Ministry of Ecology, Energy, Sustainable Development and Land Planning

Ministry of Health, Youth, Sports and Public Life

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The Minister of Ecology, Energy, and Sustainable Development and Land Planning
The Minister of Health, Youth, Sports and Public Life

to

Ladies and Gentlemen District Representatives,
Regional Administration of Sanitation and Social Affairs
(for information)

Ladies and Gentlemen Departmental Representatives,
Departmental Management of Sanitation and Social Affairs
(for information and execution)

INTERDEPARTMENTAL CIRCULAR No. DGS/SDEA1/DPPR/2008/225 (July 9, 2008) related to the implementation of “ECODAS T150”: Equipment for pretreatment by disinfecting potentially infectious medical waste

Application Date: Immediate
NOR: SJSP0830596C
Thematic Classification: Healthcare Establishments

Summary: This circular allows the implementation of “Ecodas T150" for the pretreatment by disinfecting potentially infectious medical waste.

Keywords: Pretreatment by disinfecting potentially infectious medical waste

Reference Documents:
- Public Health Code, including articles R.1335-1 to R.1335-14.
- Department of Health Regulations (article 88 and 164).
- Circular No. 53 dated as of July 26, 1991 regarding the implementation of the disinfection

process of contaminated waste at hospitals and similar healthcare institutions **Modified Texts:** Circular No. 53 dated as of July 26, 1991 regarding the implementation of the disinfection process of contaminated waste at hospitals and similar healthcare institutions
Annexes: Provisions regarding equipment for pretreatment by disinfection "T 150"

Pending the publication of the decree on the approval of equipment for disinfecting clinical waste under Article R.1335-8 of the Public Health Code, provisions of Department of Health Regulations remain applicable. Under the Article 164 of this regulation, District Representatives may authorize the obligation of incineration of clinical waste, by order of the decree, the use of disinfection equipment validated beforehand at the national level.

As previously suggested by the Higher Council of Public Health of France, the validation process shall now move towards a certificate of compliance issued by a qualified third party based on a reference system, in particular, the standard NF X 30-503, relative to devices developed for the reduction of microbiological and mechanical risks through pretreatment by disinfection of medical waste. As a transitional measure and until the publication of the above in 2009, INERIS would provide technical support for this validation process.

The INERIS report dated April 3, 2008 states that technical and microbiological efficacy tests performed on the ECODAS T150 in accordance with the applicable standard, meet requirements. The technical requirements of implementation and monitoring associated with this device are specified in the annex.

We would like to remind you that the processes T1000, T2000 and T300 of Ecodas company (formerly Lajtos company) have already been approved according to circulars No. 48 dated as of July 15,1994, No. 96-09 dated as of January 8, 1996 and No. 98-533 dated as of August 19, 1998.

Waste permitted for this type of installation is clinical waste with infectious risks as defined in Article R. 1335-1 of the Public Health Code that shall be removed as this waste is likely to contain non-conventional transmittable agents. In addition, it is strictly forbidden to place into these devices chemotherapy drugs used for cancer treatment.

The pre-treated waste can be disposed of either by incineration or by deposition in a storage facility for non-hazardous waste, according to the common procedures relating to non-hazardous waste from all sources. It is necessary to exclude composting techniques because of the characteristics and origin of such waste.

Please keep us informed of any difficulties you may encounter from the implementation of this circular.

For the Minister and by authority Laure TOURJANSKY Sub-director of Products and Waste	For the Minister and by authority Jocelyne BOUDOT Sub-director of the Prevention of Risks Related to Environment and Food

Annex

Provision regarding “T150” from ECODAS company, a device for the pretreatment by disinfecting potentially infectious medical waste.

Considering the standard NF X 30-503 regarding the reduction of microbiological and mechanical risks by devices of pretreatment by disinfecting clinical waste with infection or possible risks;

Considering the process parameters: disinfection by moist heat (Temperature 138 ° C with a duration of 10 minutes pressure 3.8 bars) preceded by shredding: average capacity of 15 to 25 kilograms per hour;

Considering that the results of technical and microbiological tests, conducted on the site of the Clinique du Parc in Croix (59) by the department of expertise in Hygiene Hospital of the Pasteur Institute of Lille. The efficacy of the process is demonstrated by disinfecting infectious clinical waste during the efficacy study of the treatment using microbiological indicators and regenerated germs inside the treated waste and under the conditions described above;

Considering the results of tests on the size of shredded waste and on the air contamination, which meet the standard mentioned above;

Considering the statement of the Higher Council of Public Health of France dated as of November 16, 1999;

The local implementation of the device and the conditions of use must comply with statutory measures relating to health and safety.

The following wastes are excluded from the pre-treatment: silver salts, X-rays, chemicals, high-power oxidant explosives, mercury waste, radioactive waste, anatomical parts and animals carcasses intended for cremation or burial, toxins, waste associated with the use of Cytotoxic drugs, waste that could impair functionality of the machine, waste that could contain Transmissible Spongiform Encephalopathy.

Since the introduction of the waste into the machine is manual, precautions is required according to industry safety, primarily for packaging of clinical waste with infection risks, handling and loading medical waste that rule out manual packing and pushing down, and disinfecting of loading area as necessary.

The operator shall record continually the parameters of disinfection and retain recordings and results of the control parameters for any government's request for three years.

The operator must carry out quarterly microbiological indicator tests described in the Higher Superior Council of Public Health of France statement dated November 16, 1999 (Biological indicators including spores of Bacillus Stearothermophilus ATCC 7953, to an advanced 10^5 bacterial spores). These efficacy studies are carried out by a laboratory approved by the Department of Management of Health and Social Affairs for device implementation. Test results shall be retained for any government's request for three years.

In the event of non compliance of testing (Logarithmic reduction of less than 5), the tests shall be repeated within 48 hours following the publication of the result. If two consecutive tests are non-compliant, the owner must implement all corrective actions to obtain compliant tests.

In the event the biological indicators tests are non-compliant or in case of machine defects or breakdown, the owner must eliminate the clinical waste with infection risks through the course prescribed by the prefecture authorizing its operation. In these cases, the owner must inform the Departmental of Management of Health and Social Affairs.

The owner shall conduct a yearly microbiological control of air quality in the machine's vicinity by a laboratory approved by the Department of Management of Health and Social Affairs. The results shall be sent to State services.

Any change concerning the pre-treatment parameters or the functionality of the device must be subject to a new validation where a request must be sent to the General Department of Health.