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# 14 Operational Control

## 14.1 INTRODUCTION

The area of operational control concerns itself with the management of the day-to-day impact of your operations on the environment. The overall intent is to identify those aspects of your operation that will create a significant impact on the environment and implement controls to manage them. You can see from this opening statement that Operational Control (Sub-element 4.4.6) is influenced by ISO 14001 Element 4.3, *Planning*, and Sub-element 4.4.4, *Training, Awareness and Competence*. This will become more apparent as the chapter progresses.

## 14.2 ISO 14001 REQUIREMENTS

Element 4.4.6 of ISO 14001 states:

The organization shall identify those operations and activities that are associated with the identified significant environmental aspects in line with its policy, objectives, and targets. The organization shall plan these activities, including maintenance, in order to ensure that they are carried out under specified conditions by:

- (a) establishing and maintaining documented procedures to cover situations where their absence could lead to deviations from the environmental policy and the objectives and targets;
- (b) stipulating operating criteria in the procedures;
- (c) establishing and maintaining procedures related to the identifiable significant environmental aspects of goods and services used by the organization and communicating relevant procedures and requirements to suppliers and contractors.

The key factor (highlighted) stipulated in these requirements centers on the need to implement controls based on whether or not they are in line with and minimize or prevent deviations from the environmental policy and the objectives and targets. This section also indicates the need to concern oneself with the influence and impact of three other operational activities: maintenance; goods and services; and suppliers and contractors.

## 14.3 COMPARISON WITH ISO 9001

ISO 9001 has several sections where the requirements of ISO 14001 can be integrated. [Table 14.1](#) shows these interrelationships:

**TABLE 14.1**  
**Correlation of “Operational Control” Requirements**

ISO 9001		ISO 14001	
Element	Requirement	Element	Requirement
4.2.2 (a)	Quality system procedures consistent with quality policy	4.4.6 (i)	In-line with environmental policy and objectives and targets
4.9 (g)	Maintenance of equipment	4.4.6 (i)	Maintenance
4.2.2 (b)	Documented procedures	4.4.6 (a)	Documented procedures (where absence could lead to deviations)
4.9 (a)	Documented procedures (where absence could lead to deviations)		
4.9 (I)	Process control	4.4.6 (b)	Operating criteria
4.9 (d)	Monitor and control process parameters		
4.6.1	Purchasing procedure	4.4.6 (c)	Goods and services
4.6.3	Purchasing data		
4.7	Control of customer-supplied product procedure		
4.3.1	Contract review procedure	4.4.6 (c)	Suppliers and contractors
4.6.2	Evaluation of subcontractors		

- (i) indicates first paragraph of element, etc.
- (a) indicates subsection “a” of element, etc.

As you can see, the quality system provides several integrating opportunities for ISO 14001. Let’s now take each of the ISO 14001 requirements and see how we can specifically integrate them into the quality system.

## 14.4 MAINTENANCE ACTIVITIES

When discussing maintenance activities, it is important to distinguish between maintenance classified as “routine” vs. nonroutine. “Nonroutine” is considered to be equipment breakdowns that are “unplanned.” Routine maintenance is commonly called “preventive maintenance.”

Preventive maintenance is “predetermined” maintenance work performed to a schedule without specific preknowledge of any defect. In the Quality Management System it can be an effective tool to combat the development of equipment weaknesses into product defects and unplanned downtime. Preventive maintenance can have both a positive and a negative effect on the system. From a positive standpoint it can be utilized as part of a hazard assessment program for identifying potential hazardous situations and other impacts, including environmental. On the negative side, failure to perform preventive maintenance as required can result in an undesirable

impact. This is a clear example of what is meant in the standards where “*absence of such procedures could adversely affect quality (environment)*”.

A good example of a negative impact resulting from the absence or failure to implement a required procedure can be readily demonstrated with a piece of equipment which utilizes various chemicals in the manufacture of a product. If we assume the equipment has a pressurized piping system for the chemicals, it becomes obvious that regular inspections of valves and seals are required to prevent not only minor leakage, but also a major rupture in the piping system. If the equipment system is large, a valve or seal rupture could create a major release to the surrounding area and, if a sewer or stormwater system is also nearby, then you also have unauthorized contaminated water discharge.

We can also use the same scenario to demonstrate a “positive” impact. A good, well-managed preventive maintenance system could greatly minimize or even eliminate such a rupture of the system. The best way to ensure that preventive maintenance occurs is to have not only a written procedure (Maintenance Operating Procedure or MOP) of what to do, but also a scheduling system. There are a large number of preventive maintenance software packages available to manage the program. The preventive maintenance procedure can be written in such a manner as to address not only quality issues, but also environmental. An example of a MOP may include some of the following tasks:

- While checking the valves and seals, look to see if there is any evidence of chemical on the floor.
- Ensure temperature gages have been calibrated per the requirements of the Calibration Program.
- When draining vacuum pump oil, be sure to have a spill control kit available and dispose of used oil in the proper hazardous waste container.
- Check all piping surfaces for leaks and corrosion.
- Verify accuracy of pH meter to ensure chemical adheres to proper quality specifications.

The Maintenance Operating Procedure should also include information concerning the “consequences” of not following the procedures. An example of a “consequence” statement may be:

Due to the corrosiveness of the chemical in the piping system, it is critical that the valve seals be replaced on a monthly basis. Failure to replace valve seals on a monthly basis could result in a valve rupture and an unauthorized release of the chemical to the surrounding environment.

One final comment in regards to the inclusion of the maintenance as actual or potential environmental aspect. If you take the time to assess both the negative and positive impacts of maintenance on the quality of your product and on the environment, you may see the need to establish maintenance objectives and targets and subsequent programs to minimize its impact. [Table 14.2](#) shows how all this fits together for our chemical piping system.

**TABLE 14.2**  
**Chemical Piping System**

ISO 14001 Element 4.3, Planning	Evaluation		
4.3.1 — Aspect	Maintenance of chemical piping system		
4.3.1 — Significant Aspect	Severe release of corrosive chemical		
4.3.2 — Legal and Other Requirements	Potential violation of unauthorized release to sewer system of corrosive chemical		
4.3.3 — Objective	Prevent valve seal ruptures		
4.3.3 — Target	Improve preventive maintenance of system		
4.4.3 — Program/project	What	Who	When
	Investigate PM procedure: Review/modify MOP Review/modify PM schedule	Maintenance	12/31/97 12/31/97
	Evaluate current valve seal material and investigate alternative materials with more corrosion resistance	Process Engineer	12/15/97
	Install automatic shutoff valves with pressure drop sensors every 50 feet to minimize volume of material due to accidental release	Maintenance	1/31/98

## 14.5 DOCUMENTED PROCEDURES AND OPERATING CRITERIA

ISO 9001, Element 4.2.2, requires that an organization have:

“the range and detail of the procedures ... dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel in carrying out the activity” with a special note that “documented procedures may make reference to work instructions that define how an activity is performed.

Element 4.9 (a) also adds that

controlled conditions shall include ... documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality.

A procedure established under ISO 9001 can thus be an excellent vehicle for meeting the requirements of ISO 14001. It is a very easy task to take an operating procedure associated with an activity or service of your organization and assess whether or not it is an aspect of your operation that may have an actual or potential impact on the environment. Once that determination has been made, it is a simple matter to incorporate information into the procedure which will satisfy the requirements of ISO 14001. Such information may include “awareness and consequence” statements (see Chapter 10), monitoring and measurement requirements (see

Chapter 16), legal and other requirements (see Chapter 7), and employee responsibilities (see Chapter 9).

In order to demonstrate this, I will show you an example of an integrated operating procedure that incorporates both ISO 9001 and ISO 14001 requirements:

**Purpose** To ensure that the manufacture of (product) produces high yields with minimal impact on the environment, people, and equipment.

**Scope** This procedure defines the control system and specifications for the manufacture of (product).

### **Definition of Terms**

- ARB: Air Resources Board
- VOC: Volatile Organic Compound
- SPC: Statistical Process Control

### **Referenced documents**

- ISO 14001, Element 4.4.6, Operational Control

### **EH&S precautions**

- Safety glasses are required when doing setup
- Powder generated from the waste material shall not be washed or swept into the sewer/drain system
- Hazardous waste material is to be disposed of in accordance with RCRA guidelines
- This process has a permit-to-operate from the ARB. Permit conditions require that a usage log be maintained for the chemical with a total 12-month consumption not to exceed “x” gallons. Failure to maintain the log can result in a violation and/or fine.

### **Precedence**

- The health and safety of personnel and protection of the environment shall take precedence over this operating procedure.
- Customer requests and requirements shall take precedence over this procedure.

### **Responsibilities**

#### *Process Engineer*

- For maintaining and revising this procedure as needed.
- For the technical aspects of the operation.

#### *Department management*

- For ensuring that personnel operating this equipment are fully trained and certified and that they understand the consequences of not following the procedure.
- For providing all necessary resources to achieve a high quality product and to minimize the EH&S impacts.

**TABLE 14.3**  
**Operating Criteria and Controls Comparison**

Criteria/Control	ISO 9001	ISO 14001
Product conforms to specified customer requirements	•	
Minimizes the impact on the environment		•
Minimizes the impact on personnel	•	
Reduces the potential for an unscheduled breakdown	•	
Ensures continuing process capability	•	•
Provides sufficient operating time such that preventive maintenance can be scheduled with minimal conflict with overall running time	•	
Monitoring and measurement requirements	•	•
Consequences of deviating from the established procedures	•	•
Emergency shutdown procedures		•
Operator competence	•	•
Other resources	•	•

*Environmental Manager*

- For maintaining the monitoring data and usage log in compliance with the ARB permit conditions.
- For filing all permit documents and acting as liaison with the ARB.
- For training personnel on all of the environmental requirements.

*Maintenance*

- For ensuring that all temperature controls are calibrated according to ISO 9001 requirements.

**Procedure** The procedure can include both quality and environmental operational controls such as measurements, statistical process controls, etc.

As you can see, this procedure stipulates operating criteria and controls for both ISO 9001 and ISO 14001. [Table 14.3](#) shows which Standard is satisfied by the procedural criteria and controls. As stated on several previous occasions, the operating procedure can be the most valuable tool you have for integrating many of the ISO 14001 requirements.

## 14.6 GOODS AND SERVICES

We now come to a subject that deals primarily with the control of your purchased materials and supplies. [Table 14.1](#) indicates that the comparative requirements for ISO 14001 under the ISO 9001 standards lie in Section 4.6, *Purchasing*, and in Section 4.7, *Control of Customer-Supplied Product*. Let’s take each of these sections and interject where the ISO 14001 requirements might fit in:

**Section 4.6.1** The supplier shall establish and maintain documented procedures to ensure that purchased product conforms to specified requirements.

**Section 4.6.3** Purchasing documents shall contain data clearly describing the product ordered, including where applicable: (a) the type, class, grade or other precise identification; the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel, etc.

**Section 4.7** The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities ...

What has been indicated above and stands out in the ISO 9001 Standards are requirements for product specifications, identification of applicable issues for the process, and the approval of product. Although we spent a great deal of time discussing design reviews in Chapter 6, it is important to address the importance of a design review on materials once again.

#### 14.6.1 ENVIRONMENTAL REVIEWS

In Chapter 6, I discussed the importance of addressing environmental, health and safety issues early on in a design review program in order to proactively eliminate any chemicals or materials which may impact the environment and people. All too often, when a project manager is considering a new or a revised product and/or process, he fails to consider the impact beyond the financial gains for the company. It is critical that an environmental, health, and safety professional be included in the reviews and as early in the process as possible. Too few environmental, health, and safety professionals consider the significant impact of a new chemical or materials beyond the need for a new air permit, for instance. They raise the “red flag” and indicate the product will generate a new air permit, but don’t consider the possibility of replacing the material with a non-VOC material and, thus, lessening or minimizing its impact on the environment. An environmental manager who is ISO 14001 “smart” would be an extremely valuable addition to any review team.

Once again, a design review team must address the following type of questions early in the review:

- Will this new or modified process or product create a new environmental aspect?
- Will this new environmental aspect create a significant impact?
- Will this new or modified process or product potentially change or influence a current environmental aspect?
- Will this new or modified process or product potentially change or influence a current significant impact?
- Are there any new regulations that must be taken into consideration with this new or modified product and/or process?
- Is this new chemical/material currently being considered by any of the regulatory agencies for potential reporting requirements, controls, elimination, or restriction in some capacity?

- Is this new chemical/material currently being considered or has been considered for either restricted use or banning within the confines of another country for which you have sales considerations?
- Is this new chemical/material being imported from another country and, if so, are there any potential regulatory issues barring or restricting its use within the confines of your own country?
- Will this new chemical, after its use within your process, pose any restrictions or special considerations for waste disposal, including financial, technological, etc.?
- Will the purchase of this new chemical or material impact the process by requiring special technological options (e.g., abatement controls) that were not considered during initial design reviews.

Most of these questions provide sound reasoning for evaluating the environmental impacts as early in the design review as possible. Failure to consider them could result in severe financial consequences in terms of legal violations and fines, expensive add-on equipment, and other additional process expenses not considered at all. Additionally, as environmental concern increases, more and more of your customers and other externally interested parties are putting more and more constraints on their suppliers in using chemicals, materials, and substances that impact the environment. Pressure from your customers could result in the need to modify or re-engineer your product using chemicals or materials more friendly to the environment.

#### 14.6.2 PRODUCT SPECIFICATIONS

In conjunction with the design or process review, it is important to purchase supplies and materials that conform not only to your requirements, but also to your customer who may or may not be the final end-user. The best way to do this is through the development of product specification documents that describe the manufacture and acquisition requirements from your own suppliers.

The considerations being documented in the procedure must also go beyond the actual description of the product. Consideration must also extend to the supplier's own handling or manufacturing process in making the product. With ISO 9001 now being so soundly entrenched, it is much easier these days to put pressure on a prospective supplier to manufacture your product in the manner which you delegate or specify. Although I have not been including the ISO 14020 Labeling Standards in this book, the inclusion of them in your product specifications is a critical factor. If the issue of "goods and services" in ISO 14001 is very important to you, it would be highly recommend you become familiar with the series of standards dealing with labeling and packaging (see a list these standards in [Table 3.2](#)).

As I have done on several previous occasions, I will provide a sample procedure that acts as a guideline for your own. This procedure will contain, of course, requirements for both ISO 9001 and ISO 14001.

**Purpose** This purchase specification for material describes the requirements for the manufacture and acquisition of (name of material) from XYZ Co.

**Scope** This procedure applies to (name of material) used in the manufacture of widgets.

### **Definition of terms**

- A Certification is a document required from a supplier which guarantees that the material shipped meets the requirements and specifications as stated in this procedure. In cases where specified, it also requires the inclusion of supporting test data or other documents supporting the specifications.
- ARB is the Air Resources Board
- ODS is an Ozone-Depleting Substance
- (Add others as needed.)

### **Referenced documents**

- ISO 14001, Element 4.4.6, Operational Control
- ISO 9001, Element 4.7, Control of Customer-Supplied Product
- ISO 14023, Self Declaration Environmental Claims—Testing and Verification
- Drawing #A17965, Revision C, Widget

### **EH&S precautions**

- The supplier is required to supply Material Safety Data Sheets for each shipment of this material.
- The supplier must have all permits required by the Air Resources Board before manufacturing this material.
- This material must not be manufactured with any ozone-depleting substances.
- All waste generated by the supplier must be disposed or recycled in a manner consistent with the appropriate regulations.

**Precedence** In case of a conflict, the requirements in the Purchase Order take precedence over this specification document.

### **Responsibilities**

#### *Process Engineer*

- The Process Engineer is responsible for maintaining the technical content of the specification document.

#### *The Supplier*

- The supplier is responsible for conforming to all aspects of this specification document.

#### *Environmental Manager*

- For verifying that the supplier has the necessary environmental permits and is handling waste in a manner consistent with the required regulations.
- For evaluating the Material Safety Data Sheets and communicating any hazard information to appropriate personnel.

### *Material Control*

- For the proper storage of this material.
- For ensuring shelf life considerations with this material are addressed.
- For ensuring proper labeling and packaging of the material is addressed.
- For inspecting the incoming material to ensure it meets the specifications and contacting the process engineer if there are any discrepancies.

### **Procedure**

#### *Visual criteria*

- The color of the material must be (describe).

#### *Material properties*

- Describe any physical and chemical properties, such as boiling point, crystallinity, glass transition temperature, viscosity, melting point, pH, etc.

#### *Certifications*

- The supplier is required to provide certifications with supporting test data which shows that the material shipped meets the specifications of the properties listed above and will maintain these properties within the shelf life period.

#### *Shelf life*

- The material shall meet the specifications for a minimum period of (define period) from the date of shipment when stored at (define storage temperature).

#### *Labeling and packaging*

- The supplier shall ensure that the material is packaged and labeled in accordance with all relevant federal, state, and local regulations, including the Montreal Protocol.

### **14.6.3 INCOMING INSPECTION**

The procedure mentioned that Material Control has the responsibility for ensuring incoming material meets the specifications required. What is needed is a procedure to manage the incoming inspection process itself. This is extremely important — failure in this area could cause unnecessary waste and low yields (e.g., an impact on the environment). The requirement for this activity is found in ISO 9001, Section 4.10.2, *Receiving Inspection and Testing*. Rather than writing another procedure at this point, I would like to merely point out some significant information you can use when writing your own.

It is important to note that material being received for incoming inspection should at a minimum include some of the following documents:

- Process FMEA (Failure Modes and Effects Analysis)
- Design FMEA
- MSDS
- Packaging requirements

- Labeling and product identification
- Use of ozone depleting substances (including any “Pass Through” requirements)
- Material characteristics (e.g., physical and chemical)
- Other hazard warning requirements
- Material testing and data reports

If the results of incoming inspection prove to be unacceptable, the inspector or engineer needs to evaluate why the supplier was unable to meet the material specification. If the supplier cannot meet the specification and the specification cannot be changed for your process, then a reevaluation of the supplier should be made with the potential need to find another supplier.

## 14.7 CONTRACT SUPPLIERS

Now that we have discussed the specifications for purchasing materials, we will turn our attention to the supplier of the material. Taking the time to find the right supplier is as critical, if not more so, than finding the right material to do the job. A poor supplier can cause potential delays in delivery of the material, ship a poor quality material or provide a material that is inconsistent in its quality. All of these will adversely affect your own operation through unexpected slowdowns or shutdowns of your manufacturing process, poor product yields, and a high rate of waste.

What is needed now is a procedure to define the requirements for suppliers:

**Purpose** This procedure defines the minimum quality and environmental requirements for suppliers providing materials and/or services.

**Scope** This procedure applies to all actual or potential suppliers of material.

### Definition of terms

- A **Certification** is a document required from a supplier which guarantees that the material shipped meets the requirements and specifications as stated in this procedure. In cases where specified, it also requires the inclusion of supporting test data or other documents supporting the specifications.
- An **Approved Supplier List** is a list of all suppliers that can be used in the purchase of materials.
- A **Critical Commodity** is a material in which a supply disruption would have a large negative impact on sales (i.e., sole source, impact of supply disruption, difficulty of qualification or requirement of customer) or a significant impact on the environment.
- An **ODS** is an Ozone-Depleting Substance.
- (Add others as needed.)

### Referenced documents

- Procedure for Material Specifications (See Section 14.6.2 above.)
- ISO 9001, Section 4.6.2, Evaluation of Subcontractors
- ISO 14001, Section 4.4.6(c), Operational Control

## **EH&S precautions**

- The supplier is required to provide Material Safety Data Sheets for each shipment of material if not classified as an “article.”
- The supplier must have all operating permits required by appropriate regulatory agencies before material can be produced.
- The material must not be manufactured with any ozone-depleting substances.
- All waste generated by the supplier must be disposed or recycled by the supplier and in a manner consistent with the appropriate regulations.

**Precedence** In case of a conflict, the requirements in the Purchase Order take precedence over this qualification document.

## **Responsibilities**

### *Supplier*

- The supplier is responsible for meeting or exceeding all applicable requirements in this document as well as any associated material specification documents for the supplied material. The quality assurance process for the supplier shall be documented and shall be subject to review, evaluation, and audit by the customer.

### *Environmental Manager*

- For verifying that the supplier has the necessary environmental permits and is handling waste in a manner consistent with the required regulations.
- For evaluating the Material Safety Data Sheets and communicating any hazard information to appropriate personnel.

*Purchasing* is responsible for controlling the supplier evaluation and selection program and maintaining all documents concerning the ongoing evaluation of the suppliers.

## **Procedure**

### *To add to the approved list*

- Requirements for new suppliers include a positive financial profile, a suitable and effective quality management process, compliant Environmental, Health and Safety Systems (see Appendix H for an example) and process capability suitable for the material supplied.
- Supplier evaluation shall follow the ISO 9001 and ISO 14001 series of standards.

### *To remain on the approved list*

- All suppliers are required to maintain satisfactory performance in conformance with quality, environmental, and delivery requirements.

### *To be removed from the approved list*

- A supplier will be removed from the list based on a review of the quality, environmental, and delivery performance.

This procedure does not take into full account all of the minor details required under the ISO 9001 Standards due to the extensive complexity of the requirements. The intent above was to show how some of the ISO 14001 Operational Control requirements can be integrated into various procedures of ISO 9001.

## 14.8 ONSITE CONTRACTORS

The focus in this section will be on those “contractors” who perform a service directly at your facility. The communication required under ISO 14001 should be in two directions: (a) the contractor informing you of the work he performs which may affect an aspect of your operation and impact the environment (actual or potential); and (b) your need to inform the contractor of any aspects of your operation which may impact him.

When you sign a contract with another business to perform a service directly at your site, it is important to establish certain criteria within the contract itself. This criteria may include information on their EH&S history, the nature of any chemicals which may be used by them (with the provision of MSDSs to you), what waste may be generated from their activities and which aspect(s) of your operation may be affected. Any work that they perform may adversely affect your operation and create a significant impact within your own premises. You should also not forget any potential impacts on the surrounding community. Steps must therefore be taken beforehand to understand where this impact will be and to minimize or eliminate them, if possible.

When evaluating the impact, you also need to consider the manner in which the impact may affect you. The impact may not be obvious, such as the generation of hazardous waste, but may create a large or small scale change on one of your objectives with its resulting targets and programs. It may also impact your ability to comply with certain regulatory requirements or other standards for which there must be adherence.

One of the best ways to manage contractors on your premises is to develop a Contractor Safety Program. The primary focus of such a program is to “inform and train” prospective contractors on the aspects of your operation and to establish some guidelines for communication. The program contains provisions for the distribution of various “special work permits” that the contractor must obtain before beginning work. To obtain the permit, the contract workers must read about specific company environmental and safety provisions or rules pertinent to the particular work to be done. They must then sign a statement of understanding and describe the details of the work to be done. This management system can protect the environment, people, and property quite effectively. It is very important to communicate to prospective contractors the requirement to participate in your Contractor Safety Program as a condition of signing and accepting a final contract.

## 14.9 WHAT AUDITORS WILL LOOK FOR

An ISO 14001 auditor will look primarily for written operating procedures which should show whether or not the organization has *control* of its processes. They will especially be concerned about the presence of operating procedures that are directly related to any of your identified significant aspects which may very well include maintenance activities. In addition, it is important to demonstrate that personnel understand the consequences of not following the procedures. It is highly recommended that such statements be included in the operating procedure. Operator certification examinations can then include questions pertaining to the consequences of deviating from the established procedure.

The second major concern for the auditor will be how well you handle suppliers of materials, joint venture operations, and onsite contractors. As already mentioned, they can have an impact on your operation and the environment.