Changes to EMR Specifications

The various documents that comprised EMR specification v4.2, published on April 1, 2015, served as the baseline for change. This log covers changes made to the documents that comprise the Primary Care EMR Baseline Requirements 5.0 Specification, published on August 4, 2017.

Primary Care EMR Baseline Requirements 5.0

Type of Change	Description

Major Changes	• Added 1 new requirement (OMD# 20.02) updated to include the same requirement from the hosting specification which states: "The EMR vendor MUST perform all TRAs in accordance with Industry accepted standards such as: Harmonized Threat and Risk Assessment Methodology (HTRA) published by the Communications Security Establishment Canada (CSEC)."
	• The following requirements were changed from Optional to Mandatory because they are supported by all certified vendors:
	  ○ EMR05.07
	  ○ EMR05.14
	  ○ EMR05.15
	  ○ EMR08.05
	  ○ EMR11.07
	  ○ EMR13.08
	  ○ EMR13.09
	  ○ EMR13.14
	  ○ EMR13.15
	  ○ EMR14.11
	  ○ EMR14.18
	• Added 1 new requirement (OMD# 20.01) to have a Threat and Risk Assessment (TRA) conducted on the EMR offering by an Information Security Professional with the appropriate credentials (e.g., CISSP: Certified Information Systems Security Professional).
	• Updated requirement (#OMD19.01) to state the EMR vendor MUST hold and maintain ISO 13485 certification for the EMR offering and added guidance that EMR vendors MUST check Health Canada's medical device licensing requirements to determine which version of the ISO 13485 standard is currently required. This requirement was previously specific to ISO 13485:2003. ISO 13485:2016 is now available and Health Canada is giving the industry until March 1st, 2019 to make the transition.

Minor Changes	• Changed references to Weighted (W) requirements to Optional (O)

Type of Change	Description

	• Removed the interdependencies with documents in previous specifications so that the Primary Care EMR Baseline Requirements can be packaged separately. This required:
	  ○ Removing the "Discrete Data Elements", which are now published in the EMR Core Data Set specification.
	  ○ Removing cross references between the functional requirements and the discrete data elements.
	  ○ Removed requirements EMR18.03 and 18.04, which were duplicates of EMR18.02.
	• Updates throughout for use of common terms, capitalization, grammar and spelling
	• Updated OntarioMD document template, layout, fonts, colours, etc.