



# **ACCREDITATION MANUAL FOR HEALTH CARE ORGANISATIONS**

**February 1999**

Accreditation department

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## NOTICE TO PROFESSIONALS

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**This is the first version of the accreditation manual to be issued for use in accrediting French health care organisations.**

The accreditation procedure was pilot tested in 40 volunteer health care organisations during autumn 1998, using the experimental version of the manual. The present version incorporates modifications made in response to that testing.

The accreditation manual is complemented by two user guides:

- “Préparer et conduire votre démarche d’accréditation” (*Preparing for and implementing an accreditation initiative in your organisation*), which has been produced to help health care organisations gain accreditation;
- “Guide de l’expert-visiteur” (*Surveyor’s Guide*), to help surveyors in carrying out their task.

Further versions of the accreditation manual will be produced as the accreditation procedure evolves; performance indicators will gradually be introduced, and the fields of application for accreditation will be extended.

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## ACKNOWLEDGEMENTS

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This manual could not have been produced without the involvement of a large number of health professionals, who have contributed for more than 2 years to the definition of its objectives and its content. Their contribution was crucial to the project and we would like to thank them and the organisations for which they work for their support. We are very grateful to them all.

We are grateful to everyone who assisted by:

- defining the concepts and objectives of accreditation in France;
- analysing existing documentation and the results of other countries' experiences of accreditation;
- carrying out partial or in-depth pilot testing of the accreditation procedure in public and private health care organisations in France;
- leading groups within professional and academic bodies, and private and public federations of health care organisations, to reflect on the subject of accreditation.

We would like to thank the team, originally of ANDEM (National Agency for the Development of Medical Evaluation) and subsequently of ANAES, which contributed to this initiative, including members of the Accreditation Department, Evaluation Department, International Relations section, Documentation Service, Communications Service and Administration and Accounts departments, and more particularly those who were directly involved in producing this manual, by drafting it, organising the project or monitoring progress at various stages: Dr Charles BRUNEAU, Dr Lionel PAZART, Dr Vincent MOUNIC, Mrs Nadine BARBIER, Mr Hubert GARRIGUE-GUYONNAUD, Dr Jean PETIT, Mrs Elisabeth BOUVET, Mrs Marie CILLERO, Mrs Chrystelle PULCI and Dr James GOLDBERG.

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## CONTENTS

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<b>NOTICE TO PROFESSIONALS</b>	<b>3</b>
<b>ACKNOWLEDGEMENTS</b>	<b>4</b>
<b>CONTENTS</b>	<b>6</b>
<b>INTRODUCTION</b>	<b>8</b>
<b>Chapter 1 MISSION AND OBJECTIVES</b>	<b>9</b>
I.    DEFINITION	9
II.   OBJECTIVES	9
III.  RANGE OF ORGANISATIONS COVERED	9
IV.   FIELD OF APPLICATION AND LIMITS	10
V.    FOUNDATIONS AND PRINCIPLES	11
VI.   FUTURE DEVELOPMENTS	12
<b>Chapter 2 THE ACCREDITATION PROCEDURE</b>	<b>14</b>
I.    GENERAL PRINCIPLES	14
1.    The nature of accreditation	14
2.    Timing	15
3.    Mutual commitments of the parties involved	15
4.    The obligation to notify	16
5.    The health care organisation's financial contribution to accreditation	16
II.   STEPS OF THE PROCEDURE	<b>18</b>
1.    Application to enrol in the accreditation procedure	18
2.    Enrolment in the accreditation procedure	19
3.    Self-assessment	19
4.    Accreditation survey	20
5.    Conclusion of the procedure by the Accreditation College, and accreditation report	24
6.    Communication of the results of the accreditation procedure, and appeal by the health care organisation	26
<b>Chapter 3 THE STANDARDS - HOW THEY WERE DRAFTED, AND WHAT THEY COVER</b>	<b>27</b>
I.    HOW THE STANDARDS WERE DRAFTED	<b>27</b>
1.    Determining the areas for which standards would be produced	27
2.    Drafting the standards	28
3.    Testing in a sample of health care organisations	29

4.	Pilot testing of the accreditation procedure on the basis of the July 1998 version of the standards	29
5.	Role of the Scientific Council	29
II.	STRUCTURE OF THE STANDARDS	<b>31</b>
1.	Standards and criteria: definition and mode of use	31
2.	Organisation of the standards	32
3.	Properties of the standards	32
III.	STANDARDS AND CONTINUOUS QUALITY IMPROVEMENT	<b>32</b>
IV.	EVALUATION SCALE	<b>33</b>
V.	INDICATORS	<b>33</b>
1.	Definition and characteristics	33
2.	Types of quality indicators	34
3.	Methodological considerations of measurement and possible forms of bias	34
4.	Future development of indicators in relation to the accreditation procedure	35
<b>Chapter 4</b>	<b>THE STANDARDS</b>	<b>37</b>
I.	PATIENTS AND PATIENT CARE	<b>38</b>
1.	Patient rights and information	39
2.	Patient records	46
3.	Organisation of patient care	50
II.	MANAGEMENT AND ADMINISTRATION IN THE SERVICE OF THE PATIENT	<b>62</b>
1.	Management of the health care organisation and activity sectors	63
2.	Human resources management	69
3.	Logistics management	75
4.	Management of the information system	80
III.	QUALITY AND PREVENTION	<b>83</b>
1.	Quality management and risk prevention	84
2.	Special prevention programmes and transfusion safety	89
3.	Monitoring, prevention and control of the risk of infection	93
	<b>ABBREVIATIONS</b>	<b>101</b>
	<b>GLOSSARY</b>	<b>102</b>
	<b>REFERENCES</b>	<b>105</b>

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## INTRODUCTION

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The accreditation procedure was introduced into the French health care system under law no. 96-346 of April 24, 1996 providing for hospital reform, and was described in decree no. 97-311 of April 7, 1997. The purpose of the procedure is to ensure that health care organisations develop policies to ensure continuous improvement in the quality and safety of care delivered to patients. The accreditation procedure is an assessment by professionals from health care organisations, which takes place at a specific point in time within a continuous process of quality improvement.

The accreditation procedure was inspired by models from the English-speaking countries, which have been developed over many years at the initiative of health professionals aiming to improve the quality of services delivered to patients. At the same time, care has been taken to ensure that these models were adapted to suit the specific culture and characteristics of the French health system. The independent nature of the procedure conducted by ANAES is similar to the approach taken by the bodies responsible for accreditation in other countries. The fact that the procedure is compulsory for French health care organisations does not differ fundamentally from the position for similar initiatives in other countries.

ANAES has based its accreditation process on an accreditation manual, which contains a description of the objectives and principles of the accreditation process, followed by the sets of standards against which continuing progress in quality will be evaluated in each health care organisation. The standards were drafted by professionals from within the health system. The description of the accreditation procedure and of the sets of standards have been revised in the light of results from pilot testing in public and private health care organisations.

Two user guides will shortly be available to complement this manual; these are “Préparer et conduire votre démarche d’accréditation” (*Preparing for and implementing an accreditation initiative in your organisation*) for health care organisations, and a “Guide de l’expert-visiteur” (*Surveyor’s Guide*) for surveyors.

The accreditation procedure which is currently being introduced will evolve over time. It will be evaluated and adjusted in the light of the results obtained, in response to comments from professionals within the health system and the expectations of those who use health care organisations.

Professor Yves MATILLON  
Executive Director, ANAES

Chantal LACHENAYE-LLANAS  
Director of Accreditation

## Chapter 1

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# MISSION AND OBJECTIVES

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### **I. DEFINITION**

Accreditation is an external peer review carried out by professionals that is independent of the health care organisation and of health authorities; it covers all areas of the organisation's operation and practice. Its purpose is to ensure that safety conditions and quality of patient care are adequately addressed by the health care organisation.

ANAES is the body responsible for implementing the accreditation initiative. ANAES works with the stakeholders of the health system to establish the standards against which an organisation and its procedures are assessed, and the results which may be expected in terms of improved patient health and increased satisfaction.

### **II. OBJECTIVES**

The objectives of accreditation are:

- to assess quality and safety of care;
- to assess a health care organisation's ability to ensure continuous improvement in quality of overall patient care;
- to formulate explicit recommendations;
- to involve professionals at all stages of the quality initiative;
- to provide external recognition of the quality of care in health care organisations;
- to improve public confidence.

### **III. RANGE OF ORGANISATIONS COVERED**

- Accreditation applies to all public and private health care organisations, and potentially applies to military health facilities. It also applies to groups promoting cooperation in health matters between health care organisations and care networks.
- At present, accreditation does not cover sociomedical activities, even when these take place within a health care organisation.

- Accreditation applies to the health care organisation in the legal sense of the term. This means that accreditation simultaneously covers all its structures (services, departments, etc.) and activities, because of the interlocking (?) relationships (between them).

ANAES can apply the accreditation procedure on a site-by-site basis in health care organisations which have several sites.

#### IV. FIELD OF APPLICATION AND LIMITS

- The accreditation procedure applies to those activities of health care organisations which are directly or indirectly involved in patient care (e.g. logistics sectors, technical sectors etc.).
- Teaching and research activities are not subject to accreditation.
- Accreditation is a process of peer review carried out by professionals external to a health care organisation; this distinguishes it from other initiatives, which have their own procedures:
  - **planning** refers to determination of services and disciplines which are to be established in a given geographical area and for a defined period of time, in relation to health needs and existing facilities. The Regional Health Organisation Plans and the “carte sanitaire” health charters are planning tools, which fall within the competence of the Government and the Regional Hospital Agencies;
  - **the authorisation procedure** gives a designated facility permission to carry out a given activity. Approval is given by the Government at national or regional level. Creating beds, carrying out transplants, medically assisted reproduction, heart surgery and prenatal diagnosis are examples which are covered by the authorisation procedure;
  - **allocation of resources** refers to the allocation of financial resources to health care organisations. A number of different tools are used – National Quantified Objectives, the Computerised Medical Information Systems Programme (PMSI), hospital usage levels, national priorities, various surveys, and so on – and they vary according to the status of health care organisations;
  - **inspection and compliance control** have targeted objectives, use specific methods and involve specialist staff;
  - **assessment of individuals’ skills** and disciplinary procedures are the responsibility of other bodies internal or external to the health care organisation.

However, although accreditation is distinct from all these procedures, the results of its review process will provide information which is valuable to any decision-making process.

- Accreditation is distinct from **certification**, which is not a prerequisite for accreditation. Certification differs from accreditation in its mechanisms and in its field of application.

## V. FOUNDATIONS AND PRINCIPLES

- **The focus is on the patient:** accreditation is first and foremost concerned with the patient's progress through the health care organisation and care network, and with the coordination of patient care. Accreditation is a cross-functional, multidisciplinary assessment by professionals of the health care organisation, of its management and of the results obtained. The comments and level of satisfaction of patients and other users of the health care organisation (the patient's family and close friends, the patient's doctor, etc.) are taken into account during the assessment.
- **Improvement in safety of care:** safety is one of the major dimensions of quality of care, and one of the main expectations patients have of the care system. Accompanying the increase in efficacy and complexity of hospital care over the last few decades, there has been a comparable increase in potential risk to the individual. Risk prevention depends on a number of factors, including compliance with safety regulations and good practice, and the establishment of a system of assessment and improvement based on identifying risk areas and taking preventive action.
- **Continuous quality improvement (CQI):** in order to achieve continuous quality improvement, a recognised quality management system is required. CQI involves a systematic approach to improve processes and reduce errors based on active commitment from individuals. It is a pragmatic initiative which uses specific measurements to define the existing situation and then progresses by making improvements one step at a time.
- **Involvement of professionals working in the health care organisation:** quality improvement is the result of internal initiatives implemented by the health care organisation. It is essential that everyone participate in such initiatives, so that they will accept changes and adopt appropriate solutions. The various stakeholders must be involved at every stage of the accreditation process. ANAES will explain, inform and communicate regularly with professionals.
- **A continuing process:** if quality initiatives are to be successful, the health care organisation has to make a long-term commitment. Accreditation should encourage the health care organisation to set up continuous quality improvement programmes. It is a cyclical process in which the self-assessment and survey determine which priorities will be the subject of action programmes to be implemented before the next accreditation procedure. ANAES should encourage this commitment by carefully overseeing how recommendations are formulated and followed up

- **Need for objectivity:** accreditation helps the health care organisation to diagnose its situation against precise criteria which have been laid down by ANAES in cooperation with professionals.
- **Continuous assessment and improvement of the accreditation process:** the principles of assessment and continuous quality improvement required of health care organisations apply equally to the accreditation process itself. ANAES is developing a monitoring system to enable it to measure efficacy, cost and any problems or dysfunction related to the accreditation process. ANAES is modifying and improving its process in the light of results obtained from pilot testing, comments and advice from professionals in the health care organisations surveyed and from the analysis of information collected throughout the accreditation procedure (results from self-assessments, surveyors' comments, types of discrepancies encountered, opportunities for improvement and so on).

## VI. FUTURE DEVELOPMENTS

The procedure for accrediting French health care organisations was drafted and tested in 1998.

The accreditation procedure was launched in 1999.

The scope of the mission, the challenge it represents for the French health system and the need for health care organisations to adopt quality initiatives all mean that implementation of the process will have to be gradual.

This gradual development of the accreditation initiative goes hand in hand with a medium-term assessment of its development, i.e. after 5 years. This will provide visibility to all health care organisations and an opportunity to address questions raised by professionals.

- **Gradual extension of the range of organisations covered**

At the present time, the accreditation procedure covers all public and private health care organisations, irrespective of type of activity. It will subsequently cover the various systems for managing health care upstream and downstream of the health care organisations themselves, i.e. care networks, health-care cooperatives, and structures which are in the process of being set up.

- **Increased requirement for quality and safety of care**

The original standards and criteria which initially cover structures and processes will in the future be modified to satisfy outcome criteria.

Indicators to evaluate quality improvement will gradually be introduced.

- **Extending the field of application**

The original standards and criteria are basically cross-functional; they will gradually be supplemented by clinical indicators, which will provide a better means of assessment of specific clinical activities.

- **Evaluating the initiative in order to refine the procedure and the methods used**

Right from the outset, the accreditation procedure must be structured and organised in such a way that it can be evaluated.

This evaluation will ensure that the initiative itself evolves, together with its tools, methods and modes of intervention.

- **Gradual development**

Initially, the accreditation procedure will cover the 3,500 health care organisations in France. After the pilot testing period in 40 health care organisations in 1998, its pattern of development is expected to cover:

- 300 health care organisations in 1999;
- 500 to 800 health care organisations a year thereafter.

This development plan was established following a survey of health care organisations to find out when they expected to apply for enrolment in the procedure.

## Chapter 2

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# THE ACCREDITATION PROCEDURE

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### I. GENERAL PRINCIPLES

#### 1. The nature of accreditation

The goal of the accreditation procedure is to promote continuous quality improvement in health care organisations. The procedure is based on sets of standards, criteria and indicators intended in particular to ensure that health care organisations use recommendations for good clinical practice, and medical and professional guidelines. ANAES is responsible for drafting the sets of standards, disseminating them and encouraging their use.

This means that the strategy behind the accreditation procedure is one of encouragement and education, assisting health care organisations as they develop their continuous quality improvement processes. Its goal is to develop an interdisciplinary approach to patient care and to allow professionals to be responsible for quality in the health care organisation where they work.

The procedure is therefore quite distinct from that of examining compliance with standards defined by regulations to ensure that health care organisations are safe; this kind of compliance assessment falls within the competence of the Government.

However, although ANAES' involvement with health care organisations in relation to accreditation, and its field of application, differs from that within the competence of the Government, it should be emphasised that their responsibilities regarding health care organisations are complementary.

Health care organisations are obliged to comply with regulatory safety matters.

Surveyors are not responsible for checking compliance with these regulatory safety matters, but they should nevertheless ensure that all health care organisations have internal and/or external procedures in place for dealing with any comments or recommendations made after a regulatory assessment. Health care organisations should therefore make any summary reports of such assessments available to the surveyors, for consultation on-site.

These summary reports will focus on the conclusions and recommendations of reports or audits produced after routine ad hoc regulatory inspections, or instigated at the initiative of the health care organisation, demonstrating its ability to address the following areas adequately:

- safety of people and premises, including fire safety and hygiene;
- food safety, including water used for food purposes;
- pharmacy;

- specific prevention programmes (covering medical devices, labile blood derivatives and other biological products, adverse drug reactions);
- sterilisation;
- safety during anaesthesia;
- water, air, fluids;
- collection and disposal of hospital waste;
- other controls of compliance (e.g. compliance with technical specifications).

If the surveyors are not able to examine this information, or if the recommendations are not being put into practice by the health care organisation, the survey results will contain major reservations (see sub-section Chapter 2-I-3). At times, the surveyor may feel obliged to notify the agency of the situation observed before the end of the survey. These reservations will appear in the report issued by the Accreditation College.

## **2. Timing**

- **Enrolment in the procedure**

Health care organisations must have enrolled in the accreditation procedure within 5 years of publication of the statute of April 26<sup>th</sup>, 1996. If a health care organisation has not done so, the Regional Hospital Agency will formally ask it to enrol in the procedure.

- **Interval between accreditation procedures**

A period of 5 years may elapse from the end of the accreditation procedure until the next accreditation procedure is due, if there are no specific follow-up requirements.

## **3. Mutual commitments of the parties involved**

The accreditation procedure requires both parties to comply with the following commitments.

- **Confidentiality**

During the self-assessment phase, the accreditation procedure involves all professionals working in the health care organisation; later, during the survey, it involves the surveyors and finally, the members of the Accreditation College.

Neither compliance with the procedure nor the quality of results can be guaranteed if any of the individuals involved should at any time prematurely communicate any information about the course of the process, or intermediate results. It is therefore the responsibility of the health care organisation and of ANAES to maintain the confidentiality of the process, each in their own area of concern, until the conclusions of the accreditation procedure have been published.

If confidentiality is not maintained ANAES may in relation with the health care organisation, suspend the procedure.

- **Transparency and accuracy of information provided, and accessibility to information and data**

When a health care organisation has enrolled in the accreditation procedure, it is obliged to disclose faithfully any information in its possession which is required in order to assess the quality and safety of care.

The health care organisation should facilitate access to any information needed by ANAES' authorised representatives. This is particularly relevant during the accreditation survey, when the health care organisation should ensure that surveyors have access to any documents and people they wish to see.

The health care organisation and ANAES undertake to inform each other at any time of any developments or facts which could affect the course of the accreditation procedure.

For example, a health care organisation should inform ANAES of any changes which could affect the process (status, investigation, sanction, etc.), which may have occurred since it enrolled in the procedure.

If these rules of transparency are not observed, ANAES may in relation with the health care organisation, suspend the procedure.

#### **4. The obligation to notify**

It is possible that surveyors may become aware during the survey of situations or shortcomings which could compromise patient safety. The surveyors are obliged to report any such circumstances immediately to the Executive Director of ANAES, who will immediately notify the director or manager of the health care organisation, and to the competent authorities (the competent Regional Hospitals Agency, Health and Social Affairs Council for the relevant *département*, etc.). Depending on the circumstances, a decision should be taken in conjunction with the health care organisation on whether such a notification means that the accreditation process should continue or be suspended.

#### **5. The health care organisation's financial contribution to accreditation**

Health care organisations are required to pay ANAES a financial contribution towards accreditation.

- **Breakdown of expenses**

The contribution to the financing of the accreditation procedure is intended to cover the following expenses incurred in implementing the accreditation procedure in a health care organisation:

- the cost of arranging and organising surveys, consisting of the salaries of ANAES staff specifically allocated to the task of arranging surveys and managing the surveyors;

- surveyors' training costs;
- surveyors' travel costs and fees;
- compensation paid to the surveyors' usual place of work;
- expenses relating to the printing, storage, and distribution of analysis documents required for and generated by the procedure;
- the operating expenses of the Accreditation College.

Other expenses, such as the cost of producing and revising the manual and remuneration of ANAES staff dealing with the accreditation process, are financed by Agency with income obtained from sources other than the financial contribution of health care organisations.

- **Determining the financial contribution payable by each health care organisation**

The amount of the financial contribution payable by each health care organisation is decided on the basis of two criteria: the number of days required and the number of surveyors required to carry out the survey. These in turn depend on the size of the health care organisation, the number of sites (if appropriate), and the range of its clinical activities.

In particular, the findings from the pilot testing of the accreditation procedure made it possible to produce estimates for duration and composition of the team of surveyors, according to the different types of health care organisations and the way in which they are managed. Increased experience of accreditation will make it possible to refine the process of estimating survey resources.

The total financial contribution payable by each health care organisation will be determined after it has applied to enrol in the procedure and will appear in the accreditation contract (see below, Chapter 2-II-2).

- **Payment dates for the financial contribution**

Legal and regulatory provisions will determine the payment dates for the financial contribution payable by all health care organisations who have applied to enrol in the accreditation procedure.

## **II. STEPS OF THE PROCEDURE**

### **1. Application to enrol in the accreditation procedure**

As accreditation applies to the health care organisation in the legal sense of the term, it is the responsibility of the legal representative of the health care organisation to decide on the best time to apply to ANAES to enrol in the accreditation procedure.

When a health care organisation has several hospital sites, it is the responsibility of the legal representative of the health care organisation to decide on a timetable for each of the sites to enrol in the procedure, bearing in mind that the applicability of the standards to each of the sites will have to be verified.

The consultative and decision-making bodies of the health care organisation are consulted before an application is made to enrol in the procedure.

The Ministerial Order relating to the documentation accompanying an application for enrolment specifies that this documentation should be accompanied by detailed information describing the health care organisation, which should include:

- an organisation chart for the health care organisation;
- existing documents which describe the health care organisation and its activities:
  - the status of the health care organisation,
  - a description of the health care organisation's catchment area, its activities and structures, principal diseases treated, its human and financial resources – this information may be available in the annual report and/or in the Secretary's report for the previous year;
  - the development plan, or failing that, an orientation statement providing the following information:
    - methodology used to produce the development plan or orientation statement;
    - the health care organisation's future plans for satisfying environmental requirements;
    - any projects or plans concerning medical or social matters, care or communication;
    - a timetable for implementing these projects or plans,
    - most recent final implementation report;
  - a social audit for the last three years;
  - the health care organisation's information booklet for patients;
  - buildings plan and access plan for the site.

This information will enable ANAES staff to familiarise themselves with the health care organisation, its activities, size, and plans for development, and to make a first draft of how the procedure will take place, particularly in terms of the survey time required.

The application to enrol in the accreditation procedure is sent by recorded delivery to the Executive Director of ANAES.

## 2. Enrolment in the accreditation procedure

After ANAES has examined the enrolment application, a dialogue is established between the health care organisation and ANAES, leading to a draft **accreditation contract**.

The draft contract lists the principles and the commitments made by both sides, and also contains:

- a timetable for the procedure (self-assessment, survey);
- the duration of the survey, the number of surveyors and the composition of the team;
- the financial contribution to accreditation payable by the health care organisation.

The contract is sent to the legal representative of the health care organisation and the Executive Director of ANAES respectively, for signature.

As soon as the contract has been concluded, the Regional Hospital Agency is informed that the health care organisation has enrolled in the accreditation procedure and is sent the timetable for the procedure.

The accreditation contract is a formal agreement which commits both the health care organisation and ANAES to comply with the agreed timetable.

The team of surveyors will be booked in accordance with this timetable, and their employer organisations notified.

Once the contract has been signed, ANAES sends the health care organisation the analytical documentation (standards, user guides, data collection forms) that they need to begin the self-assessment phase.

## 3. Self-assessment

Self-assessment is the fundamental step of the accreditation procedure, when all professionals in the health care organisation carry out their own quality assessment against the standards.

The self-assessment covers all the health care organisation's activities.

- **The self-assessment procedure**

A user guide has been produced to assist health care organisations in carrying out the accreditation process, entitled “Préparer et conduire votre démarche d'accréditation” (*Preparing for and implementing an accreditation initiative in your organisation*).

The guide offers advice and recommendations about carrying out the various steps of the procedure. It is based on the results of the pilot testing carried out during the last six months of 1998 in 40 health care organisations. It is intended as a guide, as each health care organisation is free to implement its accreditation initiative in whatever way it considers to be appropriate to its own circumstances.

- **Results**

At the end of the self-assessment phase, the health care organisation sends the results of the self-assessment to the Executive Director of ANAES.

The results include a sheet explaining the self-assessment methodology used by the health care organisation, and an evaluation of the self-assessment results by standard.

The assessment should be presented in the structured form recommended by ANAES. It is based on the results of the analysis carried out by the health care organisation against each standard and criterion.

#### **4. Accreditation survey**

- **Surveyors**

A team of surveyors has to be formed to carry out the accreditation survey

⇒ **Selection of surveyors**

It is the surveyors who ensure that the accreditation procedure is objective; they are professionals from various health care professions, with experience and knowledge of how health care organisations operate, who recognise and understand the principles of quality and accreditation and who are trained in their new role by ANAES. They must have the ability to listen, they have to be able to use an analytical approach, and they need to be good observers; during the survey they need to identify the strong points of the health care organisation and also areas where a process of improvement can be established.

⇒ **Composition of the team of surveyors**

Surveyors work in multidisciplinary teams with at least 3 members, including a doctor, a paramedical professional and an administrator.

They may be called on to work in any type of health care organisation, quite independent of the type of facility in which they are principally employed, to encourage cross-exchange of experience.

However, in order to facilitate the dialogue between the team of surveyors and the health care organisation surveyed, ANAES will ensure that the surveyors include at least one professional who works in the same type of health care organisation as the one being surveyed. Similarly, if the health care organisation

is mainly involved in one specific activity, ANAES will ensure that one of the surveyors works or has worked in a health care organisation carrying out a similar activity.

The composition of the team of surveyors is decided by the Executive Director of ANAES and is notified to the legal representative of the health care organisation.

⇒ **Survey coordinator**

One member of the team of surveyors acts as the survey coordinator; this is not a permanent post, and it is not held by a representative of one specific profession.

The role of the survey coordinator is one of leadership, regulation and coordination. Together with the health care organisation and ANAES, the survey coordinator is responsible for validating the survey plan, coordinating the writing of the expert report, and acting as the interface between the surveyors and the members of the Accreditation College examining the expert report.

⇒ **Conditions of work – Accreditation surveyors' charter**

Surveyors may not spend more than a third of their working time on accreditation.

However, in order to allow surveyors to gain experience in carrying out accreditation surveys, they are required to conduct a minimum of 6 surveys over a 2-year period.

In order to ensure consistency in the way the accreditation procedure is applied across all health care organisations and to ensure that its fundamental principles are complied with, an “**accreditation surveyor's charter**” has been produced, which defines the conditions under which surveyors carry out the mission entrusted to them by ANAES and acts as a guarantee for both surveyors and the health care organisations surveyed.

The charter will evolve as experience is gradually acquired in conducting accreditation surveys.

⇒ **Surveyor training**

Surveys need to be conducted using a standardised, objective methodology. ANAES therefore gives surveyors both initial and ongoing training in carrying out accreditation surveys in health care organisations.

⇒ **Surveyor assessment**

ANAES assesses its surveyors to ensure that their work in health care organisations is consistent with what is required of them.

The assessment is made both by the health care organisation surveyed and by the team of surveyors.

⇒ **Right of objection**

A health care organisation may make an objection to a surveyor before the accreditation contract is signed; the objection is made by the health care organisation's legal representative to the Executive Director of ANAES. However, an objection is only admissible if it is made because the surveyor practices professionally in the region where the survey is to take place, or because of a conflict of interests.

• **Preparation for the survey**

⇒ **Planning the survey**

When the results of the self-assessment are sent to ANAES, the health care organisation proposes a survey plan, which takes account of both survey duration and the composition of the team of surveyors. The survey plan is discussed and modified, if necessary, with the survey coordinator.

⇒ **Preparation**

The user guide, "Préparer et conduire votre démarche d'accréditation" (*Preparing for and implementing an accreditation initiative in your organisation*) describes how health care organisations should prepare for the survey.

At this stage, the main focus is on preparing the documents which will be examined on-site by the team of surveyors and on informing staff about the various steps of the survey.

• **The accreditation survey**

The accreditation survey is the second step of the procedure. The survey covers all the activities of the health care organisation and is conducted on the basis of the standards that were used for the self-assessment.

The accreditation survey is conducted in order to help the health care organisation assess the effectiveness of its continuous quality improvement process, on the basis of the self-assessment results.

⇒ **Survey methodology**

Surveys are conducted in confidence. The health care organisation communicates to the surveyors all the documents they need for their analysis.

The user guide “Préparer et conduire votre démarche d’accréditation” (*Preparing for and implementing an accreditation initiative in your organisation*) gives details of the course of each step of the survey.

At the same time, the surveyors use the “Guide de l’expert-visiteur” (*Surveyor’s Guide*) which ensures that the process is carried out in a uniform and consistent manner in all the health care organisations surveyed.

- **Expert report**

At the end of the survey an expert report is produced, based on the results of the self-assessment and the information collected during the survey.

The purpose of this report is to highlight the momentum generated within the health care organisation regarding improvement in the quality of care and services delivered, and the effect of the internal organisation of the health care organisation on quality.

The report comes in two parts, i.e. an assessment of the methods used by the health care organisation to conduct its self-assessment, to prepare for the survey and to participate in the survey itself; and an assessment of the survey results against each set of standards.

The report should be presented in the structured form recommended by ANAES, and is based on the information collected and analysed at the various steps of the survey and on the results of the self-assessment.

It is sent by the Executive Director of ANAES to the legal representative of the health care organisation not later than two months after the survey has taken place.

- **Comments by the health care organisation on the expert report**

The health care organisation has a period of one month from receipt of the expert report to produce its comments.

The health care organisation can take the initiative in proposing solutions or plans for improvement in the light of the recommendations made, as well as the internal indicators which it proposes to use during follow-up to measure its progress.

## **5. Conclusion of the procedure by the Accreditation College, and accreditation report**

### **• The Accreditation College**

#### **⇒ Missions**

The Accreditation College has two missions:

- to examine and make decisions on the results of the procedure for each health care organisation;
- to produce an annual summary of the results of accreditation procedures conducted by health care organisations.

These missions are carried out as a continuation of the previous steps of the accreditation procedure.

#### **⇒ Composition**

The Accreditation College consists of:

- 3 members appointed for their competence and experience in the area of management of health care organisation
- 3 members appointed for their competence and experience in the area of medical care in health care organisations, at least one of whom is qualified in hospital hygiene;
- 3 members appointed for their competence and experience in the areas of pharmacy or paramedical care in health care organisations;
- 2 physicians appointed for their competence and experience in the areas of quality and safety of care, assessment or accreditation.

#### **⇒ Appointment of members of the Accreditation College**

Members of the Accreditation College are appointed by the Minister of Health for a period of 3 years which may be renewed once. Half the members are replaced every 18 months.

They are appointed on the proposal of a full meeting of the Scientific Council after the Administrative Council has been consulted.

A deputy is appointed for each member of the Accreditation College; the deputy only attends meetings if the member is absent or cannot attend himself.

The Accreditation College elects a chairman for a period of 3 years.

- **Conclusion of the procedure**

The expert report is sent to the Accreditation College which examines it.

For each report, the Accreditation College appoints three of its members, from three different professions, to act as reviewers for each dossier. These members of the College meet with the survey coordinator to ensure continuity.

A further accreditation survey may be requested if this is felt to be necessary.

At the end of the review, the College decides whether it is satisfied with the accreditation procedure. It will come to this decision after considering the introduction to the expert report, which relates to the methodology adopted for the various steps of the procedure.

- **The accreditation report**

The accreditation report comes in two parts. The first part contains all the relevant conclusions from the expert report and all the comments made by the health care organisation, while the second part contains the conclusions of the Accreditation College. The College makes its own assessment, decides on recommendations to be adopted taking the surveyors' proposals into account, determines how these recommendations will be followed up by the health care organisation and by ANAES, and decides when the health care organisation should repeat the accreditation procedure.

The accreditation report is therefore an individual assessment of each health care organisation which satisfactorily completes the accreditation procedure.

At the end of the accreditation procedure, the assessment is presented as a classification, specifying the nature of any follow-up and the interval before the next accreditation procedure. The classification is:

Assessment	Follow-up	Time to next procedure
no recommendations	the health care organisation pursues its quality improvement program.	5 years
with recommendations	the health care organisation produces a report of follow-up of the recommendations, to be examined at the time of the next procedure.	5 years
with reservations	the health care organisation produces a report of follow-up activities and sends it to ANAES by an agreed deadline.	less than 5 years
with major reservations	the health care organisation provides solutions within a given period for the points which were the subject of the major reservations.	less than 5 years, and a targeted survey at a specified time, concentrating on the points which were the subject of the major reservations.

The Accreditation College will take local circumstances into account when deciding on the classification category, and will ensure that dossiers submitted for its assessment are all treated in the same way.

## 6. Communication of the results of the accreditation procedure, and appeal by the health care organisation

Results may be notified at the end of the accreditation procedure in one of two ways.

- **The accreditation report**, which is sent by the Executive Director of ANAES to the health care organisation and to the director of the competent Regional Hospital Agency. The health care organisation has an opportunity to contest the conclusions of the procedure with the Accreditation College for a period of one month from receipt of the accreditation report; the Accreditation College may as a result review its decision.
- **A summary of the accreditation report** is sent by the Executive Director of ANAES to the health care organisation.

This summary contains at least any recommendations made by the Accreditation College, and the deadline by which they should be addressed. The report may be consulted on request by the public or interested health professionals.

## Chapter 3

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# THE STANDARDS - HOW THEY WERE DRAFTED, AND WHAT THEY COVER

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## I. HOW THE STANDARDS WERE DRAFTED

The standards were produced by a process of repeated review conducted with professionals working in health care organisations.

### 1. Determining the areas for which standards would be produced

- **Analysis of the professional literature and regulatory texts**

A literature analysis was conducted on the following subjects:

- accreditation in general;
- experiences of accreditation in other countries;
- the standards produced in France by health care organisations, academic bodies and groups of professionals.

Particular attention was paid to manuals from other countries which had the most developed systems (*Joint Commission on Accreditation of Healthcare Organisations, Canadian Council on Health Services Accreditation, Australian Council on Healthcare Standards, King's Fund, CASPE Research*) and documents produced in France (National Federation of Cancer Centres, various health care organisations, etc.).

In addition, exchanges have been undertaken since 1994 with foreign accreditation agencies in the form of visits, meetings and international projects, and in the ANAES Scientific Council, where some of these international agencies are represented.

- **Surveys of professionals and users of health care organisations**

Following the literature analysis, surveys were conducted among professionals working in health care organisations and among members of the public to decide which areas were to be covered.

ANAES consulted professionals in two surveys carried out by the market research organisation IPSOS in 275 health care organisations selected at random; one survey was done in September 1997, and the other in January 1998.

A third survey, a telephone survey of 1,002 people, was conducted by IFOP in February 1998.

After these surveys, an initial shortlist was produced of the areas for which standards were likely to be drafted.

## 2. Drafting the standards

- **The standards were drafted by working groups**

⇒ **Composition of the groups**

- groups were made up of 12 to 15 professionals,
- they were balanced both geographically and in terms of the type of health care organisation in which participants worked,
- they comprised people with specific expertise relevant to the subject being addressed by the working group, even outside the domain of health (for example, a legal expert for matters concerning patient rights and information),
- they included patients' representatives,
- the basic structure of each group was:
  - administrators: 1 from the private sector, 1 from the public sector
  - doctors: 1 from the private sector, 1 from the public sector
  - carers: 1 from the private sector, 1 from the public sector

150 people took part in the working groups:

- 84 came from public health care organisations,
- 50 came from private health care organisations,
- 7 were experts in specific fields (legal, quality, etc.) outside health care organisations,
- 9 were patients' representatives.

Alltogether, 57 doctors, 37 administrators, 40 paramedical professionals, 7 outside experts, 9 patients' representatives.

⇒ **Method**

A first draft of the standard was produced by ANAES and discussed at the first meeting of the group.

An amended version was then sent to each member of the group. Their comments were edited and a draft circulated to the whole group; this was then discussed at a second meeting held to define how the standards and criteria were to be assessed and weighted.

A new, corrected version was produced and again sent to each member for validation and comments.

- **Editing the standards**

- The standards were edited over four one-day meetings.
- Two or three sets of standards were dealt with at each meeting.
- Each editing group consisted of:
  - 2 members from the Department of Evaluation of Health Care Organisations of ANAES;
  - 8 to 10 members of the health care organisation assessment network;
  - 2 members from the Department of Accreditation of ANAES.

More than 30 professionals working in health care organisations were involved in this revision phase.

### **3. Testing in a sample of health care organisations**

The tests took place in May 1998 in 12 volunteer health care organisations which differed in size, status and type of activity. Each health care organisation had to test the standards dealing with the organisation of patient care and two other sets of standards.

The comments of the health care organisations were collected from an analysis sheet produced for the purpose.

Overall, the standards were judged to be relevant, and constructive proposals were formulated.

These were incorporated into the versions submitted to the Scientific Council.

### **4. Pilot testing of the accreditation procedure on the basis of the July 1998 version of the standards**

During the last six months of 1998, the accreditation procedure was tested using the standards which appeared in the 1998 experimental version of the accreditation manual. This pilot testing was carried out in 40 volunteer organisations, representing different types of health care organisations in France.

During this phase, comments and further suggestions were collected on the use of accreditation standards both during the self-assessment phase and during the survey.

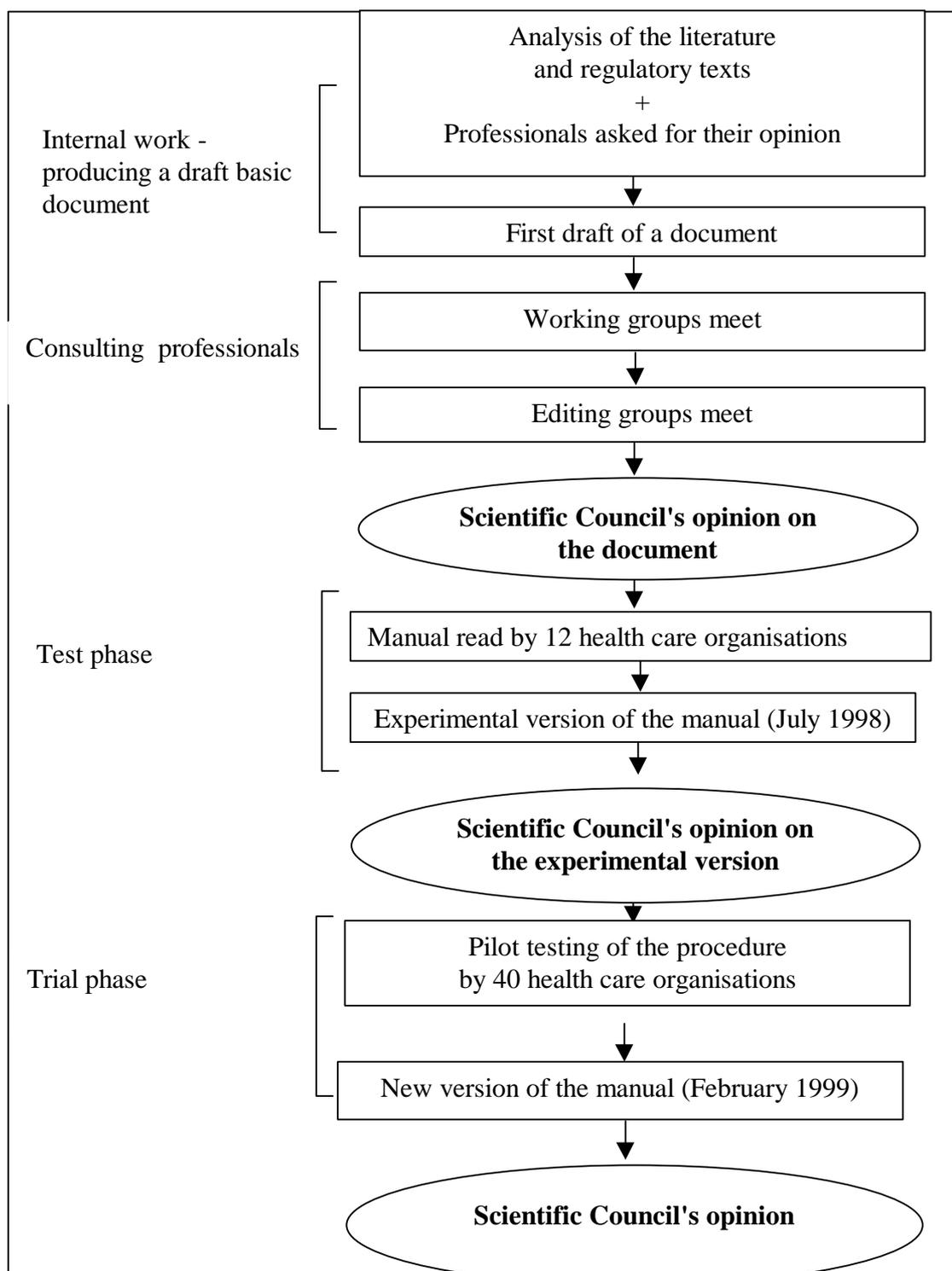
### **5. Role of the Scientific Council**

Throughout the standard drafting process, the Accreditation Section of the Scientific Council monitored progress and contributed their observations and comments.

A combined meeting of the evaluation and accreditation sections of the Scientific Council was asked for its opinion on the experimental version and the present version of the accreditation manual.

The process used to produce the standards and criteria can be represented diagrammatically, as shown below:

### How the standards and criteria were produced



## II. STRUCTURE OF THE STANDARDS

The structure of each set of accreditation standards is based on the standards themselves, broken down into criteria; the order in which they are given is the same for all sets of standards.

### 1. Standards and criteria: definition and mode of use

- **Definition**

**An accreditation standard** is defined as the statement of an expectation or requirement which makes it possible to deliver quality care or services.

**A criterion** is the statement of a method or more precise element which makes it possible to satisfy the accreditation standard. As far as possible, it should be measurable, objective, and achievable.

- **Mode of use**

The tone of the standards is affirmative and positive. They express expectations and objectives to be achieved.

The criteria used to satisfy the standards are not exhaustive; a health care organisation may have found other ways of achieving the objective.

During the self-assessment phase, professionals in the health care organisation question themselves about the standards and the criteria they are broken down into, to try to answer the following questions:

- What are we doing to satisfy ... ?
- How are we trying to make progress in ... ?
- How are we measuring our progress in ... ?

During the accreditation survey, the surveyors put similar questions to the people they meet and evaluate these objective elements which support the statements made by the health care organisation.

In order to ensure that the self-assessment results and survey assessments are objective, ANAES will gradually provide both health care organisations and surveyors with measures which will help in evaluating criteria and standards.

These supporting measures will be expanded as experience of the accreditation procedure grows and as the responses of the health care organisations are analysed.

## 2. Organisation of the standards

A common structure has been adopted for the various sets of standards in order to make them easier to use, both for self-assessment and during the accreditation survey. The standards are given in the following order:

- the policy defined by the health care organisation and/or activity sector to address the standard;
- the involvement of the various actors in formulating processes which support this policy;
- the tools and/or practices used to satisfy the standard; these are listed in order from beginning to end of the process, e.g.
  - organisation of patient care ⇒ from admission to discharge of the patient;
  - human resources management ⇒ from job planning to staff assessment;
  - patient records ⇒ from opening the record to archiving;
- evaluation of the results and levels of achievement regarding the objectives set by the health care organisation.

## 3. Properties of the standards

- **Exhaustive**

The standards adopt a cross-functional approach, covering all the activities of public and private health care organisations.

- **Applicable**

The standards were formulated and broken down in such a way that they can be applied to all health care organisations. However, in view of the regulatory provisions, some of the accreditation standards or criteria apply only to certain types of health care organisation.

- **Comprehensible**

In order to make them easier to understand, some standards or criteria contain explanatory boxes.

## III. STANDARDS AND CONTINUOUS QUALITY IMPROVEMENT

The process of continuous quality improvement within each health care organisation is evaluated particularly in the light of:

- the response made by the health care organisation to the first and last standard of **each** set of standards, which deal with the health care organisation's policy and with its evaluation of results and how far the objectives have been achieved, respectively;

- how the health care organisation is following up the recommendations made at the end of the accreditation procedure.

ANAES will continue to develop its evaluation of the process of continuous quality improvement, within the context of the accreditation procedure.

#### **IV. EVALUATION SCALE**

A four-grade evaluation scale for each accreditation standard is used to make it easier to record an evaluation during first the self-assessment, and then the survey.

Classification:

- grade A means that the health care organisation satisfies the standard;
- grade B means that the health care organisation largely satisfies the standard;
- grade C means that the health care organisation partially satisfies the standard;
- grade D means that the health care organisation does not satisfy the standard.

The classification also contains a grade which indicates that the standard does not apply to the health care organisation (NA).

#### **V. INDICATORS**

ANAES recommends that indicators should be developed and used to help in evaluating continuous quality improvement in health care organisations.

##### **1. Definition and characteristics**

An indicator is an objective data item which describes a situation in quantitative terms.

An indicator only has real significance if it makes it possible to define a situation and enable comparisons in time or space.

A valid indicator is:

- simple: understandable by the user, easy to implement, etc.;
- relevant: the measure should describe the phenomenon or expected objective.

Indicators are usually expressed as a ratio.

## 2. Types of quality indicators

- **Internal indicator / External indicator**

- ⇒ An internal indicator is an indicator chosen by a given facility (health care organisation, activity sector within a health care organisation, etc.) to evaluate change in a situation which they are trying to improve. An internal indicator may be provided only for internal use by the facility, but the facility may choose to make it a tool for external assessment of anticipated and attained results.
- ⇒ An external indicator is an indicator chosen by a structure external to a health care organisation; its purpose is to compare anticipated and achieved results in a target area.

The choice of the objective to be measured by the indicator is crucial in both cases.

- **Types of quality indicators**

Indicators can be classified as one of two types:

- ⇒ process indicators;
- ⇒ results indicators.

## 3. Methodological considerations of measurement and possible forms of bias

Indicators should be used with great caution. They should therefore possess the following properties:

- an indicator should be simple, defined, interpretable, reproducible, and measurable. The activities of health care organisations are complex and multidimensional. They may be difficult to measure, and the measures may not be meaningful until several years later. Results obtained using an indicator should be able to distinguish between what is related to the change in results itself, or to collection of data;
- an indicator should be pertinent. An indicator should apply to a significant number of cases or events. The definition and collection of data required to produce an indicator should be defined beforehand. The correct use of the data should be verified;
- an indicator should make it possible to evaluate over time a given situation or event.

The use of indicators may lead to negative or unanticipated effects, or to incorrect interpretation. Care should therefore be taken to ensure that:

- an indicator is examined in its context. It should encourage a dialogue between the professionals concerned. It may make it possible to identify problematic situations early on;
- an indicator is compared with measures derived from other sources. Any discrepancies between different measures should be examined.

#### **4. Future development of indicators in relation to the accreditation procedure**

- **Internal indicators, on the initiative of health care organisations**

- ⇒ **Indicators to support plans for continuous quality improvement**

In the context of the accreditation procedure, ANAES recommends that health care organisations develop tools to measure and evaluate anticipated and achieved results in terms of continuous quality improvement.

During the self-assessment phase and the accreditation survey, health care organisations will state which indicators they use and intend to use.

- ⇒ **Indicators used as a support for follow-up to Accreditation College recommendations**

During follow-up of recommendations for improvement made by the Accreditation College, the process will be monitored using internal indicators designed by the health care organisation itself, particularly in its comments of the expert report.

- ⇒ **Indicators to be recorded in health care organisations in 1999**

In order to be able to guide health care organisations in their assessment of quality levels, ANAES will compile a register of indicators used in health care organisations which enrol in the accreditation procedure in 1999, together with details of how they are being used and collected.

Some indicators likely to be used by health care organisations and ANAES are listed for information purposes in the user guide “Préparer et conduire votre démarche d’accréditation” (*Preparing for and implementing an accreditation initiative in your organisation*).

ANAES will produce a report on these indicators once it has collected substantial information about them.

As the accreditation process develops, ANAES will first record and then analyse the indicators used by health care organisations so that it can formulate recommendations to enable them to be used appropriately by health care organisations.

- **Indicators by activity sector**

In addition, discussion has begun with health professionals, particularly academic bodies, on the gradual development of clinical performance indicators, specific to different activity sectors.

## Chapter 4

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# THE STANDARDS

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### **I. PATIENTS AND PATIENT CARE**

1. Patient rights and information
2. Patient records
3. Organisation of patient care

### **II. MANAGEMENT AND ADMINISTRATION IN THE SERVICE OF THE PATIENT**

1. Management of the health care organisation and activity sectors
2. Management of human resources
3. Management of logistics
4. Management of the information system

### **III. QUALITY AND PREVENTION**

1. Quality management and risk prevention
2. Specific prevention programmes and transfusion safety
3. Monitoring, prevention and control of the risk of infection

## **I. PATIENTS AND PATIENT CARE**

- |   |       |
|---|-------|
| <b>1. PATIENT RIGHTS AND INFORMATION</b>                    | (DIP) |
| <b>2. PATIENT RECORDS</b>                                   | (DPA) |
| <b>3. ORGANISATION OF PATIENT CARE</b>                      | (OPC) |
| ⇒ <i>Access</i>   |       |
| ⇒ <i>Arrival</i>  |       |
| ⇒ <i>Assessment of needs and of the patient's condition</i> |       |
| ⇒ <i>Delivery of care</i>                                   |       |
| ⇒ <i>Discharge</i>  |       |
| ⇒ <i>Assessment of care</i>                                 |       |

DIP, Droits et information du patient

DPA, Dossier du patient

OPC, Organisation de la prise en charge du patient

## 1. PATIENT RIGHTS AND INFORMATION (*DIP*)

### • Introduction

The concept of patient rights arises from the universal rights of human beings and citizens, from the general principles of French law, and from rights more directly related to the patient's presence within a health care organisation. All these principles are summarised in the Hospital Patients' Charter. The health care organisation ensures that every patient can exercise his or her rights, and it implements any measures required to take these rights into account. Patient rights mainly involve access to care, freedom of choice and respect for personal dignity. Information is a specific concern within these rights.

### • Standards

*DIP - Standard 1*

**Patient rights and the right of the patient to be informed are priorities of the health care organisation.**

*DIP - Standard 2*

**The health care organisation ensures that care is accessible to all.**

*DIP - Standard 3*

**Patients are given clear, understandable and appropriate information about the conditions relating to their hospital stay.**

*DIP - Standard 4*

**Patients are given clear, understandable and appropriate information about their care and condition.**

*DIP - Standard 5*

**The patient's consent and/or that of their family or close friends is required for any procedure concerning their care.**

*DIP - Standard 6*

**The patient's privacy, personal dignity and liberty are respected throughout their stay or consultation.**

*DIP - Standard 7*

**Patients are assured that all personal, medical and social information, and details of their private life, are kept confidential.**

*DIP - Standard 8*

**There is a specific system for dealing with complaints made by patients.**

*DIP - Standard 9*

**The health care organisation evaluates how well it is respecting patient rights.**

- **Standards and criteria**

*DIP - Standard 1*

**Patient rights and the right of the patient to be informed are priorities of the health care organisation.**

*DIP.1.a.* The health care organisation has adopted the principles stated in the hospital patients' charter, and the development plan incorporates these principles.

*DIP.1.b.* The health care organisation, its Medical Committee and the DSSI or the Director of Nursing formulate a policy based on the principles of the hospital patients' charter.

*DIP.1.c.* Health professionals are made aware of the existence of the charter, and the document is available in all activity sectors.

*DIP.1.d.* Health professionals are trained in patient rights.

*DIP.1.e.* On arrival, patients are given a copy of the charter or a summary of it.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DIP - Standard 2*

**The health care organisation ensures that care is accessible to all.**

*DIP.2.a.* In an emergency, the health care organisation accepts all patients without distinction and irrespective of their situation with regard to social security cover.

*DIP.2.b.* The health care organisation is equipped to allow access and entry to disabled people.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DIP - Standard 3*

**Patients are given clear, understandable and appropriate information about the conditions relating to their hospital stay.**

- DIP.3.a.* The health care organisation ensures that patients who do not speak French have a means of expressing themselves and being understood.
- DIP.3.b.* Patients are given practical information about their stay in hospital.
- DIP.3.c.* Patients are given information about the administrative aspects of their care, fees and the total amount of the patient's financial contribution (if any).
- DIP.3.d.* Patients are given information about the function and identity of the members of staff who will be involved in their care.
- DIP.3.e.* The health care organisation encourages any measures to help the patient to receive assistance from the social services.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DIP.3.b. Examples of information about the patient's stay in hospital are:*

- *visiting hours;*
- *responsibilities related to living in a community, such as the prevention of noise nuisance, and restrictions on smoking in a hospital environment.*

*DIP - Standard 4*

**Patients are given clear, understandable and appropriate information about their care and condition.**

- DIP.4.a.* Patients or their legal representatives name the people whom they would like to be given information.
- DIP.4.b.* Health professionals give patients or the person(s) nominated by them information about the patient's condition and the care proposed for him or her; they encourage patients to ask for information.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DIP - Standard 5*

**The patient's consent and/or that of their family or close friends is required for any procedure concerning their care.**

- DIP.5.a.* The patient's informed consent is required for all medical procedures (unless the patient's condition requires a procedure to which they are not in a position to consent); when consent is requested, the patient is given information about the benefits and risks of the planned procedures.
- DIP.5.b.* Patients taking part in biomedical research give their consent in writing.
- DIP.5.c.* A patient who is a minor gives his or her opinion, which is taken into account as far as is possible. Apart from certain specific provisions, the holders of parental authority give their consent in writing.
- DIP.5.d.* The legal representatives of a legally incapacitated patient over the age of majority give their opinion in accordance with a procedure established within the health care organisation.
- DIP.5.e.* The health care organisation asks for prior agreement or refusal by the patient to donate and/or use products of the human body.
- DIP.5.f.* The patient gives his or her consent for screening for certain genetic or infectious (HIV) diseases.
- DIP.5.g.* The patient's carers are informed beforehand of any post-mortem examination (apart from a legal investigation of cause of death).

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DIP - Standard 6*

**The patient's privacy, personal dignity, and liberty are respected throughout their stay or consultation.**

- DIP.6.a.* Patients are examined and given an opportunity to have their questions answered in conditions of privacy which are conducive to a personal discussion.
- DIP.6.b.* Patients keep their personal effects with them throughout their stay in hospital, unless this is not possible for safety reasons. Arrangements are made for patients to store their personal effects and retrieve them.
- DIP.6.c.* The patient's privacy is respected while washing, while care is being given, and so on.
- DIP.6.d.* The patient's consent is obtained for students to be present during consultations.
- DIP.6.e.* Patients' religious beliefs are respected. Patients are informed that they may ask to see a minister of the religion of their choice.
- DIP.6.f.* The patient's right to go where he or she wishes is respected, except for reasons of safety or if this would contravene regulations.
- DIP.6.g.* Patients may leave the health care organisation at any time after they have been informed of any risks they may incur, unless this would contravene regulations. A request for a patient to leave against medical advice is formally documented by the health care organisation.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

<i>DIP.6.f. and DIP.6.g. Typical regulatory reasons might be compulsory hospitalisation or hospitalisation at the request of a third party.</i>
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*DIP - Standard 7*

**Patients are assured that all personal, medical and social information, and details of their private life, are kept confidential.**

- DIP.7.a.* Patients are assured that their presence in the health care organisation will not be divulged.
- DIP.7.b.* Professional secrecy is assured and the mechanisms needed to ensure this are developed by the health care organisation.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DIP - Standard 8*

**There is a specific system for dealing with complaints made by patients.**

- DIP.8.a.* The health care organisation encourages patients to make suggestions or complaints.
- DIP.8.b.* The health care organisation has established conciliation procedures and ensures that patients and professionals have information about them.
- DIP.8.c.* All complaints made by patients are investigated and responded to.
- DIP.8.d.* The activity sectors concerned are kept informed about any disputes with a patient.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

<p><i>DIP.8.a.</i> For example, the health care organisation may suggest a place where complaints may be heard.</p>
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*DIP - Standard 9*

**The health care organisation evaluates how well it is respecting patient rights.**

- DIP.9.a.* The health care organisation evaluates how well it is respecting patient rights.
- DIP.9.b.* The health care organisation has established a policy for improving respect for patient rights and information.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

## 2. PATIENT RECORDS (*DPA*)

- **Introduction**

The patient record is a crucial item in the communication of information among professionals. It is an instrument used for comment, summarising, planning, organising and ensuring traceability of care. It contains all the administrative, social, medical and paramedical information relating to a patient.

Any dysfunction in the record management system will cause problems ranging from simple loss of time to major deficiencies in patient care and the operation of the health care organisation.

The fundamentals of record management are therefore a well-organised system, clear definition of responsibilities, and daily recording of any relevant information by all professionals.

- **Standards**

*DPA - Standard 1*  
**The health care organisation formulates and implements a patient record policy for all its activity sectors.**

*DPA - Standard 2*  
**The authorities and professionals concerned are involved in formulating and implementing the patient record policy.**

*DPA - Standard 3*  
**Information contained in the patient record is covered by the rules of confidentiality.**

*DPA - Standard 4*  
**The keeping of patient records is an essential part of a reliable information management system.**

*DPA - Standard 5*  
**The information contained in the patient record ensures that care is coordinated between professionals and between activity sectors.**

*DPA - Standard 6*  
**Patient records are managed in a way that ensures access to information.**

*DPA - Standard 7*  
**The patient record is the subject of a strategy of assessment and continuous improvement.**

- **Standards and criteria**

*DPA - Standard 1*

**The health care organisation formulates and implements a patient record policy for all its activity sectors.**

*DPA.1.a.* Information is collected for each patient to ensure continuity of care.

*DPA.1.b.* There is a policy of encouraging a system where information held for each patient is collected together in one place within the health care organisation.

*DPA.1.c.* There is a policy in place to ensure that the confidentiality of records and information concerning the patient is maintained, particularly when identifiable information must be exchanged between professionals for diagnostic and treatment requirements.

*DPA.1.d.* The health care organisation has a system to ensure that patients have a right of access to their records via a practitioner who is freely chosen by the patient.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DPA - Standard 2*

**The authorities and professionals concerned are involved in formulating and implementing the patient record policy.**

*DPA.2.a.* Top management, the CME and the DSSI or Director of Nursing ensure that the procedures for keeping patient records are written down, validated, disseminated and evaluated.

*DPA.2.b.* Top management, the CME and the DSSI or Director of Nursing implement and maintain a system governing the flow and archiving of records.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DPA - Standard 3*

**Information contained in the patient record is covered by the rules of confidentiality.**

*DPA.3.a.* Health professionals are made aware of the question of confidentiality.

*DPA.3.b.* If a record is computerised, the patient is informed of this and of his or her right of access and amendment.

*DPA.3.c.* Confidentiality is maintained when items are removed from records.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DPA - Standard 4*

**The keeping of patient records is an essential part of a reliable information management system.**

- DPA.4.a.* A patient record contains all the details needed to identify the patient.  
*DPA.4.b.* The responsibilities of the various members of staff involved in keeping patient records (nurses, practitioners, house officers, medical secretaries, hospital students, other members of staff involved) are defined in writing.  
*DPA.4.c.* Prescriptions for medications are made out by the prescribing practitioner and dated, and contain the practitioner's name and signature.  
*DPA.4.d.* Patient records are organised and filed.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DPA - Standard 5*

**The information contained in the patient record ensures that care is coordinated between professionals and between activity sectors.**

- DPA.5.a.* As soon as possible after a patient has been admitted, the reasons for his or her admission to hospital and the findings of the initial assessment of his or her condition are added to the patient record, under the authority of the responsible practitioner.  
*DPA.5.b.* The patient record contains updated information on the progress of the patient's clinical condition and on their care.  
*DPA.5.c.* The patient record makes it possible at any time to find out what treatment, tests and care a patient has received or is due to receive.  
*DPA.5.d.* The patient record contains items of specialist information, when required.  
*DPA.5.e.* The patient record includes documentation of the considerations of benefits and risks related to the diagnostic and treatment strategy adopted for a patient before any invasive procedure.  
*DPA.5.f.* After the patient has been discharged, the record contains the final report of his or her stay, and of any specific requirements for follow-up.  
*DPA.5.g.* The doctor nominated by the patient is sent a written document which should arrive in sufficient time to allow for continuity of care.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DPA.5.d. Items of specialised information are, in particular:*

- *record of anaesthesia;*
- *operative report;*
- *report of labour and delivery;*
- *transfusion record;*
- *traceability record for blood products;*
- *the patient's written consent for situations which require it.*

*DPA - Standard 6*

**Patient records are managed in a way that ensures access to information.**

*DPA.6.a.* A patient record can be located and is accessible at all times.

*DPA.6.b.* Patient records are stored in a way that complies with archiving time requirements and security conditions.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*DPA - Standard 7*

**The patient record is the subject of a strategy of assessment and continuous improvement.**

*DPA.7.a.* The health care organisation assesses the quality of records.

*DPA.7.b.* The health care organisation implements a policy for improving records.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

### 3. ORGANISATION OF PATIENT CARE (*OPC*)

#### • Introduction

The functioning of a health care organisation should be such that it is possible to offer quality care and services in a safe environment, in accordance with the missions enshrined in the organisation's development plan, particularly in relation to the strategic orientations of its medical activity. The hotel services offered to patients and their carers are part of the quality of their care.

The principal ancillary medical services which interact with clinical activities are emergency care, interventional activities, clinical laboratories, anatomy, cytology and pathology, imaging, functional tests, the drug circuit and the use of medical devices.

The term “interventional activities” is used in a broad sense, as the intervention may take place in an operating theatre, a maternity unit, an endoscopy unit, or a radiological intervention unit, and anaesthesia may or may not be required.

These activities involve successive or simultaneous actions and require the services of a number of professionals, who have to work in coordination with each other. The complexity of the techniques and materials used in this interdisciplinary environment may lead to direct or indirect risks for patients; initiatives are therefore needed to safeguard patients.

This set of standards applies to all the clinical and ancillary medical activity sectors of the health care organisation.

#### PATH

- ➡ *Access*
  - ➡ *Arrival*
  - ➡ *Assessment of the patient's condition and needs*
  - ➡ *Coordination of care*
  - ➡ *Discharge*
- Care protocols and assessment of care*

- **Standards**

*Standard 1*

**The health care organisation has a policy on the organisation of patient care.**

*OPC - Standard 2*

**Access to the health care organisation and to its various activity sectors is planned and facilitated, and clear information is provided about it.**

*OPC - Standard 3*

**The health care organisation has a policy concerning the arrival of patients and their carers.**

*OPC - Standard 4*

**Care is planned on the basis of an initial and ongoing assessment of the patient's condition.**

*OPC - Standard 5*

**The patient's specific needs are identified and taken into account.**

*OPC - Standard 6*

**Patient care is coordinated within the various clinical activity sectors.**

*OPC - Standard 7*

**Continuity of care is ensured.**

*OPC - Standard 8*

**Health professionals involved in operating theatres, other intervention sectors and clinical activity sectors work together in formulating their operational procedures.**

*OPC - Standard 9*

**Health professionals in the pharmacy and the clinical activity sectors work together in formulating their operational procedures.**

*OPC - Standard 10*

**Health professionals from the laboratories and the clinical activity sectors work together in formulating their operational procedures.**

*OPC - Standard 11*

**Health professionals in the medical imaging or functional investigation sectors and the clinical activity sectors work together in formulating their operational procedures.**

*OPC - Standard 12*

**The patient's discharge is planned and coordinated.**

*OPC - Standard 13*

**Support is provided for dying patients.**

*OPC - Standard 14*

**Clinical and ancillary medical activity sectors use diagnostic and therapeutic protocols.**

*OPC - Standard 15*

**Clinical and ancillary medical activity sectors evaluate professional practices and their results.**

- **Standards and criteria**

*OPC - Standard 1*

**The health care organisation has a policy on the organisation of patient care.**

*OPC.1.a.* The medical plan and care plan are drawn up with professionals and define how patient care is organised.

*OPC.1.b* The health care organisation has a policy for its hotel services.

➔ **Access**

*OPC - Standard 2*

**Access to the health care organisation and to its various activity sectors is planned and facilitated, and clear information is provided about it.**

*OPC.2.a.* The general public and external health care professionals are informed about the activities of the health care organisation.

*OPC.2.b.* Access to emergency services is clearly signposted inside and outside the health care organisation.

*OPC.2.c.* Activity sectors ensure that the expectations of the public are taken into account, depending on the specific services they offer.

*OPC.2.d.* Activity sectors are clearly signposted within the health care organisation in order to make it easier for everyone to find their way round.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*OPC.2.c. Expectations of the public which may need to be taken into account include e.g. appointment times.*

➔ **Arrival**

*Patients are welcomed on arrival and at each step throughout their stay.*

OPC - *Standard 3*

**The health care organisation has a policy concerning the arrival of patients and their carers.**

- OPC.3.a. Patients are taken care of whenever they arrive.  
OPC.3.b. The arrival process ensures quick and efficient admission of the patient.  
OPC.3.c. The health care organisation organises immediate care for anyone arriving as an emergency, taking the degree of emergency into account.  
OPC.3.d. If a patient's situation is such that the health care organisation does not have the appropriate skills or facilities to deliver care, the organisation will send him or her to an appropriate facility.  
OPC.3.e. Measures are taken to reduce waiting times.  
OPC.3.f. The medical and administrative aspects of a planned stay are arranged prior to the patient's arrival.  
OPC.3.g. The health care organisation makes arrangements for accommodation and catering facilities for carers accompanying patients.  
OPC.3.h. The health care organisation operates a No Smoking policy.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

OPC.3.a. *The concept of welcoming patients at all times covers both answering the telephone and reception by health care professionals.*

- OPC.3.f. *The concept of arranging a planned stay is intended to cover the following:*
- *patients whose hospital stay has been planned are expected when they arrive in the care unit;*
  - *any tests planned have been scheduled for the patient's arrival;*
  - *the patient's record is at the care unit on his or her arrival.*

➔ **Assessment of the patient's condition and needs**

OPC - *Standard 4*

**Care is planned on the basis of an initial and ongoing assessment of the patient's condition.**

OPC.4.a. Any data obtained from previous consultations, previous hospitalisation or admission to an emergency service are available.

OPC.4.b. The patient's needs are identified and taken into account.

OPC.4.c. Further investigations and care are scheduled after a medical examination has been done.

OPC.4.d. The patient is involved in discussions to analyse the benefits and risks of any further investigations and care.

OPC.4.e. The patient's condition is assessed regularly and his or her care is adjusted, if necessary.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*OPC.4.b. Patient needs to be taken into account are his or her physical, psychological, social, functional and nutritional needs.*

OPC - Standard 5

**The patient's specific needs are identified and taken into account.**

- OPC.5.a. The clinical activity sector is made aware of the need to recognise situations which require a specific form of care.
- OPC.5.b. Acute or chronic pain and mental distress are looked for, prevented and managed.
- OPC.5.c. The specific needs of patients who are dying are addressed.
- OPC.5.d. Patients are educated about their disease and its treatment.
- OPC.5.e. Patients receive health education which is appropriate to their needs.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

OPC.5.a. *Examples of situations which require specific forms of management are violence, agitation, and suicidal tendencies. The specific needs of children (e.g. schooling) and of the elderly are identified.*

OPC.5.c. *In particular, training is given and interdisciplinary consultation takes place in order to meet the specific needs of a dying patient, so that a common strategy can be drawn up in collaboration with the patient's own doctor and the patient's carers.*

OPC.5.e. *Health education initiatives which patients may need include avoiding and giving up smoking, and dealing with alcoholism.*

➔ **Coordination of care**

OPC - Standard 6

**Patient care is coordinated within the various clinical activity sectors.**

- OPC.6.a. There are systems to ensure coordination between medical and paramedical professionals, so that global care can be provided for a patient within the clinical activity sector.
- OPC.6.b. The clinical activity sectors work together to provide interdisciplinary care for the patient.
- OPC.6.c. A competent opinion is sought from outside the health care organisation whenever the patient's condition calls for it.
- OPC.6.d. During the patient's stay in hospital, their referring doctor is kept informed.
- OPC.6.e. The professionals responsible for hotel services and those providing care coordinate their work with each other.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

OPC - Standard 7

**Continuity of care is ensured.**

- OPC.7.a. The patient's identity is verified at the various stages of care.
- OPC.7.b. There are rules concerning attendance, consultation and deputising, together with a duty and on-call rota system, which ensure that care is available 24 hours a day.
- OPC.7.c. There is a system to deal with major internal emergencies.
- OPC.7.d. There are procedures to ensure coordination of changeovers between medical or paramedical teams.
- OPC.7.e. Continuity of care is provided between activity sectors.
- OPC.7.f. Patient transport is arranged between activity sectors to ensure continuity of care in compliance with the rules of hygiene, quality, safety, and confidentiality.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

OPC.7.e. *Continuity of care between activity sectors is essential particularly when the patient is admitted to an activity sector from the emergency department, during internal transfers and when transported to and from ancillary medical service units.*

*OPC - Standard 8*

**Health professionals working in operating theatres, other intervention sectors and clinical activity sectors work together in formulating their operational procedures.**

- OPC.8.a.* Pre-, per- and post-intervention care is organised jointly by the operators, anaesthetists, and managerial staff of the sectors concerned.
- OPC.8.b.* In order to ensure continuity of the patient's pre-, per- and post-intervention care, the various professionals concerned transmit information in writing at each stage.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*OPC - Standard 9*

**Health professionals in the pharmacy and the clinical activity sectors work together in formulating their operational procedures.**

- OPC.9.a.* There are rules governing the conditions of prescription, validation of prescriptions, distribution and supply of medications to the clinical activity sectors.
- OPC.9.b.* There are rules governing the conditions of prescription, validation of prescriptions, distribution and supply of medical devices to the clinical activity sectors.
- OPC.9.c.* Conditions of use for medications and medical devices are available to users.
- OPC.9.d.* There are mechanisms for analysing the use of medications and medical devices.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

OPC - *Standard 10*

**Health professionals from the laboratories and the clinical activity sectors work together in formulating their operational procedures.**

- OPC.10.a. There are rules governing the conditions under which tests are prescribed, samples taken, and test results distributed and notified.
- OPC.10.b. Depending on the clinical circumstances, requests for tests give the clinical information required and the purpose of the request.
- OPC.10.c. The test results satisfy the requirements of the clinical activity sectors in terms of quality and timeframes for sending results.
- OPC 10.d. There are mechanisms for analysing the use of laboratory tests.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

OPC - *Standard 10*

*The term laboratory is used to cover, in particular, clinical laboratory tests and histopathology.*

OPC - *Standard 11*

**Health professionals in the medical imaging or functional investigation sectors and the clinical activity sectors work together in formulating their operational procedures.**

- OPC 11.a. There are rules governing the conditions under which tests are requested and carried out, and the results notified.
- OPC.11.b. Orders for imaging or functional investigations contain the clinical information required and the purpose of the request.
- OPC.11.c. Test results satisfy the requirements of the clinical activity sectors in terms of quality and timeframes for sending results.
- OPC 11.d. There are mechanisms for analysing the use of imaging or of functional investigations.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

➔ **Discharge**

OPC - *Standard 12*

**The patient's discharge is planned and coordinated.**

- OPC.12.a. Discharge planning begins when the patient is admitted, and is updated throughout his or her hospital stay.
- OPC.12.b. Patients are oriented to the care circuit appropriate to their situation.
- OPC.12.c. Discharge is arranged jointly with the patient and the patient's carers.
- OPC.12.d. When they are discharged, patients have the information and documentation they need to ensure continuity of care.
- OPC.12.e. The patient's referring doctor is informed when the patient returns home; if the patient's condition requires specific follow-up, the doctor is informed of their discharge beforehand.
- OPC.12.f. Continuity of care is provided when patients are transferred.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*OPC.12.d. The information provided to patients should enable them to participate actively in their treatment after their discharge from the health care organisation.*

OPC - *Standard 13*

**Support is provided for dying patients.**

- OPC.13.a. If a patient is in a critical condition, the people who need to be told are contacted.
- OPC.13.b. The dying person's wishes and convictions are respected.
- OPC.13.c. The patient's doctor is informed of their death.
- OPC.13.d. Psychological support is provided for the patient's carers.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

**Protocols and assessment of care**

OPC - *Standard 14*

**Clinical and ancillary medical activity sectors use diagnostic and therapeutic protocols.**

- OPC.14.a. The clinical and ancillary medical activity sectors follow the appropriate clinical practice recommendations for their type of activity.
- OPC.14.b. The clinical and ancillary medical activity sectors draw up diagnostic and therapeutic protocols in areas where such protocols are justified.
- OPC.14.c. The clinical and ancillary medical activity sectors assess the use of these protocols.

OPC - *Standard 15*

**Clinical and ancillary medical activity sectors assess professional practices and their results.**

- OPC.15.a. The clinical and ancillary medical activity sectors carry out assessments of professional practice.
- OPC.15.b. The clinical and ancillary medical activity sectors define indicators, and collect and use performance indicators.
- OPC.15.c. The clinical and ancillary medical activity sectors define the sentinel events which will be systematically analysed by a multidisciplinary team of health professionals.
- OPC.15.d. The clinical and ancillary medical activity sectors adjust their practices and instruments in accordance with assessment results.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*OPC.15.c. A sentinel event is an undesirable event which acts as a warning sign and triggers an investigation and in-depth analysis whenever it occurs. These events represent the extremes used in risk management and are difficult to subject to statistical analysis. They are defined by each clinical activity sector.*

*Examples of sentinel events are unexpected death, major complications, re-operation, the occurrence of certain nosocomial infections, unplanned readmission, discharge against medical advice, transfusion accidents.*

## **II. MANAGEMENT AND ADMINISTRATION IN THE SERVICE OF THE PATIENT**

- |   |              |
|---|--------------|
| <b>1. MANAGEMENT OF THE HEALTH CARE ORGANISATION AND ACTIVITY SECTORS</b> | <b>(MEA)</b> |
| <b>2. HUMAN RESOURCES MANAGEMENT</b>                                      | <b>(GRH)</b> |
| <b>3. LOGISTICS MANAGEMENT</b>  | <b>(GFL)</b> |
| <b>4. MANAGEMENT OF THE INFORMATION SYSTEM</b>                            | <b>(GSI)</b> |

MEA, Management de l'établissement et des secteurs d'activité

GRH, Gestion des ressources humaines

GFL, Gestion des fonctions logistiques

GSI, Gestion du système d'information

## 1. MANAGEMENT OF THE HEALTH CARE ORGANISATION AND ACTIVITY SECTORS (*MEA*)

### • Introduction

Delivering quality care to the patient means that the health care organisation and activity sectors have to make this a priority in everything they do. It is the responsibility of management to decide on the strategic orientations or development plan which will ensure that patients' needs are satisfied and to implement these plans under the best possible conditions of quality and safety, while at the same time ensuring that professionals from the various activity sectors are involved and working in coordination with each other. The involvement of top management is a determining factor in the success of these initiatives.

### • Standards

*MEA - Standard 1*

**The health care organisation has a development plan or a strategy statement.**

*MEA - Standard 2*

**Top management, the governing body, and the professionals' representatives of the health care organisation fulfil their responsibilities to the best of their abilities.**

*MEA - Standard 3*

**The health care organisation operates a communication policy.**

*MEA - Standard 4*

**The financial and budget policies contribute to achieving the goals of the health care organisation.**

*MEA - Standard 5*

**The health care organisation has a management monitoring system which provides for the involvement of activity sectors.**

*MEA - Standard 6*

**The internal management of each activity sector contributes to the promotion of improvement in patient care.**

*MEA - Standard 7*

**The position and role of professionals are identified. The head of the activity sector determines the**

**objectives to be achieved and participates actively in quality improvement activities.**

*MEA - Standard 8*

**Each activity sector monitors and assesses its resources.**

*MEA - Standard 9*

**The health care organisation and the activity sectors assess their achievements against the strategic orientations, at defined intervals.**

- **Standards and criteria**

*MEA - Standard 1*

**The health care organisation has a development plan or a strategy statement.**

*MEA.1.a.* The objectives contained in the development plan or strategy statement of the health care organisation are prioritised and achievable, and they form the basis for the planning, implementation and assessment of actions.

*MEA.1.b.* The health care organisation ensures that the representatives bodies, the activity sectors and the professionals are involved in producing the development plan or strategy statement.

*MEA.1.c.* The governing body or its equivalent determines the policy of the health care organisation by directing the designing of the development plan or strategy statement, and by approving the missions and objectives of the health care organisation.

*MEA - Standard 2*

**Top management, the governing body, and the professionals' representatives of the health care organisation fulfil their responsibilities to the best of their abilities.**

*MEA.2.a.* A functional organisation chart of top management has been produced, and professionals are aware of it.

*MEA.2.b.* The role and place of the governing body and of the representative bodies are defined.

*MEA.2.c.* The governing body and representative bodies are regularly consulted on subjects which come within their respective competence.

*MEA.2.d.* Channels of communication are defined and applied between top management and the CME, and between the CME and practitioners.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*MEA - Standard 3*

**The health care organisation operates a communication policy.**

*MEA.3.a.* The health care organisation has a policy for internal and external communication.

*MEA.3.b.* Both the public and the health professionals are made aware of the priorities of the development plan.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*MEA - Standard 4*

**The financial and budget policies contribute to achieving the goals of the health care organisation.**

*MEA.4.a.* The health care organisation has a financial strategy which extends over several years.

*MEA.4.b.* The health care organisation has a budget policy which involves the staff concerned.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*MEA - Standard 5*

**The health care organisation has a management monitoring system which provides for the involvement of activity sectors.**

*MEA - Standard 6*

**The internal management of each activity sector contributes to the promotion of improvement in patient care.**

*MEA.6.a.* The objectives and types of service provided by each activity sector are clearly defined and consistent with the development plan; they are monitored and an annual report is produced.

*MEA.6.b.* There is a system for dialogue between professionals in each activity sector in order to encourage the expression of problems and to find solutions to them.

*MEA.6.c.* Each activity sector is organised in such a way that it can deliver continuity of patient care. Professionals have rules concerning attendance, mutual consultation and delegation, and there is a system of duty and on-call rotas.

*MEA.6.d.* The head of the activity sector defines and organises its relationships with other activity sectors whose services may be required during patient care.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

MEA - Standard 7

**The position and role of professionals are identified. The head of the activity sector determines the objectives to be achieved and participates actively in initiatives to improve quality.**

MEA.7.a. Health professionals are aware of how activity sectors are organised.

MEA.7.b. The skills and areas of responsibility of the heads of activity sectors and of managerial staff are clearly defined and written down.

MEA.7.c. Heads of activity sectors ensure that all activities are measured, evaluated and improved; in particular, they see that initiatives for continuous quality improvement are operating satisfactorily.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

MEA - Standard 8

**Each activity sector monitors and assesses its resources .**

MEA.8.a. The head of the activity sector is aware of the operational costs of his or her activity sector and of its situation in relation to the resources allocated.

MEA.8.b. The head of the activity sector knows the skills of his or her staff, and uses this information for forward planning.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

MEA - Standard 9

**The health care organisation and the activity sectors assess their achievements against the strategic orientations, at defined intervals.**

MEA.9.a. Quantifiable goals are set and revised annually.

MEA.9.b. The health care organisation and the activity sectors concerned are informed of the results of this monitoring .

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

## 2. HUMAN RESOURCES MANAGEMENT (*GRH*)

- **Introduction**

The purpose of human resources management is to ensure the best possible fit between patient needs and human resources; it is essential to the proper functioning of the health care organisation.

The aim of the health care organisation's human resources plan is to generate general improvement in human resource management and in the way in which staff participate in the life of the health care organisation.

Areas where human resources management is involved are forward planning, the definition of jobs and functions, skills development, performance assessment, continuing education and social relations.

- **Standards**

*GRH - Standard 1*

**The health care organisation draws up and implements a human resources plan which is consistent with its values, mission and strategy.**

*GRH - Standard 2*

**An ongoing dialogue with staff is incorporated into the human resources management policy.**

*GRH - Standard 3*

**The Medical Committee of the organisation fulfils its responsibilities with regard to those areas of human resources management which are its concern.**

*GRH - Standard 4*

**Forward planning makes it possible to adjust available human resources according to changes in the health care organisation.**

*GRH - Standard 5*

**When staff are recruited, the job profile is taken into account and the applicant's qualifications are verified.**

*GRH - Standard 6*

**There are procedures for the induction and integration of professionals and trainees.**

*GRH - Standard 7*

**There are procedures for the assessment of staff at specified intervals.**

*GRH - Standard 8*

**There are continuing education programmes to improve staff skill levels.**

*GRH - Standard 9*

**Administrative procedures maintain the confidentiality, quality and security of personal information about staff.**

*GRH - Standard 10*

**Improvement in staff working conditions is one of the concerns of the health care organisation's human resources plan.**

*GRH - Standard 11*

**The health care organisation has processes for examining and improving the quality of human resources management.**

- **Standards and criteria**

*GRH - Standard 1*

**The health care organisation draws up and implements a human resources plan which is consistent with its values, mission and strategy.**

*GRH.1.a.* The human resources plan defines future requirements for human resources in relation to the needs of the health care organisation. It describes personalised management processes for health professionals, and it provides a framework for working conditions and social relations.

*GRH.1.b.* The structure of the health care organisation includes human resources management functions with clearly identified responsibilities.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GRH.1.a. Personalised management of professionals involves understanding their role and the relevance of their skills to the organisation.*

*The tools used in this type of management include job profiles, coaching, training and individual assessment.*

GRH - *Standard 2*

**An ongoing dialogue with staff is incorporated into the human resources management policy.**

GRH.2.a. Staff representation bodies meet at defined intervals and operate in accordance with internal regulations in dealing with subjects which fall within their competence.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

GRH - *Standard 3*

**The Medical Committee of the organisation fulfils its responsibilities with regard to those areas of human resources management which are its concern.**

GRH.3.a. The opinion of the organisation's Medical Committee is sought on the selection and recruitment of doctors, the implementation of a continuing medical education programme and the organisation of duty and on-call rotas.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

GRH - *Standard 4*

**Forward planning makes it possible to adjust available human resources to changes in the health care organisation.**

GRH.4.a. The health care organisation has a system for forward planning of human resources.

GRH.4.b. Forward planning of human resources ensures that care services are provided in accordance with job requirements, workload assessment, the need for staff replacement, and staff skills.

GRH.4.c. Up-to-date job profiles are produced. Responsibilities and requirements for all jobs are written down and notified.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

GRH.4.a. <i>Forward planning of human resources takes account of missions, types of activity, technologies used and staff demographics.</i>
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*GRH - Standard 5*

**When staff are recruited, the job profile is taken into account and the applicant's qualifications are verified.**

*GRH.5.a.* Recruitment is based on job profiles.

*GRH.5.b.* The qualifications of professionals with diplomas and degrees are verified during recruitment.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GRH.5.b. All relevant qualifications for the work are verified for everyone who applies to work in the health care organisation, whether or not they are permanent employees.*

*GRH - Standard 6*

**There are procedures for the induction and integration of professionals and trainees.**

*GRH.6.a.* The mission of the health care organisation, its strategic plan, activity sectors, organisation, functioning and management of information are explained to professionals and trainees.

*GRH.6.b.* In each activity sector, information about the job concerned is provided for each professional or trainee; this covers safety requirements, infection control and prevention, and strategies in place to improve quality of care.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GRH - Standard 7*

**There are procedures for the assessment of staff at specified intervals.**

*GRH.7.a.* An annual interview takes place between each member of staff and the managerial staff, and a report is produced.

*GRH.7.b.* Individual training needs are identified.

*GRH.7.c.* Goals are set for the following year.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

GRH - *Standard 8*

**There are continuing education programmes to improve staff skill levels.**

GRH.8.a. Staff training needs are identified.

GRH.8.b. There is a programme to maintain and improve skill levels, which is customised to fit the identified needs of the staff of the health care organisation.

GRH.8.c. Continuing education contributes to the career promotion policy of the health care organisation.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

GRH - *Standard 9*

**Administrative procedures maintain the confidentiality, quality and security of personal information about staff.**

GRH.9.a. There is an information system which collects all data required for staff administration.

GRH.9.b. A complete file is produced and kept up-to-date for each member of staff.

GRH.9.c. Information about staff is confidential.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

GRH - *Standard 10*

**Improvement in staff working conditions is one of the concerns of the health care organisation's human resources plan.**

GRH.10.a. Working conditions are evaluated at specified intervals.

GRH.10.b. An annual plan for improving working conditions is implemented, monitored and evaluated.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GRH - Standard 11*

**The health care organisation has processes in place for examining and improving the quality of human resources management.**

*GRH.11.a.* Surveys are carried out to evaluate staff satisfaction.

*GRH.11.b.* The human resources management policy is evaluated using indicators which are monitored at set intervals.

*GRH.11.c.* Measures are taken to improve the existing processes.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

### 3. LOGISTICS MANAGEMENT (*GFL*)

- **Introduction**

The logistics function ensures continuity in the services provided to the patient. The main logistic functions are the organisation of purchasing and supply, availability of equipment and appropriate facilities, transport, hotel logistics, the maintenance and safety of installations and environmental safety.

- **Standards**

<i>GFL - Standard 1</i>	<b>The health care organisation's purchasing activities and equipment are adequate for its needs.</b>
<i>GFL - Standard 2</i>	<b>The health care organisation ensures the safety and maintenance of buildings, equipment and installations.</b>
<i>GFL - Standard 3</i>	<b>Catering services comply with hygiene regulations, understand the need to provide a balanced diet, and try to satisfy their customers.</b>
<i>GFL - Standard 4</i>	<b>The laundry service is organised in an appropriate manner.</b>
<i>GFL - Standard 5</i>	<b>The cleaning of premises and equipment complies with the safety and hygiene policy.</b>
<i>GFL - Standard 6</i>	<b>Transport is organised and coordinated.</b>
<i>GFL - Standard 7</i>	<b>The health care organisation has adequate waste disposal systems.</b>
<i>GFL - Standard 8</i>	<b>The health care organisation has security systems and staff to cover property and personal safety.</b>
<i>GFL - Standard 9</i>	<b>The health care organisation has a system to ensure personal safety in the event of fire.</b>
<i>GFL - Standard 10</i>	<b>Logistics services are evaluated in the activity sectors that use them.</b>

- **Standards and criteria**

*GFL - Standard 1*

**The health care organisation's purchasing activities and equipment are adequate for its needs.**

*GFL.1.a.* Requirements are evaluated in terms of both quantity and quality.

*GFL.1.b.* The purchasing process involves the staff who will use the items concerned.

*GFL.1.c.* Activity sector users receive supplies at set intervals.

*GFL.1.d.* There is a process for emergency provision of supplies.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

<p><i>GFL.1.b.</i> Purchasing processes cover the supply of consumables as well as equipment.</p>
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*GFL - Standard 2*

**The health care organisation ensures the safety and maintenance of buildings, equipment and installations.**

*GFL.2.a.* The health care organisation implements recommendations made following external control of buildings, installations and equipment.

*GFL.2.b.* There is a maintenance policy.

*GFL.2.c.* Preventive maintenance is carried out.

*GFL.2.d.* Repairs are carried out.

*GFL.2.e.* Written protocols exist for warnings and intervention, and the staff involved are familiar with them.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL - Standard 3*

**The catering services comply with hygiene regulations, understand the need to provide a balanced diet, and try to satisfy their customers.**

- GFL.3.a.* The central kitchen has a quality assurance system.
- GFL.3.b.* The meals distribution system complies with hygiene regulations which extend as far as the consumer.
- GFL.3.c.* Catering staff are trained in the hygiene regulations covering food distribution.
- GFL.3.d.* Meal production sectors, in cooperation with the clinical activity sectors, ensure that the catering service satisfies patients' needs and expectations (menu variety, timing and temperature of meals etc.).
- GFL.3.e.* The catering service takes the expectations of staff and other consumers into account.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL.3.b. The consumers of the catering service include:*

- *patients;*
- *people accompanying them;*
- *health professionals;*
- *children of staff, etc.*

*GFL - Standard 4*

**The laundry service is organised in an appropriate manner.**

- GFL.4.a.* There are protocols and formal assessment systems to cover the laundry service.
- GFL.4.b.* Clean linen is separated from dirty linen both during transport and in the activity sectors.
- GFL.4.c.* Health professionals in the activity sectors are trained in hygiene regulations concerning laundry.
- GFL.4.d.* The laundry process is monitored at set intervals.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL - Standard 5*

**The cleaning of premises and equipment complies with the safety and hygiene policy.**

- GFL.5.a.* There are protocols to cover the cleaning of premises and equipment, and cleaning is evaluated.
- GFL.5.b.* Staff who clean premises and equipment are trained.
- GFL.5.c.* The cleaning of premises and equipment is checked at set intervals.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL - Standard 6*

**Transport is organised and coordinated.**

- GFL.6.a.* The functions and organisation of the transport service are defined.
- GFL.6.b.* The transport service is subject to protocols covering safety, quality and hygiene.
- GFL.6.c.* The transport staff are trained.
- GFL.6.d.* The transport service is evaluated at set intervals, particularly in relation to waiting times and user satisfaction.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

<i>GFL</i>	<i>Standard 6</i>
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<i>The transport service concerns transport of both goods and people.</i>
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*GFL - Standard 7*

**The health care organisation has adequate waste disposal systems.**

- GFL.7.a.* Each category of waste is processed in an appropriate manner.
- GFL.7.b.* Staff responsible for waste disposal are trained.
- GFL.7.c.* The waste disposal process is evaluated at set intervals.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL - Standard 8*

**The health care organisation has security systems and staff to cover property and personal safety.**

*GFL.8.a.* The health care organisation has a system for looking after patients' property.

*GFL.8.b.* The health care organisation implements preventive measures to ensure personal safety.

*GFL.8.c.* Protocols for warnings have been drawn up and everyone is aware of them.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL Standard 8*

*Safety of property and personal safety covers both patients and professionals.*

*GFL - Standard 9*

**The health care organisation has a system to ensure personal safety in the event of fire.**

*GFL.9.a.* The health care organisation ensures that the Fire Safety Commission has carried out an inspection, and that its recommendations are being followed.

*GFL.9.b.* The health care organisation has introduced a fire prevention system.

*GFL.9.c.* Health professionals receive up-to-date training in fire safety.

*GFL.9.d.* Protocols covering alarms and measures to be taken in the event of fire are written down and all professionals are familiar with them.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GFL.9.b. Fire prevention measures include measures to ensure that the No Smoking requirement is complied with.*

*GFL - Standard 10*

**The logistics services provided are evaluated by the activity sectors which use them.**

#### 4. MANAGEMENT OF THE INFORMATION SYSTEM (*GSI*)

- **Introduction**

The information system is crucial to the operation of the health care organisation. There are a number of information flows involving the care, logistics, administrative and management functions.

The development of information technology has given health care organisations access to increasingly sophisticated information systems. The structure and coherence of the information system are determining factors in the satisfactory performance of the health care organisation and its ability to respond to the requirements of the various professionals and patients.

- **Standards**

*GSI - Standard 1*

**An information systems policy has been defined and implemented.**

*GSI - Standard 2*

**The necessary measures have been taken with regard to information management to protect confidentiality, security of information about patients and respect for their rights.**

*GSI - Standard 3*

**An activity sector dealing with medical information, the Medical Information Department or its equivalent, has been established to organise data collection and medical information management within the health care organisation.**

*GSI - Standard 4*

**The information system satisfies the needs of the professionals using it, and is the subject of a continuous quality improvement policy.**

- **Standards and criteria**

*GSI - Standard 1*

**An information systems policy has been defined and implemented.**

*GSI.1.a.* The health care organisation's information and computer systems are based on an overall design which is consistent with the development plan and drawn up in collaboration with the parties involved.

*GSI.1.b.* The information system covers all the activities of the health care organisation and encourages a coordinated and effective approach to the use of information, in particular for the assessment policy.

*GSI.1.c.* The authorities concerned are involved in monitoring the high level architecture of the information system.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GSI - Standard 2*

**The necessary measures have been taken with regard to information management to protect confidentiality, security of information about patients and respect for their rights.**

*GSI.2.a.* A policy has been defined and implemented concerning the protection of confidentiality of information about patients, and professionals are familiar with it.

*GSI.2.b.* Data security and data access systems are in place.

*GSI.2.c.* All computer programmes containing nominative data are declared to the CNIL.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GSI - Standard 3*

**An activity sector dealing with medical information, the Medical Information Department or its equivalent, has been established to organise data collection and medical information management within the health care organisation.**

*GSI.3.a.* An activity sector manager is responsible for medical information.

*GSI.3.b.* The functions of the activity sector responsible for medical information are defined by top management after consultation with the CME. The relevant internal regulations are drafted.

*GSI.3.c.* The use of medical information in terms of treatment given and methods used is submitted to the CME for its approval.

*GSI.3.d.* The activity sector responsible for medical information takes any necessary measures to guarantee and verify the quality of the medical data produced by the information system (PMSI).

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*GSI - Standard 4*

**The information system satisfies the needs of the professionals using it, and is the subject of a continuous quality improvement policy.**

*GSI.4.a.* There is a procedure for the regular collection of information about the needs, opinions and satisfaction levels of professional users.

*GSI.4.b.* Any dysfunction in the information system is recorded, analysed and dealt with.

*GSI.4.c.* There is a quality improvement plan produced with the participation of the professionals, defining priorities for improving the quality of the information system.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

### **III. QUALITY AND PREVENTION**

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|--|------------------------|
| <b>1. QUALITY MANAGEMENT AND RISK PREVENTION</b>                                       | <b>(QPR)</b>           |
| <b>2. SURVEILLANCE AND MONITORING OF HEALTH ACTIVITIES,<br/>AND TRANSFUSION SAFETY</b> | <b>(VST)<br/>(SPI)</b> |
| <b>3. MONITORING, PREVENTION AND CONTROL OF THE RISK OF<br/>INFECTION</b>              |                        |

QPR, Gestion de la qualité et prévention des risques  
VST, Vigilances sanitaires et sécurité transfusionnelle  
SPI, Surveillance, prévention et contrôle du risque infectueux

## 1. QUALITY MANAGEMENT AND RISK PREVENTION (*QPR*)

- **Introduction**

The effectiveness and complexity of practices within health care organisations imply a multitude of potential causes of dysfunction which may prevent optimum results being achieved, or lead to risk to both patients and professionals.

These risks include iatrogenic complications from diagnostic or therapeutic technical procedures, falls, work accidents and any other events which may compromise the safety of people who are present in the health care organisation.

The goal of quality management and risk prevention is to establish an operational system for the health care organisation which contains all the human, technical and organisational resources needed to satisfy patient needs, improve the quality of services, ensure continuity of care and prevent any hazards related to the care process.

- **Standards**

*QPR - Standard 1*  
**The health care organisation initiates, leads and maintains a quality policy based on quality management and risk prevention.**

*QPR - Standard 2*  
**There is a quality management process in place which takes account of customers' needs.**

*QPR - Standard 3*  
**Quality management makes it possible to control processes, jobs and documents.**

*QPR - Standard 4*  
**There is a risk prevention programme.**

*QPR - Standard 5*  
**The effectiveness of the quality management and risk prevention programme is evaluated.**

- **Standards and criteria**

*QPR - Standard 1*

**The health care organisation initiates, leads and maintains a quality policy based on quality management and risk prevention.**

*QPR.1.a.* The quality policy is defined by top management in consultation with the representative bodies (CME, DSSI, Technical Committee or equivalent) and the staff.

*QPR.1.b.* The quality policy has precise goals which can be measured over time, and which are expressed in the quality management and risk prevention programme.

*QPR.1.c.* The quality policy is incorporated into the development plan.

*QPR.1.d.* Staff are kept informed about the quality policy and its goals during its development and during its implementation in the health care organisation.

*QPR.1.e.* Responsibilities relating to quality management and risk prevention are identified.

*QPR.1.f.* Health professionals in the health care organisation receive training and assistance in methodology.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*QPR - Standard 2*

**There is a quality management process in place which takes account of customers' needs.**

*QPR.2.a.* The organisation takes steps to discover the requirements and level of satisfaction of patients and referring physicians.

*QPR.2.b.* The information collected is communicated to the professionals.

*QPR.2.c.* The information collected is used to establish or modify the quality management programme in order to improve the service delivered.

*QPR.2.d.* There is a system for dealing with complaints. This system ensures that complaints are analysed and that appropriate measures are taken to improve the situation.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

<p><i>QPR.2.a.</i> The steps taken to establish patient requirements and their level of satisfaction include the use of questionnaires which are completed when the patient is discharged.</p>
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*QPR - Standard 3*

**Quality management makes it possible to control processes, jobs and documents.**

*QPR.3.a.* Quality initiatives are implemented in the most important areas.

*QPR.3.b.* These initiatives are conducted by professionals using a multiprofessional approach.

*QPR.3.c.* Activity sectors write protocols for areas in which they will be useful.

*QPR.3.d.* Activity sectors evaluate the use of these protocols.

*QPR.3.e.* Results indicators are defined and form part of the continuous quality improvement initiative.

*QPR.3.f.* There is a document management system for both internal (procedures, protocols) and external documents (regulatory texts, professional recommendations, etc.).

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*QPR - Standard 4*

**There is a risk prevention programme.**

- QPR.4.a.* Information relating to risks and undesirable events is collected.
- QPR.4.b.* An events reporting system is in place.
- QPR.4.c.* Undesirable events are analysed and measures that may lead to improvement are taken.
- QPR.4.d.* Sectors, practices, procedures or processes which are at risk are identified and are the subject of priority action in the risk prevention programme.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*QPR Standard 4*

*Risk prevention*

*This standard deals with the establishment of a risk management system to reduce the risk of occurrence of undesirable events or accidents involving patients or staff.*

*All health care organisations have a level of safety which is governed by the organisation and practices of the establishment.*

*If a health care organisation wishes to improve its safety beyond a level already achieved and to reduce risk to a minimum, it has to have a risk identification system in place so that it can take preventive action against the most important risks; the relative priority accorded to risks will be specific to each health care organisation.*

*Systems for identifying risks already exist in certain areas, i.e. in specific prevention programmes such as those covering medical devices, blood derivatives, biological products, adverse drug reactions, and the prevention of nosocomial infection. The information collected via these systems should be integrated into the general risk management system.*

*However, these informations represent only part of the total risks inherent to health care organisations. In a more global system, attention should be paid to identifying and preventing risk in all areas (e.g. diagnostic and therapeutic procedures, falls, fire safety, and malicious acts).*

*QPR - Standard 5*

**The effectiveness of the quality management and the risk prevention programme is evaluated.**

*QPR.5.a.* The effectiveness of the quality management programme is evaluated.

*QPR.5.b.* The effectiveness of the risk prevention programme is evaluated.

*QPR.5.c.* The operation of the undesirable event reporting system is evaluated.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

## 2. SPECIFIC PREVENTION PROGRAMMES AND TRANSFUSION SAFETY (VST)

- **Introduction**

Specific prevention programmes covering blood derivatives, adverse drug reactions, medical device safety, and risks associated with the use of parts of the human body or products derived from it (i.e. grafts and implants) involve continuous monitoring of certain areas of healthcare, in order to report, record, analyse and investigate any undesirable event and incident related to the use of therapeutic products and items; it also covers the traceability of medical equipment and the response to health alerts.

Transfusion safety goes beyond simply monitoring blood derivatives; its goal is to reduce the risks related to their use. Appropriate selection of patients, good organisation of flows and activities and compliance with good practice are essential to achieving this goal of risk reduction.

- **Standards**

- VST - Standard 1*  
**The authorities and professionals concerned are involved in establishing and implementing the organisation's policy concerning specific prevention programmes and transfusion safety.**
- VST - Standard 2*  
**Specific prevention programmes are operational in the health care organisation.**
- VST - Standard 3*  
**Health professionals know about specific prevention programmes, including transfusion safety, and receive periodic training in these areas.**
- VST - Standard 4*  
**The health care organisation observes the rules governing transfusion safety.**
- VST - Standard 5*  
**Results from specific prevention programmes, including transfusion safety, are assessed and actions for improvement are taken.**

- **Standards and criteria**

VST - *Standard 1*

**The authorities and professionals concerned are involved in drawing up and implementing the organisation's policy concerning specific prevention programmes, including transfusion safety.**

VST.1.a. After consulting the organisation's Medical Committee, top management establishes a structure for specific prevention programmes and transfusion safety.

VST.1.b. The CME, practitioners and DSSI or the Director of Nursing are involved in the specific prevention programmes and transfusion safety systems.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

VST - *Standard 2*

**Specific prevention programmes are operational in the health care organisation.**

VST.2.a. Adequate systems for operating specific prevention and transfusion safety programmes are in place.

VST.2.b. The procedures to be followed in the event of an incident are in place, and professionals are aware of them.

VST.2.c. Medical products and devices are traceable.

VST.2.d. There is a system for responding to health alerts concerning medical products and devices for therapeutic use.

VST.2.e. Data obtained from the specific prevention programmes are analysed and used as the basis for improving professional practice with regard to the use of medical products and devices.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

VST.2.d. *Products for therapeutic use are labile blood derivatives, medications, medications derived from blood, and elements and derivatives of the human body.*

VST - *Standard 3*

**Health professionals know about specific prevention programmes, including transfusion safety, and receive periodic training in these areas.**

- VST.3.a. Health professionals are aware of their obligation to report any undesirable events relating to the use of labile blood derivatives, medications, medications derived from blood, medical devices or elements and derivatives of the human body.
- VST.3.b. Health professionals are trained in the procedures to be followed in the event of any incident.
- VST.3.c. Health professionals are kept regularly informed about specific prevention programmes; information obtained from national and regional structures relating to these programmes is passed on to prescribing doctors.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

VST - *Standard 4*

**The health care organisation observes the rules governing transfusion safety.**

- VST.4.a. The health care organisation operates a policy for controlling the use of labile blood derivatives.
- VST.4.b. The health care organisation has reliable supply procedures.
- VST.4.c. A transfusion record is kept for patients who have received a transfusion.
- VST.4.d. The various stages of the transfusion process are conducted in compliance with good practice.
- VST.4.e. Information is given to patients who have received a transfusion, and they are monitored; the patient's own doctor is informed.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

VST - *Standard 5*

**Results from specific prevention programmes, including transfusion safety, are assessed and actions for improvement are taken.**

VST.5.a. The effectiveness of each of the specific prevention programmes is assessed, and measures to improve the system are implemented.

VST.5.b. The application of protocols and procedures governing the various stages of the transfusion process is evaluated.

VST.5.c. There is a continuous improvement programme for transfusion safety.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

### 3. MONITORING, PREVENTION AND CONTROL OF THE RISK OF INFECTION (SPI)

- **Introduction**

Within a health care organisation, it is possible that patients, professionals, and anyone coming into contact with patients may acquire an infection from any one of a number of origins. It is essential that the health care organisation commits itself to an active infection control policy. The principal factors to be considered in controlling infection acquired within a health care organisation are the patient's medical situation, the performance of any invasive procedures, compliance with hygiene procedures, the safety of the hospital environment, and the use of antibiotics.

*SPI - Standard 1*  
**The health care organisation establishes and operates a coordinated infection control policy among patients and professionals.**

*SPI - Standard 2*  
**The authorities and professionals concerned are involved in establishing and implementing an infection control policy.**

*SPI - Standard 3*  
**The infection control programme is operated by competent professionals.**

*SPI - Standard 4*  
**The infection control programme includes monitoring.**

*SPI - Standard 5*  
**The infection control programme includes preventive action.**

*SPI - Standard 6*  
**The infection control programme includes provisions for the proper use of antibiotics in order to control bacterial resistance.**

*SPI - Standard 7*  
**A programme for preventing and managing infection of professionals is drawn up, with input from occupational medicine specialists.**

*SPI - Standard 8*

**The risk of infection arising from the use of multiple-use medical devices and equipment is controlled.**

*SPI - Standard 9*

**The risk of infection related to the environment is controlled.**

*SPI - Standard 10*

**There are procedures to cover the handling, storage, preparation and distribution of food.**

*SPI - Standard 11*

**The operation and effectiveness of the programme to prevent and control infection are evaluated at defined intervals.**

- **Standards and criteria**

*SPI - Standard 1*

**The health care organisation establishes and operates a coordinated infection control policy among patients and professionals.**

*SPI.1.a.* An infection control policy is implemented, as a specific annual or pluriannual programme of activities.

*SPI.1.b.* This annual or pluriannual programme of activities includes identification of preventive actions, systems for monitoring and disseminating results, training programmes and assessment measures.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 2*

**The authorities and professionals concerned are involved in establishing and implementing an infection control policy.**

*SPI.2.a.* The infection control policy is drawn up jointly by top management, the CME, DSSI or Director of Nursing and the health professionals concerned.

*SPI.2.b.* The infection control programme is implemented in such a way that action taken by the various professionals or activity sectors is coordinated. Responsibilities are defined, and all health professionals are made aware of them.

*SPI.2.c.* Measures are taken to publicise the infection control policy and programme within the health care organisation and externally.

*SPI.2.d.* All temporary and permanent professionals receive training in hygiene when they arrive.

*SPI.2.e.* All professionals receive continuing training in hygiene, particularly when new procedures are being introduced.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI.2.c.* *The bodies with whom the health care organisation is likely to communicate regarding its infection control policy include the CCLIN, for example.*

*SPI - Standard 3*

**The infection control programme is operated by competent professionals.**

- SPI.3.a.* A manager from within the health care organisation is appointed to implement the infection control programme.
- SPI.3.b.* The manager has access to all data needed to implement the programme.
- SPI.3.c.* The CLIN or an equivalent body supervises the monitoring of the health care organisation's policy and the dissemination of information obtained to all clinical, ancillary medical and administrative activity sectors.
- SPI.3.d.* The CLIN or an equivalent body is consulted about projects for equipping premises, organising flows, purchasing equipment or materials, and building and renovation work scheduling, if the projects or decisions involved could have repercussions on hygiene matters.
- SPI.3.e.* The CLIN, or its equivalent, produces an annual activity report which is sent to top management, the governing body and the activity sectors with which it collaborates for information, to the CME for its opinion and to the CHSCT if appropriate.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 4*

**The infection control programme includes monitoring.**

- SPI.4.a.* There is a system for targeted monitoring of at-risk activity sectors.
- SPI.4.b.* There is a system for issuing warnings about possible epidemics, and for identifying, managing and controlling them.
- SPI.4.c.* The conclusions derived from analysis of data obtained from the monitoring systems, and recommendations made as a result, are sent to the activity sectors concerned and to top management. Infection prevention activities are modified on the basis of these data.
- SPI.4.d.* Changes in the level of antibiotic-resistant bacteria are monitored.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI.4.a. In particular, the infection control policy includes the monitoring of infections of surgical wounds, of infections related to catheters, of bacteremias and of pulmonary infections contracted in intensive care.*

*SPI - Standard 5*

**The infection control programme includes preventive action.**

- SPI.5.a.* Protocols are used to control the risk of infection.
- SPI.5.b.* Health professionals receive training in implementing the infection control programme.
- SPI.5.c.* Patients are involved in preventive actions against infections which concern them.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 6*

**The infection control programme includes provisions for the proper use of antibiotics in order to control bacterial resistance.**

- SPI.6.a.* A structure within the health care organisation is made responsible for studying how antibiotics are used, in conjunction with the CLIN or an equivalent body.
- SPI.6.b.* Recommendations are issued about the prescription of antibiotics for antibiotic therapy and prophylaxis.
- SPI.6.c.* The use of antibiotics is monitored for the health care organisation as a whole and by activity sector.
- SPI.6.d.* Antibiotic use is compared with the development of bacterial resistance.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 7*

**A programme for preventing and managing infection of professionals is drawn up, with input from occupational medicine specialists.**

- SPI.7.a.* Measures are taken to prevent accidents through exposure to blood or other biological fluids.
- SPI.7.b.* There is a system for notifying, collecting details of and analysing such accidents, and for caring for those involved.
- SPI.7.c.* All professionals are immunised against certain specific risks associated with working in a health care organisation.
- SPI.7.d.* Measures are taken to prevent the risks of contamination which are associated with working in the medical profession.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 8*

**The risk of infection arising from the use of multiple-use medical devices and equipment is controlled.**

- SPI.8.a.* There is a quality assurance system covering sterilisation.
- SPI.8.b.* Procedures for maintenance (cleaning, disinfecting) of equipment and medical devices that cannot be sterilised are written, validated and implemented by trained staff. Assessments take place at set intervals to monitor compliance with these protocols and to assess their relevance.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 9*

**The risk of infection related to the environment is controlled.**

- SPI.9.a.* Procedures are written, validated and evaluated at set intervals.  
*SPI.9.b.* Professionals receive training in the procedures.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI.9.a. Procedures cover:*

- *maintenance of all facilities, according to level of risk;*
- *the flow for clean and soiled linen (collection, transport, handling) and its processing;*
- *maintenance and quality control for water, according to the various types of use (drinking water, water for haemodialysis, water for equipment maintenance, etc.);*
- *maintenance and quality control for air in sectors which have a controlled ventilation system;*
- *management of waste from care activities from the clinical and ancillary medical services activity sectors.*

*SPI - Standard 10*

**There are procedures to cover the handling, storage, preparation and distribution of foodstuffs.**

- SPI.10.a.* There is a quality assurance system for the central kitchen.  
*SPI.10.b.* Procedures covering preparation of baby's bottles, enteral nutrition and dietary preparations are written and validated.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

*SPI - Standard 11*

**The operation and effectiveness of the infection prevention and control programme are evaluated at set intervals.**

*SPI.11.a.* The health care organisation evaluates the operation of the programme by annual analysis of good practice indicators and by comparing the results obtained with the goals set.

*SPI.11.b.* Details of these assessments are regularly sent to the clinical teams, to top management and to the CME.

*SPI.11.c.* Measures for improvement are undertaken.

*Where the health care organisation has found other ways of achieving the objective, it should state them.*

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## ABBREVIATIONS AND FRENCH ORGANISATIONS

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CA:	Conseil d'administration ( <i>Governing Body</i> )
CHSCT:	Comité d'Hygiène, de Sécurité et des Conditions de Travail ( <i>Hygiene, Safety and Working Conditions Committee</i> )
CCLIN:	Coordination des Comités de Lutte contre les Infections Nosocomiales ( <i>Coordinating body for Nosocomial Infection Control Committees</i> )
CLIN:	Comité de Lutte contre les Infections Nosocomiales ( <i>Nosocomial Infection Control Committee</i> )
CME:	Commission Médicale d'Établissement (in public and private facilities participating in public hospital service (PSPH)) ( <i>Medical Committee</i> ) or Conférence Médicale d'Établissement (in private non-PSPH facilities) ( <i>Medical Conference</i> )  ( <i>In some of the criteria or standards which are specific to the public hospital service, "Medical Committee" is spelt out in full to indicate that only public and private PSPH facilities are concerned; otherwise the term "CME" is used throughout</i> )
CNAMTS	Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés ( <i>National Health Insurance Fund for Salaried Workers</i> )
CNIL:	Commission Nationale Informatique et Libertés ( <i>French Data Protection and Civil Rights Commission</i> )
CTE:	Comité Technique d'Établissement ( <i>Health Care Organisation Technical Committee</i> )
DIM:	Département d'Information Médicale ( <i>Medical Information Department</i> )
DGS:	Direction Générale de la Santé ( <i>General Health Directorate</i> )
DH:	Direction des Hôpitaux ( <i>Hospitals Directorate</i> )  ( <i>Directorate for Administration of Human Resources and Finances</i> )
DSS:	Direction de la Sécurité Sociale ( <i>Social Security Directorate</i> )
DSSI:	Direction du Service des Soins Infirmiers ( <i>Management of the Nursing Service</i> ) = Director of Nursing
PMSI:	Programme de Médicalisation des Systèmes d'Information ( <i>Medical Information Systems Programme</i> )

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## GLOSSARY

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**Activity sector:** functional or administrative division within a health care organisation and defined by it, e.g. a care unit or service. The activity sector may be clinical, ancillary medical, etc.

**Certification:** validation by a competent and independent organisation that a quality system conforms to ISO9000 standards, and a written assurance that a product, process or service complies with the specified requirements.

(AFNOR)

**Criterion:** statement of a practice or element required to satisfy a standard.

(ANAES)

**Customer:** recipient of a product provided by the supplier.

(ISO8402)

**Development plan:** the development plan defines the strategic direction of the health care organisation over a period of several years for all its activities, covering both direct care for the patient and activities which contribute in other ways to patient care.

**Health care professional:** person whose activity is related to prevention of disease or care of patients. A health care professional may be a medical professional, a paramedical professional or a pharmacist.

(“*Dictionnaire français de santé publique*” J.-C. SOURNIA)

**Indicator:** see p.33

**Medical professional:** as defined by the French Public Health Code, i.e. doctors, midwives and dentists.

(Article L 356 of the French Public Health Code)

**Mode of discharge:** the various ways in which a patient can leave the health care organisation are return home, transfer to another facility, or death.

**Multiprofessional:** term applied to a group of health care professionals consisting of e.g. care providers, doctors, administrative staff, social services staff, or ancillary medical services staff.

**Paramedical professional:** as defined by the French Public Health Code, i.e. nurses, care assistants, dieticians, physiotherapists, physical therapists, etc.

(Annex IV of the French Public Health Code)

**Procedure:** specified way of performing an activity (ISO8402)

**Process:** set of related methods and activities which transform inputs into outputs. An example is the process of dispensing medications, or the process of care for the patient in the recovery room.

(ISO8402)

**Product:** result of activity or process.

(ISO8402)

**Professional:** person working in the health care organisation, whether a permanent employee or not.

**Professional practice *assessment*:** verification that professional practices correspond to a standard defined by a consensus of experts in the speciality.

**Protocol:** description of techniques to be applied and/or instructions to be observed.

**Quality:** the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.  
(ISO8402)

**Quality assurance:** All the planned and systematic activities that are needed to provide adequate confidence that a product or service will fulfil the stated requirements for quality.  
(ISO8402)

**Quality improvement:** the actions undertaken throughout the organisation to increase the effectiveness and efficiency of activities and processes, in order to bring added benefits to both the organisation and its customers.  
(ISO8402)

**Quality initiative:** actions carried out by a company to develop customer satisfaction.

**Quality management:** activities of the general management function which determine the quality policy, objectives and responsibilities, and implement them by methods such as quality planning, quality control, quality assurance, and quality improvement within the framework of the quality system.

**Quality of care:** level achieved by health care organisations in terms of increasing the likelihood of obtaining the desired results for individuals and groups, and within the constraints of the current state of knowledge.

**Quality policy:** overall intentions and direction of an organisation with regard to quality, as formally expressed by top management.  
(ISO8402)

**Satisfaction survey:** tool used for the regular assessment of patient satisfaction, which in particular covers conditions of admission and the stay in hospital, in accordance with the provisions of French law no. 96-346 of April 24, 1996, article 1.  
(Article L 710-1-1 of the French Public Health Code).

**Self-assessment:** see p.19

**Set of standards:** a set of standards covering an area of activity of a health care organisation.  
(ANAES)

**Staff:** all the people carrying out salaried activities in the health care organisation.

**Standard:** statement of an expectation or requirement which, when satisfied, ensures the delivery of quality care or services (ANAES)

**Survey:** see pp.20-23

**Surveyor:** see p.20

**Traceability:** the ability to trace the history, application or location of an item or activity by means of recorded identification.  
(ISO8402)

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