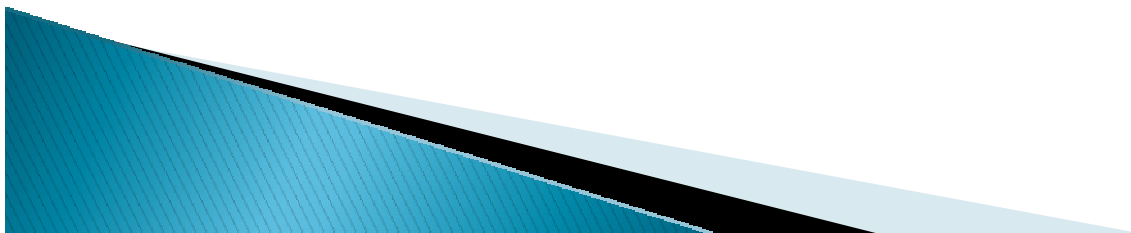


Software as a Medical Device

A Provider View from Canada



Current Situation in Canada

- ▶ Medical Device ruling – August 2009
- ▶ Revised Notice in May 2010, providing dates for compliance (Sept. 2011 for Class 2)
- ▶ Draft FAQ & ongoing dialogue with Health Canada – largely on scope & application
- ▶ Ongoing collaboration and interest with the associations (COACH, ITAC Health, MEDEC)
- ▶ Patient Mgmt. Software Conference – Sept 8
- ▶ Provincial CIOs & Vendor community perspectives differ on how best to take the first step.
- ▶ CIOs and the vendor community are very aligned with our professional association (COACH) in supporting a holistic approach to address the broader patient safety risks, notwithstanding the scope of SAMD regulation.



Examples of Definitions Being Discussed

- ▶ provides the only means and opportunity (meaning in real time) to capture, acquire or view data from a medical device for aiding directly in diagnosis or treatment (concept of software being an **adjunct** to a medical device) or
- ▶ replaces a diagnostic or treatment measurement/calculation/**decision** otherwise made by a physician or health professional

Shorter term discussion on the regulatory scope has focused on the second element



Canadian Issues & Concerns

- ▶ **Scope & application** where not adjunct to a device – given the increasing complexity of our interoperable EHR environment
- ▶ **Getting out front** of international requirements – in an increasingly global marketplace
- ▶ **Need for a risk-based approach** to software safety grounded on an integrated set of standards before diverting energy to one aspect (regulation)
- ▶ **Impact** on Canadian EHR momentum at a time when uptake is so important to improving health system sustainability & safety

All parties are aligned on these being the key issues – ISO TC215 can play an important role here.

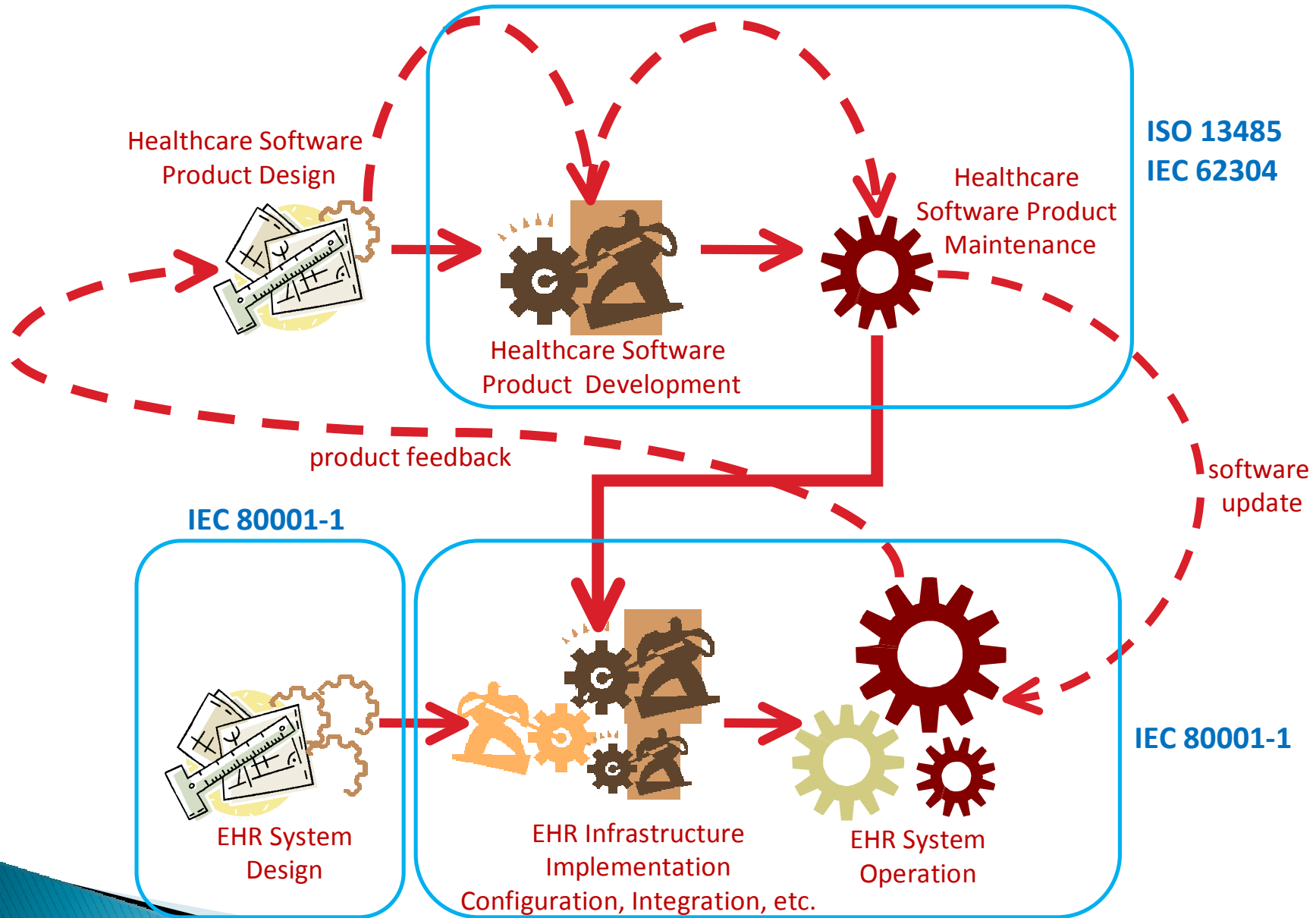


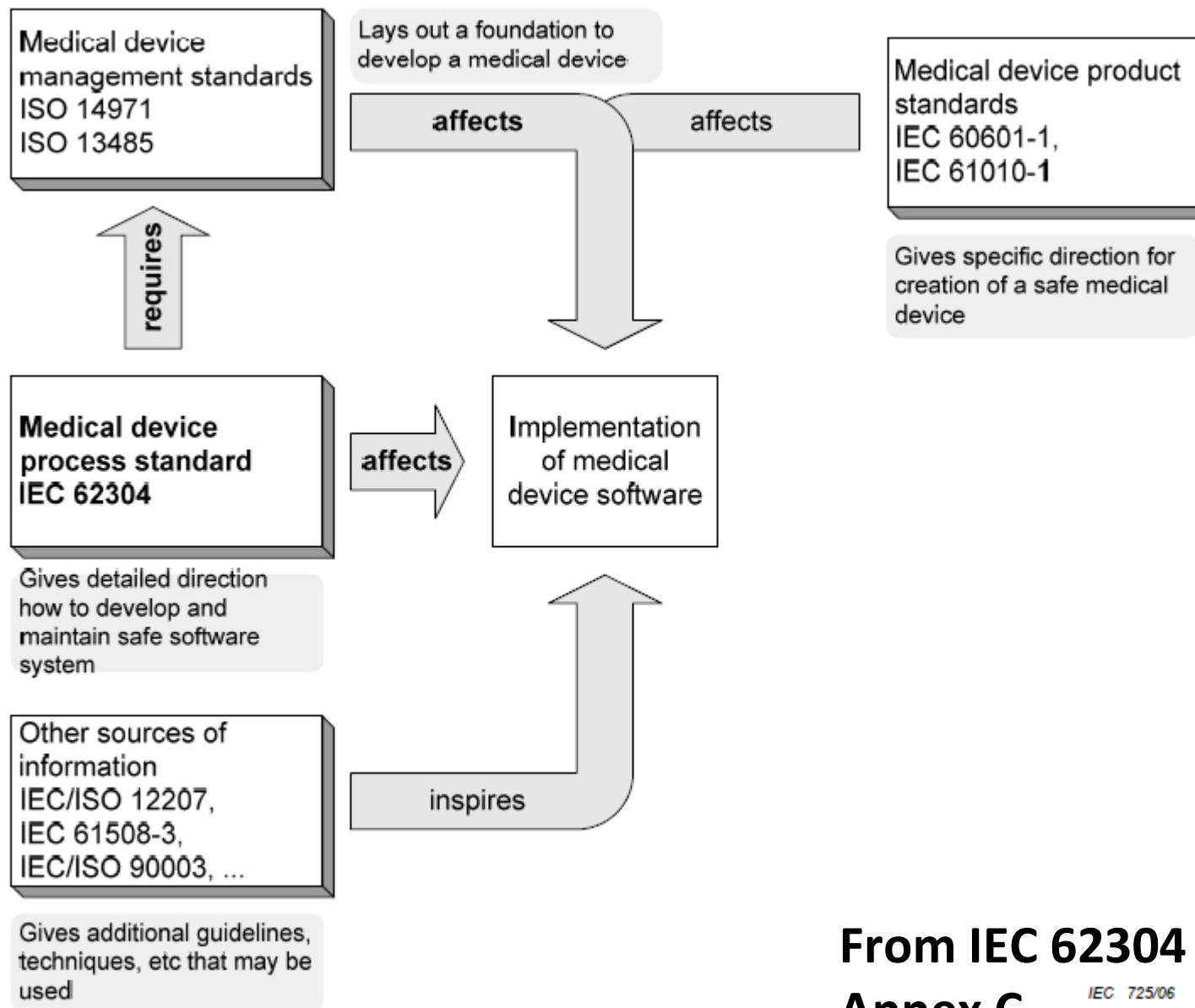
Standards & Best Practices are key to a Risk-Based Ecosystem Strategy

- ▶ Consistent practice regarding “product”
 - IEC 62304 – quality / best practices regarding healthcare-related software design, development and maintenance
 - ISO 13485 – quality management system processes regarding construction of medical devices
- ▶ Consistent practice regarding “process”
 - ISO 80001-1 – risk mitigation regarding implementation and operation of medical devices in networked environments
 - ISO 25238 – classification system for risks

Important components – developed quite independently and often in isolation of the fuller EHR context







From IEC 62304
Annex C

IEC 725/06

The EHR Ecosystem



Healthcare Policies
Healthcare System Management

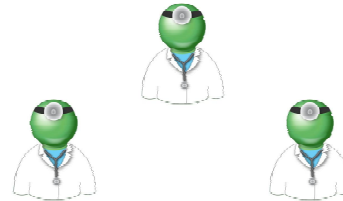
HI Professionals
Scope of Practice

Our Vendor
Community

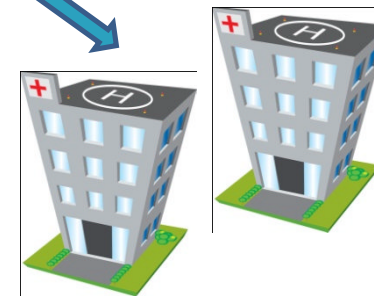
Healthcare IT
Infrastructure



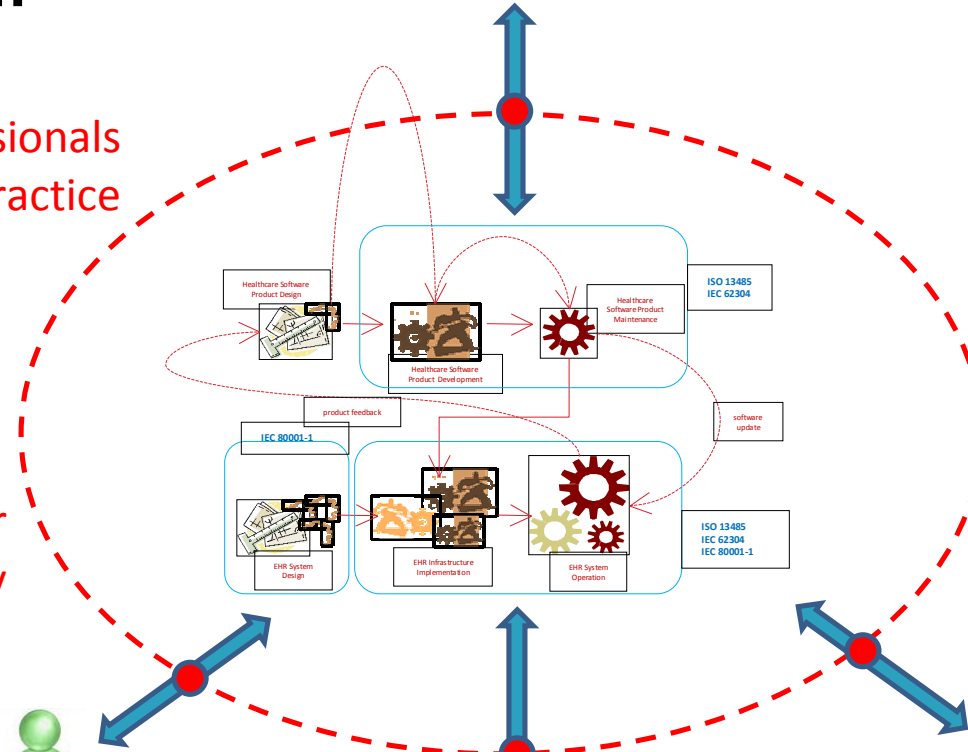
Healthcare Recipients



Healthcare Providers



Healthcare Facilities



A Canadian perspective on how TC 215 could best support countries

- ▶ We need to work towards an integrated set of standards and best practices, sooner rather than later, which:
 - Supports an international market for vendors;
 - Extends and better aligns current standards work, which has often come from the medical device field;
 - Combines the best experience of member countries
 - Begins with a tangible and immediate step, e.g. a Technical report that:
 - describes the safety challenge
 - points to current standards & best practices
 - Identifies and prioritizes the key gaps where updates and/or new standards or guidelines are required

