

- 1. Wouldn't an effectiveness check be instituted after corrective action(s) are put in place to address nonconformances? This would be checking to see that the mitigation worked and no repeat issues of the same type have occurred in significant numbers. This would also be a cost of quality. ISO 15189 mentions effectiveness checks as part of its goal to promote a culture of prevention.**

Yes, there would be an effectiveness check after a corrective action but the cost of the effectiveness check is actually a failure cost. When a nonconformance happens, the money for everything done and needed to reduce or avoid recurrence would not have been spent at all if the nonconformance had not occurred. Effectiveness checks are not part of prevention; they are a reaction to something that should not have happened if prevention was in place.

Prevention costs are for designing a process to meet regulatory, accreditation, customer, and organizational requirements; eliminating risks and implement controls to reduce, detect, or mitigate a risk; and validating that the process works as intended before use. Monitoring process performance is an appraisal cost.

- 2. Can this book (QMS 20) also apply in research environment?**

Yes, it can – why wouldn't it?

- Designing the research protocol to identify risks and mitigate those appropriately, planning the experiments, and training personnel to follow the approved experiments and accurately (and truthfully) record the results are all Prevention actions.
- Performing calibrations, recording environmental and other variables, and monitoring the results of the experiments are appraisal costs.
- Resolving experimental failures is an internal failure cost.
- Publishing erroneous or fabricated results is definitely an external failure cost.

3. How do you save cost on reagents usage ?

The best way to save cost on reagent usage is to have the tests work correctly the first time. Here are 4 ideas.

- Have an effective reagent inventory management system that eliminates outdated, emergency reagent orders, overstock, and use of expired materials.
- Ensure personnel have been trained and are competent to perform the testing so they don't make mistakes that cause repeat testing.
- Reduce and eliminate repeat testing arising from invalid or incomplete test runs.
- Use an effective QC program and decision rules appropriate for each method to minimize waste of control and calibration materials.

4. What is the best way to get Administration buy in for the Prevention costs designed to lower failure costs?

If you carefully review your laboratory's existing nonconformances you are likely to identify instances in which a prevention action that could have been taken was not and this led to quantifiable failure cost.

- Preventive maintenance is one of the easiest:
 - o Eliminating a service contract without implementing that laboratory or hospital personnel perform the maintenance instead will lead to failed test runs that cost money to repeat
 - o Instrument downtime that keeps the laboratory from meeting customer turnaround time requirements and lowers laboratory credibility with its customers.
- "Change by memo." The labor it takes to plan essential aspects of any change is an important prevention cost that keeps downstream nightmares away.

True stories:

- o Our laboratory announced a new test only to discover on go-live day that the "planners" had not ordered any of the special evacuated collection tubes necessary for the specimen collections for that test.
- o A local hospital announced to its oncology physicians the availability of new blood component irradiator, not accounting for the blood bank being on the 11th floor, which could not support the irradiator's weight. Think of the failure cost of personnel time having to go down to the hospital's basement for every irradiated blood component it had to prepare – for the lifespan of the irradiator.

- Implementing a laboratory internal audit program. This program catches nonconformances before the external accreditation organization assessors find and cite the laboratory for regulatory and accreditation deficiencies. Better this cost than the cost of all the investigation, corrective action, and report writing involved in rectifying the deficiencies to maintain accreditation.

The following questions were asked during the presentation. Please see the webinar recording for the responses.

5. How do I know if I have enough prevention and appraisal processes?
6. Is there a way to quantify external failure costs?
7. Where do I record root cause analysis and corrective actions costs in my worksheet?
8. I know I will always have some QC failures in the future which I have to troubleshoot, how can I include this in a laboratory budget?
9. Can we just assume failure costs are part of our process?