

# Document Management for ISO 9000

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**Summary**

This document provides an overview of how an effective Document Management System can help a company to meet the requirements for document control under clause 4 of the ISO 9001:2000 quality management standard. In particular it emphasises the specific features included in CogniDox that make conformance straightforward and the document retrieval, tracking and control aspects of the standard easy to achieve.

Contents	
1	ISO 9001:2000 Requirements ..... 1
2	How CogniDox Can Help ..... 2
2.1	Control Document Work-Flow ..... 2
2.2	Trace History of all Operations..... 2
2.3	Inform Users of Document Changes..... 2
2.4	User Account Management..... 2
2.5	Take the Pressure Out Of ISO Audits ..... 3

## 1 ISO 9001:2000 Requirements

Clause 4 of the standard describes the requirements on the quality management system for managing documentation. Key areas that must be addressed are:

- A documented procedure to control quality documents must exist - *How are documents updated, released and distributed?*
- Everyone must have access to up-to-date documents – *How do I know that I’m using at the most recently released version of the document?*
- The status of a particular document must be clearly identifiable – *Has this document now been withdrawn or superseded?*
- The audit trail of a particular document must be traceable – *Who wrote this document? What were the last changes made? Who reviewed it and what were their comments? Who approved it? When did all of these happen?*

Of course it is possible to control these areas manually but this is a time-consuming task that is prone to error, particularly as the number of documents grows.

## 2 How CogniDox Can Help

CogniDox is designed to solve the problems posed by the documentation management clause of the ISO 9001:2000 standard.

### **2.1 Control Document Work-Flow**

CogniDox provides a control system for managing a document through its entire lifecycle from creation through to withdrawal. It provides a structure for operations such as uploading documents or requesting reviews that is easy to follow and helps you to meet the needs of ISO 9001:2000 without being onerous to operate. And, because CogniDox is web browser based, it is accessible by all company members without the need for a special client application.

### **2.2 Trace History of all Operations**

CogniDox provides a complete history of operations carried out on the system whether they relate to documents or user accounts. Typical history information that may be required is:

- Who reviewed a document?
- What were their comments?
- When was the document approved?
- If CogniDox is linked into your Extranet, which customers received this version of the document?

With traceability such an important aspect of ISO 9001:2000 this feature of CogniDox provides an invaluable mechanism for making such history information readily available to all users.

### **2.3 Inform Users of Document Changes**

Because CogniDox is linked into your email system it allows messages to be sent to users relating to particular documents. Typical messages are:

- Inform the user of a new document release
- Notify them that a document has been updated and requires their review
- Remind the user that they have a document requiring their review if the requested review date has passed
- Request for their approval of a document for release
- Notify a user that a document has been withdrawn and is no longer available

Users may also take actions such as “putting a watch” on a particular document that they care about such that if it is updated they are notified. In addition, if CogniDox is linked into your Extranet, customers can also receive notification of documents available for download.

### **2.4 User Account Management**

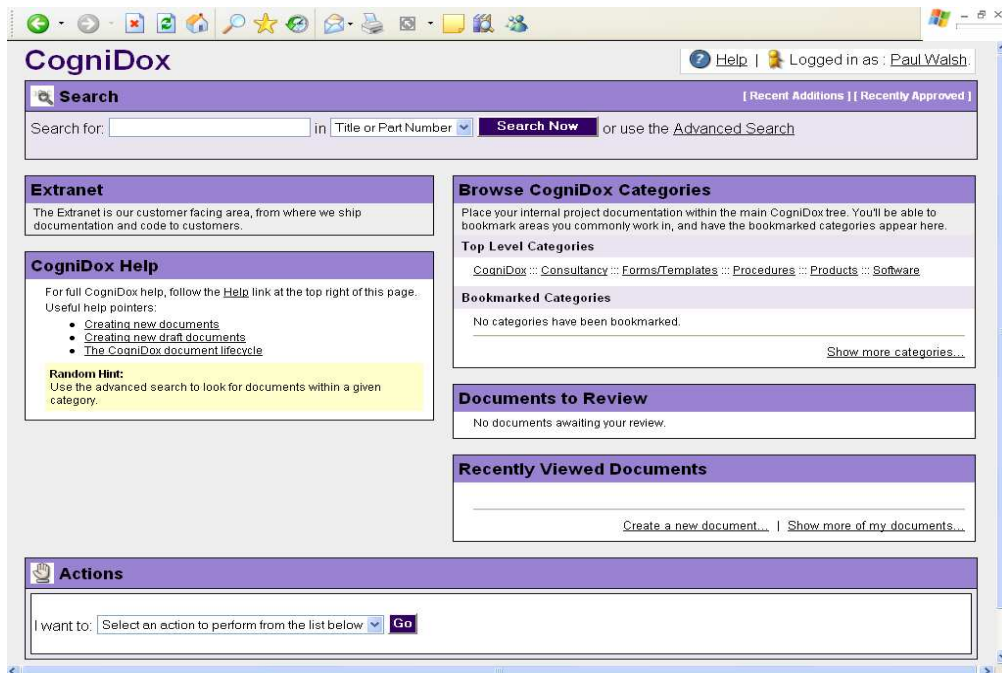
It is normal that users of a document management system will be required to have different roles and therefore want to carry out different tasks on the system. CogniDox caters for this by including a user account management system that configures the access rights for the user and provides the ability to customise the look-and-feel of their homepage. This puts controls on some operations such a document approval or release to the Extranet so that these can only be performed by certain users in line with the ISO 9001:2000 procedures in operation for the company.

## 2.5 Take the Pressure Out Of ISO Audits

During the ISO 9001:2000 certification process the auditor will ask the following questions:

1. Tell me what you do (*describe the business process*)
2. Show me where it says that (*reference the procedure manuals*)
3. Prove that that is what happened (*exhibit evidence in documented records*)

Whilst a documentation management system cannot help you answer the first question (if you don't know what you're doing then no system is going to help!), a system such as CogniDox can make answering the second and third questions as straightforward as clicking your mouse.



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