

Critical Scientific Thinking, SOPs and “Sidecars”

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Critical scientific thinking should be encouraged when SOPs are written, trained in, and followed. This paper discusses some of the assumptions that can reasonably be made about SOPs, along with some basics of critical scientific thinking. The notion of “sidecar documents” is introduced as one method of encouraging critical scientific thinking at every relevant step while minimizing disruptions to timelines related to such thinking.

A number of years ago, I wrote a white paper called “Making an SOP System Effective as a Learning Tool” [https://microbiologyforum.org/Articles_White_Papers/PMF_Making_an_SOP_System_Effective_as_a_Learning_Tool.pdf]. The paper listed a number of assumptions that I have reproduced below.

Assumptions

Learning

- The trainee may speak English as a second language.
- Some people learn better through text, some with pictures, and some with both.
- If a trainee can ask a question from a good scientific perspective, it is a good question that should be addressed.
- A regulatory agency inspector, or an auditor, will likely know no more than a typical trainee about the SOP, and thus the SOP system should serve to answer their questions as well as a trainee’s.

Linkages

- The trainee may not necessarily know where to go in a documentation system to find answers.
 - The trainee may want to understand a method derived from external sources (e.g. USP, EP, ASTM, etc.) and its underlying principle.
 - The SOP system should contain references to all necessary/associated internal/external documents.
 - The trainee may not know terms that are understood by the SOP author.
 - The SOP system should be internally consistent.
- Terms should be used consistently within and across SOPs.

SOP Specifics

- Analytical measurements will not be 100% accurate.
- Accuracy and precision requirements should be appropriate.
- The purpose of the SOP should be clear, as should its scope.
- The text of the SOP should be accurate, with no typos.
- The materials and equipment needed for the SOP should be comprehensively listed.

It must be clear how and where to record results.

Since that time, I have come up with some additional assumptions.

Additional Assumptions

- The SOP should be as succinct as possible, stating what is to be done in no less and no more words as possible.
- Although it might be reasonable to assume that people with technical backgrounds think critically, that can be a dangerous assumption to make.

Critical thinking takes time, effort, and discipline. One of the classical reasons to attend college/university was to increase one's skills in critical thinking. Some basic aspects of critical thinking are provided below.

Critical Thinking

1. Always keep an open mind! Remember that what may be thought of as absolute truth may well change as more information is gathered, even beliefs you may hold near and dear.
2. When you encounter a technical statement, always feel free to ask an honest, open-minded question about it.
3. Searching for information about your question is essential.
4. Look for consistent, corroborating information from as many sides of the question as possible, from scientifically reliable sources.
5. Understand that there may not be a single answer that covers 100% of your question.
6. Scientific understanding of many topics is incomplete. That doesn't mean what is known should thus be ignored or denied.
7. Remember that "doing" science is less about memorizing a vast body of knowledge, and more about more closely approximating or understanding of how nature, in its largest sense, works, through applying the "scientific method".
8. Remember that your question may lead to answer(s) that lead to more questions that lead to more answers, and so on.

There are many manners in which critical thinking can be disrupted. Lists of fallacies encountered in thinking processes can readily be found. Personally, I think one of the best books discussing critical thinking, as in how and how not to engage in it, is "The Demon-Haunted World" by Carl Sagan*.

I was teaching a group of nursing/allied medical students a basic biology course with a lab section. During the lab, I would be asked questions by numerous students for an answer when in fact the answer could be deduced from the experimental data. The next week, the department chair brought me in and criticized me for asking such questions because a number of the students came in and complained about my questions. This was a painful example for me of where the students themselves didn't want to bother asking themselves such appropriate questions, they also didn't want to bother answering them if someone else asked them. They just wanted to know what would be on the test so that they could get their certificates. The chair said that getting and obtaining students was critical to their budget, and losing students due to them being asked "hard" questions would cost money. That was the last time I taught the course at that school.

As a consultant, I would often sit down with technical people and ask them questions about the SOPs they were following. My goal was to ascertain whether they understood, or had even thought about, the science underlying the directions in the SOPs. All too often I would come away from such encounters with the thought that their training amounted to someone going over the SOP, reading what the SOP said to do, then quizzing the trainees (usually via a quick written assessment) with the basic requirement that they regurgitate what the SOP said with little to no demonstration of knowing why the SOP said what it did.

Why does this matter? Here are three examples.

1. I had one person call me and ask whether a product that tested as having contamination with *Yersinia pestis* would be OK to release to market because the USP monograph for that product did not list that species as a specified microorganism.
2. I audited a lab that was using remote telemetry systems for tracking incubator temperatures that, as you may well guess, showed numerous changes from the temperatures set via the thermostats based upon normal openings and closings of the incubators. However, the temperatures recorded in the log books never varied from the temperatures set with the thermostats.
3. I examined a facility that was performing L292 cell agar overlay procedures in a room immediately adjacent to a room where live cultures of microorganisms were in use with no air pressure differentials established.

I could go on and on with such examples, but the point is that had critical scientific thinking been a driving force in these cases, it is highly unlikely that these matters would have come to my attention. During the preparation of the SOPs, during the training related to the SOPs, and during the performance of the SOPs, critical scientific thinking should be encouraged, and this begins with questions. Such questions could have included:

What is the purpose of a monograph in the USP and its listing of specified microorganisms?
How certain is the identification of the species of microorganism?
Where might *Yersinia pestis* found in the samples come from?
What might a consumer of your product think is he/she became aware of what contaminating species was found in it?

What is the point of having accurate remote temperature monitoring if the data aren't being recorded?

What is a regulator likely to think about such inaccurate recording of data in log books, and might they have cause to dig even deeper into your data handling methods?

Isn't it normal procedure to use pressure differentials to minimize possible microbial contamination of mammalian cell cultures?

Should the mammalian cultures undergo routine assessment of microbial contamination?

Isn't it common practice to carefully separate any areas working with live culture of microorganisms from areas required to be free of them?

There are many more questions that could reasonably be asked during the preparation of, training in, and execution of these SOPs by anyone involved in them, and such questions should be encouraged.

One of the key factors I encountered for why such questioning required for critical scientific thinking was not prevalent is time. There is so much work to be done, and timelines are almost always too short, and management has enormous pressure heaped upon it to satisfy the short timelines. Then the driving force becomes just get it done. How can critical scientific thinking be fostered in a manner that exerts minimal effects on critical timelines?

I propose that for each SOP, a document that I will call a "sidecar" be prepared. This comes from a Google AI overview of "document sidecar": "A sidecar in the context of computing refers to a pattern where an auxiliary application or process runs alongside a main application or service, often to extend its functionality or provide additional features." You could also think of a sidecar on a motor cycle that also provides extra features (an extra passenger and stability). The sidecar I propose would be used to foster critical scientific thinking, and could be developed as the SOP is being developed. The sidecar would be part of training, and would be available for refreshers, and to promote critical scientific thinking as to the rationale for why the SOP says what it does.

Below are portions taken from the US Environmental Protection Agency Office of Pesticide Programs SOP "AOAC Use Dilution Method for Testing Disinfectants", specifically from section 12.2 Carrier Inoculation.. These have been selected to provide examples of what a sidecar document could contain to promote/support critical scientific thinking related to a specific SOP. The complete SOP is available at:

<https://www.epa.gov/system/files/documents/2023-11/mb-05-17-web.pdf>

The text from the SOP is in *italics*, potential sidecar text is in plain font.

Inoculate approximately 80 carriers; 60 carriers are required for testing, 6 for control carrier counts, and 1 for the viability control.

Why not provide a range, for example, 70 - 90 carriers, instead of using the more ambiguous approximately 80 carriers?

For P. aeruginosa, remove the pellicle from the 48-54 h test culture either by decanting the liquid aseptically into a sterile tube, by gently aspirating the broth away from the pellicle using a pipette, or by vacuum removal. Avoid harvesting pellicle from the bottom of the tube. Transfer test culture after pellicle removal into sterile 25×150 mm test tubes (up to approximately 20 mL per tube) and visually inspect for pellicle fragments. Presence of pellicle in the final culture makes it unusable for testing.

Why do the cultures have to be 48 -54 hour test cultures? What would happen if, say, 46 or 56 hours test cultures were used?

Why is it necessary to avoid using the pellicle from the bottom of the tube?

Add appropriate amount of organic soil if required. Swirl to mix.

What is an appropriate amount of organic soil, what constitutes organic soil, and how do I know if it is required?

Aliquot 20 mL portions into sterile 25×150 mm test tubes.

Would it invalidate the experiment if I aliquoted, for example, 19.9 or 20.1 mL portions?

Allow carriers to remain in the inoculum for 15±2 min.

Where does the 15 ± 2 minutes come from?

Dry carriers in incubator at 36±1°C for 40±2 min.

Similar to the previous question, where do the listed temperatures and timings come from?

Note that the emphasis of the sidecar text is to ask questions for which the answers require scientific thinking. The nature of the answers to the sidecar questions should help in determining what effects performing the experiment outside of the stated conditions might be expected to have. Additional questions can lead to answers as to what to do, and why, should unexpected circumstances arise.

Note also that answers to the questions were not provided. The danger in writing out the answers is that, once again, the reader may default to what is written rather than engaging in the critical scientific thinking process. Should it be desired to have written answers, a sidecar document analogous to a teacher's book could be developed. This would contain answers that might exist either in the mind of a consultant who might be hired to produce the sidecar document, or in my opinion, preferably, within the mind(s) of in-house staff. This "Teacher's Edition" would also be helpful should a regulatory inspector, or an auditor, ask questions along the lines of those posed in the sidecar documents.

The paragraph above alluded to authorship of the sidecar documents. These clearly could be prepared using in-house staff. The advantage is using such authors lies in their familiarity with the company's SOPs. That same familiarity could lead to problems in that such familiarity could lead to assumptions being made without question. The situation could be analogous to the "we've always done it this way" answer without remembering or asking why it's always been done that way. It is due to that potential problem that the use of a consultant might be advisable. There would be situations where the consultant could provide answers to some/all of the questions, but again, in-house staff should not habitually defer their critical scientific thinking to others.

Technical SOPs are most often based upon underlying science. They are followed most often by people with at least some degree of scientific training. Compendial specifications and regulatory requirements are most often based upon underlying science. Minimizing critical scientific thinking along the entire sequence from SOP creation, training, and adherence to, for the sake of temporal expediency may well put product quality at risk, and ultimately potentially harming the users of the products. Spend some time looking at regulatory inspection findings and ask yourself how often the negative findings reflect inadequate critical scientific thinking.

*Sagan, Carl, *The Demon-Haunted World. Science as a Candle in the Dark*, (A Ballantine Book, published by The Random House Publishing Group, New York 1996).