

Omnex Approach to Integrated Management Systems

Omnex Methodology

Omnex has been implementing Management System integrating ISO 9001 and ISO 14001 for numerous organizations worldwide since the initial release of ISO 14001 in 1996. When OHSAS 18001 was subsequently released, Omnex began developing systems incorporating all three standards: OHSAS 18001, ISO 14001 and ISO 9001. (See “Juggling Multiple Standards Worldwide”, Quality Digest, 2005)

Integrating Around Business Processes

The key to integration is the understanding that Integration focuses on the business processes of the organization. As the organization’s top management adopts new standards, the organization does not fundamentally change its business purpose. The organization continues to perform its processes but performs them with high quality, environmental impact, social responsibility, corporate responsibility, and occupational health and safety standards incorporated within. Each standard imposes requirements that the processes have to meet.

When a company creates multiple, isolated documentation structures and hence multiple processes, it creates requirements which are inherently wasteful and inefficient. It adds layers of additional requirements to the way the organization operates. This is illustrated by the following figure reflecting the documentation levels of independent management systems.

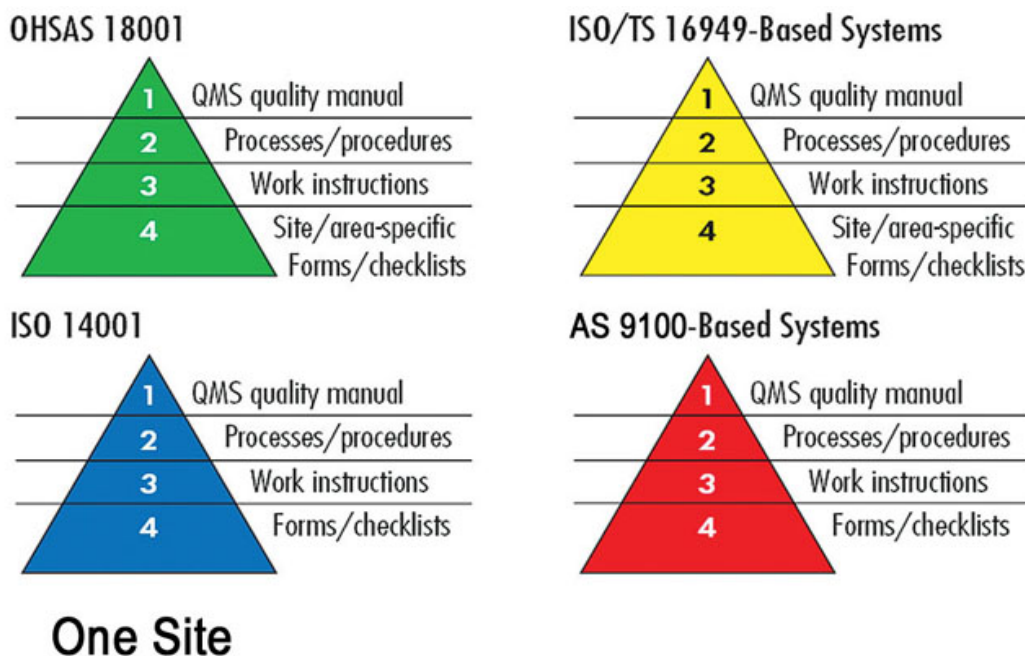


Fig. 1

Integrating Multiple, Multiple, Multiple Standards.....

There is no inherent difficulty in integrating multiple standards with different purposes. It requires the implementation team to address the larger scope and include additional **fundamental delivery processes** that may not have been included in the “Process Framework”. Many of the support processes called for in different standards, e.g. document control, records control, internal audit, management review, resource planning and provision, competency/training, etc. are, or should be, common processes with common documentation.

Omnex has successfully conducted large and small implementations focusing on integration of Quality (multiple quality standards), Environmental, Health and Safety, Food Safety, General Manufacturing Practices, Medical Devices, Semiconductor/Electronic Standards, Pre-Requisite Standards for Food, Codes of Conduct (multiple, but typically a combination of Environmental, Social and Quality/Business requirements), Corporate Responsibility, Social Responsibility, Supply Chain, Business Excellence (Malcolm Baldrige or European Quality Award), Sustainability, Green Manufacturing, and others. Figure 2, below, illustrates a documented system that has been integrated using Omnex methodology:

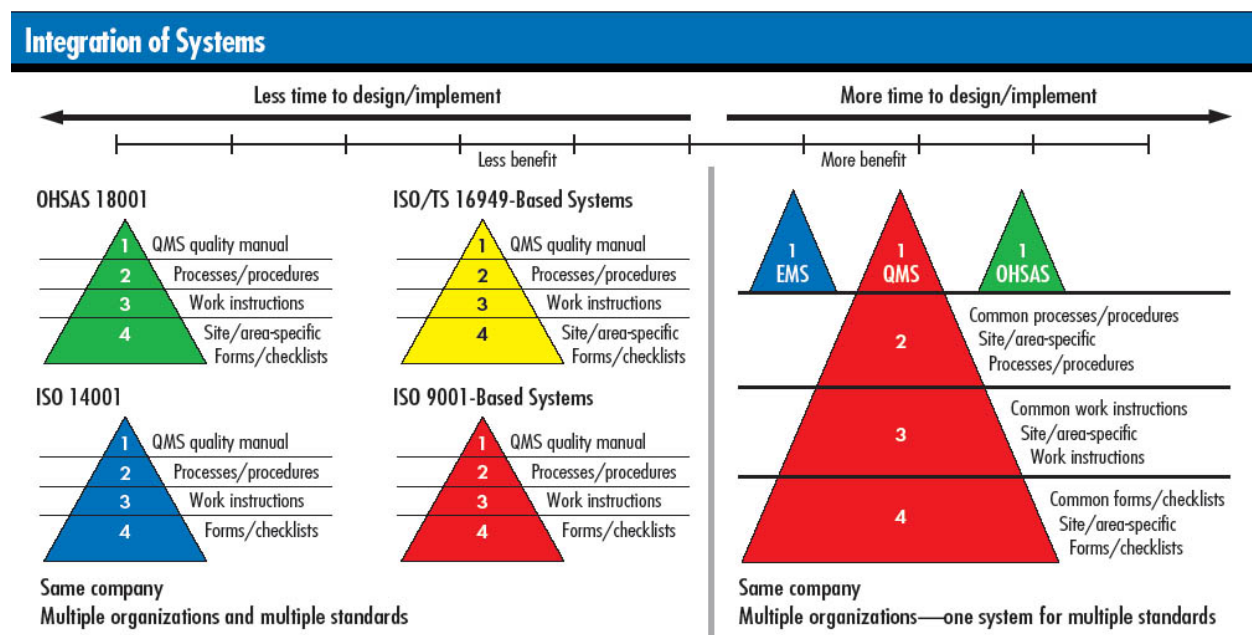
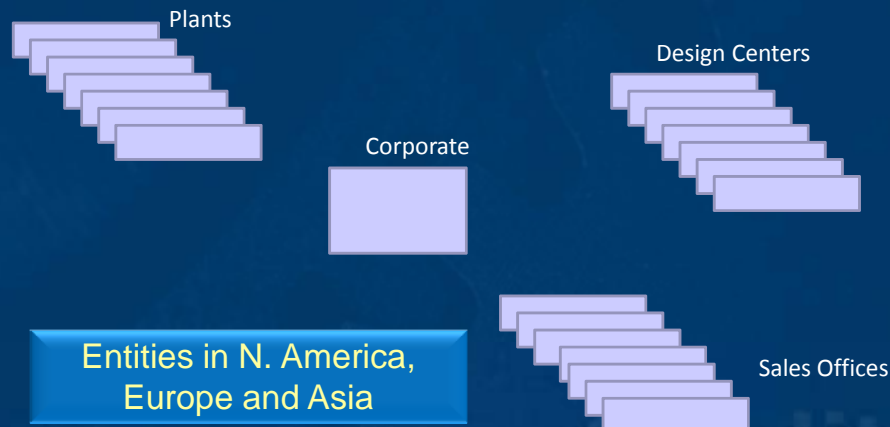


Fig. 2

Integration and Standardization

As important as systems integration is to a business, *process standardization* is of equal or greater importance. Standardization refers to having common business processes throughout all Organizational Entities. (See graphics, “Definition of Entities and the Entity Problem Statement” that Omnex has adopted, below.)

The Challenge of the Enterprise – Multi-Site, Multi-Language, and Multi-Cultural



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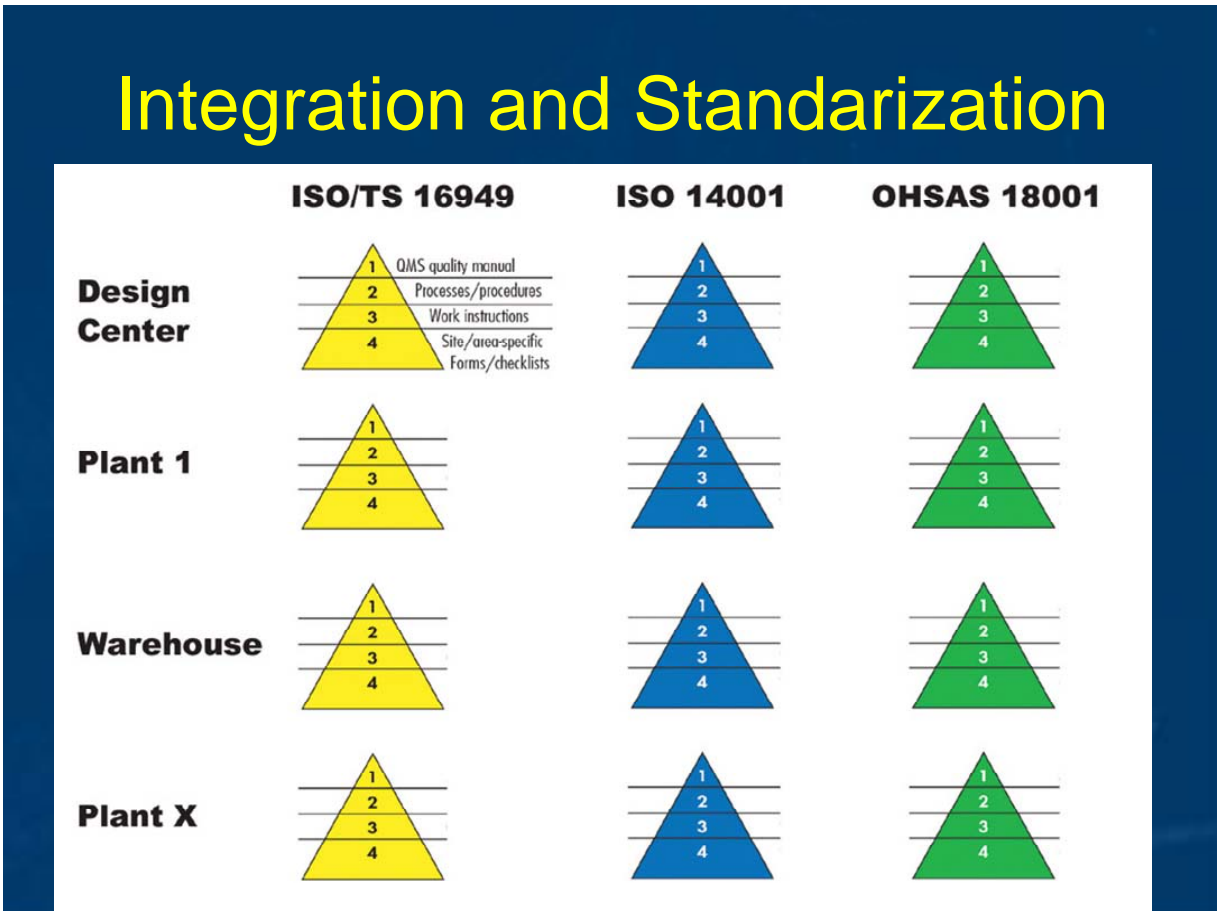
Enterprise Problem Statement

- Lack of consistency in methodology
- No central access for data
 - Outdated systems, non-complaint software
 - Systems Incompatibility – Integration needs
- Process Inefficiencies
 - little or no knowledge transfer or best practices between facilities
 - no common nomenclature for metrics
 - no integration in business processes or practices
- Lack of flexibility and functionality of present practices
- This leads to financial loss due to nonconforming products, processes, and non-value added activities.

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Integration creates processes incorporating requirements of multiple standards within one entity; standardization creates common integrated processes between and throughout entities. See figure below:



Omnex has developed an implementation methodology to help define and implement integrated and standardized processes across and between the various entities of a business. We specialize in facilitating **multi-entity, multi-disciplinary teams** to create integrated and standardized processes.

Typical Integration Steps that Omnex uses can be distilled into these six steps. (Note- these are not the detailed methodologies we use with specific customers, they were developed as generic, for public sharing.)

Steps to Integration

1. Determine standards that need to be followed – which standards?
2. Integrate the requirements of the standard – integration matrix
3. Determine Process and Process Map framework
4. Document the processes and implement them
5. Use web-based document management systems for integrated management systems
6. Implement Integrated risk management, Enterprise audits of Processes and Requirements

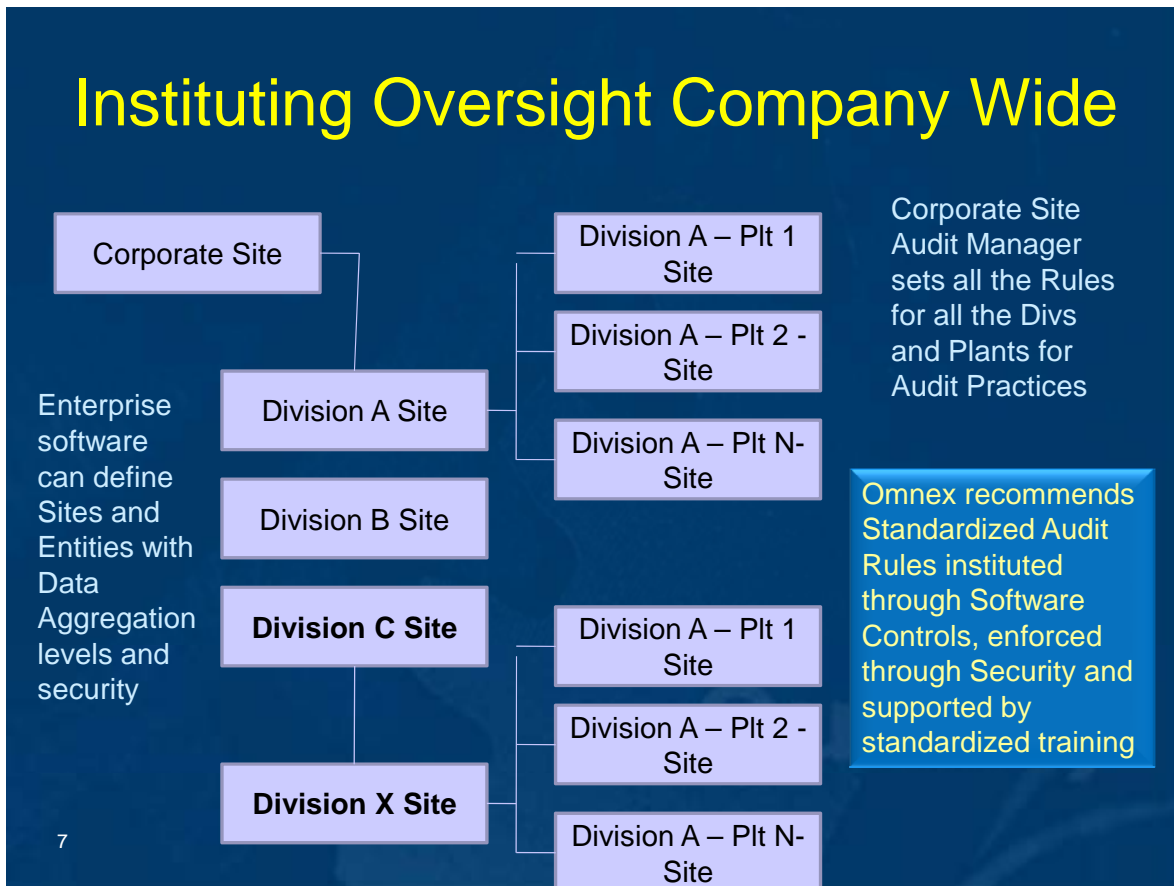
See Omnex Presentations including attachments titled – **IMS Webinar** (more information on Integration Steps), **Enterprise Audits and Document Management**

Enterprise Audits

In a global enterprise, **Enterprise Audits** may be either centralized, or decentralized in Regions, Divisions or even more discrete entities of the organization. Integration is successful only when the Facilitator understands the details of how integration takes place. In this case, integration is addressed through the use of Audit Programs – Quality, Environmental, Health and Safety, and others;(see above) and Audit Types – System, Process, Product, Supplier. Audits can be integrated around common audit formats, audit forms, processes, and checklists.

As Omnex believes, integration and standardization are neither “mantras” nor “slogans” suggesting a rote requirement that *everything* be integrated and standardized. There has to be a reason—value obtained—for processes or audit types to be integrated and/or standardized. For example, in the Omnex Enterprise Audit Scheme we provide for an integrated audit process and schedule, but allow for a choice between integrated or non-integrated audits. Integration may be based on the subject matter expertise and distinct needs of the various audit teams across the enterprise.

See attached PowerPoint on Enterprise Audits.



Enterprise Risk Management

Top Management adopts standards with the intention of reducing significant, unsustainable risks associated with various factors including Quality, Environmental Impact, Occupational Health and Safety, Food Safety, Social Responsibility, Corporate Responsibility, etc. Each of these areas of performance, and the associated standard, requires a Risk Assessment process to identify, monitor and reduce the risks represented by a variety of Business and Manufacturing Processes. This is illustrated in the graphic, below:

Business Risk – Core of Improvement

- Businesses face many types of risks including Quality, Environmental, Health/Safety, Social, and Financial

		Quality	Environmental	Health / Safety	Social	Financial
Severe Event	Threat to Viability of Organization	X	X	X	X	X
Severe Event	Severe Financial Loss	X	X	X	X	X
Severe Event	Jail Term for Top Management	X	X	X	X	X
Severe Event	Loss of Life	X	X	X	X	X
Severe Event / Moderate	Corporate Image Affected Negatively	X	X	X	X	X
Moderate to Low	Moderate/Low Financial Loss	X	X	X	X	X

Unless Risk Assessment Methodologies and Rating Schemes are integrated and standardized, organizations will have difficulty assessing relative risks posed by specific factors involving Quality, Environment, Occupational Health and Safety, Food, Social Responsibility, Corporate Responsibility, etc.

Equally important is the recognition that the enterprise employs **common global business, manufacturing and logistics processes** that share common risk factors as they are employed in the various regions and entities within an organization. And it is likely that each of these organizations are duplicating the risk assessments for each of the different schemes, be it Environment, Quality or Health and Safety, and, more importantly, *producing inconsistent results*. This is typically due to the variability of risk assessment numbers, values and criteria being applied by the different entities, in part because they are using different tables and “unique” risk assessment methodologies. (See graphic, below)

Standardizing Risk by Process Families

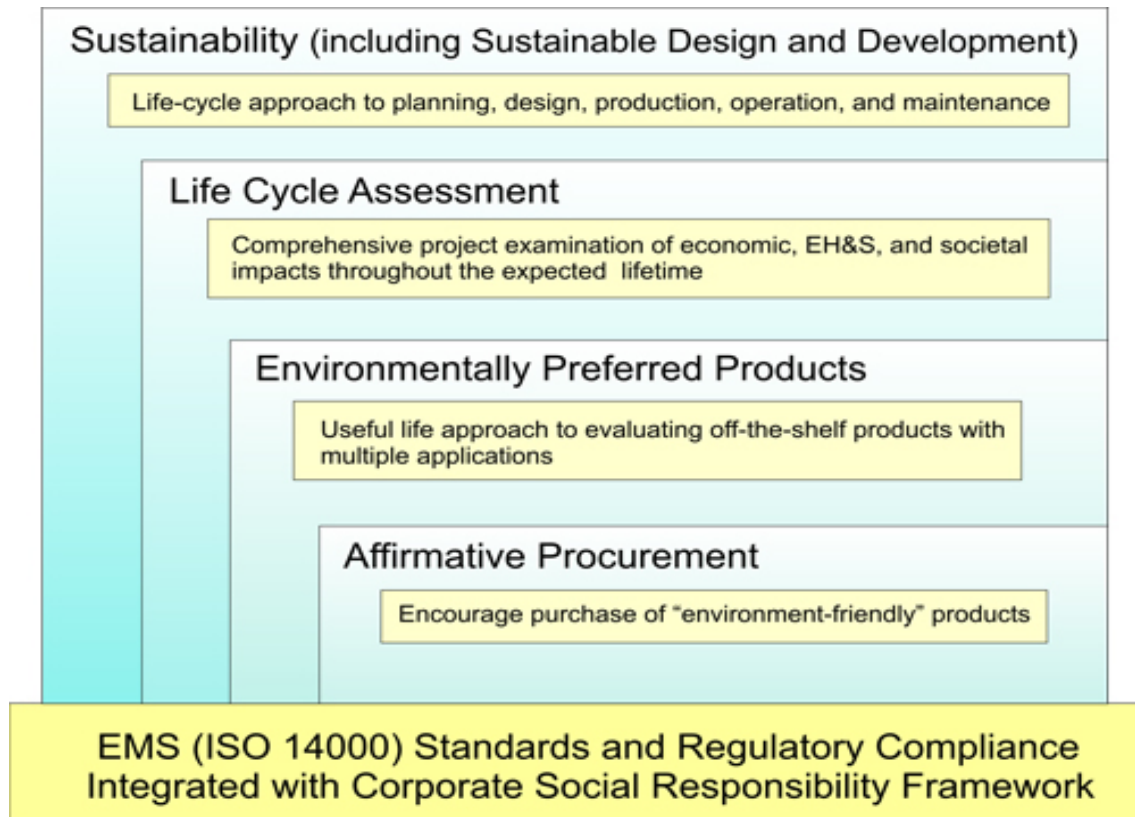
- Once we understand that there are “Global Process” types in the company, we can conduct risk analysis for an initial process for the Molding Machine and Laboratory and then use this risk assessment as the basis for other similar processes worldwide
- Organizations will use this as a starting point and if there is any disagreement on the risk rating, they can discuss this with the Global Champion

Process Families and Variations of Processes

- Sometimes the Process Family (e.g., Molding Machine) may have a newer version of Molding Machine
- How is risk calculated for the new machine?
 - We suggest a technique called Inheritance
 - In this technique, the Molding Machine is put into a Process Flow for a particular Department; for example, Green Tire
 - There can be a new sub family created – i.e., a child iteration of the same process– that can inherit all the features of the parent, except for what needs to be changed
- Of course this can be **BEST DONE USING WEB-BASED Integrated Risk Assessment Software**

Sustainability, Green, Social Responsibility and Corporate Responsibility

Omnex believes we are in the nascent stages of a larger movement towards Green, Sustainability, and Social/Corporate Codes of Conduct. We have conducted a review of the different standards and requirements in this arena and are employing the following methodology and Philosophy – <http://omnex.com/environmental/nextsteps.html>



Omnex integrates and builds on these requirements using the same methodologies we employ to integrate all the different standards. Again, all requirements integrate into the business processes of the organization as described above. Omnex can provide guidance in organizing and sustaining these movements within your organization.

Integrated Management Systems, Integrated Risk and Integrated Audits

Omnex is pleased to be a leading light on Enterprise Wide Integrated Management Systems that employ tools and methodologies to Integrate and Standardize Management Systems, Risk and Audits. In 2002, Omnex conducted a seminar for the American Society for Quality announcing the need for methodologies and Software for organizations that we called Enterprise wide Quality Management (EwQMS®) Systems. Omnex Systems coined the phrase "Enterprise Quality" for this genre of software. Since then, we have published numerous papers and moved the industry from EwQMS to "Enterprise wide Integrated Management Systems", Enterprise Audits and Enterprise Risk. (See webinar: "Juggling Multiple Standards and Multiple Risk Assessments: Too Many Standards? Reduce Complexity and Save Money!")

References Accompanying Proposal:

“Juggling Multiple Standards”, Quality Digest, June 2007

“Juggling Multiple Standards and Multiple Risk Assessments”—Webinar Presentation, Omnex, 2009

“Integrated Risk Management for Quality, Environmental, Health and Safety- Enterprise Risk Assessment”, Omnex Presentation, 2009

“Save Time and Money through Enterprise Audit Management”—Webinar Presentation, Omnex, 2009

Additional reference documents are available upon request.