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FEDERAL NEGARIT GAZETA

OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

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14th Year No 23
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PROCLAMATION NO. 571/2008

RADIATION PROTECTION
PROCLAMATION

WHEREAS, the need for using radiation and radioisotopes in the nations socioeconomic development is increasing from time to time with the entailing risks of damage to health, property and the environment, unless proper and effective protection schemes are introduced with respect to such use;

WHEREAS, it is essential to establish an Authority that regulates radiation sources and related practices in order to protect individuals, society and environment in current and future generation against the harmful effects of radiation, while such sources and related practices are used for the benefit of the public;

WHEREAS, it is essential to strengthen radiation protection activities by defining the legal responsibilities of persons, who are in charge of radiation safety and security of radiation sources, and by providing appropriate sanctions against persons who cause radiation exposure in excess of the acceptable level;

NOW, THEREFORE, in accordance with Article 55 (1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

PART ONE
GENERAL

1. Short Title

This Proclamation may be cited as the "Radiation Protection Proclamation No. 571/2008".

2. Definitions

In this Proclamation, unless the context otherwise requires:

- 1/ "Radiation" means gamma rays, X-rays, corpuscular, ultraviolet, visible, infrared, microwave or radio radiation;
- 2/ "Radiation source" means any material or device that may cause radiation exposure by emitting radiation;
- 3/ "Sealed source" means radioactive material that is permanently sealed in a capsule or closely bonded and in a solid form, excluding reactor fuel elements which is not exempted from regulatory control;
- 4/ "Atomic energy" means any type of energy emitted from radio-isotopes, nuclear reactions, nuclear reactors, X-ray equipment or other technical apparatus emitting ionizing radiation;
- 5/ "Exposure" means exposure to radiation from sources either external to the body or incorporated within the body;
- 6/ "Dose limit" means the value of effective dose or equivalent dose to individuals from controlled practices that shall not be exceeded;
- 7/ "Practice" means any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed;

- 8/ "Radiation hazard" means any injury or bodily or mental deficiency or abnormality due to radiation exposure or contamination of the environment or property with radioactive materials;
- 9/ "Radiation protection" means the task of protecting radiation workers and the public from unnecessary exposure by the accurate measurement of radiation and the design and use of methods to reduce radiation;
- 10/ "Radiation Worker" means any worker potentially exposed to radiation as a result of his occupation;
- 11/ "Radiation work" means work involving the use of radioactive materials, X-ray equipment or other devices capable of emitting radiation;
- 12/ "Exemption" means a determination by the Authority that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure due to the source or practice is small to warrant the application of those aspects;
- 13/ "Exclusion" means any exposure whose magnitude or likelihood is essentially unable to be controlled through the regulatory requirements or standards;
- 14/ "Radioactive material" means any material emitting ionizing radiation above the exemption level;
- 15/ "Notification" means a document submitted to the Authority by a person to notify an intention to carry out a practice or any other action described in the Article 16(1) and 16 (2) of this Proclamation;
- 16/ "Registration" means a form of authorization granted by the Authority for practices of low or moderate risks and accompanied by conditions and limitations as appropriate;

17/ "License" means an authorization granted by the Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the license;

18/ "Person" means a natural or juridical person.

19/ "Radiation Safety Officer" means a person who is a worker of the Authority and in connection to radiation protection has technical knowledge and the proper certificate.

3. Scope of Application

1/ This Proclamation shall be applicable to radiation sources, accessories of radiation devices and related practices.

2/ The provisions of Sub-Article (1) of this Article shall not extend to:

a) radiations and radiation sources found in nature without any human interventions; and

b) radiation sources and practices which are exempted from regulatory control.

PART TWO

THE ETHIOPIAN RADIATION PROTECTION AUTHORITY

4. Establishment

1/ It is hereby re-established the Ethiopian Radiation Protection Authority (hereinafter referred to as "the Authority") as an autonomous federal agency having its own legal personality.

2/ The Authority shall be accountable to the Ethiopian Science and Technology Agency.

5. Head Office

The Authority shall have its head office in Addis Ababa and may establish branch offices in other regions of the country as appropriate.

6. Objectives of the Authority

The objectives of the Authority shall be to:

- 1/ protect individuals, the society, its property and the environment, in current and future generations, from radiation hazards emitted from radiation sources and related practices including X-ray machines above the exempted level; and
- 2/ carryout or promote study and research on issues that could support radiation protection activities.

7. Powers and Duties of the Authority

The Authority shall have powers and duties to:

- 1/ Issue, renew, suspend and revoke licenses to perform any of the activities listed in Article 16/1/ and 16/2/ of this Proclamation and impose any necessary conditions on a license so granted;
- 2/ Formulate, as necessary, radiation protection policies and draft laws and submit to the Government for approval;
- 3/ Issue directives for the implementation of polices and laws concerning radiation protection and follow up their implementation;
- 4/ Establish a system for coordinating public and private activities with a view to ensuring radiation safety and security of radiation sources;
- 5/ Render radiation protection services;

- 6/ Carryout inspection and take appropriate measures to ensure compliance with radiation protection laws and directives;
- 7/ Carryout or promote study and research on issues that could support radiation protection activities and take measures or advise on measures to be taken based on the findings thereof;
- 8/ Advise the Government on matters related to atomic energy and radiation;
- 9/ Organise and promote the dissemination of information on radiation protection and related matters through training courses, seminars, pamphlets and the like;
- 10/ In collaboration with other concerned bodies, formulate emergency plans and set up emergency squads for accidents involving radiation and take measures or advise on measures to be taken as needed;
- 11/ Ensure the implementation of treaties applicable to the sector and to which Ethiopia is a party, and cooperate with local, foreign and international organizations having similar objectives;
- 12/ Issue directives to define dose limit, exemption, clearance and exclusion levels as well as relevant accessory equipments subject to regulatory control;
- 13/ Establish a system of national register of radiation sources and practices;
- 14/ Issue certificates of competence to those who intend to provide radiation protection related services, supervise their activities, and if necessary suspend and revoke a certificate it issued; and inform, on time, the suspension or revocation of a certificate to the concerned bodies;
- 15/ Own property, enter into contracts, sue and be sued in its own name;
- 16/ Carryout such other activities as necessary for attaining its objectives.

8. Organization of the Authority

The Authority shall have:

- 1/ The Ethiopian Radiation Protection Board (hereinafter referred to as the "Board");
- 2/ a Director General to be appointed by the Government; and
- 3/ The necessary staff.

9. Organization of the Board

The board shall be organized by the government including a senior scientist as deemed necessary.

10. Powers and Duties of the Board

The Board shall have the powers and duties to:

- 1/ approve, upon submission by the Director General, directives, fees and conditions prescribed for radiation protection activities and amendments thereto;
- 2/ review reports and approve the plans, work programmes, budget and internal regulations of the Authority;
- 3/ receive and decide on appeals by concerned bodies against decisions by the Director General;
- 4/ select and appoint technical advisers and obtain relevant professional assistance on appeal cases submitted to it;
- 5/ Recommend a senior scientist for board membership upon request by the government;
- 6/ Provide advices as appropriate on draft laws to be submitted to the Government as per Article 7(2) of this Proclamation.

11. Meetings of the Board

- 1/ The Board shall meet at least once in every six months; provided, however, that it may convene at any time when called by the Chairperson.

- 2/ There shall be a quorum where a simple majority of the members of the Board are present.
- 3/ Decisions of the Board shall be passed by majority votes; and in case of a tie, the chairperson shall have a casting vote.
- 4/ The Board may determine its own rules of procedures.

12. Powers and Duties of the Director General

- 1/ The Director General shall be the chief executive officer of the Authority, and subject to the general directives of the Board, shall be responsible for its proper administration and operation.
- 2/ Without prejudice to Sub-Article (1) of this Article, the Director General shall:
 - a) exercise the powers and duties of the Authority specified under Article 7 of this Proclamation;
 - b) employ, administer or terminate the employment of employees of the Authority in accordance with directives approved by the Government following the basic principles of the federal civil service laws;
 - c) submit reports, plans, work programs, budgets, organizational structure and internal regulations of the Authority to the Board;
 - d) effect expenditure in accordance with the approved budget and work programme of the Authority;
 - e) represent the Authority in all its dealings with third parties;
 - f) notify the concerned body forthwith in cases of radiation accidents and emergencies beyond the means of the Authority.

- 3/ The Director General may delegate part of his powers and duties to the officers and other employees of the Authority to the extent necessary for the efficient execution of its activities; provided, however, that a delegation given to act on behalf of the Director General for a period of more than 30 days, shall be subject to the prior approval of the Director General of the Ethiopian Science and Technology Agency.

13 . Radiation Protection Officers

- 1/ The Authority shall have radiation protection officers to ensure compliance with the provisions of this Proclamation and other laws relating to radiation protection.

- 2/ Without Prejudice to Sub-Article (1) of this Article, a radiation protection officer shall have the powers to:

- a) enter, inspect and examine any business premises, vehicle, boat, aircraft or any carriage, at any time, where he has reasonable cause to believe that any source of radiation above the exempted level is held, stored, used, transported or disposed of without the authorization of the Authority, and to seize the source of radiation found in such process;

- b) require the production of any license authorizing the use of radioactive material or sources of radiation and any registry, notice or document kept in pursuance of radiation protection legislation and directives, and to inspect, examine or take a copy thereof;

- c) make such enquiries and take sample for examination as may be necessary to ascertain whether the provisions of radiation protection legislations and directives have been complied with and in case of non-compliance, to seal the radiation sources of any institution or the room in which such sources are located;

- d) examine, either alone or in the presence of any other person as he thinks fit, any person with respect to matters under

radiation protection legislations and directives or to require such person to be examined provided that no person shall be compelled to answer any question or give any evidence tending to incriminate himself;

- e) require the conducting of such medical examinations as may be necessary in the discharge of his duties.

- 3/ Every radiation protection officer shall be provided with a certificate of authorization signed by the Director General of the Authority and shall produce the certificate where exercising his power under Sub-Article (2) of this Article.

14. The Budget of the Authority

The Authority shall run its activities by a budget allocated by the Government.

15. Books of Accounts

- 1/ The Authority shall keep complete and accurate books of accounts.
- 2/ The books of accounts and financial documents of the Authority shall be audited annually by the Auditor General or by auditors assigned by him.

PART THREE

NOTIFICATION AND AUTHORIZATION

16. General

- 1/ No practice shall be adopted, introduced, conducted, discontinued or ceased except in accordance with the requirements established by the Authority unless the exposure to such practice is excluded or the practice is exempted from the requirements, including the requirements of notification and authorization
- 2/ No radioactive material shall, as applicable, be mined, manufactured constructed, assembled, acquired, transited, imported, exported, distributed, sold, loaned, hired, used, commissioned, maintained, repaired, disassembled, transported, stored or disposed of except in accordance with the requirement established by the Authority unless the

exposure to such source is excluded or the source is exempted from the requirements including the requirements of notification and authorization.

- 3/ General notification and authorization obligations applicable to non-ionizing radiation sources and related practices as well as detail regulatory control mechanisms of the same shall be determined by regulations and directives issued hereunder.

17. Notification

- 1/ Any person intending to engage in any of the activities described under Article 16(1) and 16(2) of this Proclamation or to manufacture store, import or distribute radiation related consumer products shall submit a written notification to the Authority.
- 2/ Practices and radiation sources requiring only notification shall be determined by the Authority.

18. Authorization

- 1/ Unless the practice or the radiation source is exempted or requires only notification as per directives issued by the Authority, any person who engages in a practice or is in possession of radiation sources prescribed under Article 16(1) and 16(2) of this Proclamation shall apply to the Authority for authorization.
- 2/ No practice shall be authorized unless it produces sufficient benefit to the exposed individual or the society to offset the radiation harm it might cause. The applicant for an authorization shall provide sufficient information and evidence on the benefit and harm to support the justification of the practice.
- 3/ Any person who applies for a license shall:

- a) submit, together with any required documents, an application completed on the prescribed form and pay the appropriate license fee;
- b) refrain from carrying out any of the activities described in article 16(1) and 16(2) of this Proclamation until authorization has been granted;
- c) make safety assessment on the likelihood and magnitude of exposure attributed to the source depending on the nature of the practice, and submit the report to the Authority as part of the application and take all necessary steps for radiation protection and safety.

19. Issuance and Content of License

- 1/ A license shall be granted to a person that meets the practice specific requirements specified in this Proclamation and regulations and directives issued pursuant to this Proclamation.
- 2/ A license may contain any condition as the Authority deems necessary for the purpose of radiation protection.

20. Renewal of the Reapplication for License

- 1/ An application for renewal of a license shall be submitted to the Authority in accordance with the time limit and conditions prescribed by regulations issued pursuant to this Proclamation.
- 2/ A license may be renewed with or without variations in its content.
- 3/ Reapplication for a license shall be required in cases of :
 - a) use of different devices or maintenance thereof or change or modification of premises that could cause change in the radiation exposure;
 - b) use of different or modified radioactive materials.

21. Amendment, Suspension and Revocation of License

1/ A license issued under the repealed or this Proclamation may, at any time, be amended, suspended or revoked by the Authority upon providing a written notification to the licensee:

- a) where, in the opinion of the Authority, it is necessary for the safety of the society; or
- b) where the conditions prescribed for radiation protection are not complied with.

2/ Any person whose license is suspended or revoked pursuant to Sub-Article (1) of this Article shall take all necessary measures prescribed by the Authority to prevent the occurrence of any radiation hazard.

22. Duties and Responsibilities of Licensees and other Concerned Parties

1/ Any licensee shall:

- a) be primarily responsible for the security of radiation source and the facility in which the source is used for different practices and for the fulfillment of the requirements prescribed by this Proclamation and regulations and directives issued pursuant to this Proclamation, while performing any activity related to the authorized radiation source;
- b) be responsible for ensuring that exposure for radiation resulting directly or indirectly from the authorized activity shall be kept as low as reasonably achievable below the prescribed limits;
- c) appoint a qualified and experienced person in radiation health and safety measures as radiation safety officer.

2/ The licensee and the radiation safety officer shall ensure that radiation workers:

- a) are supplied with monitoring device commensurate with the level of the potential risk expected from the

authorized source or practice and other accessories necessary to carry out radiation work with the lowest reasonably achievable risk;

b) are given proper instructions on radiation safety measures and as appropriate receive medical check up every six months.

3/ The licensee, the radiation safety officer or any person involved in radiation work, shall notify the Authority any loss, theft or diversion for unauthorized use of the radiation source, any over exposure to radiation or the occurrence of any accident immediately or not later than 24 hours after such an occurrence has come to his knowledge, and fully comply with any emergency measures as may be prescribed by the Authority.

4/ The owner of any radiation source, his agent or employee shall furnish the means required by a radiation protection officer of the Authority as may be necessary for entry, inspection, examination, enquiry, the taking of samples or otherwise for the exercise of his duties under this Proclamation and regulations and directives issued pursuant to this Proclamation.

5/ Where an individual licensee dies, the person responsible for the estate shall promptly notify the Authority of the death of the licensee and shall ensure the compliance of radiation protection and safety requirements as well as the security of the radiation source.

23. Rights of Licensees and other Concerned Parties

1/ An appeal against a decision made by the Authority pursuant to this Proclamation may be submitted to the Board within 30 days from the date of notification of the decision. Decisions of the Board on such appeals shall be final.

2/ In the case of the death of a licensee, the authorization shall remain valid for three months after the death in so far as it confers the right to possess the authorized radiation source as the estate of the deceased.

24. Engagement in Radiation Work and Medical Examination

1/ Any person shall not engage in radiation work if he does not have proper training, is under the age of 18 years or is not found, by medical examination,

to be free from disease or weakness which could be considered to make him particularly vulnerable to the health hazards involved in the work.

2/ Any person engaged in radiation work shall, in addition to the periodic examinations prescribed in this Proclamation, undergo medical examination as may be required by the Authority.

3/ The Authority may ban any person who fails to observe the provisions of Sub-Article (2) of this Article from further radiation work.

4/ When a person engaged in radiation work or any person who, because of his work, may have been exposed to ionizing radiation shows signs of injury which may be suspected of having been caused by such radiation, the licensee shall have the responsibility to immediately make arrangements for medical examination of the person.

PART FOUR **MISCELLANEOUS PROVISIONS**

25. Confidentiality

No person who has obtained confidential information in the course of implementation of this Proclamation and regulations and directives issued pursuant to this Proclamation shall disclose such information to any other person unless it is necessary for the implementation of the Proclamation, regulations or directives.

26. Prohibition

No authorization, other than by the Authority, shall be issued to engage in any of the activities prescribed under Article 16(1) and 16(2) of this Proclamation.

27. Duty to Cooperate

Any person shall have the duty to cooperate in the implementation of this Proclamation and regulations and directives issued pursuant to this Proclamation.

28. Penalties

Unless severe penalties are prescribed in the criminal law:-

1/ any person who without permission from the Authority transfers, alters, disposes or disperses nuclear materials that are likely to cause death or serious injury to any person or substantial damage to property shall be punishable with an imprisonment from 3 to 15 years or with a fine from Birr 50,000 to Birr 500,000 or with both;

2/ any person who without permission from the Authority possesses nuclear materials shall be punishable with an imprisonment from 1 to 3 years or with a fine from Birr 10,000 to Birr 50,000 or with both;

3/ any person who without permission from the Authority uses nuclear materials and cause damage shall be punishable with a rigorous imprisonment from 10 to 15 years or with a fine from Birr 100,000 to Birr 500,000 or with both;

4/ any authorized person to use nuclear material who causes damage due to negligence shall be punishable with a rigorous imprisonment from 3 to 10 years or with a fine from Birr 50,000 to Birr 100,000 or with both;

5/ any person who commits other offences in violation of the provisions of this Proclamation or regulations or directives issued pursuant to this Proclamation. shall be punishable with an imprisonment not exceeding 3 years or with a fine not exceeding Birr 10,000 or with both.

29. Power to issue Regulations

The Council of Ministers may issue regulations necessary for the proper implementation of this Proclamation.

30. Repealed Laws

1/ The Radiation Protection Proclamation No. 79/1993 is hereby repealed.

2/ No law, regulation or directive shall, in so far as it is inconsistent with this Proclamation, have force or effect with respect to matters provided for by this Proclamation.

31. Effective Date

This Proclamation shall enter into force upon Publication in the Federal Negarit Gazeta.

Done at Addis Ababa, this 22th day of April, 2008

GIRMA WOLDEGIORGIS

**PRESIDENT OF THE FEDERAL
DEMOCRATIC REPUBLIC OF ETHIOPIA**