

Regulatory Authorities – Required Compliance Documentation

- EPA's Information Quality Guidelines
 - Promulgated under Public Law 106-554; H.R. 5658, Treasury and General Government Appropriations Act FY 2001
- EPA's Quality System Program
 - Promulgated under EPA Order 5360.1

Consensus Standards – Framework for Compliance Documentation

- - Quality Management Systems Requirements
- ANSI/ASQ E4
 - Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs
- OHSAS 18001
 - Occupational Health and Safety Assessment Series

Interoperability – Illustrations and Examples

- This presentation will illustrate and show examples of the interoperability of authorities with consensus standards, including –
 - How the ISO 9000 Series for Quality merges with EPA Quality System
 - How the ISO 14001 for Environmental Management Systems (EMS) merges with ISO 9000 QA Series and OHSAS 18001
 - How the ISO 9000 QA Series, ISO EMS 14001, and OHSAS 18001 support ANSI/ASQ Standards, Standard Methods, and Organizational SOPs

Interoperability - Benefits

- Organization-wide Implementation, Application, and Reporting
- Supports Deming's Plan, Do, Check, Act Lifecycle A Total Quality Management Principle
- Uniform and Complementary Documentation of Required Activities and Processes
- Demonstration of Organizational Diligence

Correlations - Defined

- Correlations Identify Points of Interoperability
- "Correlation" as Used in this Presentation is Defined as;
 - "A causal, complementary, parallel, or reciprocal relationship, especially a structural, functional, or qualitative correspondence between two comparable entities." (<u>The American Heritage® Dictionary of the English Language, Fourth Edition</u>

Step 1 – Identify Correlations in the *Nature* of the Activity

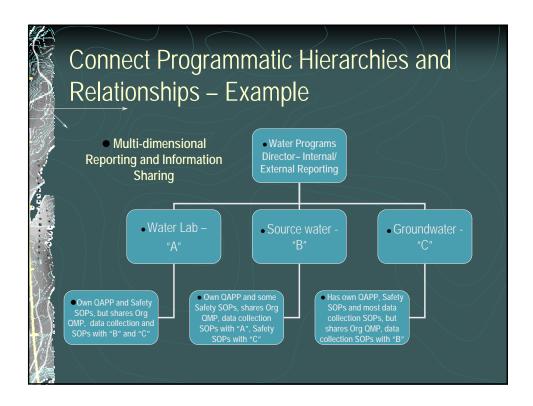
- Correlations in the *Nature* of the Activity Show Documentary Relationships, such as –
 - Compliance verification using;
 - Activity records, general and specific
 - Training certifications and documentation
 - Office, field and safety Standard Operating Procedures, and so forth

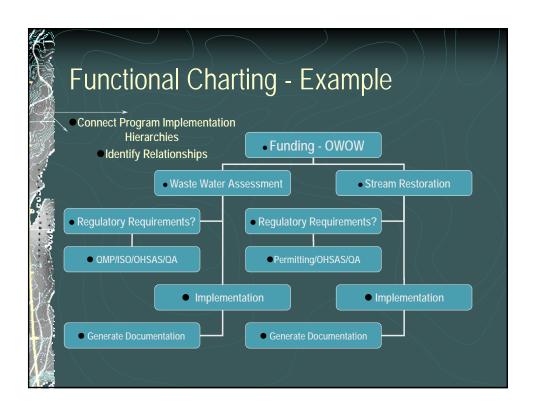
Step 2 – Identify Correlations in the **Scope** of the Activity

- Correlations in the Scope of the Activity Show Documentary Relationships, such as –
 - Organization-wide Implementation?
 - Departmental and/or Divisional?
 - Program or project related?
 - QAPP-specific?
 - Equipment based?

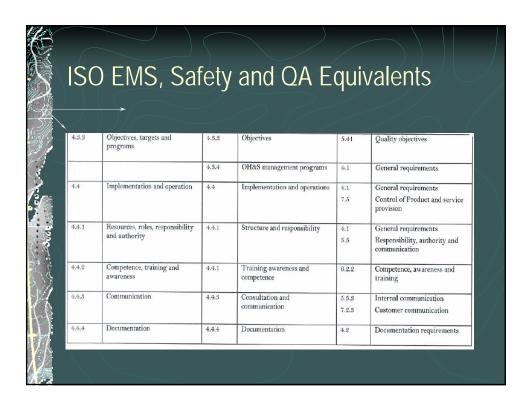
Step 3 – Information Management (IM): Functional Charting

- Reconciliation of the Organizational Chart with Programmatic Hierarchies
 - Who shares what documents?
- Charting Functional IM Needs
 - Maps "Information Bridges" that link or share information spatially across an organization – within programs, processes, and specialized areas

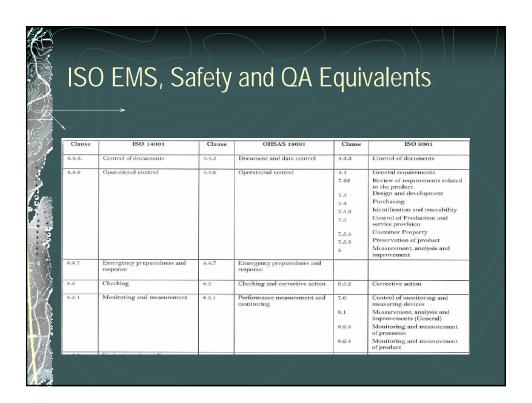


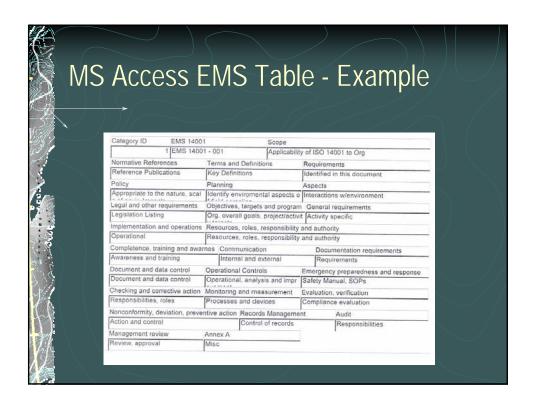


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Clause	ISO 14001	Clause	OHSAS 18001	Clause	ISO 9001		
1	Scope	1	Scope	1	Scope		
2	Normative Reference	2	Reference Publications	2	Normative Reference		
3	Definitions	3	Definitions	3	Terms and definitions		
4	Environmental management system requirements	+	OHSAS management system requirements	+	Quality management system		
4.1	General Requirements	4.1	General Requirements		General Requirements		
4.2	Environmental Policy	4.2	OH&S policy	5.3	Quality Policy		
4.3	Planning	4.3.	Planning	5.4	Planning		
4.3.1	Environmental aspects	4.3.1	Planning for hazard identification, risk assessment and risk control	5.4.2 7.1 7.3.1	Quality management system planning Planning of product realization Design and development planning		
4.3.2	Legal and other requirements	4.3.2	Legal and other requirements	7.2.1 c), d)	Determination of requirements related to product		



ISO	ISO EMS, Safety and QA Equivalents							
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4.5.2	Evaluation of compliance							
4.5.3	Nonconformity, corrective action and preventive action	4.5.2	Accidents, incidents, nonconformance and corrective and preventive action	8.3	Control of nonconforming product			
				8.5.2	Corrective action			
4.5.4	Control of records	4.5.3	Records and records management	8.5.3 4.2.4	Preventive action Control of records			
4.5.4	Internal audit	4.5.4	Audit	8.2.2	Internal audit			
4.6	Management review	4.6	Management review	5.6	Management review			
Annex B	Correspondence to ISO 9001	Annex A	Correspondence to ISO 14001, ISO 9001	Annex A	Correspondence between IS 14001 and ISO 9001			
Annex A	Guidance on the use of the specification		OHSAS 18002:2000 - OH&S management system - guidelines for the implementation of OHSAS 18001		ISO 9004:2000 – Quality management systems – Guidelines for performance improvements			





Increasing Primary Document Use and Reuse

- At a glance, each of these components use, and reuse, much of the same information, such as –
 - Program or Project Funding ID, Project Name or ID, Participant(s) ID, Research or Division-specific Activities, and so forth
 - Organizational QMP, EMS and associated QAPPs, Primary and Secondary Data Applications
 - SOPs (office, lab, field) and Safety SOPs

Increasing Primary Document Use and Reuse

- Primary Documents include
 - Programmatic Status Reports
 - Project Compliance Reports
 - Health and Safety Program Documents
 - Organizational Policy and Procedure Reviews or Approvals

The Importance of Information Management (IM)

- IM has Significant Organizational Value
- When Implemented, Data and Information are Validated Once, then Used and Reused with Confidence
- The Importance of IM is Identified When Correlations and IM Mapping are Combined, Providing the Framework for All IM Processes

The Total Quality Management (TQM) Value of IM Framework

- IM framework implements TQM across all documentation levels and supports
 - Records Management and Document Control
 - Documentation of Stipulated Activities
 - Organizational Information Sharing
 - Policy and Program Reporting

IM Incorporates the EPA Approved Plan, Do, Check, Act (PDCA) Lifecycle

- ♥ PDCA is found in all ISO-based formats, as well as EPA's Requirements for Quality Management Plans (QMPs) QA-R1 and Requirements for Quality Assurance Project Plans (QAPPs) QA-R2
- Meets EPA's PDCA Lifecycle A Structured Process for Activities and Continual Improvement

Merging IM, TQM and ISO Principles in a Database

- Relational Database Programs Support
 Unlimited IM and Documentation Benefits, such as
 - Functional Group Tables Allow Multiple Categories
 - Customized Reporting by Type

IM – An Administrative Science Supporting All Activities

"Enter once, use many": N. Wentworth, EPA QS
 Conference 2004 – Developed for Data,
 Applicable to Information

Thank You