

Names for QIBA Profile Stages (Levels)

- Over time we collect information, revise the Profile, and become increasingly confident of its ability to achieve the stated claim.
- Some users will find Profiles valuable even with only modest QIBA confidence, while others will count on achieving the claims exactly. In other words, some just want a spec to drive consistency and are happy with performance that is “as good as can be achieved with reasonably small effort” while others expect to achieve the claim numbers in practical use and will condemn QIBA if they do not.
- We don’t want to withhold Profiles until they are perfect and incontrovertibly accurate so as to avoid misleading anyone.
- Therefore, we should label Profiles to communicate the stage of maturity or confidence clearly and allow users to make their own choice about what they would like to use it for, *e.g.*, this is the Version for Public Comment of the QIBA Functional Brain Mapping Profile, or the Technically Confirmed Version of the QIBA DCE-MRI Profile.

Level Name	Level Meaning	Level Criteria
<i>The tag we hang on the profile doc.</i>	<i>What we want users of this document to understand about what it means</i>	<i>The checklist items/metrics/Rules-Of-Thumb the document should have cleared before it can be released with this tag</i>
Version for Public Comment	<p>The Technical Committee (TC) finds that the Profile describes the key factors that affect the claim and has proposed recommended procedures that address each/most of the factors.</p> <p>The TC reserves the right to make modifications.</p>	<ul style="list-style-type: none"> • All open issues have been clearly listed • Most open issues have candidate resolutions drafted into the Profile • Some groundwork projects may be underway • All major solution components and Profile details are complete enough to implement • For each actor in the Profile, it is clear what is required for a system or organization to claim compliance • Each activity in the Profile has a justification based on literature data, phantom studies, or TC consensus. • Compliance requirements appear sufficient to accomplish the claim of the Profile
Publicly Reviewed Version	<p>The TC has formally addressed each issue raised during Public Comment. All Profile changes based on received public comments are documented.</p> <p>Implementers are encouraged to start implementing the Profile.</p>	<ul style="list-style-type: none"> • All public comments have been addressed • All open issues necessary for conformant deployment have been resolved • Few, if any, groundwork projects remain active • All recommended procedures have been tested in one or more groundwork project(s) or referenced studies. (Reasonable deviations from Profile details may exist.)

Technically Confirmed Version	<p>The Profile details have been implemented in a “lab or test setting” and each participating system and person successfully met the performance specifications; the claim was achieved.</p> <p>The TC asserts that conformant deployments can achieve the Profile claim.</p>	<ul style="list-style-type: none"> • Groundwork projects are complete • All recommended procedures and Profile details have been implemented by at least one system or site • All recommended procedures and Profile details have been tested as described in the Profile • The Profile claim has been achieved in laboratory conditions
Clinically Confirmed Version	<p>The TC has collected data in the field that confirm the claim.</p> <p><i>(While the three levels above are now in active use by QIBA, the semantics of Clinically Confirmed and the criteria of this level are still under discussion. Following resolution, this level will be adopted as well)</i></p>	<ul style="list-style-type: none"> • All recommended procedures and Profile details have been implemented by multiple systems or sites • All recommended procedures and Profile details have been tested in the field as described in the Profile • The Profile claim has been achieved in clinical conditions • <i>[Additional proposed criteria that will be discussed:</i> <ul style="list-style-type: none"> ○ <i>The degree of statistical certainty has been documented and exceeds ...</i> ○ <i>Some level of Clinical validation has been demonstrated</i> ○ <i>The Profile has been implemented in a human research study]</i>
There may be more levels that are beyond the scope of QIBA, e.g.:		
Class A	Multicenter, multisystem trials and analysis of numerous papers, widespread papers on the particular biomarker covered.	
Other		

Versioning is a related question. For example, after the 2013 Edition of a Profile had been released for a few years, the technology and install-base might have advanced enough that we could release a 2015 Edition of the Profile that has a tighter claim and some additional constraints. We might write this as QIBA XXXX Profile (2015).