

Overcoming Challenges

The Evolution of System Verification Assessments



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Audit ... Auditus?

AUDIT ...

CONTROLE ...

EXAMINE ...

BILANZ ...

AUDITORIA ...

☐ ☐ ...

☐ ☐ ☐ ☐ ☐ ☐ ...

ПРОВЕРКА ...

VERIFICA ...

Trust, but verify.

Evolution of Audit as a Profession

- *Auditus*: “Hear-say... Heard!”
An ancient Roman practice of “hearing of the accounts” –
Objective: fraud detection
- In the 1800’s and early 1900’s –
Financial auditing practice focus on representation verification
- Today – Financial:
 - National Regulations
 - GAAP / Regional Financial Reporting Rules
 - SEC / Sarbane-Oxley Act of 2002 (US)Quality / Safety:
 - Canadian Medical Device Regulations
 - US FDA Quality System Regulations
 - International StandardsEnvironmental / Occupational Health & Safety:
 - National and Regional Regulations
 - International Standards

Management System Standards

➤ **British Standard 5750:1979**

First national requirements for a quality management system
→ ISO 9000 series standards

➤ **British Standard 7750:1992**

First national requirements for an environmental management system
→ ISO 14000 series standards.

➤ **ISO 9001 / AS 9100 / TS 16949 / TL 9000**

Other sector-specific quality management systems were developed and proliferated globally over the past 15 years.

➤ **ISO 13485:2003**

Canadian Medical Device Conformity Assessment System and the Canadian Medical Device Regulations

➤ **ISO 14064:2006**

International standard related to greenhouse gas emission verification

➤ **ISO/PAS 99:2006**

First specification that defines requirements for an integrated management system

Government of Canada on EMS

- 1990 – Publication of Government of Canada's *Green Plan*
- 1995 – Amendment to Auditor General Act establishing the Commissioner of the Environment and Sustainable Development (CESD) and requiring preparation and maintenance of a Sustainable Development Strategy.
- 1997 – The first Sustainable Development Strategies are tabled in Parliament.
- 1999 – The Sustainable Development in Government Operations initiative launched... CESD stated the ISO 14001 standard will be a benchmark used to evaluate federal departments / agencies' environmental management systems.
- 2003 – First report under the SDGO initiative, *Greening the Federal House* indicating that further stimulation needed in the development of Environmental Management Systems.
- 2006 – Report of the CESD / Office of Auditor General issued focusing on challenge of climate change.

US Regulatory Stance on EMS

“...EPA will encourage the use of recognized environmental management frameworks, such as the ISO 14001 Standard, as a basis for designing and implementing EMSs that aim to achieve outcomes aligned with the nation’s environmental policy goals and the principles of this Position Statement...”

Stephen L. Johnson
Administrator, US EPA
December 13, 2005

“...the Office of Enforcement and Compliance Assurance (OECA) is reiterating our support for the use of Environmental Management Systems (EMSs) by all sizes and types of organizations, whether they are in compliance or determined to be in violation. We will promote EMSs as a potentially valuable tool for maintaining compliance, achieving beyond compliance results, and minimizing environmental impacts in non-regulated areas. ...”

John Peter Suarez
Assistant Administrator, US EPA
June 12, 2003

Management System Auditing

Principles of System Auditing

- **Ethical Conduct** –
the foundation of professionalism
- **Fair Presentation** –
the obligation to report truthfully and accurately
- **Due Professional Care** –
the application of diligence and judgment in auditing
- **Independence** –
the basis for the impartiality of the audit and objectivity of the audit conclusion
- **Evidence-based approach** –
the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

EN ISO 19011:2002

Environmental Management System Auditing

- Similar to regulatory-centric medical device QMS, what sets ISO 14001 EMS auditing apart from other QMS auditing is its implicit regulatory compliance related components of system management.
- The challenge is to what extent and performance standard must an EMS be held to; and the depth and breadth of an EMS audit needs to be in order to assure audit independence and certification process creditability while enhancing business values of the management system.

Environmental Management System Auditing

Let's consider assessment of the following requirements:

- Management's commitment to:
 - continual improvement,
 - prevention of pollution,
 - comply with applicable legal requirements and with other requirements to which the organization subscribes which relate to its environmental aspects.
- Determination of aspects that have or can have significant impacts on the environment.
- Determination of how legal and other requirements apply to environmental aspects.
- Review the organization's environmental management system ... to ensure its continuing suitability, adequacy and effectiveness.

Environmental Management System Auditing

- When assessing effectiveness of an EMS, one must consider the intent of the standard requirement in its entirety.
- Design audit plan, select audit trails, and collect objective evidence not only to verify conformance, but also, collectively, to form a basis for process performance and system effectiveness evaluation.
- Explore, appreciate, and challenge operational implementation and management decisions as appropriate to assess commitment to comply and prevention of pollution.

Environmental Management System Auditing

- Performance expectations for independent EMS certification audits (ANAB, November 2005):

“For clients certified for EMS, the expected outputs should be trends of improving environmental performance, legal compliance, pollution prevention, and continual improvement...”

Further,

“... CBs need to take appropriate action that leads to a consistent approach toward determining meaningful environmental performance improvement of a certified organization...”

Environmental Management System Auditing – Overcoming Challenges

- Keeping pace with national and international standard development, guidance, or clarifications as well as any pertinent regulatory promulgation and be cognizant of regional environmental issues:
 - ***ISO/IAF – ISO Management System Alert***
 - ***SCC – Management Systems Bulletins; Standards Alert!***
 - ***ANAB – “Heads Up”***
 - ***Environment Canada***
 - ***Canada Gazette Part I – Notices and Proposed Regulations***
 - ***Alberta Environment’s Newsletter: ENViews***
- Continuing professional development and certification
- Technical conferences and networking

Environmental Management System Auditing – Outlook & Opportunities

- Evolution from system conformance verification
 - ➔ system performance validation
- Assessment of system effectiveness
 - ➔ functional alignment with business goals
- Metrics, outcomes, and responding actions
 - ➔ manifestation of management commitment

Environmental Management System Auditing – Outlook & Opportunities

- Implication in public opinion / regulatory policy similar to that in financial auditing
 - ➔ internal-external stakeholder considerations
- Critical process control
 - ➔ assurance of independence and creditability
- Outlook and opportunities
 - ➔ integration and globalization

Questions, Comments, & Discussion

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Thank You for Your Participation!