QIBA Process Committee Call

Tuesday, March 3, 2020 at 3 p.m. CT

Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Nancy Obuchowski, PhD	Daniel Sullivan, MD	Joe Koudelik
Michael Boss, PhD (Vice Chair)	Nicholas Petrick, PhD	Gudrun Zahlmann, PhD	Susan Stanfa

General Discussion

- Reminders re: Public Comment Resolution Procedure
  - All MR BC Co-chairs received procedural information in August 2019
  - A QIBA Wiki page for posting public comment resolution documents has been created
  - The purpose is to provide comment submitters access to details on how their feedback was addressed, i.e., incorporated into the subsequent draft (Consensus Profile)
  - A Google-based public comment resolution spreadsheet template was created and linked to the public comment process QIBA Wiki page
  - The Public Comment Process page provides instructions to BC members re: classifying comments
  - Before the public comment period for the DSC-MRI Profile opened, the group was provided the template
  - Staff to create sheets for all of the other active groups
  - Dr. Boss and Mr. O'Donnell to draft reminder emails to be distributed to all QIBA BCs whose public comment period has closed

- Lead Profile authors/editors/contacts listed on the QIBA Dashboard to be confirmed

Biomarker Adoption Steps and Supporting Materials

- Details related to all below discussions can be found in the **Google Doc**
- Discussion focused on Section 4: Testing Conformance
- Process Committee may prepare guidance to BCs to consider which profile requirements merit recording specific details during assessment and to then add explicit text in the Profile (either in the assessment procedure or in the requirement itself) about what must be recorded (e.g., in the image resolution assessment, record the actual resolution value achieved). Might also explain why it is relevant if not clear
- Suggestion to discuss self-attestation and third-party certification procedures, etc. during April QIBA Annual Meeting to build BC leader understanding and continue refining the concepts
  - Clarity needed from each BC re: what is needed to demonstrate conformance (report/data wise)
  - Unless a BC says otherwise, the standard checklist "Yes/No" response would be the default (minimal) recording requirement
  - Recording requirements in the profile would apply to both assessors doing self-assessment for the purpose of self-attestation, and also to third-party assessors doing certifications
  - It is conceivable that third-party assessors (and diligent self-assessors) would record additional details and preserve additional assessment data beyond what is required by the profile
  - In addition to the requirements to record certain details, QIBA should consider what obligations should be placed on assessors (self and/or third-party) to publish, or otherwise make available for inspection, the recorded details. This might be more important for certification than for self-assessment, keeping in mind the desire to minimize burden.
  - A potential benchmark for the breadth of the recorded details is whether it would allow someone who wanted to review or audit a conformance assessment to be comfortable that the assessment took place and appeared to be performed correctly

- Some open questions include whether QIBA should allocate resources to reviewing/auditing self-attestation results, and whether QIDW should be used to "publish" certain recorded details

- Suggestion to require submission of datasets to QIDW with time stamps, with RSNA as the database for all sites/products (also being discussed in the SIG)
- Discussion re: possibility of legal concerns with RSNA as a sponsor for conformance testing
  - In the DICOM example, there is no explicit review of self-attestations (DICOM Conformance Statements). Note however that the DSC is published by the vendor as part of the product documentation and as FDA-regulated medical devices, that brings any discovered non-conformance under FDA complaint/resolution mechanisms which have proven largely adequate
  - In the IHE example, again there is no explicit review of self-attestations (IHE Integration Statements) and for many products the same FDA product documentation situation holds. IHE also coordinates formal assessment events (Connectathons) that result in a record that the vendor demonstrated the ability to conform, but a claim of product conformance is still left to the vendor. After some years of work, a formal 3rd-party product certification process is being established. It remains to be seen if there is enough vendor and user financial interest to support the needed resources.
  - What is needed scientifically and legally to prove that the QIBA process is rigorous enough?
  - For self-attestation, QIBA could review that the results were documented correctly, but would not be responsible for evaluating test performance
  - It was suggested QIBA would not take a formal position on the work, but offer a general review of process (this would be more of an opinion)
  - With certification, the third-party would decide whether to:
    - involve more inspection of the methods and results rather than just the documented findings; a challenge will be that the 3rd-party should not create new profile requirements
    - focus on providing tools, but not take the responsibility of certification
  - If testing not conducted properly, the third party/applicant would be legally responsible
  - Profiles to encourage tools for automated assessment, but would not have mandatory pre-requisites requiring expense
  - QIBA should clearly specify the "rules," i.e., the metrics/calculations but might not necessarily oversee testing or validate individual implementations
    - A DRO would be assumed valid unless reported otherwise; QIBA would preserve the right to step in if an issue arises
    - QIBA Wiki could contain a list of trusted third parties, removing those who were found to be inadequate in meeting requirements

Next Process Cmte Call: Tuesday, March 17, 2020 at 3 pm CT (1st & 3rd weeks of each month)