Harmonisation Guideline Process

Scope

This document describes the process of developing harmonisation guidelines, including mechanisms for comment, review and publication of the final recommendations.

Background

A major activity of the AACB is harmonisation of laboratory activities and processes. The aim of harmonisation is simply to identify discordant practices between laboratories across Australasia and to reduce or eliminate them. Therefore, harmonisation covers many areas, such as, commonality of reference intervals, reporting units, calibration traceability, standardised terminology for test names, commonly used calculations, and critical laboratory results, to name a few.

Guidelines are systematically developed statements/recommendations to assist laboratories achieve good laboratory practice, produce valid results, and increase concordance between laboratories. A number of guidelines have already been produced by targeted Working Parties (WP). Laboratory are encouraged to consider, and where appropriate, adopt guidelines. Many of these documents have been endorsed by RCPA and released as joint guidelines.

Governance of Harmonisation Activities

The Harmonisation Committee and all harmonisation-related projects undertaken by individual WPs are a responsibility of the AACB Scientific and Regulatory Affairs Committee (SRAC). The members of a WP include invited representatives from relevant stakeholder organisations (e.g. RCPA, ESA, etc), and interested members. Regular meetings of the Harmonisation Committee are held to discuss issues associated with WP activities. Meetings of the WP are held as needed to discuss progress.

Process of Harmonisation Guideline Development

The scientific process for developing any recommendations rests with the individual WP. WP typically use evidence- and consensus-based best practice methods for determining IF and HOW discordant laboratory practices can be harmonised.

Data sharing between institutions may be necessary in the development of a harmonised guideline. In this case, it is understood that data (such as work product) is provided freely by the stakeholder, having complied with any of their Organisational or regulatory requirements in regard to data sharing. The responsibility for obtaining approval to share data resides with the person providing the data. The AACB

does not review compliance with any Organisational or regulatory requirements. Any data submitted to the WP or the Harmonisation Committee is assumed to have been approved for release by the stakeholder Organisation.

The stakeholder Organisation retains the intellectual property rights to any data shared with the WP, and the AACB will acknowledge its contribution on all publications that may arise from this activity. Where further data analysis by the WP leads to new conclusions that are also included in the draft harmonisation guideline, then this new information becomes the intellectual property of the AACB Harmonisation Committee.

Harmonisation Workshops are held regularly, usually at yearly intervals. Reports from WPs are presented at this forum, with feedback from the workshop participants used to further refine the activity of the WP. When preliminary recommendations presented for discussion at a Harmonisation Workshop are endorsed by a clear majority of participants, the recommendations may be developed further into a Draft Harmonisation Guideline.

Draft Harmonisation Guidelines

Draft harmonisation guidelines are published on the AACB website. AACB members and relevant stakeholders are invited to comment during a 90-day period. Draft harmonisation guidelines are also sent to the Chair of the RCPA Chemical Pathology Advisory Committee for review to ensure that adequate clinical consultation occurs. The WP may also invite other specified groups to comment on the draft harmonisation guideline. Comments submitted are collated by the AACB Office for distribution to the WP.

Comments submitted should be related to the draft guideline. Where appropriate, and to ensure an adequate response, all comments should refer to specific parts of the draft guideline e.g. a specific sentence, paragraph, section, table or figure.

At the end of the 90-day period for comments, any comments are given to the WP for their response. The WP is expected to address all comments received and make a summary of the comments and responses available for publication on the AACB website. If more changes are made to the draft document, the revised version is then published on the AACB website for a further 30 days to allow for any final comments. Following this, the WP will decide if the draft harmonisation guideline can be put forward for approval by AACB Executive.

Approval of Draft Harmonisation Guidelines

Final approval of any draft harmonisation guideline rests with AACB Executive. The AACB may then also invite endorsement by the RCPA Chemical Pathology Advisory Committee, if appropriate. Jointly approved guidelines are considered an important part of developing harmonisation guidelines. It recognises the contribution of chemical pathologists on the Harmonisation Committee and WP and the cohesion between scientists and pathologists in these activities. The AACB Harmonisation Committee may also invite endorsement by other relevant clinical organisations, if appropriate. Subsequent acceptance of the guideline by NATA is more likely if broad-based approved has been obtained.

Acknowledgements of Work

The WP is expected to publish the AACB-endorsed harmonisation guideline in a peer-reviewed journal as soon as possible. AACB-endorsed harmonisation guidelines are also published on the AACB website accompanied by any supporting documentation.

An acknowledgement of the work done, data sources, support and funding is provided at the end of AACB-endorsed harmonisation guideline document.

The endorsement of the guideline document by AACB Executive and other stakeholder organisations, is also stated in the published guideline document.

Review period for published Guidelines

AACB-endorsed harmonisation guidelines are date-stamped with the date of their approval and are reviewed at 5-year intervals. An earlier review may be conducted if important new evidence emerges requiring earlier revision.