**Quantitative Imaging Biomarkers Alliance**

**QIBA Conformance**

**Statement**

QIBA Conformance Statements

QIBA Conformance Statements are documents prepared and published by vendors or sites to describe the intended conformance of their products, staff or institution to one or more QIBA Profiles.

Conformance requirements are defined in the QIBA Profile document for each Actor in the Profile. For some requirements, the Profile document also defines assessment procedures.

Users can use Conformance Statements to determine whether their staff and products can be expected to deliver the biomarker performance described in the Profile Claim. Achieving the performance claim depends on all Actors described in the Profile being present at the site and conforming to the requirements.

A QIBA Conformance Statement is not intended to promote or advertise aspects of a product or site not directly related to its implementation of QIBA capabilities.

**IMPORTANT NOTE: Vendors and sites are solely responsible for the accuracy and validity of their QIBA Conformance Statements.** QIBA and its sponsoring organizations have not evaluated or approved any QIBA Conformance Statement or any related product, site or staff, and QIBA and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any QIBA Conformance Statement.

F.1 Content of a QIBA Conformance Statement

In the following statement format sections:

* Site Name may refer to a facility, a department or a specific room
* Product Name and Version are those used commercially
* Responsible Person is who takes responsibility for (ongoing?) Conformance of the actors
* Date is the publication date of the QIBA Conformance Statement

F.2 Format of a QIBA Conformance Statement for a Product

Each Conformance Statement shall follow the format shown in the following table.

The submitter may add a cover page and information required by their documentation policies.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| QIBA Conformance Statement | | | | |
| Vendor | Product Name | | Version | Date |
| Any Medical Systems Co. | AlphaScanner | | V2.3, V2.4, V3.0 | 2017-03-12 |
| This product conforms to all specifications required for the QIBA Profiles and Actors listed below: | | | | |
| Profiles Implemented | Actors Implemented | Notes | | | |
| CT Volume Change (2014) | Acquisition Device | See A.1 | | | |
| Reconstruction Software | See A.2 | | | |
| CT Volume Change (2017) | Acquisition Device | See A.3 | | | |
| Links to Additional Information | | | | | |
| Submitter’s QIBA information: www.anymedicalsystemsco.com/qiba | | | | | |
| General information on QIBA: qibawiki.rsna.org | | | | | |

## Annex A: Conformance Notes

## A.1 CT Volume Change (2014) – Acquisition Device

**Model-specific Instructions and Parameters**

The following parameter values were used when demonstrating conformance and are provided for reference. Other values may also achieve conformance.

*<<Clarify that this is an example and the actual details to include will be defined in the Profile you are claiming conformance to.>>*

Acquisition Activity Parameters

|  |  |
| --- | --- |
| kVp | 120 |
| Number of Data Channels (N) | 64 |
| Width of Each Data Channel (T, in mm) |  |
| Gantry Rotation Time in seconds |  |
| mA |  |
| Pitch |  |
| Scan FoV |  |

*<<Permit helpful notes as the submitter sees fit>>*

*<<Could include the actual metric scores, but it might turn it more into a marketing tool and less of a technical aid>>*

*<<Note that the Assessment Procedures are in the Profile so sites can always validate the results locally, and where there is automated tools (like the ADNI Phantom Analyzer provided by Image Owl - MR Distortion Service) then it would even be easy to do.>><<Tools can also be validated by the FDA and can be commercial>>*

*Discussion:*

*For Ultrasound and MR it would be analogous.*

*DWI – depending on the organ being examined – the Profile covers several organs, but the requirements/conformant settings will differ for different organs.*

*DWI Claims for both overall performance and organ by organ claims. – claims relate to b-Values. For the scanner it's less organ specific. (E.g.. if liver says b-Value 0-800, Brain 0-1800, then a scanner can hit 1800, then it is conformant for both.) An MR scanner in the same general model number might have different sub systems with different levels of performance. If they are part of the "System Model", no extra details in Annex needed. If they are not inherent in the System Model, you should document the relevant subsystem details in the Annex.*

*Use the Annex prudently, but likely of value in most Profiles.*

*Q. When does a Profile become multiple?*

*FDG-PET – there are model specific settings to get the required conformance.*

*(It's a little bit about how "foolproof" the device is for conforming. Is there more than one way to skin the cat, and is it possible to fail? )*

## A.2 CT Volume Change (2014) – Reconstruction Software

Reconstruction Activity Parameters

*Ask Turkington for the list of "site qualification" details.*

F.3 Format of a QIBA Conformance Statement for a Site

Each Conformance Statement shall follow the format shown in the following table.

The submitter may add a cover page and information required by their documentation policies.

|  |  |  |  |
| --- | --- | --- | --- |
| QIBA Conformance Statement | | | |
| Site Name | Responsible Person | | Date |
| Mercy General Hospital – Oncology Dept. | Dr. Marcus Welby | | 2015-03-12 |
| This site conforms to all specifications required for the QIBA Profiles and Actors listed below: | | | |
| Profiles Implemented | Actors Implemented | Notes | | |
| CT Volume Change (2014) | Technologist | See A.1 | | |
| Radiologist | See A.2 | | |
| Site | See A.3 | | |
| Links to Additional Information | | | | |
| Submitter’s QIBA information: www.anymedicalsystemsco.com/qiba | | | | |
| General information on QIBA: qibawiki.rsna.org | | | | |

## Annex A: Conformance Notes

## A.1 CT Volume Change (2014) – Technologist

All technologists assigned to use this scanner received training that included details of this Profile. Periodic spot checks confirm they continue to follow the profile details.

## A.2 CT Volume Change (2014) – Radiologist

All chest radiologists on staff have

* Reviewed the quality assurance guidelines described in section 3.4 of the profile
* Completed the performance assessment described in section 4.4 of the profile and met or exceeded the target in section 3.5 of the profile

## A.3 CT Volume Change (2014) – Site

List of rooms/device instances that are included in this claim.

Or do we add a section to the Table above where the devices are listed, e.g. in the Instrumentation/Devices section.