

QIBA Process Coordinating Committee

April 8, 2015 at 3:00 PM CT

Call Summary

Attendees:

Kevin O'Donnell, MASC (Chair)
Michael Boss, PhD
Cathy Elsinger, PhD

Brian Garra, MD

Alexander Guimaraes, MD, PhD

Edward Jackson, PhD

Eric Perlman, MD

Staff:

Joe Koudelik

Susan Weinmann

General Discussion

The group discussed the latest version of the template for the QIBA conformance statement

- Conformance language among the CT, MR and PET Profiles is converging
- For a site (actor) to be conformant, a device must be capable of being conformant as well as follow any necessary QA site requests; assessment procedures needed
- Sites publishing device claims in lieu of a vendor may cause confusion; being clear as to who is publishing the claim is critical; this detail needs to be added to the Conformance section
- Who should sign-off for sites claiming conformance was discussed: project PIs listed by name was suggested
- Manufacturer "user help" details based on specific devices to be included in the Appendix
- ADNI has an automated phantom software program to help check for compliance
- MR Distortion Service (Image Owl), a Phantom Laboratory service, was discussed and deemed an ideal automated process example for QIBA
- Qualifying tools for device submission is always needed and welcome by the FDA
- Questions included: What is the QIBA policy and who will spot-check for compliance? Is there a "QIBA Police"?

Next Steps:

- Profile editors were encouraged to submit 1-5 situations where they needed to modify, or deviate from the standard Profile template – these will be generalized into a template revision
- Dr Jackson to propose some language to highlight the site qualification component

Next Call: Wednesday, April 22, 2015 at 3 PM CT