

Introduction and support package : Guidance on 'Outsourced processes'

Document: ISO/TC 176/SC 2/N 630R3
October 2008

1. Introduction

The aim of this document is to provide guidance on the intent of ISO 9001:2008 clause 4.1, regarding the control of outsourced processes.

ISO 9001:2008 clause 4.1 states:

“Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

NOTE 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process may be influenced by factors such as:

- a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements;*
- b) the degree to which the control for the process is shared;*
- c) the capability of achieving the necessary control through the application of clause 7.4.”*

2. Guidance

2.1 What is an “outsourced process”?

The Oxford English Dictionary defines the verb “outsource” as “to obtain..... by contract from a source outside the organization or area; to contract (work) out”

As now defined in ISO 9001:2008 Sub clause 4.1 NOTE 2, an “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

Note: ISO 9000:2005 clause 3.4.1 defines “process” as “set of interrelated or interacting activities which transforms inputs into outputs”.

An outsourced process can be performed by a supplier that is totally independent from the organization, or which is part of the same parent organization (e.g. a separate department or division that is not subject to the same quality management system). It may be provided within the physical premises or work environment of the organization, at an independent site, or in some other manner.

2.2 Intent of Clause 4.1

The intent of Clause 4.1 of ISO 9001:2008 is to emphasize that when an organization chooses to outsource (either

permanently or temporarily) a process that affects product conformity with requirements (see ISO 9001:2008 clause 7.2.1), it can not simply ignore this process, nor exclude it from the quality management system.

The organization has to demonstrate that it exercises sufficient control to ensure that this **process** is performed according to the relevant requirements of ISO 9001:2008, and any other requirements of the organization's quality management system. The nature of this control will depend on the importance of the outsourced process, the risk involved, and the competence of the supplier to meet the process requirements. Based on the nature of the control, it should consider the processes referred to quality management system for management activities, provision of resources, product realization and measurement, analysis and improvement. The outsourced organization does not necessarily have to have a certified Quality Management System, but it has to demonstrate the capability of the previously mentioned processes.

Outsourced processes will interact with other processes from the organization's quality management system (these other processes may be carried out by the organization itself, or may themselves be outsourced processes). These interactions also need to be managed (see ISO 9001:2008 clause 4.1 (a) and (b)).

2.3 Control of outsourced processes

2.3.1 The acquisition of outsourced processes will normally be subject to the capability of achieving the necessary control through the application of requirements of both ISO 9001:2008 clause 7.4 (Purchasing) and clause 4.1 (General Requirements)

As mentioned in the Note, in some situations, the organization might not "purchase" the outsourced process in the traditional sense; it might, for example, receive the service from a corporate head office or from another division within a group of organizations, without any monetary transaction taking place (see 2.1 above). Under these circumstances, however, ISO 9001:2008 Clauses 7.4 and 4.1 are still applicable.

2.3.2 There are two situations that frequently need to be considered when deciding the appropriate level of control of an outsourced process:

- n When an organization has the competence and ability to carry out a process, but chooses to outsource that process (for commercial or other reasons).
In this situation the process control criteria should already have been defined, and can be transposed into requirements for the supplier of the outsourced process, if necessary.
- n When the organization does not have the competence to carry out the process itself, and chooses to outsource it.
In this situation the organization has to ensure that the controls proposed by the supplier of the outsourced process are adequate. In some cases it may be necessary to involve external specialists in making this evaluation.

2.3.3 It may be convenient, or even necessary, to define some or all of the methods to be used for control of the outsourced processes in a contract between the organization and the supplier. The potential impact of the outsourced process is based on the outsourcing's capability to provide product that conforms to requirements. Care should be taken, however, not to inhibit the supplier from proposing innovations to the outsourced process.

The organization's control of the outsourced process has to be based on the need for product conformity to requirements.

Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements.

2.3.4 In some situations it might not be possible to verify the output from the outsourced process by subsequent monitoring or measurement. In these cases, the organization needs to ensure that the control over the outsourced process includes process validation in accordance with ISO 9001:2008 clause 7.5.2.