ISO 9001-14001:2015 Small Business Package

Contents

Combined EMS-QMS Manual *

- Procedures & Work Instructions describing QMS and EMS System Processes
- Forms, Attachments, Registers and Tables referenced by the Procedures

(5) PowerPoint Presentations

- Requirements of ISO 9001.2015 Presentation Materials*
- Requirements of ISO 14001.2015 Presentation Materials
- ISO 9001.2015 Employee Training Presentation Materials
- ISO 14001.2015 Employee Training Presentation Materials
- Integrating ISO 9001-14001 Training Presentation

ISO 9001.2015 & ISO 14001.2015 Gap Analysis Checklists*

ISO 9001.2015 & ISO 14001.2015 Internal Audit Checklists*

ISO 9001 & ISO 14001 Employee Newsletters

*Sample Included

ISO 9001:2015

QUALITY MANAGEMENT SYSTEM

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ISO 14001:2015

ENVIRONMENTAL MANAGEMENT SYSTEM

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QMS - EMS MANUAL

Your Company Name

Street Address

City, State Zip

Introduction

Your Company developed and implemented an integrated Quality and Environmental Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers, enhance its environmental performance and improve the overall management of the company.

To fully understand the organization and its context, Your Company determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the Integrated Management System (IMS).

Your Company meets the requirements of the international standard ISO 9001:2015. The system addresses the design, development, production, installation, and servicing of the company's products. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.
Your Company meets the requirements of the international standard ISO 14001:2015. The system addresses the management of environmental aspects, compliance obligations, the actions to address risks and opportunities. The management of the interactive processes provides for the achievement of continual improvement and focus on efforts leading to the prevention of undesirable outcomes.

This process approach provides for the management of the integrated management system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

The manual is divided into sections that correlate to the clauses of ISO 9001:2015 and ISO 14001:2015. The manual describes the Integrated Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible within the system. The manual also provides the documented information with procedures or references for all activities comprising the management system that ensures the compliance to the necessary requirements of the standards.

This manual is used internally to guide the company's employees through the various requirements of the ISO quality and environmental standards that must be met and maintained in order to ensure environmental performance, customer satisfaction, and continual improvement and provide the necessary instructions that create an empowered work force. This manual is used externally to introduce our Integrated Management System to our customers and other external organizations or interested parties. The manual is also used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Management System is maintained and focused on customer satisfaction and continuous improvement. The IMS manual is approved by a top management representative.

President: _____ Date: _____

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Section 04   Document information

a. Distribution control list

As required with procedure P-750 for Control of documented information.

Quality and Environmental Manual latest revision: Letter: _____

Date of Issue: _____   Issued by: _____

The status of the manual and/or description of changes are provided in the revision status page of this manual.

Controlled copies are issued to:

Copy No. 1   President
              Vice President

Copy No 2   Treasurer / Bookkeeper / Accountant
              Administrative Officer

Copy No. 3   Quality Manager
              IMS Team / Quality-Environmental Team
              IMS team leader / Quality team leader / Environmental team leader

Copy No. 4   Operations Manager
              Technical Manager
              Materials Manager

Copy No. 5   Human Resources Manager
              Education / Training Officer

The master copy is held by the IMS team leader.

This manual is issued and controlled by the IMS team leader.

All matters or inquiries relating to its contents or usage are to be referred to that individual.

It is the responsibility of all holders of the above controlled copies to:

- Ensure that this manual is read by and available to the personnel under their control.

- Ensure that superseded pages are returned to the IMS team leader.

Uncontrolled copies of this manual will be identified with the word "uncontrolled" in bold letters across this page

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Approved by: _____ Date: _____

Includes relevant forms and flow diagrams

INSERT COMPANY NAME/LOGO HERE

For example, the **FD-810-001** Process Flow Diagram represents each step in the manufacturing process and includes other relevant factors associated with the steps.

Process Flow	Relevant Factors	

| **1**
Sources of
Materials | Raw materials, products and other components are purchased and received | Approved suppliers, Incoming inspections |

| **2**
Hauling,
Transportation | Personnel - Manpower

Equipment -Trucks | |

| **3 - Existing**
Operations and
Production | Manpower – Laborers
Machines – Automation | Quality control –
Operator self-inspect |

| **3. a - New**
Production | (x) New Machines
Manpower – Laborers | Training – machines,
maintenance
Operator self-inspect, |

| **4. Products,**
services for
delivery | Products, Sub-assemblies, Components.
Servicing | Sales and Marketing |

| **5. Deliveries to**
customers | Manpower - Drivers
Equipment –Trucks
Permits | **6. Income - Invoice for**
products/services
delivered |

Approved by: _____ Date: _____

Section 04   **Documented information** – Form F-750-001

List of Documented Information for IMS Manual Section 04

This master list for Procedures provides the responsibility, approval date, and revision status for the documents.
A latest copy of each Procedure and Instruction is included in the applicable section of the manual.

- The IMS designation indicates an Integrated Management System Manual.
- The P designation indicates Procedures.
- The WI designation indicates Work Instructions.
- The number following the document numbers listed in the Document column below identifies the section of the standard that the document is associated with.

Doc. #	Description	Responsibility	Approve date	Revise date	Revise date
Quality Management System					
IMS-001	QMS-EMS Manual – Document Information	President			
Manual Section 04 – Context of the Organization					
P-400	Organizational context	President			
Manual Section 05 – Leadership					
P-500	Leadership	President			
Manual Section 06 – Planning					
P-600	Planning for the IMS	IMS team leader			
P-610	QMS – Risk management planning	IMS team leader			
P-612	EMS – Risk management planning	IMS team leader			
WI-622-001	Environmental program – Water	Technical services manager			
WI-622-002	Environmental program – Air	Technical services manager			

Approved by: _____ Date: _____

Section 20   Records Documentation Matrix – Form F-750-002

This section of the IMS Manual contains the Records Documentation Matrix.
In support of the process approach, the last column indicates where in the IMS the documents are used.
A sample of the latest attachment, form, register and flow diagram is included.

Doc #	Description of document	1st Rev. Date	Last Rev. Date	Used with Manual, Procedure, Instruction
	Attachments			
A-520-001	Quality Policy	P. 8	Manual	IMS-001 / P-500 / P-740
A-520-002	Environmental Policy	P.9	Manual	IMS-001 / P-500 / P-740
A-530-001	Organization Chart	P. 10	Manual	IMS-001 / P-500 / P-600 / P-740
A-600-001	PDCA guidelines			P-400 / P-600 / P-740
A-600-002	Aspects and impacts guidelines			P-612 / P-740
A-620-001	Objectives and targets guidelines			P-612
A-800-001	Operational controls guidelines			P-815
	Forms			
F-440-001	IMS-Process identification worksheet			P-400 / P-600 / P-810 / P-851
F-610-001	Risk and opportunity worksheet			P-610 / P-740 / P-1010
F-612-001	Initial environmental review worksheet			P-612 / P-815 / P-911
F-614-001	Risk management worksheet			P-612 / P-740 / P-815 / P-911 / P-911
F-615-001	Environmental program planning worksheet			P-612 / P-815
F-620-001	Quality objectives planning record			P-610
F-620-002	Environmental objectives planning record			P-612 / P-911

Approved by: _____ Date: _____

Understanding the Requirements of
ISO 9001:2015

1

The requirements of ISO 9001:2015 are described in 7 clauses or sections

Section 4 - Context of the Organization

Section 5 - Leadership

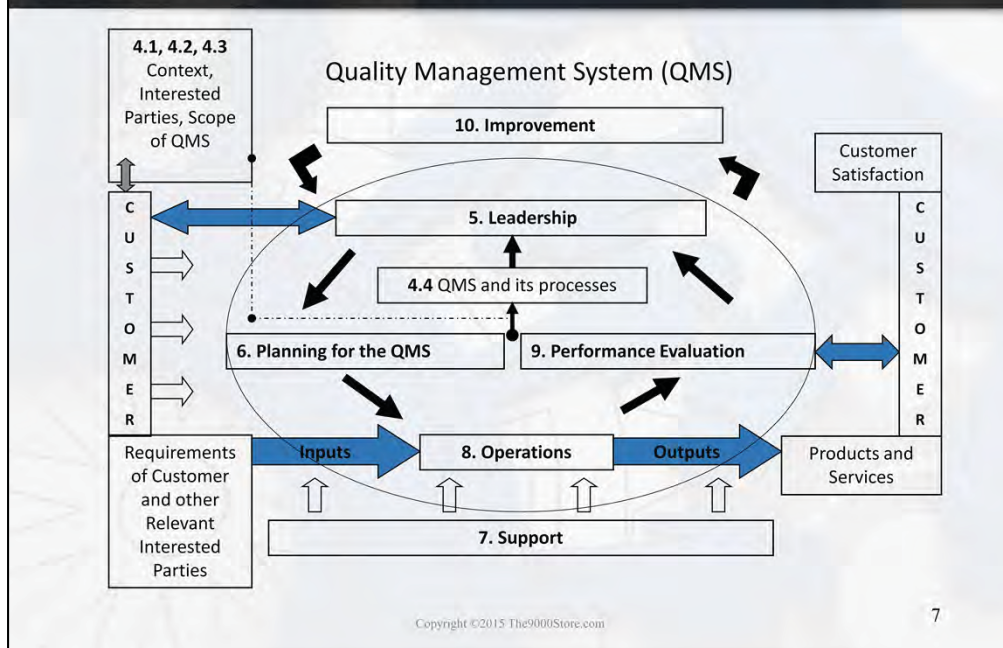Section 6 - Planning for the Quality Management System

Section 7 - Support

Section 8 - Operation

Section 9 - Performance Evaluation

Section 10 - Improvement

The Process-Based Model

This example of the process-based model is similar to the one included in the standard (Figure 1).

The seven clauses are all found on the process model.

Leadership, Planning for the QMS, Operations, and Performance evaluation form a cycle that is influenced by the Context of the organization and Support processes aimed at improvement

The most important input to this cycle is customer and other relevant interested parties requirements.

The output of the cycle is customer satisfaction and continual improvement of the quality system.
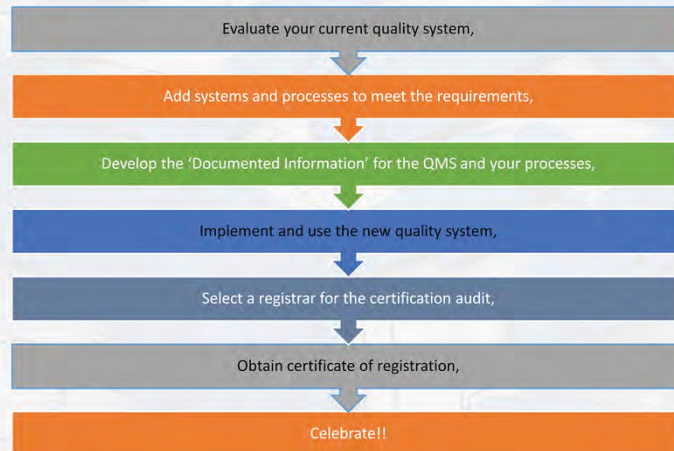
The standard is organized around this model.

The adoption of a quality management system ought to be a strategic decision for an organization.

A robust quality management system can help an organization to improve its overall performance and forms an integral component of sustainable development initiatives.

What Is Needed for Registration?

To become registered a company must first implement the requirements of ISO 9001:2015

- Evaluate your current quality system,
- Add systems and processes to meet the requirements,
- Develop the 'Documented Information' for the QMS and your processes,
- Implement and use the new quality system,
- Select a registrar for the certification audit,
- Obtain certificate of registration,
- Celebrate!!

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Evaluate your current quality system:

Many of the requirements of the standard are addressed by practices already in place.

These practices may or may not be described in documented information.

Other requirements of the standard may not be addressed at all and these need to be implemented and documented.

The standard is designed to bring control and consistency to your processes.

Documenting the processes is part of this control.

It helps ensure that people are doing the same thing, to get consistent results.

The documented information may take the shape of a Document Pyramid and include

An Operations Manual:

a top level document that describes briefly what you have in place to meet the standard.

Procedures:

describe what is done, for example the overall procedure for purchasing or training. What is included in the process?

Work Instructions:

detailed documents that describe how to perform a process, for example how to fill out a purchase order etc.

Forms: to provide the evidence that the system is in place.

Interested parties may be customers, owners, suppliers, unions, bankers, etc. and to understand their needs and expectations, you must:

• Identify the relevant interested parties, determine, monitor and review their requirements that are Relevant to the QMS.

• Consider their expectations and needs and the impact on the ability to consistently provide products and services that meet customer and statutory and regulatory requirements.

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Again -- Remember that for the QMS you only need to consider the issues that are relevant to the QMS.

To completely understand the needs and expectations of interested parties, Your Company identifies the relevant interested parties, determines, monitors and reviews the requirements that are relevant to the QMS.

Their expectations and needs and the impact or potential impact on the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements are considered.

Interested parties may be customers, owners, and people in the organization, suppliers, unions, bankers, partners or society that may include competitors or opposing pressure groups.

INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 Quality Management Systems - The Gap Analysis Checklist

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This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of ISO 9001:2015. Each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. You will need to have a copy of the ISO 9001:2015 standard to use along with this checklist so that you can refer to the requirements and the clarification sections of Annex A.

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. Reference the procedures or other documents that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents; will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if procedures and processes are being complied with, compliance is not your main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with ISO 9001:2015.

---	QUALITY MANAGEMENT SYSTEM	Currently in Place	Compliant Yes / No	If No - % Completed	Items Needed
4	**CONTEXT OF THE ORGANIZATION**				
	This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the QMS. In addition the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.				
4.1	**Understanding the organization and its context**				
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction? Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?				

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	How do you monitor and review the information related to the external and internal issues?				
4.2	**Understanding the needs and expectations of interested parties**				
	With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, have you determined: • The interested parties relevant to the QMS? • The requirements of these interested parties that are relevant to the QMS? How do you monitor and review the information about the interested parties and their relevant requirements?				
4.3	**Determining the scope of the quality management system**				
	To establish the scope of the QMS, has your company determined the boundaries and applicability of the QMS? When determining the scope of the QMS, have you considered the: • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 4.2)? • The products and services of your company? When a requirement of ISO 9001:2015 can be applied, has your company applied the				

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	requirement?				
	When requirements cannot be applied, and in order to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?				
	Is the scope of the QMS available and maintained as documented information?				
	In the scope of the QMS, have you stated the products and services covered by the QMS?				
	Has your company provided justification for any instance where a requirement of the standard cannot be applied?				
4.4	**Quality management system and its processes**				
4.4.1	Has your company obtained the current version of the ISO 9001:2015 international standard?				
	As required by the standard, have you established, documented implemented, maintained and continually improved the QMS? Have you determined the processes needed for the QMS, their interactions and applications throughout your company?				
	For the QMS processes have you determined:				
	• Inputs required and the outputs expected from the processes?				
	• Sequence and interaction of the processes?				
	• Criteria, methods, including measurements				

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ISO 14001:2015 Environmental Management Systems - The Gap Analysis Checklist

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This gap analysis checklist is prepared for use in evaluating your Environmental Management System (EMS) against the requirements of ISO 14001:2015. Each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your EMS capabilities. You will need to have a copy of the ISO 14001:2015 standard to use along with this checklist so that you can refer to the requirements and the guidance sections of Annex A.

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. Reference the procedures or other documents that you have reviewed and that will provide information for the new EMS. Take notes on the status of the documents; will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if procedures and processes are being complied with, compliance is not your main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with ISO 14001:2015.

---	ENVIRONMENTAL MANAGEMENT SYSTEMS	Currently in Place	Compliant Yes / No	If No - % Completed	Items Needed
4	CONTEXT OF THE ORGANIZATION				
	This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the EMS. In addition the scope of the EMS needs to be determined and the Environmental Management System established, implemented, maintained and continually improved.				
4.1	Understanding the organization and its context				
	Has your company determined the external and internal issues that affect your ability to achieve the intended outcomes of the Environmental Management System (EMS)? Have you included such issues as environmental conditions being affected by or capable of affecting				

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ISO 14001:2015 Environmental Management Systems - The Gap Analysis Checklist

	your company?				
4.2	**Understanding the needs and expectations of interested parties**				
	Has your company determined: • The interested parties that are relevant to the EMS? • The requirements (relevant needs and expectations) of these interested parties? • The requirements that become compliance obligations?				
4.3	**Determining the scope of the environmental management system**				
	To establish the scope of the EMS, has your company determined the boundaries and applicability of the EMS? When determining the scope of the EMS, have you considered: • The external and internal issues (per 4.1)? • The compliance obligations relevant interested parties (per 4.2)? • Your organizational units, functions and physical boundaries? • The activities, products and services of your company? • Your authority and ability to exercise control and influence? Within the defined scope of the EMS, have you included all your activities, products and services in				

	the EMS? Is the scope of the EMS available and maintained as documented information?				
4.4	**Environmental management system**				
	Has your company obtained the current version of the ISO 14001:2015 international standard? As required by the standard, have you established, documented implemented, maintained and continually improved the EMS? Have you determined the processes needed for the EMS and their interactions throughout the company? When establishing and maintaining the EMS, have you considered the knowledge gained from: • Your understanding of the organization and its context (per 4.1)? • Your understanding of the needs and expectations of interested parties (per 4.2)?				
5	**LEADERSHIP**				
This clause requires that your top management demonstrates leadership and commitment with respect to the EMS. This section also asks top management to establish, implement and maintain an environmental policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned and communicated.					
5.1	**Leadership and commitment**				
	Has top management demonstrated leadership and commitment with respect to the EMS by: • Taking accountability of the effectiveness of the				

INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 Quality Management Systems - The Internal Audit Checklist

This checklist is based on the information provided in the ISO 9001:2015 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard.
You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

The auditors are expected to use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and tittles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

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	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS / COMMENTS	STATUS
4	**CONTEXT OF THE ORGANIZATION**		
4.1	**Understanding the organization and its context**		
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction? Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)? How do you monitor and review the information related to the external and internal issues?		

	Additional Questions	
4.2	**Understanding the needs and expectations of interested parties**	
	With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, have you determined: • The interested parties that are relevant to the QMS? • The requirements of these interested parties that are relevant to the QMS? How do you monitor and review the information about the interested parties and their relevant requirements?	
	Additional Questions	
4.3	**Determining the scope of the quality management system**	
	To establish the scope of the QMS, has your company determined the boundaries and applicability of the QMS? When determining the scope of the QMS, have you considered the: • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 4.2)?	

	• The products and services of your company? When a requirement of ISO 9001:2015 can be applied, has your company applied the requirement? When requirements cannot be applied, and in order to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected? Is the scope of the QMS available and maintained as documented information? In the scope of the QMS, have you stated the products and services covered by the QMS? Has your company provided justification for any instance where a requirement of the standard cannot be applied?		
	Additional Questions		
4.4	**Quality management system and its processes**		
4.4.1	Has your company obtained the current version of the ISO 9001:2015 international standard? As required by the standard, have you established, documented implemented, maintained and continually improved the QMS? Have you determined the processes needed for the QMS, their interactions and applications throughout		

ISO 14001:2015 Environmental Management Systems - Internal Audit Checklist

This internal audit checklist based on the information provided in the Sept 2015 release of the ISO 14001:2015 international standard is used to audit the Environmental Management System in all types of organizations

Below are the lists the audit questions relevant to each sub-clause of the ISO 14001:2015 standard.

The bold numbers and tittles used in the first two columns indicate the "Requirements". The numbers and titles may be referred to in the audit report prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

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ISO 14001:2015 Environmental Management Systems - Internal Audit Checklist

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4	**CONTEXT OF THE ORGANIZATION**		
4.1	**Understanding the organization and its context**		
	Has your company determined the external and internal issues that affect your ability to achieve the intended outcomes of the Environmental Management System (EMS)? Have you included such issues as environmental conditions being affected by or capable of affecting your company?		
	Additional Questions		
4.2	**Understanding the needs and expectations of interested parties**		
	Has your company determined: • The interested parties that are relevant to the EMS? • The requirements (relevant needs and expectations) of these interested parties? • The requirements that become compliance obligations?		