

Implementing ISO 9001:2000 – US survey of user experiences

Results are in from a survey developed by the US Technical Advisory Group to ISO/TC 176 quantifying the experiences of 227 US organizations implementing ISO 9001:2000, most having made the transition from ISO 9000:1994. Little or no increase in certification costs was reported, and customer satisfaction, quality of products and services and improved productivity were revealed as key bottom line improvements of ISO 9001:2000 implementation.

This article reviews the major results of a new survey aimed at providing quantifiable measurements of the experiences of organizations implementing the ISO 9001:2000 quality management system (QMS) standard. The survey was central to a product support initiative (PSI) developed last year by the US Technical Advisory Group to ISO technical committee ISO/TC 176, *Quality management and quality assurance*.

The survey findings are based on responses from 227 organizations, 44 more than the basis for an earlier article published in *Quality Progress*¹⁾, of which this is an update integrating the fresh data. It should be noted that 17% of respondents had not previously been certified to the ISO 9001/2/3:1994 versions of the standards. From the data gathered, we expect to obtain an understanding of the major conformity challenges and provide guidance for future revisions of the standard.

The major survey findings are as follows:

- The top five areas of nonconformity were: customer satisfaction data and assessment, documentation, continual improvement, collection and analysis of data and non-measurable objectives. These conformity gaps were revealed by

comparing the structure and function of an organization's QMS with the requirements of ISO 9001:2000.

- The clauses of ISO 9001:2000 considered difficult to comply with generally reflected those top five gaps, except the second most difficult, which was 6.2.2 *Competence, awareness and training*.
- During implementation, 81 % of the organizations did not use the four guideline documents²⁾ developed by ISO/TC 176 to aid in the implementation of ISO 9001:2000.



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The survey findings are based on responses from 227 organizations

- Training courses focused on overall transition and customer satisfaction data and assessment. One unexpected result was that more than half the respondents offered courses on the eight quality management principles on which the ISO 9000:2000 series is based.
- Most organizations did not report an increase in registrar (certification body) costs.
- The most commonly identified

Notes 1) and 2), see overleaf.

benefits of management systems were the increased use of data as a business management tool, greater management commitment, improved customer satisfaction and communication, and more efficient management reviews.

- Bottom line improvements observed were customer satisfaction, quality of products and services, and improved productivity.
- The “collection and analysis of data” and “objectives not measurable” gaps were larger for non-manufacturing organizations than for manufacturing ones, while the reverse was true for “competency requirements”.
- The gaps in “objectives not measurable” and “collection and analysis of data” were higher for small and medium-sized organizations than for large organizations.

Gap analysis

Gap analysis can be carried out at four points in the conformity timeline:

1. Initial gap analyses.
2. Internal audits.
3. Pre-assessments.
4. The certification assessment.

The survey team asked for combined information on the internal audits and pre-assessments because many organizations were not pre-assessed.

Participants were asked to indicate their major conformity challenges from the following 13 categories: exclusions, documentation gaps, record-keeping gaps, customer satisfaction data/assessment, effective control of processes, continual improvement process, non-measurable objectives, objectives not consistent with quality policy, collection

and analysis of data, competency requirements, top management commitment and responsibilities, management of outsourced processes and other key issues. **Table 1** contains a summary of the results of this analysis for the most frequently mentioned categories. The numbers in parentheses are the category rankings.

**17 % of respondents
had not previously
been certified**

Requirements affecting gaps

We asked organizations to identify which of the 51 numbered ISO 9001:2000 sub-clauses caused most difficulty in terms of developing a process, in documenting or implementation. The results are summarized in **Table 2**. Entries in the first column are ranked in order of the percentage of organizations indicating process, documentation or implementation difficulties with the sub-clause. Those associated with each major gap are identified as follows.

Customer satisfaction data analysis

Ranked first in difficulty was sub-clause 8.2.1 *Customer satisfaction* requiring an organization to “monitor information relating to customer perception as to whether the organization has met customer requirements”.

Documentation

The sub-clauses to clause 4.2 *Documentation requirements* are 4.2.1 *General*, 4.2.2 *Quality manual*, and 4.2.3 *Control of documents*. These were not ranked as difficult.

Continual improvement

Sub-clause 8.5.1, the key requirement for continual improvement, was ranked fifth in difficulty to document, but not ranked as difficult to comply with or implement. This sub-clause requires the organization to create an improvement loop to “continually improve the effectiveness of the quality management system”.

1) “ISO 9000:2000 Experiences: The First Results are in”, by the author and Jim Mroz of *THE INFORMED OUTLOOK*, appeared in the April 2002 issue of *Quality Progress*, pp 52-59, published by ASQ Quality Press. The author wishes to acknowledge Jim Mroz’s efforts in developing that paper, of which this article represents an update integrating new data.

2) The four guideline documents are available free of charge on the ISO Web site: www.iso.org. *Guidance on ISO 9001:2000 clause 1.2 ‘Application’*, *Guidance on the Documentation requirements of ISO 9001:2000*, *Guidance on the Process Approach to quality management systems*, and *Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000*.

In clause 5.1 *Management commitment*, top management has the responsibility continually to improve the QMS. However, though sub-clause 8.5.1 is the responsibility of top management, it is not stated as such. This may be a point for ISO/TC 176 to note: *sub-clause 8.5.1 should belong to Section 5 as the defined responsibility of top management.*

Collection and analysis of data

Customer satisfaction data and assessment was the top ranked issue. The directly related sub-clause is 8.4 *Analysis of data* which requires an organization to “determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system”. This requirement was ranked third in difficulty.



Finding	Initial gaps	Internal audits and pre-assessments	Most extensive corrective actions	Registrar non-conformities
<i>Customer satisfaction data and assessment</i>	56 % of Organizations (1) *	39 % of Organizations (1)	36 % of Organizations (1)	7 % of Organizations (5-6)
<i>Documentation gaps</i>	47 % (2)	34 % (2)	29 % (3)	23 % (1)
<i>Continual improvement process</i>	43 % (3)	28 % (3)	30 % (2)	9 % (4)
<i>Collection and analysis of data</i>	32 % (4)	22 % (5)	22 % (5)	6 % (7-8)
<i>Objectives not measurable</i>	31 % (5)	25 % (4)	19 % (7)	10 % (2-3)
<i>Top management commitment and responsibility</i>	28 % (6)	20 % (6-7)	21 % (6)	10 % (2-3)
<i>Competency requirements</i>	22 % (8)	13 % (8-9)	11 % (9)	4 % (9)
<i>Record keeping gaps</i>	24 % (7)	20 % (6-7)	17 % (8)	6 % (7-8)
<i>Effective control of processes</i>	21 % (9)	13 % (8-9)	23 % (4)	7 % (5-6)

Table 1:
Identification of gaps and findings

* The numbers in parantheses are the rankings of each finding for each of the gap analyses.

Customer satisfaction data and assessment was ranked first for all of the gap analyses except for registrar non-conformities where it tied for 5th and 6th.



Sub-clause: % of participants (rank)	Corresponding finding
8.2.1 Customer satisfaction 30 % (1); 21 % (1); 25 % (1)*	Customer satisfaction data and assessment
6.2.2 Competence, awareness and training 24 % (2); 15 % (4); 21 % (2)	Competency requirements
8.4 Analysis of data 20 % (3); 17 % (2); 18 % (3-4)	Collection and analysis of data
8.5.3 Preventive action 17 % (5); 16 % (3); 18 % (3-4)	Continual improvement process
5.4.1 Quality objectives 13 %; 6 %; 15 % (5)	Objectives not measurable
8.5.1 Continual improvement 11 %; 12 % (5); 9 %	Continual improvement process
7.3.1 Design and development planning 18 % (4); 11 %; 14 %	Other

* Percentages, with rankings in parentheses, respectively indicate: (1) difficulty in developing a compliance process, (2) difficulty in documentation and (3) difficulty in implementation.

Table 2: Most difficult sub-clauses for which to develop a process, document and/or implement.

Non-measurable objectives

Sub-clause 5.4.1 *Quality objectives* relates directly to this issue. Top management is responsible for establishing objectives and ensuring they are measurable. In the rankings, this sub-clause was not rated as difficult except for implementation.

Competency

One possible anomaly is “competency requirements” which was ranked between sixth and eighth in the stages of gap analysis, while sub-clause 6.2.2 *Competence, awareness and training* was ranked second in difficulty. That sub-clause requires an organization to “evaluate the effectiveness of the actions taken”, which may be the major difficulty.

Implementation

The first step: closing gaps

The gap analysis and closing of gaps are the critical first steps to implementing any management system. The percentages of respondents using the four methods of gap analysis were:

- organizations conducting their own gap analysis – **68 %**;
- gap analysis carried out by a consultant – **23 %**;
- ISO 9001:2000 pre-assessment by a registrar – **27 %**;
- the organization used another means – **13 %**.

Gains: unexpected and not achieved

While responding to the results of the gap analyses, some organizations indicated the following unexpected gains:

- One third implemented QMS improvements not required by ISO 9001:2000.
- One quarter deleted or combined processes during QMS implementation to take advantage of the process approach model promoted by ISO 9001:2000.

On the other hand, respondents disclosed that an expected benefit of ISO 9001:2000 – the ability to reduce QMS documentation – was not being widely achieved. Only 22 % reported

reducing the volume of documentation; 44 % had about the same volume, while 34 % had actually increased their documentation.

Implementation aids

The ISO 9001:1994 to ISO 9001:2000 transition in many organizations also involved the use of implementation aids, including the four guideline brochures developed by ISO/176, although 81 % indicated they did not use any of the four.

Other implementation aids and their level of use were:

- sample quality manuals and documentation – **58 %**;
- handbooks – **55 %**;
- materials such as articles, books, courses and presentations – **24 %**, and
- computer programmes – **18 %**.

Training

Training was a critical factor in ISO 9001:2000 implementation for most organizations. The following types of training were provided by respondents:

- ISO 9001:2000 transition – **76 %**;
- quality management principles – **52 %**;
- customer satisfaction – **41 %**;
- data gathering and analysis – **33 %**, and
- customer contact – **16 %**.

Two points need noting about training. Firstly, it tends to address two major gaps – customer satisfaction, and collection and analysis of data. Secondly, a large proportion of the organizations provided training on the eight quality management principles.

Auditing and certification

Auditor training

We asked how much total time the internal auditors spent in attending training. In response, most organizations revealed that they spent fewer than six person months training their auditors.

Transition training was provided by 67 % of organizations; 41 % provided ASQ³⁾ certified quality auditor training, and 20 % offered internal auditor or lead auditor training.

Certification

Respondents were asked how many auditor days were required to become certified to one of the ISO 9000:1994 series of standards, and how many additional days were necessary for transitioning to ISO 9001:2000. For the 1994 versions, approximately 5 % cited one day, 30 % – two days, 27 % – three days, 18 % – four days, and 20 % – five or more days.

Interestingly, for transition to ISO 9001:2000, 35 % reported no additional days required, 22 % reported one added day, 23 % reported two, and 20 % reported three or more additional days.

Concerning auditor days for new ISO 9001 registrations, 39 % indicated that only one to two auditor days were used by the registrar, while the remainder indicated an approximately even spread for three (19 %), four (20 %) and five or more (22 %).

Cost/benefit analysis

A total of 73 % of respondents reported no added registration (certification) costs for the transition from ISO 9001/2/3:1994 to ISO 9001:2000.

Cost of compliance

It is important that an organization compares the transition from the

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Staff resource expenditure	Transition	Maintenance
Less than 1 person-month	7 %	14 %
1-6 person-months	32 %	49 %
6-12 person-months	32 %	25 %
12-24 person-months	19 %	6 %
24-48 person-months	7 %	6 %
More than 48 person-months	4 %	1 %

Table 3: Transition and maintenance costs for ISO 9001:2000

ISO 9000:1994 standards to ISO 9001:2000 on the basis of savings, return on investment and improvement. In the survey, we asked several questions about the cost of transitioning and benefits of compliance.

Two examples of estimated costs were the staff time (excluding training time) used to achieve conformity, and to maintain the QMS.

Table 3 shows a distribution of transition and maintenance costs. The results indicate that maintenance cost was generally less than the cost of transition.

Benefits of conformity

What about benefits? While it is too early to see cost benefits in most companies, 21 % reported savings and, of these, 82 % indicated that the transition and implementation costs were at least covered by the savings.

While the survey sample size should not necessarily be considered statistically valid, the following list of benefits delighted the PSI team:

- use of data in business management – **56 %**;
- increased management commitment – **56 %**;
- improved customer satisfaction – **54 %**;
- more effective management reviews – **51 %**, and
- improved customer communication – **41 %**.

Survey respondents were asked to indicate whether making the transition to ISO 9001:2000 from a 1994 version, or newly implementing the standard and pursuing certification had produced any of six bottom line improvements. **Table 4** illustrates the percentages of respondents who answered “yes” to questions regarding these improvements. Those responding “unsure” were not included in the total count.

**Bottom line
improvements observed
were
customer satisfaction,
quality of products
and services,
and
improved productivity**

Comparison of different types of organization

Comparisons of information provided by respondents considered (1) manufacturing versus non-manufacturing organizations, and (2) the size of the organization.

Manufacturing versus non-manufacturing

Table 5 compares the following gaps and findings: (1) collection and analysis of data, (2) objectives not measurable and (3) competency requirements. Non-manufacturing organizations represented the larger percentages in the first two cases, while manufacturers found more difficulties in the area of competency requirements.

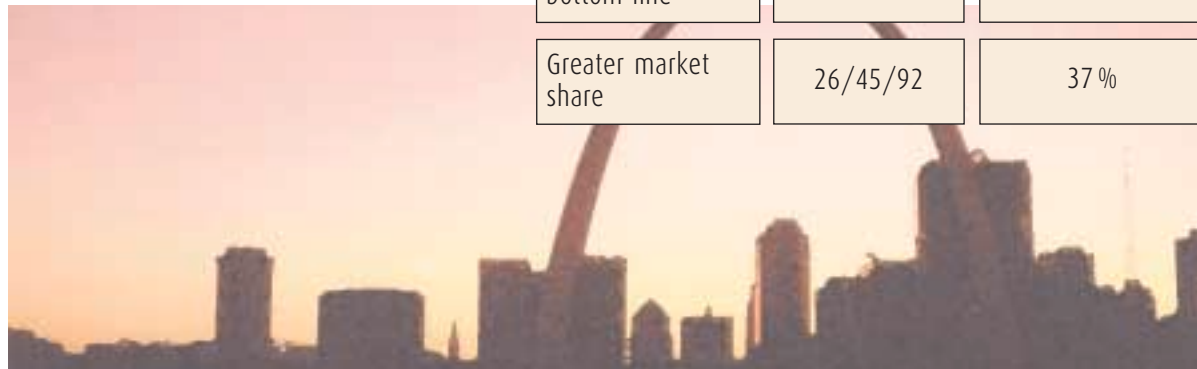
One quarter of organizations deleted or combined processes during QMS implementation to take advantage of the process approach model

A comparison of most difficult clauses supports the first two results in Table 5. However, **Table 6** summarizes the results, and shows no difference between manufacturing and



Improvement	Responses	Respondents answering "yes"
	yes/no/unsure	
Customer satisfaction	64/32/73	67 %
Quality of products/services	55/42/68	57 %
Improved productivity	52/34/79	60 %
Retained customers	38/37/89	51 %
Improved bottom-line	35/38/91	48 %
Greater market share	26/45/92	37 %

Table 4: Bottom line improvements related to ISO 9001:2000 transition or implementation.



Finding: % of participants	Initial gaps	Internal audits and pre-assessments	Most extensive corrective actions	Registrar non-conformities
<i>Collection and analysis of data</i>	28 %/40 % *	23 %/21 %	24 %/20 %	2 %/13 %
<i>Objectives not measurable</i>	30/32	17/42	13/28	6/17
<i>Competency requirements</i>	26/15	17/4	16/4	4/4

Table 5: Identification of gaps and findings Comparison of manufacturing and non-manufacturing

* Manufacturing/Non-manufacturing



Sub-clause: % of participants	Corresponding finding
8.4 Analysis of data 18 %/24 %; 16 %/18 %; 12 %/25 %*	Collection and analysis of data
5.4.1 Quality objectives 10/18; 2/12; 12/19	Objectives not measurable
6.2.2 Competence, awareness and training 24/23.5; 14.3/14.7; 20.8/21.9	Competency requirements

* Manufacturing/Non-Manufacturing for (1) difficulty to develop a compliance process for the sub-clause, (2) difficulty to document and (3) difficulty to implement.

**A total of 73 %
of respondents reported
no added registration
(certification) costs for
the transition**

non-manufacturing in relation to the third clause, 6.2.2 *Competency, awareness and training*.

Comparison by size of organization

Table 7 is a comparison of gaps and findings for (1) measurable objectives and (2) collection and analysis of data. Small and medium-size organizations had more difficulty with both. The results in Table 7 were supported by the difficult clauses data in **Table 8**.

Table 6: Most difficult sub-clauses for which to develop a process, document and/or implement

Comparison of manufacturing and non-manufacturing

What's next?

The PSI team's plans for the future include publishing updated results of the survey, developing case studies and responding to questions from organizations seeking help during implementation. Currently, the survey is only open to organizations in the United States.

**Training
was a critical factor in
ISO 9001:2000
implementation for
most organizations**

For further information visit the link to the PSI website at <http://standardsgroup.asq.org/index.htm> and click on *ISO 9000:2000 Product Support Initiative* on the left-hand side. You can also download *ISO Curves*, a one-page image of important results, and a presentation of the PSI initiative.

Responses to key implementation questions by a panel of experts comprising an implementer, a registrar, an ISO 9000 expert and others are being published firstly in THE INFORMED OUTLOOK and subsequently on the PSI Web site.

We have also formed a sub-team to gather, analyse and publish data on the use of ISO 9004:2000. Reports on the activities of this team will also be included on the Web site. ■

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Finding: % of participants	Initial gaps	Internal audits and pre-assessments	Most extensive corrective actions	Registrar non-conformities
<i>Objectives not measurable</i>	28 %/41 % / 24 % *	25 %/32 % / 20 %	22 %/29 % / 19 %	7 %/4 % / 6 %
<i>Collection and analysis of data</i>	35/34/26	17/32/20	22/29/19	7/4/6

* Small /Medium /Large

Table 7:
Identification of gaps and findings
Comparison by size



Sub-clause: % of participants	Corresponding finding
5.4.1 Quality objectives 15 %/19 %/8 %; 15 %/4 %/3 %; 16 %/12 %/17 % **	Objectives not measurable
8.4 Analysis of data 20/27/14; 25/23/9; 21/17/17	Collection and analysis of data

** Small / Medium / Large for (1) difficulty to develop a compliance process for the sub-clause, (2) difficulty to document and (3) difficulty to implement.

Table 8:
Most difficult sub-clauses for which to develop a process, document and/or implement
Comparison by size.