Lesson Information

Title	STERIS Quality Manual
Script Author	Andre Williams
Content	Quality Manual
Recording Prep:	N/A

Other tips:

E-LEARNING SCRIPT		
STERIS Quality Manual		
HEAR (Narration / Text Instruction)	**DO (Interactivity)**	**SEE (Lesson Action)**
Course Title Page "Steris Quality Management"		
Lesson One Title Page: STERIS Quality Manual		
Instructions		
Objectives		
Main Menu		
Learning Objective: STERIS Quality		
Training Topic: STERIS Quality Policy		
STERIS is committed to delivering satisfaction to our Customers by anticipating their needs and offering value, quality, and reliability that exceeds their expectations. The success of STERIS and our Customers is powered by our people, a culture of teamwork, innovative solutions, and by continually maintaining		Title: STERIS Quality Policy *STERIS is committed to delivering satisfaction to our Customers by anticipating their needs and offering value, quality, and reliability that exceeds their expectations.* *The success of STERIS and our Customers is powered by our people, a culture of teamwork, innovative*

and improving the effectiveness of our Quality System as a foundation for business performance. We value safety, integrity and mutual respect, supporting our employees, communities and Customers, and are committed to complying with all applicable laws and regulations. This is The STERIS Way, a culture of quality.	Click Previous Click Continue	*solutions, and by continually maintaining and improving the effectiveness of our Quality System as a foundation for business performance.* *We value safety, integrity and mutual respect, supporting our employees, communities and Customers, and are committed to complying with all applicable laws and regulations.* *This is The STERIS Way, a culture of quality.* Previous Continue
Learning Objective: Purpose and Scope		
This Quality Manual documents STERIS and its subsidiaries' Quality Management System (QMS) to demonstrate the company's ability to consistently provide products and services that meet Customer and legal requirements. The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system to ensure compliance to global regulations. All companies acquired by STERIS will remain under their own quality system for a period of up to 18 months to facilitate proper integration into the STERIS Corporate Quality System. This manual also presents the quality system to Customers, suppliers, regulators and other external		Title Purpose and Scope *This Quality Manual documents STERIS and its subsidiaries' Quality Management System (QMS) to demonstrate the company's ability to consistently provide products and services that meet Customer and legal requirements. The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system to ensure compliance to global regulations. All companies acquired by STERIS will remain under their own quality system for a period of up to 18 months to facilitate proper integration into the STERIS Corporate Quality System.*

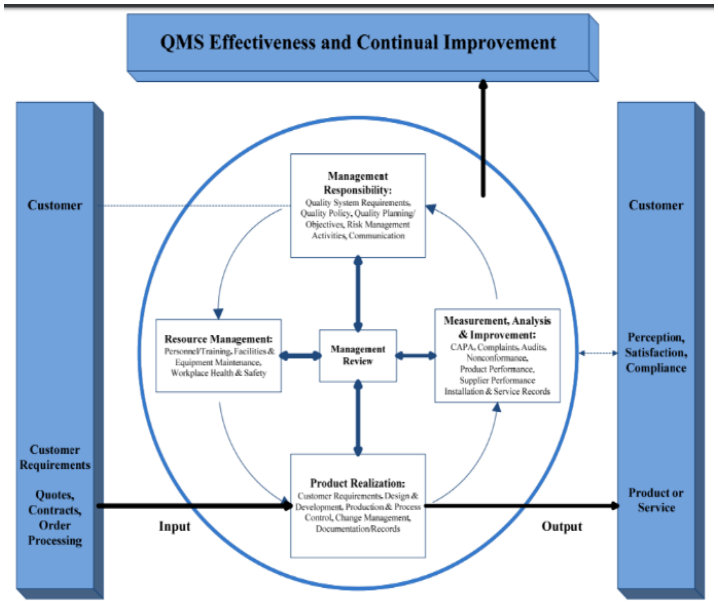
interested parties. This Quality Manual does not create any legal or regulatory obligation or standard of performance beyond that specifically required of STERIS or its subsidiaries by current applicable legal requirements. This Quality Manual extends over all operations identified in this manual, related to our business activity, and to all employees performing work that bears on quality. The purpose of this manual is to define and describe the STERIS Quality Policies and to define a uniform method of communication of quality system requirements to the facilities. Written procedures define the operational controls and provide the means to achieve our objectives. Quality procedures are a vital part of the Quality Management System. The procedures governing quality functions are followed by all facilities, unless specifically stated otherwise. Additional local or business unit work instructions may be maintained as appropriate and within the bounds of the STERIS quality system. Facility management will revise their local work instructions, as necessary, to comply with the STERIS Quality Manual. Additionally, it is the facility management's responsibility to implement training on the STERIS Quality Manual to the employees of that facility, in the manner they deem most effective.		*This manual also presents the quality system to Customers, suppliers, regulators and other external interested parties. This Quality Manual does not create any legal or regulatory obligation or standard of performance beyond that specifically required of STERIS or its subsidiaries by current applicable legal requirements.* *This Quality Manual extends over all operations identified in this manual, related to our business activity, and to all employees performing work that bears on quality. The purpose of this manual is to define and describe the STERIS Quality Policies and to define a uniform method of communication of quality system requirements to the facilities. Written procedures define the operational controls and provide the means to achieve our objectives.* *Quality procedures are a vital part of the Quality Management System. The procedures governing quality functions are followed by all facilities, unless specifically stated otherwise. Additional local or business unit work instructions may be maintained as appropriate and within the bounds of the STERIS quality system.* *Facility management will revise their local work instructions, as necessary, to comply with the STERIS Quality Manual. Additionally, it is the facility management's responsibility to implement training on the STERIS Quality Manual to the employees of that facility, in the manner they deem most effective.*

	Click Previous Click Continue	Previous Continue
Learning Objective: Management Responsibilities Company Information		
The President and Chief Executive Officer of STERIS is responsible for establishing the Company Quality Policy and is the ultimate authority for the operation of the Quality Management System. The Senior Vice President & Chief Compliance Officer is responsible for applying the company Quality Policy and Quality Management System in the STERIS Applied Sterilization Technologies business unit. The Vice President, Customer Quality is responsible for applying the company Quality Policy and Quality Management System in the Healthcare Products, Healthcare Specialty Services and Life Science business units. The Senior Vice President & Chief Compliance Officer and the Vice President, Customer Quality shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks. The STERIS Senior Management Team (SMT) includes the individuals noted above plus other senior Business Leaders designated by the President and Chief Executive Officer of STERIS (e.g., business		Management Responsibilities Company Information *The President and Chief Executive Officer of STERIS is responsible for establishing the Company Quality Policy and is the ultimate authority for the operation of the Quality Management System. The Senior Vice President & Chief Compliance Officer is responsible for applying the company Quality Policy and Quality Management System in the STERIS Applied Sterilization Technologies business unit. The Vice President, Customer Quality is responsible for applying the company Quality Policy and Quality Management System in the Healthcare Products, Healthcare Specialty Services and Life Science business units. The Senior Vice President & Chief Compliance Officer and the Vice President, Customer Quality shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.* *The STERIS Senior Management Team (SMT) includes the individuals noted above plus other senior Business*

segment Presidents, Regional Operations Directors). The SMT members collectively are responsible for the Customer management, quality, compliance, internal audit, operational management, financial performance, engineering, health and safety, and environmental management of all facilities under their direct control. The SMT members are responsible for ensuring the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented and for ensuring adequate resources are available to ensure compliance to the Quality Management System. Regular performance information is provided to the SMT to ensure compliance to all relevant company, legal, and quality regulations. The SMT members comprise the Management with Executive Responsibility. The Quality Leaders (e.g., Quality Managers) of the various operational units of STERIS are responsible for determining quality strategy, assuring compliance to all relevant company, legal, and quality regulations; implementing best practices; and harmonization across all STERIS facilities. Routine Management Review information is provided to Management to ensure compliance to the Quality Management System and opportunities for improvement. The Quality Leaders are appointed as Management Representatives to: • Ensure the QMS is established, implemented, and maintained;		*Leaders designated by the President and Chief Executive Officer of STERIS (e.g., business segment Presidents, Regional Operations Directors). The SMT members collectively are responsible for the Customer management, quality, compliance, internal audit, operational management, financial performance, engineering, health and safety, and environmental management of all facilities under their direct control. The SMT members are responsible for ensuring the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented and for ensuring adequate resources are available to ensure compliance to the Quality Management System. Regular performance information is provided to the SMT to ensure compliance to all relevant company, legal, and quality regulations. The SMT members comprise the Management with Executive Responsibility.* *The Quality Leaders (e.g., Quality Managers) of the various operational units of STERIS are responsible for determining quality strategy, assuring compliance to all relevant company, legal, and quality regulations; implementing best practices; and harmonization across all STERIS facilities. Routine Management Review information is provided to Management to ensure compliance to the Quality Management System and opportunities for improvement.* *The Quality Leaders are appointed as Management Representatives to:* *• Ensure the QMS is established, implemented, and maintained;*

• Report to Management with Executive Responsibility regarding performance of the QMS; and • Promote awareness of regulatory and Customer requirements throughout the organization. Detailed authority and responsibility for specific processes of the Quality Management System are defined in Procedures and/or job descriptions. Local Site Management shall be defined in local organization charts.	Click Previous Click Continue	• *Report to Management with Executive Responsibility regarding performance of the QMS; and* • *Promote awareness of regulatory and Customer requirements throughout the organization.* *Detailed authority and responsibility for specific processes of the Quality Management System are defined in Procedures and/or job descriptions. Local Site Management shall be defined in local organization charts.* Previous Continue
Learning Objective: Company Information		
STERIS Global Headquarters: Rutherford House United Kingdom. Our Authorized Representative is STERIS Ireland Limited.		STERIS Global Headquarters: Rutherford House Stephensons Way Derby DE21 6LY United Kingdom +44 0 1332 287100 STERIS Authorized Representative STERIS Ireland Limited

The STERIS US Headquarters	Click Previous Click Continue	IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland +44 0 116 276 8636 STERIS US Headquarters: 5960 Heisley Road Mentor, Ohio 44060 United States of America 800 548 4873 Previous Continue
Learning Objective: Quality Management System		
The Quality Management System creates a framework for the organization structure, responsibility, activities, resources, and events that together provide organized processes to ensure the capability of the organization to meet quality, Customer, and regulatory requirements. Risk Management activities are incorporated into the appropriate Quality System processes (e.g., Product Design Management, Nonconformance, CAPA, etc.). Changes to these processes are evaluated for their impact on the quality management system, the product produced under the quality management system, and are controlled in accordance with applicable standards and regulatory requirements.		*The Quality Management System creates a framework for the organization structure, responsibility, activities, resources, and events that together provide organized processes to ensure the capability of the organization to meet quality, Customer, and regulatory requirements. Risk Management activities are incorporated into the appropriate Quality System processes (e.g., Product Design Management, Nonconformance, CAPA, etc.).* *Changes to these processes are evaluated for their impact on the quality management system, the product produced under the quality management system, and are controlled in accordance with applicable standards and regulatory requirements.*

		
Learning Objective: Quality System Documentation		
The Quality System document hierarchy consists of four levels with each subsequent level designed to provide the reader with additional details as required based on the complexity of the function or process being addressed. Master copies of QMS documents are available either electronically or hardcopy. ***Quality Manual***: Single, stand-alone, controlled document that defines the company's Quality Management System (QMS) and Quality System Elements (QSEs) to ensure compliance to global regulations and standards.		Quality System Documentation The Quality System document hierarchy consists of four levels with each subsequent level designed to provide the reader with additional details as required based on the complexity of the function or process being addressed. Master copies of QMS documents are available either electronically or hardcopy. ***Quality Manual***: Single, stand-alone, controlled document that defines the company's Quality Management System (QMS) and Quality System

Policies/Procedures: These documents can have global, regional, and/or facility applicability. The scope of each individual policy/procedure will define applicability to facilities and/or departments. In periods of transition to standard STERIS policies/procedures, the new processes/procedures may be piloted at specific sites, and/or departments/project teams. The transition plan for new/harmonized procedures will be outlined in the scope of the procedure; gradual transition is acceptable and those not transitioned at the time of implementation will be permitted to continue use of the legacy procedure(s). ***Work Instructions:*** Documents which provide additional detail, step by step instructions, or guidance to ensure proper application of STERIS policies/procedures. Work instructions may apply to a business unit or specific facility; the scope of the document will be included within the work instruction. ***Forms/Records:*** Documents used to record data as required by policies/procedures or work instructions.	Click Previous Click Continue	Elements (QSEs) to ensure compliance to global regulations and standards. ***Policies/Procedures***: These documents can have global, regional, and/or facility applicability. The scope of each individual policy/procedure will define applicability to facilities and/or departments. In periods of transition to standard STERIS policies/procedures, the new processes/procedures may be piloted at specific sites, and/or departments/project teams. The transition plan for new/harmonized procedures will be outlined in the scope of the procedure; gradual transition is acceptable and those not transitioned at the time of implementation will be permitted to continue use of the legacy procedure(s). ***Work Instructions:*** Documents which provide additional detail, step by step instructions, or guidance to ensure proper application of STERIS policies/procedures. Work instructions may apply to a business unit or specific facility; the scope of the document will be included within the work instruction. ***Forms/Records:*** Documents used to record data as required by policies/procedures or work instructions. Previous Continue
Review:		
Course Title Page “Steris Quality Management”		
Lesson One Title Page		

Instructions		
Objectives		
Main Menu		
STERIS Quality Policy		
Purpose and Scope		
Management Responsibilities		
Company Information		
Quality Management Systems		
Knowledge Check		
Learning Objective: QSE #1: Quality Manual		
Overview: The STERIS Quality Manual defines the company's Quality Management System (QMS) and Quality System Elements (QSEs) to ensure compliance to global standards and regulations. The Quality Policy statement is included in the Quality Manual. Documented procedures established for the Quality Management System are referenced in the regional / local / facility specific document indexes.	Click Previous Click Continue	**Quality Manual** **Overview**: The STERIS Quality Manual defines the company's Quality Management System (QMS) and Quality System Elements (QSEs) to ensure compliance to global standards and regulations. The Quality Policy statement is included in the Quality Manual. Documented procedures established for the Quality Management System are referenced in the regional / local / facility specific document indexes. Previous Continue
Learning Objective: QSE #2: Management Review		
Overview: STERIS has established requirements for conducting periodic management reviews to ensure the continued suitability, adequacy, and effectiveness of our quality system, and to provide opportunities for process improvement.		**Management Review** Overview: STERIS has established requirements for conducting periodic management reviews to ensure the continued suitability, adequacy, and effectiveness of our quality system, and to provide opportunities for process improvement. Management reviews assess

Management reviews assess opportunities for improvement and the need for changes to the QMS, including the Quality Policy and quality objectives.	Click Previous Click Continue	opportunities for improvement and the need for changes to the QMS, including the Quality Policy and quality objectives.: STERIS has established requirements for conducting periodic management reviews to ensure the continued suitability, adequacy, and effectiveness of our quality system, and to provide opportunities for process improvement. Management reviews assess opportunities for improvement and the need for changes to the QMS, including the Quality Policy and quality objectives. Previous Continue
Learning Objective: QSE #3: Personnel / Training		
Overview: STERIS has established the requirement for ensuring any STERIS employee, contractor, or consultant assigned to a task as part of a regulated function is properly trained to perform such task and appropriate and adequate resources are available.	Click Previous Click Continue	**Personnel / Training** **Overview**: STERIS has established the requirement for ensuring any STERIS employee, contractor, or consultant assigned to a task as part of a regulated function is properly trained to perform such task and appropriate and adequate resources are available. Previous Continue

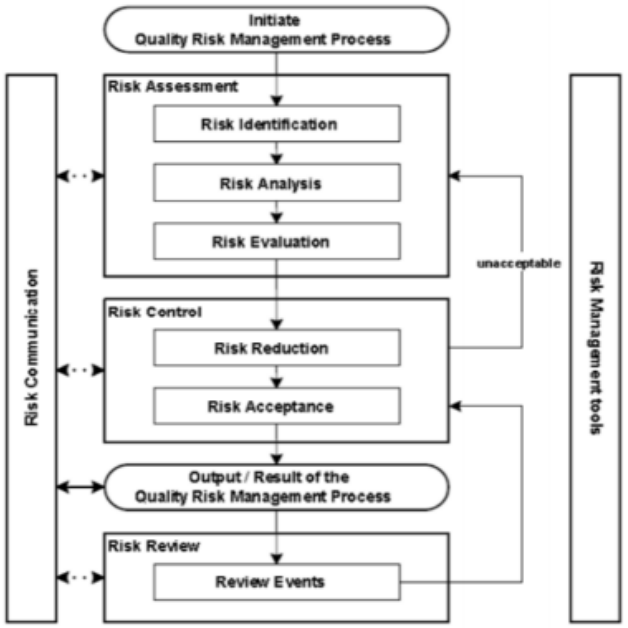
Learning Objective: QSE #4: Facilities and Equipment Management		
Overview: STERIS has established requirements for ensuring that facilities and/or equipment used in the manufacturing, processing, and control of products are properly selected, designed, constructed, installed, and maintained to comply with applicable requirements and are appropriate for their intended use.	Click Previous Click Continue	**Facilities and Equipment Management** **Overview**: STERIS has established requirements for ensuring that facilities and/or equipment used in the manufacturing, processing, and control of products are properly selected, designed, constructed, installed, and maintained to comply with applicable requirements and are appropriate for their intended use.
Learning Objective: QSE #5: Product Design Management		
Overview: STERIS has established requirements for control of the device design in order to ensure defined design requirements are met. The Product Realization processes shall be planned and developed in accordance with Customer, legal and regulatory requirements. In planning product realization, the following shall be determined, as appropriate: quality objectives and requirements for the product; the need to establish processes and documents and provide resources specific to the product, including infrastructure and work environment; required verification, validation, monitoring, measurement, inspection, testing, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; records needed to provide evidence that the realization processes and resulting product meet requirements and the output		**Product Design Management** **Overview:** STERIS has established requirements for control of the device design in order to ensure defined design requirements are met. The Product Realization processes shall be planned and developed in accordance with Customer, legal and regulatory requirements. In planning product realization, the following shall be determined, as appropriate: quality objectives and requirements for the product; the need to establish processes and documents and provide resources specific to the product, including infrastructure and work environment; required verification, validation, monitoring, measurement, inspection, testing, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; records needed to provide evidence that the realization processes and resulting product meet requirements and the output of

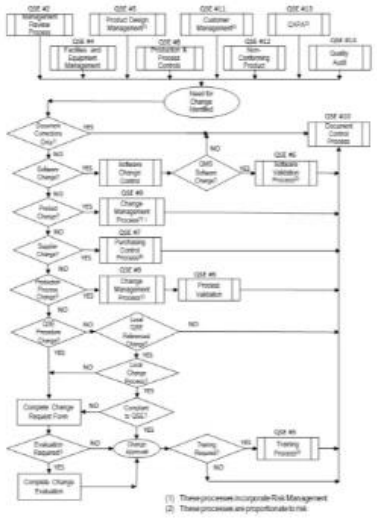
of product realization planning shall be documented in a form appropriate to the method of operations.	Click Previous Click Continue	product realization planning shall be documented in a form appropriate to the method of operations. Previous Continue
Learning Objective: QSE #6: Validation		
Overview: Validation requirements have been established by STERIS to ensure a product, service, process, equipment, or software conforms to defined user needs and intended use(s).	Click Previous Click Continue	**Validation** **Overview:** Validation requirements have been established by STERIS to ensure a product, service, process, equipment, or software conforms to defined user needs and intended use(s). Previous Continue
Learning Objective: QSE #7: Purchasing Controls		
Overview: STERIS has established a system to verify that approved suppliers consistently deliver goods and/or critical services that meet regulatory and company quality requirements. Requirements have been established to ensure levels of control for suppliers based on risk, product criticality, and performance are maintained and documented and that suppliers' quality performance is monitored.	Click Previous Click Continue	**Purchasing Controls** **Overview**: STERIS has established a system to verify that approved suppliers consistently deliver goods and/or critical services that meet regulatory and company quality requirements. Requirements have been established to ensure levels of control for suppliers based on risk, product criticality, and performance are maintained and documented and that suppliers' quality performance is monitored. Previous Continue
Learning Objective: QSE #8: Production and Process Controls		
Overview: STERIS has established requirements for production and process controls, including availability of Device Master Records, Device History Records, Processing Records and procedures		**Production and Process Controls** **Overview:** STERIS has established requirements for production and process controls, including availability of Device Master Records, Device History Records,

to document that Customer and regulatory requirements have been met.	Click Previous Click Continue	Processing Records and procedures to document that Customer and regulatory requirements have been met. Previous Continue
Learning Objective: QSE #9: Change Management		
Overview: STERIS has established the requirements for managing all changes within the scope of the QMS in a consistent manner.	Click Previous Click Continue	**Change Management** **Overview:** STERIS has established the requirements for managing all changes within the scope of the QMS in a consistent manner. Previous Continue
Learning Objective: QSE #10: Document / Records Controls		
Overview: STERIS has established the requirements for processes used to manage documents governed by the QMS.	Click Previous Click Continue	**Document / Records Controls** **Overview:** STERIS has established the requirements for processes used to manage documents governed by the QMS Previous Continue
Learning Objective: QSE #11: Customer Management		
Overview: STERIS has established processes for Customer and complaint management. These processes include mechanisms to meet regulatory and Customer quality requirements throughout the Product Realization Process. Mechanisms have been established to monitor Customer feedback for adherence to their requirements. Feedback can come from a variety of sources, including, but not limited to, surveys, site visits and complaints.		**Customer Management** **Overview**: STERIS has established processes for Customer and complaint management. These processes include mechanisms to meet regulatory and Customer quality requirements throughout the Product Realization Process. Mechanisms have been established to monitor Customer feedback for adherence to their requirements. Feedback can come from a variety of sources, including, but not limited to, surveys, site visits and complaints.

	Click Previous Click Continue	Previous Continue
Learning Objective: QSE #12: Nonconforming Product		
Overview: STERIS has established the requirements for assuring that nonconformance events identified by the QMS are documented, evaluated for risk, and that appropriate containment and segregation actions and corrections are taken to return process/product to a state of control and compliance.	Click Previous Click Continue	**Nonconforming Product** **Overview:** STERIS has established the requirements for assuring that nonconformance events identified by the QMS are documented, evaluated for risk, and that appropriate containment and segregation actions and corrections are taken to return process/product to a state of control and compliance. Previous Continue
Learning Objective: QSE #13: Corrective and Preventive Actions (CAPA)		
Overview: STERIS has established the requirements for assuring that corrective and preventive actions are developed, implemented, and evaluated to eliminate root causes of nonconformances and adverse trends to prevent occurrence and recurrence.	Click Previous Click Continue	**Corrective and Preventive Actions (CAPA)** **Overview**: STERIS has established the requirements for assuring that corrective and preventive actions are developed, implemented, and evaluated to eliminate root causes of nonconformances and adverse trends to prevent occurrence and recurrence. Previous Continue
Learning Objective: QSE #14: Internal Audit		
Overview: STERIS has established a program to ensure that the QMS is in compliance with the established quality system requirements and to determine the effectiveness of the quality system by conducting scheduled audits of company facilities, functions, contract manufacturers, and suppliers.	Click Previous Click Continue	**Internal Audit** **Overview**: STERIS has established a program to ensure that the QMS is in compliance with the established quality system requirements and to determine the effectiveness of the quality system by conducting scheduled audits of company facilities, functions, contract manufacturers, and suppliers.

		Previous Continue
Learning Objective: Quality System Element Procedures		
Learning Objective: Risk Based Approach		
Risk-based thinking shall be utilized in the development and maintenance of Quality Management System (QMS) processes to: • Determine criteria and methods needed to ensure that both the operation and control of these processes are effective. • Ensure the availability of resources and information necessary to support the operation and monitoring of these processes • Implement actions necessary to achieve planned results and maintain the effectiveness of these processes • Monitor, measure as appropriate, and analyze these processes • Establish and maintain records needed to demonstrate compliance with the quality management system and applicable regulatory requirements.		**Risk Based Approach** Risk-based thinking shall be utilized in the development and maintenance of Quality Management System (QMS) processes to: • Determine criteria and methods needed to ensure that both the operation and control of these processes are effective. • Ensure the availability of resources and information necessary to support the operation and monitoring of these processes • Implement actions necessary to achieve planned results and maintain the effectiveness of these processes • Monitor, measure as appropriate, and analyze these processes • Establish and maintain records needed to demonstrate compliance with the quality management system and applicable regulatory requirements.

Risk management shall be incorporated in the following Quality System Element (QSE) processes: • Product Design Management and/or • Change Management and/or • Execution of Customer specifications The risk management process(es) shall cover risk assessment, risk control, and risk review. Records of risk management shall be maintained. A diagram of the Quality Risk Management Process is provided below.		Risk management shall be incorporated in the following Quality System Element (QSE) processes: • Product Design Management and/or • Change Management and/or • Execution of Customer specifications The risk management process(es) shall cover risk assessment, risk control, and risk review. Records of risk management shall be maintained. A diagram of the Quality Risk Management Process is provided below. 

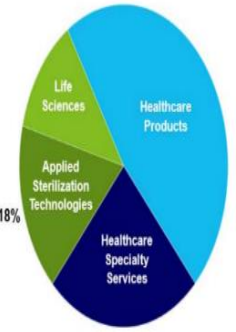
Learning Objective: Quality System Element Interaction		
Changes to the Quality Management System (QMS) processes shall be managed and controlled using a risk based approach and one or more risk management process(es) shall be established for product realization. The interactions for the Quality System Elements are shown below, in the Quality System Interaction Diagram.		**Quality System Element Interaction** Changes to the Quality Management System (QMS) processes shall be managed and controlled using a risk based approach and one or more risk management process(es) shall be established for product realization. The interactions for the Quality System Elements are shown below, in the Quality System Interaction Diagram. 

STERIS®

Learning Objective: STERIS Reporting Segments

Life Sciences 13%
Capital equipment and consumable products, and equipment maintenance and specialty services, for pharmaceutical manufacturers and research.

Applied Sterilization Technologies 18%
Contract sterilization and laboratory services for medical device and pharmaceutical Customers and others.



Healthcare Products 48%
Infection prevention and procedural solutions for healthcare providers worldwide, including capital equipment and related maintenance and installation services, as well as consumables.

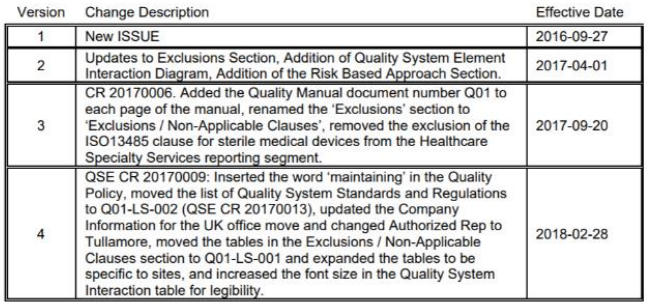
Healthcare Specialty Services 21%
A range of specialty services for healthcare providers including hospital sterilization services, instrument and scope repair.

Learning Objective: QSE Applicability by Reporting Segment / Business Unit

QSE Applicability by Reporting Segment / Business Unit

	Healthcare Products	Healthcare Specialty Services	Applied Sterilization Technologies	Life Sciences
Management Responsibility:				
Quality Manual	X	X	X	X
Management Review	X	X	X	X
Resource Management:				
Personnel /Training	X	X	X	X
Facilities and Equipment Management	X	X	X	X
Product / Service Realization:				
Product Design Management	X	NA*	NA*	X
Validation	X	X	X	X
Purchasing Controls	X	X	X	X
Change Management	X	X	X	X
Document / Records Controls	X	X	X	X
Production and Process Controls	X	X	X	X
Measurement, Analysis & Improvement:				
Customer Management	X	X	X	X
Nonconforming Product	X	X	X	X
CAPA	X	X	X	X
Internal Audit	X	X	X	X

* The AST and HSS Business Units do not perform product design activities.

Learning Objective: Exclusions / Non-Applicable Clauses		
For STERIS sites certified to ISO 13485 and/or ISO 9001, a list of Quality System exclusions / non-applicable clauses by site is provided in Q01-LS-001, along with the justification for nonapplicability.		For STERIS sites certified to ISO 13485 and/or ISO 9001, a list of Quality System exclusions / non-applicable clauses by site is provided in Q01-LS-001, along with the justification for nonapplicability.
Learning Objectives: Version History		
Version History		**Version History** 

Version	Change Description	Effective Date
1	New ISSUE	2016-09-27
2	Updates to Exclusions Section, Addition of Quality System Element Interaction Diagram, Addition of the Risk Based Approach Section.	2017-04-01
3	CR 20170006. Added the Quality Manual document number Q01 to each page of the manual, renamed the 'Exclusions' section to 'Exclusions / Non-Applicable Clauses', removed the exclusion of the ISO13485 clause for sterile medical devices from the Healthcare Specialty Services reporting segment.	2017-09-20
4	QSE CR 20170009: Inserted the word 'maintaining' in the Quality Policy, moved the list of Quality System Standards and Regulations to Q01-LS-002 (QSE CR 20170013), updated the Company Information for the UK office move and changed Authorized Rep to Tullamore, moved the tables in the Exclusions / Non-Applicable Clauses section to Q01-LS-001 and expanded the tables to be specific to sites, and increased the font size in the Quality System Interaction table for legibility.	2018-02-28

Assessment Questions		
[**Question 1**] –		A. B. **C.** D.
[**Question 2**] –		**A.** B. C. D.
[**Question 3**] –		A. B. C.

		D.