

Scope

Develop, design, manufacture, distribute, and service instrumentation that provides high quality and reliable data for laboratory, water quality, water quantity, and bioprocessing analysis.

Mission

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

Applicable Standards & Regulations

Standard Regulation	Business Unit	
	***Life Sciences	All Others
ISO 9001	✓	✓
ISO13485	✓**	
ISO 14001	✓	✓
21 CFR Part 820/830	✓	

**Cleaning procedures or sterilization not required, section 7.5.2, 7.5.5, and 7.5.7 do not apply. The device is not implantable, section 7.5.9.2 does not apply.

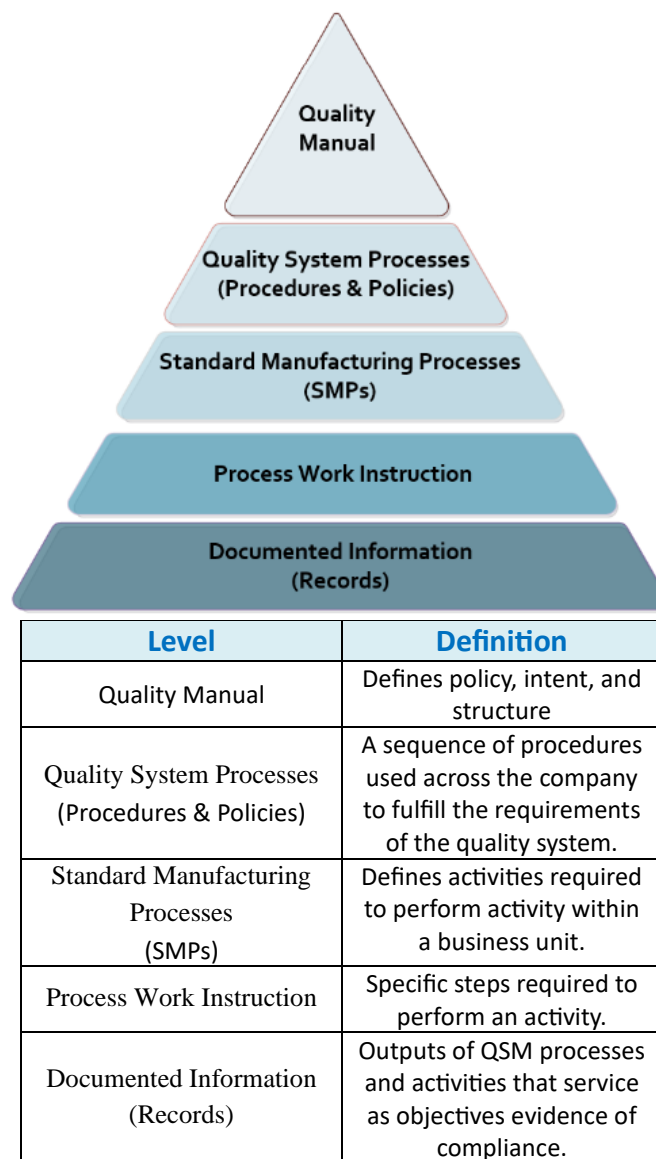
*** YSI Model 2300 was discontinued in July 2016. There are no installation or design clauses associated with this unit.

Role/Responsibilities

Management responsibilities are defined within the Management Responsibility procedures.

Top management is accountable for the quality and environmental management system, which is integrated with business processes and compatible with YSI's business strategy.

QS Documentation Architecture *



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Quality Manual

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Quality Policy

We maintain a quality management system to provide our customers 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.

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 to the company's impacts, risks, opportunities, and influence for competitive advantage and to support the company's strategic direction and scope.

Quality Management System Process model

The Quality Manual is the foundational framework by which YSI enables continual optimization of products and services, customer satisfaction, business operation excellence, and compliance. This manual:

- Establishes the quality policy that sets consistent expectations and responsibilities for the company,
- Defines the scope of compliance with applicable regulatory, standards, industry, and business requirements,
- Defines roles and responsibilities for ensuring consistent process effectiveness, suitability, and adequacy, and
- Describes the key processes of the quality system and their interaction, and identifies the documentation established for the processes.

