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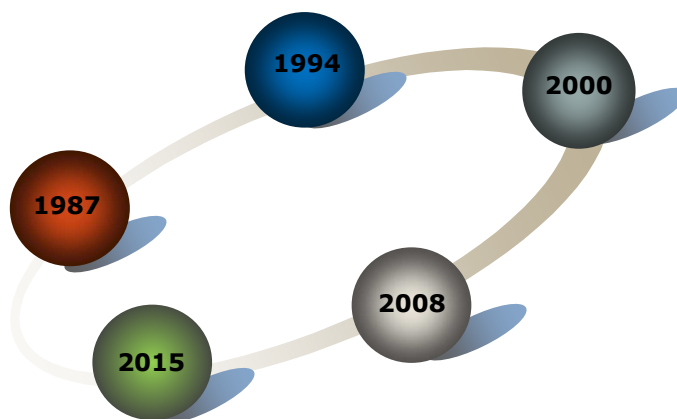
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ISO 9001:2015

ŠTO MOŽEMO OČEKIVATI OD REVIZIJE
NORME I KAKO SE PRIPREMITI ZA
PROMJENE?
23. travnja, 2014.



ISO 9001 revizije



ISO 9000 obitelj normi

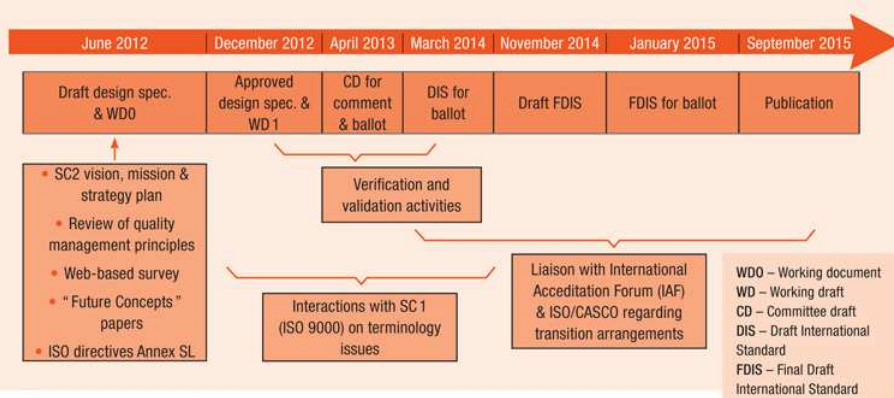
Od prve objave 1987. godine do danas ova obitelj normi je postala:

- Najpopularnija obitelj ISO normi;
- Najprodavanija obitelj ISO normi;
- Široko prihvaćena zajednička platforma i jezik za raspravu o kvaliteti;
- Osnova za uspostavljanje povjerenja u sposobnost organizacije da isporuči sukladne proizvode;
- Značajan poticaj svjetskoj trgovini.

Gradeći na 25 godina uspješe primjene norme ISO u lipnju 2012. pokreće reviziju norme ISO 9001. Reviziju provodi:

ISO technical committee ISO/TC 176, *Quality management and quality assurance*, subcommittee SC 2, *Quality systems*

ISO 9001:2015 vremenski plan



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ISO 9001:2015

DAKLE, ŠTO SE NOVO SPREMA U NORMI?

CAVEAT!

Ova prezentacija predstavlja autorovo viđenje mogućih promjena u sadržaju i formi norme, tj. izgleda budućeg izdanja norme ISO 9001:2015 i utjecaja koje bi te promjene mogle imati na sustave upravljanja kvalitetom, temeljeno na raspoloživim informacijama o procesu revizije norme koji je još u tijeku.

Nema jamstva da će ovdje predstavljene promjene zaista biti u tom obliku usvojene u konačnoj verziji norme, niti da konačna verzija neće uključiti promjene koje ovdje nisu spomenute.

Namjera ove prezentacije je potaknuti na razmišljanje i raspravu mogućim promjenama i utjecajima koje bi one mogle imati na naše sadašnje sustave upravljanja kvalitetom, kako bismo spremniji dočekali planirano objavljivanje norme u rujnu 2015. godine.

Izvori informacija

U travnju 2014. je pripremljen DIS (Draft International Standard) ali do njega još nismo bili došli, pa je ova prezentacija temeljena na:

- Nacrtu norme predloženom od tehničkog odbora ISO/TC 176/SC 2
 - ISO/CD 9001 - Committee Draft of ISO 9001, Secretariat of ISO/TC 176/SC 2
- Objavama na Internet stranicama tehničkog odbora ISO/TC 176/SC 2
 - http://www.iso.org/iso/iso_technical_committee?commid=53896
- Raspoloživim informacijama, raspravama i komentarima na web stranicama organizacija koje se bave upravljanjem kvalitetom, na primjer:
 - <http://www.irca.org/en-gb/resources/iso-90012015/>
 - <http://the9000store.com/what-is-iso-9001-2015.aspx>
 - <http://asq.org/quality-progress/2013/09/standards/standard-wise.html>
 - <https://www.qualitydigest.com/inside/quality-insider-column/3-ways-iso-90012015-will-encourage-process-approach.html>
 - <http://www.linkedin.com/groups/ISO-9001-2015-Revision-Discussion-4437530>
 - i mnogim drugim ...

10 značajnih promjena

Promjene u strukturi: HLS (High Level Structure) iz ISO smjernica

Promjene u načelima upravljanja kvalitetom

Eksplisitni zahtjev za procesni pristup upravljanju

Proširenje opsega djelovanja SUK na širi kontekst organizacije

Uvođenje modela upravljanja rizicima i prilikama

Izostanak zahtjeva za preventivne radnje

Dokumentirana informacija umjesto *dokument* i *zapis*

Dobra i usluge umjesto *proizvodi*

Poboljšanje više ne mora biti *stalno poboljšanje*

Prvi put upotrijebljen izraz *accountable*

Promjene u strukturi norme

Clause #	ISO 9001:2008		ISO 9001:2015
1.	Scope	→	Scope
2.	Normative Reference	→	Normative References
3.	Terms and Definitions	→	Terms and Definitions
4.	General Requirements	→	Context of the Organization
5.	Management Responsibility	→	Leadership
6.	Resource Management	→	Planning
7.	Product Realization	→	Support
8.	Measurement, Analysis and Improvement	→	Operation
9.		→	Performance Evaluation
10.		→	Improvement

Usvaja strukturu i nazivlje u skladu s dodatkom SL smjernica ISO:

Annex SL - ISO/IEC Directives, Part 1, Consolidated ISO Supplement - Procedures specific to ISO, Fourth edition, 2013.

Načela upravljanja kvalitetom



ISO 9000: 2005

1. Customer focus
2. Leadership
3. Involvement of people
4. Proces approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

Procesni pristup

4.4.2 Process approach

The organization shall apply a process approach to its quality management system. The organization shall:

- a) determine the processes needed for the quality management system and their application throughout the organization;
- b) determine the inputs required and the outputs expected from each process;
- c) determine the sequence and interaction of these processes;
- d) determine the risks to conformity of goods and services and customer satisfaction if unintended outputs are delivered or process interaction is ineffective;
- e) determine criteria, methods, measurements, and related performance indicators needed to ensure that both the operation and control of these processes are effective;
- f) determine the resources and ensure their availability;
- g) assign responsibilities and authorities for processes;
- h) implement actions necessary to achieve planned results;
- i) monitor, analyse and change, if needed, these processes ensuring that they continue to deliver the intended outputs; and
- j) ensure continual improvement of these processes.

Kontekst organizacije

4 Context of the organization

- 4.1 Understanding the Organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system
- 4.4. Quality Management System
 - 4.4.1. General
 - 4.4.2. Process Approach

Dva nova zahtjeva (dolaze iz HLS-a):

4.1 Razumijevanje organizacije i njenog konteksta

4.2 Razumijevanje potreba i očekivanja zainteresiranih strana

4.1 Organizacija i njen kontekst

The organization shall determine external and internal issues, that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended outcome(s) of its quality management system

Utvrđivanje vanjskih i unutrašnjih pitanja koja mogu utjecati na sposobnost ostvarenja namjeravanih ishoda SUK;

Eksterna i interna analiza: PEST, SWOT, Porter's Five Forces, Four Corners Analysis, Value Chain Analysis, War Gaming, itd.

Za razmišljanje:

- Traži li ovo da objektivnim dokazima potvrdimo razumijevanje svog poslovanja?
- Kako utvrđujemo 'namjeravane ishode' SUK?
- Kako sad radimo eksternu i internu analizu?
- Kako su one povezane sa sustavom upravljanja kvalitetom?
- Kako ćemo ih ubuduće povezivati?

4.2 Interested parties

The organization shall determine

- *a) the interested parties that are relevant to the quality management system, and*
- *b) the requirements of these interested parties*

Utvrđivanje svih zainteresiranih strana koje mogu imati utjecaja na sustav upravljanja kvalitetom, i njihovih zahtjeva

Interested party (preferred term) / zainteresirana strana

Stakeholder (admitted term) / dionik

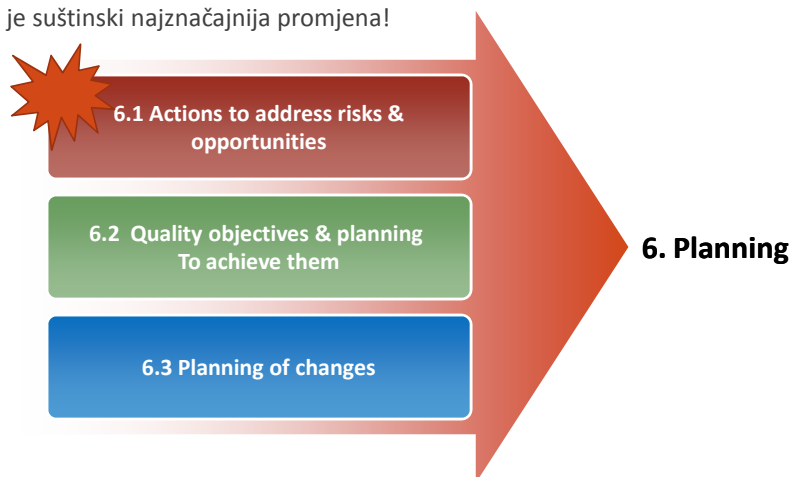
- koristi se u ISO 26000 - Guidance on Social Responsibility

Za razmišljanje:

- Pojam dionik je puno širi od pojma kupac.
- Tko su sve dionici našeg poslovanja?
- Koje su njihove potrebe i očekivanja?

Upravljanje rizicima i prilikama

Ovo je suštinski najznačajnija promjena!



6.1 Actions to address risks and opportunities

When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to

- a) assure the quality management system can achieve its intended outcome(s),
- b) assure that the organization can consistently achieve conformity of goods and services and customer satisfaction,
- c) prevent, or reduce, undesired effects, and
- d) achieve ~~continual~~ improvement.

... ima još ...

6.1 Actions to address risks and opportunities

The organization shall plan:

a) actions to address these risks and opportunities, and

b) how to

- 1) integrate and implement the actions into its quality management system processes (see 4.4), and
- 2) evaluate the effectiveness of these actions.

Any actions taken to address risks and opportunities shall be proportionate to the potential effects on conformity of goods and services and customer satisfaction.

Note: Options to address risks can include for example risk avoidance, risk mitigation or risk acceptance.

Quality Management ---> Risk Management

OBJECTIVES		RISKS
Zero defects	➔	Risk of defects
Customer satisfaction		Risk of customer dissatisfaction
Control of process variance		Risk of uncontrolled proces variance
Reliability		Risk of product unreliability
Security		Risk of security breach
Fit for purpose		Risk of lack of fitness for purpose

Za razmišljanje:

- Kako identificirati rizike?
- Koju metodu evaluacije rizika primijeniti?
- Alati za upravljanje rizicima?

Nema više preventivnih radnji?

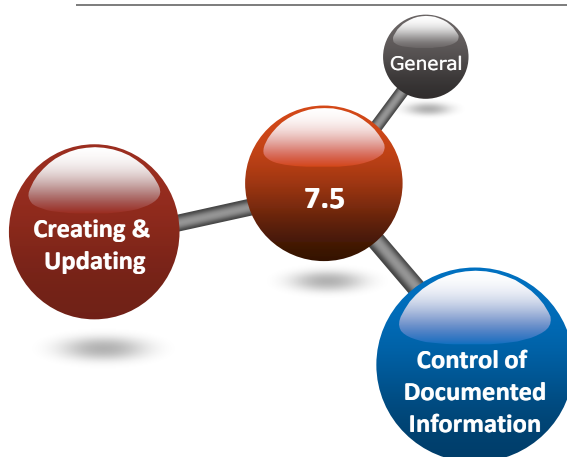
Annex SL, Appendix 2 High Level Structure nigdje nema članka u kojem bi se spominjalo *preventivne radnje*, stoga se i u nacrtu revizije norme one više ne spominju.

Međutim članak 6.1 zahtijeva:

- ... organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to
- ...
- c) **prevent**, or reduce, undesired effects,

Dakle, preventivno djelovanje je zadržano u sustavu kroz uvođenje upravljanja rizicima.

Dokumentirane informacije



Umjesto *dokumenti i zapisi* u upotrebu bi ušao termin *dokumentirane informacije* koji je općenitiji i šireg dosega.

To je u skladu s *Annex SL Appendix 2, clause on Documented Information*

Dokumentirane informacije

3.11

documented information

*information required to be controlled and maintained by an **organization** (3.01) and the medium on which it is contained*

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to

- *the management system (3.04), including related **processes** (3.12);*
- *information created in order for the organization to operate (documentation);*
- *evidence of results achieved (records).*

Proizvod -> Dobra i usluge

Ovo je promjena koja me nimalo ne veseli!

0.3 Significant Changes

Continued omission of specific reference to 'services' was considered to be unsustainable if relevance to the service sector was to be enhanced. On that basis 'product' has been replaced by 'goods and services' when specifically referring to the deliverables for the customer.

This proposed change will be subject to a specific briefing note and a request for ballot input from ISO/TC 176/SC 2 member bodies.

Za razmišljanje:

Nakon što smo desetak godina objašnjavali kako se usluga također može vidjeti kao proizvod i obratno, i najzad u tome uspjeli, ne bismo li bili sretniji da ova promjena ne bude usvojena?

Continual improvement

10.2 Improvement

The organization shall ~~continually~~ improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall improve the quality management system, processes and goods and services, as appropriate, through responding to:

- a) results of analysis of data;
- b) changes in the context of the organization;
- c) changes in identified risk (see 6.1); and
- d) new opportunities.

The organization shall evaluate, prioritise and determine the improvement to be implemented.

Accountability!

Clause 5.3 Organizational roles, responsibilities and authorities

... Top management shall be accountable for the effectiveness of the quality management system ...

Za razmišljanje:

Prijevod izraza *accountable* na hrvatski jezik?

Riječ *accountability* nastala je iz riječi *account* što znači račun, a ova pak od riječi *count* što znači *brojati*. Sažeti smisao tog izraza jest da je *accountable* onaj kome možete poslati račun na naplatu.

Doslovan prijevod *accountability* bio bi *ubrojivost* ili *uračunljivost*. Kod nas ovaj izraz najčešće susrećemo u vezi s krivičnim pravom i pravosuđem. Kažemo da je osoba *ubrojiva* u značenju da je sposobna razlučivati dobro od zla te stoga može odgovarati za svoje postupke.

Status revizija

Povjerenstvo	Norma	Faza	
ISO/TC 176/SC 1	ISO/DIS 9000	40.00	DIS registered
ISO/TC 176/SC 2	ISO/CD 9001	30.99	CD approved for registration as DIS

Podaci sa:

http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=53882&development=on

Šuška se...

Predložen novi dokument s uputama - ISO TS 9002

- „... new piece of work within TC 176 to produce a guidance standard covering implementation of the next edition of ISO 9001. The standard will be a Technical Specification (TS) and the first meeting is planned for June 2014. ...”

Revizija ISO 9004?

- Nigel Croft: “Ad-hoc group currently being formed within ISO/TC176/SC2 to review ISO 9004 ...”
- Na stranicama ISO/TC 176 nema informacija za sada

Hoće li ISO 9001:2015 početi umanjivati značaj Predstavnik uprave?

- David Hoyle: "There is an implication that top management could make all its direct reports responsible for all these activities and why not I ask? It is far easier for a line manager to ensure his staff undertake these activities than require someone else to do so.,,

