The Danish Healthcare Quality Programme Accreditation standards for medical specialist practices

1st version, 1st edition

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Danish Institute for Quality and Accreditation in Healthcare

Preface

This is the first version of the Danish Healthcare Quality Programme (DDKM) for medical specialist practices. It is to be used for external surveys performed after 1 October 2015.

The DDKM forms part of the national Danish strategy for quality development in healthcare. The DDKM is to become a joint, integrated and shared system for quality development and assessment of strategically important healthcare services and activities. Overall, the DDKM shall support and further systematic, ongoing self-assessment and quality improvement. Additionally, the IKAS shall organise periodic, uniform and impartial external assessment of quality improvements performed on a joint assessment basis, i.e. accreditation standards. External evaluations are prepared so that they may form the basis for a single accreditation of each clinic. Accreditation statuses are made public.

The IKAS Board of Directors is fully aware of the substantial challenge inherent in the development, establishment and implementation of a joint Danish quality programme. Nevertheless, over time the decision is expected to bring benefits to patients and healthcare professionals alike in Danish healthcare. The programme has a strong focus on coherent patient pathways regardless of healthcare units and sectors. Furthermore, the DDKM has been designed to facilitate coordination of both the public and the private healthcare services encompassed by the programme.

The Board is also aware that the best possible results will only be achieved through development efforts that continually involve and engage the stakeholders who strive to and are required to provide international-level quality in healthcare services on a day-to-day basis. That has been the case for this first version of the DDKM for the medical specialist practices.

The objective of the process has been to develop a set of standards that makes sense in the day-to-day clinical work and that underpins the clinics' quality development efforts and work on patient safety.

We would like to wish good luck with the upcoming work, which we hope will contribute to a joint and systematic development of quality in Danish healthcare, which may make a difference, nationally as well as internationally.

Vagn Nielsen

Chairman of the Board

Jesper Gad Christensen

President

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Introduction to the Danish Healthcare Quality Programme for medical specialist practices

Introduction

As part of the 2011 collective agreement between the Association of Practicing Medical Specialists (FAPS) and the Region's Board for Wages and Tariffs (RLTN), it was decided to develop a quality programme for medical specialist practices in Denmark. The Danish Healthcare Quality Programme would serve as the starting point for the new programme.

On this basis, efforts were initiated to develop a standards set and to prepare a hearing process along with pilot testing and assessment of the programme. The standards set was developed by a group consisting of practicing medical specialists appointed by the FAPS, representatives from Danish Regions, the regions and the Danish Institute for Quality and Accreditation in Healthcare, IKAS. You will find a list of the working group members in Appendix 2.

In "Agreement on renewal of collective agreement on medical specialist help" between the RLTN and the FAPS of 26 September 2014, it appears that all medical specialists practicing under the collective agreement on medical specialist help shall be accredited in accordance with special standards developed for medical specialist practices in pursuance of the DDKM. Accreditation covers a 3-year-period, and it is presupposed that all practices will have been accredited once by the end of 2018.

The first external survey shall take place in October 2015.

The DDKM for medical specialist practices comprises the 16 specialities that are covered by the collective agreement on medical specialist help. Therefore, standards and parts of standards will not be relevant to all specialists and clinics. The Danish Health and Medicines Authority's generic performance measures for supervision of private treatment facilities was used as a starting point and integrated into many of the standards. Additionally, the development efforts were based on current statutory provisions, national guidelines, etc.

What is the Danish Healthcare Quality Programme, DDKM?

The DDKM is a quality programme that, in time, will cover all of Danish healthcare. At present, the DDKM comprises public hospitals, private hospitals, the prehospital sector, pharmacies and part of municipal healthcare. General practice will undergo accreditation as from 1 January 2016; and in years to come, the remaining practice sectors will be added.

The DDKM is based on accreditation during which healthcare professionals, so-called surveyors, visit the clinic and assess if the clinic meets the requirements for good quality. This occurs every third year.

The objectives of the DDKM are to:

- underpin professional, organisational and patient-perceived quality in medical specialist practices
- further patient safety
- measure the quality and ensure that it is improved if assessed as being insufficient
- further cooperation across Danish healthcare
- make visible the quality of Danish healthcare.

What are my benefits from participating in the DDKM?

- You will achieve a tool allowing you to obtain a high and consistent medical quality
- You will acquire a methodology allowing you to include and employ the most recent knowledge within your field
- You will acquire tools allowing you to document the quality of the services your clinic provides
- You will achieve quality assurance of transfers to other healthcare operators. Thereby you will be underpinning the creation of more coherent patient pathways.
- You will achieve tools to prevent that errors are committed when diagnosing and treating patients and throughout the full patient pathway
- You will contribute to learning in connection with any breaches of quality or adverse events
- You will take command of your clinic's procedures, guidelines and plans
- You will receive professional sparring on the development and operation of your clinic
- You will become accredited and will therefore gain a "proof of quality".

Specifically, this e.g. means that:

- You will engage in management development activities
- There are plans for development of the quality and the operation of the clinic
- Physicians as well as non-physician employees stay updated within their field
- The ordering of paraclinical tests is handled correctly and follow-up on test results is ensured
- Utensils and medicines are handled correctly
- Equipment used for diagnostics and treatment are safe for patients and in good working order at all times
- Record-keeping is performed in line with current acts and provisions
- The right tests, examinations and treatments are provided for the right patients
- That triage of patients is consistent
- That everyone in the clinic knows how to handle cardiac arrest and acute illness
- Appropriate hygiene measures are in place
- Competences, management and operational activities are developed.

Accreditation standards for practicing medical specialists

The DDKM for practicing medical specialists consists of a series of quality standards.

The standards should be seen as a framework that the clinic itself contributes to completing. This means that the standards do not specify **how** the clinic shall handle tasks/procedures in practice, but rather **what** the clinic needs to be in control of in the day-to-day work.

The standards cover essential work processes in the clinic and include anything from referral to treatment, handling of paraclinical tests, management, recruitment and introduction of new employees.

Standards one to four outline the overall framework for the quality development work, i.e. management and operation of the clinic, how the clinic employs clinical guidelines on diagnostics and treatment, adverse events and risk management. Next follows five patient-safety critical standards and eight other standards on referral, hygiene, equipment, handling of utensils and medicinal products, etc.

Only if the patient-safety critical standards are "Completely met" or "Mainly med" can the clinic be awarded accreditation.

The five patient-safety critical standards (marked with an # after the title of the standards)
05. Sedation of patients with anaesthesiological assistance
06. The patient health record
07. Patient identification
08. Paraclinical tests
09. Basic cardio-pulmonary life support

Structure of the standards

The accreditation standards for practicing medical specialists were prepared to serve as the basis for assessment in the context of accreditations.

The standards (see template below) consist of a general description and the objective of the work with the standard. Next follows a description of the contents that provides an in-depth description of the contents of the standard and the requirements made with regard to quality and patient safety in each clinic. This section also describes if written guidelines are required and if procedures are required for certain workflows. There is no requirement for procedures to be in writing, but it may be a good idea to ensure that everyone in the clinic has the opportunity to know and follow the established procedures. Additionally, any requirements for the measurement of quality will be stated.

If the standard is linked thematically to other standards, this is stated under "Cross references". Towards the end of the standard, it is stated specifically what will be assessed (elements) during external surveys when the clinic receives visits by surveyors. For more information and a definition of central concepts used in the standards, please refer to Appendix 5.

Title	*Standard title*				
Sector	*States which sector the standard concerns*	**Version**		**Edition**	
Standard	*Describes the purpose of the standard*				
Objective	*Describes the objective of the standard - how to reach the objective*				
Contents	*Presents information allowing the reader to understand the standard and to learn what requirements are made in relation to the quality and patient safety in the clinic. Describes requirements for procedures, guidelines and plans, and states how quality will be measured.*				
Cross references	*References to other, thematically linked, standards.*				
During the external survey, the clinic will be assessed on the following:					
Elements	*Describe what the external surveyors will be assessing in the clinic during the external survey. Additionally, the methods used are stated.*				
References					

	This field holds selected references relating to the accreditation standard in question.

Acts and executive orders

The accreditation standards are based on current acts, executive orders, etc., and external surveys are always based on the statutory provisions in place at the time the survey is held.

The references do not intend to include all statutory provisions that may be related to or form the basis for the standard. Only statutory provisions that should be consulted when working with standards are included.

The references are those that apply at the time the standard is published. At www.retsinformation.dk you can search for a statutory provision's number to see if the document has been replaced by a more recent one. In such cases, a link is provided to the more recent document. Additionally, you will find any guidelines published by the Danish Health and Medicines Authority at www.sundhedsstyrelsen.dk. The Danish Health and Medicines Authority's generic performance measures for supervision of private treatment facilities was used as a starting point and integrated into many of the standards. We always recommend that you check the most recent version of the performance measures when working with the standards.

Validity and unit of accreditation

This set of accreditation standards is used for all external surveys in medical specialist practices initiated after 1 October 2015. It is the provider number (Danish: ydernummer) and any associated physicians and non-physician employees who have patient contact that are accredited. If several provider numbers share non-physician employees, the visits are held on the same day, if possible. In the following, a clinic is defined as a provider number with any associated physician(s) and non-physician employees.

When and how do you get started with the standards as a medical specialist?

- It is important that the clinic starts working with the standards and completes the required quality monitoring a minimum of 1 year prior to the survey visit and that it continues these efforts after the visit.
- Read this introduction to learn how the standards are structured.
- Then read each standard and assess if the clinic meets the requirements described under "Contents". In many cases, the requirement is simply a description of how various workflows are organised in the clinic, e.g. how follow-up on submitted blood samples is ensured, or how the clinic handles any adverse events. Where requirements include a guideline or a plan, the workflow shall be in writing. The requirements for contents are shown in the standard's contents field. If a procedure is required, the procedure may either be in writing or oral. Procedures shall always be in writing if the physician is assisted by more than 2 persons when performing the task.
- Guidelines, plans, procedures, etc., are prepared for the various standards. The overall requirements for these documents are described later in this chapter. For example, there is a requirement that the documents carry a date indicating when the document shall be revised and who is responsible for the document.
- It is ensured that the entire clinic follows the stipulated guidelines, plans and procedures.

- Quality is measured, and measures are initiated to solve any quality issues that occur.

What happens during an external survey?

Every third year, the clinic is visited by two surveyors. Typically, the survey team will consist of a medical specialist and a quality consultant, who will typically be a nurse with practice experience. They will interview the physician/physicians and any non-physician employees to assess if the clinic meets the quality requirements of the standards. The surveyors assess the elements described at the bottom of the standards. The visit lasts approx. 4 hours. Slightly longer if there are more than two physicians in the clinic.

The surveyors will:

- Establish if written guidelines and plans are in place for the required areas (see Appendix 1), and if the documents meet the requirements described in the standard's "Contents".
- Establish if the clinic's physician/physicians and non-physician employees follow the guidelines and plans that are required in accordance with the accreditation standards and that are relevant to their work tasks.
- Establish if procedures are in place for various workflows, and if the clinic's physician/physicians and non-physician employees know and follow the procedures that are required in accordance with the accreditation standards and that are relevant to their work tasks.
- Establish if the clinic has measured quality through record audits, inspection of equipment, etc., and if the clinic has taken action if the quality was unsatisfactory in some areas.
- Revise specific patient pathways with the physician to assess the quality in this manner.

Each element will be assessed and may achieve the following assessments:

Completely met (CM)
Mainly met (MM)
Partially met (PM)
Not met (NM):

The surveyors will prepare a report; and after a short hearing, the report will be submitted to the Accreditation Award Committee. On the basis hereof, the Committee may award one of the following statuses:

Accredited
Temporary accreditation
Accreditation in course

If the clinic is awarded the status Temporary accreditation or Accreditation in course, the clinic will be given the opportunity to adapt and solve the issues identified before being reassessed. Reassessment may be effected through submission of documentation, a telephone interview or a revisit at the clinic.

Finally, one of the following accreditation statuses will be awarded:

Accredited
Accredited with comments
Not accredited

What will happen in the accreditation process?

1. The clinic will receive a date for the external survey approx. a year in advance via the e-Boks associated with the company's CVR number. Normally, the date cannot be changed. The visit takes place within normal working hours. It is expected that all physicians and all non-physician employees who have patient contact are present during the external survey. The visits will be planned to ensure that all clinics from each speciality are accredited within the same period.
2. Then, within a month and via DAK-E's website, the clinic shall enter practical background information on the clinic, including form of organisation, number of physicians, number of non-physician employees, etc.
3. A minimum of three months before the visit, a detailed plan for the visit will be available at the DAK-E website. The plan will state at which times the surveyors shall have access to interviewing the various physicians, employees, etc. The clinic may then make use of any "free" time slots for patient work or other activities. The visit concludes with feedback for the clinic.
4. Few days after the visit, the clinic receives a summary report via e-Boks. The clinic may raise objections to the contents of the report if misunderstandings have occurred. This shall be done within a period of 10 days.
5. The report will then be processed in the Accreditation Award Committee and the clinic will be informed of its accreditation status via e-Boks. You will find more information about the Accreditation Award Committee at www.ikas.dk.
6. If the clinic does not achieve accreditation directly, follow-up will be needed through submission of documentation or a revisit, possibly by telephone interview, depending on the type of quality issues identified by the surveyors. The practice will receive information from IKAS concerning the follow-up, and further advice will be available, among others from eKVIS. The clinic will then be given the opportunity to have the Accreditation Award Committee reprocess the case and award an accreditation status.
7. The clinic will receive a certificate with its accreditation status, and the accreditation status is also published at IKAS' website.

Assistance with work related to the Danish Healthcare Quality Programme

Kick-off meetings are held for all specialities in the period from 1 January 2015 to 30 September 2015. The meetings introduce the DDKM in medical specialist practices.

Under the auspices of eKVIS, specialty-based network groups will be established to support the accreditation process. These network groups meet and discuss guiding documents, implementation of standards and quality measurements.

In relation to Data Capture, support is available in DAK-E.

At the IKAS website you will find help for the accreditation process in the electronic "Handbook on DDKM for medical specialist practices". The handbook contains recommendations for the clinic's work with all parts of the accreditation process.

All clinics working with the DDKM can post questions to IKAS via the FAQ on our website to clarify any doubts concerning the accreditation standards and accreditation process. You will then receive an answer within a few days. IKAS will publish any questions and answers concerning matters of principle and topics of general interest in anonymised form in a FAQ on the IKAS website.

Requirements to documents

The clinic's documents (guidelines, plans, etc.) shall comprise the following in order to be approved:

- What is the objective of the document?
- Who does the document apply to? E.g. physicians, all employees or secretaries.
- Who is responsible for the document? Who is responsible for the professional contents of the document?
- Date at which the document comes/came into force?
- Expiry date. When shall the document be revised (no later than-date)?
- The contents that are described in the Contents field of each standard.

Documents may be stored electronically and/or on paper, but the latest version should always be accessible. Documents shall be subjected to version control so that it is possible to retrieve documents that were in force at a certain point in time (document history).

At the eKVIS website (http://ekvis.dk) and the DAK-E website (http://www.dak-e.dk/), you will find examples of guidelines that meet the above requirements.

The clinic may benefit from employing a fixed template for its documents. You will find a template example in Appendix 7.

Accreditation standards

Title	**01 Management quality and operation**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic's management is unambiguous and the clinic strives to develop its operation and quality.				
Objective	To ensure: • a clear-cut management of the clinic, including a clear division of responsibility • optimal use of resources • that objectives are in place for the development of the clinic • that a quality monitoring plan is in place.				
Contents	The clinic shall be capable of accommodating current as well as future challenges and requirements. Challenges may concern the development of new technological opportunities, use of new knowledge and research in clinical practice, new requirements derived from the collective agreement, regional requirements and expectations as well as fluctuations in the financial basis. The clinic shall strive to ensure an optimal use of resources, including the reduction of any waste and adaptation of any inexpedient workflows and work divisions internally in the clinic. As a clinic you shall regularly consider these requirements and challenges and adapt the day-to-day operation to these requirements. A tool that will allow the clinic to consider these issues is a plan for the development of the clinic, including objectives for the continued development, which takes into consideration that new requirements and expectations may arise. Such a plan shall be revised annually as a minimum. The plan may include the introduction of new treatment methods, new equipment, hiring of new employees, expansion of the practice, use of ICT, introduction of SMS reminders, etc. A practice declaration may be a natural element in the plan. The plan shall comprise: a. How do we organise the DDKM work? Including who is responsible for the quality and patient safety work, meetings, course activities, preparation of guidelines, etc. b. Descriptions of the division of tasks and responsibilities for physicians and for non-physician employees. c. A quality monitoring plan, who shall monitor quality and how often shall the specific quality monitoring activities be performed, e.g. record audit, autoclave inspection, inspection of the medicine cabinet, etc., including when quality improvement measures will be decided upon if a quality issue is identified, and that the impact of such measures is assessed and new ones are implemented, as needed. You will find an example of a quality monitoring plan in Appendix 4. d. Development objectives for the clinic, including the introduction of new measures, e.g. new treatment modalities, new measures in the collective agreement, etc. Additionally, the clinic may supplement with a description of the employee situation, including the hiring of any new employees, physicians undergoing				

Title	**01 Management quality and operation**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	speciality training, etc.				
Cross references	15. Hiring, introduction and competence development				
During the external survey, the clinic will be assessed on the following:					
Element 1	A plan is in place for the development of the clinic and the plan comprises items a-d.				
Element 2	When interviewed, the physician and any non-physician employees can account for the division of responsibilities and tasks in the clinic and can define their own roles, including also the responsibility for coordination of the clinic's quality development and patient safety work.				
Element 3	When interviewed, the physician can account for the objectives for the clinic's development.				
Element 4	When interviewed, the physician and any non-physician employees can explain how quality monitoring is handled in the clinic.				
Element 5	When interviewed, the physician can explain how: • quality improvement initiatives are adopted if the quality monitoring reveals any quality issues. • it is assessed if the implemented initiatives have had the desired effect. • new initiatives are initiated if the desired effect was not achieved.				
References					
1.	Overenskomst om speciallægehjælp (Collective Agreement on Medical Specialist Help), Danish Regions and FAPS, 2011.				

Title	**02 Use of guiding documents on diagnostics and treatment**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic employs current guidelines on diagnostics and treatment as a basis for treatment decisions.				
Objective	To ensure a high and homogeneous level of professional and organisational quality in the diagnosis and treatment in line with the standard of an experienced medical specialist.				
Contents	The clinic adheres to current guidelines on diagnostics and treatment and exercises medical evaluation. Clinical guidelines on diagnosis and treatment may be international, national, e.g. from the Danish Health and Medicines Authority, treatment guidelines from medical societies, regional guidelines from hospitals, etc. Other guidelines include, among others, patient pathway programmes and healthcare agreements. The clinic shall have in place a list of the guidelines used, e.g. via links to the guidelines published by scientific societies, the Danish Health and Medicines Authority, etc. In specific cases, there may be good reasons not to follow the guidelines. Substantial deviations from the guidelines are described and motivated in patient records. Reporting is performed to relevant clinical quality databases, and the clinic monitors and assesses its own results from the databases. Data Capture is used in the cases that are implemented within the speciality and quality reports from Dara Capture are used for quality development. At the eKVIS website, you will find a list of the mandatory and voluntary clinical quality databases used within each speciality.				
Cross references	03. Patient safety 06. The patient health record #				
During the external survey, the clinic will be assessed on the following:					
Element 1	A list is in place, showing which guidelines the clinic employs for diagnosis and treatment.				
Element 2	When interviewed, the physician can explain how typical patient pathways are handled in the clinic on the basis of current guidelines.				
Element 3	When interviewed, the physician can explain in which cases the clinic typically deviates from the guiding documents on diagnosis and treatment used in the clinic.				
Element 4	When interviewed, the physician and any non-physician employees can explain how data are reported to relevant clinical quality databases and how data are extracted for Data Capture.				
Element 5	Once annually, the clinic randomly selects 20 current patient health records. These records are audited to determine if diagnosis and treatment are performed in conformity with guidelines on diagnosis and treatment. The clinic				

Title	02 Use of guiding documents on diagnostics and treatment				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	itself performs these audits. If any deficits are identified, these were corrected and a new patient health record audit was performed within 3 months. You will find suggestions for audit questions in Appendix 3.				
Element 6	Once annually, the clinic randomly selects 20 current patient health records. These patient health records undergo audit to determine if any deviations from the guiding documents on diagnosis and treatment were stated in the patient health records. The clinic itself performs these audits. If any deficits are identified, it is checked if these were corrected and if a new patient health record audit was performed within 3 months. You will find suggestions for audit questions in Appendix 3.				
Element 7	When interviewed, the physician can account for continual use of own results from clinical quality databases and quality reports from Data Capture for the development of the clinical professional quality and can refer to specific results and reports to this effect. This element is relevant only if the clinic reports to clinical databases and/or uses Data Capture.				
References					
1.	The Danish Health and Medicines Authorities guideline no. 9001 of 20 November 2000 on the preparation of instructions				

Title	03 Patient safety				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic identifies and reduces risks for its patients.				
Objective	To further patient safety in the clinic and to limit the risk of any adverse events and complications.				
Contents	The clinic shall prevent any injury to patients by identifying workflows, treatments and uses of equipment that entail an increased risk of injury to the patient or complications during the patient pathway and initiate measures to prevent these. An increased risk of injury may, e.g., be bleeding, cardiac arrest, burns or mix-ups. Potential risk areas are identified and measures are initiated to prevent any injury and complications. Additionally, it is described how any injury or complication that does occur will be handled. Among others, this includes handling of bleedings in connection with surgical interventions, cardiac arrest, anaphylactic reactions, fainting, etc. The clinic has a tool in place for risk assessment when introducing new treatments and new equipment. The tool comprises: a. Identification of risks for injury or complications in connection with the introduction of new treatments, workflows and equipment. b. How risk of injury and complications within the identified risk areas are prevented. c. How it is handled if injuries or complications do occur within the identified risk areas. A risk management table may be used, for instance where potential risks are scored, and measures are initiated to ensure the prevention and minimisation of risks. For an example, please see the eKVIS website http://ekvis.dk/. **For clinics that perform surgical procedures in local or general anaesthesia:** In connection with surgical procedures, the principles on Safe Surgery (Danish: Sikker Kirurgi) are used to avoid mix-ups. The clinic shall have in place procedures allowing it to avoid mix-ups. By mix-ups we mean surgery performed on the wrong patient, wrong type of procedure performed, incorrect side and incorrect image material, among others. It is ensured that the patient has given informed consent to the procedure and that any non-physician employees have been introduced to the type of procedure and knows how to handle potential complications. If relevant, the clinic has in place guidelines on the handling of major bleedings during and after surgery. Preparedness for bleeding includes that the clinic can treat a major bleeding on site and/or that there are competences in place to make the patient ready for transport and then transfer the patient. **For clinics that perform surgical procedures in local or general anaesthesia:** The clinic has in place guidelines on the monitoring of patients. These guidelines describe: a. What shall be monitored by whom, and what shall be documented in				

	the patient health record b. Requirements for relevant equipment in the awakening phase. The type of monitoring of patients and which parameters will be observed and documented are decided keeping in mind the patient group, type of procedure performed, etc. The clinic has in place procedures for the handling of patients whose condition deteriorates critically during or after surgery, including availability and use of antidotes. A healthcare professional shall be present who can assist the person performing the surgery in case of serious complications such as major bleedings or cardiac arrest. For patients undergoing surgery with anaesthesiological assistance, in addition to the requirements described in Standard 06, the patient health record shall include: a. The anaesthesiologist's entry of the anaesthesia assessment and plan for anaesthetics b. Monitoring periods c. Condition at discharge.
Cross references	02. Use of guiding documents on diagnostics and treatment 04. Adverse events 05. Sedation of patients without anaesthesiological assistance # 06. The patient health record # 07. Patient identification # 08. Paraclinical tests # 09. Basic cardio-pulmonary resuscitation # 10. Referral 12. Equipment for diagnosis and treatment 14. Handling of utensils and medicine
During the external survey, the clinic will be assessed on the following:	
Element 1	When interviewed, the physician can explain how the clinic identifies the workflows, treatments and uses of equipment that are associated with an increased risk of injury for the patient.
Element 2	When interviewed, the physician can explain which measures have been implemented to prevent and handle injuries and complications.
Element 3	When interviewed, the physician can explain how risks of injuries and complications are identified when new workflows, treatments and equipment are introduced
Element 4	When interviewed, the physician can explain which measures have been implemented to prevent and handle injuries and complications due to new

	workflows, treatments and equipment. This element is relevant only for clinics where new workflows, new treatments or new equipment have been introduced within the past few years.
Element 5	When interviewed, the physician can explain how principles for Safe Surgery are employed to avoid mix-ups. This element is relevant only for clinics that perform surgery in general anaesthesia.
Element 6	When interviewed, the physician and any non-physician employees can explain how major bleedings are handled and how the patient is prepared for transport and then transferred, if needed. The physician can refer to documents that describe this. This element is relevant only in clinics that perform surgery in local or general anaesthesia with a risk of major bleedings.
Element 7	When interviewed, the physician and any non-physician employees can explain how patients are monitored during and after surgery in general anaesthesia and can refer to documents describing this. This element is relevant only for clinics that perform surgery in general anaesthesia.
Element 8	When interviewed, the physician and any non-physician employees can explain how to handle patients whose conditions deteriorate critically during or after surgery. This element is relevant only for clinics that perform surgery in general anaesthesia.
Element 9	Once annually, the clinic randomly selects 20 current patient health records in which the patient has undergone surgery in general anaesthesia. These records are audited to establish if the patient health records include anaesthesiological assessment, monitoring period and condition at discharge. The clinic itself performs these audits. If any deficits are identified, these are corrected and a new patient health record audit is performed within 3 months. You will find suggestions for audit questions in Appendix 3. This element is relevant only for clinics that perform surgery in general anaesthesia.

References

1.	The Danish Health and Medicines Authority's Guideline no. 60258 of 01 May 1998 on the identification of patients and other measures to avoid mix-ups in healthcare, Danish Health and Medicines Authority
2.	Guideline no. 9808 of 13 December 2013 on the identification of patients and other measures to avoid mix-ups in healthcare

Title	03 Patient safety				
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3.	The Danish Health and Medicines Authority's guideline no. 9420 of 30 June 2006, Avoiding mix-ups in connection with surgical procedures: "The five steps"
4.	The Danish Health and Medicines Authority's guideline no. 9091 of 13 March 2013 on Control measures in connection with the use of napkins, tampons, cloth, devices, etc., in connection with surgery
5.	Safe surgery guideline checklist (Vejledning til Sikker Kirurgi Tjekliste). Danish Society for Patient Safety
6.	"Getting started with safe surgery Checklist" ("Kom i gang med Sikker Kirurgi Tjekliste"). Danish Society for Patient Safety
7.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)

Title	04 Adverse events	Number	04		
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic reports, analyses and follows up on adverse events.				
Objective	• To reduce the risk of patient injury due to adverse events • To further learning and improvement on the basis of adverse events.				
Contents	An adverse event is an event that causes injury or risk of injury in a patient. By injury we mean unintended physical harm caused by a test, examination or treatment that causes or contributes to increased treatment, discomfort, admission or the death of the patient, among others. Adverse events, then, include both near-events, where the injury can be avoided, and events that actually occurred. Adverse events are reported in pursuance of the statutory provisions published at www.dpsd.dk, and the clinic ensures safe handling and follow-up on adverse events. As a minimum, the clinic shall report adverse events that occur in connection with sector transitions and use of medical equipment and infections. Furthermore, serious adverse events are comprised. All other events may be reported (ref. no. 2, Section 4.1). Furthermore, practicing medical specialists have an obligation to report adverse events caused by other healthcare professionals of which they subsequently become aware in the course of their professional activities (ref. no. 1, Section 3). Events that occurred in the clinic and were then reported by other healthcare professionals or patients are also handled and followed up. If preferred, registration and analysis of adverse events may be performed in cooperation with key patient safety staff from the regions. The clinic shall inform patients and relatives of their opportunity to report adverse events, e.g. by making available a folder in the waiting room or through information on its website. The clinic has in place guidelines for the handling of adverse events that, as a minimum, describe: a. Who reports adverse events b. Who is responsible for follow-up on adverse events c. How the reported adverse events are analysed d. How previous adverse events are used for learning purposes in the clinic. The clinic has a procedure for the reporting of adverse drug reactions and events involving medical equipment to the Danish Health and Medicines Authority.				
Cross references	03. Patient safety				
During the external survey, the clinic will be assessed on the following issues:					
Element 1	When interviewed, the physician and any non-physician employees can explain how they would report an adverse event.				
Element 2	When interviewed, the physician and any non-physician employees can explain how adverse events are used for learning in the organisation.				

Title	04 Adverse events	Number	04		
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Element 3	Patients and relatives are informed of their possibility to report adverse events.				
Element 4	When interviewed, the physician and any non-physician employees can explain how they report adverse drug reactions and events involving medical equipment to the Danish Health and Medicines Authority.				
References					
1.	Executive order no. 913 of 13 July 2010 Chapt. 61 - The Danish Healthcare Act and any subsequent amendments				
2.	Consolidation act no. 1 of 3 January 2011 on reporting of adverse events in Danish healthcare, etc., with any subsequent amendments				
3.	The Danish Healthcare and Medicines Authority's guideline no. 1 of 3 January 2011 on reporting of adverse events in Danish healthcare, etc., with any subsequent amendments				
4.	Consolidation Act no. 1263 of 15 December 2008 on medical equipment				
5.	Consolidation Act no. 1269 of 12 December 2005 on medical equipment for in-vitro diagnostics				
6.	Consolidation Act no. 1264 of 15 December 2008 on actively implantable medical equipment				
7.	The Danish Health and Medicines Authority's guideline of 1 February 2007 for healthcare staff and users on the reporting of events involving medical equipment				
8.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				

Title	**05 Sedation of patients without anaesthesiological assistance #**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic sedates patient safely.				
Objective	To ensure patient safety in connection with sedation of patients without anaesthesiological assistance.				
Contents	The clinic identifies invasive and non-invasive procedures for which patients are sedated without anaesthesiological assistance and ensures patient safety in connection with these procedures. By sedation we mean medication with sleeping medicine or strong painkillers. The clinic has in place guidelines on the sedation of patients, which describe: a. For which groups of patients and for which procedures sedation may be used without anaesthesiological assistance b. In which situations there is an increased risk for the patient in connection with sedation c. What the physician shall assess prior to sedation d. The dosage of the medicines used for sedation e. Which parameters shall be observed and entered into the patient health record before, during and after the procedure. f. Any requirements relating to equipment used to monitor the patient clinical criteria for the patient's discharge g. Interactions with the patient's daily prescribed medicine h. Availability and use of antidotes. The clinic has in place guidelines for the handling of patients whose condition deteriorates critically during or after sedation without anaesthesiological assistance.				
Cross references	None				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain how sedation of patients is done safely and can refer to documents describing this.				
Element 2	When interviewed, the physician and any non-physician employees can explain how patients whose condition deteriorates critically during or after sedation without anaesthesiological assistance are handled and can refer to documents describing this.				

Title	06 The patient health record #				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	All patients have an updated electronic health record kept in accordance with current statutory provisions.				
Objective	That the patient health record is kept in accordance with current statutory provisions to ensure good, safe and continuous patient treatment.				
Contents	The patient health record contains all data concerning the patient's treatment thereby giving the clinic access to any knowledge about the patient's test, examination and treatment pathways. Any notes entered into the patient health record are understandable for other healthcare professionals within the same speciality. Other healthcare professionals shall be able to understand the course of the work-up and treatment and any diagnosis made. Abbreviations may be used provided these abbreviations are common in the Danish language or within the speciality. If record notes are used as discharge summary/GP letter, they shall be understandable to a GP who does not have detailed knowledge of the speciality. Patient health records contain the information detailed in Consolidated act no. 3 of 2 January 2013 on authorised healthcare professionals' patient health records, adapted to each type of practice, patients, treatments, functions, etc. (https://www.retsinformation.dk/Forms/r0710.aspx?id=144978) Once annually, the clinic audits the 20 randomly selected current patient health records to determine if the patient health records contain the data required in current statutory provisions. The clinic has in place procedures for: a. Patients' access to their own health records. b. Amendment of any incorrect/imprecise information in patient health records.				
Cross references	None				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain and demonstrate the handling of health records, including their contents, patients' access to their own record and amendment of any incorrect/imprecise information in the records.				
Element 2	Once annually, the clinic randomly selects 20 current patient health records. Health record audits were performed, and it was checked if the patient health records include the data required in pursuance of current statutory provisions. The clinic itself performs these audits. If any deficits are identified, these were corrected and a new patient health record audit was performed within 4 months. You will find suggestions for audit questions in Appendix 3.				
References					
1.	Executive order no. 877 of 04 August 2011, Chapt. 6, on authorisation of healthcare profession-				

	als and on healthcare activities with any subsequent amendments
2.	Consolidated act no. 3 of 2 January 2013 on authorised healthcare professionals' patient health records (record-keeping, storage, disclosure and transfer, etc.)
3.	Guideline no. 161 of 16 September 1998 on information and consent and about disclosure of health information, etc.
4.	Consolidation act no. 665 of 14 September 1998 on information and consent and about disclosure of health information, etc., with any subsequent amendments
5.	The Danish Health and Medicines Authority's guideline no. 9154 of 22 February 2007 on discharge summaries in connection with discharge from hospitals, etc.
6.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)

Title	**07 Patient identification #**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic correctly identifies patients.				
Objective	To ensure that: • the right tests, examinations and treatments are provided for the right patients. • the right prescriptions, test results, etc., are recorded for the right patient.				
Contents	The clinic prevents identity mix-ups in connection with testing, examination and treatment in the clinic, thereby ensuring that the right patient's data are displayed in the electronic health record and that any prescriptions, test results, referrals, etc., are recorded in the record of the right patient. Generally, patients shall be identified by their CPR number. In some situations, identification may be based on unequivocal visual recognition, but the CPR number is required whenever the patient shall be compared with other information, paraclinical tests, etc. The clinic has in place guidelines on patient identification, which describe: a. how identification is achieved in the clinic. b. when patients are identified. c. who is responsible for identifying the patient. The clinic ensures patient identification in connection with paraclinical tests, e.g., unequivocal labelling stating, as a minimum, the patient's name, CPR number, date and the responsible healthcare person, of blood samples and referrals to other parts of Danish healthcare.				
Cross references	08. Paraclinical tests 10. Referral				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain how and when patients are identified and can refer to documents describing this.				
Element 2	When interviewed, the physician and any non-physician employees can demonstrate how diagnostic material is labelled unambiguously.				
References					
1.	The Danish Health and Medicines Authority's Guideline no. 60258 of 01 May 1998 on the identification of patients and other measures to avoid mix-ups in healthcare.				
2.	Guideline no. 9808 of 13 December 2013 on the identification of patients and other measures to avoid mix-ups in healthcare				
3.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				

Title	**08 Paraclinical tests #**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic orders, handles and follows up on paraclinical tests.				
Objective	To provide the basis for: • correct and valid results from paraclinical tests • that no patients suffer any injuries or endure unnecessary harm due to lack of a timely reaction to paraclinical tests.				
Contents	The clinic has in place a procedure for the paraclinical tests performed by the clinic and for ordering of the paraclinical tests that are procured with external providers. By paraclinical tests we mean diagnostic imaging and tests of biological material extracted from patients. The procedure describes: a. How paraclinical tests are ordered from laboratories and image diagnostic departments b. Extraction, expedient storage, transport and hand-over of diagnostic material c. Handling of own laboratory samples based on manuals, guidelines or similar from the provider of the devices, materials and equipment, among others. When ordering paraclinical tests, the following is taken into account: a. Indication/issue. b. Other important conditions that may affect the execution and/or interpretation of the desired test c. Allergies of relevance to the test d. Medicines of relevance to the test e. Who is to be contacted and how contact is to be made in case of acute results - including in vacation periods and outside of normal business hours f. Need for interpretation, if relevant g. Substantial handicaps of relevance to the test. The clinic has in place guidelines on the follow-up on test results, which describe: a. How it is ensured that test results are seen in time by the person who is responsible for acting on the result b. How follow-up on lacking test results is ensured c. Procedure in case of deviant test results that may be of significant importance to the patient d. How results are communicated to patients. How information is passed on to patients and how the patient's consent to tests, examinations and treatments is achieved is pivotal to the doctor-patient relationship. The patient’s consent shall be provided on the basis of adequate information from the healthcare professional, and the patient may withdraw his or her consent at any time. Consent to treatment may be provided either orally or in writing, and shall be				

Title	08 Paraclinical tests #				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	journalised in the patient health record. The clinic has in place procedures describing how consent is obtained for prescribed paraclinical tests. It shall appear from the health record which information was given to the patient and if the patient provided his or her consent to the test. The clinic follows-up on the paraclinical tests ordered by the clinic. The clinic has in place reminder procedures that are implemented in case of lacking results, and the responsibility for performing this task has been established. If it is established that the patient has not appeared for the test in question and the test is important for the patient's state of health, the patient is contacted.				
Cross references	07. Patient identification # 10. Referral				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, physicians and non-physician employees can explain and demonstrate how the paraclinical tests are ordered and handled.				
Element 2	When interviewed, the physician and any non-physician employees can explain how paraclinical tests are followed-up and can refer to a document describing this.				
Element 3	Lacking test results are identified and the clinic follows up on these results.				
Element 4	Once annually, the clinic randomly selects 20 current patient health records. The records are audited to establish if there are any issues with the communication to the patient of the test results relating to paraclinical tests. The clinic itself performs these audits. If any deficits are identified, these were corrected and a new patient health record audit was performed within 4 months. You will find suggestions for audit questions in Appendix 3.				
References					
1.	The Danish Health and Medicines Authority´s guideline no. 9207 of 31 May 2011 on the handling of paraclinical tests				
2.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				

Title	09 Basic cardio-pulmonary life support#				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic has in place preparedness measures for basic cardio-pulmonary life support.				
Objective	To ensure a quick and qualified response when the need arises for basic cardio-pulmonary life support.				
Contents	The clinic has in place preparedness measures for acute conditions and cardiac arrest in the clinic. Competencies are present in the clinic which can perform basic cardio-pulmonary life support, as a minimum corresponding to the BLC level (Basic Life Support - cardiac massage, artificial respiration and alarm call). Training/continuing training in basic resuscitation is completed every three years. If new hires have completed basic cardio-pulmonary life support training somewhere else, e.g. at a hospital, this is accepted. Everyone in the clinic shall know their functions and tasks in connection with acute illness and/or cardiac arrest. When new employees are hired, the clinic makes sure that the new employees are introduced to the functions and tasks in connection with acute illness and/or cardiac arrest, including basic cardio-pulmonary life support depending on the person's function and tasks. The clinic has in place guidelines on resuscitation that are prepared in line with the latest national guidelines on cardio-pulmonary life support. Guidelines describe: a. How to make an alarm call. b. Handling of basic cardio-pulmonary life support c. Tasks and responsibilities of physicians and non-physician employees. The following are available in the clinic for basic cardio-pulmonary life support: medicines, possibly a defibrillator, a bag-mask for artificial ventilation. Medicines, defibrillator, etc., are available, in good working order and stored correctly to ensure that they are ready for use in case of acute disease/cardiac arrest. This includes that the battery is inspected and that the pads and medicines have not reached their expiry dates. The checks are recorded, e.g., in a log-book. The clinic has in place preparedness measures for handling of other acute treatment, e.g. in case of anaphylactic reaction, syncope, bleeding, etc.				
Cross references	03. Patient safety 12. Equipment for diagnosis and treatment 14. Handling of utensils and medicine 15. Hiring, introduction and competence development				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain how acute disease and cardiac arrest are handled in the clinic, including the physician's and the non-physician employees' responsibilities and the lo-				

Title	09 Basic cardio-pulmonary life support#				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	cation of any necessary equipment and medicine, and they can refer to documents where this is described.				
Element 2	When interviewed, the physician and any non-physician employees can explain how regular inspections are performed of medicines, defibrillator, etc., for use in acute situations, including their presence and availability, inspection of expiry dates, function, etc., and can present documentation that inspections have been performed.				
Element 3	When interviewed, the physician and any non-physician employees can explain that they have completed training in basic cardio-pulmonary life support within the past three years, and they can produce documentation to confirm such training.				
References					
1.	Danish Resuscitation Council www.genoplivning.dk				
2.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				

Title	**10 Triage and referral**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic performs triage on the basis of pre-established procedures. Referrals from the clinic to other parts of Danish healthcare are completed in accordance with the requirements that were established by the receiver of the referral.				
Objective	To ensure that: • triage of patients is performed on the basis of pre-established guidelines. • referrals are completed in accordance with the requirements established by the receiver of the referral.				
Contents	Patients are referred on the basis of a referral or direct contact to the clinic (oculists and ENT physicians) The clinic has in place guidelines on the triage of patients, which describe: a. Which acute or serious conditions require conferral with the physician or that the patient gets an appointment within a specific deadline b. How the person responsible for the triage shall act if the cause motivating the referral is unclear, but information provided by the patient raises suspicion of an acute or serious condition. In connection with referrals to the remaining parts of Danish healthcare, it is ensured that these referrals carry the necessary clinical and administrative information and any relevant information about social conditions to support the work-up and treatment. When the clinic refers patients on suspicion of heart disease, cancer or other serious conditions, it shall be ensured that the referral has reached the intended recipient and has been received. This may, e.g., be done by requiring a receipt that the referral was received, by telephone contact, etc. When the treatment and/or work-up has concluded, the physician who made the referral is informed of this and of the result of the work-up and or treatment and, if relevant, provided with recommendations for future treatment. In cases where patients attend oculist or ENT physician check-up visits over a prolonged period of time, the specialist shall inform the patient's GP of the results to the extent that this is relevant. In case of deviating test results that may be of substantial importance for the patient, these are passed on to the referring physician.				
Cross references	08. Paraclinical tests #				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain how triage are performed and can refer to documents describing this.				
Element 2	Then interviewed, physicians and non-physician employees can explain how patients are referred to other parts of Danish healthcare.				
Element 3	When interviewed, the physician and any non-physician employees can ac-				

Title	10 Triage and referral				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	count for the submission of discharge summaries/GP letters.				
Element 4	Once annually, the clinic randomly selects 20 current patient health records. These records are audited to establish if triage is performed in accordance with guidelines. The clinic itself performs these audits. If any deficits are identified, these were corrected and a new patient health record audit was performed within 4 months. You will find suggestions for audit questions in Appendix 3.				
Element 5	Once annually, the clinic randomly selects 20 current patient health records. These records are audited to establish if discharge summaries/GP letters were sent to the patient's GP/the referring physician. The clinic itself performs these audits. If any deficits are identified, these were corrected and a new patient health record audit was performed within 3 months. You will find suggestions for audit questions in Appendix 3.				
References					
1.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				
2.	Collective agreement on medical specialist help 2011, the Region's Board for Wages and Tariffs and FAPS				

Title	11 Hygiene				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic minimises any risk of infection				
Objective	To prevent transfer of infections in the clinic.				
Contents	The clinic has in place guidelines on hygiene in the clinic, both relating to the premises, equipment and employees. **Cleaning** The clinic has in place guidelines on the cleaning of its rooms and any furniture, equipment and fixtures, etc. The clinic's rooms and furniture, equipment and fixtures, etc., are kept clean to ensure the safety and health of the patients, relatives, physicians and non-physician employees us the premises. Cleaning is performed in a manner reducing the danger of infection and avoiding the spreading of contamination. Particular attention shall be given to critical risk points such as lighting near the patient, the bed/gurney, wash basin and fixtures, screening equipment other sanitary appliances, grips and handles, stands and technical installations. **Non-disposable medical equipment and materials** The clinic has in place guidelines on cleaning and storage of non-disposable medical equipment and materials. The equipment and devices used are cleaned in pursuance of the instructions of the provider, the Danish Health and Medicines Authority or other relevant operators. Sterile equipment and devices and products are stored safely to avoid contamination, and it is ensured that any expiry dates are observed. Inspection of equipment for the sterilisation and cleaning of non-disposable medical equipment is recorded in a log book, for instance, and the frequency is established in line with any recommendations from the Danish Health and Medicines Authority, for instance. **Hand hygiene** Good hand hygiene is achieved through the use of hand disinfection, hand washing and use of disposable gloves. Hand hygiene utensils and personal protection gear are available in the rooms or near to the rooms where examinations and treatments are performed. The clinic has in place guidelines on hand hygiene which describe: a. Hand disinfection, hand washing and use of medical disposable gloves b. Which situations require personal protection gear, including special clothing c. Use of hand jewellery and wrist watches. If the clinic performs surgery that requires surgical hand washing the clinic has guidelines on this issue. **Infectious patients** The clinic has guidelines for the handling of infectious patients, including MRSA patients. National Danish clinical guidelines are followed.				
Cross references	None				

Title	11 Hygiene				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1

During the external survey, the clinic will be assessed on the following:	
Element 1	When interviewed, the physician can account for procedures on cleaning of rooms and furniture, equipment and fixtures.
Element 2	When interviewed, the physician and any non-physician employees can account for procedures for cleaning and storage of non-disposable medical equipment and materials.
Element 3	When interviewed, the physician and any non-physician employees can account for the handling of hand hygiene and can refer to documents describing this.
Element 4	When interviewed, the physician and any non-physician employees can account for the handling of surgical hand washing and can refer to documents describing this. This element is relevant only for clinics that perform surgery requiring surgical hand washing.
Element 5	When interviewed, the physician and any non-physician employees can account for the handling of particularly infectious patients and can refer to documents describing this.
Element 6	Equipment for the sterilisation and cleaning of non-disposable medical equipment is inspected. The clinic establishes the frequency of these measures itself based on any recommendations from the Danish Health and Medicines Authority, for example, and ensures follow-up.
Element 7	The quality of cleaning of rooms and furniture, equipment and fixtures, and ensures follow-up. The clinic itself established the frequency of cleaning.

References	
1.	Act no. 1046 of 17 December 2002 on medical equipment and any subsequent amendments
2.	Advice and instructions on disinfection in Danish healthcare, Statens Serum Institut 2004
3.	Advice and instructions on cleaning and disinfection of flexible endoscopes, Statens Serum Institut 2004
4.	Management of infection hygiene in Danish healthcare - requirements for re-treatment of sterilisable medical equipment. DS2451-13, 2009
5.	Management of infection hygiene in Danish healthcare - requirements for the washing and handling of non-disposable textiles. DS2451-13, 2009
6.	World alliance for patient safety. WHO guidelines on hand hygiene in health care (advanced draft): A summary ”Clean hands are safer hands”. World Health Organization 2005
7.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behan-

	dlingssteder)
8.	Prevention and spreading of MRSA: Guideline. Danish Health and Medicines Authority 2012

Title	**12 Equipment for diagnosis and treatment**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic inspects and maintains equipment for diagnosis and treatment.				
Objective	To ensure that equipment used for diagnostics and treatment is safe for patients and in good working order at all times.				
Contents	It is the responsibility of the owner of the clinic that the equipment used for diagnosis and treatment are safe for patients and in good working order, and that they are CF-marked and used as intended. Maintenance and inspection may be handled by others. On the basis of a risk assessment, the clinic decides which equipment for diagnosis and treatment shall be inspected and maintained. The clinic has in place procedures for the inspection and maintenance of equipment for diagnosis and treatment and these describe: a. When the equipment is inspected and maintained b. Who performs and records inspections and maintenance c. How inspection and maintenance are performed and recorded. d. How faulty equipment is handled. Inspection includes measures to decide if equipment for diagnosis and treatment is operational and measures correctly. The inspection may be done for instance through calibration and testing that is recorded in log books. The clinic ensures that all relevant employees have received training in the operation of the equipment used.				
Cross references	03. Patient safety				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, physicians and non-physician employees can explain how equipment for diagnosis and treatment is inspected and maintained and can produce documentation that inspection and (if relevant) maintenance have been performed.				
References					
1.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				

Title	13 Personal data and confidentiality				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic prevents unauthorised access to personal information, and patient confidentiality is safeguarded for any contact with the clinic.				
Objective	To ensure: • protection against abuse of and loss of personal information • safeguarding of patient confidentiality in relation to any contacts with the clinic.				
Contents	**Data safety** Personal information is handled in a manner ensuring that unauthorised access is avoided. Personal information includes information stored in electronic systems as well as on paper. Exchange of personal information via the Danish Healthcare Data Network is automatically protected from unauthorised access. Prevention of unauthorised access to personal information also includes methods and precautions aiming to protect stored personal information and computer software against errors and viruses. The clinic ensures back-up, has in place measures to avoid unauthorised access to personal information, e.g., through the use of personal passwords, logging lists, encryption, firewalls, and antivirus software and precautions in case of attempted unauthorised access to personal information. These measures may form part of contracts entered into with ICT providers and may be handled by the ICT provider. The Danish healthcare act allows for the collection and passing on of information about health conditions, other purely private conditions and other confidential information through look-up in electronic systems in connection with current treatment of patients. Patients shall be informed that they can decline that any information be collected and passed on, e.g., through look-up in the clinic or at sundhed.dk. The clinic has in place guidelines on the handling of personal information which describe: a. How personal information is collected and passed on b. How personal information is stored safely and safeguarded from unauthorised access c. How personal information is destroyed d. How personal information is handled in case of system breakdown. **Confidentiality** The clinic has in place procedures that safeguard patient confidentiality in connection with contact with the clinic. Confidentiality shall be ensured in connection with conversations with patients, telephone conversations, on screen work, etc. **Unauthorised access** The medicine cabinet and any computers and archives used to store patient				

Title	13 Personal data and confidentiality				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	data are safeguarded against unauthorised access.				
Cross references	None				
During the external survey, the clinic will be assessed on the following:					
Element 1	Contracts with ICT providers or own procedures ensure backup and precautions against unauthorised access to personal information.				
Element 2	When interviewed, physicians and non-physician employees can explain and demonstrate how person-identifiable data, on paper and in electronic form, are handled in daily clinical practice.				
Element 3	When interviewed, physicians and non-physician employees can explain and demonstrate how patient confidentiality is safeguarded in the clinic.				
Element 4	When interviewed, the physician and any non-physician employees can explain how rooms with patient data and medicine are secured against unauthorised access.				

References	
1.	Act no. 429 of 31 May 2000 on the processing of personal data (The Personal Data Processing Act) and any subsequent amendments
2.	Consolidation Act no. 528 of 15 June 2000 on safety precautions for the protection of personal information processed for the Danish public administration, and any subsequent amendments
3.	Guideline no. 37 of 2 April 2001 for Consolidation Act no. 528 of 15 June 2000 on safety precautions for the protection of personal information processed for the Danish public administration, and any subsequent amendments
4.	Information safety - guideline for Danish healthcare 25 February 2008 (Informationssikkerhed – vejledning for sundhedsvæsenet 25. februar 2008)
5.	Guideline no. 161 of 16 September 1998 on information and consent and about disclosure of health information, etc.
6.	Executive order no. 913 of 13 July 2010 Chapt. 5. The Danish Healthcare Act and any subsequent amendments
7.	Consolidation act no. 665 of 14 September 1998 on information and consent and about disclosure of health information, etc., with any subsequent amendments
8.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)

Title	**14 Handling of utensils and medicine**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	Procurement, storage and disposal of clinical utensils and medicines are handled safely and responsibly.				
Objective	To ensure that: • the necessary utensils and medicines are available • utensils and medical products are stored responsibly • utensils and medical products are disposed of safely.				
Contents	The clinic ensures that the necessary utensils and medicines are available by keeping an adequate stock and ensuring correct storage and disposal of these. The clinic has in place procedures for the procurement, storage and disposal of utensils, which describe: a. Who is responsible for ensuring an adequate stock of utensils b. How utensils are stored c. How utensils are disposed of after use or when the utensils are pass the expiry date. The clinic has in place procedures for the procurement, storage and disposal of medicines, which describe: a. Who is responsible for ensuring an adequate stock of medicines. b. How medicines are stored safely and at the correct temperature. By stored safely we mean that no one apart from the relevant employees have access to the medicines c. How medicines are disposed of when they pass their expiry date or have been stored incorrectly d. How it is ensured that medicines that are dispensed to patients to be consumed in their homes is correctly labelled, including the medicine's trade name, indication, dosage guidelines, the expiry date of the original package and the date at which the medicine was removed from its original package, and that the medicine is suitable for storage without the package e. How opened medicine is marked if its use is limited hereafter. Medicines also include medicines stored for use in acute situations. Inspection to confirm that the medicines are stored at the correct temperature, etc., is recorded, e.g., in a log book.				
Cross references	None				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain and demonstrate their tasks in connection with the procurement, storage and disposal of utensils.				
Element 2	When interviewed, the physician and any non-physician employees can explain and demonstrate their tasks in connection with the procurement, stor-				

Title	14 Handling of utensils and medicine				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
	age and disposal of medicines.				
Element 3	It is checked that medicines are not past their expiration dates. The clinic itself establishes the frequency.				
Element 4	It is checked that utensils are not past their expiry date. The clinic itself establishes the frequency.				
Element 5	It is checked that medicines are stored correctly. The clinic itself establishes the frequency.				

References

1.	Consolidation act no. 879 of 26 June 2010, Section 45 - The Environmental Protection Act with any subsequent amendments
2.	Consolidation act no. 1222 of 07 December 2005 on the handling of medicinal products in hospital wards and departments and other treating institutions (The Medicine Cabinet Order)
3.	Consolidation Act no. 361 of 23 April 2012 on prescriptions
4.	The Danish Health and Medicines Authority's guideline no. 9429 of 30 June 2006 on prescription and handling of medicinal products
5.	Consolidation Act no. 506 of 20 April 2013 on medicinal products, Chapter 2
6.	Consolidation act no. 1263 of 15 December 2008 on medical equipment, Section 4, subsection 1
7.	Consolidation act no. 1269 of 12 December 2005 on medical equipment for in-vitro diagnostics, Section 4, subsection 1
8.	Consolidation act no. 1264 of 15 December 2008 on actively implantable medical equipment, Section 4, subsection 1
9.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)

Title	**15 Hiring, introduction and competence development**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic establishes the framework for hiring, introduction of new employees and for competence development of both physicians and non-physician employees.				
Objective	To ensure that: • any physicians and non-physician employees hired hold a relevant competence profile • new employees acquire knowledge about the clinic's tasks and operation. • the division of responsibilities and tasks in the clinic is clear to any new employees • physicians and non-physician employees at any time have the necessary competences to solve the clinic's tasks.				
Contents	The clinic has in place a procedure to ensure that any new employees hold adequate competencies, that their authorisation and any training programmes are documented, that new employees participate in an introductory programme targeted at each employee's educational background and experience and that a function description is prepared for each new employee. For physicians undergoing speciality training, the introductory programme forms part of the full training programme which shall, as a minimum, meet current requirements from the Danish Health and Medicines Authority and from the regional further education secretariats. Non-physician employees are ensured access to supervision in relation to the handling of their tasks. If non-physician employees serve as assistants, the assistant receives instruction and is supervised. Competence development measures are in place to ensure that physicians and non-physician employees have the necessary competences to solve the clinic's tasks at any time. Competence development includes all forms of development and learning, including internal and external course activity, further and continuing training. Competence development for employed physicians and non-physician employees is discussed at the annual employee development interview. A plan exists for competence development of physicians and non-physician employees. This may be either a joint plan for competence development or individual minutes from each employee development interview. The clinic owners consider their own need for professional development and competence development and prepare a plan for such development.				
Cross references	01. Management quality and operation 09. Basic cardio-pulmonary life support #				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain how the employed physicians and non-physician employees are hired and introduced to the clinic and their tasks.				

Title	15 Hiring, introduction and competence development				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Element 2	When interviewed, the physician and any non-physician employees can explain how the clinic's procedure was followed in connection with new hires. This element is relevant only for clinics that have hired new employees within the past year.				
Element 3	Function descriptions are in place for non-physician employees.				
Element 4	When interviewed, the physician and any non-physician employees can account for the opportunities provided for and the practical provision of supervision of employed physicians and non-physician employees.				
Element 5	When interviewed, physicians and any non-physician employees can explain how competence development is handled in the clinic and can refer to a plan for the physicians, any employed physicians and any non-physician employees' competence development. The plan is prepared on the basis of the employee development interviews held within the past year.				
Element 6	When interviewed, the physician can explain how non-physician employees serving as assistants are instructed and supervised. This element only applies to clinics where non-physician employees serve as assistants.				
Element 7	When interviewed, non-physician employees who serve as assistants can explain how the physician supervises them and whether they have received adequate instruction.				
References					
1.	Generic measurement points for the Danish Health and Medicines Authority's supervision of private treatment sites (Generiske målepunkter for Sundhedsstyrelsens tilsyn med private behandlingssteder)				

Title	**16 Patients' perception of quality**				
Sector	Practicing medical specialists	**Version**	1	**Edition**	1
Standard	The clinic employs feedback from patients to improve the services it provides.				
Objective	To further learning and improvement of the clinic's services on the basis of patient feedback.				
Contents	The clinic receives information about patient-perceived quality from national Danish studies on patient experiences and follow-up on such information. Studies of patient experience that include the clinic's patients are performed at least every third year under the auspices of eKVIS, but other relevant studies may also be approved. The clinic has in place a procedure describing how feedback from patients, formal patient complaints and patient insurance cases are handled. Feedback from patients may be either oral or written and may be communicated to individual persons at the clinic or to the clinic as an institution. Feedback may concern both professional competence and service level. The clinic shall have a procedure for the collection and follow-up relating to feedback. Patient complaints are formal complaints submitted to the clinic in writing via the region or the National Agency for Patients' Rights and Complaints. The National Agency for Patients' Rights and Complaints and the regions have procedures for the handling of formal patient complaints. The clinic shall actively contribute to investigating these cases and implement measures to improve the quality on the basis hereof. If the physician or another authorised healthcare professional in the clinic becomes aware of injuries that may possibly allow a patient to claim damages, the physician/healthcare professional has a duty to inform the patient hereof and to assist the patient with any reporting of the issue to the Danish Patient Compensation Association (ref. no. 1, Section 23).				
Cross references	None				
During the external survey, the clinic will be assessed on the following:					
Element 1	When interviewed, the physician and any non-physician employees can explain how feedback from patients is handled and how the clinic follows up on such feedback.				
Element 2	Patient experience studies have been performed within the past three years and physicians as well as non-physician employees can account for the ensuing follow-up.				
References					
1.	Consolidation Act no 1113 of 7 November 2011, Sections 1, 23 and 45 on access to lodge complaints and claim damages in healthcare and any subsequent amendments				
2.	Consolidation Act no. 913 of 13 July 2010, Part III on the legal position of patients - The Danish Healthcare Act and any subsequent amendments				
3.	Consolidation act no. 1097 of 12 December 2003 on the scope of the Act on patient insurance				

	and any subsequent amendments
4.	www.patientombuddet.dk
5.	www.patientforsikringen.dk

Appendix 1. Overview of requirements for description of workflows

Std. no.	Standard title	Type of description
01	Management, quality and operation	Plan
02	Use of guiding documents on diagnostics and treatment	Overview and procedures
03	Patient safety	Guidelines and procedures
04	Adverse events	Guidelines and procedures
05	Sedation of patients without anaesthesiological assistance #	Guidelines
06	The patient health record #	Procedures
07	Patient identification #	Guidelines
08	Paraclinical tests #	Procedures/guidelines
09	Basic cardio-pulmonary life support #	Guidelines
10	Triage and referral	Guidelines
11	Hygiene	Guidelines
12	Equipment for diagnosis and treatment	Procedures
13	Personal data and confidentiality	Guidelines and procedures
14	Handling of utensils and medicine	Procedures
15	Hiring, introduction and competence development	Procedures and plan
16	Patient-perceived quality	Procedures

Appendix 2. Members of the development group

The development group counted the following:

Niels Henrik Nielsen (Dermatologist)

Svend Lindenberg (Gynaecologist)

Peter Tingsgaard (ENT specialist)

Jesper Skov (Ophthalmologist)

Jannie Beier (Rheumatologist)

Niels-Anton Rasmussen (Psychiatrist)

Tom Ringstrøm (Orthopaedic surgeon)

Anne Bukholt Pedersen, Lisbet Plambech Andersen (eKVIS)

Dennis Pihl Thomsen, Jane Brodthagen, Rikke Margrethe Friis (Danish Regions)

Helle Lindkvist (Region of Southern Denmark)

Bodil Vestergaard Nielsen (Region Zealand)

Mona-Lene Kjærgård (Capital Region of Denmark)

Marie Bruun Kristensen, Henrik Kousholt (IKAS)

Appendix 3. Suggested questions for patient health record audits

A total of 20 patient health records are extracted randomly. However, the records shall broadly represent the patient composition of the clinic. If surgical procedures with anaesthesiological assistance are performed in the clinic, a minimum of 10 of the extracted records shall involve such patients. The same 20 records shall be used for all record audits performed in pursuance of this standards set (standard 02, 03, 06, 08, and 10).

An audit table is completed stating if the requirements of the standards and elements were met. Below you will find a sample audit table.

All questions may be answered by one of the following three options: Yes, No or Not relevant.

St. no.	Standard title	Questions	Patient 1	Patient 2	Patient 3 etc..
02	Use of guiding documents on diagnostics and treatment	Were the diagnosis and treatment of the patient performed in accordance with current guiding documents?			
02	Use of guiding documents on diagnostics and treatment	Are deviations from guiding documents on diagnostics and treatment stated as such in the record?			
06	The patient health record	Is the cause of the contact stated in the record?			
06	The patient health record	Are any examinations and tests and the indication for these stated in the record?			
06	The patient health record	Are treatments and the indication for these stated in the record?			
06	The patient health record	Are allergies of relevance to the work-up and treatment provided in the record?			
06	The patient health record	Are the tests/examinations, taking of specimens and the corresponding results provided in the record?			
06	The patient health record	Is oral and written information given to the patient stated in the record?			
06	The patient health record	Is the patient's informed consent for treatment stated in the record?			
06	The patient health record	Are the used materials, e.g. radiographies, images, laboratory and test results, results from scans, etc., dated and identified and do			

St. no.	Standard title	Questions	Patient 1	Patient 2	Patient 3 etc..
		they appear from the record?			
06	The patient health record	Is information on the submission of GP letter (s) included in the record?			
08	Paraclinical tests	Are the results of the paraclinical tests given to the patient stated in the record?			
03	Patient safety	Is anaesthesiology assessment and the plan for anaesthesia stated in the record?			
03	Patient safety	Are any monitoring periods stated in the record?			
03	Patient safety	Is the patient's condition at discharge stated in the record?			
10	Triage and referral	Was the triage performed in accordance with the guidelines?			

Analysis of results

Once all 20 records have been reviewed, the data are assessed. If areas are identified in which the clinic does not meet the standard and the related elements, it is assessed if the finding(s) is/are outliers or reflect a general problem. On the basis hereof, the cause may be analysed to identify why the problem occurred, and solutions to the problem may be proposed. A new audit is then performed four months later to determine if the problem has been solved.

Appendix 4. Example quality monitoring plan

	Type (element)	How	When	Completed	Responsible	Objective	Result
02. Use of guiding documents on diagnostics and treatment	Patient health record audit (5)		Annually				
02. Use of guiding documents on diagnostics and treatment	Patient health record audit (6)		Annually				
03. Patient safety	Patient health record audit (9)		Annually				
06. The patient health record #	Patient health record audit (2)		Annually				
08. Paraclinical tests #	Patient health record audit (4)		Annually				
09. Basic cardio-pulmonary life support #	Inspection (2)		To be determined by the clinic				
09. Basic cardio-pulmonary life support #	Documentation (3)		Every three years				
10.Triage and referral	Patient health record audit (4)		Annually				
10. Triage and referral	Patient health record audit (5)		Annually				
11. Hygiene	Inspection (6)		To be determined by the clinic				
11. Hygiene	Assessment (7)		To be determined by the clinic				
12. Equipment for diagnosis and treatment	Inspection (1)		To be determined by the clinic				

14. Handling of utensils and medicine	Inspection (3)		To be determined by the clinic				
14. Handling of utensils and medicine	Inspection (4)		To be determined by the clinic				
14. Handling of utensils and medicine	Inspection (5)		To be determined by the clinic				
16. Patient-perceived quality	Assessment (2)		Every three years, as a minimum				

Appendix 5. Used concepts

Concept	Definition/explanation
Accreditation	Quality assessment by which a recognised body (IKAS) assesses whether an activity, service or institution meets a set of joint standards.
Documentation for	When a requirement of documentation for something exists, the documentation shall be in writing, e.g. in the form of logging lists, check lists, informal lists, meeting minutes or the like.
Handling of	When the clinic needs to have in place procedures for the handling of something, this means that the clinic shall employ a certain mode of action that demonstrates that it is in control of the situation.
Clinic	The clinic comprises the entire practice, including clinic owners, employed physicians and non-physician employees. This does not include cleaning employees, etc.
Inspection of	When there is a requirement to inspect something, this means that is shall be tested if the current state is in accordance with pre-defined values. For example, if the autoclave sterilises the equipment used.
Physicians	Clinic owners, employed physicians and physicians undergoing speciality training.
Follow-up on	When there is a requirement that the clinic follows up on something, this means that the clinic shall consider the result of a test, inspection or the like and take action accordingly.
Plan	A description of specific measures aiming to achieve a certain objective. For example, the standards describe objectives for the development of the clinic and how these objectives are reached.
Procedure	A procedure may be a written description of a workflow or an adopted routine that has not been put into writing. Generally it is the clinic's choice if written or oral procedures are used. However, procedures shall always be in writing if the physician is assisted by more than 2 persons when performing the task.
Process	A course or series of actions.
Guiding documents	Guidelines, procedures, instructions and other documents that describe workflows in the clinic.
Guideline	Written instruction, which is to be used by clinic owners and non-physician employees when they need to make decisions concerning proper procedure.
Safeguarding	When there is a requirement that the clinic has in place procedures safeguarding something, this means that the clinic shall ensure that this is done and that no errors occur. For example, ensuring that referrals are completed correctly and that they are sent to the intended recipient.
Standard	A standard describes quality requirements for the areas in question and form the basis for the accreditation.
Assessment	When the clinic is required to perform an assessment, this means that the clinic shall consider the content, value, quality or size of something.

Appendix 6. Summary of quality monitoring

Standard	Type of quality monitoring
02. Use of guiding documents on diagnostics and treatment	Patient health record audit (5 and 6) and assessment (7)
03. Patient safety	Patient health record audit (9)
04. Adverse events	Assessment (2)
05. Sedation of patients without anaesthesiological assistance #	Assessment (1 and 2)
06. The patient health record #	Patient health record audit (2)
08. Paraclinical tests #	Patient health record audit (4)
09. Basic cardio-pulmonary life support#	Inspection (2) and assessment (3)
10. Referral #	Patient health record audit (4 and 5)
11. Hygiene	Inspection (6) and assessment (7)
12. Equipment for diagnosis and treatment	Inspection (1)
14. Handling of utensils and medicine	Inspection (3, 4 and 5)
16. Patients' perception of quality	Assessment (2)

Appendix 7. Guideline template

Document title	*Title of the document*
Date of entry into force	*When does the document come into force? E.g. 1 September 2015*
To be revised no later than (date)	*When shall the document be revised (no later than-date)? E.g. 1 September 2018 Documents shall be revised every three years, as a minimum.*
Person responsible for the document	*Who is responsible for the professional contents of the document?*
Approved by	*Who approved the document? Typically the responsible physician*
Objective	*What is the objective of the document?*
Who does the document apply to?	*Who does the document apply to? E.g. All clinic employees*
Procedure	*Description of the procedure followed in the clinic*
References	*References, if any, to the document and reference to an accreditation standard number.*