

14A - OHSAS 18001:2007 Revision – What has changed?

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The OHSAS 18001:2007 revision includes clarification in the requirements, alignment with ISO9000:2001 and ISO 14001, more emphasis on various requirements and the folding in of additional requirements.

The Occupational Health and Safety Assessment Series, OHSAS 18000, was developed to help organizations control and minimize occupational health and safety risks. OHSAS 18001 focuses on the identification, elimination, and continual improvement of hazards and risks within the work environment. The OHSAS management system methodology is based on planning for hazard identification, risk assessment, and risk control. The OHSAS 18001 Occupational Health and Safety Management System (OHSMS) then incorporates' ISO management system elements to address these risks.

This presentation will provide a detail review of the OHSAS 18001:2007 revision, specifically addressing each occupational health and safety management system element, the linkage of elements, and OHSAS 18001:2007 revision documentation needs. Featuring the following OHSMS sections: "Policy", "Planning", "Implementation And Operation", "Checking", and Management Review". Attendees will gain an understanding of the changes in OHSAS 18001, the impact to their organization, and a methodology for updating OHSMS.

Outline:

- Introduction - OHSAS 18001 Background
 - o OHSAS 18001 System Layout
 - o OHSAS 18001 Overview

- What has Changed?
 - o OHSAS 18001:2007 Review
 - o How The Revision Effects You
 - o Similarities / Differences in OHSAS18001 / ISO14001 / ISO9001

- Next Steps
 - o Revision Planning
 - o Integration of ISO 14001 / ISO 90001

Presenter:

Paula Esty brings over 15 years of system management experience. She holds a Masters of Management degree from Cambridge College. Paula's expertise includes development, implementation, training, integration of day-to-day operations, and continuous improvement for ISO14001, OHSAS18001, TS16949, ISO 90000, and global electronic environmental product compliance.

14B - Outsourcing in the Medical Device Industry

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The purpose of this presentation is to provide an overview of outsourcing in the medical device industry, trends, benefits, risks, legal issues, regulatory issues, and quality issues. For the purposes of this presentation, this includes outsourcing activities that could be performed in-house but are sent to another organization.

The presentation will define what is outsourcing and what can outsourcing include, as well as the types of activities that are being outsourced ranging from manufacturing, design, regulatory, quality, human resources, clinical studies, sterilization, testing, calibration, etc.

The presentation will outline some of the fundamental reasons why processes are being outsourced. The main reasons why companies outsource processes to other companies is usually related to one of the following reasons:

1. Capacity / Resources – The company does not have the capacity or resources to perform the tasks and therefore needs outside assistance.
2. Expertise – The company does not have the expertise to perform the task and therefore needs to utilize an expert in that field.
3. Technology – The company does not have the technology to perform the task.
4. Efficiency / Cost Effectiveness – It may be more efficient to have an outside organization perform the process at a more efficient rate or time.

The benefits including economic, core competency, efficiency, resources will be reviewed. Additionally the risks of outsourcing including intellectual property issues, costs, efficiency, loss of control, liability, and lack of accountability will be reviewed.

Organizations must choose the right outsource partner not necessarily the cheapest one. Organizations should look for a good fit and develop a relationship with the outsource partner. This is not a typical supplier – customer relationship. These relationships have a lot more at stake and should be groomed and treated as a vital extension to your business.

Legal issues such as intellectual property, product liability, safety, and government compliance will be reviewed.

Regulatory issues such as FDA compliance, safety, quality system, labeling, distribution, process controls, validation, etc will be reviewed.

A review of common mistakes made when outsourcing and how to avoid those mistakes. Actions including the following can facilitate outsourcing:

1. Planning – outlining how the outsource process will be controlled, monitored, measured, and implemented.
2. Communication – outlining communication channels, points of contacts, and methods for communication to ensure on-going and consistent communication throughout the business relationship.
3. Due Diligence – A thorough due diligence of the potential outsource partner to ensure that the organization has the experience, expertise, capabilities, and compliance, as well as good references.
4. Audit / Site Visit – A site visit to verify that the company has the controls and capabilities in place to meet requirements. This may include technical evaluations, quality system audits, regulatory compliance audits, and business review.
5. Risk Management – Identify risks with the project and outsourced relationship and how those risks will be eliminated or mitigated.
6. Written Agreement / Contract – Have a thorough comprehensive written agreement outlining responsibilities, deliverables, expectations, phases, measures for success, and objectives to ensure both parties understand the expectations.

Lastly, the presentation will include a review of international outsourcing and the unique challenges when outsourcing to foreign countries.

Presenter:

Joseph Azary has over 17 years in the medical device / healthcare products industry. He has a bachelors degree in Biological Sciences from the University of Connecticut and a Masters Degree in Business Administration (MBA) with a concentration in Public Health from Sacred Heart University. Joseph is an ASQ Certified Quality Auditor (CQA), Regulatory Affairs Certified (RAC) and has completed and passed the Lead Assessor Training Course.

Joseph has been employed by U.S. Surgical Corporation, Johnson & Johnson, and Fuji Photo Film (medical division) in various regulatory and quality positions. Responsibilities in these jobs ranged from quality system development, internal and supplier auditing, ISO certification, recall coordination, customer complaint handling, adverse event reporting, environmental, health & safety compliance, FDA compliance and submissions, and international regulatory compliance.

Joseph established Azary Technologies LLC in 1999 to provide regulatory and quality consulting services to the medical device industry. Joseph has worked with over 130 companies ranging from Fortune 500 companies to small start up companies. Joseph has experience with all types of medical devices ranging from cardiovascular, neurological, sterile disposables, surgical instruments, radiology and x-ray, PACS systems and software, electrosurgical equipment, endoscopes, wound dressings, gynecological devices, physical therapy devices and wheelchairs, orthopedic implants, in-vitro diagnostic, combination devices, pediatric, ultrasound, and a variety of medical devices.

Joseph has worked with companies manufacturing electronics, plastic molding, metal machine, assembly, chemical mixing, and clean room assembly.

Azary Technologies provides services ranging from Quality System Development (ISO 13485, FDA QSR), Regulatory Compliance, Internal and Supplier Auditing, Training, FDA submissions including 510k, FDA Compliance including labeling, registration, listing, recalls, and MDR reporting, U.S. Agent services, and international regulatory compliance including CE marking (European MDD) and Canadian Medical Device Regulations.

14C - Risk Management: Essential in Today's Global Economy

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Purpose: To provide an understanding of the risks facing organizations today and provide tools for managing those risks

The global economy has provided organizations with many opportunities that didn't exist even ten years ago. But it also presents organizations with many risks because of the flattening of the Earth via the internet and extensive outsourcing to countries such as China, Mexico and other nations. The designers of the COSO guidance commonly used for Sarbanes-Oxley Law (SOX) compliance recognized the importance of risk by including risk assessment as one element of the system of internal control.

There are four types of risk that worry an organization. Strategic risk is concerned with the inability to achieve high level goals. Operations risk concentrates on factors that prevent the efficient use of resources. Compliance risk affects the ability to comply with legal and regulatory requirements. Organizational risk is based on the organization's structure and is found on two levels, the entity level and the activity level

In the next part of the presentation I describe a specific risk analysis methodology. First, the organization determines its risk appetite and risk tolerance so that all members of the organization can understand the risk philosophy. Once this is decided, there are tools to determine the risk level and manage the identified risks. One key tool for managing risk is an organization's set of financial controls. These are especially important for compliance to SOX. Compliance includes financial controls at the entity and activity levels. The presentation will close with a discussion of controls from a top down, risk based approach defined in the new SOX auditing standard.

Presenter:

Dr. Sandford Liebesman had over 35 years experience in quality at Bell Laboratories, Lucent Technologies, Bellcore (Telcordia) and KEMA Registered Quality. He is an ISO 9000 subject matter expert and is author of the books *TL 9000, Release 3.0: A Guide to Measuring Excellence in Telecommunications, 2nd Edition* and *Using ISO 9000 to Improve Business Processes*.

Dr. Liebesman is a member of ISO Technical Committee 176 and the ANSI Z-1 Committee on Quality Assurance, is certified by the RABQSA International as an ISO 9000 and TL 9000 Lead Auditor and has performed over 95 ISO 9000 and TL 9000 audits at Lucent and for KEMA Registered Quality. He has presented seminars and published articles on QMS/EMS support of Sarbanes-Oxley Compliance and led the team that developed the 2005 and 2006 ASQ Sarbanes-Oxley conferences. Dr. Liebesman has an engineering degree from the United States Naval Academy and MSEE and Ph.D. (Operations Research) degrees from New York University. He taught statistics, quality control, quality management and operations research at Rutgers University. He is Chair-Elect of the ASQ Electronics and Communications Division and was recently elected as a Fellow of ASQ.

14D - Emerging Aviation Safety Management Systems – Adaptable to Healthcare?

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Estimates of deaths from preventable medical errors range from 100,000 to 225,000 annually, according to various authoritative sources. This equates to 250 – 550 Boeing 747-300 airliner catastrophic accidents annually. Air travel in the United States is the safest in the world, and even at its current low rate of commercial aviation fatalities which is much lower than the error rate in the healthcare industry, the intent is to reduce fatalities even further through a change in approach. Aviation has contributed methods to improve healthcare safety such as Crew Resource Management. Recent developments in aviation system safety could offer additional methods to reduce medical errors.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) publishes National Patient Safety Goals (NPSGs) tailored to specific healthcare organizations (Assisted Living, Home Care, Hospital, etc.) and NPSGs are updated annually to reflect goal changes. Similarly, the United States aviation industry seeks to reduce commercial aviation accidents and fatalities. The FAA's newest metric reports 8.8828 fatalities per 100 million passengers in 2007 – with the goal of 4.44.14 by 2025, a 50% reduction from an already low rate. Key aviation safety management system aspects which may be considered for healthcare are described.

Adopt a standard that defines requirements, is system/process based and risk focused: The FAA and the International Civil Aviation Organization (ICAO) have initiatives to bring safety into the daily management operational process to provide sound management of safety. This aviation innovation is best termed “Safety Management Systems” – which is a transition from inspection to risk based process management. Healthcare organizations follow patient safety goals set by JCAHO, goals are sets at the impact level.

Link specific operating requirements to accepted quality and risk management methods: While ISO 9001:2000 is generic and meant to be applied to almost any organization, its adoption by healthcare organizations in the United States has been minimal. Efforts by ASQ and the Automotive Industry Action Group (AIAG) since 1998 have resulted in the ISO International Workshop Agreement known - IWA-1 – “Quality Management Systems – Guidelines for process improvements in health service organizations” – to address healthcare costs in the automobile industry. JCAHO NPSGs provide specific operational guidance on safety program goals. A safety management system approach could be the means of linkage.

Target resources on high risk areas – those with high likelihood of occurrence/impact: The current FAA-promoted Safety Management System is ISO9001:2000-based, yet offers advantages regarding risk identification, including the integration of safety risk management and quality assurance processes. Safety risk management includes systems and task analysis, hazard identification, risk analysis and assessment, severity and likelihood criteria, risk acceptance procedures, causal analysis, and risk control. In healthcare, for example, medication errors are both high likelihood of occurrence and high impact.

Apply quality management methods to manage risk in a systems safety context: Couple safety risk management activities with quality activities such as internal audit, internal evaluation, external audits, analysis and corrective action and follow-up to ensure safety management system effectiveness. Implement a “system of systems” approach.

Apply Risk Management Methods to Translate Risk into Bottom-Line Impact: Include techniques to identify factors such as risk tolerance, probability of detection of risk events, operational risk factors at the process/system level, and calculation of costs of unmitigated risks.

This presentation suggests that healthcare may benefit from adopting concepts being applied in the aviation industry and that some concepts might be complementary to current healthcare

quality initiatives. These include explicit use of a quality management approach to controlling risk and management of requirements associated with safety risk. For organizations to remain financially viable, functions involved in delivery of healthcare services must be aligned with those assuring safety, with financial impact of risks emphasized. Healthcare cannot afford not to address safety, quality and business performance from a systems perspective, especially since CMS (Medicare/Medicaid) no longer pays for medical errors.

Presenters:

James M. Toney Jr. Consultant/Project Manager ICF International. Jim Toney is currently a consultant supporting a number of Federal Aviation Administration clients including the Systems Approach to Safety Oversight program. He has been involved with quality and business performance improvement for over 20 years, primarily in strategic planning, program evaluation, business process engineering and performance measurement. Assignments included quality improvement for the Road Home Program to rebuild after Hurricane Katrina, program support to the NASDAQ stock market, and teaching customer service management and quality courses at Marymount University. Jim has a BS in business from Jacksonville State University and an MA in Psychology from Catholic University. He is a member of ASQ, the Project Management Institute, the Virginia Association for Healthcare Quality, and the National Capital Healthcare Executives.

Examples of previous speaking events include: 2006 - Co-developer/facilitator of Baldrige workshop for Rockingham Memorial Hospital, Harrisonburg, VA 1999 - Taught 3 day Performance Measurement course through the U.S. Department of Agriculture, Graduate School, March 1999 - Taught two 3 day Strategic Planning courses through the U.S. Department of Agriculture, Graduate School, January and February 1998 - Taught 2 day course on Balanced Score Card for Teams, through the U.S. Department of Agriculture, Graduate School, November 1993 - Presented "Quality Consulting for Cost Conscious Companies", World Quality Congress-European Organization for Quality '93, Helsinki, Finland, June 1992 - Co-author and presenter of "Community Centers of Excellence: A Practical Model" paper to the 46th ASQC Annual Quality Congress, Nashville, Tennessee, May 1992.

He is also a Baldrige Examiner for the US Senate Productivity and Quality Award, Commonwealth of Virginia, and a Baldrige Examiner for Veterans Affairs (VA) Carey Quality Award. He is an ASQ Certified Quality Auditor, Six Sigma Black Belt and trained as an ISO 9001:2000 Lead Auditor.

Dr. Sandor-Scoma is currently Clinical Administrative Director at INOVA Mt. Vernon Hospital. She has been involved in consulting and complementary assignments leading improvements in effectiveness, efficiency and quality in healthcare. Previous work includes Physician/Consultant Specialist in Healthcare, Department of Health, Institute of Health Services Management, Bucharest, Romania (RO); Healthcare Consultant, United States Agency for International Development, Bucharest, RO; UNICEF, and World Bank. She has a Masters Degree, Health Services Management and Leadership, George Washington University, a Nursing Degree, Medical College, Arges. Romania, is an Accredited Medical Management Trainer, University of Medicine and Pharmacy, Bucharest, Romania, a Medical Degree, University of Medicine and Pharmacy, Targu Mures, Romania.

Examples of previous speaking events include: 2006 - Co-developer/facilitator of Baldrige workshop for Rockingham Memorial Hospital, Harrisonburg, VA Taught Postgraduate quality improvement course to 100 physicians, nurses and hospital directors to enable long-term sustained change in Romania.

She is also a Baldrige Examiner for the US Senate Productivity and Quality Award, Commonwealth of Virginia, and a Baldrige Examiner for Veterans Affairs (VA) Carey Quality Award.

14E - Improving ISO 13485 Management System

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ISO 13485 is an international standard, recognized throughout the world for establishing a **business management system** specific to the medical device industry. Borrowing the structure of ISO 9001:2000, ISO 13485 is applicable to organizations that manufacture private label medical devices, in vitro diagnostic medical devices, and medical components.

Created by the International Organization for Standardization, ISO 13485:2003 is based on eight quality management principles: **customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, fact based decision-making and mutually beneficial supplier relationships**. When fully adopted, these principles have been **proven to enhance organizational performance**.

QMS Benefits of Registration to ISO 13485:2003

- Provides international recognition for US manufacturers in compliance with the FDA Quality System Regulations (21 CFR 820, Oct. 7, 1996).
- Enables your organization to become more cost-effective.
- Improves internal communications, efficiency and resilience to change.
- Improves product and process quality and provides a basis for meeting regulatory requirements.
- Requires your organization to monitor and improve key business and customer satisfaction measures.
- Certification to ISO 13485 satisfies a significant portion of the EU Directive requirements for marketing medical devices in Europe.

This presentation will include “world-class” implementation techniques to ensure maximum effectiveness towards meeting product and regulatory requirements.

Presenter:

Angelo Scangas has an MBA, a Master's degree in Manufacturing Engineering and Bachelor's degree in Chemical Engineering. He is certified in lean manufacturing and quality management. Angelo specializes in business/quality systems, lean manufacturing, engineering management as well as product development and process improvement. Course participants will find it easy to learn as Angelo shares his practical knowledge and experience. Angelo has led clients to ISO 13485, ISO 9000:2000, ISO 14000, TS 16949 and Lean Sigma certifications. Angelo is a member of the American Society of Quality and AIAG. He is a Certified AIAG, IAQB, RAB-Lead Auditor.