Offices, or Center-related activities or programs shall be raised to the CSC Quality Management level.

Appendix B –Audits, Assessments, and Program Evaluations

TYPES OF AUDITS

Performance audits. Performance audits examine the degree to which a system meets its performance objectives such as safety, security, information systems performance, and environmental concerns.

Quality audits. Quality audits are performed to verify conformance to standards through review of objective evidence. They verify the effectiveness of achieving defined targets and are a management tool for achieving continual improvements. Quality auditing should address conformance and non-conformance; recommend corrective actions; and highlight areas of good practice.

Operations audit. An operations audit is an examination of an organizations operation. The audit examines the efficiency, effectiveness and economy of the operations which goes beyond auditing internal controls.

TYPES ASSESSMENTS AND PROGRAM EVALUATIONS.

Needs Assessment. An evaluation aimed at systematically determining the nature and extent of the problems that a proposed or existing program should address.

Feasibility Study. A systematic assessment of the optimal approach for evaluating a program, including which evaluation designs and data collection strategies can and should be used. This type of study is sometimes called an evaluability assessment.

Process Evaluation. A systematic assessment of program operations to determine whether a program is being conducted as planned, whether expected output is being produced, and/or how program-critical processes can be improved.

Outcome Evaluation. A systematic assessment of program accomplishments and effects to determine the extent to which a program's intermediate and/or long-term goals have been achieved.

EXAMPLE: *A program evaluation of a CDRH program would address the degree to which the program is working - assess efficiency, identify strengths and weaknesses, verify procedures, evaluate effectiveness, and recommend program improvements. The program evaluation could be used to determine whether the program should be modified or eliminated or whether or not it needs additional resources. The program evaluation will not include analyses of what the data generated by the program is telling us about medical device performance.*

Appendix C – Glossary of Terms

Accountability	ultimate responsibility for action
Authority	power to command action; right to command or give a final decision (see also: responsibility)
Authorization	approved to take a certain action
Business Process Improvement (BPI)	the process includes awareness, assessment, alignment, action, and accountability to enhance the overall performance to improve productivity, customer satisfaction, and profitability
Capability	ability of an organization, a system, or process to fulfill requested requirements
Continuous Improvement	ongoing activities to evaluate and positively change products, processes, and the quality management system to increase effectiveness
Correction	action to resolve specific nonconformance
Corrective Action	reactive activity to prevent recurrence of detected nonconformance
Customer	a person or organization (internal or external) that receives a product or service anywhere along the product's life
Customer Satisfaction	a customer's perception that a product or service has met their expectations.
Data	facts collected together for reference or information (see also: document)
Defect/ Deficiency	absence of something necessary for completeness/fitness (see also: nonconformance)
Design and Development	a set of processes to transform requirements into product/process characteristics
Deviation	variation from the standard (see also: nonconformance)
Directive	directions to be followed during standard operations; as per FDA SMG 3280.1, a written communication issued in an organized system to establish policy, organization, procedures, or responsibilities; to require action; or to set forth information needed for the effective operation of a system or program. A directive may be a policy memo, procedure, instruction or form. A directive may also be a guidance documents. (see also: document; policy procedure; instruction (see also FDA SMG 3280.1))
Document	(n) information and its supporting medium (see also: data; record); (v) to write down, to provide evidence
Effectiveness	doing the right things with least waste of resources
Efficiency	performing work correctly in least possible time
Economy	balance between benefits and costs to run the operations
Establish	define, document and implement

Evaluation	periodic process of gathering data and the subsequent analyzing or ordering it in a way that the resulting information can be used to determine whether the program or service is effective in carrying out planned activities.
Goal	objective or actions related to achievements that are quantifiable and measurable
Instruction	directive on how to carry out a task
Lifecycle	the activities that plan, produce, deliver, and service a work product
Management	the managers and supervisors in an organization who lead, direct, and oversee the organization
Measure	objective evidence used to evaluate a process or performance (see also: monitor)
Measurement	Ongoing monitoring and reporting of progress toward established controls
Metric	any type of measurement used to guage some quantifiable component of a program, process or service
Monitor	check systematically for the purposes of collecting metrics (see also: measure; trend)
Need	requirement
Non-Conformance	A non-conformance within a system or process occurs when a requirement is not fulfilled. Failing to correct a non-conformity, or the continued presence of a non-conformity, can delay the introduction of safe and effective devices to the market, and constrain the removal of unsafe, ineffective and violative products from the market
Objective	desired achievements derived from (strategic or quality) policy; something to be achieved or attempted (see also: goal)
Office Management (CDRH)	managers in the top levels of the office with responsibility for managing resources and processes
PDCA	Plan, Do, Check, Act: a process for quality improvement, also known as the 'Shewhart Cycle' or the 'Deming Cycle'
Plan	formulation or organized method by which something is to be done
Policy	a directive setting out a course of action or principle
Preventive Action	proactive activity to stop occurrence of a possible nonconformance
Procedure	directive on how to carry out an activity or process
Process	a set of interrelated activities (tasks, procedures, sub-processes) that transform inputs into desired outputs (product) (see also: system)
Product	anything delivered to a customer
Project	a process with defined start and finish dates to achieve an objective; unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming

	to specific requirements, including the constraints of time, cost and resources
Quality	a measure of a product's or service's ability to satisfy the customer's stated or implied needs
Quality Assurance	proactive and retrospective activities that provide confidence that requirements are fulfilled
Quality Control	the steps taken during the generation of a product or service to ensure that it meets requirements and that the product or service is reproducible
Quality Management	accountability for the successful implementation of the quality management system
Quality Objectives	specific measurable activities or processes to meet the intentions and directions as defined in the quality policy
Quality Plan	the documented result of quality planning that is disseminated to all relevant levels of the organization.
Quality Planning	a management activity that sets quality objectives and defines the operational and/or quality management system processes and the resources needed to fulfill the objectives
Quality Policy	a statement of intentions and direction issued by the highest level of the organization related to satisfying "customers" needs. It is similar to a strategic direction that communicates quality expectations that the organization is striving to achieve
Quality management system	formalized business practices that define responsibilities, processes, procedures, and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement.
Record	document stating results achieved or providing evidence of activities performed
Requirement	a need or expectation of the customer or other interested party that may be stated, implied, or compulsory resulting in product or process characteristics.
Responsibility	duty, action you assigned to an individual(see also: role; authority)
Role	position or function (see also: responsibility)
Satisfaction	a customer's level of approval when comparing a product's perceived performance with their expectations
Senior Management (CDRH)	managers in the top levels of the organization with responsibility for managing resources and processes
Service	an intangible product that is delivered to a customer
Stakeholders	an individual or organization having an ownership or interest in the delivery, results, and metrics of the quality management system framework or business process improvements
System	a set of interrelated elements to accomplish a purpose
Voice of the Customer (VOC)	the expressed requirements and expectations of customers relative to products or services, as documented and disseminated to the providing organization's members.