THE SOCIALIST REPUPLIC OF VIETNAM

QCVN 55: 2013/BTNMT

NATIONAL TECHNICAL REGULATION ON INFECTIOUS HEALTHCARE WASTE AUTOCLAVE

Hanoi – 2013

NATIONAL TECHNICAL REGULATION ON INFECTIOUS HEALTHCARE WASTE AUTOCLAVE

1. General provisions

1.1. Scope

This regulation specifies the requirements of technical and environmental specifications for the autoclave when used to treat infectious healthcare waste.

1.2. Subjects of application

This regulation applies to all organizations and individuals, who use, manufacture, sell (or distribute) and import health care waste autoclaves; the state management agency on environment; the unit of sampling, analyzing, and other related organizations and individuals.

1.3. Interpretation

In this regulation, the following terms shall be interpreted as follows:

1.3.1. Infectious healthcare waste is waste containing infectious agents arising from health care activities and are classified under the provisions of Circular No. 12/2011/TT-BTNMT on April 14th , 2011 on hazardous waste management of the Ministry Of Natural Resources and Environment (Circular No. 12/2011/TT-BTNMT in short) and Decision No. 43/2007/QD-BYT on November 30th, 2007 on the establishment of healthcare waste management regulation of the Ministry of Health.

1.3.2. Healthcare waste-autoclave is the equipment for sterilizing infectious healthcare waste by exposure to steam at appropriate temperature and pressure in a certain period of time to kill bacteria, viruses and biological pathogens in infectious healthcare waste without burning the waste.

2. TECHNICAL PROVISIONS

2.1. Technical requirements

2.1.1. Healthcare waste-autoclave must be designed according to the principle of treating healthcare waste using steam at sufficient temperature and pressure to kill pathogenic micro-organisms.

2.1.2. In the operation of healthcare waste-autoclave (without taking into account the vacuum stage), technical requirements of autoclave (temperature, pressure and duration) must sastisfy the provisions stated in Table 1 below:

Table 1: Design provisions on the minimum working temperature, pressure and operation duration of healthcare waste-autoclave

Type of autoclave	**Temperature of chamber (ºC)**	**Pressure of chamber (atm)**	**Operation duration (1) (minutes)**
Non-vacuum autoclave (2)	121	1	60
	135	2,1	45
Vacuum autoclave (3)	121	1	45
	135	2,1	30

Note:

(1) *Operation duration is calculated from the moment that temperature and pressure of chamber reaches the requirements in Table 1.*

(2) *Non-vacuum autoclave is the equipment that during operation, steam is released into chamber without air removal by vacuum pump.*

(3) *Vacuum autoclave is the equipment that during operation, steam is released into chamber after the air is sucked by vacuum pump.*

2.1.3. The autoclave must be equipped with a valve to release air from chamber before removing treated waste.

2.2. Requirements for treatment efficiency

The required treatment efficiency of autoclave must be equivalent the killing efficiency of one following bio-indicator:

2.2.1. Using Mycobacterium phlei or Mycobacterium bovis as bio-indicator, the minimum killing efficiency must be 99,9999% (6 log 10 reduction).

2.2.2. Using heat resistant spores *Geobacillus stearothermophilus* or *Bacillus atrophaeus* as bio-indicator, the minimum killing efficiency must be 99,99% (4 log 10 reduction).

2.3. Treated infectious healthcare waste handling

Infectious healthcare waste after autoclave treatment accordingly to this technical regulation should be handled as non-hazardous waste. Surgery waste must be grinded and shredded if buried with other wastes in sanitary landfills.

2.4. Wastewater control

Wasterwater generates from autoclave treatment of infectious healthcare waste must sastify the National Technical Regulation on Healthcare Wastewater - QCVN 28:2010/BTNMT before discharges to the enviroment.

2.5. Gas emissions control

Gas emissions generate from autoclave treatment of infectious healthcare waste must sastify the National Technical Regulation on Industrial Gas Emissions for Particulate and In-organic Matters - QCVN 19:2009/BTNMT before discharge to the enviroment.

2.6. Monitoring healthcare waste-autoclave

2.6.1. Treatment efficiency monitoring

a) For autoclave using only bio-indicators, the minimum monitoring frequency must be twice per month or once for every twenty batches.

b) For autoclave using bio-indicators and thermal indicators (defined in 2.6.2 of this technical regulation), the minimum monitoring frequency using bio-indicators must be once per month or once for every forty batches.

2.6.2. Temperature monitoring

Temperature of chamber is monitored by thermal indicators. The thermal indicators change color (defined differently for different thermal indicator) when the temperature reaches the minimum requirement in 2.1.2 of this technical regulation. When there is no appropriate thermal indicator in the market, autoclave suppliers must provide thermal indicators that meet requirements of applied standards or technical regulations according to the Law on Products and Goods Quality.

In the case of monitoring defined by 2.6.1(b) of this technical regulation, minimum thermal indicator monitoring is once per week. When the autoclave operates less than 2 batches per week, the minimum thermal indicator monitoring is once for every two batches.

2.6.3. When infectious healthcare waste treatment facility operates in groups or in a industrial zone, the autoclave must be equipped with:

a) Automatic controlling system (with programmed autoclave produres) with measuring equipment to record temperature, pressure and operation duration.

b) Shredding or pressing equipment (with proper design) for shaping and de-voluming the treated waste.

2.6.4. Users must reduce the pressure in chamber back to normal before removing the treated waste.

3. METHOD FOR DETERMINATION

3.1. Methods for analysis, determine the treatment efficiency of autoclave using bio-indicators are subjected to guidance of the manufacturers but follow the basic principles below:

Place 03 bio-indicator vials or ampules in 03 different positions in the chamber, including middle of waste block or lowest temperature and pressure areas of chamber. Operate the autoclave with the maximum capacity in the condition of time, temperature and pressure defined in 2.1.2.

After end of operation, the test vials or ampules containing microbial indicators are taken to be cultured to determine the extent of killing. Culture is taken in the laboratory or in equipment provided by the suppliers (the culture method is specified in attached Appendix). The autoclave is dertemined effective when the culture results show that bio-indicators are killed and cannot reproduce.

3.2. When there is no available bio-indicators in the market, autoclave suppliers must provide ampules with *Mycobacterium phlei* or *Mycobacterium bovis* (with the mimimum concentration of $1x10^6$ spores*) or Geobacillus stearothermophilus* or *Bacillus atrophaeus* (with the mimimum concentration of $1x10^4$ spores).

3.3. Other bio-indicators or methods of determination are accepted when there is proof of international accredit.

4. IMPLEMENTATION

4.1. Users of infectious healthcare waste autoclaves in the territory of the Socialist and Republic of Vietnam must comply with this technical regulation except the following cases:

4.1.1. Existing autoclaves before the effectiveness of this technical regulation are exempt from some provisions (except Section 2.2) until December 31st 2015 if the compliance requires upgrading, improvement and amendment of design, structure, equipment and materials.

4.1.2. Until the establishment of new technical regulation, sterilized infectious healthcare autoclaves using more advanced technologies (such as

microwave) are exempt from some provisions (except Section 2.2) if technologies and environmental impact assessment reports are approved and hazardous waste management license is granted.

4.2. When applying for hazardous management practice license, infectious healthcare waste autoclave facilities are exempt from the regulation on number of transportation means defined in Term 2 - Article 11, Circular No. 12/2011/TT-BTNMT.

4.3. Healthcare centres in the far and remote areas without centralized waste treatment and small healthcare centres with the generation of infectious healthcare waste less than 50 kg per month (600 kg annually) are permitted to use thermal sterlized equipment (such as steam sterilized equipment for medical tools and specially-made pressure cookers) for on-site infectious healthcare waste treatment. They have to comply with provisions in Section 2.1, 2.2, 2.3, 2.4 and 2.5 of this technical regulation. The approvement of those equipment is not under the scope of granting hazardous management practice according to Term 3- Article 9.c, Circular No. 12/2011/TT-BTNMT and integrated in process of granting or renewing registration book of hazardous waste source owner defined in Circular No. 12/2011/TT-BTNMT.

4.4. Infectious healthcare waste autoclave facilities that sastify the requirements of this technical regulation are permitted to treat infectious waste generated from other sources beside healthcare.

4.5. In case of the amendment or replacement of legal documents including national technical regulations and standards refered in this technical regulation, the reference is applied to the new legal documents.

4.6. The State environmental management authority has responsibility to guide, supervise and monitor the implementation of this Regulation./.

Appendix

METHOD FOR CULTURING BIO-INDICATORS FOR TREATMENT EFFICIENCY MONITORING OF INFECTIOUS HEALTHCARE WASTE AUTOCLAVES

(Attached to QCVN 55: 2013/BTNMT – National Technical Regulation on Infectious Healthcare Waste Autoclave)

A. Culture in laboratory

The bio-indicators after being placed in the chamber with autoclave operation according to provisions in Section 3.1 of this technical regulation are removed to be cultured in proper conditions. The process of removing bio-indicators from chamber and placing in the culture environment must be sterile. Bio-indicators (removed from autoclave chamber) is cultured at least for 48 hours in appropriate temperature for different micro-organisms (e.g. appropriate temperature for *Geobacillus stearothermophilus* is 55^{o}C and for *Bacillus atrophaeus* is 30 ^{o}C) to test the survival of bio-indicators.

If the results show that there is no survival or reproduction of bio-indicators, treatment efficiency of autoclave sastifies the regulation.

B. Other methods

Use ampulse containing bio-indicator spores (with concentration of $1x10^4$, $1x10^6$), proper culture environment for bio-indicators (in a smaller ampulse to separate from bio-indicators) and a pH indicator. Remove the bio-indicator ampulse after placed in the chamber with autoclave operation according to provisions in Section 3.1 of this technical regulation. Break the ampulse that contains culture environment to mix with bio-indicator spores. Bio-indicators is cultured based on supplier guidance, for 24 to 48 hours in appropriate temperature for different micro-organisms.

After culturing, if pH indicator inside the ampulse changes color, the autoclave does not function effectively according to this regulation. If pH indicator does not change color, the pathogens killing efficiency is calculated based on the concentration of micro-organisms in ampulse (e.g. with the concentration of $1x10^4$, the killing efficiency of autoclave is 99,99% or 4 log 10 reduction).

In the case there is no separation between bio-indicators and culture environment, the ampulses must be stored in low temperature to prevent the growth of micro-organisms before use.