<u>New</u> Quality Systems Training and Document Control Procedures

Participant's Guide

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Part 2

Section 1: Purpose and Goals of this Training

Purpose

There is a new direction for Quality Systems Training and that direction requires new procedures for creating and revising Standard Operating Procedures (SOPs) and the training that will often be required. Therefore, this training exists to prepare individuals affected by these changes so that he/she knows, understands, and can apply all of the changes to the following SOPs:

- SOP 362, Rev. 25.0
- SOP 002, Rev. 38.0
- SOP 642, Rev. 3.0

Goals

1. To <u>provide</u> background information regarding the need for the new training and document control procedures
2. To <u>introduce</u> the Quality Systems Training Department [team] and <u>describe</u> its goal/vision
3. To <u>outline</u> the new training procedures and changes to roles and responsibilities specified in the revised versions of SOPs 362 and 642.
4. To <u>explain</u> the Instructional Design and training methodologies used to ensure that training:
   o Meets the business and instructional needs/goals
   o Is targeted to the learner
   o Is relevant and engaging
   o Is delivered in the appropriate format
   o Is measured appropriately and effectively
5. To <u>outline</u> the changes to documentation procedures related to training as specified in the revised versions of SOP 002 and QCFM 063 (CAR).
6. To <u>illustrate</u> how to use QCFM 756 to make a training request and initiate the collaboration between the Quality Systems Training Department and the Document Owner/Designee

Section 2: Quality Systems Training

Quality Systems Training Team
- Kristie Burton – Manager
- Felicia Brown – Sr. Instructional Designer
- Ali Rim – Assoc. Training and Education Specialist
- Daniel Lee – Assoc. Business Systems Analyst

The Goal of the Quality System Training Team

"Our vision is to be the industry leader in the design and delivery of effective training and ensure that our customers reach their full potential."

Leading and Closing the Gaps

Effectiveness

- Utilizing the **SABA Enterprise learning management** system to its full potential:
  - Training records handled electronically rather than via paper
  - Paper records for most training will no longer be required
  - Training effectiveness measures implemented electronically (myLearningPortal)
- Increasing visibility for completed, due, and outstanding training that exists

Compliance

- Considering training needs before establishing a deadline for new Quality System documents/ processes or changes
- Collaborating with Quality Systems Training Team on:
  - Course design
  - Course delivery timeline(s)
  - Design and development of training/ certification plans
  - Learning Assessments
  - Engagement strategies
- Utilizing all resources (time, talent, software, etc.) to their full potential in order to meet the needs of the learner

Efficiency

- Standardizing training across the organization through the use of sound **Instructional Design Principles**
- Addressing the **Learning Outcomes** for participants: Awareness, Knowledge, Understanding, Performance
- Using the best training **Delivery Method** for the training content, learning outcomes and available resources:
  - E-Learning/Web-Based Training*
  - Instructor-Led
  - Performance-based On-the-Job Training
- Assessing training through the use of appropriate **Learning Assessments:** Objective-based, Performance-based, and/or Perception-based

Section 3: SOP 362 — Division Procedure for Training

Training Goal

During this section of the training, the trainer(s) will <u>outline</u> the new training procedures and changes to roles and responsibilities specified in the revised versions of SOPs 362 and 642.

Learner's Objectives

Upon completion of this section of training, you will be able to:

- Recognize the five (5) steps involved in the process of management and execution of training
- Identify the roles that are involved in the identification of training needs
- Identify the responsibilities of the QSC, Managers, and Document/Process owners in the identification of training needs
- Recognize the key changes to SOP 642
- Differentiate between administrative and content changes
- Identify the responsibility of training staff in the deployment of training
- Identify the roles that are involved in the delivery/completion of training
- Identify the responsibilities of the Managers, Document/Process owners, Trainers, and training Staff in the delivery and completion of training
- Recognize types of learning assessments that can be used to evaluate training effectiveness
- Identify types of training records and how they are maintained
- Identify the roles and responsibilities involved in the storage of course materials, reports for Inspections/Audits, Annual Review of Training and Training Metrics

Training Process

Management and Execution of Training

| 1 Identify Training Needs | 2 Deploy Training | 3 Deliver/ Complete Training | 4 Evaluate Training | 5 Maintain Training Records |

Identification of Training Needs

Roles and Responsibilities

Job Role	Responsibilities
Quality Systems Council	Organizational Oversight as defined in SOP 642.* *Information regarding what is meant by organizational oversight of training is outlined in SOP 642.*

Managers	• Approve training recommended by document/process owners* • Identify job-specific training required for role • Identify additional training needed to meet QS requirements • Identify training requirements for those employees that have had extended absences • Ensure that direct reports are identified for additional training when he/she when applicable (promotions, new job responsibilities, etc.) *Outlined in SOP 642 in addition to SOP 362
Quality Document/Process Owner or Designee	• Determine if training is required for new and updated documents and processes • Determine the amount of days to complete training, if applicable. *The Standard time = 30 days* • Recommend (to Managers) the employees that should be trained on new documents/processes.* • Consult with Quality Systems Training Team to determine training deliverables. *Outlined in SOP 642 in addition to SOP 362

When is Training Required?

- Training is required for all **new** documents/processes.
- For **changes** to current documents/processes
    - o **Content Change:** New Revision is NOT equivalent to previous → Training IS Required
    - o **Administrative Change:** New Revision is equivalent to previous → Training is NOT Required

Deployment of Training

Roles and Responsibilities

Job Role	Responsibilities
Training Staff	Assign employee training identified by Managers and Document/Process Owners

Delivery/Completion of Training

Roles and Responsibilities

Job Role	Responsibilities

Managers	• Ensure that direct reports have completed training that:
	  • Is necessary to fulfill the requirements of their jobs
	  • Is required for documents initiated*
	• Ensure that direct reports complete any required training within the assigned timeframe <u>and</u> that it is prior to performing any tasks associated with documents.
	• Take appropriate action if training becomes overdue.
	
	* Outlined in SOP 642 in addition to SOP 362

Document/Process Owner or Designee	• Notify trainers of their responsibilities to deliver and complete training • Ensure that training content is correct and that training activities are completed.

Trainer	• Review course/training material and ensure that it is correct and up-to-date.
	• If using a Group Training Attendance Record (QCFM 387)**,**
	  • Ensure that the form is complete and correct
	  • Submit the form to the training staff for entry into the LMS (SABA)
	  • Complete learning assessment and submit results with training records
	
	*QCFM 387 is no longer required except in cases where paper-based learning assessments are necessary or with certain types of training.

Training Staff	• Ensure training completions are record in the LMS (SABA) • Upload training content and assessments to the LMS, if applicable

Evaluation of Training

Learning Assessments

Types
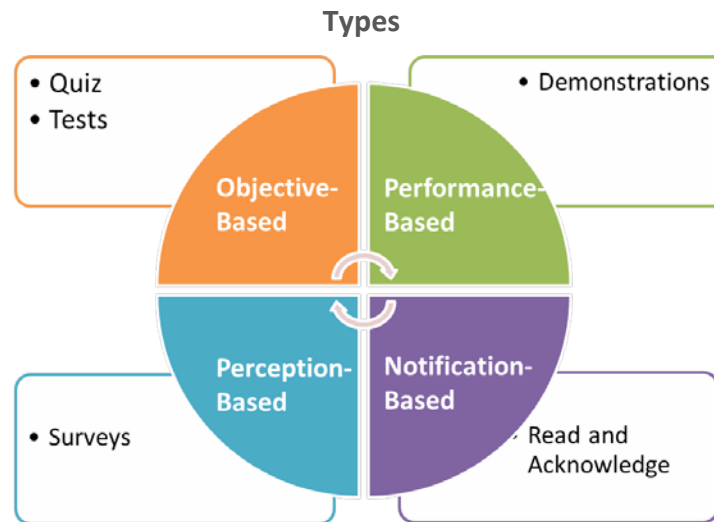
- Necessary to evaluate training effectiveness
- Should be appropriate to the learning outcomes (goals) and complexity of the learning material
- Consideration should be given to the risk associated with training
  - **High** Risk**: Direct** Impact on → Customer Safety, Employee Safety, Product Quality, Customer Satisfaction
    → Use *Formal (graded)* Objective-based or Performance-based assessments – whichever is appropriate with the learning outcome.

  - **Low** Risk: **Minimal** Impact on → Customer Safety, Employee Safety, Product Quality, Customer Satisfaction
    → Use *Informal (non-graded)* and/or *Formal (graded)*

⬛ **Maintenance of Training Records**

Training Records

- Maintained in an LMS (ex. SABA) or equivalent
- May be paper or electronic
- Types include:
  - Assignment of required training
  - In-progress courses
  - Attendance records
  - Completion records
  - Course materials
  - Completion of Annual Reviews

Process Overview

Delivery Type	Enrollment/ Assignment	Completion	Records
Read and Acknowledge -------------------- eLearning (WBT) -------------------- Classroom (ILT) -------------------- Web Conference or Live Meeting -------------------- On-the-Job Training (OJT) -------------------- External Training	Training is assigned *manually* or Training is assigned *automatically* via LMS (SABA) or Employees (EE) *Self-enroll*	EE reads document and acknowledges --------------------- EE completes training via SABA --------------------- EE attends training and takes assessments delivered by SABA --------------------- EE completes training and takes assessments --------------------- EE completes training and provides training record and certificate	Electronic training completion record is recorded in LMS or equivalent. Or, paper training completion record is archived.

Miscellaneous Roles and Responsibilities

Storage of Course Materials

Job Role	Responsibilities and Actions
Document/Process Owner or Designee + **Training Staff**	Training (course) material that is created by the Quality Systems Training department will be: • Revision controlled *-or-* • Stored by date in a controlled system (Ex. SABA)

Reports for Inspections and Audits

Job Role	Responsibilities and Actions
Training Staff	• Requests for training records shall go through the appropriate training staff for consistency and expertise • If records are paper, then a delegate may be involved in pulling those records • Training staff will analyze requests for training records and ensure that the data has been accurately provided.

Annual Review of Training

Job Role	Responsibilities and Actions
Quality Systems Council **+** **Managers** **+** **Training Staff**	• Required Training will be reviewed annually to determine if any changes are required. • Annual reviews will be performed collaboratively between QSC and Managers

Training Metrics

Job Role	Responsibilities and Actions
Training Staff	• Data on the completion of training will be tracked

Training Goal

During this section of the training, the trainer(s) will <u>explain</u> the Instructional Design and training methodologies used to ensure that training:

- Meets the business and instructional needs/goals
- Is targeted to the learner
- Is relevant and engaging
- Is delivered in the appropriate format
- Is measured appropriately and effectively

Learner's Objectives

Upon completion of this section of training, you will be able to:

- Identify the definition of learning outcome
- Identify the definition of Understanding
- Identify the definition of Performance
- Differentiate between the three types of learning outcomes
- Differentiate between the six training delivery methods
- Associate the best delivery method with an identified learning outcome
- Recognize an example of an Objective-based assessment
- Recognize an example of a Performance-based assessment
- Recognize an example of a Perception evaluation/survey
- Recognize an example of a Performance-based assessment
- Recognize an example of a Perception evaluation

Learning Outcomes

- They are also known as Learning Objectives
- They are what you want the learner to <u>know</u> and <u>do</u> upon completion of the training.
- They should be **S M A R T**:

- Good and Bad Examples of SMART learning objectives
    - **Good** = Upon completion of today's training, you will be able to **<u>define</u>** the term "Learning Outcome"
    - **Bad** = Upon completion of today's training, you will be able to <u>understand </u>what a learning objective is.
        - *Why? <u>Understand</u> is not a specific enough verb and is not measureable in its own right.*

Knowledge and Understanding

What is the difference between Knowledge and Understanding?

- **Knowledge**
  - The familiarity or acquaintance with information, a particular subject, or branch of learning.
  - Based upon study, investigation, or experience
  - Involves the recall of information such as Facts, Descriptions, Steps in Procedures, etc.
  - Objective-based learning assessments are the best for measuring knowledge obtained
- **Understanding**
  - The full comprehension, perception, interpretation, or discernment of any particular thing.
  - Based upon experience or repeated attention because the amount of knowledge that is needed to have understanding is too large.
  - Involves the application and analysis of concepts, predictions, interpretations, and critical thinking.
  - Formative assessments (of any type) are best for measuring understanding

Performance

- Is the execution of an action or accomplishment of a given task measured by known standards (or criteria) of accuracy, completeness, or speed.
- An individual can perform:
  - Behaviors
  - Skills
  - Actions
  - Tasks

Review Questions Set 1

Instructions: Select the correct type of learning outcome specified in each of the following learning objectives.

1. Upon completion of today's training session, you will be able to write a root cause statement that accurately identifies the true root cause in a given scenario 3 out of 4 times.

   ☐ Knowledge ☐ Understanding ☐ Performance

2. Upon completion of today's training session, you will be able to verbally state the parts of the 5W2H method of determining a root cause with 70% accuracy or higher.

   ☐ Knowledge ☐ Understanding ☐ Performance

3. Upon completion of today's training session, you will be able to explain the implications of not performing the steps of the 5W2H method with accurately.

   ☐ Knowledge ☐ Understanding ☐ Performance

Answers:
1. Performance
2. Knowledge
3. Understanding

Training Delivery Methods

Read and Acknowledge

Digital/electronic content is delivered to SABA myLP for employees to read and acknowledge that he/she has done so.

For →

Knowledge Awareness
- Notification of content only
- No learning assessment
- Design, development, and launch time do not have to be considered

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WBT/E-Learning

Self-paced web-based/Flash-based learning modules that are delivered to SABA myLP for employees to complete for credit.

For →

Knowledge, Understanding, & **Performance***
- WBT/eL Training content/methods
- SABA Learning assessment
- Design, development, and launch time *must be considered*

Classroom

Instructor-Led training that is delivered to employees in a classroom setting and credit granted in SABA myLP upon completion.

For →

Knowledge, Understanding, & **Performance**
- ILT Training content/methods
- SABA Learning assessment for *Knowledge and Understanding* only
- Design, development, and launch time *may be considered*

Web Conference or Live Meeting

Virtual training that is delivered to employees using a web conferencing platform and credit granted in SABA myLP upon completion.

For →

Knowledge, Understanding*, & **Performance***
- Virtual Training content/methods
- SABA Learning assessment for Knowledge and Understanding only
- Design, development, and launch time *may be considered*

On-the-Job Training (OJT)

Procedural-OJT training that is delivered to employees in their work environment and credit granted in SABA myLP upon completion.

For →

Knowledge, Understanding, & **Performance**
- OJT Training content/methods
- OJT Learning and/or Performance assessment
- Design, development, and launch time *may be considered*

External Training

Training that is delivered to employees outside of the company or by trainers outside of the company and credit granted in SABA myLP upon completion.

For →

Knowledge, Understanding, & **Performance**
- Certificate or transcript provided by training entity or vendor establishing that training requirements have been met

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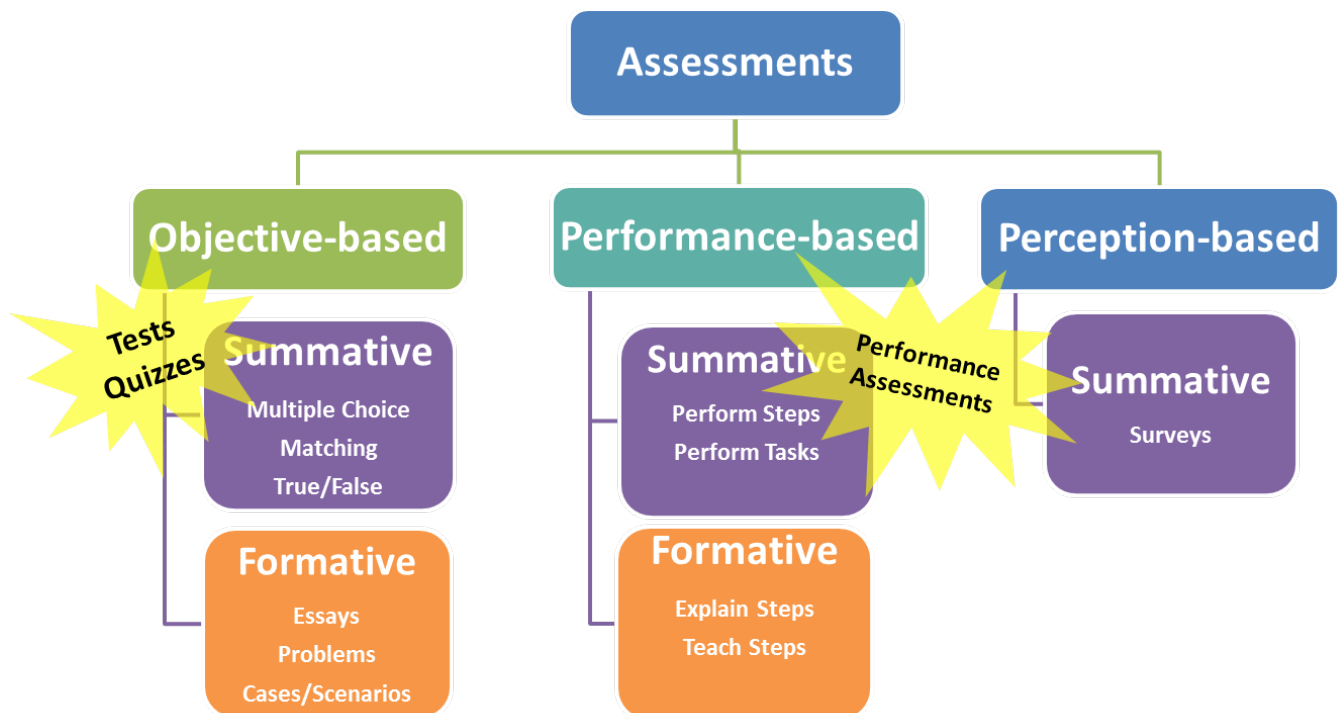
What are learning assessments?
- Evaluation instruments used to measure and document the knowledge, skills, and attitudes of an individual learner upon completion of training on specific content. They can be informal (non-graded) or formal (graded).

Types
- **Objective-based**
  - Measures an individual's **Knowledge** and **Understanding** about learning content.
  - Determines whether the learning outcomes/objectives were met
- **Performance-based**
  - Measures an individual's **Knowledge** and **Understanding** about learning content.
  - Determines whether the learning outcomes/objectives were met
- **Perception-based**
  - Measures an individual's perceived **attitude, emotion,** or **idea** towards any given topic.

Methods
- **Summative**
  - Given at the end of course or large collection of learning material.
  - Objective-based or Performance Based
  - Measures **knowledge, understanding,** and/or **performance**
  - May include formative method/style (as described below)*
- **Formative**
  - Given at any point in time in a course
  - Objective or Performance Based
  - Measures **understanding** and/or **performance**

Review Questions Set 2

Instructions: Select the type of learning assessment for each of the following.

1. A quiz composed of 5 multiple choice questions to measure knowledge obtained from a training session is a _____ assessment.

    ☐ Obj-based ☐ Perf.-based   ☐ Perception-based

2. A survey given after a training session to determine if an individual felt that the trainers and methods used were adequate is a _____ assessment.

    ☐ Obj-based ☐ Perf.-based   ☐ Perception-based

3. An evaluation that consists of a list of specific actions that an individual must demonstrate in order to show competency is a ____ assessment.

    ☐ Obj-based ☐ Perf.-based   ☐ Perception-based

4. A test given at the end of the course that is composed of multiple choice, matching, and essay questions.

    ☐ Summative ☐ Formative   ☐ Both

Answers:
1. Objective-based
2. Perception-based
3. Performance-based
4. Both

Section 5: SOP 002 Division Procedure for Preparing and Controlling SOPs and QCFMs

Training Goal

During this section of the training, the trainer(s) will <u>outline</u> the changes to documentation procedures related to training as specified in the revised versions of SOP 002 and QCFM 063 (CAR).

Learner Objectives

Upon completion of this section of training, you will be able to:
- Recognize the responsibility of document/process owners or designees in CAR requests and the completion of required training.
- Recognize the key changes made to SOP 002 related to Quality System Training
- Recognize the key changes made to QCFM 063 (CAR)

Changes to SOP 002

Roles and Responsibilities

Section 5.1 [new]

* This is a NEW section in SOP 002

Responsibilities	Roles			
	Document Owner or Designee	Approver	Document Control	People or Functional Managers
Compliance with Higher Level Rqmts.	X			
Format Requirements (per SOP 002)	X		X	
Content Requirements	X	X	X	
Periodic Reviews	X			
Reviewer/Approver	X	X		
SMEs for their Docs	X			
Auditor Interface	X			
Finding/CAPA Owner	X			
Collaborate with Owner and SME	X			
Proactive Review with QSC/QS Mgr.	X			
Facilitate Process	X			
Rep. as Applicable				X
Support Governance				X

Document Owners or Designees*

There are no major changes to the responsibilities of any role <u>except</u> that of *Document Owners or Designees* as outlined below:

- Only Document owners or designees are authorized to submit new, revision, or obsoletion CAR requests to Document Control. *However, any employee may identify and/or submit a proposal regarding an SOP directly to the Document Owner or Designee.*

*Refer to section 5.3.2 of SOP 002.

Changes to Procedures and Required Forms

QC Form 063 — Change Action Request*

Changes

Change Action Request
(Reference SOP 002)

Note: To generate completed form, select "Print Form" the Printer option appears. Select from drop down NAME list the item titled "Adobe PDF") and then OK. The content will convert to a PDF document.

Print Form

Initiator
~~Document Owner or Designee~~

Date of request

Action Type: ☐ NEW * ☐ Revision ☐ Obsolete

Changes

1. Document Affected: *Include complete title and version number*

2. Description of Action:

3. Reason for Action: **Type** - select one ☐ Administrative OR ☐ Content - QCFM 756 required

4. Training Actions: *NEW document; training is always required*
Revising a current Quality System document:

a. Do these modifications affect a defined action, activity, or requirement? ☐ YES (training required) ☐ NO (training not required)
b. If YES, do all identified personnel require training as listed on the L&D Training Matrix? ☐ NO (See Note)
Note: If NO, a documented rationale is required below:

~~5~~4. Does the change request result in the need to modify other Quality System documents? ☐ YES ☐ NO
a. If YES, list associated Quality System documents (SSOP's / SOP's/ QCFMs) affected by this change?

~~6~~5. Are all approvers required per master approval matrix? ☐ YES ☐ NO
a. If NO, list functional departments not approving the change

QCFM 063 / Rev. 18~~9~~ / Ref. 4.2

QC Form 262 - Documentation Change Request*

This form is no longer being accepted in lieu of the Change Action Request form for <u>Administrative</u> changes.

Medtronic
XOMED

Typo: # _____

DOCUMENTATION CHANGE REQUEST
(Reference SOP 002, SOP 077, SOP 394, SOP 481)

NOTE: Changes to Xomed Documentation and Specifications to correct typos and format errors that do not affect "Form", "Fit", or "Function" of a Product/Procedure do not require approval through the ECN/PCN process. Request for change maybe submitted on this form with attached documentation marked in red to indicate requested change. Changes shall be submitted to Configuration Management for review and will be processed upon approval of the Configuration Mgmt. Manager. All other changes require an ECN per SOP 077 or PCN per SOP 002. **Drawing changes can not be made using this form.**

Change

Ref ECN No.: _____ Ref PCN No.: _____
Document Type: ☐ Xomed Equipment Operating Instructions (XEOI)
☐ Xomed Visual Instructions (XVI)
☐ Xomed Inspection Instructions (XPI, XPI DS)
☐ *SOP/QCFM/SSOP
☐ Bill of Materials/ Routers
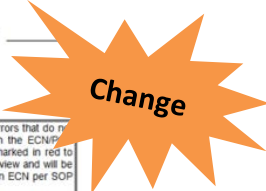☐ Other: _____

Document File Name/Part No.: _____

Document Title/Part Description: _____
*(If Division Procedure add Mystic to the notification approval route in Matrix One)
Description Of Change: _____

Submitted By: _____ Date: _____
Job Title: _____

Reviewed By: _____ Date: _____
Configuration Mgmt. Manager

Completed By: _____ Date: _____
Configuration Mgmt. Specialist

Remarks: _____

Refer to section 5.3.3.1 of SOP 002.

QC Form 756 — Quality System Training Request*

This QC Form is now a part of the process to ensure that employees receive <u>engaging</u> and <u>effective</u> training on new and revised documents and processes.

If a new document or process is released or if a document/process revision involves a **content change**, then QC Form 756 is **required.** This new QC Form initiates collaboration between the document/process owner or designee and the Quality Systems Training (QST) department which is essential to ensuring maximum training effectiveness![†]

[†]*Refer to the "When is Training Required?" section on page 7 for a review of the new training requirements.*

Quality System Training Request
(Reference SOP 002, SOP 362, SOP 4.5)

New

Section 1: Training Request Information

Date of Training Request [mm/dd/yyyy]	Document type _____ ▼	Doc #
Name of Document Owner or Designee [Type or Print]		Rev #

Section 2: Training Project Resources

Instructions: Please answer each question accurately by entering a check mark in the appropriate boxes and entering any required information as directed.

1. Do you currently have Content other than controlled documents (i.e. SOPs, etc.) available to develop training from?
☐ Yes — Go to question 2.   ☐ No — Skip question 2 and go directly to question 3

2. In what form is the currently available Content? *Select any of the following that apply. Then, go to question 3.*
☐ Microsoft PowerPoint presentation files(s)   ☐ Other. Please specify:_____
☐ Microsoft Word or Acrobat PDF File(s)   _____
☐ Paper handout(s) or note(s)   ☐ *Not Applicable (no content other than controlled documents)*

3. Learning assessments are required for an accurate evaluation of training effectiveness for <u>most</u> types of training. Do you currently have a Learning Assessment (Quiz, Test, Survey, etc.) developed?
☐ Yes – Go to question 4   ☐ No – go to question 4

4. Have you identified a Subject Matter Expert (SME), other than yourself, to work with the QST team on the project?
☐ Yes – Please provide the name of the SME(s), other than yourself, in the space provided below and proceed to section 3 below.
Name of Subject Matter Expert(s): _____
☐ No – Proceed to section 3 below

Section 3: Number of Learning Audiences (learner groups)

Instructions: Select the appropriate box below to indicate the number of learning audiences that are anticipated for this training project. Then, for each training audience [primary (1) and secondary (2)], complete Section 4: The Decision Tool for Determining the Recommended Delivery Method, on page 2. If you anticipate more than two learning audiences, you should submit an explanation of the 3rd learning audience with the submission of this form (QCFM 756).

Choices for Selection Criteria Select one choice below	Action or Recommendation
☐ There is only one learning audience (group) that will receive this training. This means that the training will be delivered using only <u>one</u> method (appropriate for the learning outcome).	Go to Section 4 and complete it for the PRIMARY Audience only. Then, complete section 5 on page 3 for the Primary audience only
☐ There are two or more learning audiences (groups). This means that the training will be delivered using <u>two or more</u> methods (appropriate for the learning outcome for each audience).	Go to Section 4 and complete it twice; once for the PRIMARY audience and again for the SECONDARY audience. Then, complete section 5 on page 3 for the both audiences.

QCFM 756 / Rev. 2.0 / Ref. 6.2.2   Page 1 of 4   Next—>

*Refer to sections 3.1, 5.3.5, 5.3.6, 5.3.13.9, and 5.3.13.10 of SOP 002.

Changes to Procedures

CAR Package Contents*

A new or revised SOP, QCFM, or Quality Manual should contain the Change Action Request package components:

- Completed CAR
- Redline proposed draft *(for revision only)*
- Final draft of proposed SOP or QCFM
- Completed QCFM 756 *(new and non-administrative changes)*

    The Training Matrix from SABA is no longer required!

Refer to Section 5.3.5 and 5.3.13.9 of SOP 002

Notification to Quality Systems Training*

Administrative Changes

Document control will now notify the Quality Systems Training department of administrative changes and will provide the following:

- Final document
- Redline document

Final Approval Action of CAR Packet

Upon final approval action, Document Control will provide the electronic approved CAR package documents, via email, to the:

- Document Owner or designee *-and-*
- Quality Systems Training department

Refer to Sections 5.3.13.7 and 5.3.13.8 of SOP 002

Training Activities and Attendance Record

- Document owner or designee is now responsible for the completion of all training activities as defined on QCFM 756.*

    Refer to section 5.3.13.10 of SOP 002

- QCFM 387 [Group Training Record] is now no longer required for *all* Instructor-led [classroom] training. QCFM 387 should only be used in instances where paper-based assessments must be given. Otherwise, training attendance will be logged through the completion of the learning assessment administered via the SABA myLearningPortal.

Promotion of Documents*

To allow for training and/or notification activities, documents will now be promoted to "implement" status after 30 days *by default*. However, documents may be promoted earlier in cases where the Quality Systems Training Department authorizes the early release.

Refer to section 5.3.14 of SOP 002

Section 6: Initiating a Training Request Using QCFM 756

Training Goal

During this section of the training, the trainer(s) will <u>illustrate</u> how to use QCFM 756 to initiate and process a training request

Learner's Objectives

Upon completion of this section of training, you will be able to:

- Complete the entire QCFM 756 with limited assistance for any given training request scenario
- Explain the reasoning behind choices made in the completion of QCFM 756 for any given training request scenario

Exploring the Form [QCFM 756]

Section 1: Training Request Information

- Date of Training Request
- Document Type
- Document #
- Revision #
- Document Owner/Designee name

Section 2: Training Project Resources

- Training content
- Learning Assessments
- Subject Matter Experts

Section 3: Number of Learning Audiences (Groups)

This section provides the document owner/ designee an opportunity to evaluate how many different learner groups exist for the training that is to be conducted and/or launched. ***To do this, document owners/ designee should simply ask themselves this question:***

Are there groups of individuals tied to this document/ process that may need different levels of knowledge and/or performance?

- **No** => One [**Primary**] audience
- **Yes** -> How many different groups/ levels are anticipated?
  - **Two** => **Primary** and **Secondary** audiences
- Three + => Primary, Secondary, Tertiary, etc. *
  *Three or more audiences are most likely exceptions to most Quality Systems training situations; therefore, this option has not been included in section 3. However, if applicable, documentation that supports the need for more than two audiences should be submitted to the QST department along with QCFM 756.

Quality System Training Request
(Reference SOP 002, SOP 362, SOP 4.5)

Section 1: Training Request Information

| Date of Training Request [mm/dd/yyyy] | | Document type _____ ▾ | Doc # |
| Name of Document Owner or Designee [Type or Print] | | Process Specifications / Standard Operating Procedures | Rev # |

Section 2: Training Project Resources

Instructions: Please answer each question accurately by entering a check mark in the appropriate boxes and entering any required information as directed.

1. Do you currently have Content other than controlled documents (i.e. SOPs, etc.) available to develop training from?
   ☐ Yes — Go to question 2.   ☐ No — Skip question 2 and go directly to question 3

2. In what form is the currently available Content? *Select any of the following that apply. Then, go to question 3.*
   ☐ Microsoft PowerPoint presentation files(s)   ☐ Other. Please specify:_____
   ☐ Microsoft Word or Acrobat PDF File(s)   _____
   ☐ Paper handout(s) or note(s)   ☐ Not Applicable (no content other than controlled documents)

3. Learning assessments are required for an accurate evaluation of training effectiveness for <u>most</u> types of training. Do you currently have a Learning Assessment (Quiz, Test, Survey, etc.) developed?
   ☐ Yes – Go to question 4   ☐ No – go to question 4

4. Have you identified a Subject Matter Expert (SME), other than yourself, to work with the QST team on the project?
   ☐ Yes – Please provide the name of the SME(s), other than yourself, in the space provided below and proceed to section 3 below.
   Name of Subject Matter Expert(s): _____
   ☐ No – Proceed to section 3 below

Section 3: Number of Learning Audiences (learner groups)

Instructions: Select the appropriate box below to indicate the number of learning audiences that are anticipated for this training project. Then, for each training audience [primary (1) and secondary (2)], complete Section 4: The Decision Tool for Determining the Recommended Delivery Method, on page 2. If you anticipate more than two learning audiences, you should submit an explanation of the 3rd learning audience with the submission of this form (QCFM 756).

Choices for Selection Criteria Select one choice below	Action or Recommendation
☐ There is only one learning audience (group) that will receive this training. This means that the training will be delivered using only <u>one</u> method (appropriate for the learning outcome).	Go to Section 4 and complete it for the PRIMARY Audience only. Then, complete section 5 on page 3 for the Primary audience only
☐ There are two or more learning audiences (groups). This means that the training will be delivered using <u>two or more</u> methods (appropriate for the learning outcome for each audience).	Go to Section 4 and complete it twice; once for the PRIMARY audience and again for the SECONDARY audience. Then, complete section 5 on page 3 for the both audiences.

Section 4: Decision Tool for Determining the Recommended Training Delivery Method

This decision tool is meant to guide the document owner/designee through the process of determining the best training delivery method under the circumstances of the training project and should be used for each learning audience that is identified.

1 - Learning Outcome

This is the ultimate goal of the training. This is what you want the learner to be able to know and do upon completion of the training.

*There are two **types of learning outcomes.** They are:

- Knowledge and Understanding
- Performance of Skill

Refer to p. 12 to review the differences between knowledge, understanding, and performance.

2 - Levels of Knowledge and Understanding About Content

- Awareness [knowledge of content]
- Understanding

3 - Knowledge and Understanding: Frequency of Content Change

- High = Three or more times per year
- Moderate to low
  - Moderate = Once every 1-2 years
  - Low = Once every 2-3$^+$ years

4 - Knowledge and Understanding: Design, Development, and Launch Time

- High to Moderate [> 6 weeks]
- Moderate to Low [< 4 weeks]

5 - Performance of Skill(s): Audience Scope

- One (or two) participants
- Multiple participants [Group]

6 - Performance of Skill(s): Frequency of Content Change

- High
- Moderate to Low

*Same as the Knowledge and Understanding: Frequency of Content Change.

Section 4: Decision Tool for Determining the Recommended Training Delivery Method

Instructions: 1) Choose the most accurate statement that applies for each set of selection criteria statements [a or b]. 2) Then, complete the action (go to item or stop) indicated for each statement that you choose to yield the recommended delivery method. 3) Then, record your responses in section 5 on the next page (3). *Remember — You must complete the decision tool and record your responses for each learning audience: Primary and Secondary.*

Item #	Selection Criteria	Choices for Selection Criteria Choose only one choice (a or b) per Selection Criterion		Action or Recommendation
1	Learning Outcome for the Learning Audience [Learning Group] *This is the ultimate goal of the training and what will be assessed upon completion of training.*	a.	The trainee(s) must acquire a level of Knowledge and Understanding from the training content.	Go to item 2
		b.	The trainee(s) must be able to Perform a skill (Observable Task) based upon or related to the training content. *(Examples: Using Software, Assembly, Manipulation, etc.)*	Skip down to item 5 (Performance of Skill)
2	Level of Knowledge and Understanding about Content	a.	The trainee(s) must only acquire an Awareness of the training content. The trainee will not need to be able to apply the content/information in the completion of job duties or as a part of job responsibilities at any point in time. [For individuals tied to SOPs that do not perform job duties]	STOP. The recommended delivery type is: Read and Acknowledge
		b.	The trainee(s) must Understand the training content/information and be able to apply that information in the completion of job duties or as a part of job responsibilities at some point in time.	Go to item 3
3	Knowledge and Understanding: Frequency of Content Change	a.	The content most likely has a High frequency of change as indicated by the following approximation: • High ≈ Three or more times per year	STOP. The recommended delivery type is: Instructor-Led Training
		b.	The content most likely has a Moderate to Low frequency of change as indicated by the following approximations: • Moderate ≈ Once every 1 to 2 years • Low ≈ Once every 2 to 3$^+$ years	Go to Item 4
4	Knowledge and Understanding: Design, Development, and Launch Time	a.	There is a High to Moderate duration of time (Approximately > 6 weeks) to develop and launch training.	STOP. The recommended delivery type is: E-Learning
		b.	There is a Moderate to Low duration of time (approximately < 4 weeks) to develop and launch training.	STOP. The recommended delivery type is: Web Based Training
5	Performance of Skill(s): Audience Scope (Number of Participants)	a.	There is most likely only one trainee required to attend the training.	STOP. The recommended Delivery type is: Individual, Performance-Based On-the-Job Training
		b.	There are most likely multiple trainees required to attend the training.	Go to Item 6
6	Performance of Skill(s): Frequency of Content Change	a.	The content most likely has a High frequency of change as indicated by the following approximation: • High ≈ Three or more times per year	STOP. The Recommended delivery type is: Group, Performance-Based Instructor-Led Training
		b.	The content most likely has a Moderate to Low frequency of change as indicated by the following approximations: • Moderate ≈ Once every 1 to 2 years • Low ≈ Once every 2 to 3$^+$ years	STOP. The recommend delivery type is: E-Learning* (*Recommended for software/technical training)

Section 5: Designation of Training Delivery Methods

This section is meant to capture the information determined from the use of *Section 4: The Decision Tool for Determining the Recommended Training Delivery Method*

The information [items/sections & choices] are identical to those in the decision tool and, as such, should be selected identically for each audience identified [Primary only *or* Primary & Secondary, as applicable]

Example:

If you selected the 'Knowledge and Understanding' learning outcome [1a] from the use of the decision tool [section 4], then you should also select the 1a box here in section 5.

Likewise, if you selected 'Understanding' as the level of knowledge about content [2b] from the use of the decision tool, then you should also select the 2b box here in section 5.

Section 5: Designation of Training Delivery Method(s)

Instructions: Complete the table below to summarize the results obtained from Section 4 (Decision Tool) for each learning audience. Provide a defining name for each audience and indicate your selections for each set of applicable selection criteria statements by entering a check mark in the appropriate choice box. *Note: The sections and data (1a, 1b, 2a, etc.) below mirror the sections/data on the Decision Tool for Determining the Recommended Delivery Method.*

Reset Primary Data **Primary Audience**	Reset Secondary Data **Secondary Audience** ☐ Not Applicable ☐ Applicable
Name(s): Enter the name of the audience in the space below	Name(s): Enter the name of the audience in the space below
	☐ N/A
1. Learning Outcome	**1. Learning Outcome** ☐ Not Applicable
☐ a. Knowledge and Understanding	☐ a. Knowledge and Understanding
☐ b. Performance of a Skill	☐ b. Performance of a Skill
Knowledge and Understanding (Only)	**Knowledge and Understanding (Only)**
2. Level of Knowledge	**2. Level of Knowledge**
☐ a. Awareness ☐ Not Applicable	☐ a. Awareness ☐ Not Applicable
☐ b. Understanding	☐ b. Understanding
3. Knowledge and Understanding: Frequency of Content Change	**3. Knowledge and Understanding: Frequency of Content Change**
☐ a. High ☐ Not Applicable	☐ a. High ☐ Not Applicable
☐ b. Moderate to Low	☐ b. Moderate to Low
4. Knowledge and Understanding: Design, Development, and Launch Time	**4. Knowledge and Understanding: Design, Development, and Launch Time**
☐ a. High to Moderate ☐ Not Applicable	☐ a. High to Moderate ☐ Not Applicable
☐ b. Moderate to Low	☐ b. Moderate to Low
Performance of Skills (Only)	**Performance of Skills (Only)**
5. Performance of Skill(s): Audience Scope	**5. Performance of Skill(s): Audience Scope**
☐ a. One [or two] trainees ☐ Not Applicable	☐ a. One [or two] trainees ☐ Not Applicable
☐ b. Multiple trainees	☐ b. Multiple trainees
6. Performance of Skill: Frequency of Content Change	**6. Performance of Skill: Frequency of Content Change**
☐ a. High ☐ Not Applicable	☐ a. High ☐ Not Applicable
☐ b. Moderate to Low	☐ b. Moderate to Low
Recommended Delivery Method for Primary Audience	**Recommended Delivery Method for Secondary Audience**
Indicate the recommended training delivery method obtained from the Decision tool for the Primary audience only.	Indicate the recommended training delivery method obtained from the Decision tool for the Secondary audience, if applicable. Otherwise, select Not Applicable.
☐ Read and Acknowledge	☐ Read and Acknowledge ☐ Not Applicable (A secondary audience has not been identified)
☐ Web-based Training	☐ Web-based Training
☐ E-Learning	☐ E-Learning
☐ Instructor-led Training	☐ Instructor-led Training
☐ Individual, Performance-based On-the-Job Training	☐ Individual, Performance-based On-the-Job Training
☐ Group, Performance-based Instructor-led Training	☐ Group, Performance-based Instructor-led Training

Section 6: Instructor-Led/On-the-Job Training — *Trainer Information*

If the recommended training delivery method is determined to be any form of Instructor-led [classroom] training or On-the-Job training, then the name of the trainer(s) who will conduct the training should be identified in section 6.

Section 7: Instructor-Led/On-the-Job Training — *Paper Learning Assessments*

All learning assessments will be administered through the SABA myLearningPortal. However, in some instances, this may not be possible. Therefore, if applicable, this section details what should be submitted to the Quality Systems Training Department upon completion of the training session [after the trainer delivers the training]

Section 8: Training Implementation Dates

A target date or date range should be provided. In addition, the relationship of the training to a CAPA or Audit action should also be designated.

*These items assist the Quality Systems Training Department in determining how best to collaborate with the document owner/Designee and/or subject matter expert on the training project.

Section 9: Submission of the form

This section provides instructions for submitting the form to the Quality Systems Training Department.

In addition, some information is also provided to help the document/owner or designee understand how the training request will be processed/handled and what the Quality Systems Training Department will submit to document control on his/her behalf.

Section 6: Instructor-Led Training or On-the-Job Training — *Trainer Information*

Instructions: If applicable, indicate the name of the trainer who will be conducting the Instructor-led or On-the-Job training session(s) in the space provided below. Otherwise, select 'Not Applicable' and skip down to section 8 to complete this form.

Name of Trainer (print or type): _____ -or- ☐ Not Applicable

Note: The document owner or designee is responsible for ensuring that the trainer conducts the training. The trainer is responsible for ensuring that all trainees successfully complete the training course and pass any assessments through the use of retraining and reassessment, when applicable.

Section 7: Instructor-Led or On-the-Job Training — *Paper Learning Assessments**

This section does not apply to most Instructor-led/On-the-Job training — it applies mainly to Operations. Therefore, read the following to determine if this section applies to your Instructor-Led/On-the-Job training.

All learning assessments (quizzes, tests, course surveys, etc.), no matter how the training is delivered, will be administered through the SABA myLearning Portal. However, in some cases (such as Operations training), there may be a need to conduct training and administer learning assessments using paper-pencil/pen methods (due to an inability of trainees to take online assessments in the SABA myLearning Portal). In this case, the following items are required to be submitted to the Quality Systems Training Department upon completion of the training.

- QCFM 387 [Jacksonville] or SOP 4.5-2 [Mystic]
- One clean copy of the paper learning assessment
- Learning assessment results for all trainees (attendance roster with all grades entered)

Section 8: Training Implementation Dates

Provide the target launch/implementation date(s) and indicate whether the date(s) are related to a CAPA or Audit Action.

Date(s) [MM/DD/YYYY]: _____ This date ☐ is / ☐ is not related to a CAPA or Audit Action.

Section 9: Submission of the Training Request Form and Next Steps

Instructions: 1) Save this completed form for your future reference. 2) Then, submit the completed form electronically to the Quality Systems Training (QST) Department via email at rs.sttrainingcompliance@medtronic.com. Please enter "Training Request" in the subject line.

Once the training request has been received, logged, and reviewed, a representative from QST will contact the document/process owner to schedule a training consultation.

After the design and development phases of the training project are complete, the finalized version of QCFM 756 will be submitted to document control to become a part of CAR package.

Do not print or type any information below this line. For QST Department Use only.
****

Quality Systems Training Consultation — *To be completed by a representative of QST dept only.*

Consultation Date [MM/DD/YYYY]: _____

Name of QST Representative [print]: _____

Practice Exercises [Scenarios]

Goal and Overview

The goal of the practice exercises to provide guided practice completing QCFM 756 so that you know how to accurately and effectively complete QCFM 756.

Instructions

Use the information provided in each scenario of the three (3) scenarios to complete a training request using QCFM 756. Practice exercise/scenario one (1) will be illustrated by your trainer; however, exercises/scenarios two (2) and three (3) will be completed individually or in groups followed by discussion

Exercise 1 — Worked Example

Scenario Information

- **Training Request Date: July 15, 2013**

- **Document Owner/Designee** = **Trey Ning,** Documents Engineer

- **Content:**
  - **SOP 997**: New Procedures for the Filing of Training Documents
  - **PowerPoint** content has been developed by Trey Ning's document retention staff
  - A **learning assessment** has not been developed Trey Ning or his staff because they do not feel comfortable developing it on their own
  - Trey Ning is the **subject matter expert** on this project
  - *The content is not expected to change again in the near future and the last known change is this process was 5 years earlier.

- **Learning Audience:**
  - Approximately 15 training staff members [**Trainers and Training Dept. Clerks**] across the sector have been identified as requiring this training.
  - All 15 staff members require the same level and type of training (receiving the training the same way)

- **Instructional Goal/Overall Learning Outcome**
  - To provide **knowledge and understanding** of the new procedures such that trainees can complete the procedures as a part of his/her job responsibilities.

- **Training Time and Resources**
  - Training must be launched within **8 weeks** (no later than **Sept 20th**) so that the **audit action** can be finalized within 12 weeks.
  - A trainer has not yet been identified and a travel budget has not been approved

Completed (Filled in) QCFM 756 for Exercise/Scenario 1 — Worked Example

Quality System Training Request
QCFM 756
(Reference SOP 002, SOP 362)

Section 1: Training Request Information

Date of Training Request [mm/dd/yyyy] 07/15/2013	Document type Standard Operating Procedures	Doc # 997
Name of Document Owner or Designee [Type or Print] Trey Ning, Documents Engineer		Rev #

Section 2: Training Project Resources

Instructions: Please answer each question accurately by entering a check mark in the appropriate boxes and entering any required information as directed.

1. Do you currently have Content other than controlled documents (i.e. SOPs, etc.) available to develop training from?

   ☒ Yes — Go to question 2.   ☐ No — Skip question 2 and go directly to question 3

2. In what form is the currently available Content? *Select any of the following that apply. Then, go to question 3.*

   ☒ Microsoft PowerPoint presentation files(s)   ☐ Other. Please specify:_____

   ☐ Microsoft Word or Acrobat PDF File(s)   _____

   ☐ Paper handout(s) or note(s)   ☐ Not Applicable (no content other than controlled documents)

3. Learning assessments are required for an accurate evaluation of training effectiveness for <u>most</u> types of training. Do you currently have a Learning Assessment (Quiz, Test, Survey, etc.) developed?

   ☐ Yes – Go to question 4   ☒ No – go to question 4

4. Have you identified a Subject Matter Expert (SME), other than yourself, to work with the QST team on the project?

   ☐ Yes – Please provide the name of the SME(s), other than yourself, in the space provided below and proceed to section 3 below.
   Name of Subject Matter Expert(s): _____

   ☒ No – Proceed to section 3 below

Section 3: Number of Learning Audiences (learner groups)

Instructions: Select the appropriate box below to indicate the number of learning audiences that are anticipated for this training project. Then, for each training audience [primary (1) and secondary (2)], complete Section 4: The Decision Tool for Determining the Recommended Delivery Method, on page 2. If you anticipate more than two learning audiences, you should submit an explanation of the 3rd learning audience with the submission of this form (QCFM 756).

Choices for Selection Criteria Select one choice below	Action or Recommendation
☒ There is only one learning audience (group) that will receive this training. This means that the training will be delivered using only <u>one</u> method (appropriate for the learning outcome).	Go to Section 4 and complete it for the PRIMARY Audience only. Then, complete section 5 on page 3 for the Primary audience only
☐ There are two or more learning audiences (groups). This means that the training will be delivered using <u>two or more</u> methods (appropriate for the learning outcome for each audience).	Go to Section 4 and complete it twice; once for the PRIMARY audience and again for the SECONDARY audience. Then, complete section 5 on page 3 for the both audiences.

Section 4: Decision Tool for Determining the Recommended Training Delivery Method

Instructions: 1) Choose the most accurate statement that applies for each set of selection criteria statements [a or b]. 2) Then, complete the action (go to item or stop) indicated for each statement that you choose to yield the recommended delivery method. 3) Then, record your responses in section 5 on the next page (3). *Remember — You must complete the decision tool and record your responses for each learning audience: Primary and Secondary.*

Item #	Selection Criteria	Choices for Selection Criteria Choose only one choice (a or b) per Selection Criterion	Action or Recommendation
1	**Learning Outcome for the Learning Audience [Learning Group]** *This is the ultimate goal of the training and what will be assessed upon completion of training.*	a. The trainee(s) must acquire a level of **Knowledge and Understanding** from the training content.	⟶ Go to item 2
		b. The trainee(s) must be able to **Perform a skill** (Observable Task) based upon or related to the training content. *(Examples: Using Software, Assembly, Manipulation, etc.)*	Skip down to item 5 (Performance of Skill)
2	**Level of Knowledge and Understanding about Content**	a. The trainee(s) must only acquire an **Awareness** of the training content. The trainee will <u>not</u> need to be able to <u>apply</u> the content/information in the completion of job duties or as a part of job responsibilities at any point in time. [For individuals tied to SOPs that do not perform job duties]	**STOP.** The recommended delivery type is: **Read and Acknowledge**
		b. The trainee(s) must **Understand** the training content/ information and be able to apply that information in the completion of job duties or as a part of job responsibilities at some point in time.	⟶ Go to item 3
3	**Knowledge and Understanding: Frequency of Content Change**	a. The content most likely has a **High frequency of change** as indicated by the following approximation: • High ≈ Three or more times per year	**STOP.** The recommended delivery type is: **Instructor-Led Training**
		b. The content most likely has a **Moderate to Low frequency of change** as indicated by the following approximations: • Moderate ≈ Once every 1 to 2 years • Low ≈ Once every 2 to 3^+ years	⟶ Go to Item 4
4	**Knowledge and Understanding: Design, Development, and Launch Time**	a. There is a **High to Moderate duration of time** (Approximately > 6 weeks) to develop and launch training.	⟶ **STOP.** The recommended delivery type is: **E-Learning**
		b. There is a **Moderate to Low duration of time** (approximately < 4 weeks) to develop and launch training.	**STOP.** The recommended delivery type is: **Web Based Training**
5	**Performance of Skill(s): Audience Scope (Number of Participants)**	a. There is most likely only **one trainee** required to attend the training.	**STOP.** The recommended Delivery type is: **Individual, Performance-Based On-the-Job Training**
		b. There are most likely **multiple trainees** required to attend the training.	Go to Item 6
6	**Performance of Skill(s): Frequency of Content Change**	a. The content most likely has a **High frequency of change** as indicated by the following approximation: • High ≈ Once or more per year	**STOP.** The Recommended delivery type is: **Group, Performance-Based Instructor-Led Training**
		b. The content most likely has a **Moderate to Low frequency of change** as indicated by the following approximations: • Moderate ≈ Once every 1 to 2 years • Low ≈ Once every 2 to 3^+ years	**STOP.** The recommend delivery type is: E-Learning* (*Recommended for software/technical training)

Section 5: Designation of Training Delivery Method(s)

Instructions: Complete the table below to summarize the results obtained from Section 4 (Decision Tool) for each learning audience. Provide a defining name for each audience and indicate your selections for each set of applicable selection criteria statements by entering a check mark in the appropriate choice box. *Note: The sections and data (1a, 1b, 2a, etc.) below mirror the sections/data on the Decision Tool for Determining the Recommended Delivery Method.*

Reset Primary Data **Primary Audience**	Reset Secondary Data **Secondary Audience** ☒ Not Applicable ☐ Applicable
Name(s): Enter the name of the audience in the space below	
Training Staff	
1. Learning Outcome ☒ a. Knowledge and Understanding ☐ b. Performance of a Skill	
Knowledge and Understanding (Only)	
2. Level of Knowledge ☐ a. Awareness ☐ Not Applicable ☒ b. Understanding	
3. Knowledge and Understanding: Frequency of Content Change ☐ a. High ☐ Not Applicable ☒ b. Moderate to Low	This section is Not Applicable; a Secondary Audience has not been identified.
4. Knowledge and Understanding: Design, Development, and Launch Time ☒ a. High to Moderate ☐ Not Applicable ☐ b. Moderate to Low	If a Secondary Audience is identified, return to section 3 and revise it.
Performance of Skills (Only)	
5. Performance of Skill(s): Audience Scope ☐ a. One [or two] trainees ☒ Not Applicable ☐ b. Multiple trainees	
6. Performance of Skill: Frequency of Content Change ☐ a. High to Moderate ☒ Not Applicable ☐ b. Moderate to Low	
Recommended Delivery Method for Primary Audience	
Indicate the recommended training delivery method obtained from the Decision tool for the <u>Primary</u> audience only. ☐ Read and Acknowledge ☐ Web-based Training ☒ E-Learning ☐ Instructor-led Training ☐ Individual, Performance-based On-the-Job Training ☐ Group, Performance-based Instructor-led Training	

Section 6: Instructor-Led Training or On-the-Job Training — *Trainer Information*

Instructions: If applicable, indicate the name of the trainer who will be conducting the Instructor-led or On-the-Job training session(s) in the space provided below. Otherwise, select 'Not Applicable' and skip down to section 8 to complete this form.

Name of Trainer (print or type): _____ -or ☒ Not Applicable

*Note: The document owner or designee is responsible for ensuring that the trainer conducts the training. The trainer is responsible for ensuring that all trainees successfully complete the training course and pass any assessments through the use of retraining and reassessment, when applicable.

Section 7: Instructor-Led or On-the-Job Training — *Paper Learning Assessments**

*This section does not apply to most Instructor-led/On-the-Job training — it applies mainly to Operations. Therefore, read the following to determine if this section applies to your Instructor-Led/On-the-Job training.

All learning assessments (quizzes, tests, course surveys, etc.), no matter how the training is delivered, will be administered through the SABA myLearning Portal. However, in some cases (such as Operations training), there may be a need to conduct training and administer learning assessments using paper-pencil/pen methods (due to an inability of trainees to take online assessments in the SABA myLearning Portal). In this case, the following items are required to be submitted to the Quality Systems Training Department upon completion of the training.

- QCFM 387
- One clean copy of the paper learning assessment
- Learning assessment results for all trainees (attendance roster with <u>all</u> grades entered)

Provide the target launch/implementation date(s) and indicate whether the date(s) are related to a CAPA or Audit Action.

Date(s) [MM/DD/YYYY] 09/20/2013 _____ This date ☒ is / ☐ is not related to a CAPA or Audit Action.

Section 9: Submission of the Training Request Form and Next Steps

Instructions: 1) Save this completed form for your future reference. 2) Then, submit the completed form electronically to the Quality Systems Training (QST) Department via email at rs.sttrainingcompliance@medtronic.com. Please enter "Training Request" in the subject line.

Once the training request has been received, logged, and reviewed, a representative from QST will contact the document/process owner to schedule a training consultation.

After the design and development phases of the training project are complete, the finalized version of QCFM 756 will be submitted to document control to become a part of CAR package.

Do not print or type any information below this line. For QST Department Use only.

****

Quality Systems Training Consultation — *To be completed by a representative of QST dept only.*

Consultation Date [MM/DD/YYYY]: _____

Name of QST Representative [print]: _____

Exercise 2 — Guided Practice

Scenario Information

- **Training Request Date**: Use today's date
- **Process Owner/Designee** = Stella Lizer, Microbiology Laboratory Supervisor
- **Content:**
    - Functional training for the use of new sterilization equipment in the Microbiology lab
    - Content has not been developed by Stella Lizer; however, a basic training guide (pdf) from the manufacturer is available.
    - A learning assessment has not been developed Stella Lizer or her staff because they are unfamiliar with learning assessments
    - Stella Lizer will serve as the subject matter expert
    - The content is not expected to change unless new equipment is purchased in the future
- **Learning Audience:**
    - Stella Lizer has identified only one individual that needs the training – an associate Microbiologist in her lab.
- **Instructional Goal/Overall Learning Outcome**
    - To provide skills on how to operate the sterilization equipment and explain why the new sterilization equipment was purchased for the lab.
- **Training Time and Resources**
    - Training must be conducted within 1 week of receiving the new equipment so as not to disrupt the sterilization work flow
    - Stella Lizer will serve as the trainer in this process since she has already been trained by the manufacturer of the sterilization equipment.
- **Miscellaneous**
    - New sterilization equipment will arrive on August 5th.
    - Since only one individual will receive the training, a paper-based performance assessment will be given instead of a SABA assessment

Exercise 3 — It's Your Turn!

Scenario Information

- **Training Request Date:** Use today's date
- **Document Owner/Designee** = Maysha Mintz, Quality Engineer
- **Content:**
    - SOP 998: Updated Procedures for measuring the mass of widgets
    - Paper training handouts on this process (from prior training session), in addition to the actual SOP (pdf), are available
    - A paper quiz (from prior training session) that aligns to most of the updated procedures is available.
    - The subject matter expert for this training project is *Milla Graham.*
      *The content has not changed in the past 4 years and is not expected to change again in the near future.
- **Learning Audience:**
    - Approximately 25 employees in Jacksonville have been identified as requiring this training.
    - Fifteen (15) Quality, Mechanical and R & D Engineers will need training; however, ten (10) Regulatory Affairs employees only need to be aware of the changes to the SOP.
- **Instructional Goal/Overall Learning Outcome**
    - To provide awareness that the SOP has changed to specifically identified employees.
    - To provide knowledge and understanding of the updated procedures such that specifically identified employees can complete the procedures as a part of his/her job responsibilities.
- **Training Time and Resources**
    - Training must be launched in less than 4 weeks from the project request date (today's date) so that the CAPA can be closed out within 6 weeks.
    - A trainer has not yet been identified.

The Road to Success

Working towards Excellence
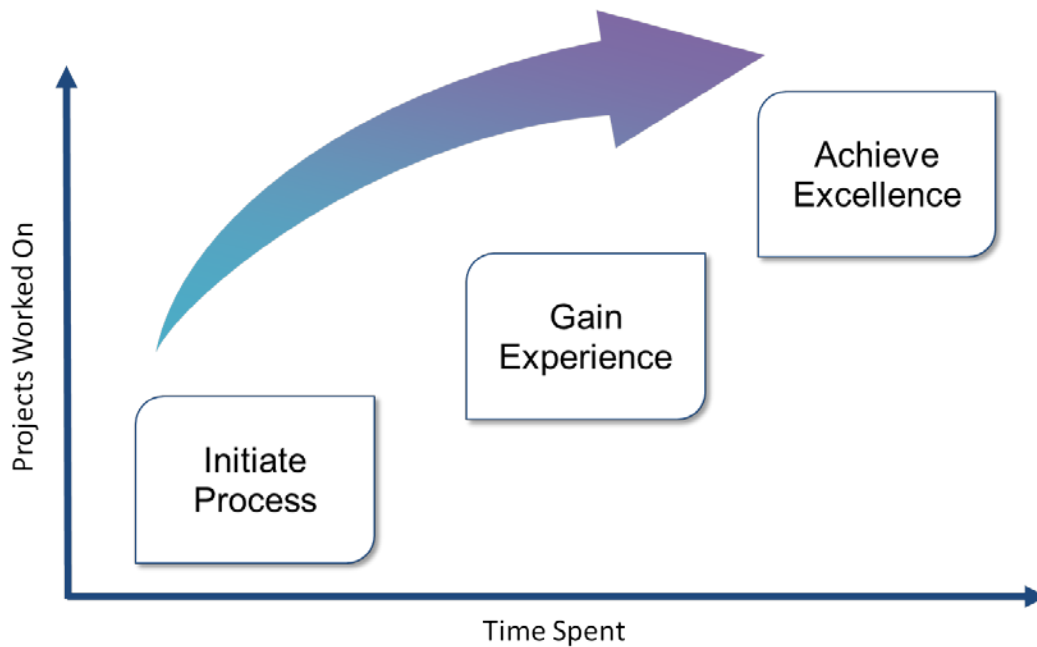
Follow-Up: What do I do now?

You need to take the post-training <u>learning assessment</u> in order to log your participation in today's training session and receive credit for the course.

To do this, log into your SABA *myLearningPortal* within a few days and you'll notice that the assessment has been added to your my To Do List.