Leaders in Medical Software and Compliance, Conformance and Accreditation working together for e-health

Leaders in the Australian health software industry and compliance, conformance and accreditation (CCA) community demonstrate their ongoing commitment to the development of e-health by a declaration of consensus to work towards compliant and conformant e-health systems in the industry.

This statement is a commitment to the collaborative development and adoption of national e-health standards and the supporting CCA framework to improve patient safety and the quality of healthcare delivery for all Australians.

The Medical Software Industry Association (MSIA), Australian Information Industry Association (AIIA), National Association of Testing Authorities (NATA), Joint Accreditation System of Australia & New Zealand (JAS-ANZ) and the National E-Health Transition Authority (NEHTA) have achieved consensus on the following:

1. The focus in e-health for Conformity Assessment will be on specific functional capabilities of software products.
2. International and Australian standards will be used as the basis for conformity assessment.
3. A tiered approach to conformity assessment will be undertaken when applying conformity assessment for quality, safety and risk-based measures.
   - Contingent on the risk involved, conformity assessment may consist of options from self-assessment through to accredited external assessment.
   - Conformity assessment will be commensurate with risk and geared to minimise resources and time.
4. Accredited conformity assessment bodies (CABs) will be responsible for accredited external testing and certification.
5. Accreditation of CABs will be carried out by internationally recognised accreditation organisations, such as NATA and JAS-ANZ.
6. It is not the intention of NEHTA to become or perform the function of a CAB.
7. Existing and future conformity assessment bodies, such as AHML, will be leveraged as the basis for e-health conformity assessment.
8. Successful completion of an appropriate CCA process will be publicly recognised.
9. Whilst the CCA Framework's primary focus is safety and quality, it will guide and assist other processes such as procurement and healthcare practice improvement.
10. The CCA Framework will focus on the foundations for e-health underpinning innovative development.

Peter Fleming	Dr Geoffrey Sayer	Ian Birks	Alan Patterson	Dr James Galloway
CEO NEHTA	President MSIA	CEO AIIA	CE NATA	CEO JAS-ANZ

nehta
National E-Health Transition Authority
www.nehta.gov.au

MSIA

AIIA
AUSTRALIAN INFORMATION INDUSTRY ASSOCIATION
LEADING THE ICT BUSINESS COMMUNITY

NATA

JAS-ANZ

Level 25, 56 Pitt Street, Sydney, NSW 2000
Phone: (02) 8298 2600
Fax: (02) 8298 2666