FRENCH REPUBLIC

Ministry of Health, Families, Autonomy
and Persons with Disabilities

Draft order of 20 April 2017, as amended, on the pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste

NOR:

The Minister for Labour, Health, Solidarity and Families, the Minister for the Economy, Finance and Industrial and Digital Sovereignty and the Minister for Ecological Transition, Biodiversity, Forests, Sea and Fishing,

Having regard to Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives;

Having regard to the Commission Decision of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council;

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the Environmental Code, in particular Articles L.541-2 to L.541-8 thereof;

Having regard to the Public Health Code, in particular Articles L.1335-2 and R.1335-8 to R.1335-8-1B thereof;

Having regard to the Labour Code, in particular Article R.4421-4 thereof;

Having regard to Law No 2000-321 of 12 April 2000 on the rights of citizens in their dealings with administrative authorities;

Having regard to Law No 2008-776 of 4 August 2008 on the modernisation of the economy, in particular Article 137 thereof;

Having regard to Decree No 2008-1401 of 19 December 2008 on accreditation and conformity assessment;

Having regard to Decree No 2009-697 of 16 June 2009, as amended, on standardisation;

Having regard to the Order of 7 September 1999 on storage procedures for potentially infectious waste from healthcare activities and other comparable healthcare waste and anatomical parts of human origin;

Having regard to the Order of 7 September 1999, as amended, on monitoring of the sectors responsible for the disposal of potentially infectious waste from healthcare activities and other comparable healthcare waste and anatomical parts of human origin;

Having regard to the Order of 24 November 2003, as amended, on the packaging of potentially infectious waste from healthcare activities and other comparable healthcare waste and anatomical parts of human origin;

Having regard to the Order of 23 July 2008 approving Decision No 2008-DC-0095 of the French Nuclear Safety Authority (ASN) of 29 January 2008 laying down technical rules to be fulfilled for the elimination of effluent and waste contaminated by radionuclides, or liable to be, due to nuclear activity, issued pursuant to the provisions of Article R.1333-12 of the Public Health Code;

Having regard to the Order of 20 April 2017 on the pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste;

Having regard to the Decree of 16 November 2021 establishing the list of pathogenic biological agents;

Having regard to notification No XX/XXX/F;

Hereby order:

Article 1

Article 1 of the aforementioned order of 20 April 2017 is amended as follows:

1. In I, the words: ‘NF X30-503-1: 2016 “Reduction of microbiological and mechanical risks associated with potentially infectious waste from healthcare activities and other comparable healthcare waste through pre-treatment by disinfection – Part 1”’ are replaced by the words: ‘NF X30-503-1: 2024 “Infectious waste (H9): reduction of microbiological and/or mechanical risks by physico-chemical treatment – Part 1: specifications and tests for collectable solid and liquid waste”’;

2. In II, the words: ‘ISO/ CEI’ are replaced by the words: ‘ISO/IEC’;

3. V is repealed.

Article 2

The annex of: ‘Annex 1’ to the same order is to be replaced by an annex worded as follows:

‘Annex - SPECIFICATIONS TO BE MET BY THE APPROVED BODIES MENTIONED IN ARTICLE 2 AND CONDITIONS FOR ISSUING THE CERTIFICATES OF CONFORMITY MENTIONED IN ARTICLE 3

‘1. Status of the body

‘1.1. Identity of the body

‘The body shall have a recognised legal structure.

‘It shall possess the necessary resources and skills to perform the examinations and tests falling within the scope of its activity, as well as to issue the corresponding certificates of conformity.

‘1.2. Impartiality, independence and integrity

‘The body shall be independent of the parties involved.

‘The body and its staff must not be subject to any commercial, financial or other pressure liable to influence their technical judgement.

‘The body and its staff must not be involved in any activity liable to compromise trust in their independence of judgement and in their integrity concerning their activities in the field covered by the body's approval. In particular, they must not be directly involved in the design, manufacture, procurement, use or maintenance of the disinfection pre-treatment devices being examined.

‘2. Field of activity

‘The body shall undertake activity relating to the issuance of certificates of conformity and to potentially infectious and other comparable healthcare waste, particularly in the following fields:

‘- assessment in the field of healthcare, and in particular of medical devices likely to become potentially infectious healthcare waste and other comparable healthcare waste (DASRIA);

‘- healthcare waste, especially with regard to standardisation and regulation.

‘3. Management and organisation

‘The body is authorised to carry out all the operations necessary for the performance of its activities in the field of conformity assessment of disinfection pre-treatment devices in accordance with standard NF X30-503-1: 2024, and shall be organised in such a way that every member of staff is aware of the scope and limits of their responsibilities.

‘Within the organisation, supervision shall be provided by people familiar with the assessment methods, test objectives (the regulations in force) and evaluation of the test results. The proportion of supervision staff to non-management staff shall be such that satisfactory technical and regulatory supervision is ensured.

‘A document describing the body’s organisation shall be available and kept up to date.

‘4. Staff

‘The body shall have sufficient staff to cover all of its needs in carrying out its activity in the area defined in paragraph 2.

‘These staff shall possess the technical and regulatory knowledge necessary, as well as the practical experience, for the functions assigned to them.

‘The body shall, as necessary, provide training for its staff and ensure the continuity of such training.

‘A document naming the staff members and their respective functions and duties shall be kept available and up to date. This shall be supplemented by supporting documents, also kept up to date, testifying that the staff are qualified for their functions and duties.

‘5. Operations and skills development

‘The body shall, as far as possible, participate in the work leading to the drafting of regulatory and standard-setting texts, including international ones, relating to potentially infectious healthcare waste and other comparable healthcare waste.

‘6. Working procedures

‘The examinations performed by the approved body within the area of its activity defined in paragraph 2 must be documented in reports which present the results of these operations and any other useful information clearly, precisely and unambiguously.

‘Without prejudice to the information required by the regulatory requirements, each report shall contain at least the following information:

‘(a) the name and address of the approved body;

‘(b) a unique identification number for the report, a number for each page of the report and the total number of pages;

‘(c) the name and address of the applicant;

‘(d) identification of the DASRIA disinfection pre-treatment device submitted for testing and a description including at least the details needed to draw up the certificate of conformity for its design type;

‘(e) the date on which the item was presented and the test date, if necessary;

‘(f) any addition, modification or deletion made to the assessment method, with its justification, as well as any useful information relating to a specific operation;

‘(g) the test results, supported if necessary by tables, graphics, drawings and photographs, as well as any shortcomings identified;

‘(h) the date on which the report was released; the signature and title, or any other equivalent mark, of the person responsible for the validity of the report;

‘Additions or amendments to a report may be made after it has been issued, but only by means of a document that refers to that report and does not call its conclusions into question.

‘7. Conditions for issuing certificates of conformity

‘7.1 Certificates of conformity

‘Certificates of conformity issued for pre-treatment devices shall include details of their issue date, validity period and disinfection parameters, and be validated by the body.

‘7.2 Records

‘The body shall keep a records system that enables all original observations and minutes of meetings to be kept for at least 10 years.

‘All minutes, reports and certificates of conformity must be preserved in a safe place and processed in such a way as to uphold the applicant's interests, in the absence of any legal provision to the contrary.

‘7.3. Confidentiality

‘The staff of the approved body shall be bound by professional confidentiality regarding all information gathered in the course of performing their duties.

‘The body shall comply with the terms and conditions stipulated by users of their services in order to preserve the confidential nature of users’ practices. ’

Article 3

The annex of: ‘Annex 4’ to the same order is to be replaced by an annex worded as follows:

‘Annex – REQUIREMENTS FOR THE INSTALLATION AND OPERATION OF

‘DISINFECTION PRE-TREATMENT FACILITIES REFERRED TO IN ARTICLE 5 (FIRST PARAGRAPH)

‘1. Purpose

‘All pre-treatment facilities shall be organised and operated in accordance with the indications featuring in this annex.

‘2. Types of waste permitted and prohibited at pre-treatment facilities for the disinfection of infectious healthcare waste and other comparable healthcare waste

‘The waste permitted at the pre-treatment facility, in disinfection pre-treatment devices, shall be the waste defined in Article R. 1335-1 of the Public Health Code.

‘This potentially infectious waste from healthcare activities and other comparable healthcare waste (DASRIA) shall only be accepted if it has been pre-packaged in the single-use packaging specified in the Order of 24 November 2003 on the packaging of clinical waste with infection risks and similar waste and anatomical parts of human origin.

‘Pre-packaged DASRIA produced by a department within a facility may be placed in disinfection pre-treatment devices without additional packaging in a large bulk container, provided that the disinfection pre-treatment device is located in the immediate vicinity of that department.

‘Disinfection pre-treatment devices may not be used for potentially infectious waste from healthcare activities and other comparable healthcare waste which:

‘- may contain group 4 biological agents referred to in the Order of 18 July 1994 establishing the list of pathogenic biological agents, non-conventional transmissible agents or plague agents;

‘- is contaminated or likely to be contaminated by radionuclides;

‘- is likely to contain residues of medicinal products with cytostatic or cytotoxic properties.

‘The following are also excluded from disinfection pre-treatment devices:

‘- expired or unused medicinal products;

‘- waste exhibiting one or more of the hazardous properties HP 1 to HP 8 and HP 10 to HP 15 as defined in Regulation (EU) No 1357/2014 and the Commission Decision of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council.

‘Potentially infectious healthcare waste that also exhibits at least one hazard property classified as HP 1 to HP 8 or HP 10 to HP 15, as defined in Regulation (EU) No 1357/2014 and the Commission Decision of 18 December 2014, shall be identified by the producer of the waste responsible for identifying the hazardous nature of the waste and for its disposal, in accordance with Articles L. 541-1-1 et seq. of the Environment Code.

‘3. Verification of waste

‘Any arrival of waste at the pre-treatment facility shall be subject to the following checks by the operator:

‘- visual examination of the load and packaging conformity check, particularly with regard to the requirements of the above-mentioned Order of 24 November 2003;

‘- verification that the waste destined for disinfection pre-treatment is free of radioactive contamination.

‘The identification of waste excluded from pre-treatment, as provided for in paragraph 2, among the waste delivered for pre-treatment shall result in all waste contained in the same packaging being refused for disinfection pre-treatment operations.

‘The operator shall have written procedures in place for the management of waste refused for disinfection pre-treatment.

‘In particular, should any radioactive waste be identified, it shall be excluded from pre-treatment and be subject to waste management rules in accordance with the Order of 23 July 2008 approving Decision No 2008-DC-0095 of the French Nuclear Safety Authority (ASN) of 29 January 2008 laying down technical rules to be fulfilled for the elimination of effluent and waste contaminated by

radionuclides, or liable to be, due to nuclear activity, issued pursuant to the provisions of Article R. 1333-16 of the French Public Health Code.

‘4. Operation of the facility

‘In operation, the facility must not release dust or odours liable to constitute a local nuisance.

‘5. Storage

‘Storage of DASRIA pending disinfection pre-treatment

‘This shall be in accordance with the provisions of the Order of 7 September 1999 on storage procedures for infectious clinical and similar waste, particularly those concerning storage premises.

‘The potentially infectious and other comparable healthcare waste shall be pre-treated within a maximum of 48 hours of its arrival at the disinfection pre-treatment facility, pursuant to the provisions of the Order of 7 September 1999 on monitoring of the sectors responsible for the disposal of infectious clinical and similar waste and anatomical parts of human origin.

‘Storage of empty large packaging (LP) or intermediate bulk containers (IBCs) and pre-treated waste

Once empty, large packaging and IBCs shall be washed, disinfected and stored in a distinct area separate from that dedicated to the storage of pre-treated waste.

‘Installation of disinfection pre-treatment devices

‘The disinfection pre-treatment device shall be installed in an area designed to collect any potential leaks. The device shall be installed in such a way that it is accessible for cleaning. It shall be cleaned regularly and whenever necessary.

‘6. What happens to waste that has been pre-treated by disinfection

‘After pre-treatment by disinfection, waste shall be treated in accordance with the provisions of Article R. 1335-8 of the Public Health Code.

‘Where waste is collected and treated by local authorities and groups of local authorities, the collection frequency shall comply with the provisions of Articles R. 2224-23 et seq. of the General Code for Local Authorities.

‘7. Failure of the disinfection pre-treatment facility

‘In the event of a failure or malfunction of the pre-treatment facility lasting more than 48 hours, the operator shall be required to use another facility capable of treating potentially infectious and similar healthcare waste in accordance with the provisions of Article R. 1335-8 of the Public Health Code. This facility, known as the “overflow facility”, shall comply with the regulations in force.

‘8. Operational register and annual statement

‘The operator shall keep an up-to-date register of incoming and outgoing waste in accordance with the provisions set out in Articles R. 541-43 and R. 541-46 of the Environment Code.

‘This register shall also include operational elements:

‘(a) maintenance operations performed on the pre-treatment device;

‘(b) information relating to the monitoring carried out.

‘This register shall be the basis for an annual statement of operations, specifying:

‘(a) the quantities of waste received at the site, the quantities of waste pre-treated and the quantities of waste refused for treatment (nature, quantity, reason and final destination);

‘(b) the final destination of waste pre-treated by disinfection, specifying, where applicable, the tonnage of waste sent to the overflow facility;

‘(c) the number of days for which the pre-treatment facility was offline, giving details of the cause (incidents, breakdowns, technical stoppages, etc.);

‘(d) the report(s) of the body that carried out the monitoring, as referred to in paragraphs 1 and 2 of Annex 5 to this Order;

‘(e) the management of non-conforming results, as referred to in paragraph 4 of Annex 5 to this Order.

‘The annual report for year n must be submitted to the director-general of the regional health agency for the area in which the facility is located by 15 March of year n + 1. ’

Article 4

The annex of: ‘Annex 5’ to the same order is to be replaced by an annex worded as follows:

‘Annex – REQUIREMENTS ON THE MONITORING OF PRE-TREATMENT FACILITIES

‘BY MEANS OF THE DISINFECTION REFERRED TO IN ARTICLE 5 (SECOND PARAGRAPH)

‘1. Monitoring of antimicrobial efficacy of DASRIA disinfection pre-treatment devices

‘Recording parameters

‘Operators of disinfection pre-treatment devices for potentially infectious and other comparable healthcare waste shall continuously record the disinfection parameters defined in the certificates of conformity.

‘Tests on biological indicators

‘Operators of disinfection pre-treatment devices shall perform tests on germ carriers containing spores of Bacillus athrophaeus or spores of Geobacillus stearothermophilus:

‘- once per quarter for disinfection pre-treatment devices processing 50 tonnes or more of potentially infectious healthcare waste per year (annual average);

‘- once every six months for disinfection pre-treatment devices processing less than 50 tonnes of potentially infectious healthcare waste per year (annual average).

‘The technical methods shall be those described in standard NF X30-503-1: 2024. The tests shall be carried out on a given day with three germ carriers. The germ count shall be carried out on given day within the cycle.

‘The acceptance criteria shall be those set out in the aforementioned standard.

‘2. Monitoring of mechanical parameters

‘Tests on mechanical parameters shall be carried out by the operator of a disinfection pre-treatment device:

‘- once per quarter for disinfection pre-treatment devices treating 50 tonnes or more of potentially infectious healthcare waste per year (annual average);

‘- once every six months for disinfection pre-treatment devices processing less than 50 tonnes of potentially infectious healthcare waste per year (annual average).

‘The technical methods shall be those described in standard NF X30-503-1: 2024:

‘- either by particle size analysis for devices that use a grinding process: the tests shall be carried out on a 50 L sample taken over a single day’s production for devices with a capacity of more than 100 L, or on a sample of at least 20 L per day for devices with a capacity of less than 100 L;

‘- or by means of mechanical tests for devices that operate by forming a “cake”: all the tests shall be carried out on a cake.

‘The acceptance criteria shall be those set out in the aforementioned standard.

‘3. Test conditions

‘The tests referred to in paragraphs 1 and 2 of this annex shall be carried out in accordance with the methods described in the standard referred to in Article 1(I) of this Order.

‘The tests mentioned in paragraphs 1 and 2 of this annex shall be performed by laboratories fulfilling the conditions provided for in Article 1(II) of this Order.

‘4. Results not meeting the acceptance criteria (antimicrobial efficacy tests and mechanical parameter tests)

‘If the result of a test does not comply with the acceptance criteria of the standard referred to in Article 1(I) of this Order, the operator shall:

‘- take the necessary corrective measures to rectify the situation;

‘- perform new tests.

‘If the results of these new tests do not comply with the acceptance criteria of the standard referred to in Article 1(I) of this Order, the operator shall, without delay:

‘- suspend the use of the DASRIA pre-treatment device that caused the non-compliance;

‘- immediately implement the overflow solution mentioned in paragraph 7 of Annex 4;

‘- notify the director-general of the regional health agency for the area in which the facility is located.

‘These actions and their implementation dates shall be formalised and preserved in the operations register mentioned in paragraph 8 of Annex 4.

‘5. Preservation of the results

‘The operator shall keep the results of the tests for at least three years. ’

Article 5

This Order shall enter into force on the day after its publication.

Article 6

This order shall be published in the Official Journal of the French Republic.

Done on [date]

The Minister for Ecological Transition,
Biodiversity and International Climate and Nature Negotiations,
For the Minister and by delegation:
The Director-General for Risk Prevention,

The Minister for Economy, Finance and Industrial, Energy and Digital Sovereignty,
For the Minister and by delegation:
The Interministerial Delegate for Standardisation,

The Minister for Health, Families, Autonomy and Persons with Disabilities,
For the Minister and by delegation:
The Director-General for Health,

The Minister for Health, Families, Autonomy and Persons with Disabilities,
For the Minister and by delegation:
The Director-General for Healthcare,

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AFNOR X30S – Packaging of waste from healthcare activities
French standardisation

NF X30-503-1

Healthcare waste – Reduction of microbiological and mechanical risks associated with potentially infectious waste from healthcare activities and other comparable healthcare waste using disinfection treatment devices

Part 1: specifications and tests for collectable solid and liquid waste

Only

Foreword

The amendments recorded in this document, compared to the previous version, have led to an extension of the scope, thus introducing:

- devices for the physico-chemical disinfection of solid and collectable infectious waste;
- the introduction of statistical tests to assess antimicrobial efficacy (paragraph 5.3);
- tests on biological indicators (paragraph 5.3.1), for which requirements regarding the quality of the preparation of these indicators are set out in the annex.

Introduction

Reminder of the regulatory framework

Article R.1335-8 of the Public Health Code, Article R.541-8 of the Environment Code and Directive 2008/98/EC allow two methods of disposing of potentially infectious waste. Such waste may either be incinerated at authorised facilities or treated in a disinfection device, after which it may be channelled into a non-hazardous waste disposal stream, except for composting, under the conditions set out in Article L.2224-14 of the General Code for Local Authorities or, subject to certain conditions, channelled into a material recovery and recycling stream.

In order to be used, devices that reduce the microbiological and/or mechanical risks associated with infectious waste must comply with the specifications and test requirements set out in the relevant sections of the standard:

− Part 1: specifications and tests for collectable solid and liquid infectious waste, and

− Part 2: specifications and tests for non-collectable liquid infectious waste,

- the compliance of these devices with design requirements;

- the effectiveness of the physico-chemical treatment, demonstrated by the performance of tests whose results comply with specific acceptance criteria;

- the effectiveness of the reduction of mechanical risks, demonstrated by the performance of tests whose results comply with specific acceptance criteria. In addition, this document includes:

- instructions on the test protocols to be implemented to conduct these tests under standardised conditions (Annex A, normative);

- the arrangements for returning the results (Annex B, normative);

- the manufacturer’s instructions (Annex C, for information purposes);

- a bibliography.

1 Scope

This document applies to devices for the physico-chemical disinfection of packaged, collectable solid or liquid infectious waste, in accordance with Directive 2006/42/EC on machinery, for the purpose of obtaining the certificate of conformity provided for in Article R.1335-8-1A(III) and (IV), of the Public Health Code (CSP).

It does not apply to methods involving only the disinfection of packaged infectious waste, without altering the appearance of the waste (e.g. autoclaving used on its own, chemical or thermal inactivation), which cannot be regarded as a disinfection treatment.

This document specifies the standardised definitions, requirements and tests applicable to these devices for physico-chemical disinfection. The requirements of this document do not, under any circumstances, replace the requirements of the regulations applicable to waste.

2 Normative references

The following reference documents are essential to application of this document. For dated references, only the edition cited shall apply. For undated references, the latest edition of the reference document applies (including any amendments).

NF EN 866-1, General requirements for biological indicators (classification index: S61-921-1).

NF EN 13098:2000, Workplace atmosphere – *Guidelines for measurement of airborne microorganisms and endotoxins* (classification index: X43-247).

NF EN ISO 7218, General requirements and guidance for microbiological examinations for bacteria, yeast and mould (classification index: V08-002).

NF EN ISO 11138-1, General requirements for biological indicators (classification index: S98-004-1).

3 Terms and definitions

For the purposes of this document, the following terms and definitions shall apply.

3.1 Non-conventional transmissible agent (NTA) or prion

a natural protein (PrPc) that can adopt an abnormal structural conformation (pathological form) which, when it accumulates in tissue, causes irreversible damage. The pathological form (PrP-res or PrP-sc) has specific characteristics that make it highly resistant to heat and disinfectants

3.2 capacity of the disinfection pre-treatment device

the total internal volume of the tank capable of holding a single batch of waste to be treated by physico-chemical disinfection, as measured, calculated and certified by the manufacturer of the device

3.3 potentially infectious waste from healthcare activities (DASRI)

waste resulting from diagnostic, follow-up and preventative, curative or palliative treatment activities in the fields of human and veterinary medicine which:

a) either contain viable microorganisms or their toxins, which by their nature, quantity or metabolism are known or reasonably believed to cause disease in humans or other living organisms;
b) or, even in the absence of any infection risk, fall into one of the following categories:
   - sharp or cutting materials and equipment intended for disposal, whether or not in contact with a biological product;

- blood products for therapeutic use that have not been fully used or have passed their expiry date;
- human anatomical waste, consisting of human remains that cannot be readily identified.

[SOURCE: Article 1335-1 of the Public Health Code]

3.4 other comparable potentially infectious healthcare waste (DASRIA)
waste arising from teaching, research and industrial production activities in the fields of human and veterinary medicine, as well as waste arising from embalming practices, cosmetic surgery, body piercing and tattooing involving skin penetration, where such waste exhibits the characteristics of potentially infectious waste from healthcare activities
[SOURCE: Article 1335-1 of the Public Health Code, last paragraph, as amended]

3.5 infectious waste
waste (solid or liquid) containing viable microorganisms or toxins which by their nature, quantity or metabolism are known or reasonably believed to cause disease in humans or other living organisms (property H 9 – Article R.541-8 of the Environment Code – Directive 2008/98/EC). This waste includes, in particular, DASRI and DASRIA.

NOTE: in the remainder of this document, the term ‘infectious waste’ is used on its own, as DASRI and DASRIA are managed in the same way.

3.6 collectable infectious waste
potentially infectious waste, whether solid or liquid, placed in packaging that complies with the Order of 24 November 2003, as amended, on the packaging of DASRI

3.7 non-collectable liquid infectious waste
non-solid potentially infectious waste produced in large quantities (several hundred litres) and which cannot be collected under acceptable technical and economic conditions

3.8 mixed infectious waste
infectious waste of various origins, types and packaging, representative of the infectious waste that the device is likely to process (human and/or veterinary healthcare, agri-food, etc.)

3.9 primary packaging
component of the packaging system that maintains product integrity
[SOURCE: NF EN ISO 11138-1]

NOTE: the packaging system protects the inoculated germ carrier from contamination without preventing the disinfectant from penetrating it and must be compatible with the technology used.

3.10 secondary packaging
container in which the biological indicators are packed for transport and storage
[SOURCE: NF EN ISO 11138-1]

3.11 ibiological indicator
test system containing viable microorganisms, ensuring a defined resistance to a specified disinfection process

[SOURCE: NF EN ISO 11138-1]

3.12 pathogenic microorganisms

Microorganisms which by their nature, quantity or metabolism are known or reasonably believed to cause disease in humans or other living organisms

3.13 group 4 pathogenic microorganisms
microorganisms (bacteria, viruses, fungi), including genetically modified microorganisms, cell cultures and human endoparasites, which are capable of causing serious illness in humans (infection, allergy or poisoning) and of posing a serious risk to workers. They are highly contagious within the community and there is no effective prevention or treatment (Article R.4421-2 of the Labour Code). The list of these pathogenic biological agents is set out in the Order of 16 November 2021 establishing the list of pathogenic biological agents

NOTE: materials and articles not assigned to UN number 3291 (ADR), but to UN numbers 2814 or 2900 for the transport of dangerous goods by road.

3.14 germ carrier
a medium onto or into which test microorganisms are placed
[SOURCE: NF EN ISO 11138-1]

3.15 inoculated germ carrier
a medium onto or into which a specific number of viable test organisms has been placed [SOURCE: NF EN ISO 11138-1]

3.16 liquid discharge
all liquids resulting from the treatment of infectious waste by disinfection

3.17 risk
a combination of the probability of damage and its severity
[SOURCE: NF EN ISO 14971:2012]

3.18 infection risk
risk arising from the fact that waste, and in particular waste from healthcare activities, contains viable microorganisms or toxins which by their nature, quantity or metabolism are known or reasonably believed to cause disease in humans or other living organisms

3.19 mechanical risk
physical risk posed by hazardous phenomena that may cause injury through the mechanical action of machine parts, tools, components or loads or the projection of solid materials or fluids

3.20 treatment of infectious waste by physico-chemical disinfection (inactivation) a process that reduces the microbiological contamination of infectious waste, whether solid or liquid, collectable or not, and alters the appearance of solid waste. Altering the physical appearance of solid waste helps to reduce mechanical risks and ensure the effectiveness of the waste disinfection process. Waste generated through treatment by physico-chemical disinfection is managed through a non-hazardous waste treatment stream or a material recovery stream, in accordance with the provisions of the Public Health Code

NOTE: the following waste is excluded from the physico-chemical disinfection treatment stream.
Waste:
• with one of the dangerous properties described in Annex I to Article R. 541-8 of the Environment Code, with the exception of the property ‘H 9: infectious’;
• that is contaminated or likely to be contaminated by radionuclides;

• having cytostatic or cytotoxic properties;
• likely to contain non-conventional and/or group 4 transmissible agents (e.g. agents causing plague, smallpox and viral haemorrhagic fevers).

3.21 transfer hopper
the part of the device or superstructure where incoming waste is emptied manually or loaded mechanically.
[SOURCE: definition from EN 1501-1: 2021 (refuse collection vehicles)]

3.22 buffer tank
tank for collecting all liquid effluent awaiting treatment

4 General requirements

Disinfection treatment devices must meet the design requirements described in this document. In addition, they must comply with the French and European regulations in force in order to ensure the safety of people and the environment.

4.1 Design requirements

These treatment devices are not designed to accept chemically hazardous waste as defined by the Environment Code, or group 4 highly pathogenic agents, or waste that may contain NTAs.

Devices for the treatment of packaged infectious waste by disinfection must meet the following functional characteristics:

a) they must reduce the microbial contamination of infectious waste in order to limit the risk of infection;
b) they must alter its appearance in order to reduce the mechanical risk and ensure the antimicrobial effectiveness of the treatment;
c) they may only operate in steps carried out in the same place and at the same time (as part of an uninterrupted process requiring no human intervention);
d) they must be designed in such a way that they can treat packaged infectious waste in accordance with Article R.1335-6 of the Public Health Code;
e) they must be designed in such a way that treatment tests using biological indicators may be carried out;
f) they must, in the case of the waste generated by the treatment process, take into account the appropriate disposal or recovery stream;
g) in the case of chemical treatment, they must provide for the appropriate neutralisation of the chemical used for disinfection;
h) they must be equipped with a device for collecting and disposing of their liquid discharge, which must be easily accessible for maintenance and inspection purposes.

The device or technology used for the treatment must not generate, in liquid discharges:

a) suspended solids;

b) products that may, directly or indirectly, release:

− flammable toxic gases or vapours or unpleasant odours;

− any products likely to impair the preservation and proper functioning of the works;

− toxic substances that are harmful and/or cause discolouration of the receiving environment;

c) specific bacterial indicators defined in this document.

The device or technology used for the treatment must not generate additional airborne microbial contamination.

4.2 Requirements for disinfection parameters

The physical and/or chemical and technical parameters of the treatment device that ensure the disinfection of infectious waste (or ‘disinfection parameters’) must be specified and controlled at every point within the device. They must be registered in order to ensure that they have been achieved.

5 Test programme

5.1 Test conditions

The tests must be carried out on an operational device, installed in accordance with the manufacturer’s instructions (Annex C), and under the operating conditions referred to in those instructions. During the testing period:

- the disinfection parameters must be recorded;
- the loads must be traced;
- waste from treatment by disinfection shall always be considered infectious waste and must be managed as such. The tests must be carried out in premises that comply with the provisions of the Order of 7 September 1999, as amended, on the arrangements for the storage of potentially infectious waste from healthcare activities (Article 8).

The sampling shall be supervised or carried out by a laboratory and the analyses shall be carried out using accredited methods or validated in-house methods. The detailed procedures for conducting each test are set out in Annex A (normative).

5.2 Assessment of compliance with the design requirements

5.2.1 Tests for liquid discharge from the disinfection treatment device

These tests on liquid discharges from the treatment device must not be carried out if the disinfection treatment device does not produce any liquid discharge.

5.2.1.1 Purpose

Tests on liquid discharges make it possible to ensure compliance with some of the design requirements and in particular the absence of bacterial indicators in these discharges.

5.2.1.2 Principle

The liquid discharges associated with the operation of the device shall be collected for each of the test cycles or over a period representative of the operation of the device and the following must be carried out:

(a) a measurement of the volume discharged;

(b) testing for specific bacterial indicators (Staphylococcus sp., Enterobacteriaceae, Pseudomonas sp. and/or related groups).

NOTE: the bacterial indicators selected are representative of the pathogenic microorganisms involved in the infections.

5.2.1.3 Acceptance criteria

Following the tests, the liquid discharge from the treatment devices must not contain the above-mentioned specific bacterial indicators, for each sample. 5.2.2 Tests for airborne microbial contamination

5.2.2.1 Purpose

The purpose of the test is to measure possible microbial contamination of the atmosphere in the vicinity of the treatment device caused by the operation of the device during the treatment of infectious waste.

5.2.2.2 Principle

The tests shall be carried out in accordance with standard NF EN 13098:2000. Air samples shall be taken in the immediate vicinity of the device. A first control sample shall be taken before operation.

For treatment devices that operate in cycles, samples shall be taken when the device is loaded, during the treatment cycle and when the treated waste is removed – that is, three sampling points per cycle – and compared with the control sample taken before the device was put into operation.

For treatment devices that operate continuously, samples shall be taken at the start of production, more specifically, during the loading phase, while the device is in operation and just before production stops – that is, three sampling points – and compared with the control sample taken before the device was put into operation.

The assessment of microbial contamination shall be carried out by:

a) the quantification (log 10) of the viable aerobic bacterial flora;

b) the identification (presence/absence) among this flora of specific bacterial indicators that can be aerosolised from infectious waste (Staphylococcus sp., Enterobacteriaceae, *Pseudomonas sp. and/or related groups*).

NOTE: the bacterial indicators selected are representative of the pathogenic microorganisms involved in the infections.

5.2.1.3 Acceptance criteria

Following the tests, the liquid discharge from the treatment devices must not contain the above-mentioned specific bacterial indicators, for each sample.

5.2.2 Tests for airborne microbial contamination

5.2.2.1 Purpose

The purpose of the test is to measure possible microbial contamination of the atmosphere in the vicinity of the treatment device caused by the operation of the device during the treatment of infectious waste.

5.2.2.2 Principle

The tests shall be carried out in accordance with standard NF EN 13098:2000. Air samples shall be taken in the immediate vicinity of the device. A first control sample shall be taken before operation.

For treatment devices that operate in cycles, samples shall be taken when the device is loaded, during the treatment cycle and when the treated waste is removed – that is, three sampling points per cycle – and compared with the control sample taken before the device was put into operation.

For treatment devices that operate continuously, samples shall be taken at the start of production, more specifically, during the loading phase, while the device is in operation and just before production stops – that is, three sampling points – and compared with the control sample taken before the device was put into operation.

The assessment of microbial contamination shall be carried out by:

a) the quantification (log 10) of the viable aerobic bacterial flora;

b) the identification (presence/absence) among this flora of specific bacterial indicators that can be aerosolised from infectious waste (*Staphylococcus sp.*, Enterobacteriaceae, *Pseudomonas sp. and/or related groups*).

NOTE: the bacterial indicators selected are representative of the pathogenic microorganisms involved in the infections.

5.2.2.3 Acceptance criteria

Following the tests, the following points must be verified for each cycle:

a) the difference between each of the three test samples and the control sample must be less than 1 $\log_{10}$ for viable aerobic bacterial flora;

b) the samples must not contain any specific bacterial indicators from this flora.

5.3 Antimicrobial effectiveness of devices for the treatment by disinfection of infectious waste

5.3.1 Treatment tests using biological indicators

5.3.1.1 Purpose

To validate the antimicrobial effectiveness of the disinfection parameters specified by the manufacturer on viable microorganisms (biological indicators) that demonstrate a defined resistance to a specified disinfection process.

5.3.1.2 Principle

The tests involve placing inoculated germ carriers in the centre of the infectious waste within the treatment device, subjecting them to the disinfection cycle and checking for any survivors.

NOTE: for details on how to carry out these tests, please refer to paragraph A.2

5.3.1.3 Acceptance criteria

Following the tests, the following points must be checked for each pre-treated germ carrier:

a) the reduction in the number of Bacillus spores must be equal to or greater than 5 $\log_{10}$;

b) the reduction in the number of Aspergillus spores must be equal to or greater than 4 $\log_{10}$;

c) the reduction in the number of adenoviruses must be equal to or greater than 4 $\log_{10}$.

5.3.2 Treatment tests on infectious waste

5.3.2.1 Purpose

To validate the antimicrobial effectiveness of the disinfection parameters specified by the manufacturer, under operating conditions, on infectious waste of different origins and types that is representative of the infectious waste which the device is likely to process (human and/or veterinary healthcare, agri-food, etc.).

5.3.2.2 Principle

The reduction in contamination, for viable aerobic bacterial flora and specific bacterial indicators, shall be determined on the basis of measurements of naturally contaminated infectious waste, before and after treatment. It shall meet the acceptance criteria.

Measurements must be taken on infectious waste from different activities (operating theatres, surgical departments, laboratories, dialysis units, etc.) and of different types (sharp, pointed, cutting, piercing and soft) that are representative of the infectious waste likely to be treated by the device undergoing validation.

The contamination assessment shall be carried out by:

a) the quantification (log 10) of the viable aerobic bacterial flora;

b) the identification (presence/absence) among this flora of specific bacterial indicators: *Staphylococcus sp., Enterobacteriaceae, Pseudomonas sp. and/or related groups*.

NOTE: the bacterial indicators selected are representative of the pathogenic microorganisms involved in the infections.

5.3.2.3 Acceptance criteria

Following the tests, the following points must be verified for each cycle:

a) the reduction in the number of microorganisms, measured by the enumeration of the viable aerobic bacterial flora, must be equal to or greater than 5 log10;

b) Among this flora, specific bacterial indicators should not be found.

5.3.3 Recovery tests

5.3.3.1 Purpose

To verify the long-term effectiveness of the disinfection achieved by measuring any recolonisation after 28 days of storage at room temperature (15–25°C).

5.3.3.2 Principle

Samples shall be taken from a single batch or consignment of waste generated during treatment (either during a single treatment cycle or over a period representative of the device's operation); half of the samples shall be analysed on day 0 and the other half on day 28.

Waste samples must be collected from the device's outlet under aseptic conditions so as to prevent contamination during collection.

The contamination assessment shall be carried out by:

a) the quantification ($\log_{10}$) of the viable aerobic bacterial flora;

b) the identification (presence/absence) among this flora of specific bacterial indicators: *Staphylococcus sp.,* Enterobacteriaceae, *Pseudomonas sp. and/or related groups*

NOTE: the bacterial indicators selected are representative of the pathogenic microorganisms involved in the infections.

For details on how to carry out these tests, please refer to Annex A3.

5.3.3.3 Acceptance criteria

Following the tests, the following points must be verified after 28 days of storage:

a) the recovery of the viable aerobic bacterial flora must be less than 2 $\log_{10}$ out of at least three counts out of five per test day in the same challenge load and at least 80 % of all counts must meet these criteria;

b) the recovery of any specific bacterial indicators among this flora: the sum of all bacterial indicators must be less than 1 $\log_{10}$, out of at least three counts out of five per test day in the same challenge load and at least 80 % of all counts must meet these criteria.

5.4 Particle size test

5.4.1 Purpose

The aim of the particle size test is to measure the effectiveness of the modification of the appearance of the waste resulting from the disinfection treatment when the disinfection treatment device being tested uses a grinding process.

5.4.2 Principle

The particle size distribution of waste resulting from the grinding process shall be determined through nine test cycles using representative mixed infectious waste.

A sample of at least 50 L / day must be taken for devices with a capacity of more than 100 litres, or at least 20 L / day for devices with a capacity of less than 100 L.

For details on how to carry out these tests, please refer to Annex A.4.

5.4.3 Acceptance criteria

Following the tests, the following points must be verified:

- for the nine cycles, at least 90 % of the mass of each sample must have a particle size of less than 30 mm;
- for all nine cycles, at least 80 % of the total mass of all samples must have a particle size of less than 30 mm.

5.5 Mechanical tests

5.5.1 Purpose

These tests must only be carried out on devices where the treatment process results in the formation of ‘cakes’ of waste that are packaged and compressed within suitable packaging.

The aim of these tests is to assess the mechanical properties of such waste cakes produced during the treatment process.

These mechanical tests are of five types: puncture test, bending test, compression test, punch test and drop test.

5.5.2 Principle

The puncture test is designed to ensure that sharp objects do not puncture the cake during its formation in the treatment device.

The bending test involves applying a central force to the cake while it is suspended between two supports in order to determine whether the force applied causes the cake to bend until it breaks.

The compression test consists of compressing the edge of the cake in order to determine whether the force applied causes the cake to break.

The punch test involves applying a randomly distributed force to the cake while it is resting on a flat surface in order to determine whether the force applied causes the cake to break.

The drop test involves determining whether the force resulting from the cake hitting the ground causes the cake to break.

Each test shall be carried out on three cakes.

For details on how to carry out these tests, please refer to paragraph A.5.

5.5.3 Acceptance criteria

Following the puncture tests, the cakes shall inspected visually to ensure their integrity and the absence of perforations and visible waste.

Following the compression tests on the edge of the cake, the following points must be verified: at both compression levels tested, 465 N and 605 N, the cake must show no signs of breakage, perforation or tearing.

Following the bending tests on the surfaces of the cake, the following points must be verified: at both bending levels tested, 1216 N and 1581 N, the cake must not show any signs of breakage, perforation or tearing.

Following the punch tests carried out on the surface of the cake in two different areas, the following points must be verified: at both punch levels tested, 1462 N and 1901 N, the cake must not show any perforations.

Following drop tests involving the cake being dropped onto a tiled floor both on its edge and flat, the following points must be verified: no permanent deformation, breakage or tearing.

Annex A

(normative) 111

Requirements for the proper conduct of efficacy testing of devices for the disinfection of collectable infectious waste

NOTE: this annex does not describe more precisely the tests for liquid discharge (5.2.1). The information contained in the body of the standard is sufficient to carry out these tests.

Annex B Tests for airborne microbial contamination

Annex C Microorganisms tested for

The assessment of microbial contamination shall be carried out on the basis of:

- the quantification ($\log_{10}$) of the viable aerobic bacterial flora;
- the identification (presence/absence) among this flora of specific bacterial indicators: *Staphylococcus sp.,* Enterobacteriaceae, *Pseudomonas sp. and/or related groups.*

A.1.2 Sampling of air samples

The measurements shall be taken using a biocollector in accordance with standard NF EN 13098:2000, in the vicinity of the device within a radius of 1 m and at the level of the part of the device affected by discharges into the air:

- before the device is put into operation (to measure the initial contamination levels in the vicinity of the device);
- when loading the device;
- during operation of the device;
- when collecting waste resulting from the treatment by disinfection of infectious waste.

Four samples are therefore taken for per day of testing.

A.1.3 Microorganism count

Colonies shall be counted and reported per cubic metre of air after incubation on culture media for enumeration.

A.1.4 Number of tests to be carried out

This test must be repeated on two further days, which may or may not be consecutive. In total, there shall be 4 sampling points per test day, i.e. 12 sampling points over the 3 days.

Annex D Treatment tests using biological indicators

The tests involve introducing packaged, non-solid infectious waste contaminated with reference microorganisms, known for their resistance to disinfection treatments, into the disinfection treatment device, subjecting it to a disinfection cycle and screening for any surviving microorganisms.

A.2.1 Test organisms

The test organisms shall be defined strains that can be obtained from a scientifically recognised culture centre. These are:

For bacterial spores*: Bacillus atrophaeus (ATCC 9372, CIP 77.18...)* or *Geobacillus stearothermophilus* (ATCC 7953, CIP 52.81...) depending on the nature of the treatment;

For moulds: *Aspergillus brasiliensis* (ATCC 16404, *CIP 1431.83*...);

For viruses: *Adenovirus* type 5, adenoid strain 75, ATCC VR-5.

A.2.2 Biological indicators

- The germ carrier must withstand exposure to the disinfection process for which it is designed in such a way as to preserve the performance characteristics of the inoculated germ carrier.

NOTE: for thermal processes, the following materials may be used: non-woven fabric or cotton.

- The medium in which the test organisms are suspended must not have any adverse effect on the stability of the germ carrier.
- An interfering substance (blood) shall be added to the test suspension in order to simulate the actual conditions under which infectious waste is disinfected.
- Germ carriers must be inoculated in such a way as to maintain a constant microbial population.
- The primary packaging must be suitable for the intended purpose.
- The number of viable organisms per inoculated germ carrier must be determined on four test samples for each prepared batch. The concentration per germ carrier must be ≥ 6 log.
- The resistance (D-value) of each batch of inoculated germ carriers must be determined using the survival curve (Annex C, ISO 11138-1).

NOTE: example for thermal processes (wet heat, low dry heat and high temperature): the D-value of bacterial spores must be ≥ 2.0 ± 0.2. A lower D-value must not be used.

A.2.3 Treatment of biological indicators

- The treatment tests shall be spread over one (1) day and over:
  - three cycles for bacterial spores in order to validate the parameters;
  - one cycle for mould and viruses to confirm antimicrobial efficacy in two other microbial groups.
- The same batch of inoculated germ carriers must be used throughout the duration of the trials.
- The laboratory must provide a quality certificate containing the following information on the inoculated germ carriers (in accordance with standard ISO 11138-1, clauses 4.1.3 and 4.3.1):
- the name of the strain and its collection number;
- an indication of the disinfection process for which the inoculated germ carrier is suitable;
- the date of manufacture;
- the expiry date;
- the concentration per biological indicator;

- the D-value of the treatment;
- the storage conditions.

- The biological indicators shall be placed in the device holding the infectious waste and mixed with the load at various points, taking care to avoid the sides of the device.

- Per cycle, the following shall be distributed within the load:
  - machine capacity < 300 L: at least 6 tests;
  - machine capacity > 300 L: at least 10 tests.

- In addition to the test germ carriers, four control biological indicators shall be transported back and forth between the test site and the laboratory to ensure their stability.

A.2.4 Analysis method

- The analysis methods shall be determined by the testing body and shall refer to known methodologies (e.g. method specified by the spore supplier, microbiological methods guidelines, etc.).
- The analysis of the test samples and control samples must be carried out using the same procedure.
- The analysis must be quantitative.
- For control samples, dilution controls are required.
- For tests, 100 % of the sample shall be analysed.
- In order to isolate any surviving microorganisms, the analysis shall begin by suspending the germ carrier in a saline solution. The suspension shall be subjected to ultrasonic treatment for 1 minute, mechanically homogenised for at least 1 minute and analysed.

NOTE: in the case of chemical treatment, neutralisation of the chemical is required.

A.2.5 Data analysis

For control samples, the following must be calculated and recorded:

1. the number of spores (cfu) recovered from each control sample;
2. the mean number M (cfu) of spores recovered from the control samples;
3. $\log_{10}$ of M;
4. subtract 5 from $\log_{10}$ of M to generate acceptability criterion Ca.

NOTE: subtracting 5 represents a reduction of 5 $\log_{10}$ for the acceptability criteria.

For the tests, for each day of testing, the following must be calculated and recorded:

1. the number of spores recovered on each of the tests (cfu);
2. the average number (m) of spores recovered;
3. the standard deviation (σ) of the recovered spores;
4. the 97.5 % upper confidence limit (Lsup) for (m) (approximated by $m+ 1.96\sigma$);
5. $\log_{10}$ of the 97.5 % upper confidence limit (Lsup) for m. ($\log_{10}$Lsup).

NOTE: if Lu = 0, then use ‘0’ for log10Lu.

This must include all the recovered germ carriers.

A.2.6 Interpretation of results

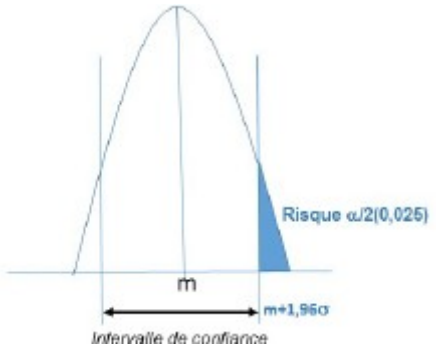
The following criteria represent the minimum standard to be achieved:

1. $\log_{10}$M must be greater than or equal (≥) to 6.
2. $\log_{10}$Lsup must be less than or equal to the pass criteria.

When these criteria are met, there is a greater than 97.5 % probability that the least favourable elements present in the infectious waste will be treated in accordance with the minimum standard.

Example for a machine with a capacity greater than 300 L:

3 cycles were carried out: 4 control samples and 10 samples per cycle.



Results for the control germ carriers (TS)											
	TS1		**TS2**		**TS3**		**TS4**				Valid test if:
TS cfu	8.1 10^6		1.7 10^6		9.2 10^6		7.8 10^6				$\log_{10}$M ≥ 6
M	6.710^6										
$\log_{10}$M	6.82										Yes
Ca	1.82										No
Results for the test germ carriers (T)											**Statistical test**
Cycle 1	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**T10**	
T cfu	6	2	78	10	9	5	20	2	3	3	m (cfu): 15.33
T $\log_{10}$	0.78	0.30	1.89	1	0.95	0.70	1.30	0.30	0.48	0.48	
Log_{10} reduction (M-T)	**6.04**	**6.52**	**<u>4.93</u>**	**5.82**	**5.87**	**6.12**	**5.52**	**6.52**	**6.34**	**6.34**	σ (cfu): 22.75
Cycle 2	**T11**	**T12**	**T13**	**T14**	**T15**	**T16**	**T17**	**T18**	**T19**	**T20**	
T cfu	7	5	3	3	75	6	4	30	9	2	
T $\log_{10}$	0.84	0.70	0.48	0.48	1.87	0.78	0.60	1.48	0.95	0.30	Upper limit (97.5 %) Ls = m + (1.96 σ) = 60 cfu
$\log_{10}$ reduction (M-T)	**5.98**	**6.12**	**6.34**	**6.34**	**<u>4.95</u>**	**6.04**	**6.22**	**5.34**	**5.87**	**6.52**	
Cycle 3	**T21**	**T22**	**T23**	**T24**	**T25**	**T26**	**T27**	**T28**	**T29**	**T30**	
T cfu	40	7	80	8	12	6	3	5	15	2	
T $\log_{10}$	1.60	0.84	1.90	0.90	1.08	0.78	0.48	0.70	1.18	0.30	**That is, $\log_{10}$Ls = 1.78 $\log_{10}$**
$\log_{10}$ reduction (M-T)	**5.22**	**5.98**	**<u>4.92</u>**	**5.92**	**5.74**	**6.04**	**6.34**	**6.12**	**5.64**	**6.52**	

Conclusion:

- Log_{10} M is ≥ 6.
- Log_{10} of the 95 % upper limit (1.78) is lower than the acceptability criterion (1.82).
- In 96.7 % of tests, we achieved a reduction of ≥ 5 log.

All criteria have been met. There is therefore a 97.5 % probability that harmful substances contained in infectious waste will be treated correctly.

Annex E – Treatment tests on infectious waste and recovery tests

The tests consist of treating infectious waste of different natures and origins, then counting the viable residual aerobic bacterial flora and searching for specific bacterial indicators. The infectious waste must have a sufficiently high level of contamination to achieve the required microbial reduction.

A.3.1 Microorganisms tested for

The level of microbial contamination is measured on the basis of:

- viable aerobic bacterial flora;
- the presence, within this flora, of specific bacterial indicators (*Staphylococcus sp., Enterobacteriaceae, Pseudomonas sp.* and/or related species).

A.3.2 Treatment tests

- The infectious waste undergoing the treatment cycle must have a contamination level of at least 7log per sample to ensure that the bacterial reduction required by the acceptance criteria is achieved.
- To ensure that this level of contamination is achieved, nine batches shall be prepared using infectious waste from various sources, for example from the following areas: operating theatres; intensive care units; surgical, gastroenterology and bacteriology departments (medical, food, environmental, etc.).
- The distribution of origins within each batch shall be identical.
- The size of each batch shall correspond to the unit capacity of the loading hopper of the device to be tested.
- The initial contamination level of these batches shall be estimated on the basis of five random samples taken immediately after grinding. Each of the three batches shall be ground to enable the contamination to be measured. This measurement shall be carried out on five test samples per batch of ground material. If the machine does not have a built-in grinder, it will need to prepare three additional control samples to assess the level of contamination in the waste.
- The residual contamination of the load on day 0 (Dd) and day 28 (R) shall be determined from waste samples taken at the discharge point at the end of treatment.

A.3.3 Analysis method

- The analytical methods refer to established methodologies (e.g. guidelines on microbiological methods).
- Samples taken before and after treatment on day 0 and day 28 must be analysed using the same procedure.
- The analysis must be quantitative: enumeration, in colony-forming units (cfu), per sample, of viable aerobic microorganisms after incubation at 30 °C for 72 hours on a TSA-type standard nutrient medium.

NOTE: in the case of chemical treatment, neutralisation of the chemical is required.

A.3.4 Number of tests to be carried out

For testing on infectious waste:

Three tests per day, spread over the operating time of the device, shall be carried out. These three daily tests shall be carried out over a period of three days, which may or may not be consecutive.

Each test shall be carried out with at least 5 samples taken after treatment, i.e. at least 45 samples taken for all treatment tests on infectious waste.

For recovery testing:

One test per day, spread over the operating time of the device, shall be carried out. This daily test shall be carried out over a period of three days, which may or may not be consecutive.

Each test shall be carried out with at least 10 samples taken after treatment, i.e. at least 30 samples taken for all treatment tests on infectious waste.

A.3.5 Data analysis

For infectious waste before treatment, the following must be calculated and recorded:

1. the average number of viable bacteria (cfu) recovered from each batch;
2. the average number M (cfu) of viable bacteria recovered;
3. $\log_{10}$ of M;
4. subtract 5 from $\log_{10}$ of M to generate acceptability criterion Ca.

NOTE: subtracting 5 represents a reduction of 5 $\log_{10}$ for the acceptability criteria.

For waste after treatment (day 0), for each day of testing, the following must be calculated and recorded:

1. the number of viable bacteria recovered from each sample (cfu);
2. the average number (m) of viable bacteria recovered;
3. the standard deviation (σ) of the recovered viable bacteria;
4. the 95 % upper confidence limit (L_{sup}) for (m) (approximated by m + 1.65σ);
5. $\log_{10}$ of the 95 % upper confidence limit (L_{sup}) for m ($\log_{10}L_{sup}$).

NOTE: if Lu = 0, then use ‘0’ for $\log_{10}$Lu.

This must include all the recovered germ carriers.

For waste processed on day 28, the following must be calculated and recorded:

1. $\log_{10}$ for MDd.
2. Add 2 to $\log_{10}$ of M to generate the acceptability criterion Ca.

NOTE: adding 2 represents the maximum acceptable limit.

1. the number of viable bacteria recovered from each sample (cfu);
2. the average number (m) of viable bacteria recovered;
3. the standard deviation (σ) of the recovered viable bacteria;
4. the 95 % upper confidence limit (Lsup) for (m) (approximated by m + 1.65σ);
5. $\log_{10}$ of the 95 % upper confidence limit (L_{sup}) for m ($\log_{10}L_{sup}$).

NOTE: if Lu = 0, then use ‘0’ for $\log_{10}$Lu.

This must include all the recovered germ carriers.

A.3.6 Interpretation of results

Example for tests on infectious waste and recovery tests:

1 test day, i.e. 3 cycles, took place: 15 samples (5 per batch) before treatment and 15 samples after treatment. The recovery test was carried out on cycle 1; 10 samples were stored at 20 ± 2 °C for 28 days.

Results for waste before treatment (D)										
	D_{batch1}		**D_{batch2}**		**D_{batch3}**					**Test valid if**: $\log_{10} \geq 7$
D cfu	3.5 10^7		2.0 10^8		6.0 10^7					
M_D	9.8 10^7									
$Log_{10}M_D$	**7.82**									Yes
$Ca_{day\ 0}$	**2.82**									No
Results for waste after treatment (Dd on day 0)										**Statistical tests day 0**
										m (cfu): 538.6 σ (cfu): 397.72 Upper limit (95 %) m + (1.65 σ) = 540 cfu **That is, 2.73 $\log_{10}$**
Cycle 1 day 0	**Dd1**		**Dd2**		**Dd3**		**Dd4**		**Dd5**	
Dd cfu	340		198		277		180		300	
Dd $\log_{10}$	2.53		2.30		2.44		2.26		2.48	
Reduction on day 0 $\log_{10}$ (D-Dd)	**5.29**		**5.52**		**5.38**		**5.56**		**5.34**	
Cycle 2 day 0	**Dd6**		**Dd7**		**Dd8**		**Dd9**		**Dd10**	
Dd cfu	183		580		420		1500		132	
Dd $\log_{10}$	2.26		2.76		2.62		3.18		2.12	
Reduction on day 0 $\log_{10}$ (D-Dd)	**5.56**		**5.06**		**5.20**		**4.64**		**5.70**	
Cycle 3 day 0	**Dd11**		**Dd12**		**Dd13**		**Dd14**		**Dd15**	
Dd cfu	645		550		809		1200		765	
Dd $\log_{10}$	2.81		2.74		2.91		3.08		2.88	
Reduction on day 0 $\log_{10}$ (D-Dd)	**5.01**		**5.08**		**4.91**		**4.74**		**4.84**	
Results for waste after treatment (Dd on day 28)										**Statistical tests day 28** m (cfu): 8136 σ (cfu): 6370 Upper limit (95 %) m + (1.65 σ) = 8137 **That is, 3.91 $\log_{10}$**
M_{Dd} on day 0	**2.21**									
$Ca_{day\ 28}$	**4.21**									
Cycle 1 day 28	**R1**	**R2**	**R3**	**R4**	**R5**	**R6**	**R7**	**R8**	**R9**	**R10**
$RDd_{day\ 28}$ cfu	1.1^E3	3.9^E3	9.2^E3	1.2^E4	8.4^E3	1.6^E4	9.6^E3	1.9^E4	1.2^E3	9.6^E2
$Dd_{day\ 28}$ $\log_{10}$	3.04	3.59	3.96	4.08	3.92	4.2	3.98	4.28	3.08	2.98
Recovery	**1.17**	**1.38**	**1.75**	**1.73**	**1.69**	**1.99**	**1.77**	**2.07**	**1.87**	**0.77**

Conclusion:

- $Log_{10}M_D$ is ≥ 7.
- Log_{10} on day 0 of the 95 % upper limit (2.73) is lower than the day 0 acceptability criterion (2.82).
- In 100 % of the tests conducted on day 0, we achieved a reduction of ≥ 5 log.

All criteria have been met. There is therefore a 95 % probability that harmful substances contained in infectious waste will be treated correctly.

- Log_{10} on day 28 of the 95 % upper limit (3.91) is lower than the day 28 acceptability criterion (4.21).
- In 100 % of the tests on day 28, we observed a recovery rate of < 2log.

All criteria have been met. There is therefore a 95 % probability that, after 28 days' storage at 20 ± 2 °C, there will be no recovery greater than 2 log_{10}.

Annex F Particle size analysis tests

Annex G Definitions and technical details required for the performance of this test

- Sieving: the process of separating the solid particles by means of a sieve with known characteristics.
- Undersize fraction: this refers to all the material that passes through the sieve.
- Oversize fraction: all the material remaining on the sieve.

Annex H Equipment

- Table or sieve consisting of round apertures with a diameter of 30 mm (135 mesh);
- Hand brush;
- Scale accurate to 1g.

A.4.3 Sample preparation

If the sample is very damp after treatment, leave it to dry at 22 ± 3 °C for approximately one night.

A.4.4 Dosage

- Weigh the empty table or sieve;
- Weigh the sample to be sieved;
- Place the sample on the table;
- Shake the sample mechanically (for 20 minutes) or manually using a hand brush to separate the solid particles and collect the undersize fraction;
- Weigh the table or sieve containing the oversize fraction.

Clean and dry the table between each test.

A.4.5 Calculation and expression of results

The undersize fraction is expressed as a percentage of the total weight of the sample analysed.

E = [(B-D) /B] x 100 with D = (C-A)

Where:

A: mass of the empty sieve (g)
B: mass of the total sample used (g)
C: mass of the sieve with oversize fraction (g)
D: mass of the oversize fraction (g)
E: undersize fraction (%)

Annex I Test acceptability criteria

E must be ≥ 90 %.

Annex J Mechanical tests

The purpose of the mechanical tests is to measure the strength of the ‘cakes’ formed by the pressurised thermal disinfection device and to assess the effectiveness of the changes in the appearance of the waste resulting from the treatment. The cakes shall be subjected to compression, bending, punch and drop tests.

Annex K Mechanical compression test

Annex L Principle

The cake is placed on its side between two plates; one of the plates is connected to a load cell for measuring forces, while the other, movable plate is connected to a drive system operating at a constant speed. The test is divided into two phases: first, a ramp-up to a base value, followed by a second ramp-up to the same value plus 30 %. A visual examination of the cake shall be carried out and any degradation shall be recorded.

Annex M Analysis conditions

The three cakes to be tested must be stored for at least 72 hours at 23 °C ± 2 °C and 50 % ± 10 % relative humidity. Compression shall be performed at a test speed of 100 mm/min, a test temperature of 23 °C ± 2 °C and a relative humidity of 50 % ± 10 % (Figure 1). For each cake, a gradually increasing force is applied to the edge until it reaches 465 N, followed by a force up to 465 N + 30 %, and a visual examination is carried out once the load has been released.

NOTE: the base value for this test is calculated according to the dimensions of the cake and the mechanical forces to which it is subjected within a household waste bin. This mechanical force is calculated as being 465 N. It has been decided to use a 30 % increase on this value as the reference for the mechanical tests, i.e. 605 N.

Figure A.1 – Cake compression test

Annex N Acceptance criteria

Following the compression tests on the edge of the cake, the following points must be verified: at both compression levels tested, 465 N and 605 N, the cake must show no signs of breakage, perforation or tearing.

Annex O Mechanical bending test

Annex P Principle

The cake is laid on two supports and subjected to a force applied at constant speed perpendicular to its surface. The test is divided into two phases: first, a base value, followed by a second at the same value plus 30 %. A visual examination of the cake shall be carried out and any degradation shall be recorded.

Annex Q Analysis conditions

The three cakes to be tested must be stored for at least 72 hours at 23 °C ± 2 °C and 50 % ± 10 % relative humidity. The bending test is carried out on the surface of the cake using a flat punch 60 mm wide and 400 mm long, at a test speed of 100 mm/min, a test temperature of 23 °C ± 2 °C and a relative humidity of 50 % ± 10 %. The gap between the support points is 240 mm (Figure 2). A gradually increasing force is applied to each face of the cake until it reaches 1216 N, followed by a gradually increasing force up to 1216 N + 30 %, and a visual examination is carried out once the load has been released. Between the two applications of force, the cake is turned over and the force is applied after rotating it 90° around its vertical axis.

NOTE: the base value for this test is calculated according to the dimensions of the cake and the mechanical forces to which it is subjected within a household waste bin. This mechanical force is calculated as being 1216 N. It has been decided to use a 30 % increase on this value as the reference for the mechanical tests, i.e. 1581 N.

Figure A.2 – Bending test on a cake

Annex R Acceptance criteria

Following the bending tests on the surfaces of the cake, the following points must be verified: at both bending levels tested, 1216 N and 1581 N, the cake must not show any signs of breakage, perforation or tearing.

Annex S Punch test

Annex T Principle

A punch with a defined geometry is pressed against the surface of the cake until a base pressure is reached. A second test is carried out at another location with the same value increased by 30 %. A visual examination of the surface where the pressure was applied to the cake shall be carried out and any degradation shall be recorded.

Annex U Analysis conditions

The three cakes to be tested must be stored for at least 72 hours at 23 °C ± 2 °C and 50 % ± 10 % relative humidity. The punching test is carried out on the surface of the cake using a rectangular punch measuring 65 mm × 75 mm with sharp but not cutting edges, at a test speed of 100 mm/min, a test temperature of 23 °C ± 2 °C and a relative humidity of 50 % ± 10 % (Figure 3).

A gradually increasing force is applied to each face of the cake, and in two different areas, until it reaches 1462 N, followed by a gradually increasing force up to 1462 N + 30 %, and a visual examination is carried out once the load has been released.

NOTE: the base value for this test is calculated according to the dimensions of the cake and the mechanical punching forces to which it is subjected within a household waste bin. This mechanical force is calculated as being 1462 N. It has been decided to use a 30 % increase on this value as the reference for the mechanical tests, i.e. 1901 N.

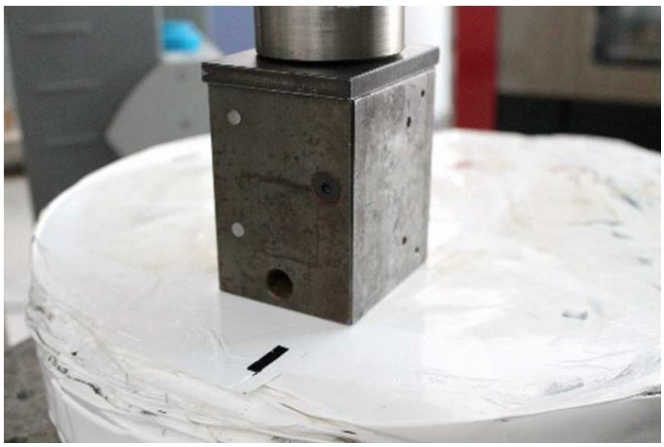


Figure A.3 – Cake punch test

Annex V Acceptance criteria

Following the punch tests carried out on the surface of the cake in two different areas, the following points must be verified: at both punch levels tested, 1462 N and 1901 N, the cake must not show any perforations.

Annex W Drop test

Annex X Principle

The cake is dropped from a defined height onto the ground. This test consists of determining whether the impact of the cake on the ground causes the cake to break.

Annex Y Analysis conditions

The six cakes to be tested, three for a flat fall and three for a fall on their edge, must be stored for a minimum of 72 hours at 23 °C +/- 2 °C and 50 % +/- 10 % relative humidity. The drop test is carried out from a height of 2 300 mm onto a tiled floor, at a test temperature of 23 °C ± 2 °C (Figure 4).

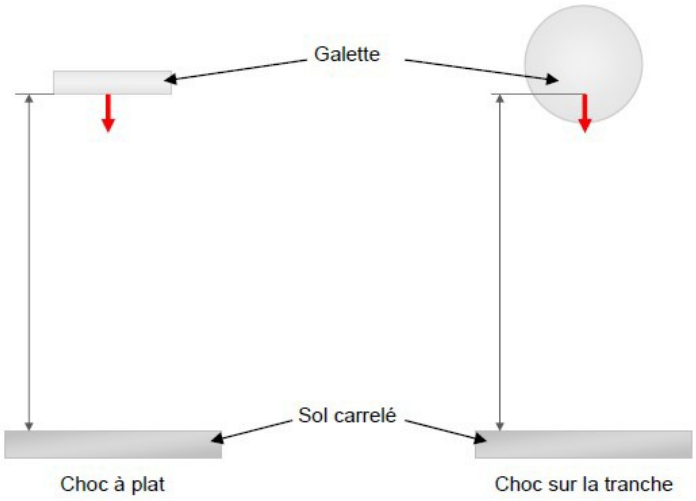


Figure A.4 – Cake drop test

Annex Z Acceptance criteria

Following drop tests involving the cake being dropped from a height of 2 300 mm onto a tiled floor both on its edge and flat, the following points must be verified: no permanent deformation, breakage or tearing. A visual examination of all sides of the cake shall be carried out to check its condition.

Annex AA

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Arrangements for reporting results

Test results must be reported in the formats specified below (Tables).

The laboratory is required to provide accurate results, not semi-quantitative ones. The results shall be accompanied by a report setting out the methodology of the tests used by the laboratories.

Annex BB Results table for liquid discharge tests (see 5.2.1)

Cycle	**Test no**	**Volume discharged**	**Indicators (cfu/100 ml)**		
			Staphylococcus sp.	*Enterobacteriaceae*	*Pseudomonas sp. and/or related group*
1	1				
	2				
	3				
2	4				
	5				
	6				
3	7				
	8				
	9				

Table B.1

Annex CC Results table for airborne microbial contamination (see 5.2.2)

Table B.2

Aerobic bacterial flora									
Cycle	**Operational stage of the device tested**	**Sample no**	**Measured contamination (log_{10})**	**Contamination of the control sample before operation (log_{10})**	**Comparison of contamination levels (log_{10})**	**Comparison of contamination levels (log_{10}) (C) = (A)**	**Indicators (presence / absence)**		
							Staphylococcus sp.	*Enterobacteriaceae*	*Pseudomonas sp. and/or related group*
1	Loading	1							
	Operation	2							
	Unloading	3							
2	Loading	4							
	Operation	5							
	Unloading	6							
3	Loading	7							
	Operation	8							
	Unloading	9							

Annex DD Results tables for treatment tests using biological indicators

(see 5.3.1)

Table B.3

Strains: Batch of inoculated germ carriers: Date of manufacture: Expiry date: Title D-value:	Test date: Treatment device: Treatment parameters: Date of analysis: Reading date:

	Results for the control germ carriers (TS)				
Controls	**TS1**	**TS2**	**TS3**	**TS4**	Tests valid if: $log_{10}M \geq 6$ • YES • NO
TS cfu					
M					
$Log_{10}M$					
Ca					

Results for the test germ carriers (T)											**Statistical test**
Cycle 1											m (cfu): σ (cfu): Upper limit (97.5 %) LS = m + (1.96 σ) = log_{10} LS = Acceptable if: log_{10} LS < Ca • YES • NO
T cfu											
T log_{10}											
Log_{10} reduction (M-T)											
Cycle 2											
T cfu											
T log_{10}											
Log_{10} reduction (M-T)											
Cycle 3											
T cfu											
T log_{10}											
Log_{10} reduction (M-T)											

Table B.3 must be completed for each of the three test microorganisms identified in paragraph 5.3.1.

Annex EE Results table for treatment tests on infectious waste

(5.3.2 and 5.3.3)

The table must be completed for each of the cycles for Dd to day 0.

For Dd to day 28, it must be completed for 1 cycle per day.

Table B.4

Results for waste before treatment (D)							
Samples	**D1 (average, batch A)**		**D2 (average, batch B)**		**D3 (average, batch C)**		Tests valid if:
D cfu							log10M ≥ 7 • Yes • No
M_D							
$log_{10}M_D$							
$Ca_{day\ 0}$							
Results for waste after treatment (Dd on day 0)							**Statistical test day 0** m (cfu): σ (cfu):
Day cycle	**Dd1**	**Dd2**	**Dd3**	**Dd4**	**Dd5**	**Dd6**	
Dd cfu							
Dd log_{10}							Upper limit (95 %) Ls cfu = m + (1.65 σ) = **That is, log10 Ls =**
Reduction on day 0 log10 (D-Dd)							
Results for waste after treatment (Dd on day 28)							**Statistical test day 28** m (cfu): σ (cfu):
M_{Dd} on day 0							
$Ca_{day\ 28}$							
Day cycle	**Dd7**	**Dd8**	**Dd9**	**Dd10**	**Dd11**	**Dd12**	
$Dd_{day\ 28}$ cfu							Upper limit (95 %)
$Dd_{day\ 28}$ log_{10}							Ls cfu = m + (1.65 σ) =
M_{Dd} on day 28							**That is, log10 Ls =**

Annex FF Results table for particle size analysis (5.4)

Particle size			**Test date:**		
Samples	**A** Weight of the empty sieve	**B** Total weight of sample analysed	**C** Weight of the sieve with oversize fraction	**D** Weight of oversize fraction (C – A) / B	**E** **Undersize fraction %** **[(B- D) / B] x 100**

Annex GG

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Manufacturer’s instructions

For each device used for the treatment by disinfection of infectious waste, the manufacturer must provide an instruction manual as defined in paragraph 1.7 of Annex I provided for in Article R. 4312-1 of the Labour Code.

The contents of this instruction manual must provide the following information, as applicable:

- the essential parameters of disinfection (see 4.2);
- the characteristics of emissions: liquid and gaseous effluents;
- average consumption measurements for steam, water, gas, electricity and consumables;
- changes in the volume and weight of waste, and the temperature of waste resulting from treatment;
- the treatment capacity of the device in kilos/hour (or, failing that, litres/hour) and in tonnes/year on the basis of a number of hours to be specified, compatible with good operating practice and the applicable regulations;
- the essential characteristics and dimensions of the device with diagrams (plan and elevation views);
- a description of the device's operating cycle;
- the nature of the treatment device's security features and the parameters and indicators for the correct operation, reliability and effectiveness of the treatment;
- the procedures for maintenance operations (disposal of infectious waste before repair, condition of access to the components of the device, etc.);
- the procedures to be followed by operators, particularly in the event of a breakdown (operating procedures for the exceptional ‘safety’ disinfection procedure, restarting operations and the disposal of untreated infectious waste);
- the clothing and personal protective equipment (such as gloves, face masks, etc.) to be worn by operators during operations;
- the documentation and mandatory archiving for each treated batch of infectious waste: weight (and/or volume), cycle, treatment duration, treatment parameters, confirmation of decontamination, possible malfunction of the machine;
- traceability of infectious waste treatment protocols – retention period: 10 years;
- compliance with the requirements of the EU Machinery Directive (2006/42/EC);
- information on the regulatory requirements applicable to the treatment device.

A simplified document containing the essential information specified in the manufacturer’s instructions shall be drawn up and provided by the manufacturer for permanent installation at the machine's main control position.

Bibliography

[1] Law No 77-771 of 12 July 1997 on the control of chemical products.

[2] Law No 92-3 of 3 January 1992 on water, as amended.

[3] Public Health Code – Articles R.1335-1 to R.1335-14.

[4] Environment Code – Articles L.541-1 to L.541-50 and R.512-1 to R.512-75.

[5] Labour Code:

- Article R.4311-1 to Annex II to Article R.4312-6 (‘Title 1: design and placing on the market of work equipment and protective equipment’ of Book III of Part Four – health and safety at work);
- Article R.4312-1 to Annex I, which sets out the technical health and safety rules applicable to new machinery or machinery deemed to be new, as referred to in Article R.4312-1 of the Labour Code;
- Articles L.4321 to L.4321-5 (Chapter 1 of Title II of Book III of the fourth part of the Labour Code, relating to the use of work equipment and protective equipment).

[6] Council Directive 91/689/EEC of 12 December 1991 on hazardous waste – transposed into French law by Decree No 2002-540 of 18 April 2002.

[7] Order of 7 September 1999 on monitoring of the sectors responsible for the disposal of potentially infectious waste from healthcare activities and other comparable healthcare waste and anatomical parts of human origin.

[8] Order of 22 February 2022 amending the Order of 28 March 2019 on the implementation of a pilot scheme concerning the recovery of waste resulting from the pretreatment by disinfection of potentially infectious healthcare waste and other comparable healthcare waste.

[9] Order of 20 April 2017, as amended, on the pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste.

[10] INSTRUCTION No DGS/RI3/2011/449 of 1 December 2011 on the updating of recommendations aimed at reducing the risk of transmission of non-conventional transmissible agents during invasive procedures.

[11] NF T72-190, Water-miscible contact disinfectants used in liquid state – Germ carrier method – Determination of the bactericidal, fungicidal and sporicidal activity.

[12] NF EN 866-1, Biological systems for testing sterilisers and sterilisation processes – Part 1: General requirements.

[13] NF EN 866-3, Biological systems for testing sterilisers and sterilisation processes – Part 3: Particular systems for use in moist heat sterilisers.

[14] NF EN 866-6, Biological systems for testing sterilisers and sterilisation processes – Part 6: Particular systems for use in dry heat sterilisers.

[15] NF EN 866-7, Biological systems for testing sterilisers and sterilisation processes – Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilisers.

[16] NF EN ISO 11138-1, Sterilisation of healthcare products – Biological indicators – Part 1: General requirements.

[17] NF EN ISO 11138-3, Sterilisation of healthcare products – Biological indicators – Part 3: Biological indicators for moist heat sterilisation processes.

[18] NF EN ISO 11138-4, Sterilisation of healthcare products – Biological indicators – Part 4: Biological indicators for with dry heat sterilisation processes.

[19] NF EN ISO 14161, Sterilisation of healthcare products – Biological indicators – Guidance for the selection, use and interpretation of results.

[20] NF EN ISO 14971, Medical devices – Application of risk management to medical devices.

[21] NF EN ISO 23907-1, Sharps injury protection – Part 1: Single-use sharps containers.

[22] NF X30-501, Packaging of waste from healthcare activities – Bags for soft potentially infectious healthcare waste.

[23] NF X30-507, Packaging of waste from healthcare activities – Box with inner bag for solid or soft potentially infectious healthcare waste.