

QDT meeting 2008-02-27

Wednesday, February 27, 2008
8:30 AM

Subject	QDT meeting
Date and Location	Wednesday, February 27, 2008 8:30 AM - 5:00 PM, Req Room
Attendees	
Message	

Notes

The meeting started with a quick review of the Assurance Council. Jed pointed out that the systems listed in the 08-May-2007 AC meeting are rather high-level systems, and so are probably not the best place to start when identifying activities for first applying the graded approach.

We started looking at the graded approach procedure (started with A7). We left off on the section on documenting the results. We agreed that we liked the concepts as recorded in A7, but perhaps we can wordsmith it to include a description that we really have a spectrum of activities. Jamie will take a look at this offline.

We then looked at the section on approving the results. A question was raised about documentation of the decisions to not implement the identified controls. Right now the lab does not do so well in documenting decisions, so this is a shift in how we do business. Who would be responsible for ensuring these records are maintained? The process owner? The QAR? Do we expect the original control proposals are kept? No, the original intent was to document when a strategy was changed from "treat" to "tolerate", and in those times we would like to retain the original "treat" controls. It was acknowledged that the current form does not include this part of the process. Should the record simply be the final state of the analysis and decisions? Should we add a place on the form to record the status or plan for implementation? Should we add a section for recording the management response to the analysis and proposed controls?

These were the thoughts of the original statement:

"If during this review and approval process a risk management strategy is changed from "treat" to "tolerate", this decision is to be documented without losing the record of the originally proposed additional control."

In the end we decided to remove this remark: "Changes made by management to the risk management strategies are documented, without losing the record of the originally proposed additional control."

It was removed with some reservation by a few folks; the concern was that we lose an opportunity to record (and hence make available down the road) some of the ideas/thoughts that were generated from the analysis. There was general agreement that our first "release" of the graded approach process should only require the final result be documented. Perhaps as we progress and grow in our QA program we can incorporate the idea of codifying the ideas/thoughts that weren't implemented. We added this to the "parking lot."

It was also brought up that the record needs to be under change control after it is approved by management. This was agreed to, so we added a remark to the approval section: "Upon approval the final results are subject to revision control." A concern was raised that revision control may not be actually performed on these records when we first implement the system because it's an additional requirement. It may turn out that each division/section uses their own document control systems which are already being used.

Tim shared some thoughts on the white board. He described the model used by the Medical Department for organizing and documenting their interactions with patients. There is an analogy to our

QA program, in that it's a model for collecting information, assessing it, and making decisions/plans.

Patient interaction date/time

Subjective - collect data

Objective - collect data

Assessment - analyze data

Plan - decide what to do

This model is designed to capture ad-hoc interactions, and is working well for the medical folks. There are principles which we can apply to our graded approach process.

Bill pointed out that an ISO14000 surveillance audit result in a major finding regarding lack of a document control system/procedure. Tim mentioned that the primary concern is that folks print out forms, and then the form changes, but the folks don't go back to the electronic version they instead use the ones they printed off before. During the certification audit it was a minor finding, and the lab said it would be taken care of with the implementation of the QA program. The ES&H Section has crafted a draft FESHM chapter to address this (scope is safety-related documentation). As document control is thought about within the framework of the QA program, we'll need to keep the FESHM chapter in mind.

This is the current draft FESHM chapter:

http://tdserver1.fnal.gov/blowers/projects/QA/QDT/FESHM-1051_022508.doc

Frank mentioned that Heath O'Connell has begun working on a records management system.

We then moved onto talking about the section on implementation. There is general agreement that implementation of the additional controls is out of scope of the procedure. However, there are some ideas (recorded at the bottom of the procedure in blue) which imply implementation is completed (e.g. verification/validation of the effectiveness of the controls).

Verification: this would be to verify that the output of the analysis is deemed to be "sufficient". This could be done by an independent person (e.g. a different QAR). It was generally agreed that we probably don't prescribe this, but that it will likely take place naturally as the program is implemented.

Validation: this would be assess the adequacy of the implemented controls at some point "down the road". Should it be part of the procedure?

We probably don't want to use the terms verification/validation, but we generally agreed that some QA checks are done (checking that the output is sufficient, and checking that the implemented controls are adequate).

We talked about how the output of this process is in essence a QA Plan for the activity. Would a process which describes how to develop a QA Plan have to explicitly name that the plan needs to be implemented? Does it need to explicitly require verification/validation, or are those already part of the process? In the end we converged on not having a section which explicitly naming implementation, verification and validation (i.e. we removed section F). We added a remark to section 2: ...and the means to determine their effectiveness.

We had a discussion about what to do when things change (e.g. boundary conditions, activity steps, ...). Does the procedure need to enumerate that a reevaluation should be done? How does the lab institute when activities need to be reevaluated (for whatever reason)? When do we require that this procedure (and the selection criteria thresholds) is reviewed? Director's Policy #13 says that these sorts of documents need to define the frequency of review. We wondered if these frequencies should be defined in the to-be document control document, or should it be incorporated into this document? We converged on defining the review frequency in this document in the OQBP responsibility section (and we chose 3 years).

Regarding reevaluation of the output, we agreed that the management systems will take care of this as appropriate (although the triggers are not codified anywhere), so we did not put it into the document. The idea of reevaluation triggers was added to the "parking lot".

We then went back to the last bullet under C2, where the QAR participates in the evaluation and maps the controls to the 10 Criteria. The main question is whether or not this mapping should be done for only the additional controls, or for both existing and additional controls? One argument for not mapping all of them is that perhaps it doesn't actually add value to the lab (other than helping an auditor); also we don't know if we'll have the resources to perform this activity. A counter argument is: if we agree that the mapping is helpful for the additional controls, why is it not helpful for the existing controls? In addition, since we are starting the QA program without this mapping (i.e. there are very few QA-specific documents around the lab), we should perform the evaluation/mapping for all the controls. It was agreed that we would start out with this approach, and then adjust it, as needed, based on our experience. We added the statement "...and ensures the QA controls found in the Applicability List in appendix y are adequately addressed." It was agreed that this statement defines a "what", and not a "how", so we like it. However, should we refer to the IQMP, or just to the applicability list? The applicability list (appendix y) is intended to basically provide a summary of the controls described in the IQMP.

We continued our discussion regarding if/how the QA program (and the graded approach procedure) defines QA requirements; there is the remaining "blue" statement about this at the end of the procedure. A model was proposed which makes the controls listed in column "2" of the applicability list required if/when it is determined that that specific criteria is applicable to the activity. In this model the degree to which each of these required controls is implemented is up to the process owner (but they have to address them all to some degree). The majority of the team viewed this approach as a fundamental shift from what we converged on some time ago, i.e. that the process owner defines what QA controls should be implemented to manage the identified risks. It was pointed out that the lab's QA program implementation in the past has always been based on divisions/sections defining and documenting how they "do" QA, and that the Directorate (via the QA "program") has never tried to prescribe specific QA requirements (other than divisions/sections need to have defined and documented their approach to implementing QA). Basically we're still back to questioning the fundamental approach: does the QA Program define QA control requirements, or does the QA Program define that process owners (i.e. divisions/sections) must define their QA requirements.

We reviewed the language in the 1996 FQAP (replace the term "FQAP" with "IQMP", and "SQIP" with "graded approach"):

3.2 Division/Section Heads

Division/Section Heads are responsible for the implementation of the FQAP in their organizations through the mechanism of Specific Quality Implementation Plans (SQIPs). The SQIPs are the primary documentation of FQAP implementation within the Division/Sections as discussed in Section 4.0. Division/Section Heads should use a graded approach so that the extent and level of detail of implementation for a particular Division/Section sub-element or activity reflected in a particular SQIP is commensurate with the scale, cost, complexity, hazards, and programmatic significance of the work. Each Division/Section Head will ensure that Division/Section SQIPs are developed, implemented and maintained for their organizations. SQIPs will be developed using the guidance found in Appendix 4.

We will continue to wrestle with this topic.

At our next meeting we will work through what the "base" controls are (i.e. the controls which are applied to everything across the lab).

Here is version A8 of the graded approach procedure:

<http://tdserver1.fnal.gov/blowers/projects/QA/QDT/Graded Approach-Procedure Rev 000 A8.doc>