GENERAL REGULATION OF RADIOLOGICAL SAFETY (Published in the DOF of November 22, 1988)

CURRENT TEXT

In the margin a seal with the National Shield, which says: United Mexican States. Presidency of the Republic.

MIGUEL DE LA MADRID H., Constitutional President of the United Mexican States, in exercise of the power conferred on me by section I of article 89 of the Political Constitution of the United Mexican States and based on articles 1, 2, 4th., 18, 19, 21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40 and 50 of the Regulatory Law of Article 27 Constitutional Law on Nuclear Matters, and

CONSIDERING

That within the permanent objectives assumed by the Government under my charge, the strengthening of the legal framework that regulates public activities stands out, in order to promote the changes imposed by the thesis of moral renewal of society, which in practice translates as the granting of the mechanisms through which the State promotes the satisfaction of collective needs;

That for the achievement of such objectives, in the National Development Plan 1981-1988 is consigned as a strategy, to face the great challenges of the country, thoroughly review the national regulatory system and simplify administrative procedures, proposing and, where appropriate, sponsoring the legal and regulatory reforms that are deemed necessary;

That the direct domain of the Nation over our natural resources and the right to regulate their exploitation, use and exploitation are expressed expressly in Article 27 of the Constitution and in due course, the
The Executive in my charge proposed the adaptation to the Legal System to which Nuclear Matter is governed;

That on February 4, 1985, the Regulatory Law of Article 27 of the Constitution on Nuclear Matters was published in the Official Gazette of the Federation, whose validity began the day after its publication;

That the aforementioned Law regulates Article 27 of the Constitution and regulates the exploration, exploitation and benefit of radioactive minerals, the use of nuclear fuels, the uses of radioactive material and nuclear energy, the investigation of science and nuclear techniques, the nuclear industry and everything related to it;

NOTE: The Secretary of Energy exercises functions entrusted to the Secretary of Energy, Mines and Parastatal Industry.

That the same Law establishes that safety is paramount in all activities involving nuclear energy, and must be taken into account from the planning to the dismantling of nuclear and radioactive facilities and the final destination of these wastes, defining in turn the radiological safety in accordance with the guidelines of the National Civil Protection System, such as that which aims to protect workers, the population and their property, as well as the environment in general by preventing and limiting the effects that may result from exposure to ionizing radiation;

That the Regulatory Law of Article 27 of the Constitution on Nuclear Matters establishes that nuclear and radioactive facilities must have radiological safety systems and their operation will require the satisfaction of the requirements determined in this regard in the same law and in the regulatory provisions therefore, it is pertinent to have the regulatory instruments to make effective the provisions of the same Law, I have seen fit to issue the following

GENERAL REGULATION OF RADIATION SAFETY

FIRST TITLE
GENERALITIES

SINGLE CHAPTER

Article 1.- This Regulation governs the entire national territory and its purpose is to provide in the administrative sphere for the observance of the Regulatory Law of Constitutional Article 27 on Nuclear Matters in relation to radiological safety.

Article 2.- The Secretariat of Energy, Mines and Parastatal Industry is empowered to issue, through the National Commission for Nuclear Safety and Safeguards, the appendices, technical standards, manuals and instructions, as well as their updates, necessary to develop, make explicit and determine the manner in which the provisions of this Regulation must be complied with.

Article 3.- Both the documents referred to in the previous article, as well as their updates, for their mandatory nature and general observance, must invariably be published in the Official Gazette of the Federation.

Article 4.- The Secretariat of Energy, Mines and Parastatal Industry, through the National Commission for Nuclear Safety and Safeguards, is empowered to interpret and apply this Regulation, as well as the appendices, technical standards, instructions, manuals and conditions of licenses, authorizations and permits that are issued based on it and, to determine the radiological safety standards that in their opinion are applicable

without prejudice to the competence that according to the Law corresponds to other Secretaries of State.

Article 5.- In all cases in which this Regulation refers to the Law, it will be understood that it is the Regulatory Law of Article 27 of the Constitution on Nuclear Matters. When it refers to the Secretariat, it will be the Secretariat of Energy, Mines and Parastatal Industry, and when it mentions the Commission, it will be the National Commission for Nuclear Safety and Safeguards under the terms of Article 50 of the Regulatory Law of Article 27 of the Constitution on Nuclear Matters. .

SECOND TITLE

TERMINOLOGY

SINGLE CHAPTER

Article 6.- For the purposes of this Regulation, it will be understood as:

ACCIDENT AND/OR INCIDENT: Any abnormal event involving sources of ionizing radiation.

ACTIVITY: The number of spontaneous nuclear transitions that occur per unit of time in a given amount of radioactive material.
Formally, the activity A, of a given amount of radioactive material, is the ratio of dN to dt, where dN is the number of spontaneous nuclear transitions that occur in the interval dt. The unit of activity is the becquerel (Bq), where 1 Bq= 1 disintegration/s (1 Ci= 3.7 X 1010 disintegrations/s).

TEMPORARY WAREHOUSE: The radioactive facility authorized by the Commission to store sources of ionizing radiation for a limited time and that will necessarily be expressly determined in the corresponding authorization.

WAREHOUSE IN TRANSIT: The areas used during the transport of radioactive material in which packages, containers, packages and uncontrolled areas are stored, such as: parking area; final station; warehouse room or loading and unloading yard.

AUDIT: The examination of the records, documents, programs and procedures related to the radiological safety of the radioactive facility, as well as the inventory of radioactive material or the equipment that contains it in accordance with the provisions of the corresponding authorization, permit or license, as well as as in the provisions of this Regulation.

AIR-DERIVED CONCENTRATION: The air-derived concentration (ADC) for a given radionuclide is a derived limit that designates the concentration in air that, if breathed by a worker

during a working year of 2,000 hours at a respiration rate of 1.2 m3 h-1 , the annual incorporation limit (LAI) would be reached.

SURFACE RADIOACTIVE CONTAMINATION: The presence of a surface in quantities greater than: 4X103 Bq m-2 (10-5 uCi/cm2) in the case of beta and gamma emissions, or 4 X 102 Bq m-2 (10-6u Ci/ cm2), in the case of alpha emissions, it can be fixed or removable.

DECONTAMINATION: Process by which radioactive contamination is reduced or eliminated.

RADIOACTIVE WASTE: Any material that contains or is contaminated with radionuclides or concentrations or levels of radioactivity greater than those indicated by the Commission in the corresponding technical standard and for which no use is anticipated. They are classified into low, intermediate and high level radioactive waste.

IONIZING RADIATION GENERATING DEVICES: It is the equipment that produces ionizing radiation in a controlled manner.

ABSORBED DOSE: The energy deposited by ionizing radiation on matter. Technically, the absorbed dose, D, is defined as the ratio of dE to dm, where dE is the average energy deposited by ionizing radiation in a mass dm.

The unit is the gray (Gy), where:

1 Gy = 1 J kg-1 (1 rad = 10-2 J/kg).

THRESHOLD DOSE: The value of the dose below which it is considered that a certain non-stochastic effect will not manifest itself.

EMERGENCY: Act, omission, situation or event that causes a significant risk and, for whose control or elimination it is necessary to undertake immediate corrective actions.

LOCATION: The selection process of a suitable site for the location of a radioactive facility and the determination of its physical and demographic characteristics, in order to adequately evaluate and define the bases for their design, construction and operation, with so that these do not translate into an appreciable detriment to the safety of people or the quality of the environment.

DOSE EQUIVALENT: For radiological protection purposes, it has been found convenient to introduce a physical magnitude that correlates the absorbed dose with the most important deleterious effects of radiation exposure, in particular with late stochastic effects. The dose equivalent is the quantity resulting from the equation: H = DQN, where D is the absorbed dose in Gy, Q is the quality factor and N is the product of all other modifying factors, taking for now

a value for N equal to unity. The special name for the dose equivalent unit is the sievert (Sv). The rem can be used temporarily.

EFFECTIVE DOSE EQUIVALENT: The effective dose equivalent, HE, is the weighted sum of the dose equivalents for the different HT tissues, both by extreme irradiation and by incorporation of radionuclides. Is defined as:

$$HE = \ddot{y}_{T} WT\ HT$$

Where WT are the power factors.

COMMITTED EFFECTIVE DOSE EQUIVALENT: The committed effective dose equivalent, HE,50' resulting from the incorporation of radioactive material, is the effective dose equivalent that will accumulate over 50 years as a result of the incorporation.

OPEN SOURCE: Any radioactive material that, during its use, may come into direct contact with the environment.

SOURCE OF IONIZING RADIATION: Any device or material that emits ionizing radiation in a quantifiable way.

SEALED SOURCE: Any radioactive material permanently incorporated into a material enclosed in a hermetic capsule with sufficient mechanical resistance to prevent the escape of the radioisotope or the dispersion of the radioactive substance under foreseeable conditions of use and wear.

DOSE EQUIVALENT INDEX: In the case of external irradiation of the whole body, the concepts of:

a) SURFACE DOSE EQUIVALENT INDEX: The surface dose equivalent index HI,S at a point is the maximum dose equivalent within the volume between 0.07 mm and 1 cm, measured from the surface of a sphere of 30 cm in diameter centered on that point and made of material equivalent to soft tissue with a density of 1 g cm -3.

b) DEEP DOSE EQUIVALENT INDEX: The deep dose equivalent index HI,P' is the maximum dose equivalent within the 28 cm diameter core inscribed in a 30 cm diameter sphere centered at that point and formed by material equivalent to soft tissue and with a density of 1 g cm-3.

INSPECTION: The examination of the physical and radiological safety conditions of a radioactive facility, its systems, equipment and the application of operating procedures, documents and records.

ANNUAL INCORPORATION LIMIT: It is the secondary limit for internal occupational irradiation, and it is the lowest value of the incorporation of a radionuclide determined in a year by the Reference Man, which would translate well into a committed effective dose equivalent of 50 mSv (5 rem) or, in a committed dose equivalent in the lens of 150 mSv (15 rem) or in a committed dose equivalent in any other organ or tissue of 500 mSv (50 rem).

RADIATION SAFETY MANUAL: Document whose objective is that all actions involving radiation sources be carried out under adequate radiological protection standards and procedures, to reduce occupational and public exposures to values as low as reasonably achievable.

PERMISSION HOLDER: Natural or legal person who owns the authorization, permit or license issued by the Commission to carry out an activity authorized by it.

OCCUPATIONALLY EXPOSED PERSONNEL: Those who in exercise and due to their occupation are exposed to ionizing radiation or the incorporation of radioactive material. Workers who may occasionally be exposed to this type of radiation in the course of their work are excluded, provided that the annual effective dose equivalent they receive does not exceed the limit established in this Regulation for the public.

IONIZING RADIATION: All electromagnetic or corpuscular radiation capable of producing ions, directly or indirectly, due to its interaction with matter.

RECOGNITION: The examination and verification of the information provided to the Commission of facts or circumstances that could mean a radiological risk to people and property.

VERIFICATION: The review and examination of the information provided to the Commission on the occasion of the activities regulated by this Regulation and corrective actions derived from the deficiencies or anomalies that have been found as a result of the inspections or audits.

BIOLOGICAL HALF-LIFE: It is the time necessary for half of an administered substance to be excreted from the body of an organ or tissue.

PHYSICAL HALF-LIFE: It is the time required for a radionuclide to lose 50% of its activity, through radioactive decay. Each radionuclide has its own physical half-life.

CONTROLLED AREA: It is the area subject to supervision and special controls for radiological protection purposes.

THIRD TITLE

OF THE DOSE LIMITATION SYSTEM

CHAPTER I

GENERAL DISPOSITION

Article 7.- The doses received as a result of exposure to sources of ionizing radiation and practices involving irradiation with ionizing radiation or incorporation of radioactive material, will be subject to a dose limitation system whose foundations are:

I.- No practice will be approved unless its application produces a positive net benefit;

II.- The design, planning, use and subsequent application of sources and practices must be carried out in such a way as to ensure that exposures are kept as low as can reasonably be achieved, taking into account social and economic factors;

III.- The establishment of limits for dose equivalent.

Article 8.- The purpose of the dose limitation system is to avoid non-stochastic effects and limit the occurrence of stochastic effects to an acceptable level, for which limits are established for each case, and the one that is most restrictive for the organ must be applied. or irradiated tissue.

Article 9.- Non-stochastic effects are those in which the severity of the effect is a function of the dose and they appear from a threshold value.
These effects occur in the exposed individual. Stochastic effects are those in which the probability that the effect occurs is considered as a function of the dose, without there being a threshold dose, and can manifest both in the exposed individual and in their offspring.

Article 10.- For the exclusive purposes of this Regulation, in the calculation of dose equivalents, the factors established in the corresponding technical standard will be considered.

CHAPTER II

ON THE APPLICATION OF THE DOSE LIMITATION SYSTEM

Article 11.- For the application of the Dose Limitation System, limits and reference levels will be established:

A limit is the value of a quantity that must not be exceeded. A reference level is not a limit, but the value of a magnitude that is used to decide on a certain behavior.

The limits may be primary, secondary, derived and authorized. The reference levels may be registration, investigation and intervention.

Article 12.- The primary limits are defined for the dose equivalent, the effective dose equivalent, the committed dose equivalent or the committed effective dose equivalent, according to the circumstances of the exposure. These limits apply to each individual, and in case of public irradiation, to the critical group.

Article 13.- Secondary limits are used when the primary dose equivalent limits cannot be applied directly. For external irradiation, the secondary limits may be expressed in terms of either the deep dose-equivalent index or the superficial dose-equivalent index. In the case of internal irradiation, the secondary limits can be expressed in terms of the annual intake limits.

Article 14.- The derived limits apply to magnitudes different from those of the primary limits, they are determined from these by means of a defined model, in such a way that, if the derived limits are satisfied, the primary limits are also satisfied. They can be established, for example, for quantities such as the speed of exposure in a workplace, air, water and surface contamination, among others.

Article 15.- The authorized limits are those established by the Commission for any magnitude and that are generally lower than the derived limits, although in exceptional cases they may be the same. These limits apply only to limited circumstances that should be clearly defined. Authorized limits take precedence over derivatives.

Article 16.- For the purposes of Article 11, above, the permit holder, as part of its radiological protection program, must establish reference levels, including at least the following: registration level, investigation level and intervention level.

Article 17.- The registration level is a value defined by the Commission for the dose equivalent, effective dose equivalent or the incorporation of radionuclides, above which the information is of sufficient interest, from the point of view of safety. radiological, for its registration and conservation.

The investigation level is a dose equivalent, effective dose equivalent, or intake value that is considered significant enough to warrant an investigation into the cause(s) of the exceedance.

The intervention level is the value previously established for any quantity used in radiological safety, which, if exceeded, indicates a situation that requires taking corrective measures.

CHAPTER III

OF DOSE EQUIVALENT LIMITS

Article 18.- No person should receive an equivalent dose that exceeds the corresponding limits indicated in this Title.

Article 19.- The dose equivalent limits indicated in this Title do not apply to the medical exposure of patients, nor to that due to natural radiation. However, they must be applied in cases of irradiation for medical research purposes when there is no direct benefit for the exposed individual, and in cases of irradiation due to natural sources of increased radiation for technological reasons, for which the Commission will establish the limits in each case.

Article 20.- For occupationally exposed personnel, the limit of the annual effective dose equivalent HE,L for stochastic effects is 50 mSv (5 rem).

Article 21.- For occupationally exposed personnel, the annual dose equivalent limit for non-stochastic effects is 500 mSv (50 rem), regardless of whether the tissues are irradiated alone or jointly with other organs. This limit does not apply to the lens, for which a limit of 150 mSv (15 rem) is established.

Article 22.- The dose equivalent received by any organ or tissue as a result of irradiation will include the dose equivalent due to external sources and the committed dose equivalent due to internal sources incorporated in the same time interval.

Article 23.- The limit for the control of stochastic effects is expressed as a function of the effective dose equivalent, and it must be fulfilled that:

$$\ddot{y}\ w_T \qquad H_T < H_{E,L}$$

Where HE,L is the annual effective dose equivalent limit and whose value is 50 mSv (5 rem); w(T) is the tissue weighting factor T; and H(T) is the annual dose equivalent of tissue T.

Article 24.- In the event that occupationally exposed personnel are irradiated internally and externally and in order not to exceed the annual dose equivalent limits, the following two conditions must be met:

$$\frac{H_{I,S}}{500\,mSv} < 1$$

$$\frac{H_{I,P}}{500\,mSv} + \ddot{y}\ \frac{I_j}{I_{j,L}} \leq 1$$

Being: HI,s the superficial rate of dose equivalent.

HI,p the deep index of dose equivalent.

ij the annual intake due to ingestion and inhalation of radioisotope j.

Ij,L the annual intake limit for radioisotope j.

Article 25.- The secondary limits of incorporation for occupationally exposed personnel will be those established in the corresponding technical standard of this Regulation.

Article 26.- When a limit is expressed as the average value corresponding to a period, it is understood that the real value of the limited magnitude may present considerable fluctuations in shorter periods of time.

Article 27.- The irradiation received by occupationally exposed women with reproductive capacity must be distributed as

uniformly possible over time, in order to protect the embryo during the period of organogenesis before pregnancy is known.

Article 28.- Occupationally exposed women who are pregnant may only work in conditions where the irradiation is distributed as evenly as possible over time and the probability that they receive an equivalent annual dose greater than 15 mSv (1.5 rem) is very low.

Article 29.- Occupationally exposed women who are pregnant or nursing should not work in places where there is a risk of incorporating radioactive materials.

Article 30.- Students who, due to the nature of learning, must carry out experiments with sources of ionizing radiation will be considered as members of the public, however they will only be allowed to receive, for teaching purposes, one tenth of the limits established in these Regulations. for individuals in the public.

Article 31.- Students who take courses at a professional or technical level, whose purpose is training for the use of ionizing radiation sources, will be subject to the following rules:

I.- If they are 18 years old or older, they will be considered as occupationally exposed persons and therefore subject to the annual dose equivalent limits corresponding to that quality, established in this Regulation, and

II.- If they are under 18 years of age, but over 16, they will be considered as occupationally exposed persons, however, they may not receive an equivalent whole body dose of more than 15 mSv (1.5 rem) annually.

Article 32.- Outside of the cases referred to in the previous Article, no person under 18 years of age may be considered occupationally exposed.

Article 33.- Students considered as occupationally exposed personnel will be subject to the requirements, obligations, supervision and individual and medical radiological surveillance that are established in this Regulation for that quality.

Article 34.- In order to maintain permanent surveillance of the trends of the dose equivalent received by the occupationally exposed personnel and to be able to optimize the safety conditions at work, a record of the monthly dose equivalent must be kept, of the accumulated during the 12 previous months and the total accumulated during the working life of occupationally exposed personnel, of which they must be informed.

Article 35.- All irradiation received by occupationally exposed personnel must be recorded in the record of the individual's dose equivalent.

Article 36.- Non-occupational exposed persons who work in the proximity of controlled areas or who occasionally in the course of their work enter a controlled area, are considered as members of the public.

Article 37.- The dose equivalent limits for individuals from the public are one tenth of the limits stipulated in Articles 20 and 21. These limits must be applied to the critical group of the population or to the most exposed individual.

Article 38.- When the same individuals from the public may be exposed for prolonged periods to an effective dose equivalent equal to or close to the annual limit, measures must be adopted in order to reduce their effective dose equivalent for life to a value corresponding to an annual average of 1 mSv (0.1 rem).

Article 39.- In calculating the dose equivalent for individuals in the public due to the incorporation of radioactive material, biological and metabolic parameters must be taken into account, as well as other factors that are characteristic of the critical group, such as eating habits, demographic distribution and land use.

CHAPTER IV:

OF THE IRRADIATION CONDITIONS

Article 40.- The conditions under which an individual can be exposed to ionizing radiation are classified as normal and abnormal.

Normal irradiation conditions are those in which the occurrence of irradiation is foreseeable and can be limited by control of the source and by application of the dose limitation system, in particular by establishing satisfactory operating procedures.

Abnormal irradiation conditions are those in which the radiation source is not subject to control, so that the magnitude of any resulting irradiation can only be limited, eventually, through corrective measures.

Article 41.- If, as a result of abnormal situations, certain occupationally exposed persons receive equivalent doses greater than those

limits indicated in Articles 20 and 21, the permit holder must adopt the following measures:

I.- Gather the information that helps to estimate the dose equivalents and the additions of radioactive material;

II.- Obtain, as appropriate, samples of excreta for bioanalysis;

III.- Start medical tests and make the consequent diagnoses, and

IV.- Gather information on the circumstances of the accident.
The need to control contamination should not hinder or deter the provision of first aid and follow-up treatment to individuals requiring medical assistance for other reasons.

Article 42.- If, as a result of abnormal situations, certain members of the public receive dose equivalents greater than the limits indicated in Article 37, the permit holder must adopt the following measures:

I.- Gather the information that helps to estimate the dose equivalents and the additions of radioactive material of the affected people, and

II.- Collect information on the circumstances of the accident.

The need to control contamination should not hinder or dissuade the provision of first aid and the respective treatment to individuals who require medical assistance for other reasons.

CHAPTER V

OF PLANNED AND EMERGENCY IRRADIATION

Article 43.- Planned irradiations will be considered as exceptional cases and will be justified only when the techniques that avoid overexposure of occupationally exposed persons are not practicable or available.

These irradiations may be allowed provided that: I.-
In a single event, the sum of the dose equivalent due to external irradiation and the committed dose equivalent due to the incorporation of radioactive material does not exceed twice the annual dose equivalent limits corresponding, established in this Regulation, and

II.- In the lifetime of occupationally exposed personnel, the sum of the dose equivalent due to external irradiation and the compromised dose equivalent due to the incorporation of radioactive material, does not exceed five times the limits of the corresponding annual dose equivalent.

Article 44.- The personnel who participate in the planned irradiations must:

I.- To be consulted for the planning of the operations to be carried out; II.- Be informed about the risks involved in irradiations that exceed the limits of dose equivalents established in this Regulation;

III.- Be trained in the specific operations to be carried out;

IV.- Have the written consent of the person in charge of radiological safety, and

V.- To be provided with the appropriate equipment and clothing for their protection, so that external irradiation and contamination are minimal.

Article 45.- The permit holder must previously justify before the Commission any planned irradiation.
Article 46.- An individual may receive doses that exceed the dose equivalent limits established in this Title, only in emergency operations.

Article 47.- In emergency operations aimed at saving lives or avoiding the irradiation of a large number of people, the estimated effective dose equivalent limit will be 1 Sv (100 rem), and for hands and forearms it will be 3 Sv (300 rem).

Article 48.- When emergency operations are aimed at actions other than those indicated in the previous Article, such as protecting valuable installations or controlling fires, the estimated effective dose equivalent limit will be 250 mSv (25 rem) and for hands and forearms will be 1 Sv (100 rem).

Article 49.- The personnel that participate in the emergency operations must, in the terms of the Emergency Plan:

I.- Preferably be volunteers and over 45 years of age, when they are not required to do so due to their functions or responsibilities;

II.- Be informed about the risks involved in irradiations that exceed the dose equivalent limits established in this Regulation;

III.- Be trained, if possible, in the specific operations to be carried out;

IV.- Have the written consent of the person in charge of radiological safety;

V.- Be provided with the appropriate equipment and clothing for their protection, so that external irradiation and contamination are minimal, and

VI.- Avoid procreation during the 6 months after irradiation when the effective dose equivalent is 1 Sv (100 rem) or greater.

Article 50.- Emergency irradiation should be limited to once in the lifetime of occupationally exposed personnel.

Article 51.- Once control over the initial incident or accident has been achieved, the rest of the corrective action must be carried out respecting the dose equivalent limits. Exceptionally, situations may arise that require studying the advisability of authorizing a planned irradiation of a limited number of individuals to carry out various essential operations, leaving the rest to be carried out subject to limits.

Article 52.- Women with reproductive capacity and students who are being trained in the use of ionizing radiation sources may not participate in planned irradiations or emergency operations.

Article 53.- Any dose equivalent or accidental, planned or emergency incorporation must be recorded in the dose equivalent record of occupationally exposed personnel. But it should be distinguished from normal irradiations.

Article 54.- Any accidental or emergency irradiation that reaches or exceeds an effective dose equivalent of 250 mSv (25 rem), must be communicated to the Commission so that it may formulate the recommendations it deems appropriate regarding the future occupational irradiation of personnel. The application of these recommendations will be the exclusive responsibility of the permit holder.

Article 55.- Occupationally exposed personnel who have received an effective dose equivalent greater than 100 mSv (10 rem), which corresponds to double the annual limit for stochastic effects in a single event, must undergo a medical examination under the terms of the standard corresponding technique of this Regulation and will be able to continue in their routine work if there is no objection to it from the medical point of view, taking into consideration their previous irradiations, their health, their age, their special abilities and their economic and social responsibilities, and, if applicable, proceed in accordance with the Federal Labor Law.

FOURTH TITLE
OF SOURCES OF IONIZING RADIATION

CHAPTER I
GENERAL DISPOSITION

Article 56.- The devices that generate ionizing radiation and equipment that contain sources of ionizing radiation must have the appropriate security systems that prevent their use by unauthorized personnel.

Article 57.- The permit holder may only modify the design, the operating conditions and the use of the equipment indicated in the previous Article or its components if he has the prior authorization of the Commission.

Article 58.- For the purposes of this Regulation, radioactive materials are classified into sealed sources and open sources. No radiation source subject to a license may be transferred to third parties, unless the recipient has the respective license and the Commission authorizes the transfer.

CHAPTER II
FROM SEALED SOURCES

Article 59.- All sealed sources of radioactive materials must have a certificate issued by the manufacturer indicating their activity and the corresponding leak tests.

Article 60.- The certificates referred to in the previous Article must include, at least, the information related to: radioisotope, activity and date on which it is valid, physical and chemical forms, material and type of encapsulation, brand, model and source serial number, and if applicable the leak test procedure and result.

Article 61.- To transfer sealed sources of radioactive material, tests and measurements must be carried out in order to ensure the integrity of the encapsulation of the source and the container, in accordance with the provisions of Articles 67 and 69 of this Regulation.

Article 62.- Sealed sources may only be handled through the use of appropriate manual or automatic remote handling devices.

Article 63.- Sealed sources must be properly stored in appropriate containers when they are not in use.

Article 64.- Sealed sources must undergo leak tests upon receipt and periodically thereafter, in accordance with the conditions established in the license issued by the Commission, taking into consideration the characteristics and use given to these sources.

Article 65.- A record must be kept of the leak tests carried out on each of the sealed sources. This record will contain the data related to the method used, the equipment used, the result of the test and the date on which it was carried out, as well as the name and signature of the person who carried it out.

Article 66.- The result of the leak test must be sent to the Commission within five business days following the date on which the results are available. If a leak is detected, the Commission must be notified immediately.

Article 67.- A sealed source will be considered hermetic when the result of the leak test is less than 185 Bq (5 nCi) of removable radioactive material for sources other than Radio-226. For Radon-226 sources, the Radon-222 leak in 24 hours must not be greater than or equal to 37 Bq (1 nCi).

Article 68.- In the event that the fountain is not airtight in accordance with the provisions of the previous Article, the fountain will be placed in a suitable container and may not be used until the necessary repairs have been made and the requirements of air tightness.

Article 69.- The permit holder will be responsible for the measurements of the radiation levels around the transport, storage or use containers that house sealed sources are carried out at the time of receipt and then periodically at least every six months. These levels will be measured on the surface of the container and one meter from it in different directions.

Article 70.- Based on the radiation levels measured, the permit holder will limit the permanence time of occupationally exposed personnel in the area where the container is located, so that the equivalent dose received by the personnel is as low as reasonably possible. can be achieved, without exceeding the limits established in this Regulation.

Article 71.- The areas where the containers that house sealed sources are located must be considered in the physical and radiological safety procedures of the facility, contained in the Radiological Safety Manual.

Article 72.- Proper functioning tests must be carried out periodically on the equipment that operates with sealed sources and calibration on those that require it.

Article 73.- A record of the proper functioning tests and calibrations must be kept, in which the date, type of tests carried out, equipment used, as the case may be, as well as the name, position and signature of the person who executed them.

Article 74.- Equipment containing sealed sources will be used with accessories or components previously authorized by the Commission.

Article 75.- The containers that are used to transport, use or store sealed sources and equipment that contain them, will carry fixed labels with the international symbol that indicates the presence of radiation, the information in Spanish relative to the radioisotope, activity and date on which is valid, model, brand and serial number of the source, as well as the transport index, the names and telephone numbers of the permit holder and the person in charge of radiological safety when applicable.

Article 76.- Each time the source that houses the container is changed, the information on the label will be modified.

Article 77.- The signs will always be kept in good condition and in case of deterioration they will be replaced immediately.

Article 78.- The rate of exposure on the surface of sealed source containers should not exceed 5.2 X 10-5 Coul/kgh (200 mR h-1), nor 5.2 x 10-7 Coul/Kgh (2 mR h-1) one meter from it.

Article 79.- The same container may be used for the storage, use and transportation of sealed sources, if in the opinion of the Commission it meets the necessary safety requirements.

Article 80.- Containers for the transport of sealed sources are also subject to the requirements established in the corresponding regulations.

Article 81.- All permit holders who have sealed sources of radioactive material must keep an inventory of the same in which it is stipulated: date of receipt, brand, model and serial number of the source, radioisotope, activity and date on which it is valid, source container, brand, model and number and series of the same, and its location. The date and reason for withdrawing the source from routine work, as well as its final destination, must also be noted at the time.

CHAPTER III
FROM OPEN SOURCES

Article 82.- For the reception and opening of packages containing open sources, a procedure previously established by the permit holder must be followed, specifying at least the place and conditions of

reception and opening, the review of the integrity of the packaging and the measurement of radiation levels.

Article 83.- Open radioactive sources must be stored in closed containers that prevent their dispersion. The mechanical design of the containers must consider the pressures that could be produced by the chemical nature of the source. These containers should facilitate the handling of the sources.

Article 84.- Every container that contains open sources, when not in use, must be in an appropriate container and in an area dedicated to the storage of open sources, which must be adequate from the point of view of radiological and physical safety. .

Article 85.- The vessels and containers that house open sources must carry a label in Spanish in which it appears:

I.- The international symbol that indicates the presence of radiation;

II.- The radioisotope it contains;

III.- The activity and date on which it is valid, and

IV.- The chemical and physical form of the source.

Article 86.- The signs must always be kept in good condition and, in case of deterioration, they will be replaced immediately.

Article 87.- At the end of the working day, the levels of radiation and contamination in the work surfaces, equipment and clothing of the personnel must be reviewed and, in the event of a radiological incident or accident, this review will also be carried out in all the places where contamination is suspected. When the readings obtained are greater than those established by the Commission in the corresponding technical standard, the necessary corrective measures will be applied.

Article 88.- The equipment used to carry out these surveys of radiation and contamination levels will be calibrated and in good working order, will be adequate to detect the type of radiation involved and will have sufficient sensitivity to accurately measure 50% of the applicable limit for removable contamination indicated in the corresponding technical standard.

Article 89.- When handling open sources, the equipment and accessories that provide due radiological protection must be used.

Article 90.- Any permit holder who owns open sources must keep a record, in which it will be recorded: type of radioisotope, activity to which

date on which the source is received, activities used and their use, residual activities disposed of, as well as the date and method of their disposal.

CHAPTER IV
OF IONIZING RADIATION GENERATING DEVICES

Article 91.- In the case of X-ray devices for medical diagnosis purposes, what is indicated in the corresponding technical standards issued by the Secretariat through the Commission must be complied with.

Article 92.- Before the operation of an ionizing radiation generating device for authorized activities begins, the proper functioning of all the device's systems must be verified, including the alarm systems, indicator lights, control panel, collimation of the radiation beam, exposure time, and others. This review will be carried out every six months from the start of operations and records of these reviews will be kept, as well as the preventive and corrective maintenance that is carried out.

Article 93.- Before the operation of the ionizing radiation generating device for authorized activities begins for the first time, the radiation beam must be calibrated, in order to know the intensity of radiation with different voltages, electric currents, filters, collimation areas and distances. This calibration must be carried out according to the use of the device. Subsequently, the calibration must be carried out every six months, of which a record will be kept, indicating the date, procedure and signature of the person who carried it out.

Article 94.- The permit holder must verify by means of tests that the radiation levels existing in the areas adjacent to the facility, when the device is in the on position, are less than or equal to those indicated in the accepted Radiological Safety Report. by the Commission. If the radiation levels are higher than the accepted values, the necessary corrections must be made.

Article 95.- "DANGER" and "CAUTION" signs must be installed, as well as the international symbol that indicates the presence of radiation at accesses to controlled areas. These signs must be changed immediately in case of deterioration.

Article 96.- The alarms associated with the ionizing radiation generating devices must always be calibrated and in operating conditions.

Article 97.- In order to apply the radiological safety measures, during the operation of particle accelerators, the following aspects must be considered and evaluated:

I.- The distribution of energy and intensity of the radiation field;

II.- The activation of materials belonging to the accelerator, shields or the installation;

III.- The production of radiation derived from the interaction of the primary radiation with the materials of the installation;

IV.- Radioactivity induced in the air and the production of harmful gases;

V.- Alteration due to radiation of electronic components, and

VI.- The effects of heating and possible risks of fire or explosion.

FIFTH TITLE
OF RADIOACTIVE FACILITIES

CHAPTER I
CLASSIFICATION

Article 98.- For the purposes of this Regulation, radioactive facilities are classified as:

Type I.- Those in which sealed sources or devices that generate ionizing radiation are produced, manufactured, stored or used; in which radioactive ore is extracted or processed, or in which low- and intermediate-level radioactive waste is treated, conditioned or stored.

Type II.- Those in which open sources are produced, manufactured, stored or used.

Article 99.- Considering the magnitude of the risk related to the operations in which radiation sources are involved, the facilities referred to in Type I of the previous Article, are classified in turn into three groups: A, B and C.

Article 100.- Type IA facilities are considered to be those that have irradiators installed in which the sources come out of the shielding during their operation or particle accelerators with energies equal to or greater than 10 MeV; mines and plants for the treatment of radioactive minerals, their tailings dams and the work zones associated with them, and temporary or definitive storage facilities for low or intermediate level radioactive waste. remain

Included in this type of facility are places where industrial radiography work is carried out with portable equipment, whether based on radioactive material or X-rays. Also included in this classification are places where geophysical studies of wells are carried out in where the radiation source comes out of its container, and the places where patients stay with brachytherapy applications.

Article 101.- Type IB facilities are considered to be those that house teletherapy, brachytherapy, X-ray units for therapeutic purposes, irradiators in which the sources do not come out of the shielding during their operation, or particle accelerators with energies less than 10 McV. This type includes fixed installations in which industrial radiography work is carried out, either with radioactive material or with X-rays.

Article 102.- Type IC installations are considered to be those in which ophthalmic applicators, thickness, density or level gauges, or static electricity meters and eliminators are used.

Article 103.- Based on the activity and radiotoxicity of the radiation sources used, Type II facilities are classified into three groups: A, B and C.

Article 104.- For the purposes of this Regulation, radionuclides according to their toxicity per unit of activity, may be of very high, high, moderate or low radiotoxicity, in accordance with the corresponding technical standard.

Article 105.- Type II-A facilities are those in which more than 370 MBq (10 mCi) of radionuclides of very high radiotoxicity, more than 3.7 GBq (100 mCi) of radionuclides of high radiotoxicity, more than 37 GBq (1 Ci) of radionuclides of moderate radiotoxicity or more than 370 GBq (10 Ci) of radionuclides of low radiotoxicity.

Article 106.- Type II-B facilities are those in which up to 370 MBq (10 mCi) of radionuclides of very high radiotoxicity may be present, at any given time, up to 3.7 GBq (100 mCi) of radionuclides of high radiotoxicity , up to 3.7 GBq (1 Ci) of radionuclides of moderate radiotoxicity or up to 370 GBq (10 Ci) of radionuclides of low radiotoxicity.

Article 107.- Type II-C facilities are those in which up to 370 KBq (10 uCi) of radionuclides of very high radiotoxicity, up to 3.7 MBq (100 uCi) of radionuclides of high radiotoxicity may be present at any given time. , up to 37 MBq (1 mCi) of radionuclides of moderate radiotoxicity or up to 370 MBq (10 mCi) of radionuclides of low radiotoxicity.

Article 108.- The limits established in the previous Articles for the classification of Type II facilities must be modified due to the complexity of the operations carried out with the sources in accordance with the corresponding technical standard.

Article 109.- Those radioactive facilities that are not included in the previous Articles, will be evaluated and classified in each particular case by the Commission.

CHAPTER II
CONDITIONS OF RADIOACTIVE FACILITIES

Article 110.- In the design of radioactive facilities, the following aspects must be taken into consideration, among other things: classification and use of the source; workload, usage factors, and materials of construction of the primary and secondary barriers; distances from the source to areas occupied by individuals; occupancy factors of the areas adjacent to the facility and radiation levels and derived concentrations in the air, in order to comply with the applicable provisions of Title Three of this Regulation.

Article 111.- In the design of the facilities that will house ionizing radiation generating devices, the electromechanical specifications of the manufacturer of the equipment to be installed must be taken into account, as well as the shielding of the peepholes, ducts and access doors.

Article 112.- During the construction of the facilities, the permit holder must ensure that the barriers and shielding of the peepholes, ducts and access doors comply with the specifications and commitments indicated in the Radiological Safety Report presented to the Commission.

Article 113.- In every radioactive facility, controlled zones will be established in which the permit holder will exercise supervision and control in order to provide adequate radiological protection.

Article 114.- According to the expected radiation levels and for better radiological control, the following will be defined within the controlled area, depending on the case:

I.- Radiation area: that area accessible only to occupationally exposed personnel, in which the equivalent dose to the whole body could be greater than 0.05 mSv (5 mrem) in one hour or 1 mSv (100 mrem) in any consecutive period. five days,

II.- High radiation area: that area accessible only to occupationally exposed personnel, in which the equivalent dose to the whole body in one hour could be greater than 1 mSv (100 mrem).

III.- Zone of radioactive material suspended in air: a)
That which is not normally occupied by people and in which the concentration of existing radioactive material is higher than that indicated in the corresponding technical standard, and

b) That which may be occupied by occupationally exposed personnel and in which the concentration of existing radioactive material, averaged with the weekly permanence time of the personnel in the area, is greater than 25% of the concentration indicated in the technical standard mentioned in the previous paragraph.

Article 115.- In the controlled areas, those of radiation, those of high radiation and those of radioactive material suspended in air, there must be signs, appropriate access controls, emergency instructions and evacuation routes.

Article 116.- Regardless of the different control requirements in each of the areas referred to in the previous Article, the maximum permitted stay times and the special radiological protection equipment that is required will be specified on clearly visible signs in the access places.

Article 117.- The permit holder must periodically review all the areas mentioned in Article 115, in accordance with the provisions of the Radiological Safety Report in order to check the levels of radiation and contamination and, where appropriate, delimit again the extensions of the same.

Article 118.- The places where radioactive material is applied and where the patient is being treated with radioactive material, will be duly marked with signs indicating the presence of radiation and the speed of exposure to one meter from the geometric center of the organ with the greatest amount of radioisotope or implant and contact with the patient.

Article 119.- The areas of radiation, high radiation and radioactive material suspended in air must be provided with adequate and properly placed radiation detectors, with which radiation levels, concentrations of radioactive material suspended in air and concentrations of material can be determined. radioactive in the effluents as appropriate in each case.

Article 120.- When the Commission so determines, they must be installed at the entrance and exit of the areas where there is a risk of radioactive contamination,

changing rooms for personnel to change clothes as necessary, as well as specific areas for the decontamination of personnel and components, tools and equipment.

Article 121.- When the radioactive contamination of any equipment or surface is greater than the levels established in the corresponding technical standard, it must be decontaminated or discarded.

Article 122.- The warehouses and workshops where radioactive material is handled, as well as the laundry of contaminated clothing, will be located within a controlled area.

Article 123.- Equipment, components, objects or people that are contaminated will not be transferred to uncontrolled areas, unless it is strictly necessary, in which case the pertinent radiological safety measures must be taken.

Article 124.- Prior to the start of operations, every radioactive facility must have an Emergency Plan consistent with the guidelines of the National Civil Protection System and based on the study of the radiological consequences of accidents that may occur at the facility.

Article 125.- The Emergency Plan referred to in the previous article will have the purposes of: restricting exposure to radiation, keeping it as low as can reasonably be achieved, ensuring that the dose equivalents are kept below the limits established in this Regulation , control the accident that will occur; and obtain the necessary information to determine the causes and consequences of said accident. The Emergency Plan must contain at least:

I.- The procedures and equipment for the radiological measurements necessary to evaluate and determine the situation created by the accidents;

II.- The necessary protection measures to reduce exposures to ionizing radiation;

III.- The means and resources available to carry out the protection measures referred to in the previous section;

IV.- The levels of intervention that will serve as a guide to apply the measures referred to in section II above, and

V.- Establish protection measures for the surrounding population, consistent with the guidelines of the National Civil Protection System.

Article 127.- All places of use or storage of radioactive materials must be duly marked, in addition to having the

appropriate security systems that prevent access by unauthorized persons. The same must be observed in those places where ionizing radiation generating devices are installed.

Article 128.- The places intended for the reception, storage and use of radioactive material must have a relative location such that during the internal transportation of the sources the risks of contamination and irradiation of individuals are reduced.

Article 129.- The facilities where sources of ionizing radiation are manufactured, used, manipulated or stored that may give off radioactive gases, smoke, vapors or dust, must have adequate ventilation systems so that the concentration of radioactive material suspended in the air in the work area, is kept as low as reasonably achievable, without exceeding the limits established in the corresponding technical standard.

Article 130.- The permit holder must calculate the derived limits for the concentrations of radioactive isotopes in the effluents, on the border with the uncontrolled zone, in such a way as to demonstrate that the limits authorized in each case by the Commission will not be exceeded, and will describe detail the model used for it, so that it can be evaluated and, if applicable, approved.

Article 131.- In controlled areas, the permit holder must establish the measures that prevent occupationally exposed personnel from inhaling in one year an amount of radioactive material greater than that which would result from the constant inhalation of the same radionuclide at the concentrations derived in air that are established in the corresponding technical standard.

Article 132.- When the work with sources of ionizing radiation is carried out outside the fixed installations, barriers and signs must be installed on a perimeter such that access to the controlled area is restricted.

Article 133.- It is prohibited to introduce and ingest beverages and food, as well as smoking and putting on make-up in the areas of the facilities where there is a risk of radioactive contamination.

Article 134.- During the operation of ionizing radiation sources, the presence of unauthorized personnel within the controlled areas of the radioactive facilities will not be allowed.

SIXTH TITLE
OF THE TEAM

SINGLE CHAPTER
GENERAL DISPOSITION

Article 135.- The equipment required to comply with the Radiological Protection Program is for:

I.- The detection and measurement of ionizing radiation;

II.- Personal dosimetry;

III.- The use of ionizing radiation sources;

IV.- Individual protection, and

V.- Decontamination.

Article 136.- The equipment used must be designed in such a way that its operation is not affected by the environmental conditions and mechanical effects in which its operation is expected, such as temperature, humidity, pressure, smoke, vapors, chemical contaminants in the atmosphere, shock and vibration.

Article 137.- The equipment referred to in Article 135 sections I and II and those of section III that require it, must be periodically calibrated in accordance with the provisions of the license, permit or authorization issued by the Commission.

Article 138.- The permit holder must keep a calibration record in which it is stated as a minimum:

I.- Procedure used;

II.- Brand, model and serial number of the calibrated equipment;

III.- Brand, model, serial number, radioisotope, activity and calibration date of the radiation source used as reference;

**IV.- Calibration factors or calibration curves obtained; V.-
Linearity and directional response of the instrument, and**

VI.- Date, name and signature of the person who performed the calibration.

Article 139.- The precision of the ionizing radiation detection and measurement equipment must satisfy the requirements established in the corresponding technical standard.

Article 140.- The equipment must be labeled with the date and the calibration factors for each scale and, if applicable, the calibration graphs.

Article 141.- The calibration of the ionizing radiation detection and measurement equipment must be carried out by applying standards and methods approved by the Commission.

Article 142.- The detection and measurement equipment for ionizing radiation and those that allow the use of sealed sources will be subject to a proper functioning test program approved by the Commission. A record will be kept of these tests in which the type of test to which the team was subjected and the date, name and signature of the person who performed them will be recorded.

Article 143.- Individuals or legal entities that use radiation sources to provide calibration services to the equipment indicated in Article 135 sections I, II and III, must have the authorization of the Commission.

Article 144.- Individuals who provide maintenance services to the equipment indicated in Article 135 sections I, II and III, must demonstrate that they have taken and passed a technical training course on the matter, recognized by the Commission.

SEVENTH TITLE
OF THE PERMISSION HOLDER, IN CHARGE OF RADIATION SAFETY AND OCCUPATIONALLY EXPOSED PERSONNEL

CHAPTER I
GENERAL DISPOSITION

Article 145.- The internal organization of the permit holder must have a Radiological Safety Group that will have under its direction and supervision everything related to radiological protection in the workplace. This group will report directly to the Holder of the license, permit or authorization.

Article 146.- The Radiological Safety Group must be supported by the permit holder in all aspects related to the preparation, execution, supervision and modification of the Radiological Safety Program. The Head of this Group will be appointed as the person in charge of radiological safety.

CHAPTER II
OF THE OBLIGATIONS OF THE PERMISSION HOLDER

Article 147.- The permit holder will be directly responsible for the radiological safety of the institution or company before the Commission.

Article 148.- The permit holder's obligations are:

I.- Register before the Commission the occupationally exposed personnel and the members of the Radiological Safety Group, documenting their level of studies and training, which must be consistent with the work and functions that will be assigned to them in the facility;

II.- Support the person in charge of radiological safety in all aspects related to the preparation, execution, supervision and modification of the Radiological Safety Program;

III.- Provide all occupationally exposed personnel with training, information, clothing, equipment, accessories and radiological protection devices appropriate to the work they perform and the necessary medical care in cases of radiological accidents;

IV.- Comply with the commitments contained in the Radiological Safety Report approved by the Commission and with the conditions of the license, permit or authorization;

V.- Give notice and deliver the reports to the Commission in case of radiological accidents, regardless of the notices that must be given to other Units;

VI.- Immediately notify the Commission of any theft or loss of sources of ionizing radiation;

VII.- Monitor that the person in charge of radiological safety complies with his functions, analyzing and evaluating together with him the reports, reports and records that are presented to him on radiological safety;

VIII.- Ensure that reviews and analyzes of the work procedures, the equipment used and the facilities are carried out periodically, in accordance with what is indicated in the radiological safety report;

IX.- Prepare and maintain the Emergency Plan in operational conditions;

X.- Prepare and make known to all occupationally exposed personnel the Radiological Safety Manual;

XI.- Issue to occupationally exposed personnel, the annual certificates and records at the end of the employment relationship, of the individual dose equivalents received in the previous 52 weeks and of the total dose accumulated to date. A copy of these documents will be sent to the Commission with the receipt signature of the individual;

XII.- Keep a record of the medical examinations carried out on occupationally exposed personnel, which will be carried out under the terms and conditions referred to in the corresponding technical standard;

XIII.- Keep a record of all release, dumping and destination or final disposal of radioactive materials;

XIV.- Monitor that in the radioactive material storage premises records of entry and exit of the material are kept;

XV.- Periodically verify the inventory of radioactive material in accordance with what is stated in the Radiological Safety Report;

XVI.- Grant the facilities that are required during the inspections, audits, verifications and examinations carried out by the Commission;

XVII.- Provide the information that is required during the proceedings referred to in the previous section;

XVIII.- Submit to the inspectors the manuals, records or documents related to radiological safety, when requested;

XIX.- Carry out the tests and operations that are required during the inspection, audit, verification or recognition;

XX.- Allow Commission inspectors to take sufficient samples to carry out the pertinent analyzes and verifications;

XXI.- Correct the deficiencies and anomalies detected in the inspections, audits, verifications and surveys, and send the corresponding correction report to the Commission, in due course;

XXII.- Provide the information and documentation required by the Commission, within the terms established by the Commission in this regard;

XXIII.- Sign and initial all the documentation that is sent or presented to the Commission;

XXIV.- Where appropriate, cover all expenses arising from radiological accidents, including compensation to third parties;

XXV.- Notify the Commission, for its authorization, of the sale, loan, lease, donation, assignment or any other act that implies the transfer of ownership and deposit of ionizing radiation sources;

XXVI.- Notify the Commission immediately when it stops using or definitively possessing the authorized radioactive material;

XXVII.- Take all the radiological and physical safety measures required to safeguard the integrity of the radiation sources in the event of a strike or work stoppage;

XXVIII.- Notify the Commission of the outbreak and termination of the strike or work stoppage that occurs in the facility, and

XXIX.- Comply with any other obligations imposed by this Regulation.

CHAPTER III
OF THE REQUIREMENTS, CLASSIFICATION AND OBLIGATIONS OF THE HEAD OF RADIATION SAFETY AND AUXILIARY

Article 149.- The person in charge of radiological safety will be classified in A, B or C, according to the type of radioactive facility that he/she is in charge of.

Article 150.- To be in charge of class A radiological safety, the following is required:

I.- Professional title in the areas of physical-mathematical or chemical-biological duly registered and professional license issued by the corresponding authority.

II.- Certificate or proof of approval of an advanced radiological safety course recognized by the Commission;

III.- Certificates that demonstrate three years of experience in radiological safety:

IV.- Records that prove one year's experience in radiological protection aspects, related to the use that the permit holder of radiation sources;

V.- Reside in the town where the facility is located, and

VI.- Have authorization from the Commission regarding their qualification and training.

Article 151.- To be in charge of class B radiological safety, the following is required:

I.- Professional title and identity card in the terms of section I of the previous Article;

II.- Certificate or proof of approval of an advanced radiological safety course recognized by the Commission;

III.- Certificates that demonstrate one year's experience in radiological safety;

IV.- Certificates that prove six months of experience in radiological protection aspects related to the use that the permit holder makes of ionizing radiation sources;

V.- Reside in the town where the facility is located, and

VI.- Have authorization from the Commission regarding their qualification and training.

Article 152.- To be in charge of class C radiological safety, the following is required:

I.- Professional title and identity card in the terms of section I of Article 150 or internship letter in the areas of physical-mathematical or chemical-biological, and

II.- Proof of training on radiological safety in the use that the permit holder gives to sources of ionizing radiation recognized by the Commission.

Article 153.- The person in charge of class A radiological safety may be in charge of a single Type IA or II-A radioactive facility; the class B manager may serve up to two Type IB or II-B facilities; and the Class C manager up to three Type IC or II-C installations.

Article 154.- The obligations of those responsible for radiological safety are:

I.- Establish the radiological and physical safety procedures applicable to the acquisition, import, export, production, possession, use, transfer, transportation, storage and destination or final disposal of radioactive materials and devices that generate ionizing radiation; for review and approval in its case of the Commission;

II.- Train and qualify the occupationally exposed personnel in the correct application of the norms and procedures of radiological and physical safety, as well as monitor their compliance during the operations carried out with the sources of ionizing radiation;

III.- Establish the radiological surveillance program for the determination, registration, analysis and evaluation of the dose equivalents received by occupationally exposed personnel;

IV.- Ensure that occupationally exposed personnel are provided with the appropriate clothing, equipment, accessories and radiological protection devices and ensure that they use them properly;

V.- Identify the zones, places, operations and conditions that could potentially cause exposure to radiation;

VI.- Communicate immediately to the permit holder any fact that in his opinion may imply an increase in the risk of exposure to radiation during the handling of ionizing radiation sources in order to apply the pertinent corrective measures;

VII.- Immediately notify the Commission of any theft or loss of sources of ionizing radiation;

VIII.- Develop projects, procedures, and methods to maintain the radiation exposure of occupationally exposed personnel and the public, as low as can reasonably be achieved, but lower than the dose equivalent limits established in this Regulation;

IX.- Elaborate and supervise the test program for proper functioning and calibration of all the ionizing radiation detector and meter equipment;

X.- Prepare, supervise and participate in training programs for occupationally exposed personnel;

XI.- Keep a record of the dose equivalents received by occupationally exposed personnel, attaching the dose equivalent received in previous jobs when the respective certificates have been presented;

XII.- Ensure that the handling and disposal of radioactive waste are carried out in accordance with the applicable radiological safety standards;

XIII.- Carry out leak tests on ionizing radiation sources at the time of their reception and in the periods established in the conditions of the license, authorization or permit, as well as after the occurrence of a radiological accident;

XIV.- Keep a record of the leak tests, calibration and proper functioning of the sources of ionizing radiation and of the detector equipment and meters of said radiation, in the terms of this Regulation;

XV.- Be present during the development of the inspections, audits, verifications and examinations carried out by the Commission on the permit holder;

XVI.- Provide the information requested by the inspectors in the course of the proceedings indicated in the previous section;

XVII.- Correct the deficiencies and anomalies detected in the inspections, audits, verifications and recognitions;

XVIII.- Prepare and collect the necessary documentation for obtaining and timely renewal of licenses, permits and authorizations;

XIX.- Prepare, update, control and file the plans, reports, records and writings related to the Radiological Safety Report and with the inspections, audits, verifications or surveys carried out by the Commission;

XX.- Participate in the preparation, updating and application of the Radiological Safety Manual and the Emergency Plan of the facility;

XXI.- Go immediately to the facility in the event of a radiological accident to coordinate and supervise the operations that must be carried out, advising the Commission of the fact, in accordance with the provisions of Title Ninth, Chapter I of these Regulations;

XXII.- Prepare a training program for emergency cases, which includes both potential radiological accidents during routine operations, as well as those that could occur as a result of a fire, explosion, flood, landslide or other accidents, including periodic drills with the occupationally exposed personnel;

XXIII.- Provide the information or documentation required by the Commission, within the terms established by it in this regard, and

XXIV.- Comply with the other obligations indicated in this Regulation.

Article 155.- The number of assistants that the person in charge of radiological safety must have is determined by the type and group of installation in question, activity, characteristics, number and specific use given to the sources of ionizing radiation. Auxiliaries may be class A or B.

Article 156.- To be an assistant to the person in charge of radiological safety, class A, the following is required:

I.- Possess a professional title and identity card under the terms of section I of Article 150;

II.- Accredit one year of experience in radiological safety matters;

III.- Accredit six months of experience in aspects of radiological protection related to the use that the permit holder gives to the sources of ionizing radiation;

IV.- Demonstrate having taken and passed a radiological safety course, recognized by the Commission, and

V.- Have authorization from the Commission regarding their qualification and training.

Article 157.- To be an assistant to the person in charge of radiological safety, class B, the following is required:

I.- Possess a professional title and identity card in the terms of section I of Article 150, or letter of internship in the areas of physical-mathematical or chemical-biological;

II.- Accredit the approval of a radiological safety course recognized by the Commission or demonstrate six months of experience in the specific use that the permit holder gives to the sources of ionizing radiation, and

III.- Have authorization from the Commission regarding their qualification and training.

Article 158.- It is the obligation of the assistants of the person in charge of radiological safety to send to the permit holder all the documentation related to the inspections, audits, verifications and surveys carried out by the Commission, and in which they intervene in substitution of the person in charge of radiological safety.

CHAPTER IV
OF THE REQUIREMENTS AND OBLIGATIONS OF THE PERSONNEL OCCUPATIONALLY EXPOSED

Article 159.- Occupationally exposed personnel must:

I.- Be registered with the Commission;

II.- Being over 18 years old;

III.- Possess a certificate of studies, as stipulated by the corresponding technical standard. This certificate must be issued by the corresponding authority, and

IV.- Have authorization from the Commission regarding their qualification and training.

Article 160.- The obligations of occupationally exposed personnel are:

I.- Know and correctly apply the basic principles of radiological safety;

II.- Avoid all unnecessary exposure to radiation of your person and the public;

III.- Take care and monitor that when the sources of ionizing radiation cease to be used, they are in adequate conditions of radiological safety and

physical; the radioactive material in its containers and the equipment that contains the sources or the device that generates ionizing radiation in the off position;

IV.- Check when you leave an area where there is a risk of radioactive contamination, that your person and clothing are not contaminated;

V.- Know and correctly apply the standards, instructions and procedures contained in the Radiological Safety Manual and in the facility's Emergency Plan;

VI.- Know the correct handling and use of ionizing radiation sources, radiation detection and measurement equipment, radiological safety devices and accessories, and shielding, distance and time factors, to the extent required by their functions and responsibilities;

VII.- Carry the required personal dosimeters during the working day in accordance with the provisions of the Radiological Safety Manual;

VIII.- Ensure that in the development of its activities the least amount of radioactive waste is produced;

IX.- Know and correctly apply the procedures authorized by the person in charge of radiological safety for the elimination of radioactive waste;

X.- Find out about the dose equivalents that he has received in the performance of his duties with the periodicity with which they are recorded in the corresponding registry;

XI.- Submit to the taking of biological samples that are required for medical surveillance and for bioassay tests;

XII.- Truthfully provide the data required during the inspections, audits, verifications and surveys carried out by the Commission;

XIII.- Know the conduct to follow in the event of a radiological accident;

XIV.- The personnel who provide their services in various facilities and are professionally exposed, must inform the person in charge of radiological safety, of each one of them, so that all of them have the complete dosimetric history, and

XV.- Inform the person in charge of radiological safety about any high-risk situation, incident and radiological accident.

Article 161.- The Commission may impose on those in charge of radiological safety, auxiliaries and occupationally exposed personnel, additional requirements in those cases in which radiological safety so requires.

EIGHTH TITLE
OF MEDICAL APPLICATIONS

SINGLE CHAPTER
OF THE ADMINISTRATION, APPLICATION AND IMPLANTATION OF RADIOACTIVE MATERIAL

Article 162.- Any administration, application or implantation of radioactive material will be recorded in the patient's clinical file, indicating the date and time it was performed, the date and time of withdrawal in the case of temporary application or implantation, radioisotope and activity used, via of administration and name and signature of the responsible physician.

Article 163.- In cases of administration of radioactive material for therapeutic purposes, in which it is anticipated that there will be a significant dissemination of the radionuclide in the patient or a significant excretion of it, the speed of exposure to one meter will be measured every 12 hours. from the center of the organ with the greatest amount of the radioisotope, until completing 96 hours after administration. These readings will be recorded in the patient's clinical file.

"The person in charge of radiological safety will establish the appropriate procedures for the handling, treatment and disposal of contaminated excreta, making them known to the doctor, nurses and cleaners in the area, who in turn will instruct the patient in this regard."

Article 164.- In any administration, application or implantation of radioactive material, for therapeutic purposes, the radioisotope and the activity to be used will be previously verified, and the identification of the patient in question will be verified. The rate of exposure to one meter from the implant or the organ with the greatest amount of radioisotope immediately after and 12 hours after it has been applied, administered or implanted will be recorded in the patient's clinical record.

Article 165.- In those cases in which it is necessary to transfer, within the same institution, patients who are undergoing treatment with incorporated radioactive material, the transfer will be made by predetermined routes, chosen in such a way as to avoid unnecessary exposure of people. not occupationally exposed or from the public.

Article 166.- Treatments with teletherapy equipment, deep therapy or superficial therapy, will be recorded in the patient's clinical file, indicating the dose administered.

Article 167.- The area of the patient that is going to be irradiated with teletherapy, deep therapy or superficial therapy equipment, will be clearly identified and its location will be verified by the doctor in charge during the course of the treatments; while the areas that are not to be irradiated must be protected with the appropriate devices.

Article 168.- In therapy equipment with ionizing radiation sources, adjustable diaphragms and collimators will be used to delimit the useful radiation beam.

Article 169.- When the patient's conditions warrant it, in teletherapy treatments, deep or superficial therapy, bras that prevent mobility will be used.

Article 170.- Hospitalization of the patient will be required from the point of view of radiological safety when the activity administered or permanently implanted or the speed of exposure to one meter from the center of the implant or the organ with the greatest amount of radioisotope are greater than stipulated in the corresponding technical standard. This standard will establish the radiological safety conditions that must be taken into account when these patients are discharged.

Article 171.- The patient who is subjected to applications or temporary implants with sealed sources of radioactive material with a physical half-life greater than 125 days, must remain hospitalized during the treatment. Radiation sources must be removed before the patient is discharged.

Article 172.- When it is necessary to intervene surgically on patients to whom radioactive material has been administered, applied or implanted, the person in charge of radiological safety will be informed so that he or she can determine the pertinent measures.

Article 173.- In the cases of embalming, autopsy, burial or cremation of corpses that contain therapeutic doses of radioactive material, the person in charge of radiological safety must be previously consulted, who will evaluate the situation and determine the precautions that must be followed regarding radiological safety, notifying the same to the Commission.

Article 174.- Corpses containing sealed sources used for temporary implants will be removed before being cremated or buried.

NINTH TITLE
OF RADIOLOGICAL ACCIDENTS AND PREVENTIVE OR SAFETY MEASURES

CHAPTER I
OF NOTICES AND REPORTS

Article 175.- The permit holder, the person in charge of radiological safety or the occupationally exposed personnel, must immediately notify the Commission of any radiological accident, regardless of the notices that must be given to other Units.

Article 176.- The permit holder must submit to the Commission a written report of the radiological accident within the following 24 hours.

Article 177.- The report referred to in the previous article will contain:

I.- Description of the accident that occurred;

II.- Probable causes thereof;

III- Sources of radiation involved and, if applicable, quantity and physical and chemical form of the radioactive material released into the environment;

IV.- Immediate actions that were taken and people who intervened in them;

V.- Estimation of the dose equivalent received by occupationally exposed personnel;

VI.- Estimation of the dose equivalent received by members of the public who were exposed;

VII.- Data of the people involved in the accident, such as: Name, address, telephone number, gender, date of birth, occupation, IMSS or ISSSTE affiliation number and relationship with the permit holder, and

VIII.- The signature of the permit holder and the person in charge of radiological safety in the margin of each of its pages and at the bottom of the last one.

Article 178.- The permit holder, within 15 business days after delivery of the report referred to in Article 176, shall deliver a written report to the Commission containing:

I.- Description of the accident, magnitude of the same and specific causes that motivated it;

II.- Description, brand, model, serial number and physical and chemical form of the radiation sources involved and, if applicable, the amount of radioactive material released into the environment;

III.- Actions taken to manage the accident, people who carried them out and calculation of the dose equivalent received by them;

IV.- Measures that have been taken to prevent the accident from happening again;

V.- Calculation of the effective dose equivalent received by the personnel occupationally exposed due to the accident;

VI.- Calculation of the effective dose equivalent received by members of the public who were exposed due to the accident;

VII.- The data referred to in section VII of the previous Article;

VIII.- The signature of the permit holder and the person in charge of radiological safety in the terms of section VIII of the previous Article, and

IX.- Attach, if applicable, a copy of the record drawn up before the Public Ministry due to the accident.

Article 179.- The permit holder shall provide the Commission with the additional information required in relation to the accident that occurred.

Article 180.- Cases of radiological incidents or accidents are the direct responsibility of the permit holder.

CHAPTER II
PREVENTIVE OR SECURITY MEASURES

Article 181.- For the purposes of this Regulation, it is considered that there is imminent danger or risk for the personnel of a radioactive facility or for society in general, when:

I.- The authorization, permit or license required by Law is lacking;

II.- Sealed fountains lose their hermeticity;

III.- The systems or equipment to control the radiation source or the equipment that contains it are in conditions that contravene the provisions of this Regulation;

IV.- The required ionizing radiation measurement equipment is not available or is not in adequate operating conditions;

V.- The use of radiation sources or equipment containing them is carried out in contravention of the provisions of this Regulation;

VI.- The physical and radiological protection engineering barriers do not meet the specifications required by the Commission;

VII.- The personnel in charge of the use of the radiation sources or equipment that contain them, lacks the authorization of the Commission regarding their qualification and training;

VIII.- The release of radioactive material outside the facility exceeds the limits set in the respective permit or license;

IX.- The control systems of the radiation sources or equipment that contain them, operate in a deficient manner or are about to suffer a failure;

X.- The hermeticity of the sealed sources is lost and surface contamination is caused in the installation that exceeds the limits established in the corresponding technical standard;

XI.- The amount of radioactive material suspended in the air exceeds the limits established in the corresponding technical standard;

XII.- The levels of surface contamination of movable or immovable property exceed the limits established in the corresponding technical standard, and decontamination is not possible, and

XIII.- The conditions of the facilities that house the radiation sources or equipment that contain them, could affect their safety.

Article 182.- The Commission may order and execute the following preventive or security measures:

I.- Retention, insurance or deposit of ionizing radiation sources or equipment that contains them, as well as any contaminated property;

II.- Temporary closure, partial or total, of radioactive facilities or contaminated real estate;

III.- Definitive closure of radioactive facilities or contaminated real estate, and

IV.- Temporarily occupy nuclear and radioactive facilities under the terms of article 34 of the Law.

Article 183.- The retention, insurance or deposit of the sources of ionizing radiation or equipment that contains them will proceed, in the cases to which it is

Sections I, II, III, IV, V, VI and VII of Article 181 refer, as well as in the case of section VIII of the same precept, when the release does not exceed twice the limits mentioned.

Article 184.- The retention, insurance or deposit of any contaminated personal property will proceed in the case of section XII of Article 181.

Article 185.- The temporary, partial or total closure of radioactive facilities will proceed in the cases referred to in sections VIII, when the release of radioactive material exceeds twice the limits indicated, IX, X, XI, XII and XIII of Article 181.

Article 186.- The temporary, partial or total closure of contaminated real estate will proceed in the case of section XII of Article 181.

Article 187.- Once the temporary closure referred to in Articles 185 and 186 has been executed, the Commission will set the term to correct the deficiencies or anomalies found.

Article 188.- Prior to the corresponding technical opinion, the Commission will proceed to the definitive closure of radioactive facilities or contaminated real estate, when after the period set for this purpose, the deficiencies or anomalies that caused the temporary closure have not been corrected.

TENTH TITLE
AUTHORIZATIONS, PERMITS AND LICENSES

CHAPTER I
OF THE AUTHORIZATIONS

Article 189.- Any activity with sources of ionizing radiation is prohibited when the respective authorization, permit or license is lacking.

Article 190.- To request an authorization for the acquisition, import, export, possession, use, transfer, transportation, storage and destination or final disposal of radioactive material and devices that generate ionizing radiation, the interested party must present the documentation and information to the Commission indicated for each case in these Regulations, on the letterhead of the requesting company or institution and duly signed by the legal representative and the proposed candidate for radiation safety manager of said company or institution.

Article 191.- To request authorizations for the acquisition and transfer of ionizing radiation sources, the interested parties must meet the following requirements:

I.- Submit: a).-
Request in the corresponding official form;
b).- Articles of incorporation of the requesting company, duly registered in the Public Registry of Property. In whose corporate purpose the acquisition and transfer of radioactive material must be included, and c).- Bond or surety from an institution or company legally authorized to guarantee damages caused by ionizing radiation to third parties.

II.- Attaching in writing the information related to: a).-
Activity and radioisotopes by product and physical and chemical form;
b).- Category of the packages and type of packaging used during the transport and storage in transit of the ionizing radiation sources, as well as the transport index;
c).- Procedure for the transfer of ionizing radiation sources to the permit holders;
d).-Training program in radiological protection for permit holders, for the use of ionizing radiation sources; e).- Technical and administrative advice plan that the applicant will provide to the permit holders of ionizing radiation sources, regarding the procedures before the Commission and the different activities with said sources; f).- Program for the delivery of ionizing radiation sources, and g).- Physical and radiological safety conditions to be applied by the applicant during storage in transit of ionizing radiation sources.

Article 192.- To request import authorizations for sources of ionizing radiation, the interested parties must submit the following information in writing to the Commission:

I.- Number of the recipient's authorization, permit or operating license;

II.- Radioisotopes; exercise; physical and chemical form; and specifications of the equipment containing the radioactive material or the specifications of the ionizing radiation generating device;

III.- Customs where the importation is intended to be carried out;

IV.- Type of packages, packages or containers that will be used in the transport;

V.- Copy of the import petition, and

VI.- Physical and radiological security plan.

Article 193.- The Commission shall suspend the processing of an application for authorization to import sources of ionizing radiation, when the information referred to in the previous Article is incomplete, or the recipient or applicant is in any of the following cases:

I.- Lacks authorization, permit or license, or these are suspended or cancelled, and

II.- The activity of radioactive material or capacity of the ionizing radiation generating device, which is intended to be imported, exceeds what is authorized by the Commission.

Article 194.- Once the import of ionizing radiation sources has been carried out by the holders of the respective authorization, they must submit to the Commission within five business days from the date of delivery of the same, the acknowledgment of receipt of the sources by the addressee indicated in the application that was submitted pursuant to Article 192 of this Regulation, and the transportation certificates of said sources issued by the competent authority in matters of radiological safety of the country of origin.

Article 195.- To process the export authorization for ionizing radiation sources, the applicant must submit the following information and documentation in writing to the Commission:

I.- Authorization, permit or operating license number of the permit holder;

II.- Radioisotopes, activity, physical and chemical form, and specifications of the equipment that contains the radioactive material;

III.- Customs through which the export is intended to be carried out;

IV.- Name, address and telephone or telex number of the recipient;

V.- Physical and radiological safety plan;

VI.- Original of the radioactive material transport authorization, and

VII.- Copy of the export petition.

Article 196.- The requirements to process the authorization of acquisition, possession and use of sources of ionizing radiation, will be those established in Articles 219, 220 and 221 of this Regulation.

Article 197.- The possession and use of radioactive material in buildings intended for habitation will not be authorized.

Article 198.- To request authorizations for the transport of radioactive material, the interested parties must: I.- Submit an application in the corresponding official form;

II.- Exhibit the company's articles of incorporation, duly registered in the Public Registry of Property, whose corporate purpose must include the transport of radioactive material;

III.- Propose a person to be in charge of radiological safety;

IV.- Propose the people who could serve as occupationally exposed personnel;

V.- Describe the radioactive material that is intended to be transported, as well as the containers and transfer packaging;

VI.- Detail the physical and radiological security plan;

VII.- Describe the equipment and security devices;

VIII.- Present risk analysis and emergency plan for the case of accidents with radioactive material during transport and storage in transit;

IX.- Detail the route to be followed by the vehicle that will transport the radioactive material;

X.- Describe the procedures for reception and delivery of radioactive material, and

XI.- Bond or surety from an institution or company legally authorized to guarantee damages caused by ionizing radiation to third parties.

Article 199.- The radiological safety regulations applicable to the transport of radioactive materials will be those contained in the respective Transport Regulations.

Article 200.- Ionizing radiation generating devices will not require authorization for their transportation.

Article 201.- To process the authorization of a temporary store of radioactive material, the applicant must:

I.- Submit: a)
Application in the corresponding official form;

b) Constitutive Act of the company, duly registered in the Public Registry of Property and Commerce, whose corporate purpose must include the storage of radioactive material;

c) Analytical memory of the installation;

d) Architectural plans of the facility, indicating the areas adjacent to it and the type of use to which such areas are intended;

e) Radiological Safety Manual;

f) Risk Analysis and emergency plan;

g) Proposal of a person to be in charge of radiological safety, and

h) Proposal of the people who could serve as occupationally exposed personnel.

II.- Attaching in writing the information related to:

a) Maximum activities of radioisotopes;

b) Procedure and record of receipt and delivery of materials radioactive, and

c) Characteristics of ionizing radiation detector equipment.

Article 202.- The requirements to process the authorization of a definitive storage facility for radioactive material shall be those established in Articles 219, 220 and 221 of this Regulation. In addition, a program must be presented for the definitive closure of the installation and the maintenance that will be provided after the active use of the same has ended. This program must include plans for the immobilization of radioactive materials, and their isolation from the environment as effectively as can reasonably be achieved, as well as for monitoring the retention of radioactive contaminants and the stability of the facility.

Article 203.- The holder of the authorization of a definitive storage facility for radioactive material shall take the pertinent corrective actions to maintain the stability and integrity of the facility during the duration of his responsibility.

Article 204.- The definitive storage of flammable radioactive waste, pyrophoric explosives, in liquid state, in the form of compressed gases or unknown compounds is prohibited.

Article 205.- The definitive storage of radioactive waste in the sea is prohibited.

Article 206.- The necessary information for the processing of the authorization for the processing, conditioning, dumping and final disposal of low and intermediate level radioactive waste, will be those established in Articles 219, 220 and 221 of this Regulation.

Article 207.- For the purposes of the previous Article, the Commission will classify radioactive waste according to its specific activity, speed of exposure on the surface of the container or packaging, half-life, radiotoxicity, chemical and physical form and taking into account its origin, properties of the radionuclide, risk of external irradiation, characteristics of the container, packaging or package, ecological dispersion mechanism and form of release into the environment.

Article 208.- It is not allowed to mix radioactive waste with other materials, except as part of a procedure or conditioning approved by the Commission.

Article 209.- The Commission shall authorize the incineration of radioactive waste as long as the permit holder demonstrates to the Commission that the radioactive releases involved in said process will not result in the exposure of the general public to dose equivalents that exceed the authorized limits.

Article 210.- The burial of radioactive waste may only be carried out in facilities authorized by the Commission provided that they have the respective operating license.

Article 211.- The holder of an operating license for a radioactive facility in which low and intermediate level radioactive waste is produced from open sources shall be authorized by the Commission to discharge it into the facility's drainage system as long as it verifies that:

I.- Liquids are completely soluble or dispersible in water;

II.- The concentrations in daily average discharge of radioactive liquids, will not be higher than the values indicated by the Commission in the corresponding technical standard;

III.- The monthly average concentration of radioactive liquids, diluted in the monthly average amount of water discharge from the facility, shall not exceed the values indicated by the Commission in the corresponding technical standard, and

IV.- The maximum allowed total activity of discharge of radioactive liquids to the drainage, will not exceed 37.0 GBq (1 Ci) per year.

Article 212.- The Commission may allow releases that exceed the authorized limits in each case, when in its opinion there are reasons that justify it, upon request submitted in writing by the permit holder attaching the information required.

Article 213.- The Commission may limit the amount of radioactive material that is dumped into uncontrolled areas with discharges of liquids or gases

of an installation, when it is estimated that the corresponding authorized limits could be exceeded for the critical group.

Article 214.- The procedure, conditioning and final disposal of radioactive waste with high-level open and sealed sources, shall be subject to the provisions of the Safety Regulations for Nuclear Installations.

Article 215.- Sealed sources with activities higher than those indicated with the corresponding technical standard, can only be disposed of in two ways:

I.- Sending them to a definitive radioactive waste warehouse, or

II.- Sending them abroad with prior export authorization under the terms of the Law and this Regulation.

Article 216.- For the destination or final disposal of sealed sources, the permit holder must previously request the corresponding authorization from the Commission, providing the following information in writing:

I.- Radioisotope, activity and date on which it is valid, brand, model and serial number of the source;

II.- Number and date of issue of the authorization, permit or license, in which the source is protected;

III.- Reason for the removal of the source;

IV.- Type, brand and model of the container with which the source is intended to be transported, and

V.- Proposed destination or final disposition.

Article 217.- To obtain authorization to install or provide service to ionizing radiation sources and equipment containing them, as well as to calibrate ionizing radiation detector and meter equipment, the applicant must submit to the Commission:

I.- Application in the corresponding official form;

II.- Copy of the Constitutive Act of the company in question, duly registered in the Public Registry of Property, whose corporate purpose must include the installation or provision of services to ionizing radiation sources and equipment that contain them;

III.- Radiological Safety Report;

IV.- Proposal of a person to be in charge of radiological safety, and

V.- Propose people who could serve as occupationally exposed personnel.

Article 218.- The Radiological Safety Report referred to in section III of the previous Article, must contain:

I.- The detailed procedures of each of the activities that will be carried out to grant the services or calibrations involved, indicating the applicable national or international standards, and

II.- List and characteristics of the equipment and the sources of ionizing radiation used to carry out the procedures described.

CHAPTER II
PERMITS AND LICENSES

Article 219.- To apply for construction permits and operating licenses, modification, cessation of operations, dismantling or definitive closure of radioactive facilities, the interested parties must submit the following documentation to the Commission:

I- Application in the corresponding official form;

II.- Copy of the articles of incorporation of the company duly registered in the Public Registry of Property and Commerce;

III.- Radiological Safety Report;

IV.- Radiological Safety Manual, and

V.- Bond or surety from an institution or company legally authorized to guarantee damages to third parties.

Article 220.- In the case of the application for a construction permit for a radioactive facility, the Radiological Safety Report has the purpose of describing the radiological safety characteristics that will be applied in: the conception of the project, the design, the methods of calculation and controls for procedures and materials used. The above information must be submitted to the Commission according to the following points:

I.- Proposed facilities and activities;

II.- Evaluation of options;

III.- Location;

IV.- Installation design, and

V.- Quality Assurance Program.

The scope and content of this Report is established for each case in the corresponding technical standard.

Article 221.- In the case of an application for an operating license for a radioactive facility, the Radiological Safety Report will contain the information regarding:

I.- General specifications of the installation;

II.- Organization of the applicant;

III.- Radiological safety policy;

IV.- Quality Assurance Program;

V.- Radiological Safety Group;

VI.- Radiation sources;

VII.- Design characteristics in relation to radiological safety;

VIII- Estimation of dose equivalents;

IX.- Radiological safety program;

X.- Risk analysis and emergency plan;

XI.- Environmental impact, and

XII.- Cessation of operations, dismantling and definitive closure.

The scope and content of this Report is established for each case in the corresponding technical standard.

Article 222.- In the case of an application for a license to modify a radioactive facility, the Radiological Safety Report will contain the information regarding:

I.- The reason for the modification;

II.- The implications of radiological safety, and

III.- The estimation of the dose equivalent.

The scope and content of this Report is established for each case in the corresponding technical standard.

Article 223.- The Radiological Safety Report, in the case of the request for a license to cease operations or dismantle a radioactive facility, will contain:

I.- If applicable, the report of modifications to the "program of activities for the cessation of operations or dismantling", contained in the Radiological Safety Report that was presented to the Commission on the occasion of the application for its operating license facility. In this program of activities, it will be considered that the radioactive facility must be free of removable surface contamination;

II.- A detailed list of the procedures to follow to comply with the "program of activities for the cessation of operations or dismantling" mentioned in the previous section, and

III.- In the case of generation of radioactive waste and control of residual radiation sources, the procedures for processing, conditioning, dumping and final disposal must be indicated.

Article 224.- The Radiological Safety Report, in the case of the request for a license for the definitive closure of a radioactive facility, will contain the documents that prove that the conditions established in the Radiological Safety Report presented together with the request for an operating license have been fulfilled. compliment.

CHAPTER III

OF THE REQUIREMENTS FOR RENEWAL OF AUTHORIZATIONS, PERMITS OR LICENSES

Article 225.- The request for the renewal of authorizations, permits and licenses must be submitted 30 calendar days before their expiration date.

Article 226.- Applications for the renewal of authorizations, permits or licences, provided that the conditions under which they were granted do not change, must be accompanied by a detailed report on the radiological protection experiences acquired.

CHAPTER IV
OF THE EVALUATION OF THE REQUEST FOR AUTHORIZATIONS, PERMITS AND LICENSES, AND THEIR RENEWAL

Article 227.- No authorization, permit, license or renewal request will be processed when:

I.- The data contained therein is incomplete or the signatures are missing or do not correspond to the applicant, his legal representative and the person in charge of radiological safety, or, these are deleted, amended or crossed out;

II.- The installation or equipment is not adequate for the specific use that will be given to the sources of ionizing radiation;

III.- The person proposed to be in charge of radiological safety does not meet the corresponding requirements.

IV.- The information provided in the Radiological Safety Report is not true;

V.- The authorization, permit or license previously conceived, have been suspended or canceled and the causes or reasons for that suspension or cancellation subsist or affect the conditions of the new application;

VI.- The person proposed to be in charge of radiological safety, has held the position previously and his appointment has been annulled by the Commission;

VII.- The sanction has not been fulfilled or any fine or damages to third parties and expenses derived from any radiological accident have been covered;

VIII.- The documentation provided by the applicant is not clear, incomplete or contradictory, or

IX.- The deficiencies or anomalies detected in the inspections, audits, verifications and recognitions, have not been corrected.

Article 228.- The processing of the application may be continued, when it is shown that the cause that interrupted it has disappeared.

Article 229.- When the Commission considers that the documentation presented for the processing of an authorization, permit or license or its renewal is incomplete or its content is insufficient to carry out its evaluation, it will require the applicant to complete, clarify, correct or expand it.

Article 230.- The Commission reserves the right not to receive documentation submitted for the processing of an authorization, permit, license or its renewal, when it considers that it is incomplete or that its content is

insufficient to carry out its evaluation, in accordance with the requirements indicated in the Regulation.

Article 231.- The Commission will verify the information and documentation provided by the applicant.

CHAPTER V
OF THE GRANTING OF AUTHORIZATIONS, PERMITS, LICENSES OR THEIR RENEWAL

Article 232.- When the documentation is deemed sufficient and the deficiencies found are corrected, the Commission will grant the corresponding authorization, permit, license or its renewal.

Article 233.- The authorizations, permits or licenses or their renewals, will only be valid for the permit holder whose name, address and classification are expressed and under the specific conditions for which they were issued, whose validity will be stated in the document itself. The original of the permit, license or authorization must be kept at the legal domicile of the permit holder and a copy of these documents must accompany the sources of ionizing radiation, in order to be presented during the audits, inspections, verifications and surveys carried out by the Commission.

Article 234.- When the permit holder stops using or definitively possessing sources of ionizing radiation, the authorization, permit or license or its renewal that has been granted will be cancelled.

ELEVENTH TITLE
ADMINISTRATIVE PROCEDURES

CHAPTER I
OF THE INSPECTIONS, AUDITS, VERIFICATIONS AND ACKNOWLEDGMENTS

Article 235.- The authorized personnel of the Commission for the practice of inspections, audits, verifications and recognitions, will have the inherent faculties and access to the places, establishments and equipment object of said proceedings.

Article 236.- The inspections, audits, verifications and recognitions will be carried out by the Commission at the request of the interested party or ex officio with the frequency that it determines in each case.

Article 237.- The inspection, audit, verification and reconnaissance visits will be carried out on working days and hours by authorized personnel of the Commission. The Commission may authorize said visits to be carried out on non-business days and hours in order to avoid interruptions, in which case such authorization shall be expressed in the corresponding order.

Article 238.- The inspectors of the Commission, for the practice of inspections, audits, verifications and recognitions must be duly identified and be provided with the respective orders.

Article 239.- The orders referred to in the previous Article must comply with the following requirements:

I.- Be in writing;

II.- Point out the authority that issues it;

III.- Be substantiated and motivated and, express the resolution, object or purpose;

IV.- Show the signature of the competent official and, where appropriate, the name or names of the persons to whom it is addressed, indicating sufficient data to allow their identification;

V.- Indicate the place or places where they must be carried out;

VI.- Contain the name of the person or persons who must carry them out, which may at any time be replaced, increased or reduced in number by the Commission. These changes will be notified to the interested party in a timely manner. The designated persons who must carry out the aforementioned procedures may do so jointly or separately, and

VII.- Mention the date or dates on which the corresponding diligence will be carried out.

Article 240.- During the practice of inspections, audits, verifications and recognitions, all natural and legal persons, as required, must grant facilities, provide information, submit documentation, carry out tests and operations, and allow the taking of sufficient samples. to carry out the pertinent analyzes and checks.

The above provisions shall be applicable both in proceedings carried out at the legal domicile of the permit holder and in the field.

Article 241.- Once the procedure in question has been initiated, it may not be interrupted or suspended without an order or express authorization from the Commission. In cases where personnel are prevented from carrying out their duties, the Commission will adopt the appropriate measures, including requesting the support of the public force, in order to allow the execution of the same.

Article 242.- In cases in which due diligence is prevented, obstructed or hindered for any reason, the inspector will draw up the record indicating these facts so that the corresponding sanctions are applied.

Article 243.- Every inspection, audit, verification or recognition will be documented in the presence of two witnesses.

Article 244.- In the minutes of inspection, audit, verification or recognition, the following shall be stated:

I.- Hour, day, month and year in which the diligence is carried out;

II.- Street, number, population and federal entity in which the place where the diligence or full identification of the site is carried out is located;

III.- Number and date of the order that motivated it;

IV.- Name and character of the person with whom the diligence is understood;

V.- Name and address of the persons who serve as witnesses;

VI.- That the person with whom the diligence was conducted was informed of his right to make observations to the inspector during the practice of the same;

VII.- Data related to the performance;

VIII.- Declaration of the person referred to in section VI above, if he/she wishes to do so;

IX.- That the person with whom the diligence was conducted was informed of the right to make written observations on the minutes, having a term of 10 working days from the date on which the diligence was carried out, and

X.- Name and signature of those who participated in the procedure.

Article 245.- The facts that are recorded by the inspector in the documents that they prepare in the exercise of their functions, will be considered true until the contrary is proven.

Article 246.- A copy of the minutes will be left to the person with whom the proceeding was understood even if they had refused to sign it, which will not affect its validity, and this circumstance will be recorded in the respective minutes.

Article 247.- The Commission will send the interested parties, within 20 business days following the procedure, the respective opinion indicating, where appropriate, the anomalies and deficiencies found and the terms available to correct them.

Article 248.- The interested party must communicate to the Commission, within the established deadlines, the measures adopted to correct the anomalies and deficiencies indicated in the aforementioned opinion. The Commission may verify compliance with these measures.

Article 249.- The Commission may extend the deadlines set upon request of the interested party, in which it will state the reasons for the request.

Article 250.- When the deficiencies or anomalies detected are not corrected to the satisfaction of the Commission, the corresponding sanctions will be applied.

Article 251.- If during the diligence deficiencies or anomalies are found that imply an imminent danger or risk for the occupationally exposed personnel or for society in general, the inspector will be empowered to apply the preventive or security measures referred to in Article 182 of these Regulations, prior order of the Commission, in which case it will proceed to draw up minutes in the terms of Article 244 above.

Article 252.- When the content of the record reveals the possible commission of a crime, the Commission will notify the competent authority.

CHAPTER II
OF SANCTIONS

Article 253.- The violation or breach of the precepts of the Law, this Regulation and other provisions derived from it, regardless of what is appropriate according to other laws or regulations, will be sanctioned administratively by the Commission as follows:

I.- Fine of five to five thousand times the general minimum wage in force in the place and time in which the violation is committed. In the event that the infraction persists and the term granted for its correction expires, the Commission may impose fines for each day that passes without obeying the respective mandate, provided that it does not exceed the indicated limit, and regardless of the other sanctions provided in this Regulation;

II.- Suspension of the authorization, permit or license, and

III.- Cancellation of the authorization, permit or license.

Article 254.- The sanctions will be imposed based on the results of the inspection, audit, verification or recognition acts, and the resolutions derived from them, in accordance with the provisions of this Regulation and other provisions derived from it; taking into account the evidence and arguments of the interested party. In any case, the resolutions that are issued in matters of sanctions must be founded and motivated in accordance with the law and taking into consideration the criteria established in Article 256 of this Regulation.

Article 255.- The fine applies to the responsible permit holders in cases of violation of Articles 16, 18, 27, 28, 29, 32, 34, 35, 38, 41, 42, 44, 45, 49 sections I, II , III, IV and V, 50, 52, 53, 54, 56, 57, 59, 60, 61, 62, 63, 64, 65, 66, 68, 69, 70, 72, 73, 74, 75, 76 , 77, 78, 81, 83, 84, 85, 86, 87, 88, 89, 90, 92, 93, 94, 95, 96, 97, 110, 111, 112, 113, 114, 115, 116, 117 , 118, 119, 120, 121, 122, 123, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 137, 138, 139, 140, 141, 142, 143, 144, 148 , 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 189, 194, 203, 204, 205, 208, 210 , 225, 240 and 248.

Article 256.- For the quantification and imposition of sanctions, the following will be taken into consideration:

I.- The seriousness of the offense committed,

II.- The economic conditions of the offender, and

III.- Recidivism, if any.

Article 257.- In case of recidivism, the fine originally imposed will be doubled, without its amount exceeding twice the maximum set in section I of Article 253 of this Regulation.

Recidivism is understood for the purposes of this Regulation and other provisions derived from it, each of the subsequent infractions of the same precept that are not continuous, committed within the two years following the date of the resolution in which the violation was recorded. preceding infraction, provided that this had not been distorted.

Article 258.- The suspension proceeds when:

I.- From the inspection, audit, verification or recognition carried out, it appears that the conditions of the authorization, permit or license have not been met;

II.- In the inspection, audit, verification or reconnaissance, the non-compliance with the applicable physical and radiological safety standards will be verified;

III.- From the inspection, audit, verification or examination it appears that the equipment, instruments or installation do not meet the conditions for its safe and adequate use;

IV.- I confirm that the permit holder has provided false information or documentation to the Commission, and

V.- The lack of a Radiological Safety Officer.

Article 259.- Cancellation proceeds when:

I.- The inspection, audit, verification or examination carried out on the permit holder demonstrates negligence in the use, transportation, storage and other activities related to the sources of ionizing radiation, and

II.- Once the terms granted to correct the anomalies or deficiencies that have been found in the inspections, audits, verifications or recognitions carried out have expired, these have not been properly corrected.

Article 260.- The suspension or cancellation of the licenses, authorizations and permits granted will imply that the Commission orders and executes the security measures referred to in section I of Article 182 of this Regulation regarding the sources or equipment, in which In this case, a record must be drawn up under the terms of Article 244 above.

Article 261.- The cancellation or suspension may be decreed in addition to the fines or without them having been imposed.

Article 262.- As long as an activity is suspended or canceled authorization, permit or license, none of the activities covered by such documents may be carried out or continued.

Article 263.- The suspension of the authorization, permit or license will be lifted when, to the satisfaction of the Commission, it is verified that the causes that motivated it have been corrected.

Article 264.- The application of the sanctions referred to in this Chapter, will be done without prejudice to the civil, criminal and labor liability incurred by the permit holder if damage is caused to people or property.

CHAPTER III
OF THE APPEAL FOR RECONSIDERATION

Article 265.- The resolutions issued based on these Regulations may be appealed within the term of 15 working days following the date of their notification.

Article 266.- The appeal will be directed and presented in writing to the Head of the Secretariat, in which the evidence related to the contested administrative act must be offered. Once the evidence has been submitted and the proceedings ordered have been exhausted, within the following 30 business days, the corresponding resolution will be issued.

Article 267.- The filing of the appeal will only suspend the execution of the appealed resolution, when this implies payment of fines and the affected party guarantees it in accordance with the Fiscal Code of the Federation.

Article 268.- The appeal will be deemed not filed:

I.- When it is presented outside the term referred to in Article 265 of this Regulation;

II.- When the documentation related to the personality of the person who signs it has not been presented or has not been legally accredited, and

III.- When it is not signed, unless it is signed before the expiration of the term to file it.

Article 269.- The resolutions not appealed within the term established in the previous Article 265 and those issued when resolving the appeal or having it not filed, will have the administrative character of final.

Article 270.- Regarding other resolutions, the suspension of the execution of the resolution will only proceed if the following requirements are met:

I.- That the appellant requests it;

II.- That the appeal is appropriate;

III.- That it does not bring with it the consummation or continuation of acts or omissions that imply non-observance or contravention of the provisions of this Regulation and other provisions derived from it;

IV.- That no damages or losses are caused to third parties, unless these are guaranteed in the case of not obtaining a favorable resolution, and

V.- That the execution of the contested resolution produces damages or losses that are difficult to repair.

TRANSIENT

FIRST ARTICLE.- This Regulation will enter into force the day after its publication in the Official Gazette of the Federation.

SECOND ARTICLE.- The Commission will issue the radiological safety standards applicable to the transport of radioactive materials until the respective Transport Regulations are issued.

THIRD ARTICLE.- All those provisions that oppose these Regulations are repealed.

Given at the Residence of the Federal Executive Branch, in Mexico City, Federal District, on the eighth day of the month of November, nineteen hundred and eighty-eight.- Miguel de la Madrid H.- Signature.- The Secretary of the Interior, Manuel Bartlett Díaz.- Signature.- The Secretary of Foreign Affairs, Bernardo Sepúlveda Amor.- Signature.- The Secretary of Programming and Budget, Pedro Aspe Armella.- Signature.- The Secretary of Energy, Mines and Parastatal Industry, Fernando Hiriart Balderrama. - Signature.- The Secretary of Communications and Transportation, Daniel Díaz Díaz.- Signature.- The Secretary of Urban Development and Ecology, Gabino Fraga Mouret.- Signature.- The Secretary of Health, Guillermo Soberón Acevedo.- Signature.- The Secretary of Labor and Social Welfare, Arsenio Farell Cubillas.- Rubric.