

# Report of voting

## Ballot Information

<b>Ballot reference</b>	ISO/NP TS 19669-N1369 ISO/TR NP Reusable component strategy use case dev
<b>Ballot type</b>	NP
<b>Ballot title</b>	ISO/NP TR Reusable component strategy for use case development
<b>Opening date</b>	2013-12-24
<b>Closing date</b>	2014-03-24
<b>Vienna agreement</b>	ISO lead

## Member responses - Votes by members

Country (Member body)	Status*	1a. Agree to add to work programme							Market relevance	1b.Stakeholders consultation		2. Relevant documents		3. Comments		4. Participation	
		Yes				No		Abs		Yes	No	Yes	No	Yes	No		
		20.00	20.20	30.00	40.00	PWI: Yes	PWI: No										
Armenia (SARM)	P							X		X		X		X		X	
Australia (SA)	P					X			X	X		X		X		X	
Austria (ASI)	P							X		X		X		X		X	
Belgium (NBN)	P							X		X		X		X		X	
Brazil (ABNT)	P	X							X		X		X		X		
Canada (SCC)	P							X			X		X		X		
Czech Republic (UNMZ)	P							X			X		X		X		
Denmark (DS)	P	X							X	X		X		X		X	
Ecuador (INEN)	O	X							X	X		X		X		X	
Finland (SFS)	P							X		X		X		X		X	
Germany (DIN)	P						X		X	X		X	X			X	
India (BIS)	P							X		X		X		X		X	
Iran, Islamic Republic of (ISIRI)	P							X		X		X		X		X	
Ireland (NSAI)	P							X			X		X		X		
Italy (UNI)	P							X								X	
Japan (JISC)	P	X							X		X		X		X		
Korea, Republic of (KATS)	P	X							X		X		X		X		
Sub-Total Question 1a		5	0	0	0	1	1	10									
<b>Totals</b>		<b>5</b>				<b>2</b>		<b>10</b>	<b>7</b>	<b>9</b>	<b>7</b>	<b>1</b>	<b>15</b>	<b>3</b>	<b>13</b>	<b>3</b>	<b>14</b>

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Country (Member body)	Status*	1a. Agree to add to work programme							Market relevance	1b.Stakeholders consultation		2. Relevant documents		3. Comments		4. Participation	
		Yes				No		Abs		Yes	No	Yes	No	Yes	No	Yes	No
		20.00	20.20	30.00	40.00	PWI: Yes	PWI: No										
Malaysia (DSM)	P							X		X	X		X		X		
Mexico (DGN)	P							X		X	X		X		X		
Netherlands (NEN)	P		X						X		X		X		X		
Norway (SN)	P	X							X	X		X		X	X		
Peru (INDECOPI)	P							X		X	X		X		X		
Russian Federation (GOST R)	P							X		X	X		X		X		
South Africa (SABS)	P							X		X	X		X		X		
Spain (AENOR)	P							X		X	X		X		X		
Sweden (SIS)	P	X							X	X		X	X		X		
Switzerland (SNV)	P							X		X	X		X		X		
Tunisia (INNORPI)	P							X		X	X		X		X		
Turkey (TSE)	P							X		X	X		X		X		
United Kingdom (BSI)	P		X						X	X		X	X		X		
United States (ANSI)	S	X							X	X		X		X	X		
Sub-Total Question 1a		8	2	0	0	1	1	19									
<b>Totals</b>		<b>10</b>				<b>2</b>		<b>19</b>	<b>12</b>	<b>18</b>	<b>12</b>	<b>1</b>	<b>29</b>	<b>5</b>	<b>25</b>	<b>5</b>	<b>26</b>

Member responses - Votes not cast (4)																
China (SAC)																
Kenya (KEBS)																
Luxembourg (ILNAS)																
Philippines (BPS)																

Comments from voters																
Member	Comment														Date	
<b>Australia (SA)</b> <b>Manevska, Natasha Ms</b>	<p><b>See linked comment file:</b> <i>N1369 ISO TR NP Reusable component strategy use case dev SA.doc</i> (access restricted to ballot audience)</p> <p><b>Comment to Q.1:</b> Australia considers that the proposed topic of "reusable component strategies for use-case development" may deserve exploration by means of a TR but the state of the art is still in its infancy, there is negligible industry and international engagement and it is considered premature for a standards document to be solely focussed on "offering a methodology" based on the US model as implemented and/or proposed. There is little benefit for this current NWIP to proceed as an international work item, unless there is true international interest and broad stakeholder support among those who might be expected to use the final products that it may propose Attempting to assess the market relevance of such innovative work on the basis of an outline alone is also problematic.</p> <p><b>Comment to Q7:</b> Australia names Mr. Richard Dixon Hughes - <a href="mailto:richard@dh4.com.au">richard@dh4.com.au</a></p>														2014-03-21	

Comments from voters		
Member	Comment	Date
Australia (SA) Manevska, Natasha Ms	<p><b>Comment to Q.5:</b> Standards Australia eHealth Interoperability Framework and processes and procedures developed by the National E-Health Transition Authority (NEHTA) and used for requirements engineering on the Australian eHealth program.</p> <p><b>Comment to Q7:</b> Australia SME: Richard Dixon Hughes - <a href="mailto:richard@dh4.com.au">richard@dh4.com.au</a>).</p>	2014-03-21
Brazil (ABNT) Rangel, Rose Mrs	<p><b>Comment to Q.1:</b> We believe it would be desirable to have an ISO TC 215 document proposing a methodology specifically driven for HC purposes to describe use cases, that allows for re-use and establish the links to the functions and conformance criteria of ISO/HL7 EHR/PHR FM.</p> <p><b>Comment to Q.6:</b> Brazil has a software certification process for electronic health record systems that already references the HL7 EHR/PHR functional model. It would be interesting to also have the use cases conformance criteria. This would facilitate the certification process and software evaluation.</p> <p><b>Comment to Q.7:</b> Marcelo Rodrigues dos Santos ( <a href="mailto:marsantos@terra.com.br">marsantos@terra.com.br</a>)</p>	2014-03-24
Denmark (DS) Meltofte, Gitte Ms	<p><b>Comment to Q.1:</b> The proposed standard will be for the benefit for those who are concerned</p>	2014-02-17
Ecuador (INEN) Chicaiza, Erika Eng.	<p><b>Comment to Q.1:</b> This standars provides the metodology for identify cataloguing and re-use core components in development of subsequence</p>	2014-03-24
Germany (DIN) Moser, Heike Dipl.-Ing.	<p><b>See linked comment file:</b> <i>N1369 ISO TR NP Reusable component strategy use case dev DIN.doc</i> (access restricted to ballot audience)</p> <p><b>Comment to Q.1:</b> The scope and purpose of the proposed standard is not in the scope of ISO/TC 215. This might be discussed in JTC 1.</p>	2014-03-20
Japan (JISC) Masuda, Chihiro Ms.	<p><b>Comment to Q.1:</b> We consider this proposal important, and for the work item to be successfully carried out, usability from a global perspective should be taken into account.</p> <p><b>Comment to Q.7:</b> Hideshige Hasegawa - <a href="mailto:hide.hasegawa@mx8.ttcn.ne.jp">hide.hasegawa@mx8.ttcn.ne.jp</a></p>	2014-03-20
Korea, Republic of (KATS) Park, In-Soo	<p><b>Comment to Q.1:</b> This document can contribute to popularize and organize of requirement for common style of use and reuse.</p>	2014-03-19
Netherlands (NEN) Hendriks, Petra	<p><b>Comment to Q.1:</b> Guidance on use of use-cases is relevant for the Netherlands.</p>	2014-03-14
Norway (SN) Lindelien, Knut Mr.	<p><b>Comment to Q.1:</b> Seems usefull</p>	2014-03-17
Sweden (SIS) Acaralp, Jenny Mrs.	<p><b>See linked comment file:</b> <i>N1369 ISO TR NP Reusable component strategy use case dev SIS.doc</i> (access restricted to ballot audience)</p> <p><b>Comment to Q.1:</b> The market relevance are well stated in the scope of the proposal</p> <p><b>Comment to Q.7:</b> Per-Arne Lundgren <a href="mailto:perarne.lundgren@skane.se">perarne.lundgren@skane.se</a> +46-76-887 14 78</p>	2014-03-24

Comments from voters		
Member	Comment	Date
<b>United Kingdom (BSI)</b> <b>Committee Service Centre, CSC Mr</b>	<p><b>Comment to Q.1:</b>  We welcome that fact that this is being brought forwards as a Technical Report, and that in doing so will promote open international consensus building in the interplay between use case modelling and the HL7/ISO functional models.</p> <p><b>Comment to Q.6:</b>  The Technical Report should address ease of use issues, and the characteristics of projects that would benefit from using the strategy. For example, the proposed source documents presume a wider specification development methodology, and the Technical Report should clearly define any such assumptions.</p>	2014-03-11
<b>United States (ANSI)</b> <b>Team, ANSI ISO</b>	<p><b>Comment to Q.1:</b>  The US TAG is really excited about this item - it is a great idea and much needed. Essentially, this item will describe a methodology to identify, catalogue and create a common repository of re-usable building blocks/core components fo the development of standardized use cases. Something like this has been needed for a long time not only in the US but worldwide as well.</p> <p><b>Comment to Q.7:</b>  Mr. Gary Dickenson - gary.dickinson@ehr-standards.com - Industry and Commerce</p>	2014-03-24

Comments from commenters		
Member	Comment	Date
<b>France (AFNOR)</b> <b>Marcet, Sylvia Mme</b>	<p><b>See linked comment file:</b> <i>N1369 ISO_TR NP Reusable component strategy use case dev_AFNOR.doc</i>  (access restricted to ballot audience)</p>	2014-01-09
<b>1. Australia</b>	Mr. Richard Dixon Hughes - <a href="mailto:richard@dh4.com.au">richard@dh4.com.au</a>	
<b>2. Brazil</b>	Marcelo Rodrigues dos Santos ( <a href="mailto:marrsantos@terra.com.br">marrsantos@terra.com.br</a> )	
<b>3. Japan</b>	Hideshige Hasegawa - <a href="mailto:hide.hasegawa@mx8.ttcn.ne.jp">hide.hasegawa@mx8.ttcn.ne.jp</a>	
<b>4. Sweden</b>	Per-Arne Lundgren <a href="mailto:perarne.lundgren@skane.se">perarne.lundgren@skane.se</a>	
<b>5. US</b>	Mr. Gary Dickenson - gary.dickinson@ehr-standards.com	

# Template for comments and secretariat observations

Date:2014-04-03

Document: N1417

Project: ISO/NP  
19669\_Reusable use case

MB/ NC <sup>1</sup>	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment <sup>2</sup>	Comments	Proposed change	Observations of the secretariat
AU 001							
DE 002				ge	The scope and purpose of the proposed standard is not in the scope of ISO/TC 215. This might be discussed in JTC 1.		
Fr 003					ABSTENTION DUE TO A LACK OF EXPERT		
AU 004		All		ge	Australia considers a document that objectively explores the feasibility of globally relevant approaches and distils the core elements of the topic would align better with the role of a TR as specified in the ISO Directives, which is to allow a TC to publish <i>"data of a different kind from that which is normally published as an International Standard (this may include, for example, data obtained from a survey carried out among the national bodies, data on work in other international organizations or data on the "state of the art" in relation to standards of national bodies on a particular subject),"</i>	Revise the approach and the proposed scope of the work to align more closely with the nature of an ISO/TR as set out in the ISO Directives, to include evaluating and discussing the feasibility, applicability and needs for such an approach internationally.	
AU 005		All		ge	Australia considers that the proposed topic of "reusable component strategies for use-case development" may deserve exploration by means of a TR but the state of the art is still in its infancy, there is negligible industry and international engagement and it is considered premature for a standards document to be solely focussed on "offering a methodology" based on the US model as implemented and/or proposed.  There is little benefit for this current NWIP to proceed as an international work item, unless	Progress the work to a full draft as a PWI or as a white paper outside the standards process until there is a significant and diverse community of stakeholders who agree on the core elements to be standardized and are ready to seek international endorsement of the recommended approaches.  Within such a context, detailed exposition of current and proposed US approaches as a model for analysis and discussion is considered	

<sup>1</sup> MB = Member body / NC = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by \*\*)

<sup>2</sup> Type of comment: ge = general te = technical ed = editorial

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					there is true international interest and broad stakeholder support among those who might be expected to use the final products that it may propose	appropriate, with a view to the proposed document identifying specific core principles and components that might reasonably be addressed by further international standards work with broad public benefit and international stakeholder support.	
AU 006		All		ge	Australia considers that the scope and outline as they presently stand provide insufficient information in an area of such significant innovation and change with limited established practice. For a peak standards body such as TC215, approval of NWIPs based on outlines should be the exception and should be limited to straight forward proposals in established fields of standardization.	If continuing to seek approval and progression to publication as an ISO document (rather than as, say, a white paper) consider seeking TC 215 approval to progress to a completed draft as a Preliminary Work Item (PWI) under a revised scope meeting the above requirements. The full draft can then be submitted for NWIP approval.	
SE 007		Purpose		te		Clarify meaning of "Standing methodology"	
AU 008		Purpose & justification	p.1	te	The purpose statements appears to endorse US ONC S&I approach to Use Case development without any justification If this is the case, then what is the purpose of setting up a project? Why not simply make a statement that the ONC S&I approach is to be adopted and dispense with the need for a project?	If this proposed project is about evaluating the validity and usefulness of the ONC S&I approach to Use Case development, then the project title, scope and method statement should be rewritten to reflect that  If this proposed is about evaluating other existing approaches/methodologies, then the purpose, scope, etc subsections must be rewritten accordingly	
AU 009		Purpose & justification	p.1	te	This section asserts that use cases are designed to include components that:		

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					<ul style="list-style-type: none"> <li>• offer a ready capability to specify once, re-use multiple times;</li> <li>• can be linked to implementable data and software constructs;</li> <li>• can be linked to standard implementation guides;</li> <li>• can be linked to standard test methods for conformance testing.</li> </ul> <p>Yet, the “technical report outline” section (p.4) makes no mention of what methods may be considered to ensure that these purposes are achieved</p>		
SE 010		Scope		te		Clarify the meaning of <i>implementation</i> in the planned methodology (“ a methodology for use case development and implementation”)	
AU 011		Title Scope statement Purpose & justification Technical report outline	p.1 p.1 p.2 p.4	te	<p>The title and various section of the proposal document use the two concepts: “strategy” and “methodology” somewhat interchangeably and apparently without giving the two concept any clear consideration of their differences.</p> <p>It also appears to confuse “method” and “methodology”</p>	<p>“Strategy” is a high level plan [of actions] to achieve one or more goals under the constraints or operating environment of the business</p> <p>“Methodology” is a system of principles, rules from which specific methods or procedures are derived to solve problems within the scope of the discipline or business. A methodology is not a set of formulae, but a set of practices</p> <p>“Method” is a particular procedure for accomplishing goals or for solving target problems</p> <p>The proposal uses “methodology” in way that is likely to mean “method”, e.g.:</p> <p>Methodology with spreadsheet</p> <p>Methodology with use case authoring tool</p>	

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						<p>Recommendation: Determine what the proposed project is about, i.e. whether it is about developing a set of strategies, some methodology or a set of methods to guide the development of use cases. Once the author is clear what is the goal/objective of the proposal, use the appropriate term and use it consistently.</p>	
SE 012		Whole document		te		<p>The methodology should incorporate a possibility <i>to include the use of a general business process model with defined concepts as the basis for the development process. This for those situations where there is a need to be able to achieve a comprehensive development of clinical interoperability and avoid the pitfall of creating a lot of use cases that are more or less like silos.</i></p>	
SE 013		Whole document		ge		<p>The intent of a use case methodology is often to capture the requirements of a specific business together with the core stakeholders. The “new” methodology based on the use/reuse of standardised components must also be based on the understanding of the need for uniqueness in the process of creating and documenting a common understanding of problems and possibilities.</p>	

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