Ministry of Ecology, Sustainable Development and Energy
Ministry of Social Affairs and Health

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The Minister of Ecology, Sustainable Development, and Energy
Minister of Social Affairs and Health
to
Distinguished regional prefects
(for information)
Distinguished general directors of regional health agencies
(for information)
Distinguished department prefects
(for information)

INTERMINISTERIAL CIRCULAR No. DGS / EA1 / DGPR / 2013/173 of March 1, 2013 concerning the implementation of the pre-treatment device by disinfection of Infectious waste (HCW) "ECODAS T100" of ECODAS company and to the departmental administrative procedure applicable to pre-treatment devices by disinfection of infectious waste (HCW).

Application Date: Immediate

NOR: AFSP1310810C Theme: Environmental Health

Certified by CNP on January 18, 2013 - Visa CNP 2013-04

Summary: this circular:

- allows the implementation of the pre-treatment device by disinfection of Infectious waste (HCW) "ECODAS T100" of ECODAS company;
- describes the evolution of departmental administrative procedures applicable to pre-treatment devices by disinfection of infectious waste (HCW)

Keywords: pre-treatment by disinfection, Infectious waste (HCW)

Mandate:

- Public Health Code and particularly Articles R.1335-1 to R.1335-14;
- Departmental Health Regulations (Article 88 and 164.);
- Circular No. 53 of July 26, 1991 relative to the implementation of contaminated waste disinfection processes of hospitals and similar establishments;
- Circular of December 24, 2010 relative to detailed rules for implementing the decrees n° 2009-1341, n° 2010-369 and n° 2010-875 amending the nomenclature of classified installations carrying a waste treatment business.

Repealed or amended texts: amendment of Circular n° 53 of July 26, 1991 relative to the implementation of contaminated waste disinfection processes of hospitals and similar establishments.
Appendices Appendix 1: provisions relative to the pre-treatment device by disinfection of Infectious waste (HCW) and similar waste "ECODAS T100." Annex 2: Opinion of the High Council of Public Hygiene of France (HCPHF) of November 16, 1999 relative to the monitoring of the effectiveness of disinfection devices of infectious waste (HCW) after validation by the HCPHF.
Distribution: concerned establishments or organizations to be recipients of this circular, through decentralized services or Regional Health Agency (RHA), as the existing system at the regional level.

I Validation of the pre-treatment device by disinfection of HCW "ECODAS T100" of ECODAS company.

Previously subject to an opinion of the High Council of Public Hygiene of France, the national validation procedure of pre-treatment devices by disinfection of HCW must now upgrade to a compliance certificate issued by an accredited body on the basis of a system of reference relying in particular on the standard NF X 30-503 relative to the reduction of microbiological and mechanical risks by pre-treatment devices by disinfection of HCW and similar risks, developed for this purpose. Transiently, the issue, instructed by the General Directorate of Health, is the subject of a review by a committee of experts before validation. INERIS provides its technical support for this approval procedure.

The INERIS report of December 4, 2012 on the device "ECODAS T100" attests that the technical and microbiological tests achieved on the device "ECODAS T100" according to the protocol approved by the committee of experts, whose results are consistent with the standard NF X 30-503, have demonstrated the effectiveness of this device in the shredding and disinfection of HCW and similar risks. The technical requirements for implementation and monitoring associated with the device are specified in Annex I.

Waste allowed on this type of installation is the HCW defined in Article R. 1335-1 of the Public Health Code which simply subtract waste which may contain non-conventional transmittable agents. Furthermore, it is strictly forbidden to bring in these devices cytotoxic drugs used to treat cancers.

Pre-treated waste can be disposed of either by incineration or by disposal in a non-hazardous waste storage facility, according to the usual procedures relative to non-hazardous waste from all sources. It is appropriate to exclude composting technologies because of the characteristics and origin of such waste.

II- Evolution of the departmental administrative procedure relative to pre-treatment devices by disinfection of HCW

Pending the publication of the decree relative to the rules of issuance of the certificate of conformity of disinfection devices of HCW, pursuant to Article R.1335-8 of public health code, provisions of Article 88 of the departmental health regulations (DHR) requiring incineration of health care waste remain applicable. Pursuant to Article 164 of this regulation and as outlined in the Circular n° 53 of July 26, 1991 referred to above, prefects may derogate by order from the requirement of the obligation to incinerate HCW and authorize the use of disinfection devices previously approved at national level.

Furthermore, provisions of Decree n° 2010-369 of April 13, 2010 amending the nomenclature of classified installations and establishing especially the section 2790 relative to hazardous waste facilities, apply to HCW treatment facilities by disinfection. However, as it emerges from the circular of December 24, 2010 relative to detailed rules for implementing decrees n° 2009-1341, n° 2010-369 and n° 2010-875 amending the nomenclature of classified installations having a waste treatment business, a treated waste on its production site should not be considered as a waste only if its holder intends to dispose of it at the time of treatment. Thus, if a facility that processes HCW waste from various sources has indeed to be permitted under section 2790 seeing that it receives external waste, an internal facility that handles HCW from one care facility only isn’t the concern of this section.

Thus, pending the publication of the decree above-mentioned, the pre-treatment devices by disinfection continue to be an order of the prefect:

- either an exemption of departmental sanitary regulation (DSR) for internal devices of a facility that only treat the HCW of this facility, procedure conducted by the regional health agency on the same basis as before (in this case, the regional health agency is also in charge of the inspection of these devices),
- or an authorization on behalf of classified facilities for environmental protection (CFEP) for the another (facilities that process HCW from various sources). In the latter case, Regional Directorate of Environment, Development and Housing (RDEDH) has to ensure the investigations of this issue, to write the order of the prefect with its technical requirements and to support on-site inspections.

New information relative to devices that do not fall under section 2790 of the nomenclature of CFEP will be given with the publication of the above-mentioned decree, when Article 88 of the DSR will be repealed, making obsolete the exemption to the incineration obligation allowing currently to authorize by order of prefect the installation of pre-treatment device by disinfection of HCW.

Would you please keep us informed of the difficulties you might encounter during the implementation of this Circular.

For the Minister of Ecology,
Sustainable Development
and Energy

For the Minister of Social Affairs
and Health

The General Director of Risk Prevention

The General Director of Health

Dr Jean-Yves GRALL

APPENDIX I

Provisions relating to the pre-treatment devices by disinfection of infectious waste (HCW) and similar risks "ECODAS T100"

According to the standard NF X 30-503 relative to the reduction of microbiological and mechanical risks by pre-treatment devices by disinfection infectious waste and similar risks,

Whereas the process parameters: heat treatment by wet heat, with a step of 138 ° C for 10 minutes under 3.8 bar, preceded by a shredding step (identical technology to the disinfection processes of devices ECODAS T150 and ECODAS T300 approved by the circular DGS / SDEA1 / DPPR n° 2008-225 of July 9, 2008 relative to the implementation of the pre-treatment device by disinfection of HCW "ECODAS T150" and the circular of January 8, 1996 relative to the implementation of the disinfection process "Lajtos TDS 300" for contaminated waste from hospitals and similar); average production capacity of 100 kg per hour;

Whereas the results of technical and microbiological tests achieved on the site of the ECODAS company in Roubaix (59) by the laboratories Biorisk Expertise and SOCOR demonstrate the effectiveness of the process in terms of HCW disinfection during the microbiological indicators tests and the tests of revival of germs in the treated waste, under the conditions described above;

Whereas the results of size tests on shredded waste and air contamination tests meet the above-mentioned standard;

Whereas the opinions of the High Council of Public Hygiene of France dated of November 21, 2003 and November 16, 1999;

The implementation of the pre-treatment device by disinfection of HCW "ECODAS T100" of ECODAS company is subject to the following provisions:

The installation site of the device must comply with the decree of September 7, 1999 relative to the storage of HCW and conditions of use must comply with the regulations relative to hygiene and safety rules.

The following waste are excluded from pre-treatment: silver salts, X-ray negatives, chemicals, high oxidizing power explosives, mercury waste, radioactive waste, anatomical parts and dead animals intended for cremation or burial, toxic, waste associated with the use of cytostatic drugs, waste that may damage the operation of the device, waste which may contain Unconventional Transmissible Agents (NCTA).

The holder must conduct continuous recording of disinfection parameters when the unit is in service. Records and results of control parameters remain available to state services for three years.

The holder must achieve quarterly microbiological indicators tests described in the notice of the High Council of Public Hygiene of France dated of November 16, 1999 (biological indicator containing spores of Bacillus subtilis CIP 7718, as a 10^5 bacterial spores). These tests are performed by a laboratory using the sampling and analysis methodology described in the standard NF X 30-503. Test results are at the Regional Health Agency and state services disposal for three years.

In case of non-compliant tests (less than 5 log reduction), the tests are repeated within 48 hours following the publication of the result. If two consecutive tests are not in conformity, the holder must implement all corrective actions to achieve compliant tests.

Thenceforth microbiological indicators tests are non-compliant or in case of failure of the device, the holder is required to dispose of waste of infectious waste (HCW) as required by the order of prefect authorizing its operation. In these cases, the holder must keep informed the regional health agency and the competent states.

The holder shall annually achieve a microbiological control of air quality described in the notice of the High Council of Public Hygiene of France dated of November 16, 1999 in the immediate vicinity of the device by a laboratory, according to the sampling and analysis methodology described in the standard NF X 30-503. Test results are available to the Regional Health Agency and state services for three years. In case of non-conformity of the test results with the NF X 30-503, the tests are repeated within 48 hours of publication of the result. If two consecutive tests are not in conformity, the holder must notify the Regional Health Agency and the competent departmental state services where the device is installed and implement all corrective actions to achieve compliant tests.

Any change on the pre-treatment parameters or device capacity must be subject to a new validation request addressed to the Directorate General of Health.

Appendix II

HIGH PUBLIC HEALTH COUNCIL OF FRANCE
SECTION LIVING ENVIRONMENTS
Meeting on Tuesday, November 16, 1999

OPINION

Relative to the control of the effectiveness of disinfection devices
For infectious waste (HCW) after approval by the HCPHF

Whereas the experience gained in the field of disinfection of infectious waste (HCW) and similar risks;

Whereas the future of disinfected waste of care activities (landfill site class II or household waste incinerator after possible transit by the waste reception pit);

The High Council of Public Health of France gives the following opinion:

1. Any holder of a disinfection device conducts a continuous recording of disinfection parameters (time, temperature, pressure, ...). If the technology of the device permits, a control of disinfection parameters is achieved monthly by treatment chemical integrator strip. Records and results of control parameters remain available to state services for one year;

2. Any holder of a disinfection device proceeds to microbiological indicators tests (Bacillus subtilis or Bacillus stearothermophilus spores, calibrated and meeting to the Pharmacopoeia). These tests are conducted quarterly by a laboratory that received the approval from the Departmental Directorate of Health and Social Affairs where the device is installed. They are made on D + 0 (day of collection) and D + 14 (after 14 days of storage in the laboratory, to ensure the absence of revival of germs). Upon receipt, the results are sent to the Departmental Directorate of Health and Social Affairs (DDHSA) and if necessary the inspection of classified installations for environmental protection. If reduction is less than five logarithms, the concerned state services are immediately warned. The holder shall arrange new tests within 48 hours. If the results are confirmed, the State services require the shutdown of the facility. Then, infectious waste (HCW) are routed to the backup installation (disinfection or incineration);

3. Any holder of a disinfection device achieves annually control of the air quality in the immediate vicinity of the device by a laboratory that received the approval of the DDHSA. This control consists of a bacterial and a fungal air count;

For producers whose monthly waste production of infectious waste (HCW) is less than or equal to five kilograms,
- a control of disinfection parameters is monthly achieved by treatment chemical integrator strip. Results of this control are available to the state services for a year,
- once a year, microbiological indicators tests are achieved as described in point 2 above,
- annual control of the air quality as described in point 3 above is recommended.

State services may request that additional controls are performed if necessary, the involved costs are supported by the holder or by the producer when the monthly production of waste is less than or equal to five kilograms.

In case of repeated failures, approval shall be suspended and the issue must be presented again to the High Public Health Council of France.

This opinion may be distributed in its entirety only, without suppression or addition.