Rules of Procedure for Authorisation of Manufacturers, Reconditioners, Thermal Reinsulators of Perishable Foodstuffs Carriage Equipment and Agents Applying for Certificates

Fabricant habilité
Cemafroid
L'expertise de la chaîne du froid

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MEMBERS OF THE "CTS TRANSPORT" SPECIALIZED TECHNICAL COMMITTEE ON THE TEMPERATURE-CONTROLLED CARRIAGE OF PERISHABLE FOODSTUFFS

PANELS
DGAl - Direction Générale de l'Alimentation (Directorate General for Food and Nutrition) DDPP - Direction départementale de la protection des populations (District Office for the Protection of Populations)
CEMAFROID – Management Representative CEMAFROID – Certification Manager and Commission Secretary CEMAFROID – Auditors
Body Makers Carriers Rental Companies Unit Manufacturers Test Centers Container manufacturers

For each panel an incumbent and a substitute are nomminated.

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1. Scope of Document

This document presents and defines the various steps of the assessment and authorisation process for any organisation involved in the manufacture of temperature-controlled carriage equipment for professional use subject to applications for technical compliance certificates, and specifies the rights and obligations of CEMAFROID and authorised or applicant organisations.
These rules supplement the authorisation technical reference document number CER-72-001-P which defines the scope of authorisation (see § A.1 of said technical reference document).

This document concerns all public or private companies:

- manufacturers and assemblers of cells (bodies, tanks etc.);
- manufacturers or fitters of insulating systems on existing cells (tanks or bodies);
- manufacturers of thermal appliances (refrigeration units, eutectic plates, gels, dry ice, etc.);
- manufacturers of packaging for temperature-controlled carriage (cardboard boxes, envelopes, crates, coolers, flexible/rigid, disposable/reusable appliances, etc.) of any size;
- manufacturers of insulated containers less than 2 m^3 in size, which may or may not be fitted with a thermal appliance;
- body-to-chassis clamping
- thermal-appliance-to-equipment fitters;
- thermal appliance commissioning operators;
- reconditioners of mechanically refrigerated equipment;
- thermal reinsulators of insulated or mechanically refrigerated tanks;
- manufacturers of ATP-compliant marine containers.

2. Definitions and References

2.1. DEFINITIONS

In addition to the terms defined in the technical reference document for authorisation of organisations (document CER-72-001-P), the terms used herein have the meanings given below:

Audit	A systematic, independent and documented process for obtaining **audit evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled (§ 3.9.1. of ISO 9000)
Audit Client	Organisation or person requesting an **audit** (§ 3.9.7. of ISO 9000)
Audit Conclusion	Outcome of an **audit** provided by the **audit team**, after consideration of the audit objectives and all **audit findings** (§ 3.9.6. of ISO 9000)
Audit Criteria	A set of policies, procedures, and requirements (§ 3.9.3. of ISO 9000)
Audit Evidence	Records, statements of fact or other information which are relevant to the **audit criteria** and verifiable (§ 3.9.4. of ISO 9000)
Audit Findings	Results of the evaluation of the collected **audit evidence** against **audit criteria** (§ 3.9.5. of ISO 9000)
Audit Plan	Description of the activities and arrangements for an **audit** (§ 3.9.12. of ISO 9000)
Audit Program	A set of one or more **audits** planned for a specific time frame and directed toward a specific purpose (§ 3.9.2. of ISO 9000)
Audit Scope	Extent and boundaries of an **audit** (§ 3.9.13. of ISO 9000)
Audit Team	One or more **auditors** conducting an **audit,** assisted, where required, by **technical experts** (§ 3.9.10. of ISO 9000)
Auditee	Organisation being audited (§ 3.9.8. of ISO 9000)
Auditor	Person with the demonstrated personal capability and the competence to conduct an **audit** (§ 3.9.9. of ISO 9000)

Competence	Personal qualities and demonstrated capability to apply knowledge and skills (§ 3.9.14. of ISO 9000)
Contractual Documents	Documents mentioned in the certification contract or annexes thereof governing relations between CEMAFROID and the organisations seeking authorisation
CTS	Specialised technical commission for the temperature-controlled carriage of perishable foodstuffs, established within the framework of CEMAFROID's designation by the Ministry in charge of Food and Agriculture for delivery of technical compliance certificates. CTS Transport is comprised of representatives from all parties involved in temperature-controlled carriage and operates so as to ensure impartiality and confidentiality. An internal policy sets the terms of establishment, operation, dissolution and duties of this commission.
DD(CS)PP	*Direction départementale de la (cohésion sociale et de la) protection des populations* : departmental directorate for (social cohesion) and population protection (formerly *DDSV, Direction départementale des services vétérinaires* : departmental directorate for veterinary services)
Network	An organisation of organisations, such as defined in Annex 3 of these rules.
Organisation	Refers to the body applying for authorisation such as defined in these rules. An organisation can be either of the following: ➢ a unit composed of corporate headquarters (corresponding to the main facility) and an identified geographical location where all participants able to perform activities to be authorised are located; ➢ a unit composed of corporate headquarters (corresponding to the main facility) and one or more identified geographical locations where all participants able to perform the activities to be authorised are located; ➢ the organisation which is the head of an organisation of organisations (or network)
Scope of Authorisation	Formal and accurate statement of products/activities and sites (French and/or foreign) for which the organisation is requesting authorisation
Technical Expert	Person who provides the **audit team** with specific knowledge or expertise (§ 3.9.11. of ISO 9000)

2.2. REFERENCES

This document incorporates the obligations of third party certification bodies contained in NF EN 45011 (General requirements relating to product certification bodies) and in the relevant COFRAC accreditation documents (available on www.cofrac.fr).

This document is based on the standard definitions of quality management systems found in ISO 9000: 2005 (fundamentals and vocabulary).

It is also based on the provisions defined in the following standards:

- ISO 2859-1, Sampling Procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit for lot-by-lot inspection
- NF EN ISO 19011, Guidelines for Quality and/or Environmental Management Systems Auditing
- FD guide ISO/IEC 28. Conformity Assessment - Guidance on a Third Party Certification System for Products
- FD guide ISO/IEC 67. Conformity Assessment - Fundamentals of Product Certification

3. Applicability

This document, approved by DGA1 and published in February 2016 on the competent authority website, is applicable as of March 1st, 2016.

This document results from the revision of the authorisation reference document for "Manufacturers of New Equipement and Agents applying for Certification", March 2007 version, regarding the "Authorisation Process" section and any applicable provision relating to the same topic prior to the date of effect of the present document. During the transitional period, from April 1st, 2012 to June 30th, 2012 either the March 2007 reference document or the present one may be used. As of July 1st, 2012, the 2007 version will cease to be valid.

This document will be reviewed annually, or whenever justified by a change (regulatory, normative, technological, or resulting from audit feedback, etc.).

Any change to these rules will be subject to consultation of the CEMAFROID technical commission and written approval by the DGA1. Once the change has been approved, CEMAFROID, via its website and the DATAFRIG® IT system, will inform all authorised organisations, specifying what changes have been made and issuing an explanatory note if necessary.

4. Authorisation Process for Organisations: General Information

Any company involved in the manufacture of temperature-controlled carriage equipment and the application for technical compliance certification may, if it so wishes, apply to CEMAFROID for "new equipment" authorisation. No company size criterion will be considered when reviewing the application. There is no upper or lower limit in the number of authorised organisations.
An organisation with a network may request authorisation for its network and all of its facilities.
An organisation using subcontractors may request their incorporation for services concerning the organisation within the scope of authorisation.

The CEMAFROID Certification Unit alone processes the applications and information received by organisations and supervisory authorities.

CEMAFROID circulates information about a particular organisation only to government officials. Any statistical information reported by CEMAFROID must pertain to at least 3 organisations, none of which shall represent more than 50% of the sample.
CEMAFROID CTS Transport, and any expert or group of experts consulted for their opinion, deals only with anonymous documents.
The procedures relating to organisation authorisation process are separate from other CEMAFROID procedures. All information collected for the authorisation procedure is strictly confidential.

CEMAFROID personnel and CTS members sign a confidentiality commitment.

Authorisation of an organisation is delivered by CEMAFROID and under its full responsibility. The CEMAFROID manager is responsible for the overall process and decisions relating to authorisation.
Operation of CEMAFROID and its decision-making process regarding authorisation are impartial. Decisions are made, following opinion of CTS Transport, by the CEMAFROID manager, and not by the auditors who conducted the audits.

5. Requirements Set out for Authorisation

5.1. General Requirements

When signing a certification contract, the organisation agrees meet the requirements of the technical reference document for authorisation of organisations (document CER-72-001-P) and the applicable requirements of this document and the CEMAFROID documents relating to authorisation rates and fees.

The general requirements to be met by authorised or applicant organisations are defined in the standards, normative documents and guidelines mentioned in the technical reference document for authorisation of manufacturers (document CER-72-001-P).

5.2. SPECIFIC REQUIREMENTS

As the authorisation is being granted in relation to a regulatory activity, and as it is being requested by a government body, the latter is systematically informed together with the applicant of any decision made by CEMAFROID in regard to authorisation.

In addition to these rules, there is the obligation not to create, maintain or elicit ambiguousness between the CEMAFROID authorisation and any other recognition granted to the organisation, as well as between the CEMAFROID authorisation and the ownership of a test report resulting in a type compliance certificate (now collectively referred to as a test report) issued by CEMAFROID as part of its official testing station activities under the ATP agreement.

As part of the harmonisation of its practices, the CEMAFROID Certification Unit may publish technical documents for use by auditors and organisations, in the form of authorisation guides. These are not specific technical requirements which are binding on organisations. They contain recommendations that the organisation is free to apply. These are included in the recommendations on which CEMAFROID may rely to meet the requirements of the above standards.

Note: being granted authorisation by CEMAFROID does not influence in any manner the decision to issue compliance certificates for products manufactured by the organisation.

6. Processing an Application for Authorisation

All information collected by CEMAFROID or by its auditors and experts, and the very existence of an application for authorisation, are considered confidential and subject to professional secrecy.

6.1. EXAMINATION AND CONCLUSION OF A CONTRACT FOR THE AUTHORISATION APPLICATION

If the application for authorisation is being filed for the first time, the authorisation process comprises 5 main phases which break down into several steps as described below.

6.1.1. Application Admissibility Phase (prior to examination)

Upon receipt of a letter of intent from an organisation requesting Manufacturer authorisation such as defined in these rules, CEMAFROID sends the applicant, among other documents, a manufacturer authorisation application form allowing the organisation to formally confirm its application. This form is used to collect the following information:

- the legal status of the organisation and its detailed layout: the organisation must specify as clearly as possible the geographic location(s) concerned by the application;
- the management system in use;
- the detailed activities concerned by the authorisation application.

The authorisation application becomes official only after the applicant organisation has returned the authorisation application form duly filled in to CEMAFROID.

Examination of the application, supervised by a CEMAFROID officer, has the following purposes:

- to check that the application file is complete; in particular, that the information in the authorisation application scope is complete;
- to ensure that the applicant's general line of business is compatible with the authorisation application filed;
- to check whether CEMAFROID is able to process the application;

- to prepare the file for presentation to CTS.

CTS Transport is asked to give its opinion on the technical admissibility of the application.
An application fee is charged, in accordance with the applicable price list, whatever the outcome of the application.

CEMAFROID will close any file that has remained inactive for more than 1 year from the date of recording and opening of the file. A file is regarded as inactive if CEMAFROID receives no written response to its requests. CEMAFROID will give a month's notice prior to closing the application file of an applicant organisation. To reopen a file, the applicant organisation must initiate a new application for authorisation and pay the fees of any initial authorisation application.

6.1.2. Signing a Contract

Upon completion of the preliminary phase of examining the authorisation application, a certification contract and a contract for services and subscription to the DATAFRIG®[1] online database are established between CEMAFROID and the organisation applying for authorisation.

The certification contract specifies:

- the name and address of the organisation applying for authorisation;
- the mutual commitments of the applicant and CEMAFROID during assessment of the organisation;
- the description of the authorisation application scope such as accepted by CEMAFROID on completion of the preliminary examination phase;
- the financial terms.

The contract for services and subscription to the DATAFRIG® online database specifies:

- the name of the organisation having access to the database;
- the mutual commitments of the organisation and CEMAFROID regarding database access and use;
- the terms of access to the services;
- the financial terms.

6.1.3. Assessment Phase

This phase can start only after the certification contract signed by the applicant organisation and by CEMAFROID has been received.

The purpose of the assessment is:

- to examine the preestablished organisational and technical provisions; in particular, provisions made by the organisation to ensure compliance of the produced equipment specifications;
- to examine the implementation of those provisions; in particular, to check that correct and fair usage is made of the DATAFRIG® IT system for (remote) application for technical compliance certificates in accordance with the relevant contractual requirements;
- to inspect (physically or on file) the equipment produced. The equipment assessed during audits are sampled according to the methodology described in ISO 2859-1 based on the information available in DATAFRIG®; the auditor checks the compliance of the produced equipment to the certified types or the allowed variations thereof, and the compliance of certificate applications filed for these equipment via DATAFRIG®;
- to evaluate control of the organisation personnel's skills;

against the general and specific requirements as defined in § 5 of this document.

Most of the assessment is performed as part of the onsite audit, and generally includes:

- preliminary assessment of the documents collected from the organisation (e.g. quality manual, general procedure, method of operation or technical instructions, etc.);

[1] Requests for certificates are made and examined electronically, using the IT application and the DATAFRIG® developed, administered and managed by CEMAFROID.

- onsite evaluation of the quality system and equipment inspection (physically or on file)

The onsite audit arrangements (audit duration, number of sites visited) are set according to the rules found in Annex 2 of these rules.

CEMAFROID proposes to the organisation, at least 15 working days prior to the the audit, an audit team having the overall organisational and technical skills necessary to evaluate the technical fields specified in the scope of the authorisation application.

An auditor or training expert ("junior") may be included in the audit team. His/her participation in the assessment is under the responsibility of the auditor manager; the expenses arising from his/her participation in the audit are entirely paid for by CEMAFROID.

The audit team may be accompanied by an observer or supervisor, appointed by CEMAFROID as part of its auditor/expert monitoring and harmonisation procedure. The team may also be accompanied by observers from the government authorities or the accreditation body as part of the CEMAFROID assessment process. Observers and supervisors are not involved in any way in the assessment of the organisation; the expenses arising from their participation in the assessment are entirely paid for by CEMAFROID.

The organisation may, within eight working days after the audit proposal letter was sent, reject all or part of the proposed audit team, specifying the reasons for the request in writing. Acceptance or rejection of the request for recusal is confirmed in writing by the CEMAFROID Certification Director.

When either the audit team has been accepted by the organisation or CEMAFROID has rejected the reasons for the recusal, CEMAFROID sends the team members an assignment file. The audit manager can then agree with the applicant organisation and, where appropriate, with the other members of the assigned audit team, on the date of auditing in the organisation premises, and on the forecasted plan of execution of the audit.

Following the *in situ* assignment, the audit team writes an audit report which substantially includes:

- the description of the situation observed;
- the persons met;
- general impressions;
- a list of the strong points and possibilities for improvement identified during the audit;
- a list of the equipment examined (physically or on file);
- the sheets on the deviations noted, on which the approval or reservations, responses, and comments of the organisation are recorded, along with the opinion of the person who wrote the deviation sheets regarding the relevance of the actions decided on by the organisation;
- conclusions as to the capability of the organisation to meet the authorisation requirements for the services for which authorisation is being requested.

In case a deviation is observed between the provisions or practices of the organisation and the requirements of the reference document, the CEMAFROID auditor draws up a deviation sheet. The description of the deviation formalised on the sheet is signed by the auditor and countersigned by the organisation who either approves or disapproves the deviation, stating its reasons. A copy of any sheets drawn up is given to the auditor on completion of the audit. The organisation retains the original sheets, completes them by suggesting corrective actions to be implemented, and hands the sheets back to the audit manager no later than 8 days after completion of the audit.

The audit manager, within no more than 15 working days, delivers his/her report to the CEMAFROID Certification Director who, after ensuring that the report is complete and usable, transfers it to the organisation within no more than 8 working days. The organisation can then respond to CEMAFROID within eight days regarding this audit report.

6.1.4. Decision-Making Phase

The audit report is presented anonymously to CTS Transport, no later than on the first meeting held after the audit completion date plus one month. Depending on the case, this commission may be consulted by letter (post or e-mail) between two meetings.

Following examination, CTS issues an opinion on whether or not the applicant organisation can be authorised. This includes ensuring that the authorisation may not go into effect before any deviations directly affecting the result have been corrected.

Thus, two situations arise:

- in case the audit reports do not mention any non corrected deviations which directly affect the products, the opinion can be:
  - either favorable without reservation; or,
  - favorable subject to implementation, within a period determined by CEMAFROID, of actions further to those possibly decided on by the organisation;
- in case the audit reports mention non corrected deviations which directly affect the products, the opinion can be:
  - either unfavorable pending examination by CEMAFROID of evidence that the corrective actions to be implemented in response to said deviations have been executed within a a period determined by CEMAFROID; or,
  - unfavorable.

6.1.5. Notification of the Authorisation Decision

The authorisation decision, issued in view of the aforementioned opinion by the CEMAFROID Manager, is notified to the organisation by letter within a period not exceeding 15 days after the opinion was issued by CTS.

The notification specifies the nature of and the reasons for the decision, as well as any further actions necessary to help process the file.

A decision to reject authorisation does not prohibit the applicant organisation from filing a new application for authorisation, if it considers that it has taken the necessary steps to ensure compliance with the authorisation requirements. In this case, its application is processed in the same way as any initial application for authorisation.

When the decision is favorable, the notification letter includes an authorisation certificate stating:

- the identification of the organisation,
- the scope of authorisation,
- the site(s) covered by the authorisation,
- the authorisation number assigned to the organisation,
- the period of validity of the authorisation.

The organisation has a right of appeal against the decision (see § 12.2).

6.2. PERIOD OF VALIDITY OF AN AUTHORISATION

The initial authorisation is granted for a period of 36 months.

During this period, the organisation's authorisation is monitored (see Section 7). The organisation may ask for extension, suspension or termination of its authorisation as specified in Sections 9 and 10. CEMAFROID may suspend or withdraw the authorisation in case any failures to comply with the authorisation requirements are noted, as specified in Sections 9 and 10.

At the end of the period of validity, the organisation authorisation is renewed (see Section 8). Subsequently, the period of validity of the authorisation is 36 months.

6.3. FOLLOWING UP ON AUTHORISATION APPLICATIONS

If the authorisation application fails to go through within a year, CEMAFROID examines the reasons for the failure and may close the current application process. In this case, any new application shall be handled in the same way as an initial application for authorisation.

7. Monitoring of an Authorisation

Authorisation is monitored through scheduled audits, initiated by CEMAFROID, on a yearly basis as shown in Annex 1.

The organisation and technical skills of the audit team selected and proposed by CEMAFROID to the organisation cover all or part of the activities authorised according to the terms defined in Annex 2, these terms being adapted to the organisation's situation (e.g. notable changes reported since the previous audit, stability of the qualification and supervision process of key personnel).

The provisions applicable to the scheduling and execution of an audit are those defined in Section 6.1.3.

After review of the quality manual and associated procedures, the audit team essentially ensures that:

- any corrective actions to which the organisation had committed itself were implemented within the specified period;
- internal audits and management reviews are relevant, properly held and made use of;
- the developments made by the organisation to its management system, its organisation and its means, and the changes in key personnel made since the last audit ensure that the authorisation requirements are continually met;
- the organisation has applied its quality management system and followed the rules on use of the CEMAFROID brand2 and reference to authorisation;
- the sample(s) of the produced equipment are compliant. The equipment assessed during audits are sampled according to the methodology described in ISO 2859-1 based on the information available in DATAFRIG®; the auditor checks the compliance of the produced equipment to the certified types or the allowed variations thereof, and the compliance of certificate applications filed for these equipment via DATAFRIG®.

Following the monitoring audits, audit reports are drawn up and disclosed according to the same terms as described in Section 6.1.3. for initial authorisation audits. They are presented to CTS according to the applicable provisions defined in Section 6.1.4.

Following its examination, CTS issues an opinion on whether or not the organisation's authorisation can be maintained. This opinion may consist in:

- maintaining the authorisation without reservation;
- maintaining the authorisation subject to the transmission, within a period determined by CEMAFROID, of information relating to the implementation of corrective actions decided on by the organisation, for verification through documentation; particularly when shortcomings or abuses of the quality system having no immediate effect on product compliance are noted during monitoring audits;
- maintaining the authorisation subject to satisfactory results after a further audit conducted within a period determined by CEMAFROID;
- temporary suspension of the authorisation;
- withdrawal of the authorisation.

The decisions of suspension or withdrawal of authorisation result in the suspension or withdrawal of access to the DATAFRIG® system.

In any case, the CEMAFROID decision is notified to the organisation by letter, according to the applicable provisions set out in Section 6.1.5.

[2] Use of the logo and brands is subject to a specific contract between the user organisation and CEMAFROID.

8. Renewal of an Authorisation

The period for the renewal audit is set by CEMAFROID so that the new authorisation certificate can be drawn up prior to the end of validity date of the previous authorisation period. CEMAFROID informs the organisation of the period set for the audit and asks the organisation, where appropriate, to provide all information necessary for arranging the audit. CEMAFROID reserves the option to suspend authorisation of any organisation who fails to provide the requested items within the specified period.

The assignment of the renewal audit team is identical to that of an initial audit.

The terms and conditions applicable to the scheduling and execution of the audit, the production of the audit report and its presentation to CTS are those defined in Sections 6.1.3. and 6.1.4.

Following examination, CTS issues an opinion on whether or not the organisation's authorisation can be renewed. This opinion may be:

- to renew the authorisation without reservation;
- to renew the authorisation subject to the transmission, within a period determined by CEMAFROID, of information relating to the implementation of corrective actions decided on by the organisation, for verification through documentation;
- to maintain the authorisation subject to satisfactory results being obtained after a further audit conducted within a period determined by CEMAFROID;
- not to renew the authorisation;
- to withdraw the authorisation.

The decisions of suspension or withdrawal the of the authorisation result in suspension or withdrawal of access to the DATAFRIG® system.

In any case, the CEMAFROID decision is notified to the organisation by letter, according to the applicable provisions set out in Section 6.1.5.

Following the decision-making phase, if the decision is favorable, a new authorisation certificate is sent to the organisation.

In case an organisation's authorisation is either not renewed or withdrawn, CEMAFROID informs all DD(CS)PPs and the DGA1 via a specific message issued by e-mail or in DATAFRIG®.

9. Extension of an Authorisation

An organisation may at any time ask that its previously granted scope of authorisation be extended:

- to other types of activities falling in the scope of authorisation;
- to a new geographic location;
- to new members, in an organisation of organisations.

Application for extension must be sent to CEMAFROID at least 3 months prior to the selected extension audit period, or 3 months before the period planned for the audit as defined by the authorisation cycle (see Annex 1), for a joint audit. However, it remains the responsibility of CEMAFROID to seek a date which is compatible with the schedules monitoring or renewal periods. CEMAFROID reserves the right to refuse the joint processing of an extension.

The terms and conditions of examination and assessment of such an application are usually identical in principle to those provided for in a first application. However, they may be streamlined based on the content of the previous audit reports.

The authorisation extension audit report is examined by CTS, the latter submits an opinion to the CEMAFROID manager who, in turn, makes a decision. When the decision is favorable, a revised certificate is issued and sent to the organisation. Extension of the authorisation scope does not affect the end of validity date of an authorisation which is valid when the extension occurs.

10. Reduction, Suspension, Termination, and Withdrawal of an Authorisation

An organisation may, at any time, wish to reduce the scope of its authorisation, or suspend or terminate the authorisation. The organisation must send its request to CEMAFROID in writing, to enable the request to be considered.

In case of a reduction of the authorisation scope, or a suspension of a part thereof, a new, revised certificate is issued. Such a reduction or partial suspension does not affect the end of validity date of an authorisation which is valid when the reduction or suspension of scope occurs.

In regard to organisations of organisations having multiple locations for conducting the activities relating to authorisation, no expulsion of a member of the authorised organisation shall occur without prior approval of CEMAFROID, who shall evaluate how the scope of authorisation is to be updated. CEMAFROID may, during a periodic audit, ask that information regarding this member be made available for assessment purposes.

11. Transfer of an Authorisation

Whenever changes are made which affect the conditions in which the authorisation was granted, the authorised organisation must inform CEMAFROID in writing before these changes occur. Changes may be of a legal, organisational, or administrative nature, such as:

- a change in designation or company name;
- a change in legal form or structure;
- a grouping, demerger, divestiture or any change which may lead to a new authorisation contract being issued;
- a change of address (with or without a move).

In any case, the information is reviewed by CEMAFROID who, when it is satisfactory, updates the information relating to the organisation's authorisation or to the transfer of authorisation.

Cases of changes causing the certificate and organisation file to be updated <u>without the authorisation being transferred:</u>

- a change in the company name only, without the SIREN number changing:
- a change in the legal form only, without the SIREN number changing;
- a change of address for the headquarters or one of the sites, without the legal form changing.

Cases of changes leading to <u>the authorisation being transferred:</u>

- a change of SIREN number, with or without a change of legal form;
- a complex change relating to the legal entity, such as a merger, demerger, diverstiture, transfer of goodwill, or business leasing contract.

When an authorisation is transferred, its end of validity date remains the same as that of the authorisation prior to the transfer.
In all cases of transfer, an audit is scheduled within 2 months following the transfer in order to check for continued compliance. This audit may be coupled to a regular audit in the authorisation cycle.

12. Complaints, Appeals

All complaints or appeals are recorded and processed either at Certification Director level, or at CEMAFROID Manager level, or by CTS who may, where appropriate, refer to the DGA1 for arbitration.

12.1. COMPLAINTS

Complaints are demonstrations, other than appeals, of insatisfactions expressed by any natural or legal person regarding, among other things, services provided by CEMAFROID or services provided by an authorised organisation, or use being made by an organisation, whether authorised or not, of the CEMAFROID brand or reference to authorisation, when a response is expected.

All complaints lodged in writing are recorded and processed by CEMAFROID.

CEMAFROID records the complaints against an organisation which have come to its knowledge. It may either add them to the file for examination during a monitoring or renewal audit, or present them to CTS for an opinion, or immediately initiate a new audit, or immediately suspend authorisation.

12.2. APPEALS

An appeal is any request expressed by an authorised or applicant organisation with the aim to reconsider any unfavorable decision made by CEMAFROID in regard to the authorisation status requested by the organisation.

The appeal is notified to CEMAFROID by registered letter with acknowledgement of receipt, within 15 working days following the notification of the decision under appeal. The appeal is not suspensive of the decision. It is examined at first instance by the Certification Director and the Manager of CEMAFROID and subsequently, at second instance, by CTS Transport.

13. Obligations of CEMAFROID

13.1. GENERAL OBLIGATIONS

The authorisation criteria defined in these rules, which are validated on the recommendation of the CEMAFROID CTS Transport by the Directorate General for Food and Nutrition (DGA1), must be complied with by CEMAFROID who may not depart from them unless approved in writing by DGA1.

Under its delegation of public service, CEMAFROID must be accredited as a certification body for products and services. For this purpose, CEMAFROID is developing a management system in compliance with the accreditation requirements.

CEMAFROID does not subcontract its organisation authorisation activity.

13.2. DOCUMENTATION AND IMPROVEMENT LOOP

CEMAFROID is required to record all information from authorised or applicant organisations, their clients, and supervisory authorities in order to improve the authorisation reference document and policy. A register of such information is maintained by CEMAFROID.

CEMAFROID maintains a register of authorised organisations and keeps the complete files of audits as well as the letters exchanged with the organisations within the Certification Management. Records relating to the authorisation procedure are kept for 6 years.

CEMAFROID delivers to the DD(CS)PPs and the DGA1 via DATAFRIG®, any and all information relating to the authorisation system.

Should the DD(CS)PPs, CEMAFROID, or any other body detect a problem with the authorised organisations, DGA1 must be informed. CEMAFROID then takes all steps necessary to deal with the problem, going as far as the temporary suspension, or even the withdrawal, of an organisation's authorisation.

13.3. PERSONNEL

The personnel of the CEMAFROID Certification unit is qualified according to a CEMAFROID internal procedure based on the criteria of NF EN ISO 19011. This qualification is reviewed on a regular basis.
Auditors are CEMAFROID personnel, who have been trained on the organisation authorisation reference document and on the management of onboard refrigeration.
Auditors and all personnel involved in the organisation authorisation process have a commitment to confidentiality with respect to CEMAFROID and all the organisations they come to audit.

14. Obligations of Authorised or Applicant Organisations

Obligations of organisations which have been authorised by CEMAFROID or who are applying for authorisation are precisely defined in the certification contract.

For information, it is recalled that when signing a certification contract with CEMAFROID, the organisation agrees, in particular:

- to offer CEMAFROID or its representatives all reasonable and necessary cooperation, including:
  - access to all of its premises, personnel, documents and records concerned by the application and useful for conducting the assessments:
  - permission to attend the production activities for which authorisation is being requested;
  - where appropriate, communication, prior to the audit, of all the documentation necessary to prepare the work of the audit team;
- to pay all expenses relating to the assessments, irrespective of the conclusions to which they may lead;
- to state that it has authorisation only for those activities for which it has been granted authorisation and which are executed in accordance with the recommendations of the applicable reference document and those of CEMAFROID;
- to abstain from using its authorisation in any way which might harm the reputation of CEMAFROID and to abstain from making any statement relating to authorisation which CEMAFROID could reasonably regard as false;
- to ensure that the rules of usage of the CEMAFROID brand and reference to the authorisation are complied with by its own clients;
- to inform CEMAFROID of any significant change made to the structure, organisation and means which are the subject of the authorisation.

The organisation agrees to inform CEMAFROID of any change which may modify the scope of the authorisation granted (sites covered by the certificate, cessation of activity, subcontracting or outsourcing of critical processes etc.) as well as any change in procedures or key personnel having an impact on the audited activity.

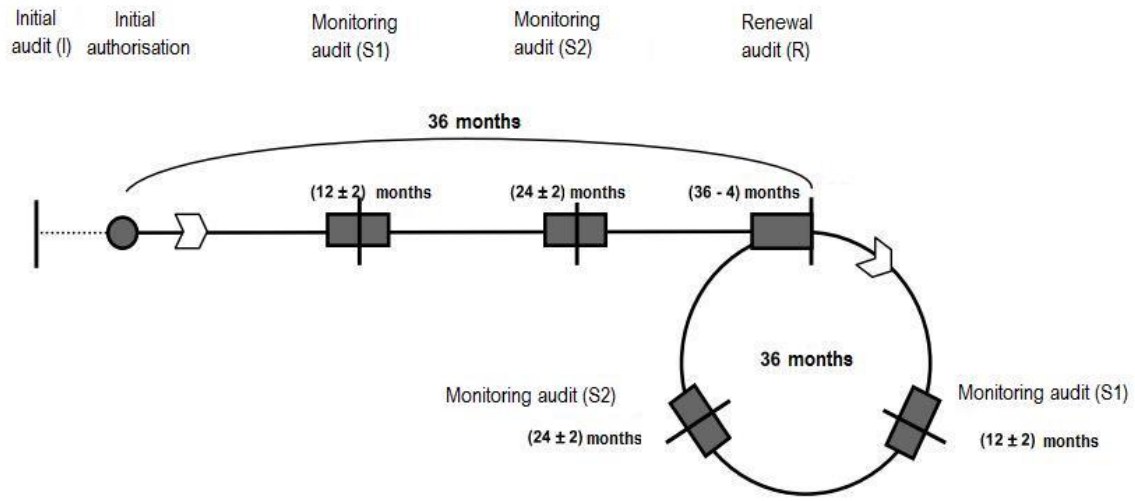
In case of a minor change, CEMAFROID may decide, without necessarily calling on the CTS opinion, to arrange for a further audit to ensure that the organisation's quality system is compliant with the requirements of the reference document.

Should the authorisation contract be terminated, the organisation agrees to:

- give CEMAFROID free access to the product manufacturing files in the period between the last audit in the authorisation cycle and the date of interruption of the contract;

- implement any corrective actions requested by CEMAFROID if the latter provides evidence, in the transmitted files, of any non-compliant products, equipment or certificate applications.

Annex 1
Authorisation Cycle



In the above figure, neither the audits relating to extension of authorisation, nor any additional or complementary audits decided on by CEMAFROID are taken into account.

When the number of equipment for which one or several applications for authorisation have been filed in the calendar year preceding the nominal audit date is greater than 1,201, an equipment inspection audit is scheduled (physically or on file) between two monitoring audits, after (6 ± 2) months, after (18 ± 2) months, or after (30 ± 2) months, depending on the case.
The number of equiment to be inspected (see table below), is determined in accordance with the methodology described in ISO 2859-1 based on the information available in DATAFRIG®.

Number of equipment for which a certificate has been requested	2 to 8	9 to 15	16 to 25	26 to 50	51 to 90	91 to 150	151 to 280	281 to 500	501 to 1,200	1,201 to 3,200	More
Number of equipment to be inspected	2	3	5	8	13	20	32	50	80	125	see ISO 2859-1

For example, for an annual production of 38 equipment, the number of equipment to be inspected is 8.

The duration of this audit is then computed as follows: 0.5 day for every 20 equipment to be inspected (physically or on file) as determined above.

Annex 2
Rules for the Establishment of Onsite Audit Terms and Conditions

In all cases, CEMAFROID determines the audit duration based on the information tables below.

A. CERTIFICATE APPLICANT

Audit Duration in man-days Initial, monitoring, renewal, or extension audit	
No. of audit days no. of applications*$_{(n-1)} \leq 25$	0.5 day (1 day for initial audit)
No. of audit days $26 \leq$ no. of applications*$_{(n-1)} \leq 500$	1 to 1.5 days
No. of audit days $501 \leq$ no. of applications*$_{(n-1)}$	2 days (**)

* Number of equipment for which one or several applications for authorisation have been filed in the calendar year preceding the nominal audit date
** Reminder: when the number of equipment for which one or several applications for authorisation have been filed in the calendar year preceding the nominal audit date is greater than 1,201, an equipment inspection audit is scheduled (physically or on file) between two monitoring audits, after (6 ± 2) months, after (18 ± 2) months, or after (30 ± 2) months, depending on the case.
The number of equiment to be inspected is determined in accordance with the methodology described in ISO 2859-1 based on the information available in DATAFRIG®. The duration of this audit is then computed as follows: 0.5 day for every 20 equipment to be inspected (physically or on file) as determined above.

These durations are established in consideration of a maximum of 40 equipment inspections (physically or on file) per audit day. Above 40 inspections per days, 0.5 auditing day is added for every 20 additional inspections (i.e : if 50 isnpections are to be made :1.5 auditing days). The number of equiment to be inspected is determined in accordance with the methodology described in ISO 2859-1 based on the information available in DATAFRIG®.

B. OTHER THAN CERTIFICATE APPLICANT

The table below applies to companies who are authorised or are applying for authorisation for processes other than that relating to the certificate application. The company may be, for instance (the list is non exhaustive) a manufacturer, a fitter or commissioning operator for thermal appliances, or a panel manufacturer, etc.

Audit Duration in man-days Initial, monitoring, renewal, or extension audit	
Case of an independent business no. of units*$_{(n-1)} \leq 25$	0.5 day
Case of an independent business $26 \leq$ no. of units*$_{(n-1)} \leq 500$	1 day
Case of an independent business $501 \leq$ no. of units*$_{(n-1)}$	2 days
Case of an organisation of organisations (**Network**)** Head of organisation and Each of the remaining sites (other than head of organisation)	• 1 day and 1 day every 6 years spread across the full 6-year period

* Number of units produced, fitted or commissioned in the calendar year preceding the nominal audit date
** For example, for a network comprising 10 sites:
- ✓ the site of location of the head of this network is audited each year (audit duration: 1 day), and
- ✓ the other 9 sites are audited once every 6 years (audit duration: 1 day),

which corresponds to 15 audit days over a 6 year period, i.e. 2.5 audit days per year for the network.

C. SIMULTANEOUS AUDIT FOR CEMAFROID AUTHORISATION AND CERTIFICATION

It is possible that the management system of the authorised or applicant organisation is certified compliant with quality standards. Compliance with any reference document other than CEMAFROID's is not sufficient to assume that this system is compliant in the specific field covered by the CEMAFROID authorisation. In fact, the prime objective of the CEMAFROID authorisation is to control every health risk related to the thermal design and manufacture of the products, which is not the objective of a general certification.

When an organisation wishes to have assessments conducted jointly within the framework of the CEMAFROID authorisation and a certification of its quality management system, CEMAFROID and the accredited certification body will seek to coordinate their actions to the extent possible. This type of approach can be implemented only on request of the organisation, who will be responsible for conducting all the actions relating to the joint arrangement, including determination of the onsite audit date.
If the CEMAFROID audit team manager is not the same person as the one appointed by the accredited certification body, both shall draw up the audit plan together and submit it to the organisation for validation.

Particular cases of joint audits
One same audit manager, qualified by CEMAFROID and the accredited certification body, may be appointed by each. He/she will write two separate reports intended for each of the two organisations.

Annex 3
Special Terms for Organisations of Organisations (Networks)

Entities (or networks) comprising organisations of organisations may be granted authorisation, provided they meet the organisational and authorisation requirements defined below.

A. GENERAL CHARACTERISTICS

As a pre-requisite, the head of the organisation is an organisation which comprises a statutorily identifiable, legally responsible entity having the status of a legal person, and each member of the organisation is a legal person whose relation with the head of the organisation - within the framework of the authorised activity - is based on clear, contractual ties.

For the same activity, an organisation cannot not be both authorised in its own name and member of a group in which the head of the organisation is authorised.

Item 1
An authorisation contract is previously jointly signed between the CEMAFROID manager and the representative of the Entity which is the head of the organisation. The members of the organisation are identified in an attachment to the contract.

Item 2
Authorisation is issued to the statutory, legally responsible entity having the status of a legal person, which is the head of the organisation signatory to the authorisation contract.

Item 3
There shall not be any ambiguity, whether on the nature of the technical service provided or on the name of the authorisation holder which appears on all commercial documents (including invoices). For the activity concerned, the order is in the name of the head of the organisation.

Item 4
All technical and quality documents which comprise the authorisation application file are established in the name of the head of the organisation.

Item 5
Authorisation is issued according to an authorisation scope and an administrative scope previously evaluated and fully described in the documents forming the application file. Any change to this configuration shall cause said file to be updated and CEMAFROID to be previously informed, at the very least, before the entity can be covered - provided the assessment results are satisfactory - by the authorisation.

Item 6
Dissolution of the legal personality of the head of the organisation causes immediate withdrawal of the authorisation for the head and all members of the organisation.

Item7
Any change in the articles of the legal personality of the head of the organisation or its members must be notified to CEMAFROID and may lead to suspension of the authorisation issued.

Item 8
The head of the organisation must have access to the list of personnel qualified to intervene within the framework of its authorisation. It must have clearly defined the qualification level and criteria required, and formalised its qualification and follow-up process. It must have clearly defined the terms and conditions of action, especially for services which are provided on the clients' sites.

Item 9

The head of the organisation must have access to the list of the various permissions issued to persons in order to cover the various responsibilities associated with its overall activities within the framework of authorisation.

Item 10
The head of the organisation itself must master all of the activities claimed for the organisation's overall scope of authorisation.

Item 11
For the activity concerned, reports are in the name of the head of the organisation, excluding any other mention or reference to a member. Reports must however contain any and all relevant information allowing, among other things, clear identification of the operator and the location where the service was provided.

Item 12
For the activities concerned, and regardless of the method of organisation, the head of the organisation retains full responsibility for the work performed: it agrees to provide an insurance certificate stating this explicitly for the entire scope concerned.

B SPECIAL PROVISIONS

B.1. Situations where all business units belong to the same legal entity as the head of the organisation

Typically, the organisation is a company with several branch offices.
The personnel in charge of the activities is employed by the head of the organisation, permanently or not.

Terms and Conditions

Item 1.1
The head of the organisation must explicitly assume all responsibilities relating to the activity concerned, for itself and for each member of the organisation. This provision must appear legibly in the articles of association, the rules of procedure, the contracts or conventions between the parties comprising the organisation, the customer contracts or the general terms and conditions of supply.

Item 1.2
For the activity concerned by the authorisation, all commercial documents are in the name of the head of the organisation.

B.2. Situations where the legal entities controlling secondary business units belong to the legal entity controlling the head of the organisation

Typically, this is a group with a holding company and subsidiaries, and the head of the organisation is controlled by the holding company.
The personnel in charge of the activities is not employed by the head of the organisation, but by each of its members.

For the activity concerned, each member's own legal person may be exercised through its client invoicing process.

Terms and Conditions

Item 2.1
The head of the organisation must explicitly assume all responsibilities relating to the activity concerned, for itself and for each member of the organisation. This provision must appear legibly in the contracts which bind the various members of the organisation to the head of the organisation.

Item 2.2
For the activity concerned by the authorisation, all commercial documents are in the name of the head of the organisation.

B.3. Situations where there is no legal connexion (in terms of capital) between the legal entity controlling the head of the organisation and the the legal entities controlling the secondary business units

Practically speaking, this is a network within which the head and the other members are bound by a contract of commercial nature.

For the activity concerned by the authorisation, each member of the organisation is an identifiable legal entity which retains its own status as a legal person, different from that of the head of the organisation, but which is bound to the head by a contract specifically conferring the head the full responsibility for the work performed.

The general provisions of the contract examined during review of the authorisation application file must be the same for all members of the organisation.

Item 3.1
The contract which binds the head of the organisation to the members must namely confer the head of the organisation:

- responsibility for the contents of all management system documents;
- responsibility for the definition and the implementation of the management system with respect to the reference document, in particular as regards the training and qualification of the personnel in charge of the activities;
- responsibility for the definition and the implementation of work methods and means (including human and material);
- full responsibility for the result of all technical operations performed;
- professional liability for all activities included in the scope of authorisation.

Item 3.2
Termination of the contract with one of the members causes the scope of the authorisation granted to be changed.

Item 3.3
Any change in the contract with one of the members must be notified to CEMAFROID and may cause a change in the scope of the authorisation issued or the suspension of the authorisation issued. The outgoing site may be audited even if it is no longer part of the organisation.