4.1.1 Quality Policy

In addition to being relevant to the customer's needs, it will now be applicable to organisational goals and your customer's expectations.

Moreover, there will be a requirement for executive responsibility, to ensure total commitment from management.

4.1.2.1 Responsibility and Authority

Planning of resources now applies to management, performance and verification of work and not just to verification resources. In addition to the product itself, it also includes responsibility for prevention and recording of process and quality system problems.

4.1.2.2 Resources

There is now a need to include trained management and staff, in addition to verification resources. Requirements for independence of personnel, conducting review audits, etc, are not now included in this clause, but are stated in the appropriate activity sections.

It is not anticipated that this change will result in alternative assessment methods to check for adequacy of resources. If there is a resource related problem, it will manifest itself by affecting compliance to one of the other clauses.

4.1.2.3 Management Representative

There is now a responsibility for the management representative to report on the performance and status of the quality system. The use of a shared quality manager such as the Q-Share scheme would not be precluded, but the review of the total system lies firmly with the executive management.

4.1.3 Management Review

It is now made clear that this must be carried out by executive management. This review will take into account the stated quality policies and objectives. The frequency must be such as to maintain confidence, which may be different in each case. This will provide few problems for an organisation with a well structured review procedure.

4.2.1 Quality System (General)

There is now a requirement that the structure of the documentation shall be defined in the quality manual.

The quality manual will now be made mandatory, although it was always implied by the need for a documented system. This change should not cause many problems for most organisations. Reference is made to ISO 10013 which provides additional guidance on quality manuals.

4.2.2 Quality Systems Procedures

The procedures must now address both the standard and the quoted Quality Policy.

There is a refreshing reminder that the degree of documentation is dependent on the methods, skills and training.

4.2.3 Quality Planning

This has been taken from a note in the standard, altered to a requirement and brings no significant change. An effective Quality Management System would already have a facility for Quality Plans when appropriate. A Quality Plan for a simple product may only need to be an inspection sheet. When Quality Plans are contractually specified, they must be submitted to the customer.

4.3 Contract Review

Each accepted tender, contract and order, whether written or verbal, shall have its requirements defined and reviewed. How orders are communicated between customer and supplier needs to be established and documented as well as the mechanism to communicate amendments. This clause now refers also to orders received by verbal means.

4.4 Design Control

This section is not applicable to ISO 9002 and ISO 9003.

4.4.2 Design & Development Planning

Responsibilities are no longer identified, they are now defined.This is not a significant change.

4.4.4 Design Input

This must now include applicable statutory and regulatory requirements. This was previously mentioned in design output. There is a reminder that the results of the Contract Review be considered at this stage. This was always implied and creates little change in practice.

4.4.5 Design Output

This must be expressed in terms which can be verified and validated. Characteristics which are crucial to the product, eg storage, handling, disposal, etc, must be identified. Documents are to be reviewed prior to release. This is not a significant change and should not cause ISO 9001 organisations too many problems.

4.4.6 Design Review

Design reviews are now compulsory at appropriate stages and need to be formally documented. They must be systematic and involve all sections of the organisation which have an input to the product or service. Design reviews are currently mentioned as a means of design verification.

4.4.7 Design Verification

Designs should now be verified at appropriate stages and these verifications must now be recorded.

4.4.8 Design Validation

This is not a new requirement but emphasises that not only should the design output meet the design input requirements, but that the product should conform to defined user needs and/or requirements.

Notes associated with this clause indicate that the validation process should follow successful design verification (4.4.7), is normally under defined operating conditions, and is usually carried out on the final product. However, validation may be necessary at earlier stages and multiple validations may be performed. Typical methods of design validation might include prototyping, type testing, trial marketing (of services), modelling or commissioning (construction industry).

4.4.9 Design Changes

There are no significant changes. However, they must all be identified, documented and approved.

4.5.1 Document & Data Control (General)

This section now refers to documents and data which can be in any format, eg hard copy or electronic media.

A mention is now made about documents received from outside the organisation. Documented procedures should be established to control this requirement.

4.5.2 Document & Data Approval & Issue

Invalid and obsolete documents are to be removed. The retention of these for record purposes is allowed. All documents are to be reviewed and approved prior to issue to the relevant functions.

4.5.3 Document & Data Changes

Reference to re-issue of documents after a practical number of changes has been deleted. All changes, including those which are hand written, should be controlled in accordance with procedures.

4.6.1 Purchasing (General)

It now makes it clear that controls should be described in documented procedures. Purchased product is extended to include purchased services. Organisations must ensure their controls on the selection of subcontractors are covered by documented procedures and not just by a statement of policy.

4.6.2 Evaluation of Subcontractors

Subcontractors are now to be evaluated as well as selected. The extent of the control exercised will be dependent on the reported findings of the quality audits and/or their quality performance.

4.6.4 Verification of Purchased Product

This now includes for the organisation to verify the product or service at source as well as the customer.

4.6.4.1 Supplier Verification at Subcontractor's Premises

Arrangements for verification at the supplier's premises and method of release of purchased product must be specified in the purchase documentation.

4.7 Control of Customer Supplied Product

No significant change. The word "purchaser" has been replaced by "customer".

4.8 Product Identification & *Traceability*

It now states that the records shall provide a means of traceability. This change is for clarification only. This record should be traceable during all stages of production, delivery and installation.

4.9 Process Control

Controlled conditions now include for the maintenance of equipment which directly affects the product quality. For special processes, process parameters and qualified operators must be controlled. The procedures should state what type of maintenance is relevant to each piece of equipment, eg planned/breakdown, etc. Objective evidence will be required by the assessor to prove the maintenance has been carried out and would normally be expected, unless it can be demonstrated that there is no need for it.

4.10.1 Inspection & Testing (General)

This states that inspection and testing should now be identified and documented in the Quality Plan or Procedure.

4.10.3 In-Process Inspection & Testing

It no longer makes a specific reference to process monitoring and control. It does, however, put more emphasis on the inspection and testing of the product.

4.10.5 Inspection & Test Records

There is now a requirement in this clause for the authority of the conforming product to be shown prior to release. This was previously a requirement under inspection and test status.

4.11.1 Control of Inspection, Measuring & Test Equipment (General)

It is now made clear that software is to be included where it is used to demonstrate conformance.

4.11.2 Control Procedure

This contains no significant changes but reference is made to ISO 10012 which provides additional guidance on measuring equipment.

4.12 Inspection Test Status

The Inspection and Test Status of a product must be identified by a suitable means.

It is also made clear that inspection and test status should be identified during servicing. Examples of status indicators, however, have been deleted, eg tags, labels, etc, but the method to identify status must be included in the Quality Plan or Procedures.

4.13 Control of Nonconforming Product

No significant changes, except minor changes to the wording. Concessions for the customer to receive nonconforming products or services must be recorded.

4.14 Corrective & Preventive Actions

Now in two subsections. Preventive action is now defined separately instead of being regarded as an integral part of corrective action.

Customer complaints not only have to be analysed, but also handled effectively. Investigations are to take place on nonconformities in the quality system as well as in the product or service and process. Actions taken are to be submitted for management review. Although there appears to be additional requirements here, it should have a minimal effect on most corrective action systems as it is consistent with current interpretations. An aspect which may need organisations to review their existing procedures, however, is in 4.14.3 a) for procedures to include "the use of appropriate sources of information ..... to detect, analyse and eliminate potential causes of nonconformities".

4.15 Handling, Storage, Packaging, Preservation & Delivery

No significant changes except in format and wording. It now simply clarifies what was always required. Some simplification has been adopted such as "designating" storage areas rather than having to find "secure" storage space. Preservation is added, but has no significant ramifications.

4.16 Control of Quality Records

This includes a note reminding us of electronically held records. In addition, it will now be required to document procedures for the control of Quality Records, rather than simply to have them installed. This is not a significant change. All records should be legible and readily accessible.

4.17 Internal Quality Audits

It is made clear that audits must be planned as well as carried out. The ISO 9002 standard now has the same wording as ISO 9001. Reference is made to ISO 10011 which provides additional guidance on Quality Systems Auditing.

There is now also a requirement that procedures for planning and implementing internal quality audits are to be documented.

4.18 Training

No significant changes apart from existing procedures now have to be documented and there are no differences between the requirements in ISO 9001 and 9002.

4.19 Servicing

Servicing is now included in ISO 9002 as well as ISO 9001, but is only applicable where it is a specified requirement (in a contract). There are no significant changes to the content of this clause.

4.20 Statistical Techniques

Whereas there was previously only a requirement to establish procedures for identifying statistical techniques where applicable, the standard now calls for an organisation to identify the need for statistical techniques. Also there must be documented procedures to implement and control the application for statistical techniques. This clarifies what was previously implied.