



Certification and Accreditation

Considerations and early thoughts

Ted Cizadlo
November 2009



Definition of Terms

- Accreditation: Approval of a providers of products or services
- Certification: Testing and/or evaluation of products

What is the context?

- A practice wishing to procure an Clinical system module
- A community of practice wishing to ensure consistent Clinical system functionality nationally
- A vendor wishing to develop or enhance an Clinical system module
- A developer wishing to interface to a given Clinical system module across multi-vendor systems
- All may be:
 - searching for trustworthy products
 - seeking design guidance
 - wishing to obtain quality labeling certification



Considerations

- **Criteria Definitions**
 - Clinical perspective
 - Technical Perspective
- **Governance**
 - Accreditation
 - Certification / Testing
- **Funding Considerations**

Reporting

Principles

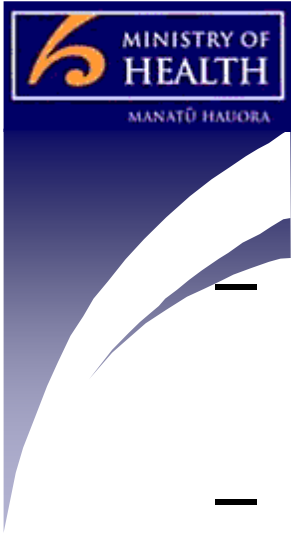
- Improve the quality of healthcare information and enhance patient safety
- Protect the privacy of personal health information
- Credible, objective, and collaborative governance
- Seek input and deliver compelling value for all key stakeholders
- Testing process must be objective, fair, reliable, repeatable
- Clear value to users and vendors
- Certification must be efficient, timely, and cost-effective

Source – environmental scan



Questions

- Why are we doing this?
- Do I have to?
- What will I gain from it?
- What will it cost me?

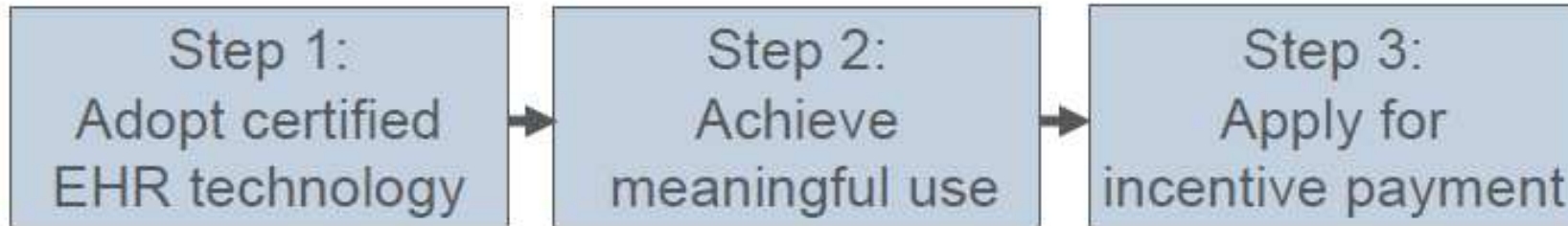


Environmental Scan

- **CCHIT (United States of America)**
- **NHS – CFH (England)**
- **Infoway (Canada)**
- **Ministry of Education Student – NZ
Management System Accreditation**
- **Australia (NEHTA)**



USA - CCHIT



Clinical Inspection

CCHIT Proctor



Web conferencing
and concurrent
audio conferencing



Juror A
(Practicing
physician)



Juror B
(Healthcare
professional/
practitioner;
nurse if
inpatient)



Juror C
(Healthcare
professional/
practitioner)

Applicant demonstrates
against test steps in each
required scenario

Jurors may not
have a
financial
relationship
with any
vendor

Canada - Infoway

Certification Processes	<p>A structured process which is clearly visible to all interested parties via the Infoway website.</p>
<p>Pre-implementation certification service (i.e. applies to Market Ready solutions)</p>	<p>A review of a Consumer Health Platform to determine whether it conforms to the Infoway assessment criteria on Privacy, Security, Interoperability and Management.</p>
<ul style="list-style-type: none"> •Apply 	<ul style="list-style-type: none"> •Inquire about certification •Request application package •Submit application for certification •Including self assessment •Receive registration confirmation and payment receipt.
<ul style="list-style-type: none"> •Assessment Report 	<ul style="list-style-type: none"> •Verify self assessment package •Provide self assessment confirmation •Assess solutions stages •Complete assessment report.
<ul style="list-style-type: none"> •Assessment Criteria 	<ul style="list-style-type: none"> •Functionality, privacy, security & interoperability. •Assessment criteria shared & reviewed by 4 jurisdictions, one vendor and privacy commissioner

Canada - Infoway

<p>ation cess (Ctd)</p>	<p>A structured process which is clearly visible to all interested parties via the Infoway website.</p>
<p>demonstration of compliance</p>	<p>Test scenarios and test data supplied and applicant is expected to demonstrate (virtually) execution of all tests for the assessment team. Assessment divided into:</p> <ul style="list-style-type: none"> •Security •Privacy •Interoperability •Functionality •Management control.
<ul style="list-style-type: none"> •Certify 	<p>Various steps are covered between the parties but culminating in:</p> <ul style="list-style-type: none"> •A Certification Letter & Certification Mark •Initially One year with opportunity to recertify (extend certification) for up to two additional years (fixed certification renewal dates – twice a year) •With complete re-certification every three years.
<ul style="list-style-type: none"> •Maintain (changes to product). 	<p>Any material changes must be communicated to Infoway and may require new certification.</p>

NZ - Ministry of Education

<p>Verification Processes</p>	<p>Two parallel, independent testing streams – Business Categories and software categories. To ensure fairness no results were put together or published until both streams had completed their independent assessments.</p>
<p>•Assessment Criteria</p>	<p>The vendor assessed against:</p> <p>5 business categories: Organisation, Support services, Quality assurance, Software development management, Future directions</p> <p>8 Software Categories Roll return & audit approval, Access control, Installation Technical architecture, Usability, Student database, Attendance, Assessment</p>

NZ - Ministry of Education

tify	Must pass all five business categories and all eight software categories to be accredited. Accreditation is for life unless significant changes are made.
•Results	Results published and made available to vendors, purchasers and the wider public.

Accredited

eMinerva ACCREDITED ✓

Category	Score
A	85
B	80
C	95
D	90
E	75
F	95
G	85
H	95
I	85
J	90
K	85
L	85
M	80

Company Name: MXL Consolidated Pty. Ltd
T: 0800 MXL NOW (0800 695 669)
E: enquiries@mxl.co.nz
Web: www.mxl.co.nz
Platform: Mac & Windows
Current school type: All
Number of schools: 0—100
Hosted: Yes, with web browser

eTAP ACCREDITED ✓

Category	Score
A	85
B	80
C	75
D	70
E	85
F	95
G	85
H	75
I	85
J	85
K	85
L	85
M	80

Company Name: Educational Software Distributors (ESD)
T: 09 263 4827
E: info@etap.co.nz
Web: www.etap.co.nz
Platform: Mac & Windows
Current school type: Primary & Intermediate
Number of schools: 0—100
Hosted: Yes, with web browser

Integris ACCREDITED ✓

Category	Score
A	85
B	80
C	85
D	85
E	75
F	95
G	85
H	85
I	85
J	85
K	85
L	85
M	85

Company Name: Itas Education Division, Renaissance Ltd
T: 0800 367 482
E: info@itas.co.nz
Web: www.itas.co.nz
Platform: Mac & Windows
Current school type: All
Number of schools: 200 +
Hosted: Yes, with MS Terminal Services

KAMAR ACCREDITED ✓

Category	Score
A	85
B	85
C	85
D	75
E	85
F	95
G	85
H	85
I	85
J	85
K	85
L	85
M	85

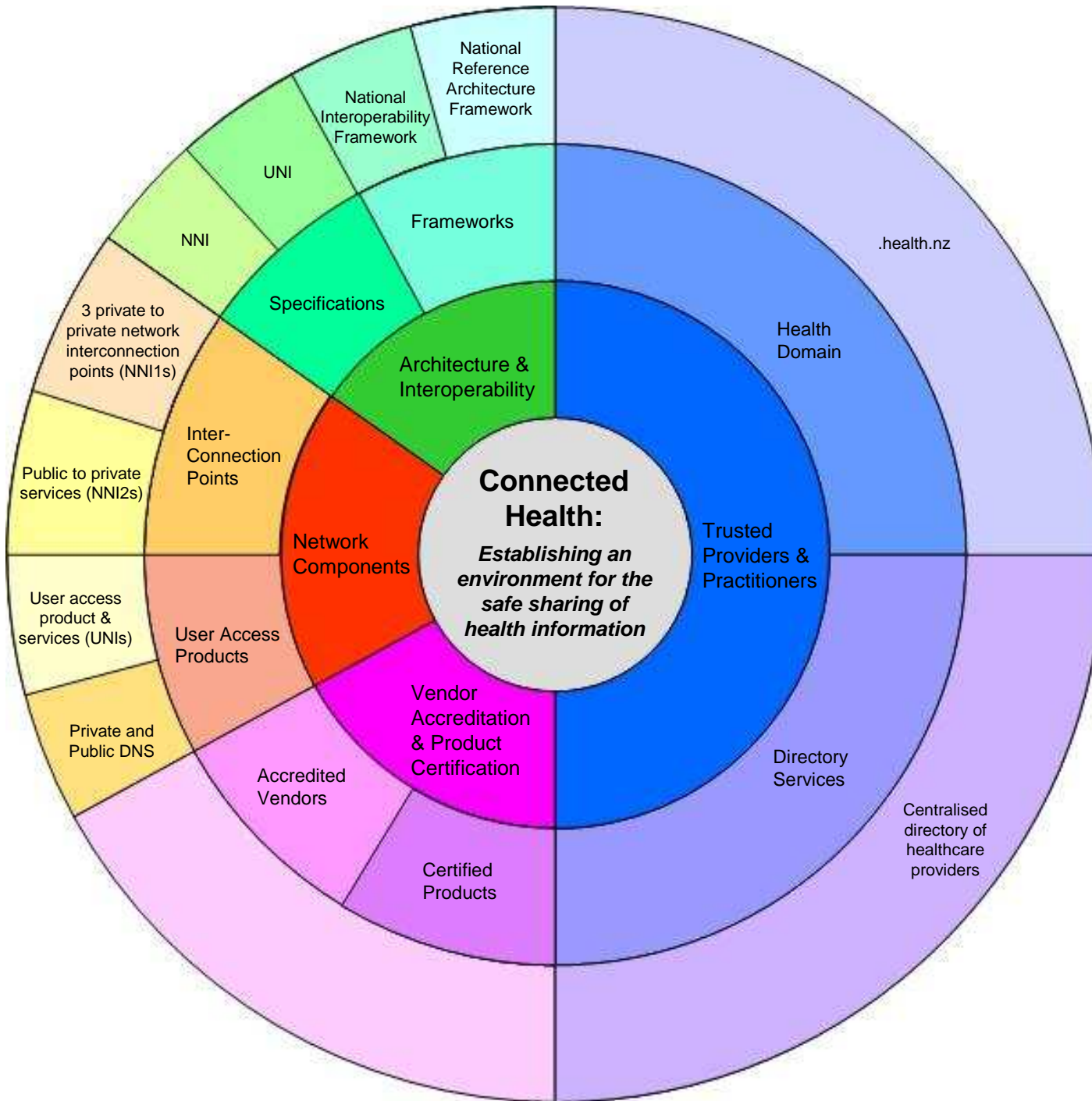
Company Name: KAMAR Ltd
T: 07 572 0936 or 021 0356 849
E: kent@kamar.co.nz
Web: www.kamar.co.nz
Platform: Mac & Windows
Current school type: All
Number of schools: 0—100

Conformance test documentation

Proposed conformance testing documents based on:

- IEEE829-1998 *Standards for Software Test Documentation*
- Mainstream software methodologies

Document	Purpose	Proposed Scope
<p>Conformance Test Scenarios Specification</p>	<ul style="list-style-type: none"> ▪ Converts each use cases into one or more testable interactions. ▪ May support a specification submitted to Standards Australia 	<ul style="list-style-type: none"> ▪ High-level features to be tested ▪ Suggested test approach ▪ Expected behaviours
<p>Conformance Test Conditions Specification</p>	<ul style="list-style-type: none"> ▪ Translates a single conformance point/criteria into the basis of a test. ▪ Isolated, reusable, extensible. 	<ul style="list-style-type: none"> ▪ Condition being tested ▪ Type of test (positive, edge etc.) ▪ Pass / fail criteria ▪ Proposed means of testing
<p>Conformance Test Procedures Specification</p>	<ul style="list-style-type: none"> ▪ Complete instructions to carry out a conformance test. ▪ May suggest or prescribe the use of a test harness or tool. 	<ul style="list-style-type: none"> ▪ Environmental needs ▪ General setup/operation guide ▪ Steps to undertake each test ▪ Inputs, Data & Expected Output





Questions?

