e-post: christina.stange@sis.se

SIS
Remissvar
Christina Stange
118 80 STOCKHOLM

SIS/TK 457, Ledningssystem för kvalitet i hälso- och sjukvården

Svar på SIS-remiss 8619

avseende prEN 15224

Senaste svarsdatum **2011-05-13**

Uppgifter om svarslämnaren

☒ Företag/Organisation/Myndighet ☐ Enskild person

Företag/Organisation/Myndighet: Svenska Läkaresällskapet (SLS)

Handläggare (namn, telefon): Anna Borgström, 08-440 88 92

Datum: 2011-05-11

Remissvar

☐ Avstår

☐ Tillstyrker utan kommentarer

☒ Tillstyrker med kommentarer

☐ Avstyrker med motivering

☒ Har erfarenhet inom det område förslaget täcker

☐ Har tillämpat förslaget

☐ Ej berörd

☐ Kommentarer till föreslagen svensk titel

Se även separat remissvar på svenska

Datum

Svarslämnare: Svenska Läkaresällskapet (SLS) 2011-05-11

Kommentarer på: SIS-remiss 8619 **Förslag: prEN 15224**

1	2	(3)	4	5	(6)	(7)
ID	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/Table/Note** (e.g. Table 1)	**Type of comment**	**Comment (justfication for changes)**	**Proposed change**	**Fylls i av SIS**
SE	general		ge	This as an important update of CEN/TS 15224:2005. But the Enquiry draft need clarifications and changes in accordance to our suggestions before the final version can be approved.		
SE	general		ge	We are somewhat concerned that this prEN 15224 is intended as a stand-alone standard for certification and not as the previous CEN/TS as a guide for health care services to the use of the well known intersector ISO 9001. ISO 9001 and certification against this has already taken place in some Swedish health care organizations. The general scope of ISO 9001 is that it is applicable in all sectors and we do not see anything in the present draft EN 15224 that deviates from ISO 9001. There are also many other sector specific guides to ISO 9001.	Therefore it is our recommendation to keep it formally as a guide to the use of ISO 9001 but we welcome that it contains all the requirements needed.	
SE	Introduction		ed	The introduction clause which according to ISO rules is non-normative is too extensive as it is now and repeats certain normative requirements that comes later in the document. This is particularly important for the 11 quality criteria	Move most of clauses 0.1.1-0.2.1.3 to clause 4.	

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				which are introduced for the first time in this document shall not be mentioned in the introduction. The different types of processes in health care are also not appropriate to mention in the Introduction. Both of these sets should also be discussed and we propose, changed.		
SE	0.1.1		ed	The draft says World Health Organisation	The name of WHO also in the European office is Organization with a “z”. Note several occurrences of this in the document npot pointed out again.	
SE	0.1.2		ed	“in WHO and ICF” change to	“of ICF by WHO”	
SE	0.1.2		ed	“tertiary care (e.g. nursing homes). In all WHO publications checked, tertiary care does not include a nursing home. One definition from WHO: tertiary care refers to medical and related services of high complexity (e.g. regional or central hospitals).	Change to “tertiary care (e.g. regional university hospital)	
SE	0.2.1		te	The introduction of the graphics of health care processes in Figure 1 is good, but we would like to see it in the normative part of the document. However, the definitions of “health care process” and “clinical process”, also repeated later in clause 3. are ambiguous. In the definition on page 10 and in 3.5.1 states a clinical process is-a health care process. But then wording so frequent in this standard “health care processes and clinical processes” is totally inappropriate and therefore wrong.	Change definitions. It is not obvious that both terms are required. Our prime suggestions is to just use “clinical process” as a core process of health care services. Figure 2 contains a concept diagram. We suggest it should use proper Unified Modeling Language and use specialisation open arrow heads towards the core processes. See ISO/TR 24156:2008 Guidelines for using UML notation in terminology work	
SE	0.2.2		te	Figure 3 which is adapted from a similar one in ISO 9001 is not an improvement and has several problems. The flanking boxes are labelled interested parties while in ISO 9001 and more	Suggest to use the original figure with a comment that the main customer in health is the patient and that the main product is called health care service.	

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				appropriately the boxes are labelled customer		
SE	0.3		te	When mentioning other relevant management standards it would be appropriate to mention the health specific security management standard:	The correct title of 27001 is: ISO/IEC 27001:2005 Information technology -- Security techniques -- Information security management systems -- Requirements We prefer that the following standard is mentioned: ISO/EN 27799:2008 Health informatics -- Information security management in health using ISO/IEC 27002	
SE	0.3		te	There is no mentioning of the CEN/TR 15592:2009 document entitled: Health services- Quality management systems – Guide for the use of EN ISO 9004:2000 in health services for performance improvement. This is odd and this extensive document should be mentioned. Since it was aligned with the previous CEN/TS 15224, this is another factor to consider when deciding how great changes should be made in the new prEN 15224. Noting that the base standard ISO 9004 has been substantially updated in 2009, we consider this an important additional guide for health care services.		
SE	1.1		ed	The wrong template seems to be used. The second level clauses such as 1.1 should be left justified as all other headings in EN/ISO standards	Please use the correct template for drafting.	
SE	3.1		te	The definition of clinical is stated as ”any occurrence related to the interaction between patients and health care personnel”. The starting point here “occurrence” is not adequate. Other	Change to “pertaining to the interaction between patients and health care personnel for the promotion of good health or managing health issues”	

Kommentarer på: SIS-remiss 8619 **Förslag: prEN 15224**

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				definitions of clinical use “pertaining or relating to”		
SE	3.2		ed	The term is here called customer in health care. This term is however, not used in the standard which instead uses just customer. The authors want to point out in this definition and other related terms with the added suffix “in health care” is that the standard (definition) applies in health care. This should be written differently. In line with the general aim not to deviate from ISO 9001, we suggest to keep the general definition of customer with the informative notes as in CEN/TS 15224:2005 The proposed phrase “person or organisation that receives a health care service and/or product” is anyway not acceptable since it is contradictory to the ISO 9000 notion that services are products..	Change to : customer (in health care) Keep ISO 9001 definition with Notes related to health.	
SE	3.2.1		ed	Clause numbering not in line with ISO requirements		
SE	3.3		ed	Customer satisfaction in health care	Change to: “customer satisfaction (in health care)”	
SE	3.4.2		ed	The term health care personnel is used here while other ISO and CEN committees use the term “health professional” which is here said in an a note to be a synonym. We prefer the term health professional to be consistent even if it is not used in Swedish. An accepted synonym shall in according to the ISO directives in a standard be written below the term but without the bold face, not indicated in a note	Change to health professional with health care personnel as a synonym and change the whole document consequently. Or, alternatively write the synonym health professional according to the rules of ISO directives part 2.	
SE	3.9		te	The term in CEN/TS 15224 as in ISO 9000 was product. Here the draft proposes the term “product of health care”. However, there is not a single occurrence of this term in the standard other than in 3.9 which is a clear violation of ISO rules for standards and indicates there is a problem.	Change to: “product”. The possible expression “(in health care)” would only be necessary if the definition is changed as proposed but the generic one “result of a process” is quite OK as was used in the CEN/TS 15224. Keep the text från CEN/TS 15224 but add Note	

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				This is a central term in ISO quality management and should not be changed. In the CEN/TS 15224, the following note (but without the heading Note) was added: "The health services sector carries out a wide variety of processes, see 3.8. The results of these processes could in general be called health services. The result of processes that include patients/subjects of care could be called health care services, as in Contsys"	and change Contsys to EN 13940-1.	
SE	3.10		te	The term "quality in health care" is defined but not used other than in the informative annex.	Please use only the generic term and its definition. A note could be appropriate to point at the health specific quality characteristics defined.	
SE	3.11		te	The following text appears in the draft: "quality characteristics in health care quality characteristics of health care: distinguishing features, which consider several aspects as, a) appropriate, correct care; b) availability; c) continuity of care; d) effectiveness e) efficiency; f) equity; g) evidence/knowledge based care; h) patient centred care including physical and psychological integrity; i) patient involvement; j) patient safety; k) timeliness/accessibility" This is an important concept of this standard where eleven "aspects" are introduced. We welcome to	We propose to have the term in 3.11 as "quality characteristic (in health care)" The definition could become: "one of the following inherent characteristics of a health care product related to a requirement: a) evidence/knowledge based b) effective c) efficient d) co-operative for continuity e) safe f) timely g) accessible h) patient centred i) equitable Proposed explanations: evidence/knowledge based means that appropriate activities for the patient's needs are performed which are based as much as	

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				have a normative structure for such different aspects of quality characteristic in health. However, the term with or without plural ”s” does only exist in the informative annex A 3.3 which is the only place where the different aspects are explained. The definition given in 3.11 starts by repeating the term itself and then the phrase ”distinguishing features, which considers several aspects as”. This is not a good definition. It should be based on the ISO 9000 definition as in the CEN/TS 15224: ”inherent characteristic of a product, process or system related to a requirement” The set of aspects in CEN/TS 15224 was: - appropriateness; - safety; - effectiveness and efficiency; - caring, respect and privacy; - continuity of care; - patient and customer perceptions; - availability and accessibility We think that the eleven proposed now are too many and partly overlapping but the previous set also had problems. An important issue is to define each and every one of these aspects somewhere in the normative document. It could be done in the clause 3 with one entry from each aspect but it could also be	possible on established scientific evidence or other form of knowledge of the organisation or the health professional. This includes tacit knowledge. effective means that the activities performed produce the expected outcome efficient means that the expected outcome is achieved using a minimum of resources in material and personnel co-operative for continuity means that one health care unit/provider shall be effective in communicating with the patient and other units caring for the same patient to ensure a smooth total and continuous chain of activities safe means that the activities performed do not cause undue or unexpected harm to the patient Note: An operation to remove a cancer will always cause pain and perhaps permanent loss of function but in relation to the need may be considered the safe option. timely means that the patient is able to	

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				done in clause 4.1. The term quality characteristic is then repeated many times in the normative part. The explanation/definition of these aspects appear only in the annex A3.3 as: a) appropriate, correct care; - the patient is examined and treated according to the needs as judged by health care professionals of his/her health condition with no/minimal complications or side-effects b) availability - health care services are within reach and possible for the patient to receive c) continuity of care - there is a seamless chain of health care services for the patient from referral to care, treatment, rehabilitation and follow-up d) effectiveness - health care activities give an expected positive outcome to the patient in a relatively short time e) efficiency - the expected outcome to the patient is achieved by using a minimum of resources f) equity; - patients with the same kind of needs are provided the same type of care g) evidence/knowledge based	receive health care services without unreasonable waiting time Note: What is a reasonable waiting time can be debated. This characteristic has both a customer satisfaction aspect and a potential medical risk associated. Also, costs caused for the patient or society because of lack of ability to work during the waiting time for a health care service may be taken into account. accessible means that health care facilities and services are available to everybody irrespective of cultural, ethnic and linguistic background and possible functional impairments patient centred means that services are given with respect for the patient's perspective, always informing and whenever possible including the patient in decisions. It also means to include the patient as an active possible participant in the caring for his/her health. This aspect also includes respect for privacy equitable means that all patients in a country with the same needs are given the same	

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				- examinations and treatments in health care are based on scientifically proved facts and/or experience based knowledge/best practice h) patient centred care including physical and psychological integrity - health care activities are concentrated on the patient's perspective and always performed with the patient's agreement including physical and psychological integrity i) patient involvement - the patient is informed, consulted and whenever possible actively participating in all operations planned and performed on him/her j) patient safety - the risks included in health care operations are recognised and managed, all avoidable harm to the patient is prevented k) timeliness/accessibility - the patient is able to receive health care services without unreasonable waiting	chances of optimal care	

Svenska Läkaresällskapet

2011-05-11

SIS, Swedish Standards Institute
118 80 Stockholm

Remiss Ledningssystem för kvalitet i hälso- och sjukvården, SIS-remiss 8619

Svenska Läkaresällskapet (SLS) är en politiskt och fackligt obunden organisation, som arbetar för förbättrad hälsa och sjukvård med patientens bästa för ögonen.
Efter synpunkter från Svensk Förening för Medicinsk Informatik lämnar SLS följajnde yttrande.

Inledning
Denna standard om Ledningssystem för kvalitet i hälso- och sjukvården som nu är i remiss är den naturliga utvecklingen av att förstandarden CEN/TS 15244 blir en riktig standard och att den kompletteras. I det separata dokumentet på engelska finns kommentarer som Svenska Läkaresällskapet (SLS) anser skall skicka till CEN som remissvar.

Det är bra att få allt som rör vården samlas i en ledningsstandard, men det är olyckligt att avvika från ISO 9001 (och ISO 9000) som båda är mycket kända och även använda i vården också i Sverige. SLS tycker att man bör följa ISO 9001 (och ISO 9000) och gärna inkludera relevanta delar direkt i den nya standarden (EN 15224) men med förtydliganden för hälso- och sjukvård så att man kan läsa standarderna parallellt. Det är också väsentligt att standarden (EN 15224) kompletteras med en vägledning på svenska som relaterar till aktuella föreskrifter från Socialstyrelsen, som just nu är under förändring. Likaså är det avgörande för spridning och användning av standarden att den översätts till svenska. Svenska Läkaresällskapet deltar gärna i översättningsarbetet om det blir aktuellt.

I denna remissutgåva finns termer och definitioner som inte verkar vara helt övertänkta, se detaljerade kommentarer i mallen. En stringent terminologi är något av det viktigaste en sjukvårdsanpassad standard kan tillföra, varför termer och begrepp måste vara väl definierade. I detta avseende rekommenderas ett nära samarbetet med Socialstyrelsen.

ADRESS Svenska Läkaresällskapet, Box 738, 101 35 Stockholm BESÖKSADRESS Klara Östra Kyrkogata 10
VXL 08-440 88 60 FAX 08-440 88 99 INTERNET www.sls.se

God Vård
En intressant och svår fråga som bör diskuteras brett är vilka kvalitetskriterier man ska ha för vården. Socialstyrelsen har i God Vård som vägledning till SOSFS 2005:12 skrivit att det innebär följande aspekter:

- Kunskapsbaserad och ändamålsenlig
- Säker
- Patientfokuserad
- Effektiv
- Jämlik
- I rimlig tid

Dessa kriterier har använts mycket och täcker rätt bra alla aspekter på kvalitet i hälso-och sjukvård och är i sin tur delvis baserade på Institute of Medicine's beskrivning i Crossing the Quality Chasm men de var inte helt identiska.

Föreslagna kriterier i prEN15224
In den nya standarden (EN 15224) föreslås följande 11 kriterier

- appropriate, correct care
- availability
- continuity of care
- effectiveness
- efficiency
- equity
- evidence/knowledge based care
- patient centred care including physical and psychological integrity
- patient involvement
- patient safety
- timeliness/accessibility

De 11 kriterier som finns i nuvarande remissutgåvan är, enligt SLS åsikt för många Vi anser att det är tillräckligt med nedanstående nio kriterier för att följa kvaliteten och kvalitetsutvecklingen i vården. För definitioner se bifogad svarsmall.

- evidence/knowledge based
- effective
- efficient
- co-operative for continuity
- safe
- timely
- accessible
- patient centred
- equitable

Sammanfattning
SLS anser att den förslagna standarden prEN15224 är bra, dock behöver den förtydligas på vissa punkter som vi påpekar i svarsmallen – antalet kriterier är för många och inte helt entydiga. Likaså skall standarden vara uppbyggd på samma sätt som ISO/EN 9000.

För att hälso- och sjukvården skall förstå och tillämpa standarden är det av stor betydelse att den översätts till svenska liksom att man utarbetar Guidelines (på svenska) för att beskriva hur standarden är uppbyggd och hur den skall användas.

För Svenska Läkaresällskapet

Stockholm den 11 maj 2011

Margareta Troein Töllborn *Hans Rutberg* *Björn-Erik Erlandsson*
Ordförande