



Technical Integrity in Auditing

Presented by Qualified Specialists, Intl.





What is Technical Integrity?

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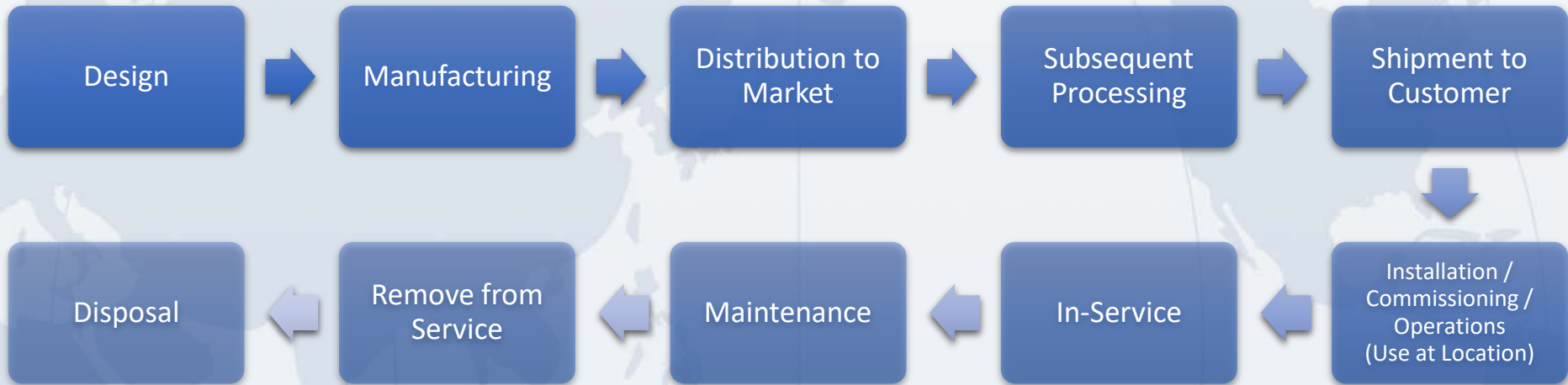
- ✓ Confidence that products and services meet **Design and Specified Requirements**, including their specified **lifecycle**.

What are design & specified requirements?

- Internal
 - Customer
 - Regulatory or statutory
 - Codes & standards
 - Industry-specified codes and standards
-
- ✓ Technical integrity may be further extended into subcategories to the extent necessary, for example:
 - Dimensional stability (e.g., calibration to ISO 17025)
 - Design input (comprehensive input containing all specified requirements)
 - Product realization equipment maintenance, maintaining product tolerances
 - Post-delivery, user manuals, maintenance requirements, product or service life cycle
 - Production processes and processes requiring validation

What is Technical Integrity?

Product / Service Lifecycle Phases



Topics Common to all phases:

- Transportation
- Interim Storage
- Health & Safety
- Drop Shipments
- Determination of Conformity
 - Monitoring, Measuring, Inspection, Test, Verification, and Validation
- Management of Change
- General Processes
 - Handling, Cleaning, Preservation, Storage, and Identification
- Leased Equipment



Why Technical Integrity?

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Technical Integrity is focused on Prevention

- TRAGEDY
 - Product or system failures
 - Catastrophic disaster (e.g., explosions, fires, pollution, contamination, spills to environment, death)
- LEGAL
 - Statutory, regulatory
 - Loss of product technical integrity
 - Conformance vs. compliance
 - Contractual
 - Nonproductive time
- SYSTEMIC
 - Customer dissatisfaction
 - Supply chain quality
 - Risk reduction



Technical Integrity Integration Into an Organization

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Technical integrity extends to all departments, for example engineering, sales and marketing, purchasing, quality, operations, field services.

- Ensure all departments understand how specified requirements are identified, through:
 - Clear definition of the organization's product or service
 - Incorporation of other specified requirements into its product or service and processes (i.e., customer, regulatory, industry)
- How each department communicates that as part of its input and output, for example:
 - Engineering through design input and output
 - Sales through clearly documenting customer requirements
 - Purchasing through maintaining technical requirement flow-down to the supply chain
 - Quality through verification points such as receiving inspection, participation in contract review meetings
 - Production through incorporating industry or design specified requirements from codes and/or standards
 - Field Service through installation, test, service and maintenance requirements



Technical Integrity Incorporation Into Internal Audits

Technical Integrity Incorporation Into Internal Audits

In auditing, Technical Integrity will include technical + quality requirements.

- Utilization of personnel competent in the areas being audited
- Supplement the audit with subject matter experts
- Specialized technical checklists could be developed, for example:
 - Design & Development, Contract Review, Purchasing, Inspection & Testing
 - Processes Requiring Validation:
 - Welding
 - Heat treating
 - Nondestructive examination
 - Plating
 - Coating
 - Outsourced Services
 - Calibration

Technical Integrity Incorporation Into Internal Audits

Nondestructive Examination Example

#	Topic	Requirement Specified Through	Via
1	QMS Requirements	Applicable QMS: 9001, Q1, Q2	Specified Standard
2	Personnel Competence	ASNT-TC-1A Qualification of NDT Personnel American Society for Nondestructive Testing	Spec 6A
3	Method: Magnetic Particle Inspection	ASTM E709 ASTM International Standard Guide for Magnetic Particle Testing	Spec 6A
4	Acceptance Criteria	Specified by API Product Specifications such as API Spec 6A, Specification for Wellhead and Tree Equipment	Spec 6A

Notes:

1. Pay attention to the interaction of external requirements that may have to be integrated into your processes.
2. In this example there are 3 different external documents that have been identified.
3. Determine how they have been integrated into your quality management system.

Technical Integrity Incorporation Into Internal Audits

Outsourced Services Example

#	Standard	Title
1	Standard 20D	Qualification of Nondestructive Examination Services
2	Standard 20G	Welding Services
3	Standard 20H	Heat Treatment Services – Batch Type Functions
4	Standard 20J	Qualification of Distributors of Metallic Materials
5	Standard 20L	Qualification of Polymeric Seal Manufacturers
6	Standard 20M	Qualification of Suppliers of Machining Services
7	Standard 20N	Heat Treatment Services – Continuous Line
8	Standard 20S	Qualification of Additively Manufactured Metallic Materials



Additional Topics for the Internal Audit Checklist

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What additional topics should our internal audit checklists include:

- ✓ Process to be audited
- ✓ Inputs/outputs
- ✓ Procedures, work instructions, forms
- ✓ Acceptance criteria
- ✓ Required equipment
- ✓ Calibration of inspection, measuring, testing, monitoring and detection equipment
- ✓ Qualification of personnel
- ✓ Use of specific methods, including identified operating parameters
- ✓ Identification of acceptance criteria
- ✓ Requirements for records
- ✓ Revalidation

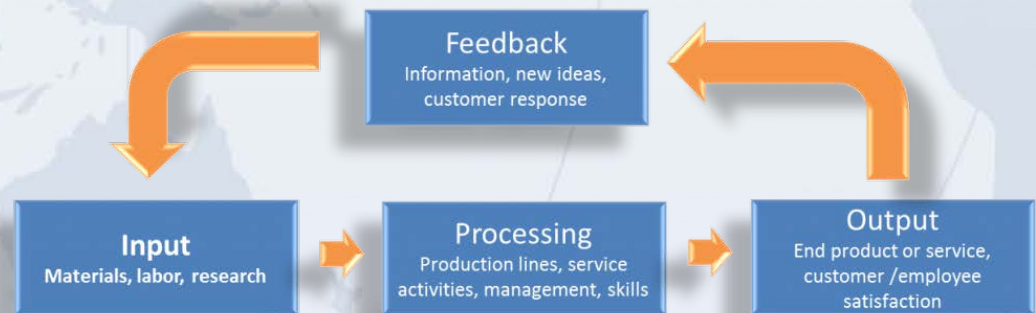


Visualizing Requirements

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How can I visualize all these requirements?

- High-level Mind Maps
- Matrices
- Topic-specific checklists
- Input/Output Diagrams





How Can My Organization Ensure Technical Integrity?

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Through specifying the following and maintaining consistency in all aspects of your quality management system.

