Q Community QMS SIG webinar, 1st November 2022

From Sam McIntyre to Everyone 01:15 PM

Here's that link: <https://the9000store.com/iso-9001-2015-requirements/iso-9001-2015-context-of-the-organization/what-is-a-process-approach/>

Response:

Tom

Thanks Sam. Also accessible via my index diagram.

From Louis Faber to Everyone 01:16 PM

I've heard of TZD - Towards zero defects :)

Response:

Tom

Thanks Louis. It MUST be the aim of all of us. We will never change if defects are accepted as the norm. Active processes MUST be designed and implemented to address defects. This is a key part of a proper QMS.

Zero defects is **a way of thinking and doing that reinforces the idea that defects are not acceptable, and that everyone must strive to "get it right the first time."** When you strive for zero defects it can improve the quality of your product or service, and reduce costs associated with waste.

Error, non-conformance, never event, etc. They are all defects.

Isabel

Towards zero defects is an approach more suitable for manufacturing processes, definition of defects varies and is context dependant.

From BRUCE GRAY to Everyone 01:19 PM

'Deficiencies' in an NHS world.....lean 8 wastes can give us a way-in to describing 'deficiencies'.

Response:

Tom

Thanks Bruce. Not having the items required to complete your work (deficiencies) is certainly a QMS issue.

From Lesley Morgan to Everyone 01:21 PM

We are accredited to ISO 15189:2012 (which is specific to Medical Laboratories) in Pathology so we have a well-structured and documented QMS which underpins all of our processes, but ISO 9001 is a good generic place to start.

Response:

Tom

Thanks Lesley. Any Trust that is considering a QMS should have a really good look at what has already been successfully implemented in certain parts of their own organisation. They will learn a lot about Quality Management.

Radiotherapy use ISO9001 and have the scope clearly defined although we currently do not have a radiotherapy specific standard like ISO 15189.

From Dave Grewcock to Everyone 01:21 PM

So if we adhered to ISO 9001, by definition we have a QMS?

Response:

Tom

Thanks Dave. Yes that’s right. Adherence to the full requirement of ISO9001 is a big task and, in my view, some of the clauses need some careful thought and application in a healthcare setting. It is not necessary to meet the requirements of the standard for you to have a QMS. ISO9001, in my view, details the best starting point for anyone wanting to implement a QMS. It is not necessary for external certification, other than where it is a contractual requirement, for a Trust to have an effective QMS.

ISO9001 is a set of generic standard that’s scalable and will need to be define in the organisation, it can be a service line e.g. a whole cancer service or a specific process e.g. medical device management or the whole hospital or a network of hospitals.

From Yvonne Morgan to Everyone 01:24 PM

ISO 15189 is quality management for Medical labs which branches off from the main standard of ISO 9001

Response:

Tom

Thanks Yvonne. Good Quality Management Systems are not new to the NHS. Their Labs, and some other areas, have a great deal of knowledge on QMS. Their standards, as Yvonne points out, are specific to their scope but are based around ISO 9001. Did you know that there is a British and European QMS standard for healthcare? It is BS EN 15224:2016. It is based on ISO9001 but I would not recommend it for a Trust before they have had the experience of implementing an ISO9901 QMS and several years practice at running their QMS..

From Sam McIntyre to Everyone 01:27 PM

Thomas do you have any advice for moving your audit results from 'yes we have x process on file' to 'yes we are confident that x process works well and is robust'?

Response:

Tom

Thanks Sam. Yes I do. The answer is to design a Process Management System adopting the process approach. There is a good example a good a PMS that can be found from my Index diagram. It would be a great example for your organisation to run such a system. I can help with the design.

From experience this depends on the maturity of your QMS, likely to be more clause based first and evolved into process focus audit program.

From Helen Meese to Everyone 01:33 PM

We have a great tool for defining terminology <https://www.iitoolkit.com/resources/terms.html>

Response:

Tom

Thanks Helen. Nice definitions. This is more relevant to quality management: [https://efrcertification.com/Ref/ISO+9000-2005.pdf](https://efrcertification.com/Ref/ISO%2B9000-2005.pdf)

Quality Professional do not expect Clinicians to change their language so do not expect then to change theirs. If you want help from Quality Professional, and you need it, then you will have to start using their language. It’s not too difficult.

Terminologies are clearly defined in glossary in ISO9001.

From Sid Beech to Everyone 02:00 PM

Very true Bruce. A big potential complexity with implementing QMS is the challenge of "treading on toes" as there are a lot of politics, established hierarchies, relationships that would need exploring.

Response:

Tom

Thanks Sid. If the NHS want to start managing the quality of their services then never mind the politics – just get on with it.

Yes and therefore the focus is on how we manage risks/opportunities and interested parties we work with.

From Sid Beech to Everyone 02:01 PM

I disagree Tom... Quality isn't so easy to define

Response:

Tom

Thanks Sid. Quality is defined in the two links above and the WHO has a definition for Quality which is used by the NHS. I don’t see any problems with any of them. It’s defining quality management that the NHS has a problem with.

Agreed. Quality is not generic to all interested parties involved and therefore a clear scope / context of organisation is essential. In healthcare this is no longer just defined by the department/service provider but also need input from all other interested parties involved hence codesign/coproduction are essential.

From Louis Faber (CLCH) to Everyone 02:02 PM

The real challenge is how to define quality standards when there is a great deal of Variability (patient needs, complexities, demographics between geographies)

Response:

Tom

Thanks Louis. It’s not a problem with the standard. It’s a problem with their interpretation/application. Standards should never take away the need for professional to make on the spot decisions. Of course we are all accountable for our actions after the event. Patient variability has always and will always be present and must be understood when considering standards.

From Sam McIntyre to Everyone 02:03 PM

Quality is neatly definable in a broad sense, but for me when looking at a QMS there are many complexities and specifics that you need to define quality again and again for each process/work area.

Response:

Tom

Thanks Sam. Work standardisation and work standards are not the same thing. Trained professional should not need to be told, for most work activities, what the standard is. Work or process certainly dose need to be defined and standardised. There are many ways to skin a cat but not all of them are effective and efficient. The key benefit to following a process approach is the then you can improve the process. That is how you manage quality. One part anyway.

From Louis Faber (CLCH) to Everyone 02:03 PM

Very difficult to stick to these standards when there are so many exceptions and curveballs

Response:

Tom

Thanks Louis. That is not the case when you have a system in place. I think it will take the NHS some time to get there but they have to start some time.

From Yvonne Morgan to Everyone 02:04 PM

I think it has to be customized but also align with ISO 9001 in this context of QMS. The ISO clauses include the Context of the organisation

Response:

Tom

Thanks Yvonne. I agree with you - but the ‘customizing’ must be carefully managed or you are in danger of creating something other than a QMS.

Agreed. Quality is not generic to all interested parties involved and therefore a clear scope / context of organisation is essential. In healthcare this is no longer just defined by the department/service provider but also need input from all other interested parties involved hence codesign/coproduction are essential.

From Tegid Williams to Everyone 02:05 PM

It’s a very interesting question. What should the aim be: follow these standards and get accredited (certified, only UKAS can accredit) say? or take the principles of what these standards are trying to achieve and implement them into our own healthcare systems - whatever this look like.

Response:

Tom

Thanks Tegid. The aim, at this stage, should be to follow the principles of what the QMS standard (ISO9001) is trying to achieve and implement it into our own healthcare system. A staged approach will be required with the basic system being designed around a single area and starting with process management.

Many organisations have bits and pieces of the processes but they are not integrated necessarily. Mapping them is a huge task at trust level although some services such as medical lab and radiotherapy have this relatively well established in healthcare.

From Yvonne Morgan to Everyone 02:07 PM

That is true Tegid but accreditation or regulatory could also be an interested party within the context of the organisation.

; so I agree it depends on what the Trust's strategy is.

Response:

Tom

Thanks Yvonne. Accreditation for a whole Trust is too big a hurdle and would cost so much in terms of effort and money. The first step is to create the right strategy. This could be designing Quality Management Policy at the top of the organisation. This policy should outline requirements for specific areas of the organisation to design and implement a Process Management System, based on a Process Approach, for key processes in that area. Process standardisation should be the initial aim and not process standards. Process standardisation must take account of the very humanistic nature of healthcare work. Would this be a QMS? Not yet but is is the right starting point. Designing the right strategy is so so important.

From Matthew Mezey (Q team) to Everyone 02:10 PM

@Emma - I'd suggest that the findings of the VMI-NHS Lean report perhaps suggests that we need to become aware of the quality of 'Relational Coordination' between groups of people inside our organisations.No standards for that yet... ;-)Should there be...?!

Response:

Tom

Thanks Matthew. VMI report accessible from my Index diagram.

From Isabel ho to Everyone 02:10 PM

PAS1616 is the clinical service standard developed by BSI, HQIP and a few professional bodies <https://www.hqip.org.uk/resource/bsi-pas-1616-2016-healthcare-provision-of-clinical-services-specification/#.Y2Eoh3bP2Uk>

Response:

Tom

Thanks Isabel. PAS 1616:2016 is a very good standard. Its scope is restricted to clinical services only. It is not the specification for a QMS but includes some of the elements of one i.e. document control. It is a shame that a ‘process approach’ was not adopted by the standard. It will sit very nicely alongside ISO9001. Annex B, B.2 includes the sentence ‘Clinical service delivery should be designed such that risk is minimised, that clinical service users receive person-centred treatment and/or care and that clinical effectiveness is maximized to achieve the best value for money.’ How this is achieved without a Process Management System I do not know.

It needs to sit alongside ISO9001 not as a standalone standard. This is an UK recognised standard not ISO recognised internationally but it’s a good starting point for some disciplines when there’s no agreed standards available.

From Joanne Woolley to Everyone 02:15 PM

Isn't "quality" the minimum aspiration though?

Response:

Tom

Thanks Joanne. Quality and Quality Management are not the same thing. Quality is set by Service specifications; quality management is about how you work. I would not use the term ‘minimum aspiration’ for either.

Agreed. They are not the same – quality management involved lots of process design/process management (efficiency, effectiveness, reliability etc.).

From Emma Adams to Everyone 02:15 PM

Again - comes back to language. Quality can mean everything depending on how you look at it!

Response:

Tom

Thanks Emma. I do not have a problem with the term Quality or, more importantly, Quality Management.

From BRUCE GRAY to Everyone 02:15 PM

I think variation is the bigger problem for NHS processes than error, because unwarranted variation is far more widespread than actual error - it's more a problem of productivity-sapping waste creation... IMHO

Response:

Tom

Thanks Bruce. Your opinion is valued. IMHO error is the problem and unwarranted variation is the reason. Adopting a Process Approach could be the solution.

One of the QMS requirement is effective monitoring and one should be able to monitor variation with a properly setup QMS.

From Jem Ramazanoglu to Everyone 02:20 PM

We also have more complexity due to commissioner vs provider relationships. It is quite possible for a service to be commissioned on a basis that doesn't meet all patient requirements (Emma suggested that sometimes specifications are vague). We often fall into conflicts where providers identify ways to improve the way we can meet patient needs but there isn't funding available to commission what is needed. That dynamic can make QMS development more challenging. Does a mature QMS need to be developed in partnership between commissioners and providers?

Response:

Tom

Thanks Jem. The specification should be developed between commissioners and providers (+ patients?). A QMS is the responsibility of the provider. In my view this would having a QMS would be included in the commissioner’s specification and I would expect the QMS based on a recognised QMS standard. I don’t think we are ready for that yet though.

The organisation context / scope should be clear on requirements from interested parties and I feel we are at the very early stage of this.

From Jit Olk to Everyone 02:21 PM

Trusts already have most of the facets of a QMS

Response:

Tom

Thanks Jit. If you mean that Trusts already meet the requirements of say ISO9001 then that is not the case. They are a long long way off.

It’s a big beast and Trusts have some but mostly not a well-integrated system from experience.

From Jit Olk to Everyone 02:24 PM

@emma agree they aren't aligned to give us the assurance and insight to make meaningful change

The QMS gives us the framework to bring these elements together

Response:

Tom

Thanks Jit. I agree.

Agreed. QMS gives a structural approach / infrastructure and brings the puzzles together but it’s a huge challenge in the complex healthcare environment with many moving parts.

From Emma Adams to Everyone 02:27 PM

Some Trusts have not called their QMS just that, but have used a 'softer' approach in language e.g. The Leeds Way, Delivering Excellence, Brilliant Basics etc. This has tended to land better with staff and patients.

Response:

Tom

Thanks Emma. The Leeds Way is not a QMS it’s far from it. At their last inspection Half the hospitals in the Trust were rated ‘Requires Improvement’ under the ‘safe’ heading and one of the hospital ‘Requires Improvement’ in 3 out of the 6 headings and in one case it was the ‘overall’ heading. Overall the Trust only gained a ‘good’ rating. I’m sure that if Leeds implemente Quality Management they would do a lot better. Likewise Delivering Excellence and Brilliant Basics are not descriptors of a QMS. If you want to implement a QMS then call it a QMS and we will all know what you are talking about. Many NHS patients are familiar with the term Quality Management. Most of the UKs larger businesses have a QMS. Overall rating of a Trust using ‘Brilliant Basics’ – ‘Requires Improvement’.

I agree they are not QMS but more of a QI initiative/program. QMS requires more systematic approach in managing information flow not just solving or improvement of a particular pathway or issue.

From Joriam Ramos to Everyone 02:28 PM

the storytelling is better, right? QMS sounds so technical.

Response:

Tom

Thanks Joriam. What’s wrong with technical?

Being technical is like good design of the infrastructure needed to support the QMS and in turn support the daily operation of the service e.g. clearly defined processes, roles & responsibilities, how to do things safely, effectively, reliably etc. depending on the context of the organisation/service.

From Jem Ramazanoglu to Everyone 02:28 PM

That is what we are going to do - we are looking for a different way to describe this as a Trust Management approach rather than as a QMS

Response:

Tom

Thanks Jem. A QMS should be designed to manage quality and not people. It’s the people (front line staff) that do the managing in a well-designed QMS. I do not see any problem in that.

Not sure the need to reinvent the wheel consider ISO9001 is the most used set of standards internationally – it’s important to educate the teams not reinvent/re define things, the purpose of having standard terminology is they don’t change frequently. Change in staff, organisation structure etc. bring in different interpretation which is not necessarily helpful.