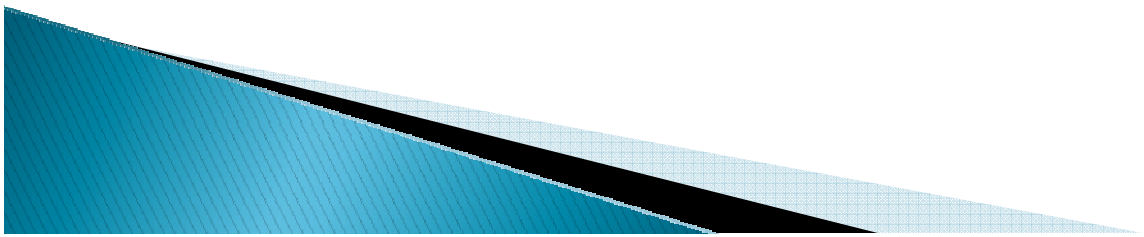
Software as a Medical Device

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

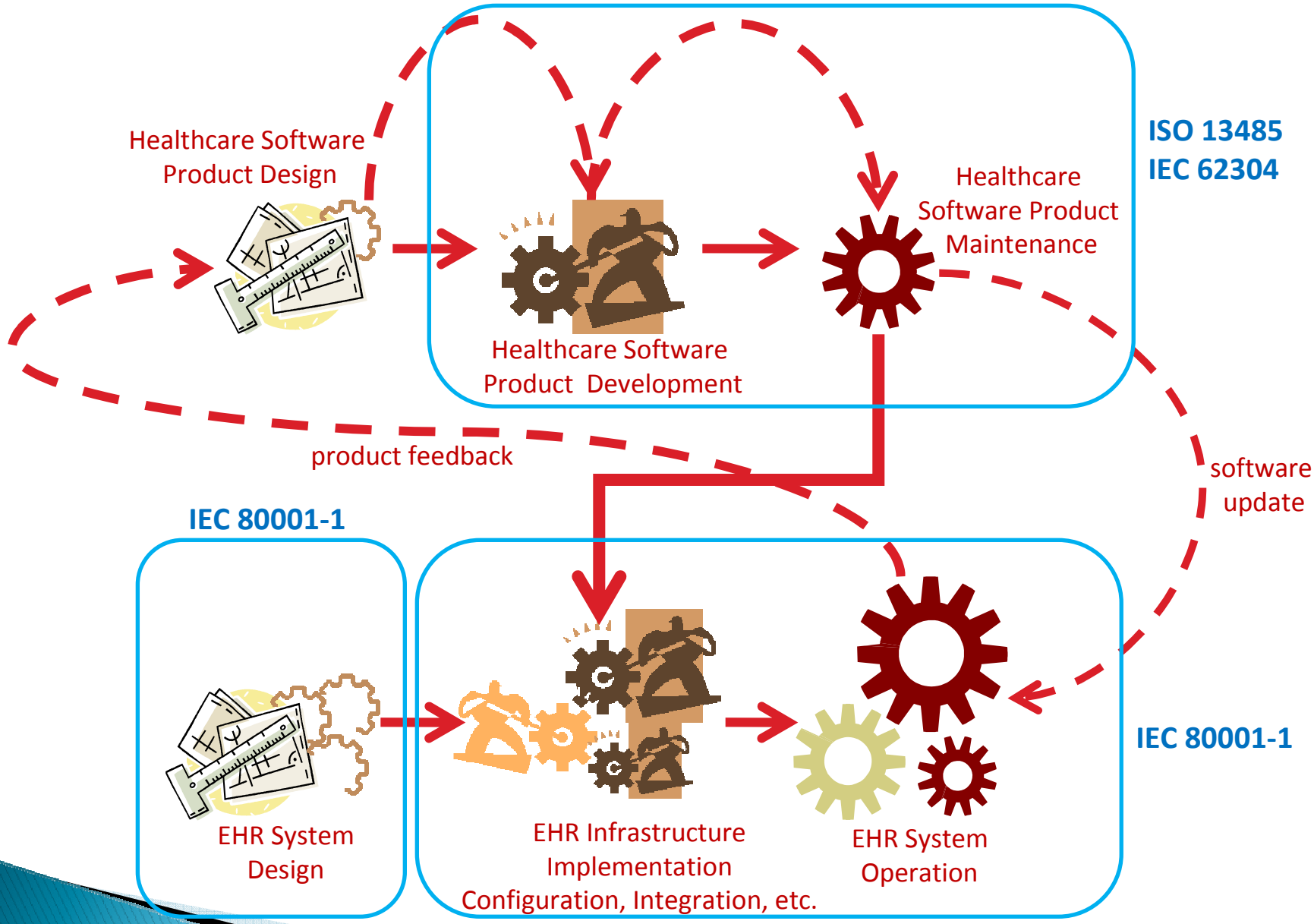
- **Scope & application** where not adjunct to a device – given the increasing complexity of our interoperable EHR environment
- **Getting out front** of international requirements – in an increasingly global marketplace
- **Need for a risk-based approach** to software safety grounded on an integrated 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

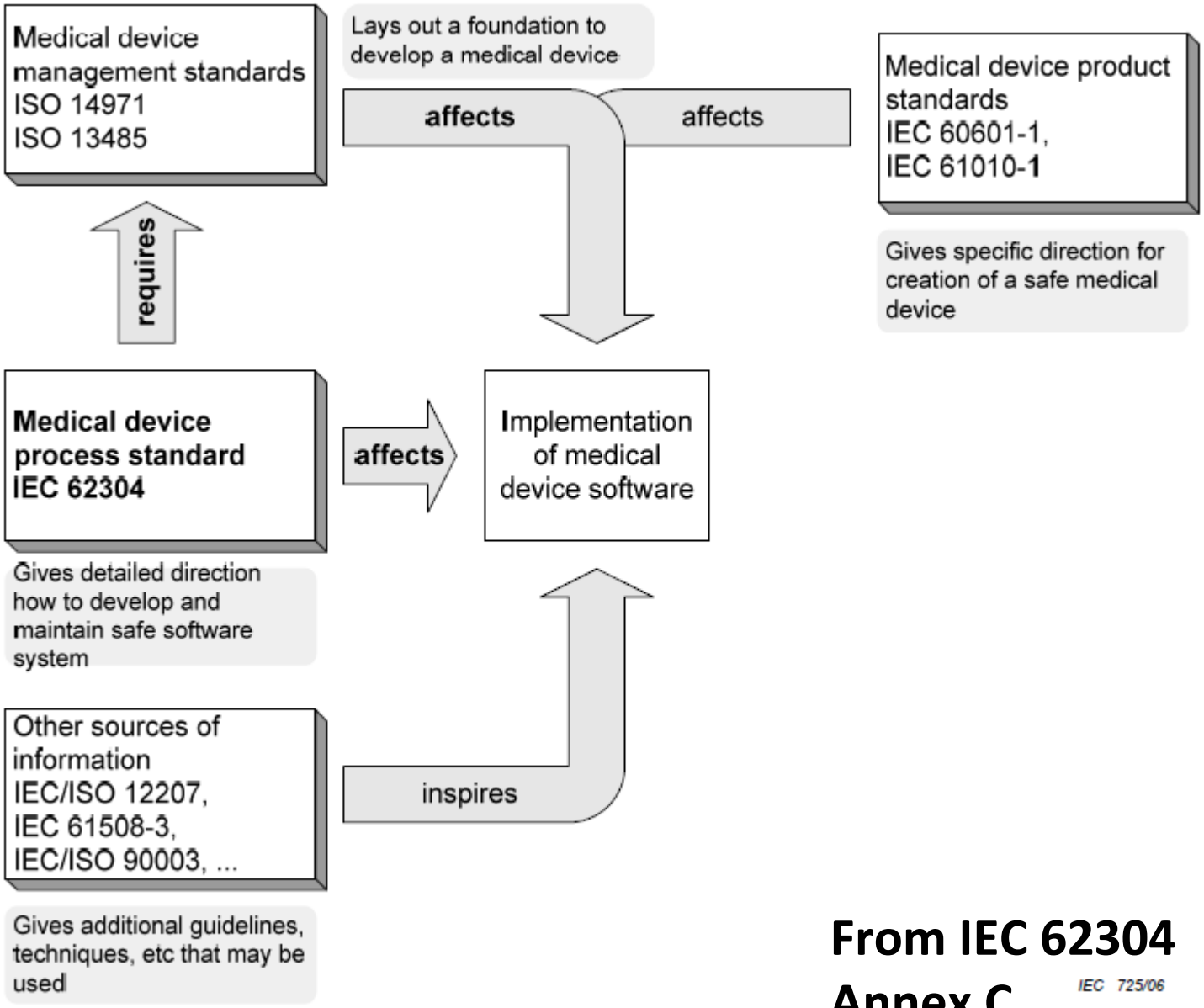
All parties are aligned on these being the key issues – ISO TC215 can play an important role here.

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


Healthcare Software
Product Design
Healthcare Software
Product Development
Healthcare
Software Product
Maintenance
ISO 13485
IEC 62304
product feedback
software
update
IEC 80001-1
EHR System
Design
EHR Infrastructure
Implementation
Configuration, Integration, etc.
EHR System
Operation
IEC 80001-1

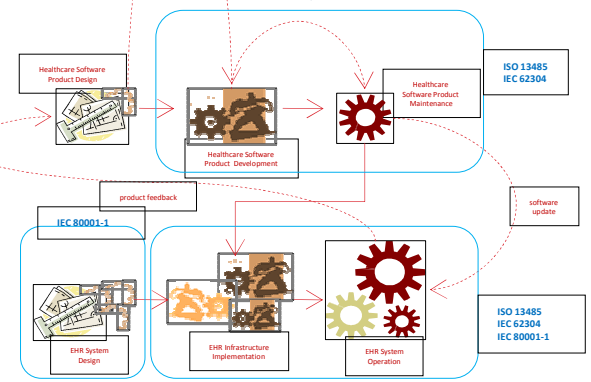


From IEC 62304 Annex C

The EHR Ecosystem

Healthcare Policies
Healthcare System Management

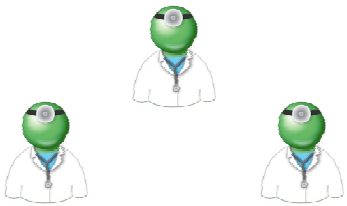
HI Professionals
Scope of Practice



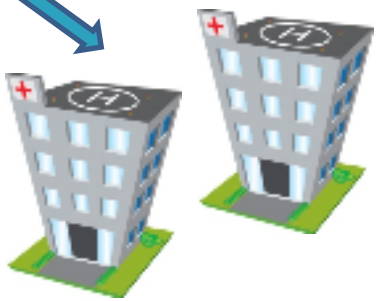
Healthcare IT
Infrastructure

Our Vendor
Community

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