

DIGITAL HOSPITAL QUALITY FRAMEWORK

Additional requirements for the quality management system of industrial IT solutions providers to health institutions

Version 1.1 – October 2015



The Ministry of Health, via its "Digital Hospital" programme, supports the improvement of service quality and performance of health facilities through developing and promoting the appropriate use of information technology. The actions carried out in this context involve all stakeholders, both users and information systems providers. The result of these actions will only be fully achieved if all stakeholders are fully committed and comply with the state of the art.

The Digital Hospital Quality certificate, developed as part of the Digital Hospital Programme, is awarded to a manufacturer whose quality management system (QMS) complies with the requirements of the Digital Hospital Quality Framework, which are related to its QMS.

The Agency for Shared Information Systems in Healthcare (ASIP Santé) published in July 2015 the Digital Hospital Quality Framework, following a public consultation which took place from February 6th 2015 to March 31st 2015.

Reference Documents
<ol style="list-style-type: none">1. Reference # 1: NF EN ISO 9001 October 2015: European Standard with the charter of French Standard and complete reproduction of the International Standard ISO 9001: 20152. Reference # 2: NF EN ISO 13485 September 2012: European Standard with the charter of French Standard and complete reproduction of the International Standard ISO 13485: 20033. Reference # 3: ASIP Santé: General Policy on the Security of Health Information Systems(PGSSI-S) (http://esante.gouv.fr/pgssi-s/corpus-documentaire)4. Reference # 4: NF EN ISO 9001 November 2008: European Standard with the charter of French Standard and complete reproduction of the International Standard ISO 9001: 2008¹

¹ The requirements of the Digital Hospital Quality Framework are attached to sections of ISO 9001 and ISO 13485 in force. The current version of ISO 9001 is the 2015 version. The 2008 version of ISO 9001 is referenced provisionally until the end of the validity period of this version.

Document History		
Version	Date	Comments
V1.0.0	July 2015	Validated and published version
V1.1.0	October 2015	Updated reference material (page 2): Reference # 1 becomes the NF EN ISO 9001: 2015 and reference No. 4 becomes the NF EN ISO 9001: 2008. Update of the footnote of page 2.

Summary

1	Introduction.....	5
2	Compliance with a QMS standard	5
3	Transparency Requirements	6
3.1	Communication of the note "Manufacturer's Policy"	6
3.2	Communication of the note "Annual Policy Evolution"	6
4	Service and quality requirements	7
4.1	Criteria related to product design, development and evolution	7
4.1.1	Documentation related to product development.....	7
4.1.2	Detection of malfunctions.....	8
4.1.3	Factory product testing	8
4.1.4	Pilot site	9
4.1.5	Corrective maintenance and interventions.....	9
4.1.6	Management of legal and regulatory developments.....	10
4.1.7	Limiting the frequency of deliveries.....	10
4.1.8	Product documentation update	11
4.2	Criteria for the management of production services.....	12
4.2.1	Sustainability of solutions.....	12
4.2.2	Operation in degraded mode	12
4.2.3	Warranty.....	13
4.2.4	Unavailability & hotfix update.....	13
4.3	Project criteria	14
4.3.1	Sustainability of the manufacturer's teams	14
4.3.2	Reinforced guidance.....	14
4.3.3	Quality	15
4.3.4	Joint steering tools	15
4.3.5	Project security and risk analysis.....	15
4.4	Criteria for interoperability	16
4.4.1	Interoperability.....	16
4.5	Criteria for data security.....	16
4.5.1	Security of sensitive data.....	16
4.5.2	Respect of PGSSI-S security policy.....	17
5	Annexes	18
5.1	Plan type of the note "Manufacturer's policy"	18
	1. Activity of the manufacturer	18
5.2	Functional and Technical Mapping of Hospital Software Offers.....	20
6	Glossary	21

1 Introduction

The Digital Hospital Quality Framework is based on a standard of quality management system requirements (ISO 9001:2015, 9001: 2008 and 13485: 2012 standards) and specific additional requirements for suppliers of IT solutions for health facilities and professionals. This document describes the specific additional requirements of the Digital Hospital Quality Framework.

The requirements of the Digital Hospital Quality Framework also apply to manufacturers of software for medical devices, unless they conflict with the regulatory provisions specific to this class of software.

The Digital Hospital Quality Framework is a public document that addresses:

- manufacturers, wishing to enrol in the certification process;
 - software vendors (standard shelf products, software packages),
 - software developers (tailored software) either service providers (companies that provide development services) or health facilities and professionals who develop their own software and market it,
 - software integrators who distribute business applications and / or who sometimes develop integrated systems destined to be marketed,
 - solution as a service (SaaS) providers ;

NOTE: THROUGHOUT THIS DOCUMENT, THE TERM "MANUFACTURER" REFERS TO ALL POTENTIAL OPERATORS AS MENTIONED ABOVE.

NOTE: WHEN THE MANUFACTURER IS NOT A SOFTWARE EDITOR ITSELF BUT ONLY DISTRIBUTOR OR INTEGRATOR, THE REQUIREMENTS OF THIS FRAMEWORK RELATING SPECIFICALLY TO MANUFACTURING, DESIGNING AND CHANGING THE PRODUCT DESIGN APPLY TO OPERATORS LOCATED UPSTREAM ON THE DISTRIBUTION CHAIN, AND THE MANUFACTURER HAS TO CERTIFY THE COMPLIANCE OF THESE UPSTREAM OPERATORS WITH THESE REQUIREMENTS

- certifying bodies, as a Framework of support of their evaluation;
- health facilities and professionals, who wish to know more about the evaluation criteria.

NOTE: THROUGHOUT THIS DOCUMENT, THE TERM "HEALTH FACILITIES AND PROFESSIONALS" REFERS TO HEALTH INSTITUTIONS, HEALTH CARE FACILITIES AND FREELANCE PROFESSIONALS.

NOTE: THROUGHOUT THIS DOCUMENT, THE TERM "PRODUCT" REFERS TO A SOFTWARE SOLUTION ISSUED BY A "MANUFACTURER" TO "HEALTHCARE FACILITIES AND PROFESSIONALS".

NOTE: THROUGHOUT THIS DOCUMENT, THE EXPRESSION "PROVIDED THAT A CONFIDENTIALITY AGREEMENT EXISTS" [BETWEEN THE MANUFACTURER AND A CUSTOMER], REFERS TO THE SIGNATURE OF A PRIOR CONFIDENTIALITY AGREEMENT BETWEEN THE PARTIES IMPLEMENTED BY A SPECIFIC CONTRACTUAL DOCUMENT OR NOT.

2 Compliance with a QMS standard

The present document specifies additional requirements that aim at making concrete quality objectives as part of the manufacturer's quality management system (QMS) certification which complies with ISO 9001 or ISO 13485 standards.

The assessment of compliance with these additional requirements, covered by this document can be performed as part of the certification audit of the manufacturer's QMS or as part of an inspection audit for a manufacturer whose QMS is already certified according to ISO 9001 or ISO 13485.

3 Transparency Requirements

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of the standard
ISO 9001:2008 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments"
ISO 9001:2015 standard	8.2.1 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments"
ISO 13485:2012 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments"

3.1 Communication of the note "Manufacturer's Policy"

Provided that a confidentiality agreement exists, the manufacturer informs its customers and prospective customers about its policy by producing the note "Manufacturer's Policy", which is part of the documents provided during the consultations, orders and contracts and their amendments.

The note "Manufacturer's policy" produced by the manufacturer respects the standard plan as described in Annex 5.1.

3.2 Communication of the note "Annual Policy Evolution"

The manufacturer produces a note called "Annual Policy Evolution" including evolutions of its policy compared to what is described in the note "Manufacturer's Policy" (see paragraph 3.1). Instead of this note, the manufacturer can also produce an annual update of the note "Manufacturer's Policy", which specifies all the modifications that have been made.

The note "Annual Policy Evolution" is provided to the manufacturer's customers and prospective customers, under the same conditions as the note "Manufacturer's Policy" (see paragraph 3.1).

This note "**Annual Policy Evolution**" may include the manufacturer's additional commitments but no regressions, except in the case where the primary cause of this regression is related to changes in the product's ecosystem.

4 Service and quality requirements

4.1 Criteria related to product design, development and evolution

4.1.1 Documentation related to product development

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of the standard
ISO 9001:2008 standard	7.2.3 "Customer communication / a) information about the product"
ISO 9001:2015 standard	8.2.1 "Customer communication / a) information about the product"
ISO 13485:2012 standard	7.2.3 "Customer communication / a) information about the product"

The manufacturer maintains a **product plan** for each of its products.

Provided that a confidentiality agreement exists, the manufacturer releases the product plan for use to its customers using this product.

The product plan lists the different product versions that are distributed and provides the forecast of future versions. For each version (distributed or future) the product plan specifies:

- The version's nature according to the categories defined in the manufacturer's process of design modification and development (e.g. "major release", "minor / intermediate version");
- the list of new and modified functionalities in the version;
- for a distributed version, the documentation reference of this version which details its content;
- the release date (known or planned) of the version;
- a list of compatible versions of third party software required for the usage of the product;

NOTE: BY THIRD PARTY SOFTWARE WE MEAN, WITHOUT LIMITATION, THE OPERATING SYSTEM OF THE CLIENT, THE OPERATING SYSTEM OF THE SERVER, THE DATABASE MANAGEMENT SYSTEMS (DBMS), THE BROWSERS, THE APPLICATION SERVERS (THIS LIST IS NON-EXHAUSTIVE). IT CONSISTS OF THE NECESSARY TECHNICAL ENVIRONMENT FOR THE CUSTOMER TO BE ABLE TO USE THIS PRODUCT VERSION.

The product plan specifies for each third-party planned dates of software commissioning, end of distribution or marketing, end of maintenance and support;

Example: Windows 8 support for the client workstation from May 2013 until May 2016

The documentation of a distributed version of a product is made available to customers using this version. This documentation includes at least:

- the list of new or evolved functionalities, including relevant documentation;
- the list of fixed bugs;
- version's release date;
- a list of compatible versions of third-party software required to use this version of the product.

The **list of known bugs of a product version** is regularly updated and made available to customers using this version.

4.1.2 Detection of malfunctions

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of the standard
ISO 9001:2008 standard	8.3 "Control of nonconforming product"
ISO 9001:2015 standard	8.7 "Control of process output items, nonconforming products and services"
ISO 13485:2012 standard	8.3 "Control of nonconforming product"

The manufacturer maintains and keeps all documented information concerning detection and systematic communication of critical malfunctions² affecting a version of a product in operation.

This documented information requires immediate communication of the information to all customers using versions of the product potentially affected by the critical malfunction, either via the client extranet (if any) or by electronic mail to an address provided by the customer.

4.1.3 Factory product testing

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of the standard
ISO 9001:2008 standard	7.3.6 "Validation of design and development" 7.2.3 "Communication with customers/ a) information about the product"
ISO 9001:2015 standard	8.3.4 "Design and development control / d) validation is performed [...]" 8.2.1 "Communication with customers / a) information about the product"
ISO 13485:2012 Standard	7.3.6 "Validation of design and development" 7.2.3 "Communication with customers" / a) information about the product"

The manufacturer maintains documented information governing validation each new version's design and development.

This documented information requires performing factory tests before implementation on the pilot site. It also requires that these factory tests include regression testing.

Factory tests are based on test cases and produce a report certifying the test results.

The test results and this report are provided to the customers of the product version or patch, provided that a confidentiality agreement exists.

² The concept of critical malfunction refers to a bug or a malfunction affecting the patient's health or the good functioning of health care organizations.

4.1.4 Pilot site

The specific requirements described in this article are related to the following standards:

Standard requirements of QMS	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.3.6 "Validation of design and development" 7.2.3 "Customer communication / a) information about the product"
ISO 9001:2015 standard	8.3.4 "Control of design and development / d) validation is performed [...]" 8.2.1 "Customer communication / a) information about the product"
ISO 13485:2012 standard	7.3.6 "Validation of design and development" 7.2.3 "Customer communication" / a) information about the product"

The documented information governing the validation of design and development requires, for each *major version* of a product, at least once a year, an evaluation phase on a pilot site before the version is released, in order to test the features in a production environment.

The manufacturer has a testing plan on a pilot site specifying the tests to be performed and the functional blocks involved, in view of Annex 5.2 (Functional and Technical Mapping of Hospital Software Offers).

The implementation of the testing plan on a pilot site produces a test report documenting test results and listing of the tested functional requirements.

This testing report on a pilot site is made available to users, customers of the product release, provided that a confidentiality agreement exists between customers and the manufacturer. This test report contains the details of the pilot customer, provided that he has agreed to it.

In case the product is used by a single customer site, the site itself is the pilot site.

4.1.5 Corrective maintenance and interventions

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.2.3 "Customer Communication » / b) processing of enquiries, contracts or orders and their amendments" 7.3.7 "Control and development changes" 8.3 "Control of nonconforming product"
ISO 9001:2015 standard	8.2.1 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments" 8.3.6 "Design and development changes" 8.7 "Control of output elements of processes, nonconforming products and services"

Standard QMS requirements	Reference to the requirement of quality standard
ISO 13485:2012 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments" 7.3.7 "Control of design and development changes" 8.3 "Control of nonconforming product"

In its contracts with its customers, the manufacturer specifies the deadlines for bug correction, according to a criticality classification of bugs established by the manufacturer.

For each customer, the manufacturer maintains a registry of interventions made on the customer production system, keeping for each intervention the name of the operator, the beginning, the end and the purpose of the intervention. This register is either continuously shared with the customer or communicated to the customer on a periodic basis, monthly at a maximum.

Before any hotfix on the operating product at the customer’s location, the documented information concerning the control of non-conformities of the product requires:

- if the customer has a local or hosted specific instance of a product: a prior customer approval phase,
- if the customer has the software in SaaS mode: a phase of prior notification to the customer.

4.1.6 Management of legal and regulatory developments

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments"
ISO 9001:2015 standard	8.2.1 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments"
ISO 13485:2012 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments"

Customer contracts contain a commitment clause related to conditions of adapting to legal and regulatory changes in product evolutions, throughout the duration of the contract.

4.1.7 Limiting the frequency of deliveries

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.5.1 "Control of production and service provision" / "f) the implementation of product release activities, delivery and service provision after delivery"
ISO 9001:2015 standard	8.5.1 "Control of production control and service provision / h) the implementation of product release activities, delivery and service provision after delivery"

Standard QMS requirements	Reference to the requirement of quality standard
ISO 13485:2012 standard	7.5.1 "Control of production control and service provision" / f) the implementation of product release activities, delivery and service provision after delivery"

The documented information concerning the product delivery limits deliveries to customers to a maximum of one *major version* and 7 *intermediate versions* per year.

The following versions are exempted from this limitation:

- versions correcting critical anomalies,
- versions taking into account new versions of third party software (see note to article 4.1.1),
- versions allowing compliance with changes in security requirements or regulatory requirements,
- updates of reference document databases (e.g. a drugs database), with which the software interfaces.

This limitation of the frequency of version delivery does not apply to products whose evolution is managed under *continuous development*, subject to:

- a frequency of deliveries set beforehand in agreement with the customer (e.g. monthly deliveries),
- the initiative to activate the functional evolutions in the version delivered is left to the customer.

4.1.8 Product documentation update

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.5.1 "Control of production and service provision" / a) availability of information describing the characteristics of the product" 7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments "
ISO 9001:2015 standard	8.5.1 "Control of production and service provision / a) availability of documented information defining the characteristics of products and services" 8.2.1 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments "
ISO 13485:2012 standard	7.5.1 "Control of production and service provision / a) availability of information describing the characteristics of the product" 7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments "

The documented information concerning the delivery of a new version of a product stipulates that the following documentary evidence should be available to the customer:

- Installation Guide in French (unless the product is not installed by the customer or running in SaaS mode);
- Operations guide (unless the product is not installed by the customer or running in SaaS mode);
- User guide in French;

- Configuration guide in French;
- Document describing the steps of the software installation at the customer' site, as well as the points to observe and control for each stage (configuration, training, going into operational phase);
- Interface administration document;
- Document describing the prerequisites.

NOTE: THE LIST OF DOCUMENTARY ELEMENTS ABOVE DOES NOT RESTRICT THE FORM OF THIS DOCUMENTATION, WHICH MAY BE IN THE FORM OF PAPER, DIGITAL, ON-LINE OR INTEGRATED WITHIN THE PRODUCT...

Customer contracts on a product will allow read access to data contained in the system by customers, and specify the conditions of access (providing the database model or views or extractions). The product documentation details the modalities of such access.

4.2 Criteria for the management of production services

4.2.1 Sustainability of solutions³

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments" 7.5.5 "Product preservation"
ISO 9001:2015 standard	8.2.1 "Customer communication / b) processing of enquiries, contracts or orders, and their amendments" 8.5.4 "Preservation"
ISO 13485:2012 standard	7.2.3 "Customer communication / b) processing of inquiries, contracts or orders, and relevant amendments" 7.5.5 "Product preservation"

The duration of support of versions is formally specified in the contract.

The manufacturer takes measures to ensure the sustainability of its products. For this purpose, the manufacturer deposits the sources of its products to a trusted third-party for each major release, or at least once a year, in particular for software maintained under continuous development.

4.2.2 Operation in degraded mode

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.5.1 "Control of production and service provision / a) availability of

³ The provisions of this article shall be adapted where the European regulations concerning medical devices will be enforced.

	information describing the characteristics of the product"
ISO 9001:2015 standard	8.5.1 "Control of production and service provision / a) availability of documented information defining the characteristics of products and services"
ISO 13485:2012 standard	7.5.1 "Control of production control and service provision / a) availability of information describing the characteristics of the product"

The product documentation delivered or made available to the customer includes the procedures of product use in degraded mode, including:

- the functional scope of the degraded mode;
- any performance restrictions;
- the degraded mode implementation procedures;
- the procedures to return to the nominal mode.

These procedures may be adapted to the customer's context.

4.2.3 Warranty

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts, orders and their amendments"
ISO 9001:2015 standard	8.2.1 "Customer communication / b) processing of enquiries, contracts, orders and their amendments"
ISO 13485:2012 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts, orders and their amendments"

The customer contract concerning a product formally describes the warranty period and the services associated with this period.

During the warranty period, the manufacturer offers a range of additional services for the evolution of the solution, allowing the customer to benefit from the level of service of a maintenance contract.

4.2.4 Unavailability & hotfix update

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.2.1 "Determination of requirements related to the product / d) any additional requirements considered necessary by the agency"
ISO 9001:2015 standard	8.2.2 "Determination of requirements for products and services"
ISO 13485:2012 standard	7.2.1 "Determination of requirements related to the product / d) any additional requirements considered necessary by the agency"

The customer contract refers to the product update process at the customer's location. This procedure stipulates the maximum period of product unavailability during an update and is subject

to customer's compliance with the technical prerequisites provided by the manufacturer. This period lasts 4 hours between the beginning of product unavailability on all workstations of the health institution and the return to production of the first user workstation.

The possibility of updates outside working hours, on customer's request, is also mentioned in the contract.

As regards healthcare provision software, the manufacturer informs the customers on its ability to implement, from July 1st 2016, a hotfix update system (without stopping the service), allowing the reduction of the duration of unavailability of its applications.

4.3 Project criteria

4.3.1 Sustainability of the manufacturer's teams

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery" 6.2 « Human resources»
ISO 9001:2015 standard	8.5.1 "Control of production and service provision / h) implementation of product release activities, delivery and service provision after delivery" 7.1.2 "Human resources"
ISO 13485:2012 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery" 6.2 "Human resources"

The documented information governing the delivery of a product to a customer and all related service provision include:

- a stable project team as regards the number or competence;
- a dedicated point of contact for the customer;
- the procedures of changes in the project team and the procedures of systematic transfer of skills with the quality objective of minimising the impact on the project for the customer;
- informing the customer in advance in case of change in the project team.

4.3.2 Reinforced guidance

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"

ISO 9001:2015 standard	8.5.1 "Control of production and service provision / h) implementation of product release activities, delivery and service provision after delivery"
ISO 13485:2012 standard	7.5.1 "Control of production and service provision / f) the implementation of product release activities, delivery and service provision after delivery"

The manufacturer’s catalogue includes services necessary for the proper product implementation, which cover the different needs of customers who do not have the necessary skills (training, installation, going into operational phase, system operations support, assistance in the drafting of documentation and assistance in configuration).

4.3.3 Quality

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	4.2.1 "Documentation requirements / General"
ISO 9001:2015 standard	7.5 "Documented information / General "
ISO 13485:2012 standard	4.2.1 "Documentation requirements / General"

The manufacturer offers systematically to the customer to establish a quality assurance plan of the project as part of an implementation project of one of the manufacturer’s products at the customer’s location.

4.3.4 Joint steering tools

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"
ISO 9001:2015 standard	8.5.1 "Control of production and service provision / h) implementation of product release activities, delivery and service provision after delivery"
ISO 13485:2012 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"

For every project of product implementation for the customer the manufacturer offers to the customer to share project management tools: cost management tool, planning of key milestones, risk management.

4.3.5 Project security and risk analysis

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
---------------------------	--------------------------------------------------

ISO 9001:2008 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"
ISO 9001:2015 standard	6.1 "Actions to be implemented in dealing with risks and opportunities"
ISO 13485:2012 standard	7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"

For every project of product implementation for the customer, the manufacturer performs a project risk analysis, involving the identification of risk factors, criticality and probability of occurrence as well as actions to mitigate these risks. The choice of the risk analysis method is left to the manufacturer, after consultation with the customer.

4.4 Criteria for interoperability

4.4.1 Interoperability

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders and their amendments"
ISO 9001:2015 standard	8.2.1 "Customer communication / b) processing of enquiries, contracts or orders and their amendments"
ISO 13485:2012 standard	7.2.3 "Customer communication / b) processing of enquiries, contracts or orders and their amendments"

For each version of a product, the product documentation given to the prospective customer as part of a consultation, or to the customer as part of a contract, an order or an addendum, specifies any characteristics of interoperability and the modalities to implement this interoperability.

This documentation specifies the risks and additional costs linked to the implementation of specific connectors needed for use by the customers of proprietary interfaces.

4.5 Criteria for data security

4.5.1 Security of sensitive data

The specific requirements described in this article are related to the following standards:

Standard QMS requirements	Reference to the requirement of quality standard
ISO 9001:2008 standard	6.2 "Human resources" 7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"
ISO 9001:2015 standard	7.1.2 "Human resources"

	8.5.1 "Control of production and service delivery / h) implementation of product release activities, delivery and service provision after delivery"
ISO 13485:2012 standard	6.2 "Human resources" 7.5.1 "Control of production and service provision / f) implementation of product release activities, delivery and service provision after delivery"

Documented information concerning interventions of the technical teams of the manufacturer on the customer system requires that all the members of these teams sign a confidentiality agreement. This commits the manufacturer, its employees and any subcontractors and co-contractors, prior to any access to a customer's information system.

The manufacturer keeps the documented information concerning activities on a customer's system, specifying the name of the operators. This documented information is made available to the customer.

4.5.2 Respect of PGSSI-S security policy.

The manufacturer keeps up to date the documented information demonstrating that it meets the requirements, for manufacturers and providers, contained in the following published documents of the global policy guidelines on security of health information systems. (PGSSI-S):

- Rules for remote interventions on Health Information Systems (HIS)
- Rules for the connected devices of a Health Information System

NOTE: THE PRESENT DIGITAL HOSPITAL QUALITY FRAMEWORK WILL BE REVISED, WITH RESPECT TO PGSSI-S REQUIREMENTS EVOLUTION. IN CASE OF A SIMILAR REQUIREMENT BETWEEN THE "QUALITY FRAMEWORK OF HEALTH SOFTWARE" AND THE REQUIREMENTS OF PGSSI, THE PGSSI REQUIREMENTS WILL TAKE PRECEDENCE OVER THOSE OF THIS FRAMEWORK.

5 Annexes

5.1 Plan type of the note "Manufacturer's policy"

1. Activity of the manufacturer

- a. What is the distribution of manufacturer revenues between license sales, maintenance / evolutions, hardware, SaaS and various services (training, project control, etc.)?
- b. What is the manufacturer's global workforce expressed in full time equivalent worldwide and the health workforce in France?
- c. What is the manufacturer's workforce distribution among the following categories: Support function (finance, HR, quality, internal IT), sales and marketing, Research and Development (including testing and maintenance 3rd level), Quality (quality and methods), deployment and support (including project management, advice and assistance - installation), Training and Hotline?
- d. Are development teams the same as the software testing teams?

2. Good practices implemented by the manufacturer

- a. Does the manufacturer possess certifications? If so, which ones? Specify when and by whom these certifications were obtained.
- b. Is the manufacturer CMMI certified for his development teams?
- c. Does the manufacturer make use of ISTQB certified testers?
- d. Is the manufacturer holder of ITIL certification for its support processes or for its delivery process?
- e. What safety practices does the manufacturer apply? (ISO 27000, risk analysis methods, other frameworks or security best practices, etc.)
- f. What quality practices does the manufacturer apply? (ISO 9001, ISO 13485, other quality standards, etc.)
- g. What practices of continuous improvement does the manufacturer apply? (PDCA, etc.)

3. Security

- a. What practices do you implement to ensure the intrinsic safety of software?
- b. Do you have additional practices for critical software (as regards a patient's life)?
- c. How do you guarantee the confidentiality of data contained in the software?
- d. Do you carry out risk analysis? If so, under which conditions? Under which arrangements? With which methods?
- e. Have you provided in your software a mechanism to monitor / control the read access or data modification for each user?

4. Relations with users

- a. Do you have a user forum?
- b. Are the users of your products involved in the definition of future versions?

- c. What activities do you offer as part of your user forum?
- d. What practices of contract governance do you apply? (governing bodies, management tools, etc.) Do you offer a single contact for the organisation? Which escalation circuits do you apply?

5. Warranty Maintenance and management of evolutions

- a. How do you formalise contracts for regulatory maintenance?
- b. How long and what warranty terms do you offer for your products?
- c. Do you offer software that can be updated through hotfixes?
- d. What practices do you put in place to reduce software downtime during an update? (problems of critical software / sensitive e.g. restart, etc.)

6. Solutions tests

- a. What is the coverage of the tests performed (% of the functional coverage of the software)?
- b. Do you accept to communicate on your references? Do you accept to link your prospective customers with your existing customers?
- c. How do you communicate on critical software bugs (from a patient's point of view)?

7. How do you control the implementation of projects?

- a. What methods, practices and project management tools do you put in place?
- b. Do you offer shared control tools (manufacturer, integrator, institution)?
- c. What method (s) of project management do you apply?
- d. Do your implementation project managers have certifications in project management?

8. Offers of services by the manufacturer

- a. What is the service offer of the manufacturer? (offered services, functional scope covered by the solutions, etc.)
- b. Do you offer your software in SAAS, if so, under what conditions?
- c. Do you offer support services? If yes, which ones? (training, pilot project, etc.)

5.2 Functional and Technical Mapping of Hospital Software Offers

The document is included with the Digital Hospital Quality Framework in the folder of the deliverable, available on the website for download.

6 Glossary

Functional Block: coherent grouping of indivisible features in software packages, used for the construction of Annex 5.2 (Functional and Technical Mapping of Hospital Software offers).

Document of interface administration: document describing the operations necessary for the creation and administration of external interfaces of the software (e.g. configure an interface, test it, turn it on, turn it off).

Document describing the prerequisites: document describing environment elements necessary for the proper operation of the software (e.g. network infrastructure elements, OS versions and DBMS).

Lifecycle of a software version: period starting from the commercialisation of a software version and ending at the end of the manufacturer's support date of this version.

Operations guide: guide or manual containing practical information necessary to assist the customer in the daily operation of the software and data.

Installation guide: guide or manual describing how to install the software on the customer site.

Configuration guide: guide or manual containing practical information necessary to assist the customer in software configuration in order to adapt its operation to the local organisation.

User guide: guide or manual containing practical information necessary to assist the customer in the daily use of the software.

Proprietary interface: Interface between two software applications, whose technical characteristics do not meet any of the standards adopted nationally, but instead are defined and imposed locally by the customer.

Health care software: A product that implements at least one of the blocks of the functional section "Clinical care production" or the functional section "Medical laboratory production" of annex 5.2 (Functional and Technical Mapping of Hospital Software Offers).

Maintenance: The term "maintenance" used in this framework without a qualifier includes both corrective software maintenance ("maintenance performed after detecting a fault and designed to deliver a commodity to a state in which it can perform a required function", extract of the NF EN 13306 X 60-319 standard) and evolutionary software maintenance ("action consisting of the modification of the behaviour or proposal of new functions of a software artefact, for example as a result of user requests").

Hotfix update: The ability to update the application code without interrupting the service.

SaaS: "Software as a Service" is a concept of offering a subscription to software rather than buying a license. Resources (data, application servers, etc.) are outsourced instead of being installed at the customer.

Patch: Any element modifying the source code or a correction on the configurations of software, non-specific to the customer and not involving any functional evolution of the software.

PGSSI-S: Global policy guidelines on the security of health information systems.

Project quality assurance plan: a document issued by the manufacturer reporting on the practices, resources and sequence of activities related to the conduct of a project or the execution of a particular contract.

QMS: Quality Management System.

Knowledge transfer: The knowledge transfer is organised in three steps at a minimum: formalised and transferred knowledge of the customer's business frameworks, formalisation of the customer's activities, data collection. This transfer requires on the part of the manufacturer an inventory of practices and problems involved, the methodology, and IT tools.

Minor / intermediate version: a version that fixes bugs and / or provides new functionalities that have no impact on the rest of the software and do not modify the operation mode or the user organisation.

Major version: a version that brings new functionalities that have an impact on the rest of the application or modify the operation mode, or the user organisation.

Continuous development: unlike the mode of development through the implementation of major and minor (or intermediate) versions, the continuous development process involves the delivery of versions at fixed dates and the activation of new functionalities launched at the initiative of each customer.

