QDT meeting 2008-01-18

Friday, January 18, 2008
8:30 AM

Subject	**QDT meeting**
Date and Location	Friday, January 18, 2008 8:30 AM - 5:00 PM, Req Room
Attendees	
Message	

Link to Outlook item

Notes
Ed began the meeting with a short overview of some items we need to remember to consider:
What are the controls in "level 1"?
How to we appropriately "bound" the process being graded?
Pre-filters still need to be finalized (particularly the thresholds).
Who is going to use the process?
Remember the idea brought up last time: a process may have different "quality levels" for the different QA criteria.
(there might have been others as well, but I didn't get them all down here)

We then reviewed our overall concept of the graded approach:
We want to provide a simple (short) and flexible framework to identify risks and the controls necessary to manage those risks. There was complete agreement on this. We then looked at the outline which Bill Shull sent around (in italics below):

Team Consideration:

Graded Approach Application Guidelines:

Graded Approach thresholds for assessing the degrees of impact and frequency for safety, mission, cost, reputation for applicable criteria includes the use of judgment and the application guidance table.

The QAP graded approach depends upon employee judgment in understanding and application of the intent of the quality assurance plan. The purpose of this approach is to ensure that adequate attention and resources are allocated based upon the impact of non conformance to the ten QAP criteria.

Applicable filters may be used to help determine which and to what extent the formal applicability matrix may apply and includes:

Reasonable likelihood of significantly delaying the Laboratory schedule, failure to meet its goals (as defined in the PEMP), or a significant reduction in the public trust.
Project cost exceeds $500K
The impact of a failure, or repetitive failures, of a process, activity or item exceeds $100K
Personal safety or environmental hazards, liabilities or risks greater than those generally accepted in an industrial environment.
Item is deliverable to an outside organization
Judgment of line management

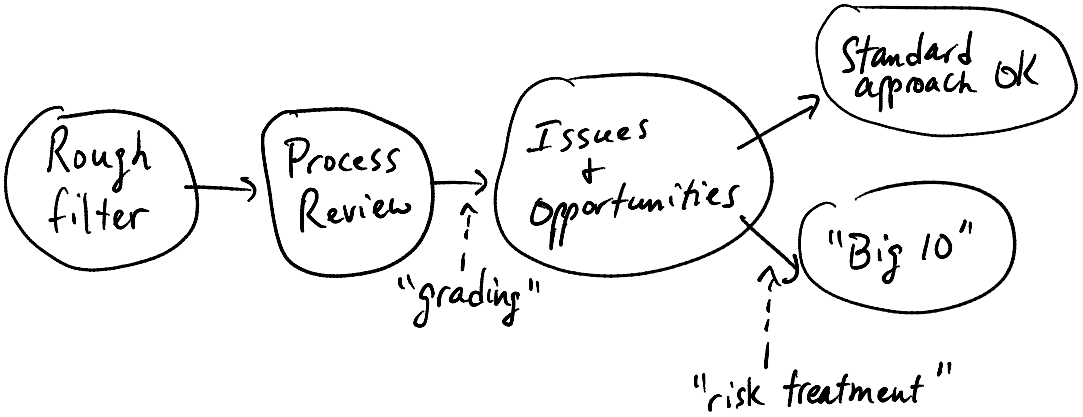
Once an activity has passed through a pre-filter the assessment and application steps may include, as applicable:

1. *Assembling needed expertise*
2. *Determining boundaries*
3. *Evaluating hazards, consequences and frequencies on non mitigation.*
    a. *What can go wrong?*
    b. *What is the consequence?*
    c. *What is the likelihood of occurrence?*
4. *Evaluate quality impact*
5. *Determine which controls maybe required for this category.*
6. *Determine what controls are not in place (??)*
7. *Apply the graded approach principles in the applicability table that follows.*

There was overall agreement with this. There were also some concerns raised in regards to whether or not this simplistic approach will help the lab to appropriately consider all (most?) of the risks inherent in their process. It's possible that this simplistic approach will result in a simplistic output. There was general agreement that we should test out the framework to get some experience with this.

Our approach to rolling this out should include framing the system in a way which people will accept. One approach would be to describe it as a way to identify and control the things that keep people up at night or otherwise could come back to bite them sometime in the future.

Here's a flow chart that Tim put up on the whiteboard:



There was general agreement with this overall flow. Some concerns: are the "standard approach's" really adequate? Is the level of granularity adequate? It was agreed that These just need to be considered as we go through this.

It was also agreed that the output of this process is that risks and their controls are identified. The output is not a grade, per se. It's entirely possible that a grade is not even identified.

On the concern of the level of granularity: perhaps our approach, at least to start with, is a rule of thumb that new processes get a high level of granularity (e.g. FMEA), and current processes have a lower level of granularity. In viewing this implementation from a viewpoint of maturity, we have to keep in mind that the maturity level is going to (hopefully) increase with time, so we cannot expect that we will have a fully mature system right from the start. We need to have a reasonable place to begin, and the rule of thumb above is probably a good place to start.

It was also mentioned that we need to consider effectiveness of the controls, which means follow-up on

them (perhaps assessment?).

Should we call the FQAP the "Integrated Quality Management Plan"?
Editor's note: there was a Fermilab lunch cooler in the Procurement frig which had the phrase "First in science and safety". If someone is wanting to have a catchy phrase on the Plan cover page, this could be considered.

An example to push through the framework:

Minerva is going to purchase 500 PMTs ($1M):

- This passes the pre-filters by $ (yen versus dollar is a consideration) and by schedule (it is the critical path of the project, manufacture 50/month, risk of failure of the tubes, there's only one manufacturer in the world).
- Primary risks:
    - Cost exceeds the estimate by too much
    - Tubes don't meet the specification (this assumes the spec is correct)
    - Tube delivery is delayed by too much

We then had some discussion over the concept of understanding the failure modes, and whether or not we should try to understand them before we go to the applicability table. After about 15-20 minutes, it was acknowledged that this "simple" example was becoming more and more complicated (this gets at the level of granularity). It was suggested that we approach this by looking at the process as a series of steps. For each step we consider the potential failure modes, and then consider the applicable controls. This was agreed to so we tried it (briefly):

Specify tube requirements
Select vendor
Design and construct the test stand
Test the tubes

After a short period we got ourselves into a lengthy conversation about the documented output of this process, and there were concerns raised about what our expectations are regarding the level of documentation. We never got back to working on the example, but agreed that we need to. Next time we will try to put this into some form (e.g. the Hazard Analysis: http://www-esh.fnal.gov/FESHM/2000/2060_FormHA.pdf).

Ed ended the meeting by saying that he and Jed spoke with Bob about our concerns with the schedule and the fact that it was published without our input. He acknowledged our concern and is going to try and meet with us in the near future.

Next meeting: Wednesday 23-Jan, and we will try to pick up our Minerva example by trying to use a form.

Note: after the meeting Bill Shull sent out a Word file which captures most of what we have been putting into other documents as we've been working through the graded approach process.
http://tdserver1.fnal.gov/blowers/projects/QA/QDT/Graded_Approach_PreFilter_18Jan08_Shull.doc

One section which is absent from the above is the connection between the pre-filter entry points and the "typical" risk assessment tools. Whether or not this connection should be included in the procedure is open for discussion. These connections can be found at the bottom of page two in this document (section entitled "What pre-filters got you here"):
http://tdserver1.fnal.gov/blowers/projects/QA/QDT/Graded_Approach_Process_Steps_2008-01-16.doc