Best Practices on Reviewing QMS Documents

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This article notes five best practices and provides a sample list of likely items that OWM will review during the Quality Management System (QMS) assessments for evaluating compliance to the ISO/IEC 17025:2017 standard during the recognition review this year.

Keep in mind that OWM reviews and NVLAP (or any Accreditation Body) reviews are "sampling" exercises. It is up to the lab to evaluate and demonstrate compliance, regardless of whether a non-conformity is found or not (*i.e*., assessments, by design, will normally not cover 100 % of QMS material). It is the lab's obligation to ensure 100 % compliance with the standard and not wait for assessment feedback! Since the QMS being "sampled" think about what is most likely! For example, if you are taking a semester course that is 12 weeks long and 4 of the weeks are spent on ONE topic, it is highly likely that the final examination will pull heavily from that one topic!

Top Five Best Practices

Your Internal Audit is your best tool to ensure compliance!

The initial review of your laboratory documents using the internal audit is to make sure that you can find adequate references to all requirements in your quality manual and administrative procedures. This is called a "desk audit". It is simply making sure that your Quality Management System (QMS) complies with the ISO/IEC 17025:2017 standard. Failure to find a reference to the standard should result in identifying a non-conformity followed by documenting and completing corrective action(s). All corrective actions on laboratory documents should be fixed prior to the 2020 submission cycle! Putting a deadline for fixing corrective actions sometime in the future at this point means your lab is not currently compliant with the standard (or the deadline)!

The second step after a desk audit is to look for objective evidence of compliance. This is often called a functional audit. This means that you have a document that complies with the standard *and* that you are following it. OWM has covered internal audits many times. We have a webinar that covers this topic that many metrologists have attended. The topic of internal auditing and technical auditing has also been covered at the Regional Measurement Assurance Program sessions – the idea of a desk audit and a functional audit is not new! Yet, many internal audits were submitted in 2019 that only referenced documents, did not identify corrective actions, and had numerous examples of non-conformities within the Quality Manual (QM) or Standard Administrative Procedures (SAP), and failed to include objective evidence. There are two take-aways to this point: 1) make sure that your laboratory quality system review is complete and action items are documented and then completed; and 2) ensure that your internal audit is effective, includes the functional review, and includes objective evidence that shows the documents have been implemented (*i.e*., don't just say it; show that you do it too).

Identify changes in the ISO/IEC 17025:2017 standard – and make sure those items are updated first!

Changes to the standard are most likely to be evaluated by OWM or by a third-party assessor like a customer or accreditation body. OWM has focused on changes to this standard for the past five years. We did our first training on it in 2016 while the document was still a final draft. There are several critical sources of information that can be used for identifying what changed from the prior version of the standard (2005). As one example, Titilayo Shodiya-Schneidewind (NVLAP) covered changes to ISO/IEC 17025:2017 extensively at the 2019 Combined RMAP. Her slides are in the notebook or on the USB stick participants received at that event. Second, the RMAP webinars on ISO/IEC 17025:2017 in 2020 covered highlights and gaps from prior OWM observations and provided recommendations on addressing new items. Slides were circulated to all participants. If you were not there or did not participate, ask OWM for the content.

Make sure you fully cover this one area – we have covered it many times: RISK!

OWM began covering risk topics in the 2016 RMAP sessions. Two tools from those sessions are posted on the State Laboratory Program Resources page on the NIST OWM website (**https://www.nist.gov/pml/weights-and-**

measures/laboratory-metrology/state-lab-program-resources). This includes a risk management matrix in Excel and a summarized list of potential risks. (None of them at the time included how you might address a pandemic or 100 % teleworking!) Responding to planned and unplanned events might well be a useful training topic in the future. In addition to these two tools, is the updated Management Review Outline that includes a new section on Risk. Even adding two sentences on risk to your management review about something you considered this year meets the requirements to discuss risk. There is no requirement for a "risk procedure" as a part of the standard. If you add one, that's fine, but it's not a requirement. The OWM feedback letters have been providing specific feedback on the incorporation of risk for several years now. There is no excuse for a gap in covering risk at this point.

Use one file for the Quality Manual and one file for the Standard Administrative Procedures if possible.

Being able to "search and replace" or "copy and paste" when working in laboratory documents is a useful tool. If your quality manual is in 17 to 20 extra pieces, you would have to do this multiple times. Same with the standard administrative procedures. Even making sure that footers and adoption dates are the same and consistent in all parts of the documents requires opening, editing, and saving each one. That's all lot of extra work with little value added. If you adopt all changes each year in one review, even if there are no changes, you can simply add one date to one file and speed up the review time and avoid potential inconsistencies in dates and/or formatting. Being able to search on all sections at one time can save you a lot of time. When you provide on-the-job training for a new staff member, you can have them open the quality manual and find a section of interest/need with just one search instead of opening all potentially related files. If you absolutely insist on multiple files for every section, be sure to include titles in the file names as these files will likely be reviewed more critically (fair warning, think "risk").

Reference information – don't repeat it!

Over the years, as changes have been made to the laboratory documents, a lot of repetition has crept in. In fact, if you have a standard administrative procedure for calibration certificates, and haven't updated it, it likely contains complete duplication of what WAS in SOP 1 (an earlier version). There is absolutely no need to completely repeat that information. Simplify! Delete all the duplicated text and reference SOP 1 within that procedure instead. Then, when SOP 1 is updated again, you already have that covered and it will save you even more time.

Top 10 Most Likely Items to be Sampled

1. *Has risk language been updated?*

As noted earlier: make sure you have included risk in your laboratory documents and management review.

Has the Standard Administrative Procedure (SAP) on calibration certificates been updated to reference rather than repeat requirements from ISO/IEC 17025:2017 section 7.8 and SOP 1? Have all SAPs been updated and integrated?

During the 17025 sessions in the 2020 RMAP webinar sessions, the homework assignment was to review certificates. As noted earlier, make sure your administrative procedure is not repeating the requirements of the standard; instead, reference SOP 1. OWM will be looking for this! Additional SAPs should be reviewed to ensure that you are not duplicating procedures and can simplify your internal document requirements. Standard Administrative Procedures on 1) ensuring validity of measurements, can reference GLP 1; 2) software quality assurance, can reference GLP 15; 3) method validation, can reference GLP 14; 4) SAPs on corrective and preventive action can reference risk requirements rather than creating a new SAP (remember: preventive action is now considered risk assessment and mitigation); 5) supplier evaluation should be completed "prior to use" rather than "annually" or "periodically". Finally – make sure every SAP is referenced in your Quality Manual to ensure the administrative procedures are identified and integrated in your quality system and are not isolated documents.

Have laboratory calibration certificate templates been updated to ensure compliance?

Extensive feedback was given to all participants on the calibration certificate homework from the 2020 webinar sessions. The primary action item from that homework would be to ensure all templates in the laboratory are updated

for compliance. The feedback from the RMAP sessions is your objective evidence that certificates were reviewed. Take the opportunity to review the updated templates (or better yet, have staff who didn't participate in the activity review them), to ensure the updates are compliant with the standards.

Are all document references up to date with the latest versions?

One of the biggest gaps in quality manuals, references, and master lists that were submitted for review in 2019 were references to out of date documentary standards. Feedback was provided during the 2020 RMAP webinar sessions with several examples. The standard requires you to use the latest valid version of a standard (unless not possible for some reason). Supplements to the procedures can easily be added rather than "deviations" that require further validation. Some of the inconsistencies in documents were between the quality manual, document master list, and what gets put on calibration certificates. If the latest version of the Guide to the Expression of Uncertainty in Measurements is noted on your master list, make sure that is also what is referenced on your calibration certificate. If you don't actually use a document in your laboratory, it doesn't necessarily belong on your lists of references!

Do the QMS and laboratory documents address Conformity Assessment and Reciprocity – for legal metrology applications?

One of the requirements in the 2019 Handbook 143 is to address legal metrology requirements, most of which require conformity assessment. If your laboratory or weights and measures program accepts calibration certificates (this is reciprocal acceptance, not supplier evaluation) from other organizations or state laboratories, your program may need to ensure that the calibrated standards also comply with legal requirements. The current SOPs also note the evaluation of compliance with documentary standards and most note the decision rule requirements as well (which simplifies your life by being able to reference the documents rather than have a discussion with each customer as required by the standards). Make sure you have addressed this topic in your quality manual or program documents.

Has the QM addressed conflict of interest requirements?

Another new area of the standard is that of conflict of interest. Most programs can simply reference on-boarding training or employee manuals/handbooks to address this new requirement. But, make sure it is addressed in the quality manual. Your laboratory doesn't need a new procedure – reference the training and/or handbooks that are required for all staff.

Are the QM and SAPs adopted by current management with consistent "dates" throughout the document?

Simplify all the dates of adoption by having ONE date on the cover page that can be consistently implemented in the footer of the single document as noted before. Have a signature page with the appropriate laboratory management signing off on the document and dating it each year. Then include that same date throughout the document. Submitting an unsigned/undated document implies that it has not been implemented in practice. Again, this practice will save you time!

Do any of the QMS documents reference out of date or inappropriate laboratory records/files regarding facility, staff, equipment, etc.? Have all traceability essential elements been integrated into the QMS?

Look for past training requirements that are not valid for current staff. Evaluate any facility environmental requirements to ensure that they comply with current SOPs and reference documents. There are many outdated requirements noted in the current Quality Management System documents based on prior failures to update them when changes were published in updated documents. Make sure all traceability documents and records related to implementing traceability are up to date and integrated into your QMS. Adoption of GMP 11 and GMP 13 on the calibration program and traceability require up to date calibration status for all equipment and standards used in the laboratory. Do not leave open action items such as calibrations that are past the due date. Make sure everything on your Scope is addressed in your inventories of standards, calibration due dates and status, and traceability hierarchies. Follow procedures in GMP 11 if and when calibration due dates need to be extended (especially if due to COVID-19). Extending due dates must be based on technical analysis of data and not budgets/pandemic constraints; standard calibrations must be up to date or those services must stop. Remember, OWM issues a certificate of Recognition

regarding metrological traceability. First and foremost, current calibrations of standards and traceability assessments must ensure all essential elements are in place and up to date.

Language of the standard – versus application in the laboratory.

When updating or writing the quality manual, be sure not to use verbs such as "shall" and "must". These are verbs used throughout requirement documents and indicate what the laboratory must do in order to be considered complaint. Instead, the quality manual should state what the laboratory does to comply with the requirements. "T*he laboratory shall*…." statements are inappropriate in the quality manual.

Make sure they are polished! (Just say "no" to black dots!)

It's a good idea to perform a spell check and a grammar check on your laboratory documents. When files are submitted with things like traceability spelled wrong, it certainly makes the reader question the validity of measurement results. Customers rely on your laboratory to provide high quality measurement results. Make sure your laboratory documents reflect the same attention to detail and excellence! Have another person proof-read the documents before submitting to your management or to OWM. Also, check your file names for spelling errors!

Summary

The OWM Recognition Program is requiring all participating labs to be compliant with ISO/IEC 17025:2017 this year. OWM has been preparing labs for this transition for five years by providing training and feedback to labs on their progression to the new standard based on annual submission reviews. This newsletter outlines best practices for updating your QMS and primarily what OWM will be expecting and looking for in a compliant QMS. To allow for a smooth assessment via sampling of critical components, all metrology laboratories should submit a thoroughly done (1) internal audit, (2) address past year nonconformities, and (3) update references and terminologies in the QMS documents. Doing a good job with these items will give OWM great confidence in the laboratory QMS. If you have any questions regarding this Best Practice guide for reviewing QMS documents, please contact Mike Hicks at **Micheal.Hicks@nist.gov**.