1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted
FR 001			Ge	This document, meant to become an ISO International Standard, does not conform AT ALL to the ISO/IEC Directives, Part 2 "Rules for the structure and drafting of International Standards" while this is the case for another standard developed with HL7, i.e. ISO/HL7 21731. Strangely, however, in the 'How-To Guide for Creating Functional Profiles' Chapter, the last sentence of 'PART 2: Functional Profile Registration and Balloting' (Page 29) shows "Note: the ANSI and ISO processes would need to be followed in order to obtain standardization from these organizations." For instance, and among others, no normative reference is quoted in an appropriate section and there is no 'Terms and definitions' Section. Only a few ISO standards are mentioned in places in some chapters. On the contrary, many HL7 documents are quoted that are not available to the ISO standards users. Terms as, for instance, 'encounter' and 'episode (of care)', but also many others, are seemingly not defined anywhere in the document. As a consequence, beyond the practical usability of the document being highly questionable, this disregard and indifference for ISO rules suggests a distance being deliberately taken with the normal standard drafting process in ISO, as well as, and moreover, with the existing corpus of international standards. In term, going ahead with this behaviour jeopardizes the consistency of International Standards and, in turn, the standardization process itself. Since this comment does not focus on the technical		

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				content of the document, would these common sense requirements be fulfilled, France would be ready to turn its negative vote into one of approval.		
FR 002						
NO 003			ge	Norway has provided both general and detailed comments to the previous draft, but almost all comments have been rejected. Without a distributed *Disposition of comments* it is hard to evaluate the reasons for these decisions. We therefore resend the general issues (below). In order to achieve consensus we expect the comments to be dealt with in a serious way.	Reconsider the Norwegian comments to the previous draft and document the decisions in *Disposition of Comments*. In order to achieve a positive vote at the next ballot we expect changes in the document or convincing arguments for not making changes.	
NO 004			ge	This document is not according to ISO rules for standard documents. This makes the separation between normative and informative text unclear.	Reformat the document according to ISO rules. Use notes for informative comments in normative text.	
NO 005			ge	This document contains a large number of functional requirements that should be fulfilled. However, since the profiling process may modify these requirements they are no longer absolute requirements as stated.	Make the chapter concerning profiling the only part of this DIS document. Move the detailed lists of requirements to a separate ISO TS.	
NO 006			ge	The title is misleading as there is no model involved.	Propose "Electronic Health Record System – Functional Requirements" for the part containing the detailed requirements.	
DE 007	Whole		Ed	Please take the ISO/IEC Directives "Internal regulations – part 3: rules for the structure and Drafting of International Standards (PNE-Rules)" into account (only **one document**, structured as described in the rules)		
UK 008	Chapter 3, Section 3,	Id# DC.1.1.1 Identify and maintain a patient record Conformance Criteria 10	GE	The documents describe a (not the) functional model for the development of an EHR. The case is not proven that this is the sole and best way of implementing an EHR, and we recommend that it be published as a technical specification rather than a standard. In general it has the following weaknesses as a functional model: · Individual requirements are in many cases too vague to		

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				measure implementation – e.g. "The system SHOULD provide the ability to obsolete, inactivate, nullify, destroy and archive a patient's record in accordance with local policies and procedures, as well as applicable laws and regulations." In order to be measurable the requirement needs to specify the laws and regulations.		
UK 009	Chapter 3, Section 3,	ID#DC.1.1.2 Manage Patient demographics and generally	GE	Requirements sections are incomplete– e.g. the demographics aspects do not acknowledge the requirements for gender reassignment, adoptions, deaths. These are important events that are common across the world (especially death), and failure to address them in an EHR system would introduce clinical risk. We therefore propose that an additional statement be included in the document to clarify that it may be used as the basis for defining an EHR system Function Model, but that it should not be used as a complete specification without additional requirements being elaborated.	We therefore propose that an additional statement be included in the document to clarify that it may be used as the basis for defining an EHR system Function Model, but that it should not be used as a complete specification without additional requirements being elaborated.	
UK 010	Chapter 3, Section 3,	ID#DC.1.1.1 Identify and maintain a patient record Conformance criteria 7	GE	Experience has shown that some requirements are not implementable in a large number of cases – e.g. "IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to mark the information as erroneous in the record of the patient in which it was mistakenly associated and represent that information as erroneous in all outputs containing that information." This has been shown to be incredibly difficult where two medical records have become incorrectly merged.		