Assessment principles in DDKM 2014 for the prehospital sector

Guidelines for surveyors and accreditation award committee

Danish Institute for Quality and Accreditation in Healthcare

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1. Introduction

The assessment principles herein apply to the second version of the DDKM for the prehospital sector.

Other specifics concerning the survey concept are available in "Handbook on the DDKM for the prehospital sector".

The concept of "organisation" is used as an umbrella term describing the organisational level being accredited within the prehospital sector, e.g. regional prehospital organisations or ambulance providers.

1.1 Assessment objective

The assessment of the degree to which the requirements in the accreditation standards of the DDKM is met serves to:

- Provide feedback to the organisation by stating to which degree it meets the DDKM requirements
- Provide guidance for the organisation's continued work with the DDKM
- Form the basis for awarding of an accreditation status
- Provide input for research analysis.

Furthermore, it is desirable that in addition to being useful for health professionals, the result of the assessment is understandable for any citizen.

1.2 General principles

The assessment of the degree to which an organisation meets the requirements of the DDKM is exclusively made at the element level. It is the overall adherence to the requirements of the elements that forms the basis of the awarding of an accreditation status. The assessment of the degree to which the requirements of the elements is met is based on the below 4-point scale:

Degree of fulfilment
COMPLETELY MET (CM)
MAINLY MET (MM)
PARTIALLY MET (PM)
NOT MET (NM)

In the following section, the assessment principles are specified, and instructions are provided concerning the practical use of the principles.

2. Element assessment

2.1 Result of element assessment

The assessment of the elements leads to one of the outcomes presented in Table 1.

Table 1: Definition of the four element assessment outcomes

Degree of fulfilment	Definition
COMPLETELY MET (CM)	All requirements are met.
MAINLY MET (MM)	Some requirements are met, and the observed shortcomings do not significantly affect the requirements of the element.
PARTIALLY MET (PM)	Some requirements are met, and the observed shortcomings do significantly affect the requirements of the element.
NOT MET (NM)	No requirements are met, or only plans are presented.

The assessment of whether an organisation meets the requirements of the accreditation standards is always based on the elements. The elements state that which shall be fulfilled (the "requirements" or "outcome measures"). The field Contents does not serve to add new requirements to be met, but to determine what specifically is needed for an element to have been met. Specifically, three types of contents within this field are important:

In some standards, this field is used to define the phenomenon comprised by the standard. These definitions are binding, i.e. a document is not a business mission unless it meets definition of a business mission.

In some standards, specific requirements concerning the contents of guiding documents are provided. These requirements form the basis when it is assessed if the guiding documents exist. However, a case-by-case approach is used to assess whether any shortcomings constitute a significant part of the element requirement or not.

For some elements, the specific context decides which specific items shall be present for the element to have been met. The field provides instructions as to how this context-dependent interpretation can be made.

If the element text holds explicitly specified sub points, including e.g. bullet points with requirements for the contents of guiding documents, complete lack of completion of a sub point shall be assessed as a significant shortcoming, and therefore the assessment outcome cannot exceed PM unless context-dependent conditions indicate that another assessment would be appropriate.

2.2 Assessment is context-dependent

It is an important principle that the survey team's assessment shall be context-embedded. This means that the element requirements shall be understood with reference to the current organisation and the tasks and activities of this organisation.

This means that an element will always be assessed as CM if all elements are present that relate to the organisation and its particular tasks and context.

The text in the "Contents" field serves, among others, to clarify the framework of the context-dependent assessment.

2.3 Interpretation of the DDKM concepts

The assessment is based on the wording of the element text, as the used terms shall not be understood to have other contents than explicitly expressed in the text or list of terms. Similarly, no additional requirements shall be added, e.g. from the contents of the standard. The term "shall" should be interpreted as a recommendation and not as a "must", i.e. something which is decisive for the outcome of the assessment.

The above principle also applies to quality monitoring objectives, the level of which is determined by the organisations unless the element text explicitly states specific objectives.

In exceptional cases, the organisation's interpretation of concepts can be assessed as unacceptable because it deviates too much from a common-sense understanding of what is acceptable. In such cases, the shortcomings shall be fully and explicitly motivated in the survey report.

Concepts shall be understood from a user's perspective.

Example: "Easily accessible" shall be assessed on the basis of whether users find that the documents are easily accessible, whereas the specific meaning of the terms "ongoing" and "systematic" is determined by the organisation. Any specific requirements concerning time should be stated explicitly.

2.4 Elements assessing the existence and contents of guiding documents

2.4.1 The basis of the assessment

These documents include, among others, business missions, policies, plans and guidelines. Which of the elements from the total standards set are concerned is shown in Appendix 1

The assessment is based on the following:

- If a single joint document is required for the organisation as a whole: Does the document exist?

- If a single joint document is not required for the organisation as a whole: Does one or more documents exist which together apply in the relevant part of the organisation?
- Does the document(s) have the contents required by the element? In the accreditation standards, there will generally be contents requirements that support the assessment. The specific contents and the specific degree of detail should, however, reflect the context.
- Is the document understandable for those who are to use it? If the document (or documents) is unclear, it should be checked how the people using it interpret its contents. The assessment of how clear the documents are will be made on the basis of the answers provided. Usually, it is only necessary to assess the clarity of the document(s) if there is a specific reason to do so.

Approval of documents shall be done before the external survey. If this has not been done, the best possible assessment that can be awarded is MM. An MM assessment presupposes that the document is approved before the survey is concluded. If the document(s) is(are) approved during the survey, the focus shall be on whether the document(s) as a whole fulfils the requirements of the element of if there are shortcomings. It is thus the presence of any shortcomings in the contents that will determine if the outcome of the assessment will be lower than MM and not the point in time at which it(they) is approved.

2.4.2 Outcome of the assessment

COMPLETELY MET (CM)

A document is in place that covers the requirements in the element and any points in the contents field or the element. Users understand the document.

MAINLY MET (MM)

A document is in place with few and insignificant shortcomings that are not critical to patient safety or which only apply in special situations. Users understand the document.

PARTIALLY MET (PM):

A document is in place, but has significant shortcomings that are critical to patient safety.

OR

Users do not understand the document.

NOT MET (NM)

The document does not exist. This is also the case if an unapproved version or draft or similar is used.

2.5 Elements assessing the implementation and use of documents and elements assessing implementation as such

2.5.1 The basis for the assessment

These elements establish if one or more personnel groups can account for, explain or explain and demonstrate a process and refer to documents describing it. Which elements from the total standards set are concerned is shown in Appendix 1

The assessment is based on spot checks performed in the unit where the element is relevant.

- Can the personnel explain and/or demonstrate how the process is performed?
- Can the personnel's explanations be confirmed through objective observations? These may e.g. be direct observations of documentation from health records.
- Can the personnel's explanations be confirmed through patient interviews?
- Does the personnel know where to find help, if they are in doubt about what to do?

The following observations may in some cases support an assessment that a process has, in fact, been implemented. Shortcomings with regard to these, however, cannot be used to motivate lacking implementation:

- Are any supportive measures in place to ensure that the process is performed as desired (e.g. IT systems, checklists, etc.)
- How will the personnel react if they observe any deviations from the process described in the documents?

As part of the survey concept, IKAS will point out special standards applying a principle whereby an assessment shall be based on a minimum of "square root n" of all possible units. The principle should be understood as follows: If a process is performed at 12 units, it shall be assessed on the basis of a minimum of 4 ($\sqrt{12}$ = 3.46 rounded up to nearest full number.) If it is not possible to make a decision on the basis of the established spot checks, the process is assessed at one additional unit. This modus operandi is repeated until an assessment outcome can be produced. In the remaining standards, this principle is merely instructive.

2.5.2 Outcome of the assessment

COMPLETELY MET (CM):

Consistent implementation (and reference to documents, if required) at all units where the element was assessed.

OR

Consistent implementation (and reference to documents, if required) at all units at which the element was assessed, but isolated deviations were observed at no more than half of the units.

MAINLY MET (MM):

Consistent implementation (and reference to documents, if required) at all units at which the element was assessed, but isolated deviations were observed at more than half of the units.

OR

Consistent implementation (and reference to documents, if required) at more than half of the units where the element was assessed, but implementation was weak at up to half of the units. The weaknesses observed were not critical to patient safety.

PARTIALLY MET (PM):

Consistent implementation (and reference to documents, if required) at less than half of the units where the element was assessed.

OR

A weak and lacking implementation (and reference to documents, if required) at a minimum of one unit, and this is critical for the patient safety at the (one or more) units affected.

NOT MET (NM):

Not implemented at the units where the element was assessed. This may be the case even if isolated cases were observed that were in line with the requirement of the element.

2.6 Elements assessing quality monitoring

2.6.1 The basis for the assessment

These elements establish if quality monitoring has been performed at the required intervals, and if the results achieved have been assessed and analysed. Which elements from the total standards set are concerned is shown in Appendix 1

If organisations were previously accredited, they shall be able to demonstrate that they have continued the quality monitoring that was in place at the previous survey if such monitoring is also required under the next version of the standards. Those elements for which there are requirements concerning quality monitoring in both the first and the second version of the standards are listed in Appendix 2. The assessment CM therefore presupposes that quality monitoring has be continued without any gaps in the period separating the two surveys. If the quality monitoring has gaps, the assessment MM, PM or NM will be awarded, depending on whether the monitoring has been characterised by "gaps", has been "sporadic" or has been "absent".

In elements in which the method can be chosen freely, the quality monitoring requirement has been observed even if the specific form of monitoring has been changed, provided there has not been any gaps in the monitoring.

To achieve CM, organisations who have not previously been accredited shall present a minimum of one quality monitoring for the element at survey, and it shall have been made clear how quality monitoring will continue. The same applies to all organisations if the element concerns quality monitoring that was not required under the previous version of the standards.

2.6.2 Outcome of the assessment

COMPLETELY MET (CM):

Quality monitoring was performed and fulfils all requirements as to frequency, contents and continuity. This is also the case if the quality monitoring does not literally fulfil all requirements of the element, but it is assessed that, given its actual context, the organisation fulfils the element's requirements.

MAINLY MET (MM):

Quality monitoring was performed. The contents are characterised by some shortcomings, but these comprise only a less substantial part of the total tasks performed. This criterion is only relevant if the element includes specific requirements for contents.

OR

Quality monitoring was performed, but a limited number of gaps in frequency are observed. Quality monitoring was thus implemented systematically, but not without some imperfections

PARTIALLY MET (PM):

Quality monitoring was performed, but there were substantial shortcomings with regard to contents. This criterion is only relevant if the element includes specific requirements for content.

OR

Quality monitoring was performed, but only sporadically. Monitoring activities were thus performed, but not systematically.

NOT MET (NM):

Quality monitoring was not performed. This is also the case if quality monitoring was planned but not implemented, or if only isolated examples of quality monitoring are observed in the organisation.

2.7 Motivations for the assessment of elements

The survey report shall be prepared in a manner that allows the receiving organisation to learn from it, and it shall contribute to ensuring a consistent assessment practice.

The assessments MM, PM and NM shall always be motivated. The assessment CM is motivated in those cases in which there are shortcomings when compared with the element text, but where everything required from the organisation given its tasks and situation is in place (context-dependent assessment cf. Section 2.2).

2.8 Requirement for follow-up on elements

If an element was assessed as PM or NM, follow-up is recommended. The recommendation shall clearly describe:

- What the follow-up recommendation comprises
- Which type of follow-up is recommended
- Motivation for any recommendation concerning follow-up with a short deadline

The survey report shall include an overview of standards that include elements that require follow-up. The guiding follow-up deadlines are as follows:

- Submission of documentation within three months
- Focused re-visit[1] within six months
- Focused re-survey[2] within three months, or within one month in case of conditions of critical importance for user safety.

In special cases, additional provisions concerning the awarding of accreditation status may mean that a recommendation for follow-up is also provided for organisations that were awarded MM.

2.8.1 Assessment of elements that assess quality monitoring at follow-up after survey

It is not possible to re-establish continuity in quality monitoring after gaps have occurred. Therefore, follow-up shall assess if the organisation has now implemented systematic quality monitoring in accordance with the element's requirements.

3. Awarding of accreditation status

3.1 The role of the Accreditation Award Committee

After the external survey, the survey report is presented to the independent Accreditation Award Committee. The Committee can change assessments of elements that are not in line with the assessment principles or with established assessment practice. Based on the fulfilment of the elements, the Accreditation Award Committee then draws on the below principles to make its decision concerning accreditation status and about the content, form and deadline for any follow-up.

[1] Focussed re-visit may be used as follow-up if the status awarded was "temporary accreditation".

[2] Focused re-survey is used for follow-up when the status awarded was "conditional accreditation/accreditation in course".

3.2 Process and criteria for awarding an accreditation status

The main principles for awarding of accreditation status are that the overall efforts are assessed across the entire standard set. After external survey, the next steps in the process are determined on the basis of the element assessments.

The criteria are both used at assessment after external survey and at assessment after follow-up, and they are always based on the assessments of all of the elements in the standard set (barring irrelevant elements). For every element, the most recent assessment is used.

Process in case the accreditation status is awarded without specific assessment by the Accreditation Award Committee:

- The organisation can be awarded the status accredited with no comments and no requirements for follow-up when all elements in the patient safety critical standards and in standard 1.2.2 Quality monitoring and improvement initiatives and standard 1.2.4 Risk management were assessed as CM and all of the remaining elements of the standard set were assessed as CM or MM
- The organisation can be awarded **temporary accreditation** with requirements for follow-up when a minimum of one element among the patient safety critical standards and in standard 1.2.2 Quality monitoring and improvement initiatives and standard 1.2.4 Risk management were assessed as MM and all of the remaining elements of the standard set were assessed as CM or MM. After follow-up, if the organisation fulfils the criteria for accreditation (without comments), it is accredited. If not, the organisation will be **accredited with comments**.

Process in case the accreditation status is awarded following specific assessment by the Accreditation Award Committee:

If one element was assessed as PM or NM, the Accreditation Award Committee makes one of the following decisions following a specific assessment:

- The organisation is awarded **temporary accreditation** with follow-up. After follow up, if the organisation fulfils the criteria for accreditation (without comments) it is accredited. If not, the organisation will be **accredited with comments**.
- Any previous accreditation is made conditional[3]; follow-up is established in the form of focused re-survey which may lead to any of the following statuses: **accredited, accredited with comments, not accredited**.
- The organisation is awarded the status of not accredited. This only occurs in exceptional cases and if the Accreditation Award Committee assesses that there is no chance that the organisation will be able to fulfil the standards adequately within the deadline for focused re-survey. Specific assessment in the Accreditation Award Committee comprises an assessment of whether the shortcomings of element fulfilment substantially affect the institution's ability to keep users safe and provide them with any statutory rights they may have. In this connection, safety is de-

[3] If the organisation does not hold any accreditation, this situation is denominated "**accreditation in course**"

fined as safety against damaging events and safety against damage due to insufficient efforts on the part of the institution. Furthermore, shortcomings from previous surveys that remain after a new survey has been done can be given a particularly high weight when the committee decides on an accreditation status.

Organisations that are awarded the final accreditation status of "accredited with comments" should be considered as having achieved accreditation, but some subsequent development work will be needed.

Appendix 1 – Overview of element types

Std. no.	Standard title	Elements assessing the existence and content of any guiding documents	Elements assessing the implementation and use of documents	Elements assessing implementation	Quality monitoring
1.1.1	**Management**	1	2	-	-
1.1.3	**Contracts and agreements between the regions and their providers**	1-7	8-9	-	10
1.1.4	**Planning and operational activities**	-	1-3 and 5-8	4	-
1.1.6	**Data safety and confidentiality**	-	-	1-2	3-4
1.1.7	**Supply systems**	-	-	1-2	3
1.2.1	**Quality policy**	1	2	3	-
1.2.2	**Quality monitoring and improvement initiatives**	1	5	2-4 and 6	7-9
1.2.4	**Risk management**	1	2-3	-	4
1.2.5	**Patient identification**	1	2	-	3
1.2.6	**Adverse events**	-	-	1-3	4
1.2.7	**Patient complaints and patient insurance cases**	-	1	2-3	4
1.2.8	**Violence and threats against staff**	-	-	1-2	3
1.3.1	**Document management**	-	1	2-3	-
1.3.2	**The patient health record**	1-2	-	3-4	5
1.4.1	**Hiring of staff**	-	1	2-3	4
1.4.2	**Introduction of new staff**	-	-	1-4	-
1.4.3	**Work planning**	-	1-2	-	-
1.4.4	**Training and competence development**	-	1	2-3	-
1.5.1	**Hygiene policy**	1	-	2	-

Std. no.	Standard title	Elements assessing the existence and content of any guiding documents	Elements assessing the implementation and use of documents	Elements assessing implementation	Quality monitoring
1.5.2	**Procedures and workflows for re-use of medical equipment and textiles**	-	1 and 3	2	-
1.5.3	**Hand and uniform hygiene**	-	1	2	3
1.5.4	**Handling sources of infection**	-	1	2	-
1.5.5	**Handling waste and hazardous substances**	-	1	-	-
1.5.6	**Handling waste**	-	1	-	-
1.6.1	**Emergency plan**	1	-	2-4	5-6
1.7.1	**Implementation of medical equipment**	-	-	1-2	-
1.7.2	**Medical equipment**	-	-	1-4	-
1.8.1	**Acquisition, use and maintenance of vehicles and equipment**	-	-	1-4	-
1.8.2	**Safety during transport**	-	1	-	2
1.9.1	**Interhospital transports**	-	1	2	3-4
1.10.2	**Telemedicine**	-	1	2	3-4
1.10.3	**Communication equipment**	-	1	2	-
2.1.1	**Informed consent**	-	-	1	2
2.1.2	**Involvement of patient and relatives**	-	-	1	2-3
2.1.4	**Bringing in of patients with a deviant behaviour**	-	1	-	2
2.2.1	**Health professional triage in the Acute Medical Coordination Control Centre**	1	2	-	3-4

Std. no.	Standard title	Elements assessing the existence and content of any guiding documents	Elements assessing the implementation and use of documents	Elements assessing implementation	Quality monitoring
2.2.2	**Technical disposition in the Acute Medical Coordination Control Centre**	1	2	-	3
2.2.3	**Notification and communication**	1-2	-	3	4-5
2.4.1	**Coordination of medical treatment**	-	1	2	3
2.5.1	**Medicine #**	1	-	2-4	5-8
2.5.2	**Handling and storage of medicine #**	2	-	1 and 3-6	-
2.6.1	**Treatment of cardiac arrest #**	1	-	2-3 and 5	4
2.7.1	**Concluding the prehospital efforts on site #**	1	-	2	3
2.8.1	**Transfer #**	-	-	1	2-3
2.9.1	**Care for the terminally ill patient**	1	-	-	-
3.1.1	**Patient assessment and treatment #**	-	1 and 5		9

Appendix 2 - Overview of the elements for which there are requirements concerning quality monitoring in both version 1 and 2 of the standards

Requirements for continued quality monitoring from the 1st to the 2nd version		
Standard	Element no. in version 2	Element no. in version 1
1.1.6 Data safety and confidentiality	3	4
	4	6
1.2.6 Adverse events	4	3
1.2.8 Violence and threats against staff	3	3
1.3.2 The patient health record	5	4
1.6.1 Emergency plan	5 and 6	4
1.9.1 Interhospital transports	4	5
1.10.2 Telemedicine	3	3
	4	4
2.1.1 Informed consent	2	3
2.1.2 Involvement of patient and relatives	3	4
2.1.4 Bringing in of patients with a deviant behaviour	2	4
2.2.1 Health professional triage in the Acute Medical Co-ordination Control Centre	3	3
2.2.3 Notification and communication	4	5

2.4.1 Coordination of medical treatment	3	3
2.5.1 Medicine #	5, 6, 7 and 8	4, 5, 6 and 7
2.7.1 Concluding pre-hospital efforts on site #	3	4
2.8.1 Transfer #	2	3