



Writing and Reviewing SOPs -- The “KISS” Approach

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Agenda



- **SOP Hierarchy**
- **Operational vs Analytical Procedures**
- **SOP Content Simplification**
- **SOP Review**
- **Training**
- **Don't forget...!!**

SOP Hierarchy



You will want to establish a Document Hierarchy

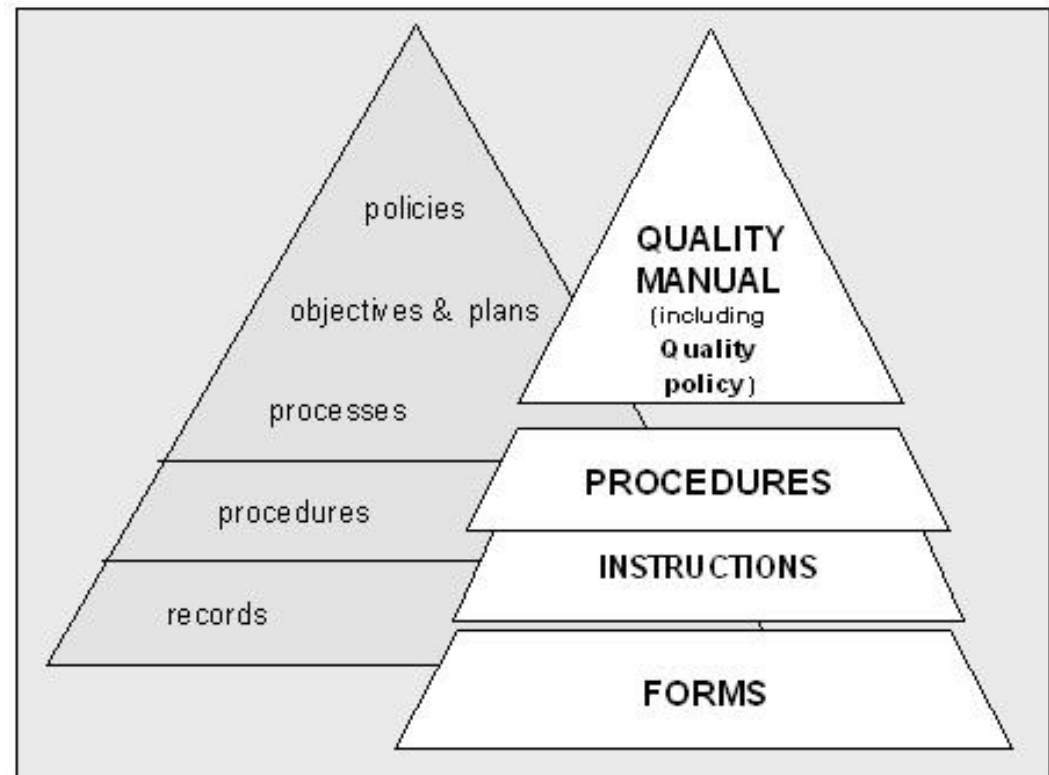
This allows for content to not be restated at every level. By default the **top level documents apply to all that fall below them**, unless something is clearly stated as an exception in the lower document.

For example, your quality manual should include definitions for the types of QC that are used. These do not need to be defined again in your work instruction documents.

SOP Hierarchy (cont.)



- **Level 1** – Policies, Quality Manual, Ethics/Data Integrity, Chemical Hygiene
- **Level 2** – Procedures for overall lab operations and processes
- **Level 3** – Area or Department specific procedures
- **Level 4** – Forms



Operational vs Analytical Procedures



In our business we tend to refer to every document as the “SOP” or Standard Operating Procedure. To clarify the different content needs, try thinking of them as **Operational Procedures vs Analytical Procedures**.

Analytical Procedures define how (the specific steps) the lab performs tests that correspond to published analytical methods (i.e. SW-846 8270C, EPA 200.7).

Operational Procedures define the supporting processes that the lab performs (i.e. data review, balance calibration checks, reagent preparation) which may not be detailed in the published methods.

SOP Content Simplification



We all know that there are 23 elements that need to be included in SOPs.

These are primarily needed in the Analytical Procedures as many are not applicable in the Operational Procedures (i.e. Reagents and Standards do not apply to a data review SOP).

It seems like once you use all the elements the SOPs are pages long before you even get to Step 1 of the actual test.

That being said, **there are ways to simplify and shorten the documents.**

SOP Content Simplification



- **Safety, Waste handling, Pollution prevention**
 - can be combined into one section and can reference your **Chemical Hygiene Plan** for general requirements.
 - Details are only needed if there is something very specific to that procedure.

- **Acronyms** can be used by **spelling out the term the first time with the acronym in parentheses. After that the acronym can be used.** This is not needed for QC types that were already defined in the Quality Manual.

SOP Content Simplification



- **Revision logs** – shorten your documents by only keeping the **past two rev logs in the latest version.**
- **Definitions** – as noted before, **define the common terms in your Quality Manual**
- **Reagent/Standard storage** –
 - If all are stored frozen, **note that once at the start of the section rather than with each listing**
 - If all but one or two are stored frozen your note can say “unless otherwise stated” and then only specify the exceptions

SOP Content Simplification



Think about the intended user and what he/she needs to know to perform their part of the process.

- **Don't combine preparation and analysis in one SOP if these are performed in two different areas.** Just because method 525 or 8151 includes prep and analysis does not mean that your SOP needs to be combined.
- **If calculations are performed by the data system or your LIMS then put all calculations in one SOP and then cross reference it in the individual SOPs.** If the analyst is not typically doing the manual calculation they don't need to have it in their daily SOP.

SOP Content Simplification



Covering topics in higher level documents or dedicated SOPs rather than in each individual SOP helps to prevent those pesky audit findings when a change was made and it was missed in one or two of all the SOPs that you needed to revise. It is great to only have to make the change in one place.

SOP Review



While you would have designated timelines (annual or biannual) the actual SOP review/evaluation process is ongoing and covered in a number of ways.

- **Remind analysts that they are the first line of defense in the accuracy of SOPs.** If something will need to change in their process they need to request or initiate a revision to the document.
- **Internal audits** would also cover the accuracy of the SOP content. **Observational audits (watching as a process is performed)** will very quickly identify if there are discrepancies in the process or the SOP.

SOP Review (cont.)



- Your **annual or biannual** review should include a **recheck of compliance with the associated published method**. In general, this should be handled by technical staff performing the test with QA review and input.
- **General process changes need to be assessed for impact to SOPs**. Again this is why you want to limit where general information is defined to minimize the number of SOPs that would need to be revised.
- **New versions of published methods may require a completely new SOP or a revision to existing SOPs**.

SOP Review (cont.)



Of course, we all know that external audits will point out flaws in SOPs.

The goal is to catch those internally first.



How do you train your staff on SOPs?

- Is **reading the SOP** sufficient? In some cases, maybe.
- Do you use a **quiz**? Might be a useful option.
- In most cases it is a matter of **reading**, the trainee **observing** the trainer and the trainer **observing** the trainee.
- **Listen to your trainees for feedback.** Training could be a good test of the ruggedness of your SOP.

Don't forget...



While “Simplification” is good don’t forget some key points.

- **What does the analyst/tech actually need to know to do their job efficiently and correctly?** Be sure bench level staff have input in the writing/review processes.
- **Should, May, Can, Shall, Must, Will** – be careful how and when these word are used as they have very different meaning and intent.

Don't forget...



- **Be sure to list ranges where it is allowable and keep in mind the meaning of decimals in measurements.**
 - Weigh 30 g of sample.
 - Weigh 30.0 g of sample.
 - Weigh 30 +/- 0.5 g of sample.
 - Weigh approximately 30 g of sample.

The above instructions all have different meaning and could yield different results. If your SOP states to weigh 30.0 g and you weigh 30.1, you are not compliant with the SOP.

Don't forget...



- Explain any preventive action steps that you perform.
 - Address any **routine maintenance** steps, **cleaning procedures**, etc. that are not truly part of the referenced method but are **needed to ensure accuracy** of your data.

Don't forget...



- Explain what needs to occur if something does not go as planned.
 - Do your SOPs just list the QC frequency and limits or do you also explain **what happens when/if the QC fails?**
 - Do you address what happens when sample results **exceed calibration** ranges?
 - Do you explain what to do if a **calibration point does not seem to be accurate?**

Don't forget...



Again, this preventive and corrective action type of information could be addressed in your quality manual or other higher level SOP, if it is an overall action, rather than in every individual SOP.

Most importantly...



“If you don’t give people information, they’ll make something up to fill the void.” **Carla O’Dell**

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QUESTIONS???

Panel discussion after the break.

Submit your questions for our experts!

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