

Below are the questions received during the Platinum Presentation on ISO 9001:2015 Expectations along with our answers to them. Thank you for your involvement in the presentation and you questions! It was a pleasure presenting to you!

1. Have any of Platinum's customers transitioned to 2015 yet? What was learned from those clients?

Mostly, our clients thus far have been conservative and have maintained formal written procedures and other levels of control (like systems tools) to control and demonstrate their management systems. We have also certified new clients to the 2015 Standard. Formal documented systems (procedures and system tools) are tried and true and worked as well this time as they have in the past.

2. You must maintain conformance to 9001:2008. However the 2015 standard (as an example) does NOT have all of the same requirements. Please explain if Platinum expects its customers to maintain processes, such as preventive action through the transition? Duplicative work?

Correct. You must maintain your ISO 9001:2008 management system during the transition to the 9001:2015 system. This originated not as a Platinum Requirement, but as an accreditation requirement – which of course we have to flow down.

The thinking behind this is that you have a certificate currently stating that your system conforms to 9001:2008 and you need to maintain that until the transition is complete. Also if you have your audit far enough back, and you have trouble during your transition audit, you would still have demonstrated conformance to the old standard and could continue to remain certified to the old standard.

Certification Bodies were given no choice in this as it is mandated and all Certification Bodies must do it. It is not difficult for you to maintain a few extra processes in place but it's actually a lot of work for a CB to make sure the requirements of two dissimilar standards are met – just in case.

You need not develop two systems (though you can if you want), but more commonly, an integrated system and then once transitioned with your 9001:2015 certificates in hand – you can modify out the old requirements that are no longer found in the Standard, if you wish.

So – for example, if you have a preventive action system, we will verify that the system is in place and that you know how to use it, but we won't expect activity in that system as you transition to risk analysis – if that is your approach. If you elect to keep you preventive action system – that's okay too! We will continue to monitor it as part of your management system.

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4. Are you saying that you do not need a Leadership process? So maybe the best question is "what does not require a process?"

Management (Leadership) requirements are presented as responsibilities and as requirements that demonstrate "leadership and commitment." You can address some or all of these leadership requirements as a process (or multiple processes) that causes the requirements to be met, or as responsibilities to be achieved or using any other method you wish. Having defined processes are likely to be more successful than simply defining responsibilities, but the standard does not mandate an approach and if you choose to not have a process, so long as you have demonstrable evidence, our auditors will accept your approach. Remember – you are in charge! You can develop your system any way that best suits you as long as you satisfy the requirements of the Standard.

5. Can a Platinum customer opt out of the extra days for transition audits (e.g., extra .5 to 1 days)?

l'm sorry, no.

It is essential with any new management system audit to ensure readiness and understanding. There are many ways to do this including a document review or process analysis and we have application document (and tools) that can help you demonstrate that you are ready and that help us understand what your system looks like so we can be prepared. If you are transitioning, a stage 1 assessment may be used if you cannot provide information for us to be prepared and be confident in your readiness. Please take a look at our application documents for more explanation of the process.

Next we have to audit two standards – making sure conformance with the 2008 standard and 2015. At the simplest level this is a paperwork exercise but it is an involved paperwork exercise and we are mandated to do it.

Then, this new standard is different enough that the whole system must be reaudited. The transition audit does not allow for a partial audit and so the full system must be audited.

Finally, we all know that there are a lot of new requirements and significant changes elsewhere that represent significant addition to the management system. Even if there were requirements removed (preventive action and the management representative are the only notable ones) we have to audit them anyway. Every way you look at this, it's a lot more auditing.

The quality of the audit suffers if the auditor does not have adequate time and the accreditation authorities have made it clear that additional time is expected. The amount of time – can be variable based upon your approach and readiness.

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6. Where is the expectation for additional days recorded?

See IAF ID 9, Transition Planning Guidance for ISO 9001:2015, Issue 1. In the certification industry IAF guidance are requirements which we had to respond to in our application to ANAB to be approved to certify to 9001:2015.

7. As an existing client...the External Auditor should already be familiar with the QMS right?

Yes, but we still have the work to do...there are new requirements and most others have changed – some significantly and we do not know how much each client has modified their approach and system until they tell us.

Remember that we partner with our clients to prove that their system satisfies requirements every time we perform an assessment. We cannot rely on what we saw a year ago.

8. My recertification is due in May of 2018. Can I wait until that date to recertify or does it NEED to be done in 2018?

It's least expensive to do your transition audit at recertification. You are so lucky, because your re-assessment falls at an ideal time for transition. You can absolutely wait until May 2018 to transition.

For other people, don't wait to start your project and don't rely on being able to get an audit during August of 2018. Just plan ahead.

9. I hold a 9001 and 9120 certification. Is 9120 being rewritten as well?

The AS Standard Series are being re-written (AS9100 and 9120 alike) and this series of standards will be adopting 9001:2015 as the foundation upon which additional requirements will be placed. We expect the AS standards to be revised first and to be released in April or May 2016. We know that the expiration date for AS9100 will be the same as for 9001:2008 since that portion of the standard becomes obsolete at that time. AS clients will have less time to implement their revised standards. Also training systems and requirements for auditors are not expected until later and similar there has been no notice of the plans for certification body processes. Getting the 9001:2015 Standard and/or training and working on implementation will give these clients the jump that they need to prepare for transition. At the very minimum...watch for the standards publication and begin working early.



11. Are risks and opportunities the same as preventive action?

No not entirely. Preventive actions are responses to potential nonconformities. Risks can be much bigger than that! Risks can include aging work forces, changing circumstances, etc. These are the things that can cost an organization a lot of money or the organizations ability to survive! Preventive actions could certainly have been applied that broadly, although we never really saw them as strategic as risk evaluation and response. Opportunities of course are completely new. This new section of the Standard has so much potential to help your organization. Give it the attention and time that it really deserves.

12. Leadership has always been a requirement hasn't it?

Yes it has – but this time it more specifically calls out process approach, strategic involvement and accountability. I think this time the standard finally removes the single guy scapegoat from business systems. Management will have to demonstrate that they understand what the management system is there to do for them. This empowers the quality team and brings the right focus to the system and its purpose. In practice it will mean that top management will get a lot more attention during audits and will not be able to fully rely on the protection of the "management representative." Management will also have to think how they are going to demonstrate their commitment and leadership with tangible evidence. Verbal acknowledgement will only go so far.

13. I'm confused by the title of the presentation. It's about requirements – not the certifiers' expectations right?

You are right! We will be auditing the requirements of the standard and Platinum Registration has never interpreted the standard, so you do not need to worry about that...but what you do have to worry about is whether or not you have enough of a defined system and enough evidence to prove that your system is established and meets the requirements of the 9001:2015 Standard. And you have to worry about auditor variation as your system is reviewed from auditor to auditor. Remember the dreaded moving target?

The standard has provided more flexibility for people to demonstrate conformance how they want, but this has created confusion and anxiety over what is sufficient. Some auditors say that verbal evidence is allowed (and it is) and others say that they will not accept it because it is too loose (which may be justified). Platinum, with this presentation and expectations document is attempting to better describe the choices regarding flexibility of these requirements. This document will help organizations and auditors alike have a starting dialogue about the solutions for some of the requirements and a good place to start for proving conformance. You will get an idea of what *we* expect to see in processes we audit and our auditors are given direction to ensure they are consistent. If you aren't currently a Platinum client, it gives you a starting point;

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things to think about and hopefully will inspire questions and dialogue between you and your Certification Body.

We're just doing what we can to clarify– without advising/consulting because many people are expressing concerns over this issue and nobody seems to be trying to address them.

14. Do I need to consider the context of my organization as I define my scope?

Absolutely.

15. So Platinum expects to perform a Stage 1 and Stage 2 when already certified and just transitioning. Please clarify why a client should afford the extra expense.

Remember – stage 1 audits can be performed at any time. We need to know you are ready for your transition (and so do you). Note this is an accreditation requirement and all Certification Bodies have to do this one way or another. If you can provide the information that we need, we may not need a formal stage 1 to prepare and confirm your readiness. We are doing everything we can to keep the costs (both direct and indirect) as low as possible for our clients and we are flexible to accept any effective demonstration of conformance. We've really spent time thinking about and asking for feedback on our transition process and we'll continue to learn and adjust as we need to.

16. I have transitioned other standards without any additional days whatsoever! Why are there costs for transition?

Good question. The answer is because there is a lot of work to do. When you read the 2015 Standard, you'll see that there are more requirements – and we have to make sure you are still conforming to 9001:2008! This is a major rewrite. In previous transitions, the changes were minimal and we did not charge for them. The accreditation body recognizes this and has stated that additional audit time is expected. There were rumors that some Certification Bodies were attempting to provide a transition without extra time but you cannot get a quart in a pint. It remains to be seen.

17. Isn't this biased on Platinum role, not an overall perspective from a general certification body?

Yes. As it was advertised, it is what one certification body is doing. It's Platinum's policy/expectations and our presentation. Our goal is to provide a tool that can be used by our auditors, clients and other implementers to better understand what is expected of an ISO 9001:2015. We don't understand why other certification bodies aren't doing the same.



18. How far in advance of our transition date should we notify Platinum of the intention to transition? How far in advance should we submit out paperwork?

We are asking you to tell us your transition intention as soon as possible. The paperwork should be submitted once you have completed implementation – this should be well before your transition assessment. And please don't cut things fine in 2018 – we are going to be coping with organizations that are unprepared and disorganized.

19. If this is such a good standard, why should we wait to transition?

It is a good standard and you should start as soon as possible. Purchase the standard, read it, think about it, re-read it, get trained and begin implementation. The integration into business systems and the strategic approach are significant improvements that will drive value into your business. Do not procrastinate – because that will cause you problems. Think positively about change and about the benefits that you may be missing out on by not addressing some of the new requirements.

20. I'm own a small shop and do all the activities except for receiving, making parts, inspections and shipping parts. I want to just manage forms instead of procedures. I can do that right? And I don't need any records for risks, right?

You can control your operation any way you want to. Some processes can be effectively controlled with forms and templates and software, etc. However, processes often do not completely align with the requirements in the standard and you still have to ensure all requirements are addressed. For instance, with the requirements for document control (control of documented information), it might be possible to demonstrate conformance with a change form and an approval form, but documents of external origin probably will require some documented description to explain control.

You also need to be able to coherently describe to an auditor the conformance of your system in terms of the standard requirements. And a good auditor is likely to challenge and question. If you are not an expert in the standard then this might not be a practical approach for you. Documented procedures that describe processes including records to demonstrate it is an approach that everyone is familiar with and has proven reliable to ISO auditors for years. You still need to make sure that all of the required documented information maintained has been established. It's not enough just to be good – you have to prove it too. Do not cut corners here or there will be difficult discussions with auditors. Specifically, records of risks are not mandated. But how are you going to prove that you have a system? You can claim they are all verbal and technically that is conforming...but how will you prove it? How will you give confidence to your

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auditor or customer that the process is repeatable and independent of the people involved? It has to work when you are not around. You can choose to argue but it is far easier to go the extra mile and put clearly defined processes in place (procedures) that generate clear records that it works.

21. To me there is a fine line between an opportunity and a planned improvement. If I identify something as an opportunity and the auditor says it's an improvement (or vice versa), who's right or does it even make a difference?

From ISO 9001:2015 0.0.3, "Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities."

From ISO 9000:2015 3.3.1, "improvement - activity to enhance performance (3.7.8)"

Based upon the definitions, opportunities are based on situations, circumstances, in short – context. Both opportunities and improvements address capability to achieve intended results. But an opportunity is a noun, and improvement is a verb. An opportunity would be expressed as a statement of fact – it exists (or is perceived to exist) whether we do anything about it or not. Improvement is activity to enhance performance, and it may come from an identified opportunity, but it could come from some other source.

22. We hired a consultant to help us. She is making us do records for the new stuff even though it doesn't say that records are required. Is the consultant right or is she just having us do busy work?

It is probably most likely that your consultant is defining your business using a conservative approach. This approach leaves the least amount of risk for demonstrating conformance of your management system and for assuring that the expected process has been agreed.

You should ask her testing questions. Consider other alternative methods if you feel the system being developed is overly complex or burdensome.

Remember that the system has to work for your business needs. But on the principle that you not only need to be good but that you need to prove it too, you have to make sure the system will work when she is not around and even be independent of specific people (such as yourselves).

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23. If we are not transitioning, but going for initial certification to ISO 9001:2015 what happens?

You get the benefit of focusing on one standard and you don't need to supply an application for transition! You will be required to have a stage 1 audit – where we check your readiness and mitigate the risk of proceeding to your stage 2 assessment and confirm our understanding of your system, resources allocated to the audit and prepare our auditing tools. After the stage 1 is successfully completed, you will receive an audit report explaining the results of the audit (you will be kept informed throughout the audit as well). You will make adjustments as needed and then we will come out and perform the Stage 2 assessment. Once you successfully complete that assessment and have made any required adjustments, a certificate to the new standard will be issued. Check out our website - it describes the process in detail.

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