Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

March 14, 2007

ADMINISTRATIVE ORDER
NO. 2007 - 0014

SUBJECT: Guidelines on the Issuance of Certificate of Product Registration for Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste.

I. RATIONALE / BACKGROUND

The safety of the public against the adverse health and environmental effects of the improper treatment and disposal of health care waste in the Philippines has always been a concern of the society. In order to address this issue, the Department of Health included the regulation of such in Chapter XVIII "Refuse Disposal" of Code of Sanitation of the Philippines (PD. 856) in April 1998.

In line with 7.10.1 of section 7 of the implementing rules and regulations of Chapter XVIII, "Other types of or methods of solid waste processing and disposal such as incineration technology, microwave technology, autoclave technology and others shall be subject to compliance with pertinent laws and the rules, regulations and standards set by appropriate government agencies".

Pursuant to Joint Department of Environment and Natural Resources - Department of Health (DENR-DOH) Administrative Order No. 02 series of 2005 dated August 24, 2005 entitled "Policies and Guidelines on effective and proper handling, collection, transport, treatment, storage, and disposal of health care wastes" Section V, item b.7, the Department of Health (DOH) shall require all health care waste treatment, storage, disposal (TSD) facility operators and health care waste generators with on-site waste treatment facilities to use DOH registered equipment or devices used for the treatment of health care wastes.

The Bureau of Health Devices and Technology (BHDT) of the DOH is hereby mandated to implement these guidelines for the issuance of Certificate of Product Registration for equipment and devices used to treat sharps, pathological and infectious waste in accordance with the existing rules and regulations of laws relevant to the management of sharps, pathological and infectious waste.

II. SCOPE

These guidelines shall apply to all manufacturers, importers, distributors and users of equipment and devices for treating sharps, pathological and infectious waste in the Philippines.

III. OBJECTIVE

This Administrative Order is developed to establish a guideline with respect to the registration, monitoring and evaluation of devices and equipment used in the treatment of sharps, pathological and infectious wastes with DOH-BHDT to ensure safety and efficiency of said equipment/devices.

IV. DEFINITION OF TERMS

For purposes of this order, the terms below are defined as follows:

1. APPLICANT - shall refer to health care waste TSD facility operator, waste generator with TSD facility, local or foreign individual/establishment that seeks to include its equipment or devices used in treating health care wastes in the BHDT list of registered devices;

2. AUTOCLAVE - shall refer to the treatment process using steam sterilization to render waste harmless;

3. BHDT - shall refer to the Bureau of Health Devices and Technology of the Department of Health;

4. CERTIFICATE OF PRODUCT REGISTRATION (CPR) - shall refer to a certification issued by the Secretary of Health through his duly authorized representative, the Director of BHDT, attesting to the safety and efficacy of the equipment/device;

S. CHD - shall refer to the Center for Health Development of the Department of Health.

6. CHD CERTIFICATION - shall refer to the certification issued by the CHD regional office attesting the validity of the CPR issued by the BHDT upon request of the client.

7. CHEMICAL DISINFECTION - shall refer to the treatment process where chemicals like aldehydes, chlorine compounds, phenolic compounds, etc. are added to waste in order to kill or inactivate pathogens present in health care waste;

8. DOH - shall refer to the Department of Health;

9. DEVICE - shall refer to a piece of equipment including its accessories and appurtenances, used in the treatment of health care wastes;

10. DISTRIBUTOR - shall refer to a person or establishment to where a device is delivered or sold for the purpose of selling to waste treater, TSD facility operators and health care waste generators;

11. HEALTH CARE WASTE GENERATORS - shall refer to health care facilities, institutions, business establishments and other similar health care services with activities or work processes that generate health care waste (Please see Annex A);

12. HRDRD - shall refer to the Health Related Device Regulation Division of the Bureau of Health Devices and Technology (BHDT) of the Department of Health;

13. HYDROCLAVE - shall refer to a treatment process similar to the autoclave where steam, heat and pressure are used;

14. IMPORTER - shall refer to any person or establishment that receives devices used in the treatment of health care wastes from a foreign manufacturer for the purpose of offering them for sale and/or distribution in the Philippines;

15. INFECTIOUS WASTE - shall refer to type of waste suspected to contain pathogens (bacteria, viruses, parasites or fungi) in sufficient concentration or quantity to cause disease in susceptible hosts;

16. ITDI-DOST - shall refer to the Industrial Technology Development Institute of the Department of Science and Technology;

17. MANUFACTURER - shall refer to any maker or assembler of equipment or devices used in treating health care wastes provided that if such a device is manufactured or assembled for another person/ establishment who/which attaches his/its own brand name to the product, such shall be deemed the manufacturer;

18. MATERIAL SAFETY DATA SHEET (MSDS) - shall refer to a form containing general information on the properties, safety and potential hazards of a particular chemical;

19. MICROWAVE - shall refer to a technology that typically incorporates some type of size reduction device. Shredding of wastes is being done before disinfection or after disinfection. In this process, waste is exposed to microwaves that raise the temperature to 100°C (237.6°F) for at least 30 minutes. Microorganisms are destroyed by moist heat that irreversibly coagulates and denatures enzymes and structural proteins;

20. NRL-EAMC - shall refer to the National Reference Laboratory for Environmental and Occupational Health, Toxicology and Micronutrient Assay - East Avenue Medical Center in East Avenue, Quezon City;

21. PATHOLOGICAL WASTE - consists of tissues, organs, body parts, human fetus and animal carcasses, blood and body fluids. This category should be considered as a subcategory of infectious waste, even though it may also include healthy parts;

22. PYROLYSIS - shall refer to the thermal decomposition of substance and materials in the absence of supplied molecular oxygen in the destruction chamber in which the said material is converted into gaseous, liquid or solid form;

23. SHARPS - shall include needles, syringes, scalpels, saws, blades, broken glass, infusion sets, knives, nails and any other items that can cause a cut or puncture wounds;

24. TREATMENT, STORAGE AND DISPOSAL (TSD) FACILITIES - shall refer to facilities where hazardous wastes are stored, treated, recycled, reprocessed and/or disposed of, as prescribed under DENR AO No. 2004-36, Chapter 6-2 (Categories of TSD Facilities) (as defined in section IV "Definition of Terms" in the Joint DENR-DOH Administrative Order No. 02 Series of 2005);

25. HEALTHCARE WASTES - shall include all wastes generated as a result of the following:

a. Diagnosis, treatment, management and immunization of humans or animals;
b. Research pertaining to the above activities;
c. Producing or testing of biological products; and
d. Waste originating from minor or scattered sources (i.e. dental clinics, alternative medicine clinics, etc.).

V. POLICIES AND GUIDELINES

A. General Guidelines

1. All local manufacturers, importers and distributors, including generators of healthcare wastes that sell and/or use equipment and devices in treating sharps, pathological and infectious wastes shall apply for a Certificate of Product Registration to the Department of Health through the Bureau of Health Devices and Technology if their product falls under any of the following conditions:

a. Equipment and devices that are already installed and in operation prior to the publication of this guideline;

b. New devices and/or equipment (refer to Article X: Transitory Provisions) that shall be used to treat sharps, pathological and infectious waste either for commercial or exclusive use by an institution and/or business entity in the Philippines;

c. Devices or equipment using new technology to treat sharps, pathological and infectious wastes into commercial distribution for the first time in the Philippines;

d. Equipment / device that has undergone significant change in design that could affect safety and efficiency.

The registration shall be applied on a per device per model basis.

2. The following shall be exempted from registration requirements:

a. Manufacturers / distributors and suppliers of equipment and devices used to treat sharps, pathological and infectious waste that are not being marketed or commercially distributed and

being used in the Philippines.

b. Autoclaves and sterilizers in hospital laboratories, dermatology and dental clinics that are used only to sterilize surgical instruments, needles, hand pieces and the like.

3. The National Reference Laboratory-East Avenue Medical Center (NRL-EAMC) and the designated laboratories of the DOH shall conduct the performance evaluation tests for wastes samples collected after the treatments that used equipment or devices with reference to regulated reduction levels for different technologies. For the guideline limits for microbiological testing, please see Annex B (NRL-EAMC Guidelines on Microbiological Efficacy Testing).

The results of the performance evaluation shall be valid for three (3) years subject to monitoring by the BHDT. Tests other than microbiological test may be required subject to compliance with the applicable standards such as but not limited to air quality sampling, leachate toxicity characteristics test.

4. The following are the approved technologies or processes that maybe used in the treatment of sharps, pathological and infectious wastes:

a. Autoclave
b. Hydroclave
c. Pyrolysis
d. Microwave
e. Chemical disinfections

Technologies or processes not listed above that have been given a technology approval by the DOST-ITDI are likewise required to secure a Certificate of Product Registration upon review by the BHDT.

5. The Certificate of Product Registration (CPR) to be issued by the BHDT Director shall be valid for one (1) year from the date of issuance and subject to annual renewal unless sooner suspended or revoked in accordance with the rules of the Department of Health.

6. The following shall be grounds for disapproval or revocation of CPR:

a. Material misrepresentation or concealment of significant data or information about the product sought for certification;
b. Submission of falsified documents by the applicant;
c. Failure of device;
d. Failure to meet the required standards; and
e. Non-reporting of the failure of the device during operation.

B. Specific Guidelines

1. All fees are payable to the Bureau of Health Devices and Technology (BHDT) in accordance with the following schedule. Fees for initial applications shall be based on the total cost of the equipment.

a. The registration fee for initial applications of TSD Facilities, manufacturers / distributors of equipment / device used for the treatment of sharps, infectious and pathological wastes are the following:

Registration Fee	**Capitalization (Total Cost of Equipment)**
PhP 5,000.00	Below PhP 1,000,000
PhP 8,000.00	PhP1,000,000 - PhP5,000,000
PhP 10,000.00	Above PhP 5,000,000

b. The registration fee for the renewal of the CPR for manufacturers, distributors and TSD facility operators shall be Php 3,000.00 per equipment per device.

c. The registration fee for initial and renewal applications of healthcare waste generators shall be PhP 3,000.00 and PhP 2,000.00 per equipment/device respectively.

2. The registration fee is exclusive of the performance evaluation fee.

3. Fees arid charges are subject to change, as maybe deemed necessary.

4. Filing of renewal for CPR shall be made within two months before the expiration date. A penalty of fifty (50%) percent of the registration fee shall be paid by the applicant for late filing of CPR renewal.

VI. PROCEDURAL GUIDELINES

A. Documentary Requirements

1. Initial CPR Applications of Manufacturers and Distributors

a. Properly filled up application form;
b. Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration (original copy should be presented for verification);
c. Technology Approval from DOST-ITDI for new technologies (original copy should be presented for verification);
d. Certificate of Technical Evaluation from NRL-EAMC or any designated laboratory;
e. Technical Report that includes the following data:

i. Company Profile including the office address and manufacturing plant;

ii. Characteristics and Sources of generated waste;
iii. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;
iv. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;
v. Storage, handling and volume capacity;
vi. Applicable emission controls for suspected emissions;
vii. Potential hazards/toxicities of waste residues;
viii. Energy efficiency;
ix. Occupational safety and health assurance.

f. Copy of Operation Manual of the device / equipment including the Pollution Control Installations, and additional components;
g. Layout / Plans;

i. Location of installation;
ii. Design / Drawing or picture of the device / equipment applied for;

h. Supplementary requirements for equipment / devices used for:

i. Thermal Process (Pyrolysis, Plasma Pyrolysis etc.)
a) Results of Leachate Toxicity Characteristics Tests.
b) Operation / Maintenance Logbook (for healthcare waste generators and TSD Facility only)

ii. Chemical Disinfections
a) Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfections
b) Results of Microbiological Tests.
c) The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.
d) Operations Logbook

iii. Wet and Dry Thermal Treatment (Autoclave, Microwave, Hydroclave)
a) Results of Microbiological Tests.
b) Operations / Maintenance Logbook

For healthcare waste generators (e.g. hospitals, clinics) and TSD Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements.

2. Renewal applications for CPR of Manufacturers, Distributors, TSD Facility Operators and Healthcare waste generators.

a. Properly filled up application form.

b. Photocopy of issued CPR
c. Results of valid Microbiological Tests/Leachate Characteristic Toxicity Tests
d. Location of Installation.

B. Specific Procedures

1. The applicant shall submit all the documentary requirements to the Health Related Device Regulation Division (HRDRD) Secretariat. All information must be submitted in English. When the material is not originally in English, an authenticated translation shall be submitted. BHDT may request the original material at any time.

2. The Secretariat shall receive the documents submitted by the applicant and indicate the time and date the documentary requirements were received and issue the Order of Payment for the application.

3. The applicant pays the required fees at the Cashier Section of the DOH, and then submits a photocopy of the receipts upon presentation of the original copy to the Secretariat for further processing of the application. The Secretariat forwards the application to the HRDRD Chief who then assigns an HRDRD technical staff to evaluate the documents

4. The BHDT-HRDRD technical staff shall evaluate the documents forwarded by the Chief for review of all the requirements. If all the requirements are complete, an ocular inspection shall be undertaken and a report submitted to the HRDRD Chief.

5. The HRDRD Chief shall recommend approval / disapproval of the application based on the following:

a. Completeness of the documents and results of Microbiological Tests of the equipment and/or device
b. Compliance of the devices / equipment used in health care waste treatment with the provisions of the Philippine Clean Air Act (RA 8749), Toxic and Hazardous Waste Act (RA 6969), Ecological Solid Waste Management Act (RA 9003), The Clean Water Act of 2004 (RA 9275), Sanitation Code of the Philippines (PD. 856) and other applicable laws.

6. Applicants whose documents have deficiencies shall be notified and be given (30) thirty calendar days abeyance period to correct the deficiencies otherwise the application shall be discarded.

VII. ROLES AND FUNCTIONS OF THE CENTERS FOR HEALTH DEVELOPMENT

A. The Centers for Health Development nationwide shall assist the BHDT in the implementation of this Administrative Order in the following:

1. Disseminate information to the stakeholders regarding the implementation of this Administrative Order (A.O.);

2. Distribute application forms and set of requirements to the clients in remote areas applying for a CPR with the BHDT;

3. Issue the CHD Certification indicating the validity of the issued CPR by BHDT to the clients in remote areas upon request;

4. Coordinate with the BHDT and the local government units in their area of jurisdiction on the implementation of the A. O;

B. The CHD may receive applications for CPR in remote areas provided that such shall be forwarded to the BHDT office in Manila for evaluation and issuance of CPR.

Clients with valid CPR may opt to get a Certified True Copy (CTC) of the document from the BHDT record's office in lieu of the CHD Certification.

VIII. TRANSITORY PROVISIONS

Upon effectivity of this Order, healthcare waste generators / TSD facility with equipment / devices that are already installed and in operation shall be given six (6) months from the date of publication of this Order in leading newspaper to comply with the provisions of this guideline. A certificate of pending application shall be given upon request of the company.

Likewise, manufacturers and distributors of new equipment or devices used in the treatment of sharps, pathogenic and infectious wastes that have been marketed or commercially distributed in the Philippines prior to the publication of this guideline shall be given a grace period of six (6) months upon publication of this guideline to comply with the above requirements.

IX. SEPARABILITY CLAUSE

In the event that any rule, section, paragraph, sentence, clause or words of these rules and regulations is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

X. REPEALING CLAUSE

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of this guideline are hereby repealed or amended accordingly.

XI. EFFECTIVITY

This order shall take effect fifteen (15) days after its publication in an official gazette or in a newspaper of general circulation.

FRANCISCO T. DUQUE III, MD. M.Sc.
Secretary of Health