

HDH accreditation reference system

Version 1.1 - June 2018

This document is the English version of HDH accreditation reference system v1.1. In case of litigation, only the French version shall be considered as authentic, valid and taken into consideration for any purpose of interpretation.

Reference documents**Reference no. 1: NF ISO/CEI 17021-1:2015**

Conformity assessment -- Requirements for bodies providing audit and certification of management systems

Reference no. 2: NF ISO/CEI 27001:2013

Information technology -- Security techniques -- Information security management systems -- Requirements

Reference no. 3: NF ISO/IEC 20000-1:2011

Information technology -- Service management -- Part 1: Service management system requirements

Reference no. 4: Requirements and controls of the HDH reference system**Reference no. 5: IAF MD1:2018**

IAF Mandatory Document for Certification of Multiple Sites Based on Sampling

Reference no. 6: IAF MD2:2017

IAF Mandatory Document for Transfer of Accredited Certification of Management Systems

Reference no. 7: IAF MD4:2008

IAF Mandatory Document for Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems

Reference no. 8: IAF MD5:2015

Determination of Audit Time of Quality and Environmental Management Systems

Reference no. 9: IAF MD11:2013

IAF Mandatory Document for Application of ISO/CEI 17021 for Audits of Integrated Management Systems (IMS)

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1.Introduction

1.1. Purpose of this document

This document is intended for certification bodies seeking accreditation for the certification of “physical infrastructure providers” or “IT managed services providers” and for hosts seeking to obtain certification. It describes the accreditation process for certification bodies and the certification process for hosts.

1.2. Structure of the document

This document is composed of seven sections and four appendices:

1. introduction;
2. description of the scope of application of the accreditation reference system;
3. description of the applicable standards within the accreditation reference system;
4. list of the acronyms used in the accreditation reference system;
5. description of the conditions, criteria and terms of accreditation of certification bodies;
6. definition of the responsibilities of accreditation bodies;
7. description of the conditions, criteria and terms of certification of hosts;

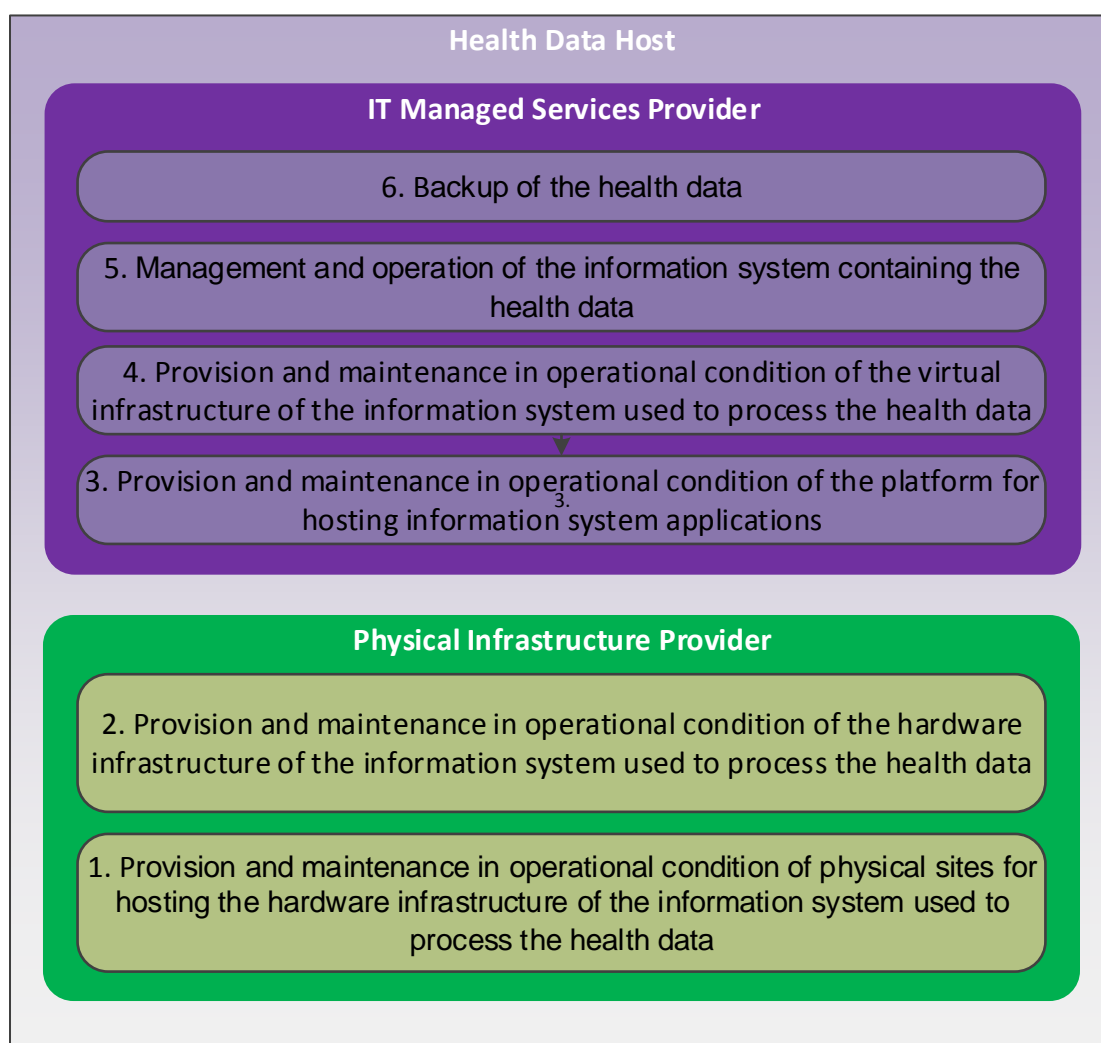
Appendices

1. appendix A, setting out the items necessary for the calculation of the audit time for HDH certification;
2. appendix B, containing the document templates to be used by certification bodies to send information to the competent authority;
3. appendix C, containing the template for notification of suspension of certification;
4. appendix D, containing the template for notification of withdrawal of certification.

2.Scope of application

The hosting of personal health data in digital format consists in performing on behalf of a third party (data controller, patient, etc.) all or some of the following activities:

1. the provision and maintenance in operational condition of physical sites for hosting the hardware infrastructure of the information system used to process the health data;
2. the provision and maintenance in operational condition of the hardware infrastructure of the information system used to process the health data;
3. the provision and maintenance in operational condition of the platform for hosting information system applications;
4. the provision and maintenance in operational condition of the virtual infrastructure of the information system used to process the health data;
5. the management and operation of the information system containing the health data;
6. the backup of the health data.



A host seeking to obtain certification for the hosting of health data must identify the activities concerned by its application for certification.

When the scope of activities only includes the activities numbered 1 and/or 2, the host is assessed for its conformity to the requirements applicable to physical infrastructure providers. The certification obtained is entitled “physical infrastructure provider” certification.

When the scope of activities only includes the activities numbered 3 to 6, the host is assessed for its conformity to the requirements applicable to IT managed services providers. The certification obtained is entitled “IT managed services provider” certification.

When the scope for which the host is seeking certification includes at least one activity belonging to both scopes of certification, the host is assessed for its conformity to all the requirements and obtains both certification scopes.

Throughout the rest of the document, the term “HDH certification” may mean one or other of the above certification scopes indifferently.

3. Normative references

The documents listed below are normatively referenced in this reference system and are essential for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NF ISO/CEI 27001:2013, *Information technology -- Security techniques -- Information security management systems -- Requirements*

NF ISO/CEI 20000-1:2011, *Information technology -- Service management -- Part 1: Service management system requirements*

NF ISO/CEI 17021-1:2015, *Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements*

Throughout the rest of the document, these standards will be referred to as follows:

- NF ISO 27001 for standard NF ISO/IEC 27001:2013;
- NF ISO 20000-1 for standard NF ISO/IEC 20000-1:2011;
- NF ISO 17021-1 for standard NF ISO/IEC 17021-1:2015.

4.Acronyms used

| | |
|---------------|---|
| COFRAC | Comité Français d'Accréditation |
| SoA | Documented Statement of Applicability describing the security objectives, and the appropriate measures applicable to an organization's Information Security Management System |
| HDH | Health Data Host or Health Data Hosting |
| IAF | International Accreditation Forum |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| CB | Certification Body |

5. Conditions, criteria and terms of accreditation

The conditions, criteria and terms of accreditation are based on standard NF ISO 17021-1. Accreditation attests to the competence, impartiality and reliability of a body to verify conformity to established, formal requirements. Accreditation constitutes a level-two control, which aims to control the way in which the controller operates.

5.1. Conditions and criteria of accreditation

Certification bodies authorized to issue HDH certificates of compliance must be accredited by a national accreditation body as defined in Regulation (EC) No. 765/2008 (COFRAC in France or its equivalent in the other countries that are signatory to the international multilateral recognition agreements) in accordance with this accreditation reference system which will be regularly reviewed in order to integrate, in particular, technological changes in health information systems, as well as changes in the hosting professions.

Through the application of and compliance with the requirements of the accreditation reference system, it is possible to guarantee that accredited bodies are competent to issue HDH certifications.

Accreditation concerns the assessment of bodies seeking certification as personal health data hosts.

For a body to be accredited to issue HDH certifications, it must fulfil the conditions described in standard NF ISO 17021-1 and apply the rules in force for the audit and certification of information systems security management. In addition, this accreditation reference system defines the specific requirements that apply to HDH certification.

5.2. Accreditation requirements

5.2.1. General requirements

5.2.1.1. Legal and contractual matters

The requirements of §5.1 of standard NF ISO 17021-1 apply.

5.2.1.2. Management of impartiality

The requirements of §5.2 of standard NF ISO 17021-1 apply.

5.2.1.3. Liability and financing

The requirements of §5.3 of standard NF ISO 17021-1 apply.

5.2.2. Structural requirements

5.2.2.1. Competence of personnel

The requirements of §7.1 of standard NF ISO 17021-1 apply.

Upon the selection of the audit team, the certification body ensures that the competencies brought to each engagement are appropriate. The team must have sufficient knowledge of the aspects relating to information security, sensitive data storage, and the services provided by health data hosts.

In particular, the certification body's auditors who take part in the HDH certification activities must be able to demonstrate that they possess competencies in the fields of information systems security, notably healthcare information systems security.

The certification body's management must define the processes and have the necessary resources to enable it to determine whether the auditors are competent for the tasks that they are required to perform within the scope of HDH certification. The certification body must be able to provide its clients with details on the competence of its personnel involved in the certification activities.

5.2.2.2. Personnel involved in the certification activities

The requirements of §7.2 of standard NF ISO 17021-1 apply.

The team of auditors may be supplemented by technical experts. Such technical experts do not substitute for the auditors, but assist them on matters of the adequacy of the means used in relation to security within the context of health data hosting.

It is recommended that the experts should possess specific competencies relating to healthcare, acquired through training or a project.

The certification body must implement a procedure making it possible to:

- a) select auditors and technical experts on the basis of their competencies, training, qualifications and experience;
- b) assess the conduct of the auditors and technical experts during certification and surveillance audits.

5.2.2.3. Use of individual external auditors and external technical experts

The requirements of §7.3 of standard NF ISO 17021-1 apply.

5.2.2.4. Personnel records

The requirements of §7.4 of standard NF ISO 17021-1 apply.

5.2.2.5. Outsourcing

The requirements of §7.5 of standard NF ISO 17021-1 apply.

5.2.3. Information requirements

5.2.3.1. Public information

The requirements of §8.1 of standard NF ISO 17021-1 apply.

5.2.3.2. Certification documents

The requirements of §8.2 of standard NF ISO 17021-1 apply.

The certification body provides each of its clients that are certified as personal health data hosts with the documents attesting to their certification.

These documents must:

- specify the scope of the service certified on the basis of the activities defined in chapter 2 "Scope of application";
- specify the ISO standards to which the body is already certified and with whose existing requirements it complies (NF ISO 27001 and NF ISO 20000-1).
- specify the location of all the sites falling within the scope of certification.

5.2.3.3. Reference to certification and use of marks

The requirements of §8.3 of standard NF ISO 17021-1 apply.

5.2.3.4. Confidentiality

The requirements of §8.4 of standard NF ISO 17021-1 apply.

Before any action on the part of the audit team, the certification body must ensure with the applicant that the information to be disclosed during the audit does not contain any personal health data or any confidential or sensitive data. If applicable, the certification body and the applicant must define the conditions of access to the system to be audited (confidentiality undertaking, etc.).

In the event of inability to audit the information system without accessing personal health data or other confidential or sensitive data, the certification body must inform the applicant thereof, a confidentiality agreement must be drawn up and a health professional acting under the responsibility of the client must be informed.

Chapter 8.4.2 of standard NF ISO 17021-1 is supplemented as follows: the personal health data and all other confidential or sensitive data to which the certification body may have access within the context of the audit may not be disclosed or re-used by the certification body or by the certification applicant.

Any access to personal data by the certification body must be logged, date- and time-stamped, and include the name of the auditor.

5.2.3.5. Exchanges of information with the competent authority

a. HDH suspension report

The certification body must inform the competent authority in French or in English of any decision to suspend certification of a health data host.

The following information relating to the health data host whose certification has been suspended must be disclosed:

- designation or corporate name of the health data host whose certification has been suspended;
- ID number of the suspended certificate;
- date of suspension of the certificate;
- reasons for the suspension of HDH certification.

The information must be sent electronically using the template provided in Appendix B: Exchanges of information between the certification body and the competent authority.

b. HDH withdrawal report

The certification body must inform the competent authority in French or in English of any decision to withdraw certification of a health data host.

The following information relating to the health data host whose certification has been withdrawn must be provided:

- designation or corporate name of the health data host whose certification has been withdrawn;
- ID number of the withdrawn certificate;
- date of withdrawal of the certificate;
- reasons for the withdrawal of HDH certification.

The information must be sent electronically using the template provided in Appendix B: Exchanges of information between the certification body and the competent authority.

c. HDH client inventory

The certification body must provide the competent authority with an inventory of the valid, suspended and withdrawn certifications on a monthly basis. This inventory, in French or English, must contain the following information for each health data host:

- designation or corporate name of the health data host;
- certificate ID number;
- type of certificate;
- scope of certification;
- address of the site certified and, in the event of multi-sites, address of the registered office and of all the attached sites;
- certification status (valid, suspended or withdrawn);
- date of certification.

The inventory must be sent electronically using the template provided in Appendix B: Exchanges of information between the certification body and the competent authority.

d. HDH annual report

The requirements of § 8.5 of standard NF ISO 17021-1 apply.

Each year, the certification body must provide the relevant authority with an annual report in French or English, including:

- an anonymized summary of the HDH certifications, audits performed and non-conformities noted;
- a summary of the difficulties encountered during the certification of hosts and any proposed changes to be made to the certification and accreditation reference systems;
- indicators relating to the HDH certification procedure, such as:
 - number of health data hosts in the process of certification;
 - number of health data hosts that have failed to obtain certification;
 - number of recertifications;
 - average duration of the audits.

The annual report must be sent electronically between 1 and 31 January of the following year using the template provided in Appendix B: Exchanges of information between the certification body and the competent authority.

5.2.4. Process requirements

5.2.4.1. Pre-certification activities

a. Application

The requirements of § 9.1.1 of standard NF ISO 17021-1 apply.

In the event of the transfer of certification, the IAF MD 2:2017¹ guide applies. In addition, the accepting certification body must inform the competent authority of any transfer of certification and state the name of the issuing certification body.

b. Application review

The requirements of § 9.1.2 of standard NF ISO 17021-1 apply.

¹ <https://www.cofrac.fr/documentation/IAF-MD2>

c. Audit programme

The requirements of § 9.1.3 of standard NF ISO 17021-1 apply.

Chapter 9.1.3.5 is supplemented by the following requirement: the description of the scope of certification must include the list of activities given in chapter 2 for which the applicant is seeking certification in order to determine the type of HDH certification.

The requirements applicable for each of the types of certification (“physical infrastructure provider” certification and “IT managed services provider” certification) are specified in the document describing the requirements and controls of the HDH reference system.

d. Determining audit time

The requirements of § 9.1.4 of standard NF ISO 17021-1 apply. In addition, the requirements of IAF Mandatory Documents MD 4:2008² and MD 5:2015³ apply.

The audit time must be determined applying the method and tables set out in the following appendix hereto: Appendix A: Audit time for HDH certification.

If the result obtained after calculation is not a full number of days, the number must be rounded to the nearest half-day (e.g., 5.3 days of audit becomes 5.5 days of audit, and 5.2 days of audit becomes 5 days of audit).

e. Multi-site sampling

The requirements of § 9.1.5 of standard NF ISO 17021-1 apply. In addition, IAF Mandatory Document MD 1:2018⁴ applies.

f. Multiple management systems standards

The requirements of § 9.1.6 of standard NF ISO 17021-1 apply, as does the IAF MD 11:2013⁵ guide.

5.2.4.2. Planning audits

The requirements of § 9.2 of standard NF ISO 17021-1 apply.

5.2.4.3. Initial certification

The requirements of § 9.3 of standard NF ISO 17021-1 apply.

5.2.4.4. Conducting audits

The requirements of § 9.4 of standard NF ISO 17021-1 apply.

5.2.4.5. Certification decision

The requirements of § 9.5 of standard NF ISO 17021-1 apply.

5.2.4.6. Maintaining certification

The requirements of § 9.6 of standard NF ISO 17021-1 apply.

Certification is issued for a duration of three years. Certified hosts must file an application for recertification with the certification body no later than three months before the expiry date of the certification validity.

² <https://www.cofrac.fr/documentation/IAF-MD4>

³ <https://www.cofrac.fr/documentation/IAF-MD5>

⁴ <https://www.cofrac.fr/documentation/IAF-MD1>

⁵ <https://www.cofrac.fr/documentation/IAF-MD11>

5.2.4.7. Appeals

The requirements of § 9.7 of standard NF ISO 17021-1 apply.

5.2.4.8. Complaints

The requirements of § 9.8 of standard NF ISO 17021-1 apply.

5.2.4.9. Client records

The requirements of § 9.9 of standard NF ISO 17021-1 apply.

5.2.4.10. Management system requirements for certification bodies**a. Options**

The requirements of § 10.1 of standard NF ISO 17021-1 apply.

b. Management system requirements in accordance with ISO 9001

The requirements of § 10.2 of standard NF ISO 17021-1 apply.

c. General management system requirements

The requirements of § 10.3 of standard NF ISO 17021-1 apply.

5.2.5. Possible evaluation methods

Annex B of standard NF ISO 17021-1 applies.

6. Responsibilities of accreditation bodies

The roles of the accreditation bodies (COFRAC, in France, and its European counterparts), consist in ensuring that the bodies that they accredit are competent and impartial, and that they remain so over time, whatever the context.

To establish this competence, the accreditation body performs regular assessments of the operation of the accredited bodies. The assessments comprise a documentation review, as well as the observation of an audit by the assessors to verify the quality of the procedures and the way in which they are applied.

6.1. Accreditation process

The accreditation process complies with standard NF ISO 17021-1.

If the certification body is already accredited to standard NF ISO 17021-1, a major extension of the accreditation scope to another field will be necessary. This will lead to an assessment at the head-office of the body concerned and, at minimum, the observation of the activity.

If the certification body is not already accredited to standard NF ISO 17021-1, the initial accreditation process must be applied.

After the accreditation application has been granted approval by the national accreditation body for HDH certification (operational approval, etc.), the certifying bodies for which an accreditation application is in progress are allowed to issue certificates for a period of nine (9) months.

Accreditation must be obtained within a maximum period of nine (9) months as from the date of notification of the positive decision of operational approval.

If accreditation has not been obtained within that time, the certification body informs its clients so that they can contact another certification body to obtain a new certificate.

Certificates issued during the nine-month (9-month) period must be re-issued under accreditation if they were initially issued in the same conditions as those in which accreditation was able to be delivered.

The scope of accreditation is expressed as follows:

| Subject of certification | Certification reference | Accreditation reference system |
|---|---|---|
| Systems for the management of health data host information systems security | HDH Requirements and Controls Certification Reference System (version in force) | HDH accreditation reference system (version in force) |

6.2. Accreditation suspension process

6.2.1. Suspension decision

In the event of suspension of accreditation on the initiative of the accreditation body, the latter immediately informs the certification body and the competent authority thereof.

Notification of suspension must be sent electronically using the template provided in Appendix C: Notification of suspension of certification.

The suspension decision is notified by registered letter with return receipt requested, specifying the scope of the suspension of accreditation, the grounds for the accreditation body's decision, and the conditions in which the accreditation body may restore the accreditation of the certification body.

If the certification body does not provide the answers requested by the accreditation body within the time limits specified in the suspension decision, accreditation is withdrawn for the personal health data host certification activities.

Upon receipt of the decision to suspend its accreditation, the certification body is obliged to inform its clients and to cease all further reference to accreditation. A body whose accreditation is suspended must no longer perform any certification audits, or issue decisions relating to health data host certificates.

6.2.2. Restoring accreditation

In the event of suspension on the initiative of the accreditation body, the conditions for restoring accreditation are specified in the suspension decision sent to the certification body.

The decision to restore accreditation can only be issued following an on-site assessment of the certification body or the review by the accreditation body of an internal audit report provided by the certification body. If the report does not provide sufficient evidence of compliance with accreditation requirements, the certification body is informed by letter that accreditation can only be restored on the basis of the results of an on-site assessment. The decision to restore accreditation is notified by the accreditation body. A new accreditation certificate stating the effective date of restoration of accreditation is drawn up and the technical appendix defining the activities for which accreditation has been granted is updated. The accreditation validity expiry date remains unchanged in relation to the initial accreditation.

In the event of refusal to restore accreditation, the certification body may appeal the decision to the accreditation body.

6.3. Accreditation withdrawal process

In the event of withdrawal of accreditation, the accreditation body immediately informs the certification body and the competent authority thereof.

Notification of withdrawal must be sent to the competent authority electronically using the template provided in Appendix D: Notification of withdrawal of certification.

Withdrawal of accreditation takes effect as of the date of notification of the withdrawal by the accreditation body. The decision is notified to the certification body by registered letter with return receipt requested, specifying the grounds for the decision.

The body is no longer authorized to issue certificates or to maintain existing certificates.

The certification body whose accreditation has been withdrawn must cease all activities relating to the certification of health data hosts and must immediately inform the competent authority and its clients thereof so that the latter may contact another certification body accredited for that purpose, in order to transfer the certification held if appropriate.

The accreditation body has the option to carry out an inspection at the certification body's site to ensure that the activities relating to the certification of health data hosts have been suspended and that the competent authority and the clients have been informed.

6.4. Transfer of certification to another certification body following withdrawal

A new certification body that receives a request for transfer must apply the provisions described in §7 hereof. If it is unable to obtain the client's file from the former certification body, the client's request will be handled as an initial certification. In any case, it is up to the "accepting" certification body to assess the details provided and to establish whether the certification cycle can be resumed at the same stage of certification as that which had been reached with the initial certification body.

6.5. Cessation of activity of a certification body

The accreditation body immediately informs the competent authority of any announcement of cessation of activity by a certification body.

The certification body is also obliged to inform the competent authority, as well as the clients concerned, at the earliest opportunity so that they can contact another certification body accredited for that purpose, in order to transfer the certification held if appropriate.

7. Conditions, criteria and terms of certification

7.1. Conditions and criteria of certification

An applicant seeking to obtain HDH certification must meet the requirements of the HDH certification reference system and submit an application for certification to a certification body accredited in accordance with the HDH accreditation reference system.

To obtain HDH certification, an applicant must:

- be certified to ISO 27001 for a scope covering at least that for which the applicant is seeking HDH certification (the candidate may obtain ISO 27001 certification as part of the HDH certification and conversely HDH certification may be obtained during ISO 27001 certification);
- take into account in its information security management system the requirements of the HDH certification reference system applicable to the type of certification sought (requirements under standard ISO 20000-1, and requirements relating to the protection of personal data and specific health-related requirements).

A host who has already obtained ISO 27001 certification or ISO 20000-1 certification may have these certifications recognized if it meets the conditions set out chapter 7.2.

An applicant already possessing these certifications is assessed on the scope of the requirements of the certification reference system not covered by them. The certifications already obtained are verified in the conditions defined in chapter 7.2.

7.2. Equivalence

If the applicant wishes to have the certification(s) it has already obtained according to standards NF ISO 27001 and NF ISO 20000-1 taken into account, these certifications must meet all of the following conditions:

- the scope of application of the certification obtained by the host must include the scope for which the applicant is seeking HDH certification;
- the audit reports: the initial audit report and the surveillance audit reports relating to the certification for which equivalence is requested must be provided upon request by the certification body;
- for an applicant possessing ISO 27001 certification, the statement of applicability (SoA) for the organization's information security management system must expressly include:
 - detailed justification of any ISO 27001 controls excluded;
 - detailed justification of any non-applicable control;

- certifications must:
 - be currently valid;
 - have been issued by a certification body accredited by a national accreditation body as defined in Regulation (EC) No. 765/2008⁶ for the issue of these certificates and whose accreditation must be currently valid (COFRAC in France or its equivalent in the other countries that are signatories to the international multilateral recognition agreements);
 - not have been the subject of a suspension or withdrawal procedure;
 - not be the subject of a transfer request.

The above conditions must be verified by the certification body receiving the HDH certification application, which must register the information received (copies of certificates, in particular) and justify the results of its verification stating which certification(s) is (are) approved by the certification body prior to the initial audit of the applicant.

Certifications obtained according to international standards equivalent to the French standards stated above may be accepted according to the same conditions.

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>

Appendix A: Audit time for HDH certification

The audit time table below provides the framework that must be used to plan an HDH certification audit by identifying a starting point based on the total number of people working under the control of the organization for all the positions involved in the health data hosting service and by adjusting significant factors.

The certification body must provide the client with the calculation of the audit time and supporting documents. The latter form an integral part of the contract and must be made available to the accreditation body upon request.

The starting point for the determination of the audit time for an HDH certification must be based on the actual number of employees involved in the health data hosting service, then may be adjusted according to significant factors applicable to the client to be audited.

| Number of people involved in the health data hosting service | HDH certification audit time (stage 1 + stage 2) A+B | | |
|--|--|---|------------------------------------|
| | (A) NF ISO 27001 audit time | (B) Audit time for requirements excluding NF ISO 27001 | Total HDH certification audit time |
| 1 - 10 | 5 | 1 | 6 |
| 11 - 15 | 6 | 1 | 7 |
| 16 - 25 | 7 | 1.5 | 8.5 |
| 26 - 45 | 8.5 | 2 | 10.5 |
| 46 - 65 | 10 | 2 | 12 |
| 66 - 85 | 11 | 2 | 13 |
| 86 - 125 | 12 | 2.5 | 14.5 |
| 126 - 175 | 13 | 2.5 | 15.5 |
| 176 - 275 | 14 | 3 | 17 |
| 276 - 425 | 15 | 3 | 18 |
| 426 - 625 | 16.5 | 3.5 | 20 |
| 626 - 875 | 17.5 | 3.5 | 21 |
| 876 - 1175 | 18.5 | 4 | 22.5 |
| 1176 - 1550 | 19.5 | 4 | 23.5 |
| 1551 - 2025 | 21 | 4 | 25 |
| 2026 - 2675 | 22 | 4.5 | 26.5 |
| 2676 - 3450 | 23 | 4.5 | 27.5 |
| 3451 - 4350 | 24 | 5 | 29 |
| 4351 - 5450 | 25 | 5 | 30 |
| 5451 - 6800 | 26 | 5 | 31 |
| 6801 - 8500 | 27 | 5.5 | 32.5 |

| | HDH certification audit time (stage 1 + stage 2) A+B | | |
|--|--|---|------------------------------------|
| Number of people involved in the health data hosting service | (A) NF ISO 27001 audit time | (B) Audit time for requirements excluding NF ISO 27001 | Total HDH certification audit time |
| 8501 - 10700 | 28 | 5.5 | 33.5 |
| > 10700 | Follow the sequence above | Follow the sequence above | Follow the sequence above |

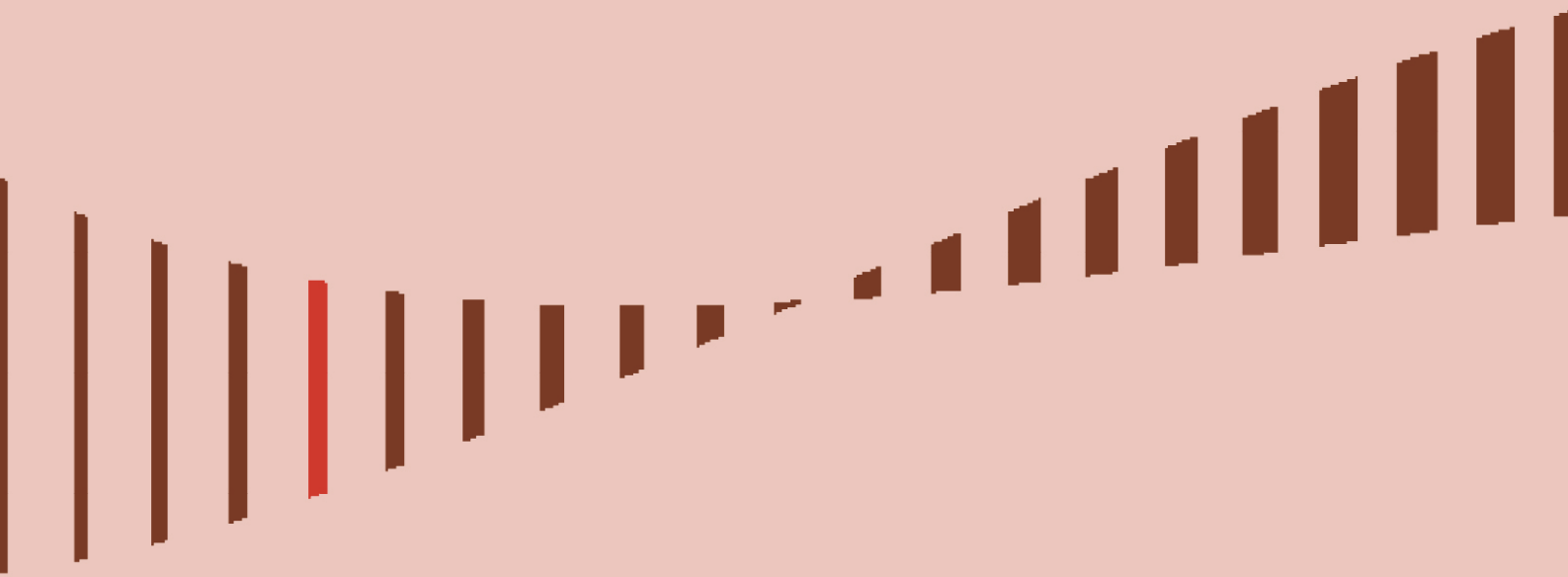
The duration of the audit may be adjusted upwards or downwards depending on specific factors in accordance with current best practices. Such factors may include, for example, the complexity of the environment to be audited, logistics constraints related to the audit, or prior knowledge of the context.

Appendix C: Notification of suspension of certification

| HDH suspension report | |
|--------------------------|------------|
| Certification body: XXXX | |
| Date: dd/mm/yyyy | |
| Health data host | XXXX |
| Certificate ID number | No. XXXX |
| Date of suspension | dd/mm/yyyy |
| Reasons for suspension | XXXX |

Appendix D: Notification of withdrawal of certification

| HDH withdrawal report | |
|--------------------------|------------|
| Certification body: XXXX | |
| Date: dd/mm/yyyy | |
| Health data host | XXXX |
| Certificate ID number | No. XXXX |
| Date of withdrawal | dd/mm/yyyy |
| Reasons for withdrawal | XXXX |



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