

# **YSI Incorporated Integrated Management System for Quality, Environmental, and Trade Compliance Processes**

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# YSI Quality and Environmental Management System Manual

## A. Context of the Organization

Top management is accountable for the quality and environmental management system, which is integrated with business processes and compatible with YSI's business strategy. YSI management has determined external and internal issues that are relevant to its purpose and its strategic direction, including their potential effect (risks or opportunities) on the organization's ability to achieve the intended results and outcomes of its quality and environmental management system (Q/EMS).

YSI's management has determined:

- a. the interested parties that are relevant to the Q/EMS
- b. the needs and expectations of these interested parties that are relevant to the Q/EMS
- c. for environmental concerns, an interested parties communication plan, identification of environmental compliance obligations, and impacts of product and process life cycles.

YSI has established the scope of its Q/EMS, which is in YSI's Q/EMS manual and ISO certificates, available online. When determining this scope, the organization considers:

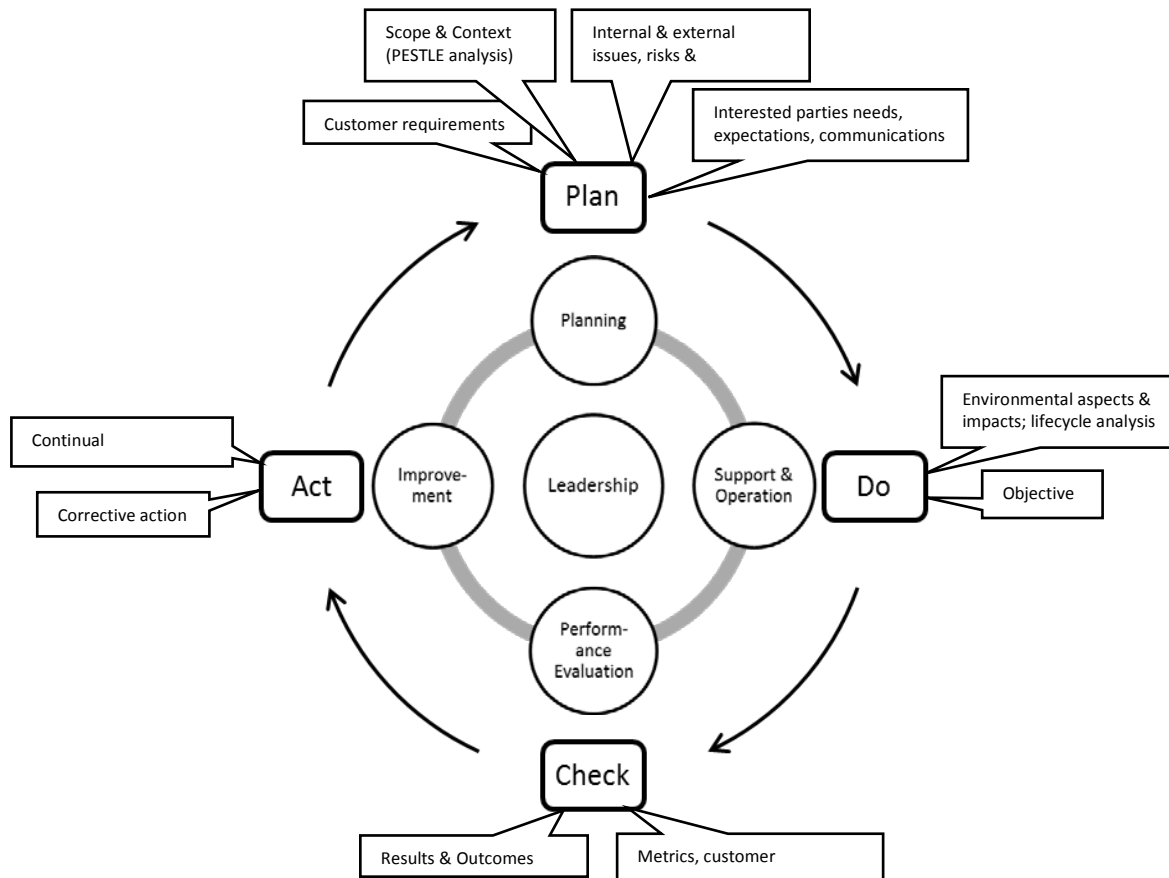
- a. external and internal issues;
- b. requirements of relevant interested parties;
- c. organizational units, functions and physical boundaries;
- d. activities, products and services;
- e. authority and ability to exercise control and influence on environmental conditions

YSI's management monitors and reviews information about external and internal issues, interested parties and their relevant requirements, and the relationship of all of these to quality and environmental objectives, per at least an annual management review of the Q/EMS.

YSI's management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a. customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c. the focus on enhancing customer satisfaction is maintained.

A graphic representation of YSI's Q/EMS is shown here:



## B. Scope

Location: YSI Incorporated, 1725 Brannum Lane, Yellow Springs, OH 45387.

Locations covered: All facilities in Yellow Springs, Ohio.

Company scope: Design, assemble, distribute, and service equipment that provides high quality and reliable data for water quality, water quantity, and bioprocessing.

YSI is a *manufacturer* of reagents and membranes for its discontinued IVD, Model 2300.

YSI is a brand of Xylem Incorporated.

Company mission: We provide technology solutions to protect water resources for all generations.

Number of employees at locations covered: 180-250 employees (estimated 30 FTEs for IVD support products), 1 shift in Yellow Springs.

Markets served: Coastal/estuaries, surface water, groundwater, drinking water, aquaculture, wastewater, bioprocess monitoring, healthcare, food & beverage processing.

Standards and regulatory requirements covered: ISO 9001:2015; ISO 14001:2015; ISO 13485:2016, In-vitro Diagnostic (IVDD), FDA QSR (21CFR Part 820), FDA UDI (21CFR Part 830), Export Administration Regulations (EAR).

Voluntary or product directives ascribed to: Product safety (UL/ETL); CE Marking; EU Electro-Magnetic Compatibility (EMC); Low Voltage Directive (LVD); EU Restriction on Hazardous Substances (RoHS); EU Waste Electrical and Electronic Equipment (WEEE); EU Battery Directive, REACH, FCC-related (intentional & unintentional radiators); Xylem trade compliance policies; Xylem EHSS&S policies.

The management system established by YSI integrates several types of documentation into a cohesive structure, allowing for an organized approach to daily business activities. These include:

- Policy statements regarding quality, environmental, and trade compliance, and the organizational objectives needed to effectively implement the policies.
- A systems manual that expresses YSI's intentions to establish and use planned activities specified in the management systems documentation.
- Procedures and subordinate documents that reflect not only those required by the recognized standards identified in the scope of the systems manual, but also those key processes that are necessary to ensure the consistent operation and performance of YSI.
- Any subordinate documentation such as forms, logs, work instructions, acceptance test protocols, etc., that enables the smooth functioning of YSI's operations, and the resulting records that demonstrate that planned arrangements have been implemented and performed.

Specific regulatory requirements for quality, environmental, medical products and trade compliance are addressed throughout the management system's key process documentation. Due to additional regulatory requirements of the Life Sciences business, a medical device reference section has been added to this manual.

## **C. What Occurs at This Location**

Yellow Springs:

New product development

Production: planning, assembly, test, packaging, shipping

Product repair and service

Procurement, receiving, incoming inspection, warehousing, distribution

Accounting and finance

Product management, marketing, and voice of customer

Customer and technical support

Quality assurance

Information technology

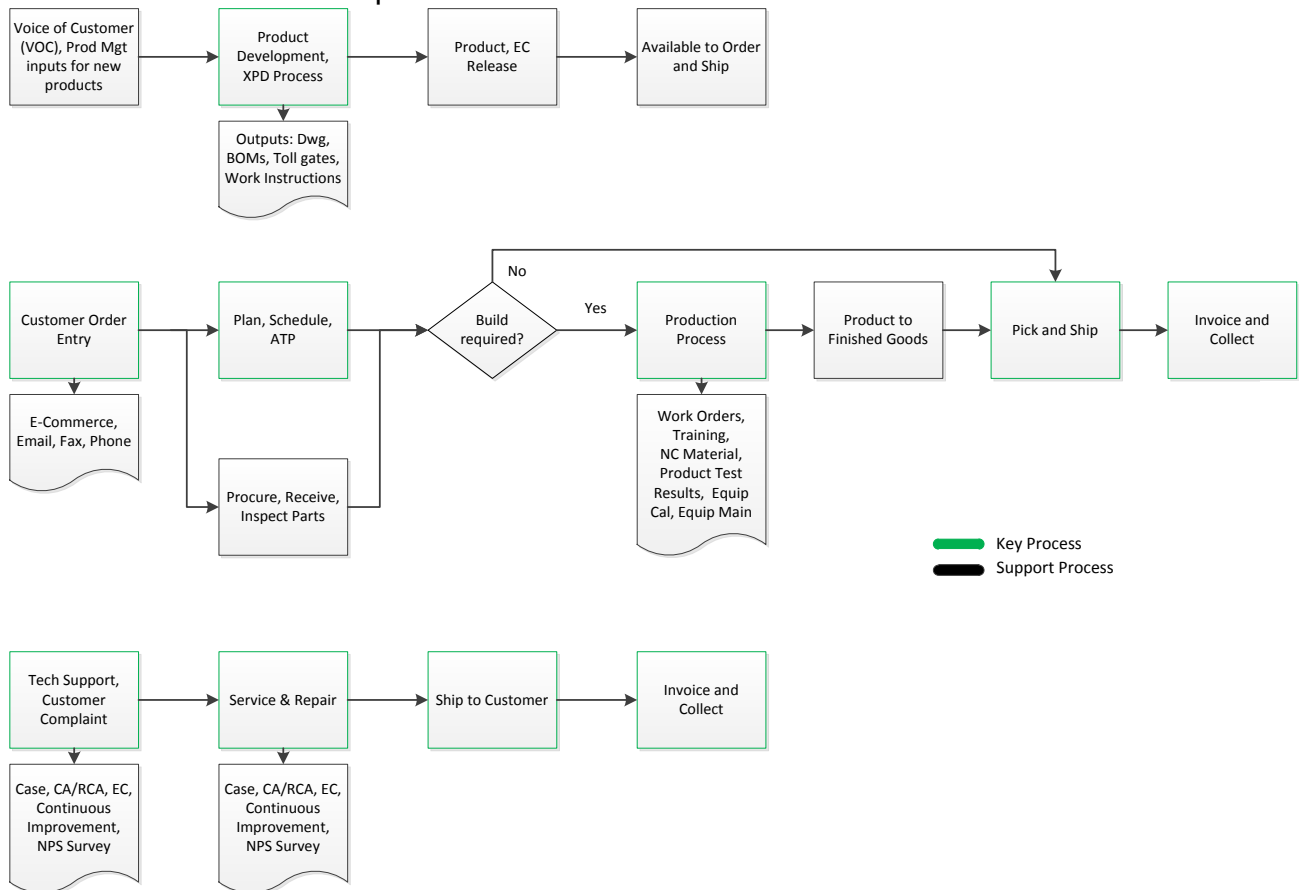
Human resources

Environmental, health, safety, security, & sustainability management

Trade compliance

YSI's business processes map is shown in the diagram below.

## YSI Business Process Map



### Note:

Support functions, such as QA, HR, and IT, are implicit in business processes as needed and as applicable. QA is directly involved in all aspects of the QMS and Plan-Do-Check-Act model, including new product development process, production and process controls, work environment, engineering and process changes, customer focus, feedback & complaints, supplier quality, product verification & validation, process validation, site leadership, management review, quality planning, competence & awareness, documentation & records control, nonconforming product, monitoring & measurement of site objectives & KPIs, data analysis, root cause analysis, corrective action, preventive action, continual improvement, internal & external audits, regulatory & compliance conformance (including medical device concerns).

## D. Policy Statements

YSI has developed separate policies for Quality, Environmental, and Trade Compliance responsibility. Each was approved by top management to be appropriate to YSI's purpose and to the nature, scale and environmental impacts of the work activities, products and services delivered. The policies provide a framework for establishing management objectives, documented through the Xylem Analytics KPI Dashboard process. Each policy is periodically evaluated during the Management Review process to determine if it continues to be suitable to the company's purposes.

**Implicit in all YSI policies is the commitment to adhere to all applicable laws, permits, compliance obligations and regulatory requirements, and to continually improve the effectiveness of the integrated management system.**

### D.1 Quality Policy

We maintain a quality management system to provide our customer with quality, innovative products and services that meet or exceed expectations.

To support this, we will:

- Establish, measure, and achieve quality objectives as an integral part of our business decision making process.
- Utilize the Quality Management System to support our strategic direction.

### D.2 Environmental Policy

Achieve company environmental objectives by:

- Protecting the environment through prevention of pollution and waste, and from harm and degradation that could be caused from the company's activities, products, and services
- Fulfilling compliance obligations and legal requirements
- Continually improving the environmental management system for enhancement of environmental performance
- Providing strategic focus on the company's impacts, risks, opportunities, and influence for competitive advantage and to support the company's strategic direction and scope

### D.3 Trade Compliance Policy

YSI's Trade Compliance Program is integrated with the YSI quality system to ensure our procedures and record keeping are in compliance with U.S. Export Administration Regulations. The YSI Trade Compliance Program ensures, among other requirements, that all employees involved in export or the release of technology overseas or to foreign nationals are aware of the requirements.

## E. YSI Business Processes

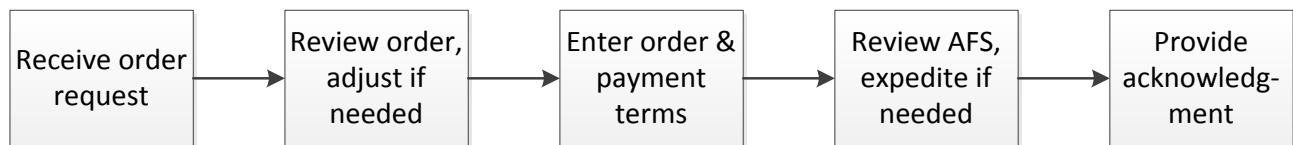
Note: General process flow is shown where applicable.

### E.1 Customer Order Support

The arrangements for direct customer communication are determined and implemented to ensure that product information, inquiries, contracts and order handling, customer feedback and complaints are managed and controlled appropriately and effectively. Contracts are reviewed prior to acceptance.

YSI designs, produces, and distributes products that are considered catalog items, or off the shelf products. Customer requirements at time of order may include YSI item number and quantity, requested delivery date, shipping method & terms, packaging material preference, and discount terms.

Throughout its business processes, YSI ensures that customer requirements are identified, understood, and managed. This includes environmental and export aspects of process, product, or service that can be controlled or influenced by daily business activities and regulatory or legal requirements.



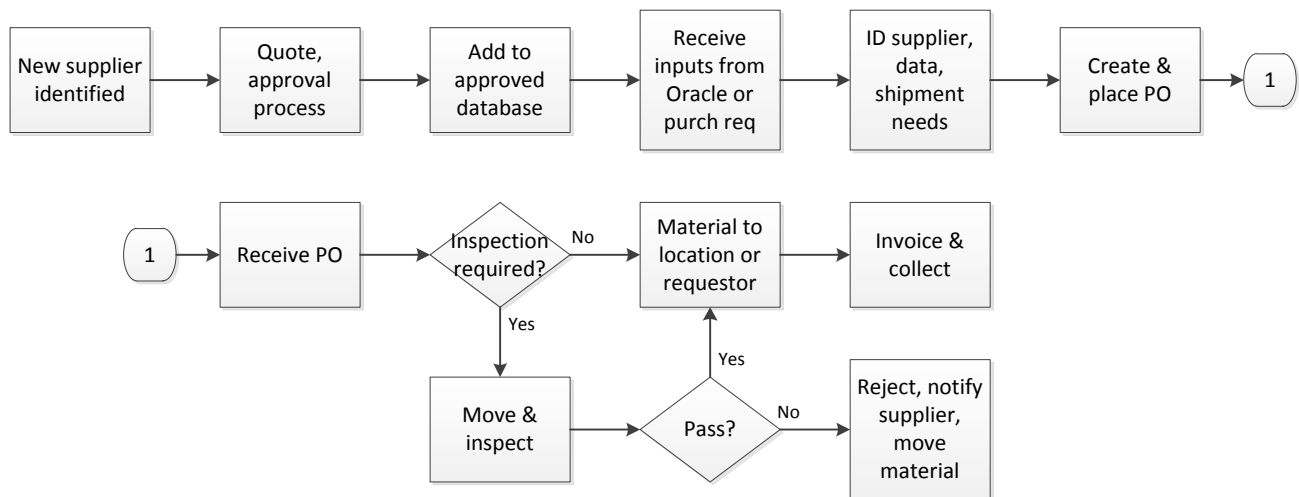
Related YSI procedures:

- Customer Requirements Review – Order Entry
- Oracle Order Management series of work instructions
- Customer Credit Card Policy



## E.2 Supply Chain Management

YSI maintains documented procedures to ensure that purchased product and services conforms to specified requirements. YSI is responsible for the quality of the products purchased from suppliers, even when the customer specifies a source. Verification of incoming products and services is planned and documented to assure conformance to specifications. Suppliers are assessed and selected based on their ability to meet established requirements. Critical suppliers are audited periodically. A list of acceptable vendors is maintained.



Related YSI procedures:

- Supplier Listings Evaluation
- Purchasing Planning Process
- Oracle Purchasing series of work instructions
- Incoming Inspection
- Nonconforming Product procedure

### **E.3 Design to Release & Demand to Build**

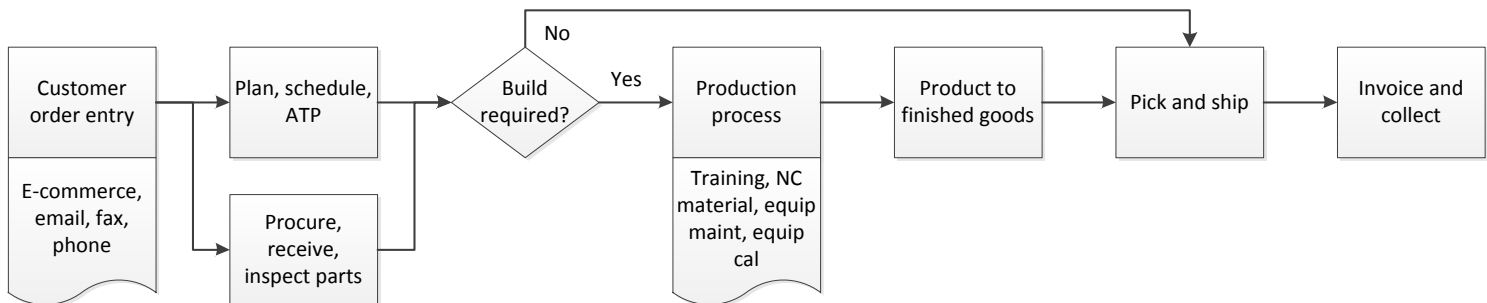
The requirements for products designed, manufactured and delivered by YSI are determined and documented as they evolve throughout the realization process. Changes to released designs are evaluated, controlled, and documented. Requirements for products and services may be specified by customers, prior product experience, statutory or regulatory requirements, environmental aspects and impacts, and others that ensure control, quality and environmental responsibility. Requirements are determined for product verification, validation, monitoring, measurement, and inspection and test activities.

YSI plans its production activities to ensure that products, processes and services are controlled and capable of yielding the desired planned results, including those where environmental impacts can have an influence and need to be managed and maintained consistent with related policies, procedures and objectives. YSI validates equipment, tools, and processes prior to their implementation in production. Product identification is maintained from receipt and during all stages of production and delivery. YSI identifies and maintains equipment calibration to control measurement and test devices that are used for product acceptance.

YSI takes action on nonconformity of product, process, system or service, as necessary to correct the immediate situation and permanently affect the root cause at a systemic level where possible. This applies equally to quality or environmental issues. Nonconforming product is controlled to prevent unintended use. Opportunities for preventive actions are identified, prioritized and acted upon to ensure that the potential for product, process, systems or service nonconformity is minimized.

- Design to Release process flow includes:
  - New product introduction process (ref Xylem XPD-STD-001-YSI for complete flowchart)
  - ECO Request to Implement
  - ECO PCN Process
  - Product Discontinuation
  - Do Not Ship/Do Not Build

Demand to Build process flow:

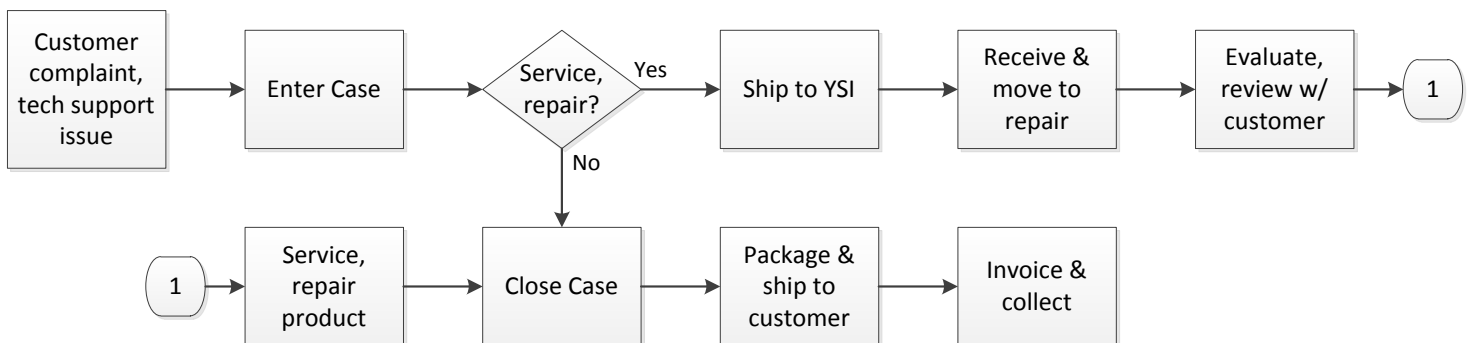


Related YSI procedures:

- YSI BP080 Design to Release
- YSI BP080 Do Not Ship
- YSI BP080 ECO
- Analysis of Data
- Calibration of Measuring & Test Equipment
- Corrective Action and Complaints
- Engineering Drawing Standards
- Expired Materials and Control of Chemicals
- In Process Checks and Rework
- Label Change Record Process Flow
- Manufacturing Process Policies & Procedures
- Nonconforming Product
- Packaging, Shipping, and Distribution
- Production Planning Daily Routine
- Product Discontinuation Policy
- Product Identification and Traceability
- Production Equipment Control
- Waiver Process
- YSO Shipping Policy
- YSI Environmental Management System

## E.4 Service & Repair

Technical data supporting the service operations is controlled and updated according to the need for product specification and compliance issues. Standard repair processes are identified and used to support the service activity, which are controlled and approved prior to implementation. Returned products are sent to YSI-authorized repair centers and are identified and kept separate from conforming products until evaluated and released from service. When servicing is performed offsite, the requirements are defined.



Related YSI procedures:

- YSI Repair Service Policy
- YSI Product Service Scrap Policy
- Analysis of Data
- Corrective Action and Complaints
- Nonconforming Product

## **E.5 Competency, Training, Safety, Security**

YSI's management team provides the resources – human and other – to support the integrated management system in all aspects of its implementation and effectiveness. People involved in work that affects the quality of process, products or services, regulatory or customer requirements, or whose work creates a significant environmental impact are determined to be competent on the basis of skills, education, training and experience. YSI job descriptions and performance plans define employee roles, responsibilities, authorities, and competencies.

Related YSI procedures:

- Training and Development

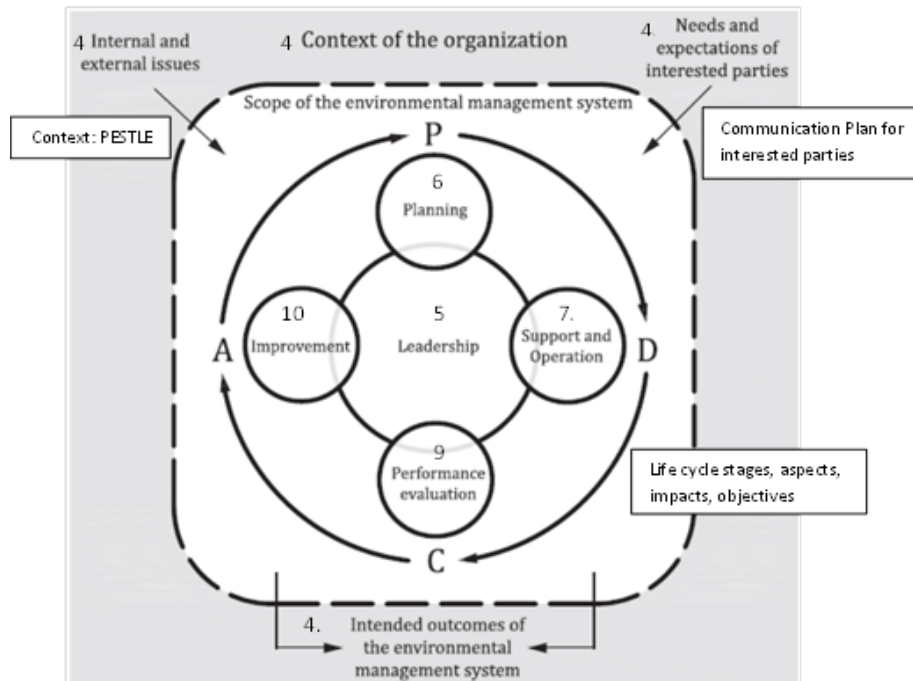
- Safety & security procedures and policies

- Xylem relevant policies

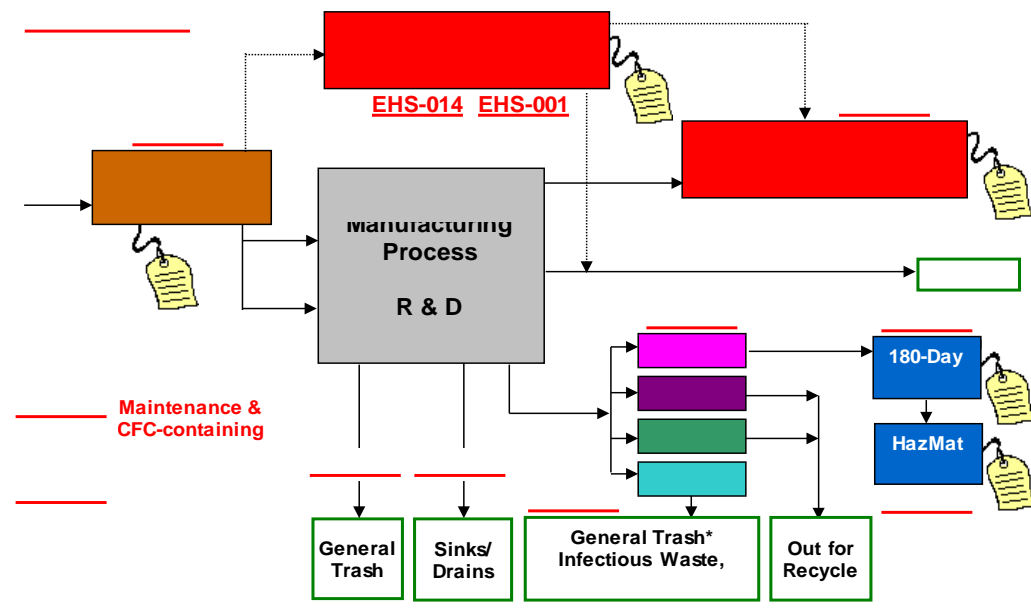
## E.6 Environmental, Health, and Safety

YSI maintains an environmental, health, and safety program that covers the control of materials coming in and going out of its facility; health and safety of all persons working on behalf of YSI; and improvements to its EHS processes. Persons working on behalf of YSI whose work is related to significant environmental aspects receive additional training regarding those areas. External communication of YSI's significant environmental aspects is given consideration by the management team.

### Environmental Management System Map



### Controlling Materials Coming In and Going Out



Related YSI procedures:

All EHS-numbered policies (e.g., EHS-001 Chemical Procurement)

Contractor Safety Manual

Global Water Safety Policy

Hazardous Waste Management System

Non Hazardous Waste Management System

Waste Management Policy

**YSI Environmental, Safety and Health Management System**

YSO Business Continuity Planning

YSO Chemical Spill Response

YSO Emergency Building Evacuation

YSO Physical Security Program

Analysis of Data

Corrective Action and Complaints

## E.7 Management Responsibility and Review

Top management is accountable for the environmental and quality management system, which is integrated with business processes and compatible with YSI's business strategy. YSI sets and measures business objectives in all areas of its operations. These include, but are not limited to quality and environmental objectives. Each objective is established by top management, and is consistent with the intent established by the respective quality and environmental policy. Objectives are targeted to specific planned performance levels, are measurable in order to gage progress to plan, and are established and communicated at relevant functions and levels within the organization. The management team reviews the Quality & Environmental Management System at regular intervals to ensure it is effective, suitable, and adequate for the business, and that it is compliant to relevant governing standards.

YSI management has selected designated employees to act as management representatives for the Quality and Environmental components of the Integrated Management System, via the Director, Manager, or Leader of Quality, for quality and environmental; and the Director, Manager, or Leader of Trade Compliance, for trade compliance.

YSI provides and maintains the facilities, equipment and services necessary to support its operational objectives, including those pertaining to product quality and environmental impacts. YSI ensures that the work environment has the attributes appropriate to achieve conformity to product and regulatory requirements. This includes but is not limited to climate controls, lighting, safety considerations and personal protective equipment.

Related YSI procedures:

- Analysis of Data

- Corrective Action and Complaints

- Enterprise Computer System Change Management

- Enterprise Operational Controls

- Internal Audits

- Management Responsibility and Review

- Risk Management Policy & Procedures

- Records of Context Review, Interested Parties, Risks & Opportunities, Communication Plans, and Objectives of the Q/EMS



## **E.8 Data, Document, and Records Management**

YSI maintains documented procedures to control all quality and environmental management-related documents and data. YSI maintains quality and environmental records to provide evidence that the quality and environmental management system elements have been effectively implemented.

Records necessary to demonstrate maintenance and achievement of quality products and services, and environmental management, are retained. These records are available to all internal and external parties as appropriate for the conduct of business and regulation of products and services.

Related YSI procedures:

- Control of Documents

- Records & Record Retention

## **E.9 Internal Auditing**

YSI plans and implements internal audits according to documented procedures to verify and assess the operation and effectiveness of the quality and environmental management system.

Related YSI procedures:

Analysis of Data

Corrective Action and Complaints

Internal Audits

YSI Environmental Management System

## E.10 Trade Compliance

YSI maintains a Trade Compliance Program that covers international trade compliance regulations.

All employees should be aware of the many types of transactions that are considered as an export: release of electronic transmissions of information and software; physical shipments; and hand-carried items.

Under no circumstances shall a shipment, release of technology, or information be undertaken contrary to applicable export regulations. Export controls apply not only to out of country shipments, but also to the transmission or release of software and technical information to foreign persons inside or outside of the U.S. Special caution must be taken to prevent transactions with individuals or entities involved in the proliferation of weapons of mass destruction. YSI employees are also required to comply with U.S. rules that prohibit, for example, participation in the Arab Boycott Against Israel, or unauthorized diversions of products.

Any failure to comply with applicable export controls may represent grounds for dismissal. Violations of export controls regulations may result in severe sanctions for the company or individuals involved.

Related YSI procedures:

- All TC-numbered policies (e.g., TC-002 Country of Origin Marking)
- Records & Record Retention
- Internal Audits
- YSI BP080 Quote to Cash

## F. Special Considerations for Medical Devices

YSI produces medical devices (IVD) in the Life Sciences area. These devices may be regulated, based on their use, by FDA, ISO 13485, or EU IVDD. This section describes any special considerations for manufacture and distribution of these medical devices.

### 1. Notifications to EU and FDA

- a. YSI is responsible for notifying its competent authority in the EU (CEPartner4U or replacement) and FDA of any malfunction, inadequacy, failure, or deterioration in the characteristics and/or performance of the device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to, or may have led to, the death of a patient or user or other persons or to a serious deterioration in his/her state of health. Details of notification may be found in the Medical Device Reporting procedure.
- b. YSI is responsible for notifying its competent authority in the EU (CEPartner4U or replacement) and FDA of any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to above that lead to a systemic recall of any medical devices. Details of notification may be found in the YSI Product Recall procedure.

### 2. Notifications For Significant Changes

- a. YSI must notify its competent authority in the EU (CEPartner4U or replacement) and its current ISO 13485 registrar of matters that affect the ability of the management system to continue to fulfill requirements of ISO 13485. This includes significant changes to:
  - Legal, commercial, organizational status or ownership
  - Organization and management
  - Scope of operations under certified management system
  - Major changes to management system and processes
  - Significant increase or decrease in number of employees
  - Contact name, address and site(s)
- b. In addition, YSI must notify its competent authority in the EU (CEPartner4U or replacement) of changes to its technical file, products listed as medical devices for sale into EU, and updates to its medical device risk analysis. These documents are also reviewed on at least an annual basis per contract with CPartner4U.

### 3. Exclusions to ISO 13485:2016 Standard

The following sections of ISO 13485:2016 do not apply to YSI medical devices:

- 7.3.1-7.3.8, New product design
- 7.5.2, Cleanliness of product
- 7.5.3, Installation activities
- 7.5.5, Particular requirements for sterile medical devices
- 7.5.7, Particular requirements for validation of processes for sterilization and sterile barrier systems
- 7.5.9.2, Particular requirements for implantable medical devices

Justification comments to exclusions:

- The YSI Model 2300, the company's only IVD instrument, was discontinued in July 2016. The product roadmap and strategy for Life Sciences does not include any new products that would be classified as medical devices, and no new reagents or membranes will be developed for the discontinued Model 2300. Therefore, the new product design clauses 7.3.1-7.3.8 do not apply to this site.
- There are no product cleaning procedures applicable to the remaining support items for the discontinued Model 2300. Therefore, clause 7.5.2 does not apply.
- There are no installation activities for the remaining support items for the discontinued Model 2300. Therefore, clause 7.5.3 does not apply.
- YSI does not produce products that are subject to sterilization. Therefore, clauses 7.5.5 and 7.5.7 do not apply.
- YSI does not produce implantable medical devices. Therefore, clause 7.5.9.2 does not apply.

4. Unique Device Identification (UDI) Labeling

Reagents and membranes that may be used with the discontinued Model 2300 (an IVD) are labeled in conformance with FDA UDI requirements, per 21CFR Part 830.