











The Elsmar Cove Forum (http://Elsmar.com/Forums/index.php)

- <u>ISO 9000, ISO 9001, and ISO 9004 - Questions and Discussions</u> (http://Elsmar.com/Forums/forumdisplay.php?f=24)

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Do Quality Objectives have to be Measurable?

(http://Elsmar.com/Forums/showthread.php?t=46928)

piningg 14th March 2011 10:35 PM

Do Quality Objectives have to be Measurable?

Does the Quality objective has to be measurable? Like " minimize rejection by 10%, Target yield of 90%..

JRKH 14th March 2011 11:01 PM

Re: Quality Objective

Yes - An objective is a goal - something you seek to attain. If you cannot measure your progress you cannot know if you are there....

Peace

James

piningg 14th March 2011 11:08 PM

Re: Quality Objective

yes my QM states one of the objective is Monitor QIR (Quality Improvement Records) closure times.. then he puts there through monthly checking..

I want to put there a measurable thing like;

number of days allowed for QIR closure or Number of QIR per month allowed..

Hopefully EGO will not prevail..

somashekar 15th March 2011 12:36 AM

Re: Quality Objective

You quality objective can be like

To improve this this (desirable) from this this level to this this level by this this this time with a this this periodic review.

To reduce this this (un-desirable) from this this level to this this level by this this time with a this this periodic review.

Measurable offcource ~~~

Pick them objectively so as to tempt you to go get it. It must not be too easy nor too unreachable. It all depends upon your process and its capability.

Colin 15th March 2011 04:12 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **piningg** (Post 423377) Does the Quality objective has to be measurable? Like " minimize rejection by 10%, Target yield of 90%..

Pretty straight forward this I think - clause 5.4.1 'The quality objectives shall be measurable and consistent with the quality policy'

AS ever, ISO 9001 doesn't tell us how many or which subjects to write objectives around, that is up to you to decide depending on what is important to you and your customers.

pldey42 15th March 2011 04:40 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

As colpart says, 5.4.2 requires quality objectives to be measurable and consistent with the quality policy.

So if the policy is to meet customer requirements, consistent measurable quality objectives could be, and often are,

% of customer orders delivered on time in full
Return rate (% of items delivered, returned because they don't work)
Number of customer complaints per month
% of complaints resolved to customer satisfaction per month
customer satisfaction index

These would be used to drive continual improvement with corrective/preventive actions.

Good measurable quality objectives are outward-looking, measuring what customers want.

I once worked with a company that did electrical and telecom installations. Their MD said, "Our biggest customer has told me that if we improve our service delivery measurement of on-time and signed of as accepted by customer from 70% of transactions to 85%, we will win a significantly larger chunk of his business - so that's our measurable quality objective." It aligned with his quality policy of satisfying customers and so was fine. More importantly, it drove the various departments involved in delivery towards common customer-facing objectives: they started to behave like one big customer-focussed team.

Measurements have to be carefully designed in order to drive the right behaviours and not the wrong ones

. . .

Number of days allowed for QIR closure

- This can drive wrong behaviours such as skimming the root cause analysis in order to meet an unrealistic target. In telecom, for example, root cause analysis of a fault in a large switch can take months of data-gathering.
- Also, other problems can take business priority and sometimes it's legitimate to defer QIR closure.

Number of QIR per month allowed..

- So, um, if the allowed number of QIRs is exceeded, how to they fix the problem without raising yet another QIR?

It's common - and IMHO unwise - to discourage audit findings, QIRs, corerctive action requests with inappropriate QIR measurements, in the mistaken belief that QIRs are bad - they're good, they're our only method for fixing things.

ISO 9001 doesn't say or even imply that. Audits and corrective actions are there to be used, not discouraged. They recognize that in any organization mistakes will happen, unforseen problems will arise. The objective is to either avoid them with preventive actions, or fix them with corrective actions - not to sweep them under the carpet -- because they're still there, costing ever more time and money, becoming embedded in the corporate culture and even harder to fix.

A better way to use QIR-style measurements is to measure the cost of QIRs and the cost savings they generate. Imagine the management review ...

"We spent \$50,000 last year on audits and corrective actions," said the Quality Manager. "And we saved \$500,000 annualized ... who wants to play quality management next year?"

Organizations do it. Not many, but some. It's one reason they're satisfying customers and making money.

Hope this helps,

Pat

howste

16th March 2011 12:24 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Another relevant clause of ISO 9001 is 8.2.3:

Quote:

In Reply to Parent Post by ISO 9001:2008

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results.

Not only should the objectives be measurable, but there need to be "planned results" i.e. targets/goals. Processes need to be measured to show that they are being met. If they're not being met, actions must be taken to improve:

Quote:

In Reply to Parent Post by ISO 9001:2008

When planned results are not achieved, correction and corrective action shall be taken...

John Broomfield

16th March 2011 03:00 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **piningg** (Post 423377) Does the Quality objective has to be measurable? Like " minimize rejection by 10%, Target yield of 90%..

piningg,

Yes, I think you already know this so let me add something new.

- 1. Determine the objective of each process in your system and align these with the objectives for the system.
- 2. Develop your process-based management system with these objectives in mind.
- 3. Authorize the process owners/teams to initiate preventive action if it looks as if their process will not fulfill its objectives.
- 4. For each new objective consider issuing a preventive action request to change the system as necessary to fulfill the objective.

Your management can then be used and improved to fulfill the process and system objectives.

John

Ka Pilo

20th March 2011 12:22 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **piningg** (Post 423377) Does the Quality objective has to be measurable? Like " minimize rejection by 10%, Target yield of 90%..

It's like shooting; you have to set up your target, have a clear area, have a measurable shooting ranges, keep eye on the sight, and then shoot.

You need to check the accuracy of your shot. You can do a corrective action or set a more difficult target.

Big Jim 20th March 2011 03:27 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **Colpart** (Post 423425)

Pretty straight forward this I think - clause 5.4.1 'The quality objectives shall be measurable and consistent with the quality policy'

AS ever, ISO 9001 doesn't tell us how many or which subjects to write objectives around, that is up to you to decide depending on what is important to you and your customers.

True, but the standard tell you what topics you need to be measuring in element 8.4. You need to determine, collect, and analyze data that helps you know the health of the quality management system. The four topics are 1) customer satisfaction, 2) product quality, 3) process conformity, and 4) supplier performance.

You should have no trouble selecting quality objectives from among those topics, and since you have to do it anyway to fulfill 8.4, why not align them with your quality objectives?

Colin 20th March 2011 04:45 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **Big Jim** (Post 424545)

True, but the standard tell you what topics you need to be measuring in element 8.4. You need to determine, collect, and analyze data that helps you know the health of the quality management system. The four topics are 1) customer satisfaction, 2) product quality, 3) process conformity, and 4) supplier performance.

You should have no trouble selecting quality objectives from among those topics, and since you have to do it anyway to fulfill 8.4, why not align them with your quality objectives?

I agree Jim, and these of course align quite nicely with what 8.2.2 wants us to monitor and measure. In addition, these are all helpful when looking for improvement, etc. :)

I think that this is one of the areas of ISO 9001 which shows some good 'joined up' thinking but so few organisations I visit have recognised this and they make hard work out of setting objectives.

malamassi 20th March 2011 06:07 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

yes it is, the quality objectives should be SMART where:

S: specific

M: Measurable

A: Attainable

R: Realistic

T: Timely

Ron tollett 21st March 2011 11:49 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Would anyone have examples of Quality Policies and aligned objectives? Much appreciated.

howste 21st March 2011 10:47 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Here's one I've posted in another thread: <u>Example Quality Policy - Objectives2.doc</u> I hope it helps.

ddchhaya 21st March 2011 11:20 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Dear Big Jim,

I need guidance. In fact anyone can chip in their bit.

The process is "Recruitment"

Metric is "Competence"

Competence is measured by the "Selection Committee"

So Committee is a measuring equipment.

Measuring equipment need calibration.

How to calibrate members of one committee? Or how to calibrate several committees that go on a big recruitment spree?

Big Jim 22nd March 2011 12:05 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **ddchhaya** (Post 424912)

Dear Big Jim,

I need guidance. In fact anyone can chip in their bit.

The process is "Recruitment"

Metric is "Competence"

Competence is measured by the "Selection Committee"

So Committee is a measuring equipment.

Measuring equipment need calibration.

How to calibrate members of one committee? Or how to calibrate several committees that go on a big recruitment spree?

That would be a very awkward approach. It is generally more useful to choose KPI from among things that you can more easily measure. If you can't easily define how to collect the data, it is not likely to be very useful.

If you still wish to look for a measure for Recruitment, you may think about tracking the number of applications, or the ratio of applicants to new hires. You might not think that would to as useful, but something burned into my brain from business school is that complete information obtained six months after you need it is not nearly as useful as incomplete information when you need it. There are limitations to the usefulness of incomplete information, but if you know the limitations it is still much more useful if it is available when you need it.

I'm also not sure why you would choose to Recruitment as a core process. If you think you need one for Human Resources, why not measure productivity?

ddchhaya 22nd March 2011 04:57 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Thanks Big Jim!

I agree that there are other things that can be measured.

I am not talking about measurement.

I am talking about the need to calibrate measuring equipment.

Here it is committees or individuals on committee who measure competence as per input data on job description or job profile. I agree, productivity can be one aspect. Here we wish to focus on measurement of objectives coupled with calibration of measuring equipment. If committee is measuring competence, we need calibration! :confused:

howste 22nd March 2011 09:35 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

People aren't equipment. I think you're trying to force the requirement where it doesn't make sense.

Big Jim 25th March 2011 12:09 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

I agree with Howste on this. What you are suggesting doesn't make sense.

pldey42 25th March 2011 02:47 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Until now we've been "Human Resources" - to be dug out of a cupboard full of mushrooms, used until exhausted, then disposed of in an environmentally friendly fashion.

Now we're equipment? To be labelled, left on a shelf, pushed, pulled, tweaked and tapped, then thrown back on the shelf?

Hmph. I quite like being "talent", as the SEI put it in the People Management Maturity Model.

That said, some organizations that deliver training services regard examinations as "test equipment" and calibrate their examinations by giving them in pilot trials to subjects whose abiilities are known, to see if the exam correctly discriminates between those who can and those who cannot.

Also, we've all seeen managers who are incompentent at assessing the capabilities of their staff, e.g. when they can't do the job themselves. Maybe we should allow ourselves to interpret the standard a little more creatively until someone revises it to truly reflect the challenges of what the SEI call Talent Management.

Just 2c,

Pat

Sardokar 25th March 2011 04:30 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

the short answer to the OP question is ... YES

now there is 2 kind of measurements:

- Ouantitative measurements
- Qualitative measurements (most frquently "yes" or No"

exemple of an objective with quantitative measurement

* Increase customer satisfaction to 85% on the 2011 survey

(you are going to quantitatively measure the results of a survey for example as to obtain a number)

Example of a qualitative measurement

* Achieve Certification with Supplier "ABC" by the end of 2011

in that case there is no number to count you will evaluate at the end of the time period if we have achieved the certification or not and take relevant corrective actions if not (or take preventive actions if for example at 3/4 of the year you feel there is a high risk of not achieving certification)

Hope that helps

MrMiagi 25th March 2011 03:32 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

I think quality goals and objectives have to be measurable per the requirement. That is a given. Ideally, there should be global, organization-wide goals that all employees are aware of. Then, there should be department goals that support the global goals and so on. The goals should be measurable and be part of a regularly updated information board. Each employee needs to understand the goals and how they can and do contribute. The overall health of the company should be easy to ascertain by checking performance to those goals by any employee.

"Quality is not free, but it has been discounted deeply for a quick sale."

Mr. Miagi

ddchhaya 26th March 2011 12:54 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

:thanx: Thanks Howste. Big Jim, Patrick, Sardokar. I Like the response to the word "equipment" applied to human beings. I also liked The response on Humans getting considered as "Resource" and now attempted to be narrowed down to merely an "equipment" to be taken from shelf and getting shelved after use! :D. Very unfair indeed!

I liked Patrick's response :bigwave: on using our creativity to apply principles of the standard to experience benefits of the intent. I wish to share the following.

There are references on profound applications of principles of organizational behavior (OB) in application of Six Sigma methodology in selection of six sigma team members, process champion, black belts and green belts. Six Sigma methodology is also one of the QSM with application of statistical principles.

OHSAS 18000 has also introduced the word "Behaviour" in relation to safety, which was not there in the earlier version. In the emerging application of OB in safety, I read :read: about "calibration of safety observers" in a book on behavior based safety that talked about safety observers as equivalent to transducers because they "measure" safety behavior. There was also a mention of application of principles of statistics to the data generated by these observers. Therefore there is a need for reliability in the observations by the observers who are basically not "equipment" in the narrow sense of the word but certainly are human beings:).

I asked similar question to one veteran LA who mentioned that he had gone to one location to "Calibrate an audit team". The audit teams comprise of humans too.

"Equipment" in the narrow sense of the word are not human beings. But once they are calibrated, they "behave" predictably. Even then we need periodic calibration because the calibration may get drifted.

Human beings in one culture respond reasonably predictably to a stimulus. That is how we identify a culture. However, it becomes more critical to develop consistency in human beings, as due to wide variety of external factors, same individual may respond differently in different situations.

Audit team members also need "personal attributes" and application of auditing skills so that each individual member, given a situation, respond predictably, solicit predictable response from the auditee (art of questioning), with high degree of consistency and identify the findings with very "narrow variability". When the variability is brought within acceptable limits, the team is considered "calibrated" and ready for launch.

Therefore, I agree with Patrick that there is a scope for using creativity in application of the requirement of standards. ISO 9001:2008 aims at making it compatible with ISO 14000. In OHSAS 18001:2007 we see annexure giving clause by clause compatibility of the three standards. And then there is PAS 99:2006 by BSI under revision, the 2010 draft of which is available, gives framework for Integrated Management System with seamless integration of the management systems of the standards that have remarkable compatibility.

I wish to clarify that I asked the question with these factors on mind. Recruitment is a process, job profile is the input, advertisement, screening applications, shortlisting, formation of committee, various assessments, preparation of merit list, etc., are steps and selected candidate fulfilling "requirements" is an output that goes to core function, who is the customer in SIPOC model.

And there, as Patrick responded, when we wish to integrate all the standards for seamless integration, there could be a scope to use our creativity and to include calibration of a committee to develop them to give consistent and output of measurement of competence - reliable personnel, again the humans with narrow variability fitting into the requirements of the organization.

Patric, I am interested in knowing more about what the SEI put it in the People Management Maturity Model:)

harry 26th March 2011 05:59 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Determination of competency in a recruitment exercise would had occurred at a much earlier stage - often taking the form of tests (whether practical or written). However, competency tells us half or less than half of the story on the candidates potential.

The soft side is as important, if not more - communication skills, personal attributes, social graces, friendliness, etc and the interview panel used towards the end is constituted precisely for determining these. It derives its strength from the diversity and strength of each individuals experience combined to make a final decision. Calibration? - not applicable at all.

ddchhaya 26th March 2011 08:21 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Ouote:

In Reply to Parent Post by **harry** (Post 425852) Calibration? - not applicable at all.

Thank you Harry, you do have a point.

However, you may like to refer to the mention of such calibration in a book titled"The behavior based safety process: Managing involvement for an injury free culture and Employee Driven Systems for Safe Behavior: Integrating Behavioral and Statistical Methodologies, both authored by Thomas R Krause. Nevertheless, individual perception may differ and not all written in books need be agreeable to all!:)

http://www.amazon.com/Employee-Drive.../dp/0471285943

http://www.amazon.com/Behavior-Based...der_047128758X

harry 26th March 2011 08:43 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **ddchhaya** (Post 425860)

...... However, you may like to refer to the mention of such calibration in a book titled"The behavior based safety process: Managing involvement for an injury free culture and Employee Driven Systems for Safe Behavior

Sorry for not making it clear. What I meant is calibration is not applicable in situations where you are looking for diverse opinions, etc such as that from the interviewing team but in the example of 'safety observers', a common yardstick should exist, hence it is possible and good to do so.

pldey42 26th March 2011 11:26 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **ddchhaya** (Post 425834) :thanx: Thanks Howste. Big Jim, Patrick, Sardokar.

[..]

Patric, I am interested in knowing more about what the SEI put it in the People Management Maturity Model:)

The SEI are world leaders in organizational capability maturity modelling. From their website at http://www.sei.cmu.edu/cmmi/tools/peoplecmm/

"The People CMM helps organizations to

- * characterize the maturity of their human resource practices
- * set priorities for improving the competence of its work-force
- * integrate competence growth with process improvement
- * establish a culture of workforce excellence"

It's a five layer model, each layer comprising increasingly mature processes. (The idea came from Crosby's "Quality is Free".)

I love their characterization of the most immature organizations: "People are herded from one disaster to another."

Cheers,

Pat

michellemmm

26th March 2011 11:30 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by Colpart (Post 423425)

Pretty straight forward this I think - clause 5.4.1 'The quality objectives shall be measurable and consistent with the quality policy'

AS ever, ISO 9001 doesn't tell us how many or which subjects to write objectives around, that is up to you to decide depending on what is important to you and your customers.

I agree...

I have adopted the "decomposition" technique for QOs. THE QO should be the derivative of QP. All metrics set for processes should be traceable to QOs.

Manoj Choyal

12th April 2011 01:27 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Yes, QO have to be measureable.

If we can not measure something, we can not control it. When we can not control something, it means we can not improve it.

So QO Measurement is must for continual improvement!

:cool:

ong0708 12th April 2011 04:46 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **piningg** (Post 423377) Does the Quality objective has to be measurable? Like " minimize rejection by 10%, Target yield of 90%..

The answer is definitely YES.

In fact it was mentioned in the **Clause 5.4.1** " The quality objectives shall be **measurable** and **consistent** with the quality policy.

For your information, instead of using percentage to indicate measurement, you can also use numbers. For example, to restrict customer complaints for 5 cases, to obtain 03 appraisals from customers, to restrict goods return for 04 cases.

Hope that my explanation will help you in developing your quality objectives. :)

DomDom 12th April 2011 10:54 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Good day,

There is a sentence I like to use:

"There cannot be any improvements without measures" To me it says it all!

As it was Iready mentionned in the thread, make sure it is SMART and do not try to eat an elephant at once, start by one leg to slow it down :D

Sidney Vianna 12th April 2011 11:03 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by ong0708 (Post 428614)

For your information, instead of using percentage to indicate measurement, you can also use numbers. For example, to restrict customer complaints for 5 cases, to obtain 03 appraisals from customers, to restrict goods return for 04 cases.

While you can do, as you mentioned, it is not very smart to do so. If you increase your customer base, chances are, you will have a higher number of opportunities for complaints. Normalizing indicators is a wise thing to do.

Also, it is CRITICAL to realize that, differently from ISO 14001, ISO 9001 does not require targets. Quality objectives (albeit obligatorily measurable) don't have to have a target associated with.

db 12th April 2011 11:16 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

2 quick points...

- 1. ISO choses its words carefully. noticed that it says "measurable", not "measured". This does not make sense to me. What good is being measurable, without measurement? Although I could make a legalistic claim that measurement is not required, it would clearly contradict many of the requirments in clause 8. A
- 2. Also rememer the first part of 5.4.1 that mentions "including those needed to meet requirements for product". Your objectives will be more than those global objectives that related to all of your product/processes. For example, order # 62537 needing to be shipped by this Thursday. They need to be consistent with the policy, but not specifically mentioned with the policy. Those individual product requirements are objectives as well, and they also have to meet 5.4.1.

Sidney Vianna 12th April 2011 11:37 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by db (Post 428720)

1. ISO choses its words carefully. noticed that it says "measurable", not "measured". This does not make sense to me. What good is being measurable, without measurement? Although I could make a legalistic claim that measurement is not required, it would clearly contradict many of the requirements in clause 8. A

The reason for that is that objectives can be an attribute (instead of a variable). For example, a quality objective could be: attain CE-Mark for product XYZ by July 2012. Or, another example, attain gold level status as a supplier to Boeing in 2014.

There was an "official" interpretation from the TC 176 on that.

Aliveguy 12th April 2011 11:40 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

We review our Objectives in Management Review, Four times per year.

This is a good time to discuss plans moving ahead and any changes to the Objectives that may be needed.

Good Luck on your Task...:D

Big Jim 12th April 2011 11:00 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by Sidney Vianna (Post 428724)

The reason for that is that objectives can be an attribute (instead of a variable). For example, a quality objective could be: attain CE-Mark for product XYZ by July 2012. Or, another example, attain gold level status as a supplier to Boeing in 2014.

There was an "official" interpretation from the TC 176 on that.

Do you have a source for that interpretation?

I can find an interpretation for ISO 9001:2008 5.4.2, but not 5.4.1. I can't find one for ISO 9001:2000 for anything in 5.4.

howste 12th April 2011 11:50 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by Sidney Vianna (Post 428714)

While you can do, as you mentioned, it is not very smart to do so. If you increase your customer base, chances are, you will have a higher number of opportunities for complaints. Normalizing indicators is a wise thing to do.

:agree1: I was thinking the same thing.

Quote:

In Reply to Parent Post by **Sidney Vianna** (Post 428714)

Also, it is CRITICAL to realize that, differently from ISO 14001, ISO 9001 does not require targets. Quality objectives (albeit obligatorily measurable) don't have to have a target associated with.

I agree that ISO 9001 doesn't require the objectives to have targets. However, the process measurements (8.2.3), which I believe should be aligned with the objectives, are required to have "planned results." In my opinion, these should be targets/goals.

Sidney Vianna 13th April 2011 12:46 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by Big Jim (Post 428814)

Do you have a source for that interpretation?

Yes, I have a source: TC 176. Below is a compilation of all "old interpretations", no longer posted in the TC 176 website. The one in red is the one I referred to.

Quote:

Clause 1.2 (N850r):

Q: Does the standard require an organization that purchases a complete design, then manufactures a product to the design and sells it under its own brand name, to include "design" as one of the processes needed for the Quality Management System?

A: Yes.

Clause 2 (N649r):

Q: Do only terms and definitions of ISO 9000:2000 constitute provisions of ISO 9001:2000 through the reference in the text of Clause 2 of ISO 9001:2000?

A: Yes.

Clause 4.1 a) (N753):

Q: Does the expression "needed for the QMS" in Clause 4.1 a) require the organization to identify the QMS processes related to product realization only?

A: No, The processes needed for the QMS include those related to product realization as well as the other processes related to the implementation of the QMS, as per the NOTE in clause 4.1. Clause 4.2.1 (N778):

Q: include "a quality manual" (item b) and "documented procedures required by this International Standard" (item c). Is it in compliance with the standard to include the "documented procedures required by the standard" in the quality manual instead of having two separate sets of documents? Background: Some advisors recommend that organizations which are implementing their quality management system develop one manual, in addition to all the six documented procedures, because of clause 4.2.1.Yet clause 4.2.2 says: "The organization shall establish and maintain a quality manual that INCLUDES:

b) documented procedures established for the quality management system or reference to them". A: Yes.

Clauses 4.2.2 c) and 4.1 b) (N718):

Q: Does Clause 4.2.2 c), require that the manual include a description of the processes, in addition to a "description of the interaction between the processes of the QMS "?

Attention is also drawn to the connection between Clause 4.2.2 c) and Clause 4.1 b), where the organization is required to "determine the sequence and interaction" of the processes. On this problem of interpretation there is a divergence of opinion between an organization and a Certification Body.

A: No.

Clause 4.2.3 a) (N638r):

Q: Does documented purchasing information that is part of the quality management system, have to be approved according to 4.2.3 a)?

A: Yes.

Clause 4.2.3 a) (N641r):

Q: Do documented inspection and test procedures that are part of the quality management system, have to be approved according to 4.2.3 a)?

A: Yes.

Clause 4.2.3 a) (N774):

15 of 22

Q: Does sub-clause 4.2.3 a) require that documents required for the QMS be reviewed as well as approved prior to issue?

A: No, Clause 4.2.3 a) is applicable to new documents which are being developed. Some degree of checking, examination or assessment by the person or persons approving is inherent in "approval for adequacy". There is no requirement for an additional "review" (as defined in ISO 9000:2000 clause 3.8.7).

Clause 5.4.1 (N765):

Q: Does Clause 5.4.1 of ISO 9001:2000 consider quality objectives defined by "YES/NO" criteria to be measurable?

Background: Several companies that we audit have established some (but not all) of their quality objectives based on "YES/NO" criteria. Example "Achieve product certification for "xxxxxxx" product by November 2002"; or "Develop a new product to meet the requirements of the "YYYYY" market by March 2003". In order to provide a consistent and technically accurate audit, we would like to know if these are considered to be "measurable objectives".

Clause 5.4.2 (N708v):

Q: Is it a requirement of Clause 5.4.2 to have a document that describes the objectives, timeframe, action and responsibilities? (Note: The description of this document is not the same as the definition of "Quality Plan" in ISO 9000:2000, paragraph 3.7.5)

Background: Some users interpret Clause 5.4.2 of the standard to require a document (quality plan) that describes the objectives and the responsibilities etc. This is in addition to the quality manual and procedures document already established to control the relevant processes.

A: No

A: Yes.

Clause 5.5.1 (N871r):

Q: Does Sub-clause 5.5.1, Responsibility and authority, address definition of responsibilities and authorities needed for an effective operation of the quality management system, not only for personnel involved in management of the system, such as the management representative and those who document, review and audit the system, but also for personnel involved in purchasing, production, development, testing, etc.?

Background Scenario: The question came up because of the fact that Clause 7.3.1 c) requires that the responsibilities and authorities for design and development have to be determined, while similar clauses like 7.2, 7.4 and 7.5 do not have such an explicit requirement.

A: Yes.

Clause 5.5.2 (N752):

Q: In our organization we have a management representative appointed by top management, who works for the company in a managerial capacity. He is not a permanent member of staff, but works full-time on a contract basis. Is it allowable under the standard, for such a person to act as the organization's management representative?

A: Yes.

Clause 5.6.3 b) (N757):

Q: Outputs from the management review shall include decisions and actions on the ""improvement of product related to customer requirements"". If an improvement consists in the realization of a new product, does it respond to this specific requirement? (This clause is the only place where the improvement deals with the ""product"". In all other places the improvement concerns the ""effectiveness of the QMS"". But it's not clear if the sentence ""improvement of product related to customer requirements" intends to limit the improvement only to the products where the requirements have been already established (e.g. contractually). A clarification on this point will help users and auditors in understanding the extent of application of this requirement.)

A: Yes, The realization of a new product to improve an old one could be one of the results of the management review (Clause 5.6.3 b).

Clause 6.2.2 (N825r):

Q: Does Clause 6.2.2 e) require the organization to maintain records to demonstrate "the evaluation of the effectiveness of actions taken" to address competence needs, according to Clause 6.2.2 c)?

A: No, It is up to the organization to decide what records should be maintained.

Clause 6.3 (N640r):

Q: Does Clause 6.3 require records of the maintenance of infrastructures?

A: No.

Clause 7.1 (N716r):

Q: Does the use of the word "form" in the last sentence of this clause, mean that the output of the planning process must be documented?

Background: There has been some confusion due to the word "form" being interpreted as meaning "document used to record data".

A: No, The word "form" means usual/suitable format.

Clause 7.2.1 (N743):

Q: In some countries, in order to perform professional work, a law requires that a professional be a member of the appropriate Order and that the Order prescribes its own rules. Some of the rules have an impact on the product. Are these rules of the professional Order to be considered requirements related to the product?

A: Yes.

Clause 7.2.1 a) (N647r):

Q: Does the word "specify" or "specified" quoted in various clauses require documentation? Clauses 7.2.1 a) and b), 7.3.3 d), 7.3.6 and others.

A: No, A relevant example to support the answer is in the definition of procedure (ISO 9000:2000, 3.4.5), "specified way to carry out an activity or process (3.4.1)", with "Note 1 Procedures can be documented or not".

Clause 7.2.1 a) (N851r):

Q: Are the contractual delivery dates of a product to be always considered as being part of the "requirements specified by the customer", mentioned in sub-clause 7.2.1 a)?

A: Yes.

Clause 7.3 (N815r):

Q: Does ISO 9001:2000 require Clause 7.3 to be applied to the design and development of the package necessary to preserve the conformity of the product during delivery?

Background: This request for interpretation does not address the packaging process, but the package that is necessary to protect the product.

A: Yes, The organization is, per sub-clause 7.5.5, responsible for preserving the conformity of the product. Preservation includes packaging. In cases where design and development of the package is necessary to preserve conformity, this has to be performed in accordance with Clause 7.3 of the standard.

Clause 7.3.1 b) (N754):

Q: Does Clause 7.3.1 b) allow the organization to decide on the need, appropriateness and extent of the review, verification and validation to be carried out at each design and development stage? A: Yes, Review, verification and validation at each stage of design and development shall be determined by the organization according to 7.3.1.b and shall be performed according to 7.3.4, 7.3.5 and 7.3.6.

Clause 7.4 (N812r):

Q: Do the requirements of Clause 7.4, Purchasing, also apply to products that are acquired without any payment being made?

A: Yes.

Clause 7.4 (N870r):

Q: Does Clause 7.4 apply to the purchase of products not intended for the organization's customer if these purchases have an effect on subsequent product realization or the final product?

A: Yes, All purchased products must conform to their specified purchase requirements, but the type and extent of the control applied depends on the effect the purchased product has on the final product or product realization process.

Clause 7.4.1 (N816r):

Q: Does Clause 7.4.1 require that records of evaluations of suppliers and any necessary actions arising from these evaluations be maintained by all organizations, irrespective of their size?

Background: In small companies where the owners are personally responsible for the purchasing of resources and know their individual suppliers, maintaining records of supplier assessments can be

very bureaucratic.

A: Yes.

Clause 7.4.3 (N639r):

Q: Does Clause 7.4.3 require records of the verification of purchased product?

A: No.

Clause 7.5.2 (N751):

Q: Does the process of an organization, whose results can be verified by means of monitoring or measurement after their realization and prior to delivery to the customer, need to be validated in order to comply with the requirements of clause 7.5.2?

Background: The organization provides transportation of orders (goods etc.) involving collection and dispatching services that can be monitored during their respective execution.

A: No.

Clause 7.5.2 (N776):

Q: Does Clause 7.5.2, Validation of processes for production and service provision, require the validation of the equipment, locations and people involved?

Background: The original query implied that the question arose in relation to a hospital)

A: No, Clause 7.5.2 does not say what shall be excluded from or included in validation of the process. It is up to the organization to determine which of the arrangements from a) to e) are applicable (refer also to 7.1).

Clause 7.5.2 (N777):

Q: Does Clause 7.5.2, Validation of processes for production and service provision, require that any applicable statutory and regulatory requirements must be taken into account?

Background: The original query implied that the question arose in relation to a hospital)

A: Yes, Clause 7.5.2 makes no reference to statutory and regulatory requirements. However these statutory and regulatory requirements are general and must be taken into account wherever applicable to the intended product (see the Note in Clause 1.1).

Clause 7.6 (N757):

Q: Is it correct that Clause 7.6 requires only the measuring and monitoring devices utilized by persons responsible for release of the product to be calibrated or verified?

Background: The Client understands that all of the workers need to have all measuring devices calibrated or verified. The contract just requires compliance with ISO 9001:2000 in this case.

A: No, Clause 7.6 requires calibration or verification of measuring equipment "where necessary to ensure valid results". It could be more than measuring equipment for product release only (i.e.: verification of purchased products; in process inspection, etc.) but does not

necessarily mean all measuring equipment. When the organization determines the monitoring and measuring required (as defined e.g. in clauses 4.1 a); 4.1 e); 7.1 c) and the first paragraph of 7.6), it shall decide which of them require calibration or verification of the measuring equipment because of the requirement of "valid results".

Clause 7.6 a) (N805r):

Q: Clause 7.6 a) states: "Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded." Can the word "OR" in the phrase "be calibrated or verified at specified intervals...." be interpreted as meaning that these two activities are always mutually exclusive?

Background: According to the concept of metrological confirmation established in ISO 10012:2003 (e.g. Figure 2 Metrological confirmation process for measuring equipment) for carrying out verification activities, it is indispensable to define the measuring equipment metrological requirements, and the latter are compared against the results of calibration activities.

A: No, Calibration and verification can both be applicable depending on the situation. Clause 8.2.1 (N804r):

Q: In the situation described in the background information, does the standard require an organization to consider also the end user as a customer for monitoring satisfaction?

Background: An organization designs and manufactures a product to its own specifications and sells it to end users through a distribution chain. It is not technically modified between the organization

and the end user. The end user can identify the organization through the use of a brand name or a trademark. The organization has contracts with distributors, which in turn sell to stores where end users buy the product.

A: Yes.

Clause 8.2.2 (N780):

Q: In clause 8.2.2 it is stated that: "An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, ...".

Is it a requirement of this clause that the criteria to determine the status and the importance of the processes and areas to be audited have to be documented?

Background: There is divergence with the auditor regarding a requirement for documentation of "status and importance criteria" despite the fact that evidence was provided that the planning of the audit programme has taken the status and importance of the processes and areas to be audited into consideration.

A: No.

Clause 8.3 (N698.1r):

Q: When an organization detects, after delivery or after use has started, a product which does not conform to one of the "requirements specified by the customer" (Clause 7.2.1 a)), does the standard require that the organization inform the customer of the nonconforming product?

A: No, The last paragraph of Clause 8.3 specifies that it is the organization's responsibility to take appropriate action regarding the nonconforming product.

Clause 8.3 (N698.2r):

Q: When an organization detects, after delivery or after use has started, a product which does not conform to one of the "statutory and regulatory requirements related to the product" (Clause 7.2.1 c)), does the standard require that the organization inform the competent authority of the nonconforming product?

A: No, The last paragraph of Clause 8.3 specifies that it is the organization's responsibility to take appropriate action regarding nonconforming product.

Clause 8.3 (N742):

Q: A product is at the final stage of realization and a nonconformity is found on a product related requirement which had been specified by the customer (ISO 9001:2000 7.2.1 a)). The organization believes that the best solution is to accept and deliver the product as is, i.e. with a nonconforming characteristic. The customer has not issued instructions on the reporting of nonconformities. Does Clause 8.3 require a concession by the customer for the use, release or acceptance as is of the product?

A: Yes, Clause 8.3 identifies three different ways to deal with nonconforming products. Clauses 8.3 a) and c) do not apply in this case. Clause 8.3 b) specifies that the use, release or acceptance shall be authorized. In this case authorization involves a concession by the customer. Furthermore, Clause 5.2 requires that customer requirements are determined and are met.

Clause 8.5.1 (N717):

Q: Does the continual improvement of the QMS required by Clause 8.5.1 also cover the "improvement of the product related to customer requirements" required by Clause 5.6.3 b) to be included as an output of the management review?

Background: Clause 5.6.3 mentions in bullet a), the improvement of the "effectiveness of the quality management system" and adds, in bullet b), the "improvement of the product related to customer requirements". Clause 8.5.1 requires only the "improvement of the effectiveness of the quality management system", with no mention to the "improvement of the product related to customer requirements".

A: No.

Clause 8.5.3 a) (N853r):

Q: Does sub-clause 8.5.3 a) require organizations to demonstrate, with objective evidence in the form of records, that they have undertaken actions to determine the existence of "potential nonconformities and their causes"?

A: No.

Ageel Abbas

25th April 2011 02:16 AM

Re: Quality Objective

Quote:

In Reply to Parent Post by somashekar (Post 423396)

You quality objective can be like

To improve this this (desirable) from this this level to this this level by this this time with a this this periodic review.

To reduce this this (un-desirable) from this this level to this this level by this this this time with a this this periodic review.

Measurable offcource ~~~

Pick them objectively so as to tempt you to go get it. It must not be too easy nor too unreachable. It all depends upon your process and its capability.

For a start up company which does not have enough non conformity data and which is just starting its operations, what kind of mesaurable objectives can be set and how? Can objective be set like: to gather this this data by this this this date and to improve them by this this amount with this this periodic review?

Please help. Thanks

John Broomfield

25th April 2011 02:44 AM

Re: Quality Objective

Quote:

In Reply to Parent Post by Aqeel Abbas (Post 430911)

For a start up company which does not have enough non conformity data and which is just starting its operations, what kind of mesaurable objectives can be set and how? Can objective be set like: to gather this this data by this this date and to improve them by this this this amount with this this periodic review?

Please help. Thanks

Ageel Abbas,

These are the data required by 8.4:

- a. Product conformity data
- b. Customer satisfaction data
- c. Process performance data
- d. Supplier performance data

May I suggest that you initially tie your quality objectives to these data streams?

From each of these data you can obtain the information you need to set your objectives and see how well your management system is helping your organization to meet them.

You do not need nonconformity data yet (the inverse of 8.4a).

John

rama cylinders

26th April 2013 06:17 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

yes offcouse objective is a target and target can't be reached without measuring. Mainly measuring is mandatory becuse as per iso 9001:2008 you need to track your objective and have to make action plans if you dont found your objective status is going inline with your target objective. As I am an auditor for iso 9001 so I can assure you that it is mandatory to have measurable targets.

Sidney Vianna

26th April 2013 10:08 AM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by **rama cylinders** (Post 517892)

yes offcouse objective is a target and target can't be reached without measuring.

Welcome to The Cove, Rama. Over the years, we've had many a discussion on this topic and most agreed that there is a difference between objectives and targets. For example, an organization could have a quality objective of improving on-time delivery, and track it's performance. Additionaly (and not mandated by the ISO 9001 standard), the organization could have a OTD target of, e.g., 90% or better, at the end of fiscal year 2013....quality objectives could even be attribute-type, such as, for example, achieve silver level supplier with customer. So, many of us differentiate the terms objectives and targets and, while ISO 9001 mandates objectives, it does not require targets.

Quote:

In Reply to Parent Post by rama cylinders (Post 517892)

As I am an auditor for iso 9001 so I can assure you that it is mandatory to have measurable targets.

There are many certified auditors in this forum and we normally tend to give the source of the requirement. In this case ISO 9001:2008 paragraph 5.4.1 clearly states

Quote:

The quality objectives shall be measurable and consistent with the quality policy.

SGquality

26th April 2013 12:39 PM

Re: Quality Objectives - Do Quality Objectives have to be Measurable?

Quote:

In Reply to Parent Post by Sidney Vianna (Post 517904)

In this case ISO 9001:2008 paragraph 5.4.1 clearly states

PHP Code:

The quality objectives shall be measurable and consistent with the quality policy.

Thus, if the objectives are like attributes, how to measure? In that context, would it be right to say that all targets (derived from objectives) need to be measurable?

The time now is 01:14 PM. All times are GMT -4. Your time zone can be changed in your UserCP --> Options.

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Identifying Waste

The Deming PDCA Cycle

8-D Problem Solving
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Discovering Change Process Capability - Cp vs. Cpk

QMS Implementation

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Lead Time Reduction

Histogram Animation

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Quick Setup

Process Loop Animation Taguchi Loss Function

Fishbone / Cause and Effects Animation

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