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Secretariat of ISO/TC 176/SC 2

To the Members of ISO/TC 176/SC 2 - Quality Management and Quality Assurance/ Quality Systems

## Working Drafts of ISO 9001:2000 and ISO 9004: 2000

Please find copies of the above working drafts attached.

It is emphasized that these drafts are at an early stage of development, and are being issued to provide members with much needed early information on the future standards, as regards structure and scope. The introductory sections to the drafts have yet to be developed.

The specified role for the future ISO 9001 standard is "To provide confidence as a result of demonstration, in product conformance to established requirements." while that for the future ISO 9004 standard is "To achieve benefits for all stakeholders groups through sustained customer satisfaction."

It is intended that the standards will be generic in nature, allowing their use in such diverse sectors as hardware, software, processed materials and services.

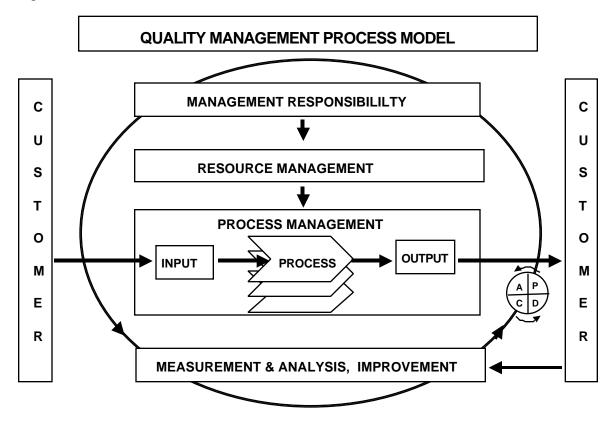
The standards are aimed to be a 'consistent pair'. The most apparent changes are the common structure of the two drafts based on a process model (see Fig. 1), and the use of the following main clause titles:

- Management responsibility
- Resource management
- Process management
- Measurement and analysis, improvement.

This takes account of the reality that many organisations have already redesigned their quality management system to be process-oriented.

The two Working Drafts are presented in a single document format, to demonstrate the 'consistency' between the future editions of the two standards.

Figure 1.



The proposed changes to the standards represent 'value added', especially in the areas of continuous improvement, customer relations and resource management.

This revision will significantly enhance the scope of the ISO 9004 quality management guidelines standard. Analysis of user needs for this standard have indicated that it should provide guidance that goes beyond the ISO 9001 quality assurance requirements, and should outline "stepping stones" for the establishment of a complete quality management system. The common structure of the pair of draft standards supports this approach by providing an opportunity for a 'seamless' progression beyond a basic quality management system .

This revision will also improve the compatibility of the ISO 9001 and ISO 9004 standards with the ISO 14001 and 14004 Environmental management systems standards respectively.

It is recognised that these revisions will change the 20 element structure of the present ISO 9001 standard. However, it must be stressed that the existing ISO 9001 does not specify requirements regarding the layout or structure of quality system documentation (e.g. it imposes no rules on the presentation of a quality manual), and neither will the future version. This will continue to allow an organisation to document its quality management system in a manner which reflects its own way of doing business rather than the structure of the standard, providing the technical requirements of the standard are met. It is intended that each of the current 20 elements will be clearly identifiable within the new structure.

The standards are being prepared using a project approach based on clearly established 'customer' needs, resulting in a task breakdown structure with well-defined tasks. Since November 1996 more than 20 task groups have been developing their assigned work on schedule. More recently (January 1998) several key task groups met to progress the drafting of the standards, to verify what was being drafted, to plan for validating that they had met their intended purpose, and to plan for the introduction of the revised standards into the market. This work is ongoing at the present time.