General Discussion (Mr. O’Donnell)

- Discussion on Profile versioning
  - Decision needed as to when Profiles are formally put under CP-based change control; Proposal is definitely when published as Technically Confirmed, possibly when published as Publically Reviewed.
  - Will need to communicate when changes are made to Profiles, as they are being used as reference, both for clinical trial designs and as the basis for claims of conformance.
  - Should specify the draft version that was used
  - Although arbitrary content changes will not be allowed, we cannot promise stability of text – rigorousness of tracking changes is needed
  - Suggested disclaimer made, such as, “living document is subject to changes – they could occur at any time.” for drafts published prior to going under change control.
  - With QIBA as the publisher, onus should be upon QIBA to track changes – will need to have a formalized publication process
  - Once through the technical confirmation phase, we may still be faced with content changes to Profiles. If they would invalidate claims of conformance, they have to go in a different Edition of the profile or in a different profile.
  - Should there be an official release of Profile from QIBA after technically reviewed?
  - The DICOM versioning process was given as an example:
    - Change is formalized
    - Form is completed to indicate nature of the issue and the change that was made
    - "Manual change tracking notation", e.g. Old formula is stricken out; new formula is shown
Approved changes are periodically folded into the master document

- Coordinating Committee leader feedback requested
- “Clinically confirmed” = claim of profile has been accomplished (widely?) in clinical conditions vs. “Technically confirmed” = claim of profile has been accomplished (at least once) in “controlled conditions”
- Feasibility test: determines if Profile is workable in clinical setting – are the Profile requirements practical? In a way this tests the site "costs" of implementing the profile
- Field test: determines if the Profile Claim is valid/accurate. In a way this tests the benefit of implementing the profile. It is part of achieving a technically-confirmed Profile.
- Field test and Feasibility test can be conducted simultaneously but don’t have to be.

Next Steps:

- Post additional topic page on QIBA wiki and point others to it
- Will check in with Joe Koudelik on engine updates so the link to the Process page in the navigation box at the left is more visible. (Currently it gets pushed down to the bottom of each page).

Next Call:  Wednesday, June 3rd, 2015 at 3 PM CT