[DOH ADMINISTRATIVE ORDER NO. 124 S. 92, June 01, 1992]

RULES AND REGULATIONS GOVERNING THE ESTABLISHMENT, OPERATION AND MAINTENANCE OF AN X-RAY FACILITY IN THE PHILIPPINES

SECTION 1. Title — These rules shall be known as the "Rules and Regulations Governing the Establishment, Operation and Maintenance of X-ray Facility in the Philippines".

SECTION 2. Authority — These rules and regulations are issued pursuant to P.D. 480 (Creation of the Radiation Health Office in the Department of Health) as amended by P.D. 1372 and consistent with E.O. 119 (Reorganization Act of the Ministry of Health) dated January 30, 1987.

SECTION 3. Purpose — These rules and regulations are promulgated to protect the health of the people by preventing the operation of substandard, improperly managed, and inadequately supported facilities using x-ray devices in medicine, dentistry, veterinary science, industry, research, education, anti-crime work, and other areas.

SECTION 4. Scope — These rules and regulations apply to all entities establishing, operating, or maintaining x-ray facilities. An x-ray facility is an establishment in which an x-ray device is intentionally used for irradiation. An x-ray device is an apparatus equipped with a high vacuum tube that produces x-rays by bombarding a target, usually metallic, with fast moving electrons.

SECTION 5. Regulatory Authority — The Department of Health, through the Bureau of Licensing and Regulation (BLR) in the Office for Standards and Regulation, shall issue and monitor all licenses to establish, operate, and maintain x-ray facilities. The Radiation Health Service (RHS) in the Office for Hospital and Facility Services shall undertake radiation protection survey and evaluation of all x-ray facilities and shall recommend appropriate action to the Bureau of Licensing and Regulation.

SECTION 6. Classification of X-ray Facilities:

- 6.1 According to functions, x-ray facilities shall be classified as follows:
 - a. *Anti-crime x-ray facility* a facility using x-ray devices for prevention, detection, and abatement or prosecution of public nuisances and crimes.
 - b. Clinical x-ray facility a facility using x-ray devices for diagnosis or treatment of human diseases. This facility is either a hospital or a free-standing (non-hospital) facility. A hospital x-ray facility operates within a hospital; a free-standing x-ray facility operates on its own or is a part of an institution other

than a hospital.

- c. *Dental x-ray facility* a facility using x-ray devices for diagnosis of human dental diseases. This facility is either hospital-based or a free-standing one.
- d. *Education and training x-ray facility* a facility using x-ray devices for teaching and training purposes.
- e. *Industrial x-ray facility* a facility using x-ray devices for industrial applications.
- f. Research x-ray facility a facility using x-ray devices for research and development work.
- g. *Veterinary x-ray facility* a facility using x-ray devices for diagnosis of animal diseases.
- 6.2 According to location of services, x-ray facilities shall be classified as follows:
 - a. *Transportable X-ray Facility* an x-ray facility whose x-ray device can be transported and is used inside a vehicle that is properly shielded.
 - b. Stationary X-ray Facility an x-ray facility where all the x-ray devices are used only within the premises of the facility.

SECTION 7. License Required —

- $7.1\ License$ a license is a formal authorization issued by the Department of Health to a person, association, partnership, or corporation to operate and maintain an x-ray facility.
- 7.2 No x-ray facility may operate without a valid license issued by the Department of Health.
- 7.3 Separate Licenses a hospital with radiographic, computed tomography and radiotherapy facilities shall have separate x-ray licenses for each one. A transportable x-ray facility shall also have a separate x-ray license. A hospital with both clinical and dental x-ray equipment shall have separate x-ray licenses for each one.

SECTION 8. Licensing Requirements —

- 8.1 All x-ray facilities shall be required to demonstrate compliance with the Technical Standards as a requirement to licensing. The Technical Standards are the requirements formulated by the Radiation Health Service and issued in the form of Bureau Administrative Orders by the BLR for control of radiation hazards from x-ray devices.
 - a. *Head of the Facility* The head is that person with qualifications indicated in the appropriate Bureau Administrative Order who assumes technical and administrative supervision and control of the activities in the x-ray facility.

- b. Personnel Every x-ray facility is required to be staffed by qualified x-radiation workers. An x-radiation worker is a person who by reason of his profession, trade, or occupation uses any x-ray device or is directly involved in such activity or operation in which an x-ray device is used and who may be exposed to x-rays as a result of being directly involved in such activity or operation. Every x-ray facility shall have a Radiation Safety Officer who must himself be an x-radiation worker.
- c. *X-ray Equipment/Device and Accessories* Every x-ray facility shall have calibrated and safe x-ray device and adequate accessories to be used in protecting an individual and the public from the hazards of x-rays.
- d. *Physical Plant* Every x-ray facility is required to be well ventilated, well lit, clean, and safe with space sufficient to accommodate its activities.
- 8.2 The Radiation Health Service shall evaluate compliance with the Technical Standards.

SECTION 9. Quality Control and Monitoring —

- 9.1 All x-radiation workers shall be provided with personal radiation dose monitors. A personal radiation dose monitor is a device that measures the radiation dose absorbed by the individual x-radiation worker. A record of occupational radiation doses received by these workers shall be kept.
- 9.2 A quality control program shall be established in all x-ray facilities. A quality control program is the overall system of activities the purpose of which is to provide better quality products of services.
- 9.3 In case of an equipment malfunction or any accident which may cause unwarranted radiation exposure of patients, staff members or others from the public, the Radiation Health Service must immediately be notified by the licensee. A written report must be sent to the Bureau of Licensing and Regulation by the licensee. The report must include information on action taken by the licensee to solve the problem or to contain the effects of the accident.

SECTION 10. Basic Licensing Requirements —

- 10.1 Any person, firm or corporation desiring to establish or operate and maintain an x-ray facility shall submit to the Radiation Health Service a sworn petition/application, on the prescribed form, containing, among others, the following data:
 - a. Name, citizenship, and domicile of the head of the X-ray facility.
 - b. Place, municipality and province where it is to be established.
 - c. Name of establishment.
 - d. Name, citizenship, and domicile of the owner of the facility.

- e. Names and qualifications of the x-radiation workers.
- f. Brand, model, serial numbers, maximum mA and kVp of the x-ray machine.
- g. Type of x-ray examinations to be performed.
- h. Statement duly notarized that applicant has complied with all business requirements under other existing laws or ordinances that are necessary in pursuance of the activity for which a license is herein applied for.
- 10.2 If the applicant is a partnership or corporation, it must be duly registered under existing laws and a copy of its registration papers must be attached to the corresponding license application.

SECTION 11. Application for Issuance of License —

- 11.1 Application shall be made by the owner or his duly authorized representative using the appropriate prescribed form for x-ray license application. Each application shall be signed by the applicant or a person duly authorized to act for and in his behalf. Application shall be filed with the RHS.
- 11.2 Upon receipt of said application, a health physics team of the RHS shall undertake within ninety (90) working days a radiation protection survey and evaluation of the facility and the work thereat.
- 11.3 Any material false statement in the application or failure to comply with requirements shall serve as basis for the RHS Director to recommend to the BLR Director the non-issuance/non-renewal of an x-ray license.

SECTION 12. License Fees -

- 12.1 The non-refundable fee listed in section 12.2 shall be charged for every application for issuance/renewal of a license to establish, operate and maintain any x-ray facility both government and private.
- 12.2 All fees shall be payable to the Department of Health in accordance with the following schedule:

a. Initial License Fees:

P400.00/Unit — X-ray devices with milliamperage of 100 mA and less.

P550.00/Unit — Units with milliamperage greater than 100 mA up to 300 mA.

P700.00/Unit — Units with milliamperage greater than 300 mA up to 500 mA.

P850.00/Unit — Units with milliamperage greater than 500 mA up to 700 mA.

P1000.00/Unit — Units with milliamperage greater than 700 mA.