

Audit Report No 33

Standard: ISO 9001: 2000
Quality Management Systems - Requirements

Audit Period Jan 08 to Dec 08

Auditor Chris Pearce

Audit Period Jan 08 to Dec 08

Dept/Function Documentation processes

Person Responsible Terry Weedon

People Seen

Typical Questions

- What triggers this process to start (CI 4.1)?
- What steps do you carry out (CI 4.1)?
- What goes wrong (CI 4.1)?
- What happens when things go wrong (CI 4.1)?
- How do you report the output of your process (CI 4.1)?
- What documentation do you have to tell you what to do, and is it effective (CI 4.2.1)?
- What data do you record about the process conditions/outputs (CI4.1)?
- What equipment do you use in the process(CI 4.1)?
- How is it calibrated/maintained (CI 7.6)?
- What improvement projects are you involved in at present (CI 4.1)?
- Are staff trained adequately and is it recorded (CI 6.2.2)?
- Are sufficient resources available and is work environment and infrastructure satisfactory (CI 4.1)?
- Are sufficient records kept of the process to enable analysis and review(CI 4.1)?
- Are there procedures required by ISO 9000 in this area? If so, are they being followed?

4.2.1 *Documentation requirements: General*

- Are 'documents' required to plan, operate and control the business included in the documentation?
- Are the minimum records required retained?
- Are the minimum required Procedures documented?

4.2.2 *Documentation Requirements: Quality manual*

- Does the quality manual contain justified and permitted exclusions?
- Does it contain or reference Procedures?
- Does it contain an accurate description of the interaction between the processes?

4.2.3 *Documentation Requirements: Control of Documents*

- Is the unintended use of obsolete documents prevented and are they identified if retained?
- Are external documents identified and suitably controlled?
- Are relevant versions of applicable documents available at point of use?
- Are changes identifiable and is the current revision identifiable?

Audit Report No 33

Standard: ISO 9001: 2000
Quality Management Systems - Requirements

Audit Period Jan 08 to Dec 08

Auditor Chris Pearce

Audit Period Jan 08 to Dec 08

Dept/Function Documentation processes

Person Responsible Terry Weedon

People Seen

Are documents approved before issue and re-issue?

Are there controlled Procedures covering these issues?

4.2.4 ***Documentation Requirements: Control of records***

Are sufficient records kept to provide evidence of conformity to requirements?

Do records remain legible, readily identified and retrievable.

Is there a Procedure for records retention and computer data backup?

Does it cover controls for identification, storage, protection, retrieval, retention time and disposition?

Is computer data retrievable in the event of a disaster?

Audit Report No 33

Standard: ISO 9001: 2000
Quality Management Systems - Requirements

Audit Period Jan 08 to Dec 08

Auditor Chris Pearce

Audit Period Jan 08 to Dec 08

Dept/Function Documentation processes

Person Responsible Terry Weedon

People Seen

Records Seen

--

Discrepancies/Suggestions

Clause No **Agreed By** **Root cause**

Discrepancies/Suggestions	Clause No	Agreed By	Root cause

Corrective & Preventive Actions

Details	Responsible for Action	Due date

Root cause

Completion history

--

- 1 Process improved, Procedure not yet updated.
- 2 Defined Procedure not being followed and should be.
- 3 Training issue
- 4 Mandatory Procedure does not include this step and should.
- 5 Process does not require written documentation and should.
- 6 Isolated Incident
- 7 Records not being kept and should be.
- 8 Violation of legal/customer requirement.
- 9 Nobody responsible for essential activity
- 10 Other

Signed

Date

Audit Report No 33

Standard: ISO 9001: 2000
Quality Management Systems - Requirements

Audit Period Jan 08 to Dec 08

Auditor Chris Pearce

Audit Period Jan 08 to Dec 08

Dept/Function Documentation processes

Person Responsible Terry Weedon

People Seen