



# Preparing For The Changes



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- ISO 9001 and ISO 14001 were approved on September 15, 2015
- Three years to upgrade to the new standard(s)
- No Certification Certificates can state the certification period for ISO 9001:2008 or ISO 14001:2004 later than September 15, 2018



- The changes that were primarily driven by Annex SL are:
  - Structure
  - Documented Information
  - Risk
  - Objectives
- Other Changes



- There are two general camps concerning the standard:
  - Major Change-you need to rewrite everything and implement a risk management program
  - Not so major change- a renumbering of the standard, a few new concepts which require action with the most important issue is risk



- This presentation will review the major changes or logic to
  - ISO 9001
  - ISO 14001
  - Logic for new RIOS
  - Logic for OSHAS 18001 or ISO 45001
- The presentation will review the major changes or logic for both camps
- You determine what and how you want to implement

# Structure and Documentation



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- Annex SL-Replaces the ISO Guide 83 for structure of ISO Management Standards
- Annex SL Appendix 2 provides requirements for:
  - High Level Structure
  - Identical Core Text
  - Common Terms and Core Definition





## Annex SL Structure Changes

- Now have 10 Clauses versus previous structure
- All ISO Management Structures has the same clauses and main sub clause structure
- The content of the clause/sub clause includes requirements that the standard is required to meet
- Although the specific words vary between ISO 9001 and ISO 14001 the implemented results are about the same
- RIOS has committed to the Annex SL Structure, however the standard is more specific for recyclers, thus in general the controls are similar
- OHSAS 18001 or soon to be ISO 45001 will have similar requirements because of the Annex SL



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- Change Document Identification to address the new numbering Structure?
- Yes, it makes implementation of the requirements easier with the Standard(s) because the numbering is the same
- No, my documents identification does not have to align with the Standard(s)-it does not matter what I call the documents



- Documented Information
- Definition: Information required to be controlled and maintained by an organization (3.1.4) and the medium on which it is contained
  - Note 1: Documented information can be in any format and media, and from any source.
- Documented Information
  - “Maintain” in place of “Procedures”
  - “Retain” in place of “Records”





- 7.5 Documented information (ISO 9001)
- 7.5.1 General

The organization's quality management system shall include:

- a) documented information required by this International Standard;
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.





- ISO 9001 Required Documented Information to be Maintained (6):
  - 4.3 Determining the scope of the EMS
  - 4.4 QMS and its processes
  - 5.2 Quality Policy
  - 6.2 Quality Objective and Planning to achieve them
  - 8.1 Operational planning and control
  - 8.5.1 Control of production and service provisions





- **ISO 14001 Documented Information to be Maintained (8):**
  - 4.3 Determining the scope of the QMS
  - 5.2 Environmental Policy
  - 6.1 Actions to address risk and opportunities
    - 6.1.2 Environmental aspects
    - 6.1.3 Compliance Obligations
      - 6.2.1 Environmental Objectives
  - 8.1 Operational planning and control
  - Emergency preparedness and response





## Documented Information vs Objective Evidence

- Organizations may be able to demonstrate conformity without the need for extensive documented information
- To claim conformity with ISO 9001:2015, the organization has to be able to provide objective evidence of the effectiveness of its processes and its quality management system. Clause 3.8.3 of ISO 9000:2015 defines “objective evidence” as “data supporting the existence or verity of something” and notes that “objective evidence may be obtained through observation, measurement, test, or other means.”





## Documented Information vs Objective Evidence

- Objective evidence does not necessarily depend on the existence of documented information, except where specifically mentioned in ISO 9001:2015. In some cases, (for example, in clause 8.1 (e) Operational planning and control, it is up to the organization to determine what documented information is necessary in order to provide this objective evidence.



## Documented Information vs Objective Evidence

- Where the organization has no specific documented information for a particular activity, and this is not required by the standard, it is acceptable for this activity to be conducted using as a basis the relevant clause of ISO 9001:2015. In these situations, both internal and external audits may use the text of ISO 9001:2015 for conformity assessment purposes.







## Corporate Controls vs Documented Information

- Because of Corporate controls normally there more procedures than the previous versions of the standards required
- Corporate controls facilitates more procedures or controls
- The minimum documentation information and controls will be a small percentage of certified companies



Can we perform Document Reviews for ISO 9001:2015 and ISO 14001:2015?

How will the Orion Auditors know what to audit?

- ISO 9001:2015 Footprint
- ISO 14001:2015 Footprint



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- **ISO 9001 Documented Information to be Retained (21):**
  - 4.4 QMS and its processes
  - 7.1.5 Monitoring and measuring resources
  - 7.2 Competence
  - 7.5.3 Control of documented information
  - 8.1 Operational Planning and Control
  - 8.2.3 Review of requirements related to products and services
  - 8.3.2 Design and development planning
  - 8.3.3 Design and development input
  - 8.3.4 Design and development controls
  - 8.3.5 Design and development outputs
  - 8.3.6 Design and development changes
  - 8.4.1 Control of externally provided processes, products and services



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- ISO 9001 Documented Information to be Retained Cont.:
  - 8.5.1 Control of production and service provisions
  - 8.5.2 Identification and traceability
  - 8.5.6 Control of changes
  - 8.6 Release of products and services
  - 8.7 Control of nonconforming outputs
  - 9.1.1 Monitoring, measurement, analysis and evaluations, General
  - 9.2 Internal Audits
  - 9.3.3 Management Review Outputs
  - 10.2 Nonconformity and corrective actions



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- **ISO 14001 Documented Information to be Retained (7):**
  - 7.2 Competence
  - 7.4.1 Communication
  - 9.1.1 Monitoring measurement, analysis and evaluation
  - 9.1.2 Evaluation of compliance
  - 9.2 Internal Audit
  - 9.3 Management Review
  - 10.2 Nonconformity and corrective action





## Corporate Controls vs ISO Records Requirement

- Normally corporate controls will have more records than the ISO Standards due to:
  - Product liability
  - What you supplied
  - Environmental records required by State & Federal Agencies
  - Corporate Measurements
  - Etc.





- 7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.





- 7.5.3 Control of documented information (text different between standards)
- 7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:
  - a) it is available and suitable for use, where and when it is needed;
  - b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).







7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

Documented information retained as evidence of conformity shall be protected from unintended alterations.



## The Issues of this change:

- The control of Documented Information can be misused
  - Example: control the document by having a “sticky” on the wall
- However most corporate controls will be more strict than the standards



# Risk What Does it Mean?



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## Risk Definition: effect of uncertainty

- Note 1: An effect is a deviation from the expected positive or negative.
- Note 2: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- ISO 9000, Note 5: The word “risk” is sometimes used when there is a possibility of only negative consequences.



- Note 3: Risk is often characterized by reference to potential “events” and “consequences” or a combination of these.
- Note 4: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” of occurrence.
- ISO 14001 uses consequences instead of risk in Clauses 8.1 Operational planning and Control, and 10.2 Nonconformity and Corrective Action
- For Recyclers risk is addressed by the R2 or e-Stewards Standards





- Risks and Opportunities Definition (ISO 14001): potential adverse effects (threats) and potential beneficial effects (opportunities)
- ISO 9001 , 6.1.2 Note 2, Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.



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## Risk-Based Thinking, ISO 9001 contained in clauses:

- 1.1 General
- 1.3 Process Approach
- 1.3.3 Risk-based thinking
- 1.4 Relationship with other management system standards
- 5.1.1(d) Leadership and commitment, General, states: “Top management shall demonstrate leadership and commitment with respect to the quality management system by:.. (d) **promoting the use of the process approach and risk-based thinking;**”
- A4-Risk-based thinking
- A.8 Control of externally provided processes, products and services





## Risk-Based Thinking,

- ISO 9001:
  - Risk-Based Thinking is used 13 times in the Appendices versus used once in the standard
  - Risk is used 36 times in the standard
- ISO 14001 contained in clauses:
  - Risk based thinking use once in Clause 1.5, Contents of this Internal Standard
  - Risk is used 40 times in the standard







## TC 176 invented Risk-Based Thinking for ISO 9001

- Risk-based thinking is not in Annex SL
- Risk-based thinking is not in the other Management Standards
- Believe TC 176 used Risk-Based thinking because they did not want a formal requirement to use a standard such as ISO 31000



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## ISO/TC 176/SC2, Document N1222, “Risk” in ISO 9001:2015

- Maintains the ISO 9001 Standard is about “Risk Based Thinking” and
  - Risk-based thinking is not new
  - Risk-based thinking is something that you do already
  - Risk-based thinking is continuous
  - Risk-based thinking ensures greater knowledge and preparedness
  - Risk-based thinking increases the probability of reaching objectives
  - Risk-based thinking reduces the probability of poor results
  - Risk-based thinking makes prevention a habit
- Relates Risk-based thinking to risk in the body of the standard



## ISO 9001, Risk requirements are contained in:

- 4.1 Understanding the organization and its context (referred to by 6.1.1)
- 4.2 Understanding the needs and expectations of interested parties (referred by 6.1.1)
- 4.4 Quality Management System and its processes (referred to by 6.1.2)
- 4.4.1.(f )Quality Management System and its processes
- 5.1.1.(d) Leadership, General
- 5.1.2.(b) Leadership, Customer Focus
- 6.1.1 & 6.1.2 Planning, Actions to address risks and opportunities
- 8.1 Operational Planning and Control, “to implement the actions determined in Clause 6...”
- 9.1.3 Analysis & Evaluations
- 9.3.2, Management Review Inputs
- 10.2.1, Nonconformity and Corrective Actions



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ISO 14001 Risk requirements are contained in

- 4.1 Understanding the organization and its content (by reference)
- 6.1.1 Planning, actions to address risk & opportunities (by reference)
- 6.1.4 Planning actions
- 6.2.1 Environmental Objectives
- 8.1 Operational planning and control
- 9.3 Management Review
- 10.2 Nonconformity and Corrective Action



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Risk is a process in ISO 9001 and ISO 14001

- Treat risk as a process not just isolated requirement
- Do not get caught in the Risk-Based Thinking versus Risk & Opportunities
- Options for Risks
  - Risk Management System such as ISO 31000 or ISO 14971
  - SWOT Analysis
  - Simple Tool
  - Other Tools



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- ISO 31000:2009 Risk Management-Principles and Guidelines
  - Is lifecycle standard that addresses and controls risks
- SWOT Analysis
  - Strengths
  - Weaknesses
  - Opportunities
  - Threats
- Simple tool to identify and controls risk
  - Document the risks and controls
  - Review during Management Review



### ISO 14001 Risk Matrix

ID	Risk	Amount Of Control	Controls for Risk	Risk Rating 1-5
a	6.1.1 Environment Aspects	High	The controls identified in the EMS Aspects have adequate controls	4
b	6.1.1 Compliance Obligations	High	Controls identified in processes to meet EPA and State requirements	4
c	6.1. 1 Organization and context	Low	Process have low risk, controls are stated in Operating Procedures	1
d	6.1.1 Needs and expectations of interested parties	Low	Had little feedback from interested parties, when receive feedback we logic and analyze the feedback	2





## Process to implement a risk

- Identify what your risk and opportunities
- Analyze and prioritize your risk and opportunities
- Plan actions to address the risks
  - How can I avoid the risk
  - How can I mitigate the risk
- Implement the plan
- Check the effectiveness of the actions
- Learn from the experience





## Summary

- Risk is not new for industry but the traditional quality system did not address risk
- For environmental system risk is addressed in the regulatory requirement
- The standards do contain a risk process
- You define how you identify and control the risk
- You do not have to implement another risk standard
- Orion upgrade checklist audit risk as a process





# Other Changes



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- 4.1 Understanding the organization and its context
- **Applicable for both Standards** (ISO 14001 text)  
The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcomes of its environmental management system. Such issues shall include environmental conditions being affected by or capable of affecting the organization.



- 4. 2 Understanding the needs and expectations of interested parties
  - For ISO 14001 this concept is not new
  - For ISO 9001 this concept is new
- Interested party: person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.

Note 1: To “perceive itself to be affected” means the perception has been made known to the organization.

EXAMPLE: Customers, communities, suppliers, regulators, non-governmental organizations, investors and employees.



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- 4.3 Determining the scope of the QMS/EMS
- **Applicable for both standards**
  - Scope available and maintained as documented information
  - No longer refer as “exclusion” (ISO 9001, A.5)



- 5 Leadership
- **Applicable for both standards**
  - Top management shall demonstrate leadership and commitment with respect to the management system
  - No longer requires a Management Representative



- 6.2 Objectives and Planning
- **Applicable to both standards**
  - Objectives at relevant functions, levels and processes
  - Maintain documented information on the objectives
  - Stronger requirements
- ISO 14001, “Environment Targets” is no longer referred, captured in the definition of “Environmental Objectives”



- ISO 9001, 7.1.4 Environment for the operation of processes (NA for EMS)

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

Note: A suitable environment can be a combination of human and physical factors, such as:

- a) Social (e.g. non discriminatory, calm, non-confrontational);
- b) Psychological (e.g. stress-reducing, burnout prevention, emotionally protective)
- c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)

These factors can differ substantially depending on the product and services provided





## ISO 9001, 7.1.6 Organizational Knowledge

- **Not in ISO 14001**
- The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.



- Life Cycle-ISO 14001
- **Not specifically in ISO 9001**

Now more central in the standard

- 6.1.2 Environmental Aspects
- 8.1 Operational planning and control
- A.6.1.2 Environmental aspects
- A.8.1 Operational planning and control
- Introduction, 1.2 Aim of an environmental management system
- 1 Scope



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- 8.1 Operational planning & control(ISO 14001)
- **Controls are not new for ISO 9001**

Consistent with a life cycle perspective, the organization shall:

- a) establish controls, as appropriate, to ensure that its environmental requirement(s) is (are) addressed in the design and development process for the product or service, considering each stage of its life cycle;
- b) determine its environmental requirement(s) for the procurement of products and services, as appropriate;



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- ISO 14001, 8.1 Continued:
  - c) Not considered a change
  - d) consider the need to provide information about potential significant environmental impacts associated with the transportation or delivery, use, end-of-life treatment and final disposal of its products and services.



- ISO 9001, 8.3.1 Design and Development of products and Services, General
- See previous slides for ISO 14001
- The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.



- ISO 14001, 10.1 Improvement, General
- **Similar for ISO 9001**
- The organization shall determine opportunities for improvement (see 9.1, 9.2 and 9.3) and implement necessary actions to achieve the intended outcomes of its environmental management system.



- 10.2 Nonconformity and corrective action
- Applies for both standards
  - No longer requires Preventative Actions



## ISO 14001 Other Clarifications

- Compliance Obligation has replaced legal requirements and other requirements
- Communication in terms of strategy and relationship with regulatory requirements



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## More Specifics for Changes

- The Orion ISO 9001 and ISO 14001 Upgrade Checklist details the changes in the Standards



# Transition Requirements



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- All ISO 9001:2008 and ISO 14001:2004 Certifications will end on September 15, 2018
- If the client is not upgraded the certification will be withdrawn in accordance with AP 05
- New Certifications to ISO 9001:2008 and ISO 14001:2008 will not be accomplished after May 1, 2018
- All upgrades audits must be accomplished by July 1, 2018



## Upgrade Options

- **Recertification Audits**
  - Required for complete rewrite of documentation
  - No additional time added to the audit
  - Results in three year certificate
- **Surveillance Upgrade Audits**
  - Can be accomplished in one or two surveillances
  - At least ½ Audit Day added to the audit
  - Results in certificate with same certification cycle





## Upgrade on Surveillance versus Recertification

- If rewrite complete documentation only eligible for Recertification Audit
- If the company has a one day surveillance for a standard or 1½ day surveillance for two standards is better financially to perform the Recertification Audit
- If less then 25 employees for ISO 9001 it is better financially to perform the Recertification Audit
- If less than 25 employees for ISO 14001 with a low complexity rating, it is better financially to perform the Recertification Audit.



## Orion Upgrade Guidance and Documents

- Roadmap-ISO 9001:2015 and ISO 14001:2015 for Upgrading Standards to the new Revisions
- Upgrade Questionnaire
- Upgrade Audit Time Guidance
- ISO 9001:2015 and ISO 14001:2015 Footprint
- ISO 9001:2015 and ISO 14001:2015 Upgrade Checklists



## Roadmap-ISO 9001:2015 and ISO 14001:2015 for Upgrading Standards to the new Revisions

- Guidance for Clients
- Contains the steps for Upgrade
  1. Understand the expiration date
  2. Purchase a copy of the standard(s)
  3. Understand the changes in the standard(s)
  4. Implement the changes in the standard(s)
  5. Decide on what method to upgrade the standard(s)
  6. Upgrade Audit Performed and Corrective Action Completed



## Upgrade Questionnaire

- Five questions used to determine if the client is ready and what upgrade method
- Asks or reminds the client if an Internal Audit and Management Review has been conducted to the new standard(s)
- Contains the request for what method or services for the update
  - Orion can perform “gap analysis” or Pre Assessments for the new standard revisions







## Upgrade Audit Time Guidance

- Provides guidance for audit time based upon scenarios which are:
  - Did you rewrite your complete documentation?
  - If you did not rewrite your complete documentation-
    - For one standard
    - For two standard(s)
  - Corporate Multi-site Certifications
  - New Certifications
  - Gap Analysis or Pre Assessments



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## ISO 9001:2015 and ISO 14001:2015 Footprint

- Completed by Client
- Purpose to provide the document, process, method, or logic that the client used to implement the 2015 requirements.
- Will be retained by Orion for use in future audits after the upgrades are completed.



## ISO 9001:2015 and ISO 14001: 2015 Upgrade Checklists

- Completed by Orion Auditors for the Surveillance Option
- Completed by Sections, the sections are:
  - Documented Information and QMS Scope
  - Risk & Opportunities, Planning
  - Other ISO 9001:2015 Requirements



## Communication Plan for the Changes

- Email Blasts
  1. Roadmap sent to clients
  2. Presentation, Upgrade Checklists, Audit Time sent
  3. Upgrade Application and Footprints
- Website contains all the documents
- Tradeshows-provide documents and discuss with clients
- Presentations
  - 2015-Two presentations at tradeshows
  - 2016 –Additional presentations



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A photograph of a beach at sunset. The sun is low on the horizon, casting a warm glow over the sky and the ocean. Several wooden lounge chairs with dark cushions are arranged on the sand in the foreground. The sky is filled with soft, wispy clouds.

# At The End of the Day



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- Make a plan for the changes for the standards
- Take your time to think through the changes
- Use the materials provided by Orion
- Contact Orion Scheduling for your upgrade
- Do not wait for over 2 ½ years to implement the changes
- If you have questions, talk to Orion