Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER No. _____

SUBJECT: Guidelines on the Issuance of an Authorization for Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste

I. RATIONALE / BACKGROUND

The Department Environment and Natural Resources (DENR) and the Department of Health (DOH) issued Joint DENR-DOH Administrative Order No. 02 series of 2005 to provide guidelines on the management of health care wastes relative to the Implementing Rules and Regulations (IRR) of Chapter XVIII – "Refuse Disposal" of the Code on Sanitation of the Philippines (P.D. 856).

The Joint DENR-DOH Administrative Order mandated the DOH to 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 treatment of health care wastes.

On 14th March 2007, Administrative Order No. 2007-0014 was issued by the Secretary of Health through the Bureau of Health Devices and Technology (BHDT) to provide guidelines on the rules and regulations with respect to registration, monitoring and evaluation of devices and equipment used in the treatment of sharps, pathological and infectious wastes.

Republic Act 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" through its IRR enhance, strengthen and rationalize the regulatory systems for establishment and products under its jurisdictions.

To effectively implement the above provisions on the regulations of all devices and equipment used in the treatment of sharps, pathological and infectious wastes in the Philippines, the FDA- Center for Device Regulation, Radiation Health, and Research (CDRRHR) (formerly BHDT) hereby issues this Administrative Order.

II. OBJECTIVE

This Administrative Order aims to enhance and strengthen the existing rules and regulations of the FDA-CDRRHR relative to the safety, efficacy and quality of equipment or devices used for treating sharps, pathological and infectious wastes.

III. SCOPE

This Administrative Order shall apply to all manufacturers, importers, distributors, traders, exporters, healthcare waste generators and Treatment Storage and Disposal Facilities of equipment or devices used for treating sharps, pathological and infectious wastes.

IV. DEFINITION OF TERMS

1. **AUTHORIZATION –** means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution transfer, and or where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption or any similar document.

2. **AUTOCLAVE –** an equipment using steam under pressure and temperature for effective sterilization.

3. **CHEMICAL DISINFECTION –** refers 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 healthcare waste.

4. **DISTRIBUTOR/IMPORTER/EXPORTER–** means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

5. **DISTRIBUTOR/WHOLESALER** – means any establishment that procures raw materials, active ingredients and/or finished products from a local establishment for local distribution on wholesale basis.

6. **DEVICE –** for the purpose of this order it refers to equipment or devices used to treat sharps, pathological and infectious waste.

7. **ESTABLISHMENT–** means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of devices used to treat sharps, pathological and infectious wastes, including the facilities and installation needed for its activities.

8. **HEALTHCARE FACILITIES** - for this purpose, are public, private and non-governmental institutions/facilities that contribute to the improvement of the health status of an individual.

9. **HEALTHCARE WASTES –** include all wastes generated as a result of the following:

    - Diagnosis, treatment or immunization of human beings;
    - Research pertaining to the above activities;
    - Research using laboratory animals for the improvement of human health;
    - Producing or testing of biological products; and
    - Other activities performed by HCF.

10. **HEALTHCARE WASTE GENERATOR-** 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)

11. **HYDROCLAVE –** an equipment similar to autoclave where steam, heat and pressure are used for sterilization.

12. **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.

13. **ITDI-DOST –** refers to the Industrial Technology Development Institute of the Department of Science and Technology.

14. **LGU –** refers to the Local Government Units.

15. **LICENSING -** means the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

16. **MANUFACTURER –** in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution: *Provided,* That the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

17. **SAFETY DATA SHEET (SDS) -** formerly (MSDS)**,** provide useful information on chemicals, describing the hazards the chemical presents, and giving information on handling, storage and emergency measures in case of an accident.

18. **MICROWAVE –** refers to a technology that typically incorporates some type of size reduction device. Shredding of wastes is being done before or after disinfection. In this process, waste is exposed to microwaves that raise the temperature to 100^0C for at least

30 minutes. Microorganisms are destroyed by moist heat that irreversibly coagulates and denatures enzymes and structural proteins.

19. **NRL-EAMC –** refers to the National Reference Laboratory for Environmental and Occupational Health, Toxicological and Micronutrient Assay – East Avenue Medical Center.

20. **PATHOLOGICAL –** refers to tissue sections and body material derived from biopsies or surgical procedures that are then examined in the laboratory.

21. **FORMANCE TESTING / EVALUATION** – refers to the test being done by NRL-EAMC and their designated laboratories to verify compliance to the test criteria set by the NRL-EAMC or to the data submitted by the applicant.

22. **PYROLYSIS –** refers 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. **REGISTRATION –** refers to the process of approval of an application to register devices prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of devices.

24. **SHARPS –** shall include needles, syringes, scalpels, saws, blades, broken glass, infusions sets, knives, nails and any other items that can cause a cut or puncture wounds.

25. **TRADER –** means any establishment which is a registered owner of a health product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

26. **TREATMENT, STORAGE AND DISPOSAL (TSD) FACILITIES –** refers to facilities where hazardous waste are stored, treated, reprocessed and/or disposed of, as prescribed under current DENR pertinent policies.

V. POLICIES AND GUIDELINES

A. GENERAL GUIDELINES

1. All establishments shall secure appropriate authorization from the FDA prior to manufacture, importation, exportation, sale, offer for sale, distribution, transfer, use, testing, promotion, advertising, or sponsorship of devices used to treat sharps, pathological and infectious wastes.

2. All applicants shall follow current rules, regulation and guidelines of the FDA in the submission of LTO and CPR application.

3. The LTO and CPR shall be issued by the CDRRHR upon the approval of the Center Director or his/her authorized representative if the application is found to be meritorious; otherwise, the application shall be disapproved.

4. All establishments shall operate based on the activities specified in their issued LTO**.**

5. All TSD, healthcare waste generators and facilities with on-site facilities treatment shall use only FDA registered devices.

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

    i. Autoclave
    ii. Hydroclave
    iii. Pyrolysis
    iv. Microwave
    v. Chemical Disinfections

7. For technologies or processes used in the treatment of sharps, pathological and infectious waste not mentioned above, a technology approval shall be secured at the ITDI-DOST first before applying for registration.

8. The NRL-EAMC and its designated laboratories shall conduct the performance testing/evaluation of devices prior to its initial and renewal registration. The results of the performance evaluation shall be valid for three (3) years.

VI SPECIFIC GUIDELINES

A. License to Operate (LTO)

1. All local manufacturers, distributors, importers, exporters, wholesaler and traders shall apply for a LTO before engaging in the manufacture, importation, sale, offer for sale, and distribution of device.

2. All establishments shall apply for LTO through FDA electronic portal (e-portal). Accessing the FDA e-portal to file for an LTO application, wheter initial, renewal or variation/s, shall be required to have an authorized User Account to be provided by the FDA Action Center (FDAAC) via email.

3. Establishments whose applications have deficiencies shall be notified and be given thirty (30) calendar days compliance period to correct the deficiencies; otherwise the application shall be disapproved. A notice shall be sent to the establishment stating the

reason for the disapproval of their application for LTO. The establishment may re-apply for an LTO by submitting the required documents and paying the prescribed fees.

4. For renewal applications filed within one hundred twenty (120) days from its original expiry date, the LTO shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal. (see Annex B for documentary requirements)

5. Establishment shall follow the current provisions of variations stipulated in AO 2016-0003 (Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration).

B. Certificate of Product Registration (CPR)

1. All local manufacturers, importers, distributors and traders, shall apply first for an LTO before applying for a Certificate of Product Registration (CPR) of device.

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. All applications with deficiencies shall be given a one-time compliance period of maximum of ninety (90) calendar days. If the deficiencies were not complied during the above stated period, the application shall be considered disapproved. However, the applicant may opt to submit a re-application within sixty (60) calendar days after the disapproval. If no compliance is received within the set compliance period, the application shall be automatically considered disapproved.

4. An application for renewal filed after one hundred twenty (120) calendar days after its expiration shall not be accepted and shall be considered an initial application. The distribution and sale of device shall automatically stop until such time that CPR have been approved. The applicant cant opt, however, to request the retention of the product registration/notification number.

5. The application for renewal shall be evaluated within thirty (30) days upon filing of the application. All applications that do not comply with the technical requirements shall be notified through a letter and shall be given a one-time chance to correct the deficiencies within thirty (30) days.

6. Upon compliance to the preliminary evaluation of the documents the application shall be indorsed to the NRL-EAMC for performance evaluation. The FDA may conduct

inspection at any given time in coordination with the LGUs and other government agencies as maybe deemed necessary.

7. Amendment for CPR shall be allowed for business name and address requirements specified in Annex B.

8. A change in design / technical specifications that would significantly affect the quality and performance of the device such as but not limited to operating pressure, temperature, time of treatment shall mean revocation of the previously issued registration. The establishment has to apply for a new CPR for the device and has to comply with the requirements for initial application of a CPR.

C. Documentary Requirements

The requirements for the issuance of LTO and CPR (initial and renewal applications). The amendments are specified in Annex B and C respectively of this Administrative Order.

FDA may request for additional documents not specified in Annex B and C if deemed necessary.

D. Validity

The LTO issued by the CDRRHR Director under the authority of the FDA Director General, is valid for three (3) years from the date of issuance and subject to renewal unless sooner suspended/revoked or cancelled after due process, in accordance with RA 9711 and/or other pertinent rules and regulations.

The CPR issued by the CDRRHR Director under the authority of the FDA Director General, is valid for one (1) year from the date of issuance and subject for renewal unless sooner suspended/revoked or cancelled after due process, in accordance with RA 9711 and/or other pertinent rules and regulations.

VII. FEES AND OTHER CHARGES

Payment of initial and renewal application fees and other charges (surcharges, penalties and legal research fund fees) shall be collected as maybe allowed subject to the existing rules and regulations of the FDA.

VIII. GROUNDS FOR , CANCELLATION OR SUSPENSION OF LICENSE AND/OR REGISTRATION

The following shall be grounds for, cancellation or suspension of license and/or registration:

1. Non-compliance with the standards and guidelines of the FDA and other concerned agencies such as the NRL-EAMC, Department of Environment and Natural Resources – Environmental Management Bureau (DENR-EMB), etc.;
2. Material misrepresentations, misbranding, and/or falsifications of the documentary requirements, licenses, registrations or any appropriate authorizations;
3. Violation of any of the terms and conditions of its licenses, registration or authorization;
4. Change in ownership or management of an establishment not reported in the FDA; and
5. Such other analogous grounds or causes as determined by the FDA.

IX. INSPECTION / COMPLIANCE MONITORING

The FDA shall conduct inspection /compliance monitoring of establishments to over sight and audit of related researches that would ensure safety, quality, purity and efficacy of health care waste treatment.

X. TRANSITORY PROVISIONS

Establishments that manufacture, import and/or distribute devices used to treat sharps, pathological and infectious wastes including TSD facility operators and health care waste generators shall be given a grace period of six (6) months from the effectivity of this Order to comply with the provisions of this guideline.

LTO and CPR are still valid provided that they will apply and shall be given six (6) months from the effectivity of this Order to comply with the provisions of this guideline.

XI. PENALTY CLAUSE

Sanctions over violations of any of the provisions of this Administrative Order shall follow the Rules of Administrative Procedure provided in the implementing rules and regulations of Republic Act No. 9711.

XII. 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 which are valid shall not be affected.

XIII. REPEALING CLAUSE

Provisions from AO2007-0014 and all other issuances that are inconsistent with this Order shall be repealed accordingly.

XIV. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days following the completion of its publication in two (2) newspapers of general circulation and submission to the University of the Philippines Law Center.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

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Keywords	Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste
Related issuances, laws, directives	Joint DENR-DOH Administrative Order No. 02 series of 2005 to provide guidelines on the management of health care wastes relative to the Implementing Rules and Regulations (IRR) of Chapter XVIII – "Refuse Disposal" of the Code on Sanitation of the Philippines (P.D. 856)

Annex A

Healthcare Facilities (HCF) - which includes:

1. Hospitals (Primary Care, Secondary Care and Tertiary Care)
2. Infirmaries
3. Birthing Homes
4. Clinics
   - [a] Medical
   - [b] Ambulatory
   - [c] Dialysis
   - [d] Health care centers and dispensaries
   - [e] Surgical
   - [f] Alternative medicine
   - [g] Dental
   - [h] Veterinary
5. Laboratories and Research Centers
   - [a] Medical and biomedical Laboratories
   - [b] Medical research centers
   - [c] Blood bands and blood collection services
   - [d] Dental prosthetic laboratories
   - [e] Nuclear medicine laboratories
   - [f] Biotechnology laboratories
   - [g] Animal research and testing
   - [h] Drug testing laboratories
   - [i] HIV testing laboratories
6. Drug Manufacturers
7. Institutions
   - [a] Drug rehabilitation center
   - [b] Training centers for embalmers
   - [c] Med-tech intern training centers
   - [d] Schools of Radiologic Technology
   - [e] Medical Schools
   - [f] Nursing Homes
   - [g] Dental Schools

8. Mortuary and Autopsy Centers

Annex B

Documentary Requirements for initial application of a License to Operate

1. Duly accomplished application form

    a. Declaration and undertaking of the responsibilities of the applicant as a condition for the processing and approval of the LTO;
    b. The location plan and global position system (GPS) coordinates of the establishment;
    c. The name of the qualified person per type of establishment, and the relevant credentials (e.g. PRC ID)
    d. The names of the following personnel shall also be listed:
        i. Production Manager/Head
        ii. Quality Assurance Manager/Head
        iii. Quality Control Manager/Head

2. Proof of Business Registration

    a. Single Proprietorship

    Valid Certificate of Business Name Registration with the Department of Trade and Industry indicating the same name, address and ownership as the establishment applying for a license.

    b. Corporation or Partnership

    i. Valid Registration with Securities and Exchange Commission (SEC) indicating the same name, address and ownership as the establishment applying for a license.
    ii. Articles of Incorporation

    c. Cooperative

    Valid Certificate of Cooperative Development Authority (CDA) indicating the same name, address and ownership as the establishment applying for a license.

    d. Government-owned or controlled corporation

    The law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter

Note: If the business name and/or address is different from the registered name and/or address in the issued DTI, SEC or CDA certificates, the following shall be submitted in addition to the documents mentioned above:

i. SEC Certificate containing the phrase "Doing business under the name and style of (Name of Establishment)". – applicable for Corporations and Partnerships
ii. Valid Mayor's Business Permit indicating the same name, address and ownership as the establishment applying for a license.

3. Supplementary requirements for:
   a. Manufacturers

      i. Layout of the Manufacturing Plant
      ii. Technical Description of the Manufacturing process
      iii. Proposed product labels and other marketing materials
      iv. List of existing clients / buyers
      v. The name of the facility/safety engineer or any other qualified professional who has knowledge in the equipment/devices used for the treatment of health care wastes, and the relevant credentials (e.g. PRC ID)

   b. Importer / Distributor

      i. Profile of the company where the device was imported
      ii. Import permit
      iii. List of distributors

4. Risk Management Plan (contingency plan)

A general Risk Management Plan (RMP) for the establishment must be submitted and contain details on how to identify, characterize, prevent or minimize risk relating to the device that the establishment is engage with.

5. Proof of payment

Documentary Requirements for Renewal of License

a. Duly accomplished application form
b. Photocopy of previously issued license
c. Affidavit of Continuous Compliance
d. Proof of payment

Requirements for Amendment of a License

a. Duly accomplished application form;

b. Letter stating the changes/amendments to be made;
c. New Business name registration from DTI/SEC; If the address registered with the DTI/SEC is different from the address in the application form, a photocopy of the valid Mayor's Permit should be submitted.
d. Proof of payment

Annex C

Documentary Requirements for initial application of a Certificate of Product Registration

1. Duly accomplished application form

2. Copy of LTO for Importer, Distributor, Manufacturer and trader.

   Note: for TSD – Hauling/Transport permit from DENR and for Hospital/Healthcare waste generator – LTO from DOH-BHFS

3. Technical Report that includes the following data:

   a. Characteristics and Sources of generated waste;
   b. Detailed description of the treatment process;
   c. Technical specifications of the device applied for a CPR;
   d. Operating procedures and conditions including treatment time, pressure, temperature, treatment cycle, chemical concentration, doses, feed rates and waste load composition whichever is applicable;
   e. Storage, handling and volume capacity;
   f. Technical description of accessories attached to the device such as shedders, boilers etc.;
   g. Applicable emission controls for suspected emission;
   h. Potential hazards/toxicities of waste residues;
   i. Energy efficiency / electrical requirements;
   j. Occupational safety and health assurance.

4. Operation Manual

5. Maintenance Manual

6. Layout / Plans
   a. Location of installation;
   b. Design / Drawing or picture of the device applied for CPR.

7. Performance Evaluation Report from the NRL-EAMC*

*The Performance Evaluation Report issued by the NRL-EAMC is not submitted when filing for initial application. The said report shall be forwarded by NRL-EAMC to the CDRRHR after the conduct of the performance evaluation of the device. The NRL-EAMC shall conduct the product performance testing after receiving the endorsement letter from the CDRRHR and shall inform the latter of the action taken within thirty (30) calendar days from the receipt of the endorsement letter.

Documentary Requirements for Renewal of Registration

1. Duly accomplished application form
2. Affidavit of Continuous Compliance
3. Copy of LTO
4. Proof of payment

Requirements for Amendment of Registration

a. Letter stating the changes/amendments to be done;
b. New business name registration from DTI/SEC; if the address registered with the DTI/SEC is different from the address in the application form, a photocopy of the valid Mayor's Permit should be submitted;
c. Notarized affidavit stating that the no change was made with regards to the design or technical specifications of the device; and
d. Proof of payment.