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*QA with a smile. struggle-free*

# The Changes in ISO 9001:2015 in a Whole New Light



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# Quality with a smile, struggle-free.

Quality is pride of workmanship.

W.Edwards Deming

Quality is such an attractive banner,  
that sometimes we think we can get away  
with just waving it, without doing  
the hard work necessary to achieve it.

Phil Crosby



# Purpose

- In the **conventional** approach, QA is most often treated as a wholly technical discipline. In my opinion and experience – this is not so. So much not so as to completely limit the profession on all sides.
- The purpose of this presentation is to help those who are transitioning to the new ISO 9001:2015 revision to understand this standard from an **alternative**, coaching, **human** perspective, not the conventional one. To remove the glass ceiling from your results.



# Interpretation

- I would like to remind everyone, that **any** reading is an **interpretation**, and that this presentation is no different in that respect.
- This is **my own, personal, interpretation**, which is in sync with my own, personal, approach to Quality Assurance.
- Intent is interpreted not just from exact words, but the reader's own **context** and **experience**. Change interpretation – get a different intent.
- I hope mine would **influence** yours somewhat.





# The need to change

It is not necessary to change.

Survival is not mandatory.

W.Edwards Deming

Slowness to change usually means  
fear of the new.

Phil Crosby

The standard is not set in stone. The definition  
of the standard is that it is the best way to  
do the job for now. It should be regarded as  
the next step to make further improvement.

Masaaki Imai



# The need to change

- ISO gives **several specific reasons** for change, some more obvious than others:
  - adapt to a changing world;
  - reflect the increasingly complex environments in which organizations operate;
  - provide a consistent foundation for the future;
  - ensure the new standard reflects the needs of all relevant interested parties;
  - ensure alignment with other management system standards.



# The need to change

- However, I would like to point out a couple of completely different reasons, which are obvious to myself, and those whose approach to Quality Assurance is closer to mine, if not to all others:
  - most people do not seek deeper **meaning**, they read literally;
  - the **exact wording** is, in fact, most important and may completely alter the understanding of the whole and, naturally, its implementation;
  - most organizations I encountered seem to **completely miss** some of the finer points. A change of wording and structure is, therefore, in order.





# The need to change

- And the most obvious reason of all for change: this is a standard in no other discipline but in **Quality Assurance**. Our profession, our whole purpose is affecting **change**, for **without change there can never be improvement**
- least of all constant improvement:
  - the established guidelines are forever no more than **a basis for future changes**;
  - reviewing, fine-tuning where they work and trying something completely different where they don't is a **constant process** – and it can actually be fun!



# Potential benefits to the user

- Focus on achieving planned results
- Flexibility for documented information
- Improved risk control
- Better process control leading to improved results
- Improved customer satisfaction
- Customer retention and loyalty
- Improved image and reputation
- Greater credibility



# Common clause structure

- A new common format has been developed, which would bring the following key benefits:
  - all ISO management systems standards will look the same with the same structure (some deviations);
  - more efficient to address multiple management system requirements;
  - provides the option of integrating management systems;
  - standardized core definitions.



# Risk-based thinking

Improvement usually means doing something we have never done before.

Shigeo Shingo

The more you seek security, the less of it you have. But the more you seek opportunity, the more likely it is that you will achieve the security you desire,

Brian Tracy



# Risk-based thinking

- Risk-based thinking **has always been** a basic requirement in ISO 9001. In fact, that's how our Universe is built/created:
  - there is **no such thing as "risk-free"** in any aspect of life;
  - there is **no concept of "safe"** in any aspect of life;
  - it is **impossible to "prevent" or avoid risk**, as it is an **intrinsic** part of any process, action or area of life, whether organizational, political, personal or other.
- It is, however, very much possible to **manage, assess and minimize risk**, in all aspects of life.



# Risk-based thinking

- We usually regard the concept of “**risk**” as something **negative**, to be avoided at all costs. This is a **mistake**.
- In fact, the other side of “risk” is called “**opportunity**”, and it is very much **positive**. There is no progress without opportunity.
- The thing is, **without the one, the other does not exist**, either. You are, probably, familiar with the phrase:

**No pain – no gain.**





# Risk-based thinking

- **Any** venture, any business, is based on some rather heavy risk management and constant search for opportunity.
  - That includes non-profit organizations, charities, states, religious institutions, families, individuals, **any unit of life**, anywhere. We just don't always pay attention to either, or forget to look for opportunity (or miss it entirely) for fear of the risk.
- Considering risk-based thinking to be new to ISO 9001:2015 is, therefore, wrong. **It has always been there**, albeit it hasn't previously been worded as a specific requirement.



# Risk-based thinking

- So why have ISO changed the wording now?  
I think, the accumulated experience made them realize, that most users:
  - **miss** opportunities entirely **for fear of the risk**;
  - **avoid dealing** with the risks, for lack of knowledge in problem-solving methodology or other skills;
  - are **unaware of the difference** between the terms risk-prevention and risk-management, mix them up;
  - or are **not aware they are doing it already**, all the time, just under various other names and tools.



# Risk-based thinking

- If that's the case, what does the change require of you?
  - **raise awareness** of both opportunities and risks, which would mean **routinely dealing with them**, identifying risks and opportunities at every turn;
  - turn **avoidance behavior** into **embracing the unavoidable**, acquire the **necessary knowledge and skills** to render risk-management effortless;
  - **eliminate** risk-prevention approach via training;
  - **document** the actions already taken, as a rule, under various other names and tools, as risk management.



# Process approach

If you can't describe  
what you are doing as a process,  
you don't know what you are doing.

W.Edwards Deming

Every real story is a never ending story.

Michael Ende, The Neverending Story



# Process approach

- As is the case with risk management, process approach **has always been** a basic requirement in ISO, and is the way our Universe operates.
  - there is no action, no operation, nothing one does, ever, in any aspect of life or Universe, which is not **a part of some process**;
  - **any process** in any aspect of life or Universe is **always connected to other processes**;
  - there can rarely if ever be **a clear beginning and ending of a process**, which is not simply a symbolic agreement between people, for **convenience**.



# Process approach

- Understanding this can simplify the acceptance of the concept of the extended organization, or rather, Ishikawa's "changing adversarial customer-supplier relationship into mutually beneficial partnerships":
  - the **same** process begun at the supplier's, **continues** in your organization;
  - then it **connects** and **continues** at your **customer's** organization;
  - in fact, it **began before** your supplier, with raw materials, and will **continue** from your customer to end customer – you are all a single chain;





# Process approach

- the chain is only as strong as its **weakest** link;
- therefore, it **makes no sense** to **separate** your organization from either your supplier or your customer; you form **one larger entity** with **one goal**;
- then it **makes sense** to work with **single** suppliers for each item, to help develop **strong long-term relationships** of loyalty and trust;
- in fact, it would be no more than **you** would **expect** from your relationship with **your own customer**;
- end result of this process would be **improved quality** and **customer satisfaction**.



# Process approach

- Considering process approach to be new is, therefore, wrong. **It has always been here**, though not previously worded as a specific requirement.
- So why the changed wording now? Realization, from accumulated experience, that most users:
  - **misunderstand** the whole concept of “process”, tending to attribute it to the technological part of the industry; but **any procedure** describes a process;
  - lack knowledge, skills or awareness of **process mapping**;
  - are **unaware they are doing it already**, all the time, just under various other names and tools.



# Process approach

- If that's the case, what does the change require of you?
  - **raise awareness** and **communicate** process approach at every level of your organization;
  - acquire the **necessary knowledge and skills** to render process mapping effortless and widely available to all, in all processes;
  - **document** the actions already taken, under various other names and tools, as process approach;
  - replace **action-thinking** with process-thinking, as a rule, via training.



# Process approach

- These small changes will allow you to:
  - easily **separate** actions within a process into **VA** (value-added) and **NVA** (non-value-added), and **eliminate** the latter;
  - pursue **Lean methodologies**, which would bring better efficiency, lower costs and improved quality;
  - develop an ever better **understanding** of your **processes**, which makes constantly correcting and improving them an easy task;
  - facilitate the **engagement** of your workers **throughout the processes** in which they participate.



# Context of the organization

If the ladder is not leaning against the right wall, every step we take just gets us to the wrong place faster,

Stephen Covey

Once you have a clear picture of your priorities – that is values, goals and high leverage activities – organize around them.

Stephen Covey





# Context of the organization

- So far we've been talking of the changes discussed mostly in the **Introduction** part of the standard, though **woven through the whole standard** in various clauses, as is fitting.
- Now, we have a **whole new clause**, with which the standards opens proper, **Clause 4: Context of the Organization**. At first glance, it is a bit difficult to understand what the authors have intended to convey via such a title. This is where I would attempt to make the difference.





# Context of the organization

- The standard says the following:
  - “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 result(s)** of its QMS”.
- What hides behind this somewhat unclear formulation, is this:
  - an organization **cannot possibly** organize itself and decide how to **best implement** a general standard, **without first understanding what it is all about**.



# Context of the organization

- Before embarking on any sort of “program”, leadership must understand what the organization itself is all about, right now, **before** any implementation and changes take place.
- It is like personal development: before you begin to change things about you, understand and accept yourself **as you are**. For that is the very **base** from which you shall begin to grow.
- The idea is: **ISO 9001 is universal,  
but NOT a one-size-fits-all solution.**



# Context of the organization

- Answer the questions for yourselves:
  - What are your **objectives**?
  - What makes you **special** in your industry, and **different** from your rivals?
  - Why do **you** think you need ISO 9001?
  - Who are your **market/suppliers** and what do they need? Where are they? What is your **relationship** with them?
  - Who are your **workers**, and what is your **relationship** with them?
- And any other pertinent question you can come up with.



# Context of the organization

- Once you have done that:
  - you can really **understand** your organization;
  - you may truly be **ready** to learn the clauses of ISO 9001:2015;
  - only then it will become clear how to best implement them for your own, unique context, **tailor your own suit**, so to speak.
- Working the other way around, as most were doing up till now:
  - leaves too much space for **confusion**;
  - makes one try to fit oneself into the **a suit which is wrong** for one.



# Context of the organization

- And now, after you have done this and **acquired** a modicum of **self-understanding** and **awareness**, you are directed:
  - to **document** that which you have discovered in the initial state;
  - to remember, that the world, and your organization in it, are **neither isolated nor static**;
  - to recognize that this initial state is but **the base for your future growth**;
  - to continue **maintaining** and **monitoring** this state of understanding yourself and your relationship with interested parties, who may affect you.



# Context of the organization

- That is why ISO were absolutely **correct** and **precise**, to place under the ***Context of the organization*** also:
  - ***the scope of your QMS***, as it is a **direct result** of your understanding of your own context;
  - ***QMS and its processes***, for they are the very **implementation**, the very custom-tailored suit we have just mentioned, out of the whole general guidelines ISO 9001:2015 provides.





# Leadership

The prevailing system of management  
has crushed fun out of the workspace.

W.Edwards Deming

Eliminate numerical quotas,  
including Management by Objectives.

W.Edwards Deming



# Leadership

- The next clause, #5, had its title changed from ***Management responsibility*** to ***Leadership***. Its contents also got to be split into several clauses, but these are small changes, and they are absolutely right and logical, once you accept the logic behind this **excellent change**.
- At first glance, one may ask: What difference does it make? Why bother changing the name?
- Words are precise, and their usage **creates a mental picture** for us, which is difficult to shake, due to the **personal** context we attach to them.



# Leadership

- When most people, especially **managers**, contemplate the word "responsibility":
  - they see a picture of a **burden**, a duty, a heavy load which they need to carry, as a punishment from God for being ambitious or something;
  - they **do not believe** their workers would take responsibility of their own volition, therefore, they feel the need to **set it up for them and make sure** they carry it.
- This doesn't make a person happy for having **himself** to take on responsibility.



# Leadership

- Taking into account the spirit of the standard ISO 9001, I can say without a doubt that **this has never been its authors' intention.**
- The intention was, from the start, that the management:
  - should **lead by personal example**, and should therefore, first and foremost, take the responsibility themselves;
  - do all that they chose to do **of their own free will and out of integrity**, before developing expectations from people at any lower organizational level to take on responsibility for their part.



# Leadership

- Clearly, the message did not come across, and the title was taken literally as a **dictate of requirements** and demands – by the standard from the management: the standard demands that management take responsibility, whether they wish to or not, and carry this burden henceforth [sigh].
- Basically, this boils down to **burden** vs **choice**. To "I **have** to do it" vs "I **get** to do it". And the way the previous title was read and understood was the first, and not the second of the above.



# Leadership

- Now, in the 2015 revision of the ISO 9001 standard, this was corrected:
  - no more talk of responsibility;
  - the word "management" disappears as well;
  - now it is all about leadership.
- So, what is a **leader** then?
  - a leader can see where you should go, he has **a vision**;
  - he can lead the people there **without force or manipulation**, but willingly;





# Leadership

- he can **share his vision** with them, allow them to see that same better future he can see and **motivate themselves** to make the journey which will take them there;
- people will maintain this self-motivation **while he is absent**.
- The intention in ISO 9001:2015 revision is to turn the tables. **Free all the managers of their burdens** and their heavy loads, and breathe new life into them, where they may become leaders, not managers. To **lead by choice, not out of duty**.



# Leadership

- Managers mostly see their role as those who **demand execution** of this or that **in such and such particular way**, limiting it to a narrow window for possibilities. The very demand results in **resistance**, while the limitation demonstrates he doesn't really see the individual workers at all, only the demand and his own solution.
- In this situation the people will do as they are told, but **not a whit more**, and only **as long as** the demand is supported by **control**.



# Leadership

- A leader **demands nothing**. He brings vision and inspiration, followed by expectation for the best you can possibly do – with **all the possibilities wide open**.
- The result is that people **do on their own**, without being told, and surprise everybody, including themselves.
- This is why this change is truly **precise and most excellent**, and if you understand it – can mean the **removal of glass ceiling** for your results.



# Planning

A bad system  
will beat a good person every time.

W.Edwards Deming

Goal setting has traditionally been based  
on past performance. This practice has  
tended to perpetuate the sins of the past.

Joseph M.Juran



# Planning

- A separate clause, #6, has been allotted for ***Planning***, which has hitherto been residing under ***Management Responsibility***. It brings together **specific planning activities**:
  - **actions**, to address risks and opportunities;
  - setting of **targets, policy, responsibility & authority**;
  - and, most important of all: the **planning ahead for changes**, making us all recognize very early on that everything we set up today is but the base for future changes, that change is good for us;
  - it also brings the planning **out** of the realm of Upper Management, and into a much wider circle.





# No more Purchasing

Quality is everyone's responsibility.

W.Edwards Deming

The problems in life come when we're  
sowing one thing and expecting to reap  
something entirely different.

Stephen Covey

Without involvement there can be no  
commitment. Mark it down, asterisk it, circle it,  
underline it. No involvement – no commitment.

Stephen Covey





# No more Purchasing

- What was clause 7.4, **Purchasing**, has now turned into 8.4, **Control of externally provided processes, products and services**. This is a change I, personally, have been waiting for a very long time.
- Once again, we are talking about the precise words, and once again I shall remind you that we use these words in order to **describe**, as accurately as we can, **concepts and ideas**. These ideas may be quite simple, and then then may not be simple at all, or only seem simple at first glance.



# No more Purchasing

- What about the **idea** represented by the word “purchasing”? What is the mental picture created by that word?
  - we see **buying**, the process of acquiring something from a third party via exchange of goods.
- This is what we do **not** see, unfortunately:
  - **responsibility** for the goods/services acquired in the process down the road after the acquisition;
  - “evaluation, selection, monitoring of performance, re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements” – ISO 9001:2015.



# No more Purchasing

- We even have a new word coined for those clerks in Purchasing departments in many, too many organizations: **buyers**. That is what they habitually see their duties come down to: they buy. Full stop. **No commitment** to anything afterwards.
- In fact, those who deal with Buyers know, that to get them to actually talk to the supplier afterward about a Quality problem is not only difficult, but the whole request meets with **resentment**, almost hostility. They claim inability, lack of knowledge... and they are right.



# No more Purchasing

- Buyers, usually:
  - **know very little** of Quality Assurance, and even of the **actual use** of what they buy in the real process;
  - **rarely** if ever **see the process** ensuing after the buying occurs;
  - **rarely** if ever are **involved** in supplier assessment.
- This is a **grave mistake** resulting in:
  - lack of a **proper relationship** with suppliers;
  - **low quality** of purchased goods, due to wrong choice of supplier and the relationship with them;
  - nearly **no Corrective actions** from suppliers' end following non-conformance;



# No more Purchasing

- **low quality** of **your** process and product, due to lower quality of purchased material;
- **higher costs** of process and product, due to costs, associated with correction of the problem;
- **higher time to market**, due to delays in processes caused by said problems;
- **lower customer satisfaction**, due to all of the above.
- ISO 9001:2015 is attempting now to correct this problem, by specifying the **precise breadth of the function's spectrum**, instead of the narrow limits of acquisition. Now, if we call their job properly, we may **engage them in the process**.





# No more Purchasing

- Engaging the former Purchasing in the process means:
  - **lower the resistance** to training for quality;
  - **better understanding** of the true nature of the purchased goods and their use and requirements;
  - **taking responsibility** in supplier assessment process;
  - **improved relationship** with suppliers by active involvement with their processes and products;
  - **higher quality** of purchased processes and products;
  - **higher quality** of **your** processes and products;
  - **lower costs** of production, better efficiency;
  - **improved customer satisfaction.**





# Corrective & Preventive actions

All improvement happens project by project, and in no other way.

Joseph M.Juran

The ideas of control and improvements are often confused with one another. This is because quality control & quality improvement are inseparable.

Kaoru Ishikawa

Failure is the seed of success.

Kaoru Ishikawa



# Corrective & Preventive actions

- Another small, but **significant** change made in ISO 9001:2015 is the separation of the **Corrective** and **Preventive actions**, which used to occupy together clause 8.5, ***Improvement***.
- Now, **Preventive action** has been virtually moved to clause 6.1, ***Actions to address risks and opportunities***, and in an **implied** way only, no longer specifically listing any methodology or suggesting any order of action; while **Corrective action** remains under ***Improvement***, clause 10.



# Corrective & Preventive actions

- While I can generally relate to the logic of this separation, I feel this particular change might be **a mistake**:
  - it separates the **Corrective action** from the ever-accompanying **Preventive action** you should **always** contemplate, **while making any** Corrective action;
  - this will, most probably, bring **down** the amount of preventive actions, which will result in **non-conformances** that could have been prevented, but weren't considered, and an **increase** in Corrective actions (post-non-conformance, or, as we say, putting out fires);



# Corrective & Preventive actions

- in addition, upon this change, Preventive action no longer has **specific** guideline or reference; which may be read as the complete elimination of requirement;
- the result might be that there will be **next to no Preventive actions at all**, as it is a more difficult course of action to take, though the more correct one;
- which shall, in turn **increase again** the “fires”, and putting them out with Corrective actions – a vicious cycle.



# Procedures

We know we need civilization, and laws, and procedures, but isn't it frustrating? Wouldn't it be great if we could just do what we needed to do?

Lee Child

When we ask bureaucrats to identify who is responsible, they reassure us that there are 'procedures in place'.

Michael Faber

Almost all quality improvement comes from simplification of design, manufacturing... layout, processes and procedures.

Tom Peters





# Procedures

- There used to be a requirement for **6 major Procedures**, which is **eliminated** in the 2015 revision. Personally, I welcome this change, but think that most users will **misunderstand** it.
- Nearly every organization I have had contact with, regards the concept of “Procedures” **directly opposite** to what ISO (and TQM before it) intended them to be. They:
  - view the procedure as **law**: once set – it is **unchangeable** and to be **enforced** at all cost;





# Procedures

- approach any **resistance** to procedures as nearly military **breaches of discipline**;
- see the **purpose** of an audit in finding out who doesn't follow procedures and make them do so;
- think that **everything which is done** must be written down;
- **confuse** procedures, guidelines and work instructions, and **pool them all** under same doc type in the same place, inevitably ending with **too many documents**; this turns them into something kept solely for the ISO auditor.



# Procedures

- Due to all above, most treat procedures, as a **necessary evil** demanded by the standard, for the sake of **bureaucracy**. In fact, nothing could be further from the truth.
- Procedures are intended to be:
  - merely **descriptions** of the way you have decided to perform your processes;
  - **basis for future changes** and **improvements**, like any other decisions, plans and policies;
  - written **only where necessary**, for simplification;
  - **tools for the workers** to use, when unsure.

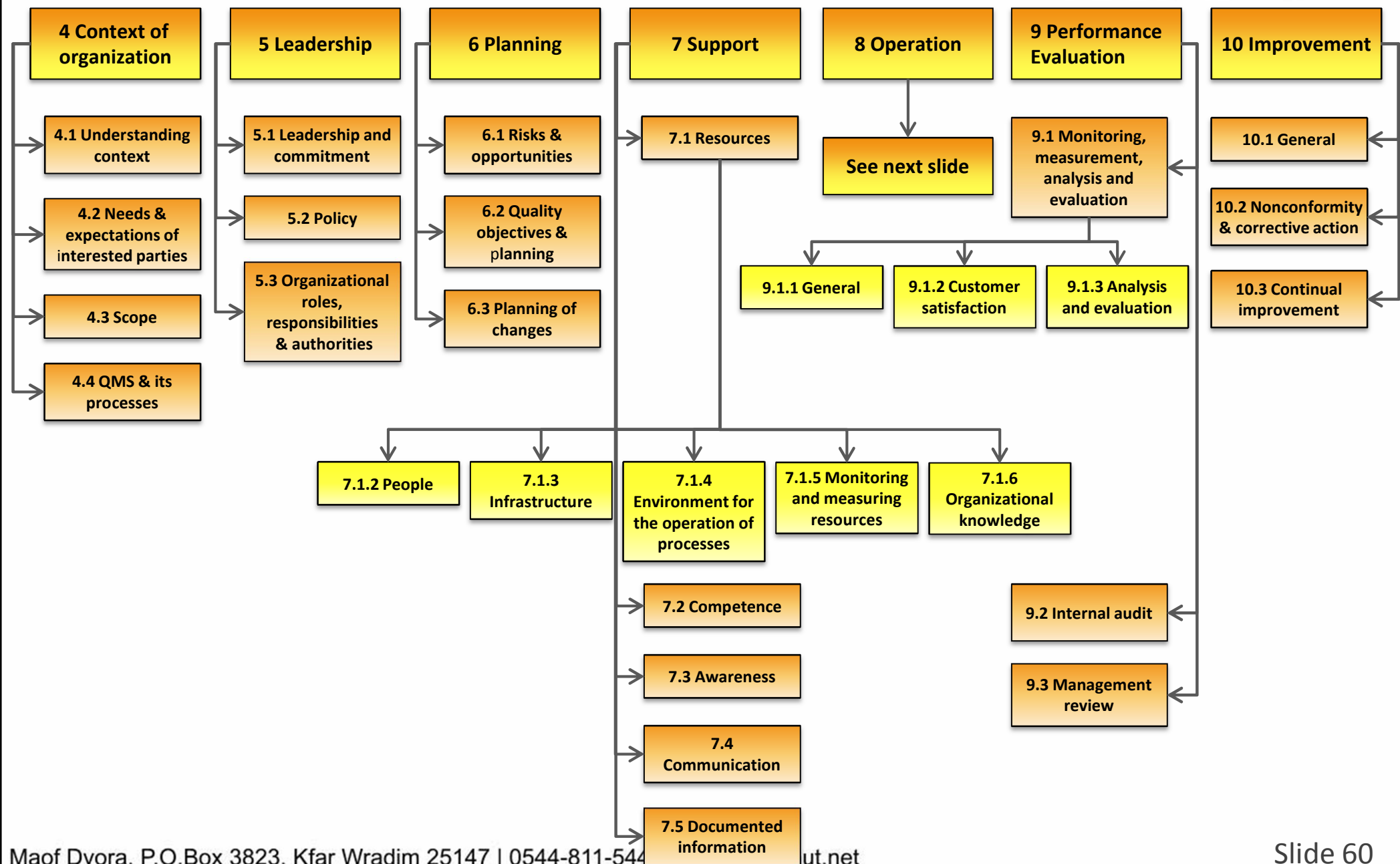


# Procedures

- Therefore, the **elimination** of the requirement for written procedures **does not mean** that:
  - no procedures are needed;
  - ISO had in any way changed their requirements about procedures;
  - you need to get rid of your procedures now; etc...
- What it means is that ISO **no longer interferes** with which procedures you need to write for yourselves and which you do not, **placing the control back in your hands**, where it belongs.

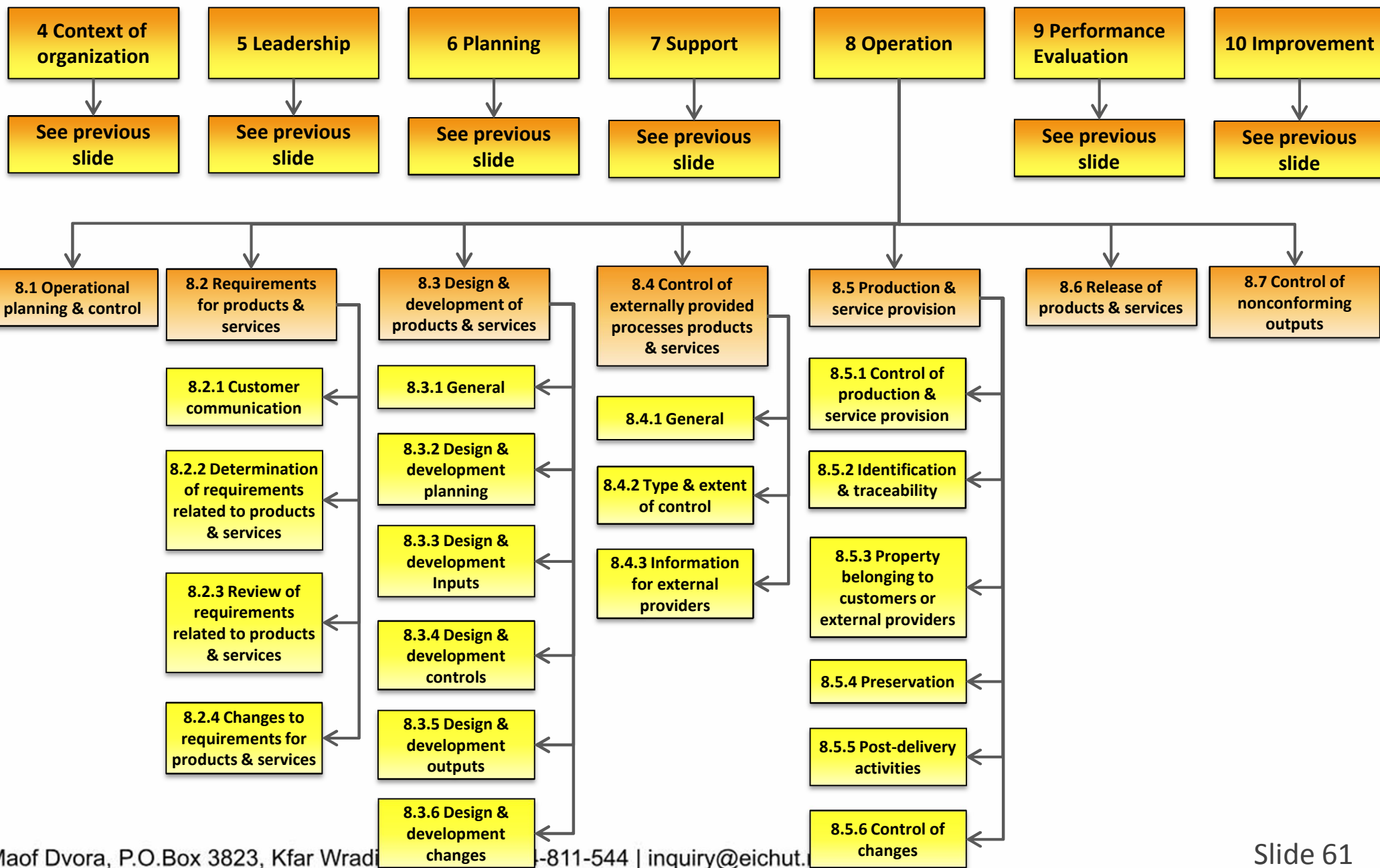


# ISO 9001:2015 clause structure





# ISO 9001:2015 clause structure





# Summary

- I have covered here **all the significant changes** in the new 2015 revision of the ISO 9001 standard.
- The changes were all discussed from a **human, psychological, and not the conventional, technical point of view**, which I know abounds in most articles on the matter of the change.
- Personally, **I welcome these changes** and am convinced nearly all are **excellent**, precise and in the TQM spirit of **constant fine-tuning** and improvement.
- **Thank you** for your attention. Hope I was successful in **lifting the mists of mystery** somewhat. 😊





## Further reading & Contact

- At my website (URL: <http://eichut.net>) you may find **some articles**, which I have written on the subject. **More will be added** as soon as I can.
- There are quite a number of articles on **other QA subjects** that you may find interesting.
- The website is **bilingual**: English-Hebrew. Everything there is written in both languages.
- **Help me improve for you!** Tell me what you would like to read about. You may **reach me** from the [Contact page](#), or via email: [inquiry@eichut.net](mailto:inquiry@eichut.net).  
**I am always happy to receive feedback.**



**Maof Dvora**

# QA with a smile, struggle-free



**Maof Dvora**

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**To know more about me and my approach:**

**<http://eichut.net>**