



THIRTEENTH CONGRESS
SECOND REGULAR SESSION

HOUSE BILL NO. 4797

Introduced by **Representatives ANTONIO P. YAPHA, JR., MD**
and EMILIO C. MACIAS II

Explanatory Note

Radiation regulation in the country is currently done by two national agencies. For radiation from radioactive materials, this is the Philippine Nuclear Research Institute (PNRI) of the Department of Science and Technology (DOST). For radiation from electrical/electronic devices, this is the Bureau of Health Devices and Technology (BHDT) of the Department of Health (DOH).

The laws governing regulation of radiation devices by the Radiation Health Service, now named the Bureau of Health Devices and Technology, have become outdated and irresponsive to the present demands of technology. In line with this, the creation in the DOH of a new agency to be called the Bureau of Devices and Radiation Health (BDRH) -- which shall have jurisdiction over **all types of radiation devices and facilities**, is urgently needed for the following reasons.

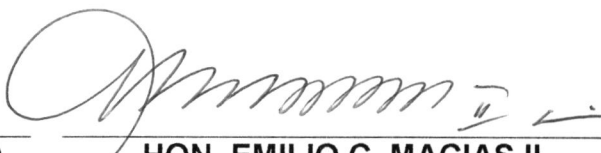
1. Radiation is harmful to human health and can kill people. It must be regulated effectively, efficiently and economically.
2. Radiation is used everywhere. It is used in medicine, dentistry, veterinary medicine, industry, education, research, military and anti-crime applications, and in the home. Some examples are x-ray machines, laser devices, ultrasound machines, broadcasting and telecommunication antennas, cell phones, and microwave ovens.
3. **The mandate of the DOH is to protect the health and ensure the safety of our people. The reason why government must regulate radiation devices and facilities is to protect the health and ensure the safety of our people.**
4. **A major function of the DOH is regulation.**

Medical device regulation is currently one of the mandates of the Bureau of Food and Drugs (BFAD) of the DOH. Under the DOH Health Sector Reform Agenda, medical device regulation would be taken out of BFAD and given to the BHDT which is being renamed BDRH under this bill.

The creation of the BDRH-- Bureau of Devices and Radiation Health -- in the DOH which shall also regulate **medical and health-related devices** is also urgently needed for the following reasons:

1. The Bureau of Food and Drugs already regulates food, drugs, cosmetics, and hazardous household substances and is also mandated to implement the Asin Law and several other laws. It cannot anymore undertake the function of regulating medical and health-related devices.
2. Radiation emitting electrical/electronic devices used in medicine are medical devices.
3. The creation of the Bureau of Devices and Radiation Health is consistent with and supportive of the ongoing global and regional effort of harmonizing the regulation of medical devices.
4. There are over 10,000 medical and health-related devices in the market. These need to be regulated for health and safety reasons. Some examples are x-ray machines, infant incubators, electrocardiographs, pacemakers, ventilators, anesthesia machines, defibrillators, syringes, scalpels, orthopedic implants, intraocular lenses, diagnostic kits, and water filters.
5. Unsafe, mislabelled, and/or misused medical and health-related devices can kill people.

The passage of this bill is being earnestly asked of the House of Representatives.


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HOUSE BILL NO. 4797

Introduced by *Representatives ANTONIO P. YAPHA, JR., MD*
and EMILIO C. MACIAS II

An Act
TO RATIONALIZE AND STRENGTHEN THE REGULATORY POWER OF THE
STATE OVER RADIATION , MEDICAL, AND HEALTH-RELATED DEVICES
THROUGH THE CREATION OF THE BUREAU OF DEVICES AND RADIATION
HEALTH, AND APPROPRIATING FUNDS THEREFOR

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

Section 1. Short Title- This Act shall be known as the "Devices and Radiation Health Act of 2005".

Section 2. Declaration of Policy - It is the policy of the state to ensure the quality, safety, accessibility and affordability of products, facilities and technologies for every Filipino. To attain these goals, government must have the mandate and capability to regulate an ever evolving and developing list of products, facilities and technologies which affect the health of our people. Pursuant to this policy, the state must enhance its regulatory capacity, capability and coherence with regard to these products, facilities and technologies.

Section 3. Objectives - The Act has the following objectives:

- (a) To enhance the administrative and technical capacity of government in health regulation;
- (b) To strengthen the government regulatory control powers in implementing health regulations;
- (c) To ensure government regulatory coverage over radiation devices, radiation facilities, medical and health-related devices; and
- (d) To provide coherence in government regulatory processes.

Section 4. Bureau of Devices and Radiation Health – The Bureau of Devices and Radiation Health, hereinafter referred to as the Bureau, is hereby created in the Department of Health. The Bureau shall be the competent authority to implement this Act. All personnel (officials and employees) of the Bureau of Health Devices and Technology of the Department of Health are hereby transferred to the Bureau. There shall be no diminution of salaries, allowances, and emoluments of all personnel transferred to the Bureau. Thereafter, all positions, powers, functions, and duties together with the facilities, equipment, supplies, records, files, appropriations, and funds of the former shall be transferred to the Bureau.

In addition, all powers, functions, duties, records, and files on medical devices and medical device regulation of the Bureau of Food and Drugs of the Department of Health shall be transferred to the Bureau.

Section 5. Definition of Terms - For purposes of this act, the following terms shall be defined as follows, to wit:

- (a) "Authorization" shall refer to a permission granted in a document by the Bureau to a legal person who has submitted the appropriate application and has complied with the appropriate requirements. The authorization can take the form of a license, a permit, a certificate of registration, accreditation, or any other type of certification.
- (b) "Devices" shall refer to medical devices, radiation devices and health-related devices.
- (c) "DOH" shall refer to the Department of Health.
- (d) "Health-Related Devices" shall refer to any device not used in health care but has been determined by the DOH to adversely affect the health of the people.
- (e) "Medical Device" shall refer to any instrument, apparatus, equipment, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to use for the following purposes:
 - Diagnosis, prevention, monitoring, treatment or alleviation of diseases;
 - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - Investigation, replacement or modification of the anatomy or of a physiological process; and,
 - Prevention of infection.

Such devices do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in their function by such means. The term also includes non-active medical devices and in-vitro diagnostic devices.
- (f) "Practice" shall refer to any human activity that increases the radiation exposure or the likelihood of radiation exposure of people or the number of people exposed.
- (g) "Radiation Facility" shall refer to a medical or non-medical facility using a radiation device for whatever purpose.
- (h) "Radiation Device" shall refer to an electrical or electronic apparatus emitting any ionizing or non-ionizing electromagnetic or particulate radiation; or any sonic, infrasonic, or ultrasonic wave. It includes ionizing radiation-emitting equipment which is not intentionally designed to produce radioactive materials.
- (i) "Radioactive Material" shall refer to a substance, whatever its physical form, that spontaneously emits ionizing radiation as part of its disintegration process.

Section 6. Organizational Structure of the Bureau- The Bureau shall be headed by a Director who shall be assisted by at least two Deputy Directors. The Bureau shall have at least five technical divisions and two non-technical divisions. The Bureau Director shall report directly to the Undersecretary of Health, Health Regulation Cluster, of the Department of Health.

Section 7. General Powers and Functions - The Bureau shall have the following general powers and functions:

a. Policy Development

- (1) Establish standards and prescribe measures to regulate the design, manufacture, construction or assembly, acquisition, importation, exportation, packaging, labeling, distribution, sale, advertisement, storage, possession, location, maintenance, use, transfer, transport, disassembly, and disposal of radiation devices, medical devices, and health-related devices;
- (2) Establish standards and prescribe measures to regulate location, installation, commissioning, operation, maintenance, decommissioning, and establishment of radiation facilities;
- (3) Formulate standards and policies that are necessary to develop alternative or equitable distribution channels or service mechanisms for economically disadvantaged and/or geographically challenged communities and areas;
- (4) Formulate plans and policies to upgrade national capacity and technical expertise in the domain of radiation devices, medical devices, and health-related devices;
- (5) Issue, implement and periodically review standards, policies, rules and regulations duly approved by the Secretary of Health;

b. Enforcement of Policies, Standards, and Regulations

- (1) Undertake inspection, radiation protection survey and evaluation, monitoring and surveillance to ensure compliance with the provisions of this Act and the implementing rules and regulations thereof;
- (2) Enforce regulatory standards and requirements falling within its jurisdiction;
- (3) Levy, assess, and collect appropriate fees pursuant to the provisions of this Act;
- (4) Issue authorizations, grant exemptions, and amend, suspend, or revoke the same in accordance with the provisions of this Act, for the design, manufacture, construction or assembly, importation, exportation, packaging, labeling, distribution, sale, advertisement, storage, possession, use, transfer, transport, disassembly, testing, maintenance, commissioning, decommissioning, waste management, and disposal of radiation devices, medical devices, and health-related devices;
- (5) Define in the regulations and authorizations the detailed conditions and obligations, including financial conditions, to be placed on those who possess radiation devices;
- (6) Require all manufacturers, assemblers, importers, exporters, distributors, retailers, installers, transporters, providers of testing, maintenance, commissioning, decommissioning, or waste management services, and users of radiation devices, medical devices, and health-related devices to report to the Bureau any incident that reasonably suggests a probability that such a source had caused or contributed to the death, serious illness, disability, or serious injury of a person/s;
- (7) Regulate the prices of radiation devices, medical devices, and health-related devices during times of public health crisis or of unreasonable increases in prices as determined by the Secretary of Health;
- (8) Call on the assistance of any government agency or instrumentality in implementing this Act;
- (9) Publish an annual list of all authorized facilities and devices covered by this Act;

- (10) Issue “stop use” orders and, when necessary, recall or seize radiation devices, medical devices, and health-related devices that were deemed, after review and analysis, to have caused or contributed to the death, serious illness, disability, or serious injury of a person/s;
- (11) Exercise contempt orders;
- (12) Investigate, hear and decide administrative cases filed for violations of this Act and its implementing rules and regulations;
- (13) Administer oaths and affirmations, and issue *subpoena ad testificandum* and *subpoena duces tecum* requiring the attendance and testimony of parties and witnesses, and/or the production of such books, contracts, correspondence, records, statement of accounts and other documents as may be material to the investigation being conducted by the Bureau;
- (14) Exercise contempt powers and impose appropriate penalties;
- (15) Enter, inspect, and search at any time and without warrant any premises, of which there is reasonable cause to believe, there is commission of the prohibited acts listed under section 19 hereof;
- (16) Summarily order the closure of radiation facilities or device establishments operating without a license or selling unregistered products;

c. Capability Building and Technical Assistance

- (1) Develop and conduct training programs on quality assurance, radiation protection and dosimetry, device and technology safety, and good device manufacturing practice (quality management systems);
- (2) Develop and maintain a regulatory staff development program to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained;
- (3) Cooperate with other relevant authorities, advise them, and provide them with information on safety matters in the areas of radiation, medical, and health-related devices
- (4) Advise client-stakeholders and relevant authorities and organizations on matters within the competence of the Bureau;
- (5) Maintain contact for information exchange and cooperation with regulatory bodies of other countries and relevant international organizations;
- (6) Establish appropriate mechanisms to inform the public about the regulatory process and the safety aspects of regulated practices;

d. Research

- (1) Conduct studies on health and safety issues concerning radiation devices, medical devices, and health-related devices;
- (2) Conduct health technology assessments of selected radiation devices, medical devices, and health-related devices based on Bureau-determined priority criteria;
- (3) Coordinate with other health technology assessment groups including, but not limited to, the present Health Technology Assessment group of the Philippine Health Insurance Corporation; and

e. Others

Exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities under this Act.

Section 8. Standards Setting – With the approval of the Secretary of Health, the Bureau shall constitute advisory groups. The advisory groups shall assess and review existing regulatory standards and requirements in cases of conflicts. They shall be multi-sectoral with representatives from the academe, industry sector, consumer sector and other sectors to be determined by the Bureau. Each advisory group shall submit its recommendations to the Secretary of Health regarding revisions to the standards and regulations of the Bureau.

Section 9. Transitional Provision- The current Bureau of Health Devices and Technology and Bureau of Food and Drugs lists of registered radiation, medical, and health-related devices; lists of licensees/registrants; and their respective pertinent standards and regulations shall constitute the initial lists, standards, and regulations of the Bureau.

Section 10. Information Technology Infrastructure – Within a year after the enactment of this Act, the Bureau shall set up an information technology link with the other health regulatory agencies, develop, and maintain web pages embodying the necessary regulatory standards and requirements, among others.

Section 13. Regulatory Support Infrastructure - A reference laboratory shall be established for the Bureau, which shall include, among others, a medical physics, radiation dosimetry, and device reference laboratory.

Section 14. Creation of New Positions - New plantilla positions shall be created for the Bureau subject to the rules and regulations of the Civil Service Commission and the Department of Budget and Management.

Section 15. Fees - Fees and fines shall be determined annually by the Bureau and, thereafter, published in two (2) newspapers of general circulation; provided that the Bureau may set and collect additional fees, to be known as the over and above regulatory fees, for facilitated processing of registration and license applications, and other reasons.

Section 16. Validity of the Authorization – The authorization issued by the Bureau such as licenses, permits, certificates of registration, accreditation, notification, or other forms of authorization shall be valid for a minimum period of one (1) year from its date of issuance.

Section 17. Devices and Radiation Health Regulatory Fund – The Devices and Radiation Health Technology Regulatory Fund is hereby established and held in trust by the Bureau; provided that all funds generated by virtue of this Act shall remain therewith, without reversion to the National Treasury, for instituting and sustaining an efficient, effective, and equitable health regulatory system; provided further that the disbursement and utilization thereof shall be subject to the rules and regulations of the Commission on Audit; provided even further that semi-annual reports as regards the fund disbursement and utilization thereof shall be submitted to the Committee on Health of the House of Representatives and the Committee on Health and Demography of the Philippine Senate.

Section 18. National and Local Government Officials The Bureau, through the Secretary of Health, shall have the power to coordinate and to enter into a memorandum of agreement with any national agency and local government office to assist in the implementation of this Act.

Section 19. Prohibited Acts - The following are prohibited acts:

- (a) Manufacture, assembly, importation, exportation, packaging, labeling, distribution, storage, retailing, advertising, installation, testing, maintenance, commissioning, decommissioning, transport, storage, operation, use, and disposal without the proper authorization;

- (b) Non-compliance with pertinent standards and regulations ;
- (c) Refusal to allow required inspections and monitoring/surveillance visits as determined by the Bureau;
- (d) Misrepresentation and/or falsification with respect to documents or any item necessary for authorization and other regulatory requirements; and
- (e) Misrepresentation in labeling, retailing and advertising of products.

Section 20. Administrative Proceedings and Sanctions - Upon verified information of the conduct of prohibited act/s, as provided under Section 19 hereof, the Bureau shall conduct an administrative hearing, with proper notices, to determine the conduct of prohibited actions and the liability of any person, partnership, association or corporation; provided that, in cases where there are findings of prohibited actions and determination of a person liable, the Bureau shall impose any or all of the following sanctions:

- (a) Suspension, revocation or non-issuance of authorization;
- (b) Seizure and/or destruction of unregistered, non-compliant or falsely represented radiation devices, medical devices, and health-related devices;
- (c) Closure of the radiation facility;
- (d) Closure of the assembly or manufacturing site, office, warehouse, store, workshop and any other facility used for production, assembly, labeling, packaging, storage, distribution, selling, testing, and maintenance of radiation, medical, and health-related devices ;
- (e) Fines as indicated in the penalty provision;
- (f) Forfeiture and destruction of seized radiation, medical, and health-related devices upon lawful order of a competent court;
- (g) Filing of criminal charges against persons liable; and
- (h) Temporary or permanent disqualification from owning and operating establishments that are subject to the regulatory mandate of the Bureau.

Section 21. Penalties - The commission of prohibited acts, as provided for under section 19 hereof, shall be punishable as follows:

- (a) For the 1st offense, a fine of not less than one hundred thousand pesos (P100,000) but not exceeding three hundred thousand pesos (P 300, 000);
- (b) For the 2nd offense, a fine of not less than three hundred thousand pesos (P300,000) but not exceeding six hundred thousand pesos (P 600,000); and,
- (c) For the 3rd and each subsequent offense thereafter, a fine of not less than six hundred thousand pesos (P600,000) but not exceeding one million pesos (P 1,000,000) and/or imprisonment of not less than one year but not more than five (5) years.

Section 22. Appeals – Decisions of the head of the Bureau on the sanctions imposed may be appealed to the Secretary of Health within a period of fifteen(15) days from the receipt thereof.

Section 23. Implementing Rules - The Department of Health shall promulgate the implementing rules and guidelines of this Act within sixty (60) days after the enactment of the Act.

Section 24. Repealing Clause – Laws, decrees, executive orders, rules and regulations or parts thereof which are contrary to or inconsistent with this Act are hereby repealed, amended or modified accordingly.

Section 25. Separability Clause – In the event any provision of this Act or the application of such provision to any person or circumstances is declared invalid, the remainder of this Act or the application of said provisions to other persons or circumstances shall not be affected by such declaration.

Section 26. Effectivity - This Act shall take effect fifteen (15) days after its publication in at least two (2) national newspapers of general circulation.

Approved,