

Feedback on ISO 9001:2000



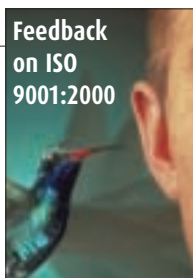
Worldwide round-up of early market reactions



ISO Management Systems presents an informal round-up of early reactions from the market to ISO 9001:2000, gathered from around the world with the kind assistance of ISO technical committee ISO/TC 176 Subcommittee 2, which developed the revised versions of ISO 9001 and ISO 9004.

The reactions do not represent “official” survey findings by TC 176/SC 2 – such an exercise needs more rigorous preparation and execution than was the case on this occasion. The round-up resulted from an appeal by the subcommittee secretariat to national delegations and organizations with liaison status to aid ISO Management Systems in composing a first, rough idea of market reactions in the first six to nine months of ISO

9001:2000. The round-up covers the range of user reactions since the feedback comes from a mix of accreditation and certification bodies and from local surveys of user organizations. Totals of certificates issued so far are given as indications and should be treated with caution as some double counting no doubt occurred. We would like to thank ISO/TC 176/SC 2, and all individuals and organizations who participated.



IQNet

The IQNet is an association of 29 certification bodies from around the world, with liaison status to ISO/TC 176/SC 2. Total estimated number of ISO 9001:2000 certificates issued by IQNet members at the end of August 2001 was 3 840.



Positive comments

“The new standard is very helpful in quality management system (QMS) implementation, not only in manufacturing industries but also for non-manufacturing sectors such as information technology and service companies, government bodies, etc. Above all, audits based on the process approach seem to enhance the effectiveness of audited QMS's. Customers get more value-added certification services.

“The process approach helps organizations eliminate complicated QMS documentation.

“ISO 9001:2000 is easier to apply in non-manufacturing industries, particularly in terminology and more relevant approaches.

“The degree of top management involvement becomes clearer because senior managers' responsibilities and roles are emphasized in the QMS.

“The standard provides the opportunity to view the complete management system. It is more closely aligned to the day-to-day practice of the general manager. All the requirements in the standard are 'common sense' and very close to 'normal' business.

“Sales and marketing departments accept the new standard better than the previous one.

“The revision of the ISO 9000 family of standards has introduced a new dynamic in the approach to quality systems and in certification processes. The open revision process

offers benefits to all interested parties, and the possibility of 'one time' analysis and comments on successive drafts.

“The process approach is one of the biggest changes in ISO 9001:2000 when compared with ISO 9001/2/3:1994.

“The new standard promotes the use of quality and management tools as such, and more flexibility when adopting these tools as a way of requirement fulfilment.

“The new standard is more generic than the previous edition and this allows organizations to be more flexible during QMS implementation. It also shifts the focus away from documentation and on to results and performance.”



Negative comments

“Many organizations have problems in understanding and complying with the requirements of ISO 9001:2000 because they see it as a quality assurance standard.

“Some difficulties were identified relating to:

- Correct interpretation of processes and controlling them through performance assessment.
- Assessment of customer satisfaction.
- Data analyses in those small companies that are not involved in batch production.
- Traceability between processes, targets, tasks and functions.
- Measurement of performance in design and development.
- Process management is considered a difficulty for many organizations.
- Many companies find it difficult to provide sufficient resources to carry out an effective transition process.

- Legal requirements are a problem for some organizations.
- New requirements and data collection (to support fact based management) present difficulties to many companies.

Asociación Española de Normalización y Certificación (AENOR)

AENOR, the Spanish national standards institute, which is an IQNet member, submitted comments independently.

“AENOR issued over 300 ISO 9001:2000 certifications by end October 2001, representing 16 % of all QMS certificates issued during 2001, the remaining 84 % were ISO 9001:1994 or ISO 9002:1994.

“A survey of 3 200 certified organizations was carried out regarding transition to ISO 9001:2000. The results are reflected in the following table:

Year planned for transition
to ISO 9001:2000

2001	2002	2003	No answer/ Don't know
9,6 %	49,9 %	19,4 %	21,1 %

“2002 is clearly the key transition year for many organizations. However, it is significant that 21,1 % have not decided when are they going to make the transition.”

Survey by Singapore Productivity and Standards Board (PSB)

The Singapore Productivity and Standards Board (PSB) is the country's national standards institute and a member of IQNet. Following is a summary of responses gleaned from a

PSB survey of local manufacturing and service companies on ISO 9001:2000 acceptance.



Positive comments

“The inception of a QMS process model in ISO 9001:2000 is a big leap forward in establishing a balance between customer focus and management aspects, and the operational elements of achieving quality. This model is well supported by five key clauses which describe all QMS requirements in a more organized and balanced manner than the 1994 version.”

(Respondent represents an electronics manufacturing company. One in five of its business units in Singapore has been certified to ISO 9001:2000.)

“ISO 9001:2000 places more emphasis on performance results and requires demonstration of continual improvement. This helps companies maintain continual improvement and achieve customer satisfaction. Flexibility in the requirement for documented procedures is a welcome change. The standard also provides a link to world-class model like the Singapore Quality Award.”

(Respondent is a Singapore Quality Award recipient from an ISO 9001:2000 certified electronics manufacturing company.)

“ISO 9001:2000 is commercially oriented and more customer focused and addresses the need for continuous improvement. Its emphasis is on preventive rather than corrective actions.”

(Respondent is an ISO 9002-certified paint manufacturer.)





“Positive elements of ISO 9001:2000 are:

- focus on customer satisfaction;
- top management involvement and commitment;
- measurable quality objectives;
- it requires not only that customer requirements are met but, also that opportunities for improvement are identified;
- audit of integrated processes.”

(Respondent represents a local taxi company that expects to complete transition to ISO 9001:2000 in a year's time.)



Negative comments

“The lack of an updated auditing standard corresponding to ISO 9001:2000 has limited the effectiveness of auditors (both external and internal) in helping organizations realize the added value of the major 2000 version update. Many auditors, especially external, are extrapolating from their experience and understanding of ISO 9001:1994. Many are very concerned about not seeing sufficient documented evidence of such elements as Management commitment, Customer satisfaction and Continual improvement.

“Clause 8, Measurement, analysis and improvement, is still not completely balanced and is rather vague in many respects.

“8.2.1 Customer satisfaction: while there is no prescribed method of determining customer perception of the organization with regard to meeting their requirements, external auditors seem to be uncomfortable with anything other than the conventional customer survey approach. Isn't it also possible to get feedback from sales and service personnel who deal directly with customers – an equally effective measure of customer satisfaction/perception?

“8.3 Control of non-conforming product seems to be part of improvement, yet this subclause seems out of place between 8.2 Monitoring and measurement and 8.4 Analysis of data.

“8.5.1 Continual improvement is too brief to shed any useful light on how and to what extent organizations are expected to implement it.

“As much as corrective action and preventive action are improvements in effect, the related process/procedures to implement them are also monitoring and measurement in effect.

“With the major swing from the ‘production-based’ ISO 9000:1987/1994 versions to the comprehensive ‘management-based’ ISO 9000:2000 standards, external auditors are overwhelmed at the prospect of auditing and certifying organizations and accounting to their own accreditors. Auditors tend to be more concerned about searching for tables of management data to use as accountability data for their own accreditors than learning about the organization's approach to management, be it commitment or understanding customer requirements or Plan-Do-Check-Act improvement.”

(Respondent represents the same electronics manufacturing company with one ISO 9001:2000-certified business unit.)

“Only six mandatory documented procedures are required by ISO 9001:2000. The remaining process operating documentation needs are mainly dependent on the complexity of the process and competency of the operator. This could result in dispute between auditor and auditee as the deciding criteria are very subjective.”

(Respondent is from the aerospace industry.)

“I would like to see documented procedures for all identified and required quality management system processes re-instated in ‘company-

level process approach'. This would ensure that organizations have clearly defined and robust QMS processes with a roadmap of processing details. Also, that they would operate as a focused team in order to continually and dependably satisfy customer requirements.

“The aim of ISO 9001 should be to help organizations realise its implementation benefits without stepping back into informally required processes. This can lead to the mistaken impression that a process approach is being achieved, while in reality following pre-ISO 9001 practices. ISO 9001 and its audit process must motivate organizations to make the standard work for them. Unfortunately, the reverse is often the case today, thus rendering ISO 9001 an ineffective quality tool while encouraging companies to window dress their quality system in order to retain or make sales.”

(Respondent is a practising consultant.)

ited by IAF members as of 31 August 2001.

The comments collated by the IAF come from a mix of national accreditation bodies, certification bodies and other actors in the “ISO 9000 industry” and are listed by country.

CANADA – BTA Inc.

“In my recent experience, I met several managers and company representatives who were sceptical about ISO 9000:1994 after three to four years' experience with the old standard. They have fundamentally and positively changed their views of ISO 9001:2000 since understanding the key elements and framework of the new standard.”

CHINA – CNAB

Response based on 546 ISO 9001:2000 certifications:



Survey carried out by International Accreditation Forum

The membership of the International Accreditation Forum (IAF) includes 36 national accreditation bodies, which accredit certification bodies as competent to carry out ISO 9000 certification. A total of 8 352 ISO 9001:2000 certificates had been issued by certification bodies accred-



Positive comments

“ISO 9001:2000 has greatly facilitated certification, it is more adaptive and operable.

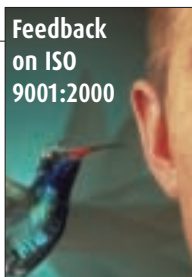
“Implementation of ISO 9001:2000 is very helpful in improving the effectiveness of quality systems.



Negative comments

“Auditors face greater challenges and are required to be more competent and better qualified.

“Some certification bodies think it is difficult to use the process approach during site assessment and question to what extent it should be demonstrated in audit documents. There is call for a guidance document on this issue so as to improve the effectiveness of ISO 9001:2000 audits.



[Editor's note: ISO/TC 176 has developed the document, *Guidance on the Process Approach to Quality Management Systems*, which is posted on ISO's Web site, along with other guidance material on implementation of the ISO 9000:2000 series.]

CZECH REPUBLIC – EZU *(Elektrotechnický ústav, s.p.)*

Response based on two ISO 9001:2000 certifications:



Positive comments

“The new standard is accepted very well by company management, particularly the visions and targets, measuring results of company performance and evaluation of people and training. The system is much better accepted by sales and marketing departments.”



Negative comments

“The following are seen as difficulties presented by ISO 9001:2000:

- the correct interpretation of processes and their control through performance assessment;
- the assessment of customer satisfaction;
- data analyses in small companies involved in single unit production or assembly, and not mass production;
- achieving accurate and valuable traceability between processes, targets, tasks and functions.
- measuring performance in design and development.”



FINLAND – Centre for Metrology and Accreditation (FINAS)

Response based on 92 ISO 9001:2000 certifications:



Positive comments

“Companies have accepted the new standard positively – it has become more up to date, and more appropriate for management.

“It is easier to link ISO 9001:2000 to environmental and safety standards.”



Negative comments

“One problem for companies has been the pressure to implement the new standard and achieve certification. The conclusion is that the benefit in many cases has been modest.”

GERMANY – DEKRA Certification Services (DCS) GmbH

Response based on 300 ISO 9001:2000 certifications:



Positive comments

“New ISO 9001:2000 has a better structure (process oriented) and is more logical. The requirements still leave room for discussion and interpretation, although the ISO guidance documents are very helpful aids to understanding and applying the new standard.”



Negative comments

“We and our clients still have some difficulties in determining the application of the standard in companies that lack certain departments, or have processes outside the scope of the QMS.

“Lack of support by the accreditation body concerning the timely introduction of the new standard, its interpretation and application (e.g.

we had to develop a procedure for performing upgrade audits by ourselves).

“The correct interpretation of certain requirements of the standard (e.g. continuous improvement or customer satisfaction) is still a problem for some clients and auditors. Although we developed a general interpretation of the standard we still have interpretation problems.”

DIN VSB Zert Zertifizierungsgesellschaft mbh Verkehr Systeme Bahnen

Responses received from DIN were in question and answer format:

Q1. *Have there been any public reactions (e.g. press articles, TV debates, communiqués by industrial associations) to the ISO 9000:2000 series? To what extent are opinions for or against?*

A. “There are many public reactions – mostly for, but also against – and some indicate that they haven’t yet understood.”

Q2. *How easy, or difficult are organizations finding implementation of ISO 9001:2000?*

A. “I can only draw from my personal auditing experience. Companies did not find ISO 9001:1994 as difficult to implement as it was sometimes thought to be. Therefore the leeway for making ISO 9001:2000 easier is not as big as some people think.”

Q3. *Are organizations implementing ISO 9000 and ISO 9004, or just ISO 9001?*

A. “Mostly they use only ISO 9001.”

Q4. *Are organizations using the quality management principles and what benefit does this bring?*

A. “The use of the quality management principles in practice is very rare.”

DVS Zert e. V

Response based on four ISO 9001:2000 certifications:

“Many companies that are already certified to the ‘old’ standards are reluctant to change since the transition needs time and money. Such work is often carried out beside normal business activities (especially in smaller companies). Business activities in most cases take precedence.”



Gütegemeinschaft Kalkstein, Kalk und Mörtel e.V., GG Zert

“We do not yet have an ISO 9001:2000-certified client, we anticipate the first certifications in 2002. So far, only a few comments about the new 2000 version, mostly positive.”

SKZ-Cert GmbH Zertifizierungen

Response based on 11 ISO 9001:2000 certifications:

(It should be noted that most SKZ customers are plastics industry companies with 2-50 employees.)



Positive comments

“In January 2001, we had a lot of re-certifications of existing ISO



9001:1994 certifications. Reduction in documentation generates the most positive comment about the new standard."



Negative comments

"The following are seen as negative aspects:

- data analyses of customer satisfaction;
- management review output (improvement of product related to customer requirements);
- evaluation of training effectiveness;
- criteria for selection and evaluation of suppliers and recording results of evaluations. (It is standard practice in the plastics industry to refer the supplier to the customer. So there is normally little opportunity to change the supplier;
- review of corrective actions taken. There is frequently no documentation;
- review of preventive actions taken.

"One comment received from a management trainer was that ISO 9001:2000 lacks the element of 'social competence'."

Materialprüfungsamt Nordrhein-Westfalen (MPA NRW)

Response based on five ISO 9001:2000 certifications:

"Our experience with the transition from the 1994 to the 2000 version is that most of our customers wish to use the whole transition period." [Editor's note: three years from the publication of ISO 9001:2000 on 15 December 2000]

ÖHMI EuroCert e.V.

Response based on four ISO 9001:2000 certifications:



Positive comment

"The firms certified by us accept the standard in a positive way as a matter of principle."

INDONESIA - Badan Standardisasi Nasional (BSN)

Response based on 47 ISO 9001:2000 certifications:



Positive comment

"ISO 9001:2000 is considered simple, generic, flexible, suitable for small businesses and consumer-focused organizations.



Negative comments

"ISO 9001:2000 has been found difficult to translate into a business process, process flow is difficult to trace and the clause is not clearly expressed (especially in product realization)."

JAPAN - The Japan Accreditation Board for Conformity Assessment (JAB)

JAB had certified 404 organizations to ISO 9001:2000 by 31 August 2001, but the comments below are drawn from the results of a recent JAB survey. "The Status of Efforts Among Conforming Organizations to Comply with ISO 9000:2000" (which can be downloaded from JAB Web site www.jab.or.jp), based on responses from 853 conforming organizations.

Comments and observations

"Among the new requirements (of ISO 9001:2000), by far the largest group of organizations cited 'continual improvement' as the most important to satisfy when restructuring the existing system."

Regarding input data appropriate for improvement of processes, the large majority of correspondents cited 'customer requirements and

their feedback' – a clear sign of the general trend of customer focus.

Regarding the introduction of the process approach, 45 % replied that "since the concept of the process approach is not clear, we will undertake some research first and then determine if any change to the QMS is required or not".

Regarding the question of greater top management responsibility, approximately 70 % considered they "need more management participation than before".

Expectations of ISO 9001:2000

Over 50 % of the JAB survey respondents expect ISO 9001:2000 will help to achieve "improvement of the efficiency and performance of the organization thanks to the process approach", and by "more involvement of top management, further dissemination and animation within the organization", compared with ISO 9001:1994.



Negative comments

Less than 20 % gave a positive evaluation of assessment based on the 2000 edition, and 30 % stated "since the requirements of ISO 9001:2000 are generic in expression, there is a concern about differences between assessments", implying the need for greater uniformity among certification bodies, or auditors, and in training of auditors, and assurance of their expertise and competence. Also, and in particular, the need was emphasized to eliminate variation in the evaluation methods of the demonstration of continual improvement of the QMS.

According to JAB, "The survey made it clear that, in order for a third party certification scheme to retain its credibility and continue to have its value recognized in the market-place, it is necessary to make continued efforts to improve the quality of certification. This includes ensuring disclosure of assessment methods rele-

vant to the new requirements of the 2000 edition, supplying appropriate information at the right time regarding the transitional arrangements, offering a better support system for its introduction and continuing this support even after the introduction of the new International Standard".

NORWAY – Norwegian Accreditation (NA)

Response based on 30 ISO 9001:2000 certifications:



Positive comment

"There have not been many comments on the new standard so far, but most of them are positive, especially about the focus on processes."



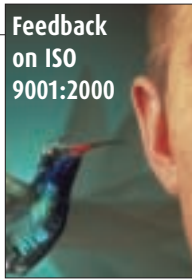
PHILIPPINES – Government Department of Trade and Industry, Bureau of Product Standards (BPS)

Response based on 32 ISO 9001:2000 certifications:



Positive comments

"There is a smooth transition among certification bodies since the audit procedures had been well defined. Client companies have also been moving from the 1994 version to Final Draft International Standard, and then later to the 2000 version.



“The questions or clarifications received from client companies provide a good learning experience.

“The involvement and commitment of senior management is very evident among companies implementing ISO 9001:2000.

“Customer enhancement is very much the focus and companies are working hard to find ways to exceed their customer's expectations.

“Companies are taking a positive approach where the supplier-organization-customer chain will benefit.

“The new version is beneficial to companies because it is based on a practical approach.

“ISO 9001:2000 is simple, clear and easy to understand and requirements are explicitly laid out. Its compatibility with other systems standards facilitates system integration.

“It is supportive of continual improvement, and is business and process oriented.”



Negative comments

“Some ISO 9001:1994-certified companies are a little confused about the requirements of the new standard.

“ISO 9000:1994 users complain that upgrading the system takes much time and resources, including the need for new training and hiring of consultants.

“As observed during a company audit, the approach was to align the documentation according to the new version. However, separate procedures specific to a particular section were written that in essence were still not system based. The implementation was seen to be section-specific, so that cross-reference with other sections was not carried out. Possibly, the concept of the process or system approach was not well understood and that ISO 9001:1994 is still very

much in place. Perhaps the process did not clearly show departmental inter-relationships, nor the inflow and outflow of information from one section to the next – the basis of the process approach.

“ISO 9001:2000 is more difficult to maintain, since it requires real commitment as a result of changes in customer requirements.

“There is some difficulty in determining or differentiating process orientation from operations, especially in the case of small companies.

“There is the question of, ‘How will the process be followed when there is less documentation in ISO 9001:2000 compared with the 1994 version’?

“ISO 9001:2000 focuses more on an organization having a business plan, while many organizations that do not have such plans.

“Environmental concern is not easy to see in ISO 9001:2000.

“When resources are limited, implementation can become difficult and possibly delayed.”

SWEDEN – SWEDAC

Response based on 50-100 ISO 9001:2000 certifications:

“4 500 ISO 9000:1994 certificates issued. We have not yet received any substantial comments about the 2000 edition.”

SWITZERLAND – Metas

Response based on 1 000 ISO 9001:2000 certifications:

“Experience so far seems to be positive, no particular point to note.”

**UNITED KINGDOM – Association of
British Certification Bodies (ABCB)**

ABCB members had issued 952 ISO 9001:2000 certificates by 31 August 2001.

*Positive comments*

“The standard is viewed favourably by organizations and the take-up is increasing.

“The standard has received a favourable reception from the more ‘quality minded’ organizations, but a fallout of some 5 % to 10 % of companies currently certified to ISO 9000:1994 is forecast.

“Organizations are commenting that the process approach of the new standard is effective in their business operations.

“The take up of the new standard in the Far East is more rapid than elsewhere.

“There is significant Far East interest in adoption of the new standard among organizations which are not currently certified to ISO 9000:1994.”

*Negative comments*

“There is an impression among organizations that the new standard is more suitable for ‘service sector’ companies.

“There is a reluctance among smaller organizations to adopt the new standard and many are staying with the 1994 version. Larger organizations are more willing to move to ISO 9001:2000.

“There is no great interest in ISO 9001:2000 among North American organizations currently certified to the 1994 version. Many seem to be waiting until the last minute before seeking to adopt the new standard.”

**ZIMBABWE – Standards Association
of Zimbabwe (SAZ)***Positive comment*

“The new ISO 9000:2000 editions were received with much enthusiasm as evidenced by the number of sales to date which far exceed our expectations and continue to soar.

“We have run several awareness courses on the new versions of ISO 9000 and the attendance was overwhelming. Many organizations have drawn up transition plans and some have already documented their QMS in accordance with ISO 9001:2000, and are ready to be audited.

“Judging from these events we can confidently say that the new ISO 9000:2000 editions have received considerable acceptance.”

