RD 1085/2009, of 3rd July, approving the Regulation on Installation and Use of X-ray Apparatus for Medical Diagnosis.

The Royal Decree 1891/1991, of 30th December, regulating the Installation and Use of X-ray Apparatus for Medical Diagnosis purposes served to comply with that provided for in Law 25/1964, of 29th April, on Nuclear Energy, which exempted these apparatus from its authorisation regime and stipulated that they be regulated in a specific regulation, without prejudice that the facilities that use said devices were already subjected, as radiation emitters, to the Regulation on Health Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July.

Since the publication of the Royal Decree 1891/1991, of 30th December, an intense production of related Spanish and international regulations has taken place, a fact that, in addition to the evolution of the sector and the experience gained in the application of the Royal Decree provisions, calls for the full revision of the text of 1991.

In this context, the aim of the present Royal Decree project is to replace the regulation included in Royal Decree 1891/1991, of 30th December, and serves to regulate:

– the use of X-ray apparatus and facilities for medical diagnosis purposes.

– the regime for the preliminary authorisation of companies that sell and service said equipment and facilities.

– the accreditation of personnel that provide services in X-ray medical diagnosis facilities.

– the provision of services and the certification of preliminary characteristics by the Radiation Protection Services or Technical Units.

In the sphere of the European Union, Directive 96/29/EURATOM, of 13th May 1996, laying down basic safety standards for the protection of health of workers and the general public against the risks arising from ionising radiations, included updated criteria from the International Commission on Radiation Protection. Likewise, Directive 97/43/EURATOM, of 30th June 1997, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposures, replaced Directive 84/466/EURATOM.

In order to adapt them, since its remote origins, to the changes in European regulations and the important modifications introduced in Spanish legislation, both the Regulation governing Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3rd December, and modified by Royal Decree 35/2008, of 18th January, and the Regulation on Health Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July, have been published.

For identical reasons, a wide revision of the regulatory developments of the General Law of Health 14/1986, of 25th April, in the sphere of the protection of people against ionising radiations during medical exposures has also taken place, standing out both Royal Decree 1976/1999, of 23rd December, establishing the quality criteria in radiodiagnosis, and Royal Decree 815/2001, of 13th June, on the justification for the use of ionising radiations for the radiation protection of people during medical exposures.

On the other hand, facilities where X-ray equipment for medical diagnosis purposes is used, with the exception of facilities intended for veterinary use, have the status of health centres or establishments, being applicable the provisions of said General Law of Health in reference to the requirements for the approval or authorisation of the facilities and equipment of said centres and establishments.

Royal Decree 1891/1991, of 30th December, entailed a revolutionary change in the medical radiodiagnosis sector, by introducing from scratch a statutory declaration and registration system supported by the intervention of entities accredited to provide specialised services, all of it without prejudice to the basic criterion of the Law 25/1964, of 29th April, on Nuclear Energy, of the unequivocal responsibility of the owner of the facility. Together with the Regulation governing Nuclear and Radioactive Facilities, said model entails the fulfilment, as far as the administrative intervention regime is concerned, of that stipulated by Directive 96/29/EURATOM.

For practical purposes, a register has been constituted where all X-ray facilities for medical and veterinary diagnosis in Spanish territory are registered, of which only a few hundreds had obtained in the past an authorisation, not intended for them, as radioactive facilities, and a large group of companies selling or servicing X-ray equipment have been authorised, being the only companies allowed to carry out these activities. This new regulation keeps both elements, introducing some improvements in the procedures for the registration of facilities and for the authorisation of companies selling or providing technical assistance and specifies the

competences and responsibilities of the latter. In addition, the new revision includes a chapter intended to regulate the operation of X-ray facilities for medical diagnosis, which requires implementing a Radiation Protection Programme, the detailed model of which is provided, which will ensure the enhancement of the radiological safety of these facilities and a greater commitment of the owners to this matter.

Royal Decree 1891/1991, of 30th December, also placed emphasis on the training of the personnel that manage X-ray medical diagnosis facilities and of those who take part in their operation, it having been necessary to recognise, according to the established procedure, some minimum requirements in radiation protection to said personnel according to their level and specialty, regardless of their professional training in the techniques applied. Such recognition has materialised in specific credentials granted directly by the Nuclear Safety Council to several tens of thousands of professionals. All this is maintained in this new drafting without any noticeable alteration.

On the other hand, the provisions relating to Radiation Protection Services and Technical Units of the Regulation on Health Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July, which transposes the reference to qualified experts of the Directive 96/29/EURATOM, have had their own expression in the application of Royal Decree 1891/1991, of 30th December, on the Installation and Use of X-ray Apparatus for Medical Diagnosis, by being entrusted with the certification of certain radiological parameters required for the registration and subsequent operation of the facilities. As a result of this, the Nuclear Safety Council has had to authorise a substantial number of such Services and Units, the object of which has been in many cases reduced to medical radiodiagnosis. The revision of said Royal Decree 1891/1991, of 30th December, affords the opportunity to carry out a regulation of the work of these entities in the field of medical radiodiagnosis complementary to that established in the mentioned Regulations on Nuclear and Radioactive Facilities and on Health Protection against Ionising Radiations.

The regulation of the activities related to the use of X-ray devices for medical diagnosis has also determined a new regulatory practice, on which the General Administration of the State, the Autonomous Communities and the Nuclear Safety Council converge and from which has been derived a knowledge that allows to improve the efficiency of the rule. In this sense, the present drafting systematises and specifies the functions attributed to the different Administrations and clarifies the relations between them.

Finally, this new regulation entrusts the Nuclear Safety Council the detailed definition of models and forms to simplify and standardise the expected communications between the licensees of the regulated activities and the Administration and expresses the interest that such communication be made preferably through telematic channels to make them easier for both parties.

The rule being approved stems from an initiative of the Nuclear Safety Council. For its preparation, the Autonomous Communities have been consulted and the sector has been listened.

This provision is announced under the exclusive competences that Rules 16 and 25 of Article 149.1 of the Spanish Constitution ascribe to the State with regard to the bases and general coordination of public health and to the bases of the mining and energy regime, respectively. With regard to this matter, it is worth indicating that, due to the content of its provisions, the Law is not a perfect instrument and its approval by means of a Royal Decree is warranted.

By virtue of it, at the suggestion of the Minister of Industry, Tourism and Trade and the Minister of Health and Social Policy, with the prior approval of the Minister of the Presidency, in accordance with the Council of State and after the deliberation of the Council of Ministers in their meeting dated 3rd July 2009,

I HEREBY DECREE:

Sole Article. *Approval of the Regulation on the Installation and Use of X-ray Apparatus for Medical Diagnosis.*

The Regulation on the Installation and Use of X-ray Apparatus for Medical Diagnosis, the text of which is included below, is approved.

First Additional Provision. *Other legal and statutory provisions.*

a) With regard to the protection of the health and safety of workers, the rules included in Law 31/1995, of 8th November, on the prevention of occupational risks, and in its statutory rules shall apply without prejudice to the more specific provisions on radiation protection included in this Royal Decree and in the Regulation on Health Protection against Ionising Radiations.

b) With regard to the approval and authorisation of facilities and equipment in health centres and establishments, the rules included in the General Law of Health 14/1986, of 25th April, and in its statutory rules shall apply.

c) With regard to the conditions and requirements applicable to the manufacture, import, clinical research, distribution, marketing, placement into service, dispensation and use to X-ray medical radiodiagnosis equipment that are considered health products, the rules included in the Law 29/2006, of 26th July, on the guarantees and rational use of medicines and health products, and in its statutory rules shall apply.

d) That established in the present Royal Decree applies without prejudice to that stipulated in the Royal Decree 1976/1999, of 23rd December, laying down the quality criteria in radiodiagnosis.

Second Additional Provision. *Updating of references.*

1. The general references to the precepts of Royal Decree 1891/1991, of 30th December, included in Articles 6.1 and 15.1 and in the Fifth Additional Provision of Royal Decree 1976/1999, of 23rd December, laying down the quality criteria in radiodiagnosis, shall be understood as carried out according to the present Royal Decree.

2. The reference to the 4th Technical Specification of Annex I of Royal Decree 1891/1991, of 30th December, included in Article 7.2 of Royal Decree 1976/1999, of 23rd December, shall be understood as carried out according to Article 18.d) of the present Royal Decree.

First Transitory Provision. *Permit, record, registration and credential validity regime.*

a) All permits, records and registrations of X-ray medical diagnosis facilities issued up to the date of the entry into force of the present Royal Decree are maintained, by virtue of that established in the Royal Decree 1891/1991, of 30th December, on the installation and use of X-ray devices for medical diagnosis, in the same terms and conditions that when they were granted or registered.

b) The credentials to manage the operation of X-ray medical diagnosis facilities and to operate the existing equipment, which were granted according to the rules in force prior to the entry into force of the present Royal Decree, will maintain their validity.

Second Transitory Provision. *Period for the implementation of the Radiationl Protection Programme for already registered facilities.*

X-ray medical diagnosis facilities that appear as registered in the corresponding Register of X-ray medical diagnosis facilities when the present Royal Decree comes into force shall have one year to prepare and implement the Radiation Protection Programme referred to in Article 19 of the Regulation that is being approved.

Sole Repealing Provision. *Statutory repeal.*

Royal Decree 1891/1991, of 30 December, on the installation and use of X-ray devices for medical diagnosis is repealed.

First Final Provision. *Title of competence.*

This Royal Decree is announced under that stipulated in Articles 149.1.16 and 149.1.25 of the Spanish Constitution, which ascribe the exclusive competence on the bases and general coordination of public health and on the bases of the mining and energy regime respectively to the State.

Second Final Provision. *Authorisation for regulatory development.*

The Minister of Industry, Tourism and Trade, the Minister of Health and Social Policy and the Minister of Labour and Immigration may pass, within the scope of their competences, the appropriate provisions for the development and application of the present Royal Decree and of the Regulation that is approved thereby.

Third Final Provision. *Development and application of the precepts.*

1. The Nuclear Safety Council is authorised to develop models and forms of the reports and documents that, by virtue of the provisions of this Royal Decree, must be sent to it, which must be preferably provided in electronic format such that the provisions of both Royal Decree 772/1999, of 7th May, and Royal Decree 209/2003, of 21st February, on the telematic relationship with the Administration, may be complied with.

2. The Nuclear Safety Council may pass instructions, circulars, guides or technical standards to facilitate the application of the Regulation that is approved by this Royal Decree.

Fourth Final Provision. *Entry into force.*

The present Royal Decree shall come into force on the day following that of its publication in the "Official State Gazette".

In Madrid, on the 3rd of July of 2009.

KING JUAN CARLOS

The First Vice President of the Government and Minister of the Presidency,
MARÍA TERESA FERNÁNDEZ DE LA VEGA SANZ

REGULATION ON THE INSTALLATION AND USE OF X-RAY APPARATUS FOR MEDICAL DIAGNOSIS

CHAPTER I

General provisions

Article 1. *Object and scope of application.*

The aim of the present regulation is to regulate:

a) The use of X-ray devices and facilities for medical diagnosis purposes, including medical-legal and veterinary uses.

b) The regime of preliminary authorisation which the activities of selling and maintaining those facilities and equipment are subjected to.

c) The accreditation of personnel that provide their services in X-ray medical diagnosis facilities.

d) The provision of services and the certification of technical characteristics by Radiation Protection Services or Technical Units.

Facilities comprising particle accelerators, X-ray equipment for therapy and other ionising radiation-generating equipment used for medical purposes not included in the preceding paragraph shall be governed by that generally established for radioactive facilities in the Regulation governing Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3rd December, and modified by Royal Decree 35/2008, of 18th January.

Article 2. *Definitions.*

The following definitions are set for the purposes of this Regulation:

a) X-ray equipment: Electrical equipment comprising a voltage generator and one or more X-ray tubes. When intended for the diagnosis of human beings, it is regarded as active health product.

b) Fixed X-ray equipment: Equipment used in a stationary manner in premises or vehicles.

c) Mobile X-ray equipment: Equipment that is susceptible of being moved to the places where its use is required.

d) X-ray medical diagnosis facility: The X-ray equipment and the premises or vehicles where it is used.

e) Owner of an X-ray facility for medical diagnosis purposes: The physical or legal person that runs the facility.

f) Sale: The introduction in the market of new or used X-ray equipment for either final users or intermediaries.

g) After-sales service: Any activity of installation, assembly and preventive or corrective maintenance of X-ray medical diagnosis equipment as well as of dismantling and destruction of equipment.

Article 3. *Authorities and competences.*

Without prejudice to the rightful functions of the Health Authority, the application of the precepts of this Regulation is incumbent on the Ministry of Industry, Tourism and Trade, the Autonomous Communities and the Nuclear Safety Council, within the scope of their competences and according to the following terms:

a) The competent bodies of the Autonomous Communities shall carry out the registration of X-ray medical diagnosis facilities in their corresponding register, the keeping of the latter and the authorisation, after a favourable report from the Nuclear Safety Council, of the X-ray equipment retail and after-sales service companies. These authorisations, which shall be appear in the corresponding central register, shall be valid in the entire Spanish territory in accordance with the data that are included in it.

b) The Ministry of Industry, Tourism and Trade shall keep the central registers of X-ray medical diagnosis facilities and retail and after-sales service companies.

c) The Nuclear Safety Council is competent to authorise Radiation Protection Services and Technical Units and to recognise the appropriate radiation protection knowledge to manage and operate X-ray medical diagnosis facilities.

Article 4. *Coordination of registers.*

The Ministry of Industry, Tourism and Trade and the competent bodies of the Autonomous Communities shall exchange the data from their respective registers on a six-month basis in order to keep them updated. The Ministry of Health and Social Policy and the Nuclear Safety Council shall receive on a six-month basis an updated copy of the central registers of X-ray facilities for medical diagnosis purposes and retail and after-sales service companies.

Article 5. *Reporting, inspection and control activities of the Nuclear Safety Council.*

The reporting, control and inspection activities that are incumbent on the Nuclear Safety Council in relation to the application of this Regulation shall be conducted according to the terms and conditions that are set for such activities in Law 15/1980, of 22nd April, creating the Nuclear Safety Council, modified by Law 33/2007, of 7th November, amending the Law 15/1980, of 22nd April, creating the Nuclear Safety Council

Article 6. *Responsibility of the owner of an X-ray facility for medical diagnosis purposes*.

The owner of an X-ray medical diagnosis facility shall be responsible for its operation in safe conditions in accordance with that stipulated in this Regulation and in the Regulation on Health Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July.

Article 7. *Requirements of the equipment.*

Only X-ray medical diagnosis equipment that meets that stipulated in Royal Decree 414/1996, of 1st March, on health products, may be marketed and put into service; it must have a certificate of conformity as a health product and display the CE marking that guarantees it fulfils the essential requirements applicable to it.

X-ray veterinary diagnosis equipment shall be subjected to the industrial quality system; it must display the CE marking that proves this.

CHAPTER II

Of retail and after-sales service companies

Article 8. *Regulated activities.*

1. Without prejudice to the fulfilment of the duties established in the Regulation on health products, any action related to the sale and after-sales servicing of X-ray medical diagnosis facilities and equipment, including its import, must be carried out by companies or entities authorised for this purpose.

2. Any legal act, such as an exchange, cession, renting or the like, whereby a diagnosis facility is handed over a piece of X-ray equipment shall be considered, even among individuals, a sale for the purposes of this Regulation.

3. The manufacture of X-ray equipment for medical diagnosis purposes, except that exclusively intended for veterinary use, shall be exempt from the authorisation regime established in Article 74 of the Regulation governing Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3rd December, and modified by Royal Decree 35/2008, of 18th January.

4. The operation of X-ray equipment for medical diagnosis purposes aimed at its adjustment, testing or calibration outside registered X-ray medical diagnosis facilities shall require having a radioactive facility authorised according to that stipulated in the Regulation governing Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3rd December, and modified by Royal Decree 35/2008, of 18th January. To this end, and in accordance with Section 3 of the aforementioned Article 74, the companies or entities who intend to carry out this activity in addition to selling and servicing may request a single authorisation.

Article 9. *Authorisation.*

1. The companies or entities that wish to obtain the authorisation which Section 1 of the preceding Article refers to must submit a request to the competent body of the Autonomous Community where they are located; they have to list in a detailed manner the activities for which

it is requested and submit as much documentation as possible proving their technical capacity to carry them out, which shall at least include the following information:

a) The identification of the Company or Entity: trade name, tax identification number and address.

b) A list of the activities to be carried out, expressly specifying whether their object is selling, after-sales servicing, or both at the same time, and, where appropriate, importing.

c) The experience of the Company or Entity's personnel in activities of the same nature.

d) The Company or Entity's personnel organisational structure and rules of operation.

e) A list of the technical staff personnel, including their degrees, qualifications and professional experience.

f) A list of the facilities, equipment and material means the company or entity has to carry out its activities.

g) Where appropriate, a procedure to assure the radition protection of workers that will be exposed because of the tasks to be carried out.

2. Following a report from the Nuclear Safety Council, which shall be binding in the sense of Article 2.b) of the Law 15/1980, of 22nd April, creating the Nuclear Safety Council, modified by the Law 33/2007, of 7th November, amending the Law 15/1980, of 22nd April, creating the Nuclear Safety Council, the competent body of the Autonomous Community shall pass the appropriate resolution.

3. The modification of the activities carried out by retail and after-sales service companies or of their ownership shall require obtaining an authorisation by means of the same procedure.

4. The body that granted the authorisation shall be notified of any change of address or cessation of activities within 30 days from the date when it effectively occurred, who shall pass the corresponding resolution.

5. A copy of the previous resolutions shall be sent to the Nuclear Safety Council immediately afterward.

Article 10. *Registration in the register.*

The Autonomous Communities shall inform the Ministry of Industry, Tourism and Trade of the resolutions they issue according to that provided for in the preceding Article in order to be included in the "Register of companies that sell and service X-ray medical diagnosis equipment and facilities".

Article 11. *Duties associated with the authorisation.*

The authorisation as a retail and after-sales service company entails the following duties for its owner:

a) Conforming to the conditions required in each case and maintaining that specified in the documentation that was submitted to obtain said authorisation.

b) Complying, where appropriate, with the duties that the Regulation on Health Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July, assign to the owners of the facilities in relation to the radiation protection of exposed workers and the public, and in particular with:

1st. The general principles and dose limits established under its Heading II.

2nd. The measures for exposure prevention and radiation and dose monitoring established under its Heading IV.

c) Carrying out the sale of X-ray equipment for medical diagnosis purposes to intermediaries only if they have the corresponding authorisation as a retail and after-sales service company.

d) Envisaging in the contracts of sale to X-ray medical diagnosis facilities the possibility that the declaration which Article 12 of this Regulation refers to is rejected, in which case the retail company must again take charge of the equipment.

e) Registering all operations of selling, after-sales servicing and returning the equipment involved in failed declarations as well as of entry and destiny of equipment removed from X-ray medical diagnosis facilities.

f) Delivering sold equipment to the owner of an X-ray medical diagnosis facility with an acceptance test certificate according to that established in Article 11.5 of Royal Decree 1976/1999, of 23rd December, whereby the quality criteria in radiodiagnosis are established.

g) Performing a calibration after any intervention in or repair of a piece of X-ray equipment for medical diagnosis purposes in accordance with Article 15.2 of Royal Decree 1976/1999, of

23rd December, and documenting it in a certificate of restitution to the operating conditions prior to the breakdown.

h) Keeping, for a minimum period of five years, a copy of the issued certificates, the acceptance tests of sold equipment, the after-sale service operations and the certificates of equipment destruction.

i) Sending to the Nuclear Safety Council, during the first quarter of every calendar year, a report covering the previous year, the content of which shall consist of:

1st. A record of the sales that have been conducted, including the name of the owner, the identification of the facility, the location and the identity of the equipment.

2nd. A list of the procedures for assembling X-ray equipment and the quality control procedures that are performed to assure its radiological safety.

3rd. A copy of the certificates of acceptance of the conducted tests.

4th. A record of the corrective and preventive maintenance operations that are carried out, indicating the personnel that perform them, the identity of the facility and the identification of the affected equipment.

5th. An updated list of the technical personnel that provide services in the technical assistance activities.

6th. A summary of the results of the contracted dosimetry service relating to the monthly dose, the annual cumulative dose and the dose accumulated in a period of five consecutive years for each of the company's exposed workers.

7th. An updated list of the equipment and tools the company has to carry out its activities.

8th. The programmes for checking and controlling the equipment that is used in the assembly and technical assistance operations and the certificates providing evidence of said checks or calibrations in the appropriate cases.

9th. A copy of the certificates of equipment destruction.

CHAPTER III

Procedure for the declaration and registration of X-ray medical diagnosis equipment and facilities

Article 12. *Declaration of facilities*.

1. Before they are commissioned, X-ray medical diagnosis facilities must be declared by their owners to the competent body of the Autonomous Community where the facility is located. To this end, they must submit the following documents by using the forms in the Annexes of the present Regulation:

a) The declaration of the owner on the expected uses of the facility and its expected operating conditions. Annexes I.a) and I.b).

b) The certification of the retail and after-sales service company that supplied the equipment assuring the latter meets the requirements of Article 7 of the present Regulation. Annex II.

c) A certification, in accordance with the model included in the Annex III, issued by a Radiation Protection Service or Technical Unit ensuring that the shielding and layout of the rooms that make up the facility are suitable for the equipment they house, according to the estimated workload thereof and the areas adjoining said rooms.

2. If the competent body of the Autonomous Community were to consider that the submitted documentation is incomplete, wrong or inaccurate, it shall notify the owner that has submitted the declaration of this within one month in order for the latter to make up for the observed deficiencies within 15 days. If this period elapses without the owner having proceeded to the correction, the owner shall be notified that the declaration has not been verified and that the registration of the facility in the register which Article 15 refers to does not apply. A copy of said notification shall be sent to the Nuclear Safety Council.

3. The owner of the facility that has not been registered according to that provided for in the preceding paragraph shall be obliged to return the equipment to its supplier, it being otherwise subject to the consequences that are regulated in Chapter VI of the present Regulation.

4. If a period of one month, provided for in Section 2 of the present Article, elapses without the correction having been made, it shall be understood that the declaration has been entered in the register of the Autonomous Community which Article 15 refers to.

5. Once the X-ray medical diagnosis facility has been registered, the competent body of the Autonomous Community shall notify this to the owner that submitted the declaration in writing within one month.

Article 13. *Declaration of modification and cancellation of facilities*.

The change of the equipment or the inclusion of additional equipment, generators or tubes, the change of location of the facility and the modification of the general layout thereof with regard to the declaration in force shall require to undergo a declaration and registration procedure, relating to the altered aspects, similar to that established in the preceding Article.

Article 14. *Change of ownership and notification of cessation*.

The competent body shall be notified within 30 days of a change in ownership as well as of a cessation of activities. In order so that this notification may result in the removal from the register, it must be accompanied by documentation that provides evidence of the destiny given to the equipment.

Article 15. *Registration.*

1. The declarations shall be entered in the "Register of X-ray medical diagnosis facilities" attached to the competent body of the Autonomous Community where the facility is located.

2. All declarations shall be entered in the "Central register of X-ray medical diagnosis facilities" attached to the Ministry of Industry, Tourism and Trade. This registration shall be made from the communications carried out by the Autonomous Communities according to that established in Article 4 of this Regulation.

3. Without prejudice to that established in Article 4 of this Regulation, the competent body of the Autonomous Community shall send to the Nuclear Safety Council on a monthly basis a copy of the declarations registered the previous month as well as of the notifications of cessation of activity and change of ownership registered in said period.

The updating of the records of a given facility will be done without modifying the registration number of the facility.

Article 16. *Specification of the design of facilities.*

The design of X-ray medical diagnosis facilities must coherently conform to the standards of a renowned Spanish or international regulatory system. Said point shall be expressly indicated in the certification of conformity of the project included in the declaration.

CHAPTER IV

Operation of X-ray medical diagnosis facilities

Article 17. *Classification of X-ray medical diagnosis facilities.*

For the purposes of the application of the requirements included in Article 18 of this Regulation, X-ray medical diagnosis facilities are classified into the following three types:

1. Facilities with CAT scan, interventional radiology, mammography, surgical and mobile equipment.
2. Facilities with general, veterinary and non-intra-oral dental diagnosis equipment.
3. Facilities with intra-oral dental or chiropodial diagnosis and bone densitometry equipment.

Facilities that fall into types 2 and 3 shall be classed as type 1 when they have any of the equipment included in the definition of type-1 facilities.

Article 18. *Duties of the owner of the facility.*

The owner has the following duties:

a) Maintaining that specified in the declaration that was used for the initial registration and in the declarations of subsequent registered modifications that faithfully represents the current state of the facility in the Register.

b) Defining and implementing a Radiation Protection Programme.

c) Without prejudice to that stipulated in Article 16 of Royal Decree 1976/1999, of 23rd December, laying down the quality criteria in radiodiagnosis, a copy of the documentation submitted in the declaration, the certificates of the initial acceptance tests of the equipment, the worksheets and the certificates of calibration after any intervention in or repair of the equipment and the records indicated in Section 4 of Article 19 of the present Regulation must be kept. The records and documentation relating to the equipment must be kept for as long as it remains in the facility; those relating to the facility, until it is deregistered.

d) Carrying out, at least annually and whenever the typical work conditions are modified or any irregularity affecting radiation protection is detected, the monitoring of radiation levels at workstations and in adjoining areas accessible to the public by means of a Radiation Protection Service or Technical Unit, which shall issue a certificate with the results obtained.

e) Obtaining, with the periodicity indicated below, a certificate of conformity of the facility, issued by a Radiation Protection Service or Technical Unit, that states that:

1st. The material characteristics included in the current registration of the facility in the Register of X-ray medical diagnosis facilities are still the same.

2nd. The Radiation Protection Programme of the facility is complied with, indicating the deviations observed, if any.

f) Facilities belonging to type 1 of Article 17 must obtain the previous certificate on a yearly basis, facilities belonging to type 2 on a biennial basis, and facilities belonging to type 3 on a five-year basis.

g) The owners of facilities belonging to types 1 and 2 of Article 17 shall send to the Nuclear Safety Council on a yearly basis and a biennial basis respectively a report whose content shall consist of:

1st. The certificate of conformity required in the preceding Paragraph e) for the indicated period.

2nd. The certificates of calibration after the interventions in or repairs of the equipment carried out in the period.

3rd. A summary of the dosimetry of the exposed personnel that provide their services in the facility.

4th. The results from the annual verifications of radiation levels at workstations and in adjoining areas accessible to the public.

h) The owners of facilities belonging to type 3 of Article 17 are obliged to have registers where the information indicated in the preceding Paragraph g) is included and have them at the Nuclear Safety Council inspection's disposal at least for a period of ten years.

i) In all cases, the periods shall be calculated by calendar year, and the report corresponding to each period shall be sent during the first quarter of the next period.

Article 19. *Radiation Protection Programme.*

It shall be mandatory to implement in all X-ray medical diagnosis facilities a Radiation Protection Programme in which the operational aspects applicable to Medical radiodiagnosis facilities provided for in the Regulation on Radiation Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July, will be developed. The purpose of this Programme will be to assure that the doses that workers and the public might receive are kept at levels as low as reasonably possible and that, in any case, they stay below the dose limits set by the law, specifically considering the situations of pregnant women, people in training and students. The development and implementation of the Radiation Protection Programme are understood without prejudice to the owner's duty to apply the entirety of the provisions of said Regulation on Radiation Protection against Ionising Radiations.

The Radiation Protection Programme shall be in written form, kept updated, prepared before the commissioning of the facility and remain at all times subject to control and inspection by the Nuclear Safety Council. Since the Radiation Protection Programme required in the preceding paragraph and the Quality Assurance Programme required in Article 2 of the Royal Decree 1976/1999, of 23rd December, have some aspects in common, a single document where both Programmes are included may be drafted in order to prevent duplications and simplify the documentation required of the owners of medical radiodiagnosis facilities.

The Radiation Protection Programme must envisage at least the following measures:

1. Preventive measures:

a) A preliminary assessment of work conditions to determine the nature and magnitude of the associated radiological risk.

b) A classification of work areas taking into account the yearly doses susceptible of being received in said areas and the physical barriers, if any, available to assure a proper control of the access thereto.

c) A demarcation and signposting of work areas such that the exposure risk existing in them becomes evident.

d) Establishing the necessary physical and/or administrative means so that the access to the controlled area when the X-ray equipment is in operation is restricted to the exposed workers assigned to the facility, who must have previously received the necessary training to perform their work.

e) A radiological classification of exposed workers into categories A or B according to the conditions in which their work takes place and the doses they might receive as a result thereof.

f) Establishing work rules and procedures adapted to the radiological classification of the different work areas and the workers that perform their work activity in them. These Rules must be in written form and known and followed by all facility personnel.

g) Initial and periodic training and education of exposed workers in relation to the radiological risks associated with their work and to the rules and procedures to be applied for the proper performance thereof.

2. Control measures:

a) Controlling the quality of the equipment according to that established in the Royal Decree 1976/1999, of 23rd December, whereby the quality criteria in radiodiagnosis are established.

b) Controlling the operating time. When the equipment is not running, it must remain under safe conditions such that it cannot be started or operated by unauthorised personnel.

c) Control by means of the distance to the source:

1st. Whenever it is necessary to immobilise a patient due to the characteristics of the diagnosis with ionising radiations, the immobilisation shall be done by using the appropriate mechanical restraints. Should this not be possible, the immobilisation shall be carried out by means of the voluntary help of one or several persons? Under no circumstances shall minors or expectant mothers be among them.

Those persons that take part in the immobilisation of the patient in radiodiagnosis health care units, which shall always be as few as possible, shall receive precise instructions so as to reduce their exposure to radiation to the minimum, try at all times not to be exposed to the direct beam and wear the appropriate personal protective clothing. If there are no volunteer personnel available, the immobilisation shall be carried out by exposed workers; rotating shifts shall be established.

2nd. In intra-oral dental diagnosis facilities, radiographic exposures shall be conducted at a minimum distance of two metres from the X-ray emitting tube. When done from inside the room, the control knob for carrying out the exposures shall have an extension cable at least two metres long, and the operator shall be protected by means of a lead apron or the like. In the exceptional case the intended aim of the exploration is compromised with such procedure, the operator shall use additional protective items specific for the existing situation. The holding of the radiographic plates shall be done by the patient himself or by means of mechanical means.

3rd. In veterinary radiography, methods for sedating or mechanically restraining the animal must be encouraged. When this is not possible, it shall be necessary for all personnel that must remain in the room to wear suitable protective clothing such as lead gloves or aprons.

d) Using fixed or mobile shielding.

e) Using personal protective equipment (such as lead aprons, gonad shields or lead glass goggles). To this end:

1st. Facilities must have suitable protective clothing for operator use or, if necessary, patient protection. Said clothing must be available in sufficient number to allow the simultaneous use thereof according to the needs of the facility.

2nd. In interventional radiology, operators shall wear suitable protective clothing such as aprons, thyroid shields, lead glass goggles and lead surgical gloves provided the intended aim of the exploration is not compromised. Whenever it is possible, scan times shall be minimised by using the proper techniques. Likewise, suitable protection, such as fixed or mobile protective shields for the table and lead visors for intervention personnel, shall be used to avoid scattered radiation.

3. Monitoring measures:

a) The radiological monitoring of the work areas in order to verify that their radiation levels are inside the characteristic values of their radiological classification and to verify the suitability of the protective measures applicable to the workers that carry out their activities in said areas. To this end, the owner shall carry out, at least annually and whenever the typical work conditions are modified or any irregularity affecting radiation protection is detected, the monitoring of radiation levels at workstations and adjoining areas accessible to the public by means of a Radiation Protection Service or Technical Unit.

b) The dose monitoring of exposed workers:

1st. The dose monitoring of the exposed workers of the facility shall be performed and the corresponding dose histories shall be kept updated.

2nd. The doses received by exposed workers shall be determined on a monthly basis, and the reading of the dosimeters used for such purpose shall be done by Personal Dosimetry Services expressly authorised by the Nuclear Safety Council.

3rd. The use of area dosimetry devices to estimate the doses received by exposed workers classed as belonging to category B will only be admissible when the systematics used and the associated dose assignment procedure are included in a written protocol that shall be subject to evaluation and inspection by the Nuclear Safety Council. Said systematics must envisage the determination of doses on a monthly basis.

4th. In interventional radiology, an estimation of the doses that operators might receive in their extremities and crystalline lens depending on the type of intervention and the workload derived from it shall be carried out.

c) The monitoring of the health of exposed workers:

1st. A health control of the exposed workers of the facility shall be carried out and the corresponding case histories shall be kept updated.

2nd. The health control of workers shall be conducted in accordance with that established in Chapter IV of Heading IV of the Regulation on Radiation Protection against Ionising Radiations, such that the specific provisions of said Regulation shall apply to category-A workers and that established in the Law 31/1995, of 8th November, on the prevention of occupational risks, and the regulations that develop it shall apply to category-B workers, the specific health monitoring protocols drawn up by the proper authority being used to perform said controls.

4. Administrative measures:

a) Registering and filing the results obtained from the dose monitoring of exposed workers.

b) Registering and filing the results obtained from the radiological monitoring of the facility.

c) Registering and filing the activities for the initial and periodical training of exposed workers that have been carried out.

d) Establishing a protocol for action in the event the legal dose limits are exceeded.

e) Establishing, if appropriate, a specific protocol for action for calculating the doses by means of area dosimetry.

Article 20. *Assignment of Radiation Protection functions.*

Without prejudice to their unequivocal responsibility, the owners of radiodiagnosis facilities that do not have their own Radiation Protection Service may hire, in accordance with Article 23 of the Regulation on Health Protection against Ionising Radiations, a Radiation Protection Technical Unit to give them specific radiation protection advice and to be entrusted with the fulfilment of the duties that fall on them indicated in Article 18.

Article 21. *Removal of equipment.*

The destiny of equipment placed out of service due to its defective state, a modification of the facility or the removal of the latter from the Register may only be the transfer to an entity authorised for the sale and after-sales servicing to either be stored and subsequently disposed of or be destroyed.

The destruction of out-of-service equipment must be carried out by an entity authorised as a retail and after-sales service company, who shall give the owner of the X-ray medical diagnosis facility the corresponding certificate.

Article 22. *Training of personnel that operate X-ray medical diagnosis facilities.*

1. The operation of an X-ray medical diagnosis facility must be managed by doctors, dental surgeons or veterinary surgeons or by those graduates which the Second Additional Provision of Royal Decree 1132/1990, of 14th September, whereby the fundamental measures for the radiation protection of people subjected to medical examinations and treatments are established, refers to who have both the proper knowledge on the design and use of the equipment, on the associated radiological risk and on the safety and radiation protection means that must be put in place and training and experience in these areas.

2. When the operation of X-ray equipment is not to be directly carried out by the graduate managing the operation of the facility but by personnel under his/her supervision, the latter must also be qualified for this purpose.

3. The person accredited according to Article 23 of the present Regulation to manage the facility shall supervise the compliance with the Radiation Protection Programme.

4. The performance of both the personnel managing the operation of the facility and the personnel running the equipment present in it must follow the work procedures mentioned in Article 19.1.

Article 23. *Proof of training.*

In order to guarantee that stipulated in the preceding Article:

a) Graduates that manage the operation of X-ray facilities for medical diagnosis purposes and operators of the equipment that act under the supervision of the former must prove their knowledge, training and experience regarding radiation protection to the Nuclear Safety Council, submitting to this end as much supporting documentation as they deem appropriate.

The Nuclear Safety Council shall examine the submitted documentation and may conduct as many checks as it deems appropriate, issuing the corresponding credentials when the capacity of the interested party has been sufficiently demonstrated in its opinion.

b) Those who pass the courses set up to this end by the Nuclear Safety Council will be accredited for the purposes of that stipulated in the preceding Paragraph a).

For these same purposes, the Nuclear Safety Council may officially approve academic programmes and specific training and advanced courses covering the subjects imparted in the courses which the preceding paragraph refers to.

c) The credentials granted by the Nuclear Safety Council in application of the two preceding paragraphs will be granted for the sole purpose of acknowledging the training in radiation protection, without prejudice to the degrees and requirements that might be required in each case in the professional sphere and because of the techniques applied.

CHAPTER V

Of the Radiation Protection Services and Technical Units that provide their services in X-ray medical diagnosis facilities.

Article 24. *Regulated activities.*

1. The owners of X-ray medical diagnosis facilities may entrust, at the Nuclear Safety Council's request or on their own initiative, their duties as regards radiation protection to a specialised unit owned by them, obtaining for the latter an authorisation as a Radiation Protection Service.

2. In accordance with that established in the Regulation on Radiation Protection against Ionising Radiations, approved by Royal Decree 783/2001, of 6th July, and the Regulation governing Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3rd December, and modified by Royal Decree 35/2008, of 18 January, the provision to third parties of specialised services as regards radiation protection with public transcendence, and in particular the execution of the certifications envisaged in Articles 12.1.c), 18.d) and 18.e) of this Regulation, shall require having an authorisation as a Radiation Protection Technical Unit.

The contracts for the provision of services that Technical Units formalise with owners of facilities must be established in writing and shall express the acceptance on the part of those who sign it that the former must inform the Nuclear Safety Council of the circumstances adverse to safety which they have knowledge of during the performance of their functions.

Technical Units may not have an interest through their executives or their personnel in or be partially owned by entities that own or carry out any type of industrial or commercial activity

whose purpose may be the object of the certifications with regard to radiation protection recognised by the Administration to them.

3. The activities of Radiation Protection Services and Technical Units regarding their performance in X-ray medical diagnosis facilities shall be regulated according to that provided for in this Regulation.

Article 25. *Authorisation.*

The companies or entities that wish to obtain the Radiation Protection Technical Unit authorisation and the owners that intend to avail themselves of a Radiation Protection Service must make a request to the Nuclear Safety Council, listing in a detailed manner the activities for which it is requested and submit as much documentation as possible proving their technical capacity to carry them out, which will at least cover the following issues:

a) The identification of the company or entity: trade name, tax identification number and address.

b) A list of the activities to be carried out.

c) The number of technical personnel, indicating their degree, qualification and professional experience, and including at least one candidate for obtaining the Head of Service certificate granted by the Nuclear Safety Council.

d) A description of the facilities, equipment and material means it has.

e) A Radiation Protection Handbook that includes the procedures for the execution of all the activities that are going to be carried out.

f) A Quality Assurance Programme.

Article 26. *Of the personnel of Radiation Protection Services and Technical Units.*

Radiation Protection Services and Technical Units shall be managed by a Head of Service accredited by the Nuclear Safety Council, as established under Heading V of the Regulation governing Nuclear and Radioactive Facilities. The candidates that are proposed to be accredited as Heads of Service in facilities located in health care centres or establishments must also comply with that established in the Third Additional Provision of the Royal Decree 183/2008, of 8 February, whereby Health Sciences specialties are determined and classified and certain aspects of the specialised health training system are developed. Likewise, they shall have a staff of technicians that are experts in radiation protection, in proportion to the volume of activities assumed and certified according to the Nuclear Safety Council's Instruction IS-03, of 6 November 2002, on the qualifications for obtaining the recognition as expert in protection against ionising radiations.

The relationship of dependency between the Service or Unit and the aforementioned technical personnel shall appear in writing, and the Nuclear Safety Council will be notified in a maximum period of one month of the number of people from the staff that join and leave thereit.

In view of the activity reports, the Nuclear Safety Council may request a justification of the sufficiency of the number of technical personnel of the Service or Unit and, if appropriate, a proposal for its revision.

Article 27. *Duties of the Head of Service.*

Without prejudice to the duties established by the Regulation on Radiation Protection against Ionising Radiations, it is the job of the Head of Service that manages the Radiation Protection Service or Technical Unit to:

a) Take responsibility with his/her signature for all certifications issued by the Service or Unit.

b) Take responsibility with his/her signature for the reports sent to the Administration and to the owners of the X-ray medical diagnosis facilities which he provides his/her services to.

c) Keep the registers.

d) See to it that the radiation protection handbook and the Quality Management Programme are complied with and take responsibility for their updating.

e) Certify the qualifications of expert technicians and see to it that they are maintained and updated by programming their ongoing training.

Article 28. *Duties of Radiation Protection Services and Technical Units.*

Radiation Protection Services and Technical Units shall have the following duties:

a) Conforming to the conditions included in their authorisation and maintaining that specified in the documentation submitted to obtain it.

b) Having at least one person with a Head of Service certificate. The lack of a Head of Service disqualifies from the exercise of the acknowledged competences.

c) Recording all their operations and keeping the records. The record keeping period shall be that established by the applicable statutory provision or, failing that, that determined by their Quality Management Programme.

d) Sending the Nuclear Safety Council, during the first quarter of every calendar year, a report from the previous year, the contents of which shall contain:

1st. The activities carried out.

2nd. The state and resources of the unit or service.

3rd. A summary of the results of the contracted dosimetry service relating to the monthly dose, the annual cumulative dose and the dose accumulated in a period of five consecutive years for each of the exposed workers of the service or unit.

e) Informing the owner of the facility of all technical or administrative actions that it carries out by virtue of the duties that have been entrusted to them.

f) Informing the owner of the facility of the circumstances adverse to safety which they have knowledge of during the execution of its functions and proposing to it the corrective measures it deems appropriate.

g) Informing the Nuclear Safety Council of the failure to implement at the proper time the corrective measures which the preceding Paragraph f) alludes to and providing it and the proper authorities as many information and reports are requested of it in relation to its actions.

CHAPTER VI

Sanctioning system

Article 29. *Infractions and sanctions.*

Without prejudice to the civil liabilities, criminal responsibilities or the like the licensees of the activities regulated in the present Regulation might incur in, the failure to observe that stipulated in the present Regulation shall constitute the infractions provided for in the Law 25/1964, of 29 April, on nuclear energy, in the drafting given in the Law 33/2007, of 7 November, reforming the Law 15/1980, of 22 April, creating the Nuclear Safety Council.

ANNEX I.a

DECLARATION OF THE OWNER FOR REGISTRATION
(Owner)

DATA OF THE FACILITY
OWNER'S NAME:
TAX IDENTIFICATION NUMBER:
TEL/E-MAIL:
ADRESS:
POSTCODE:
TOWN/CITY:
PROVINCE:
NAME OF THE FACILITY:
(If different from the owner's)
ADDRESS FOR NOTIFICATION:
(If different from the facility's)

OBJECT OF THE DECLARATION
New facility
Modification of a facility already registered as ……. [code]
Deregistration of a facility already registered as ..... [code]

ACTIVITY OF THE FACILITY
General radiology
Intra-oral dental radiology
CAT scan
Veterinary radiology
Chiropodial radiology
Interventional radiology
Panoramic dental radiology
Radiology for bone densitometry
Surgical radiology
Mobile equipment
Other (specify)
Mammography

PROVIDED DOCUMENTATION
Basic information of the project and drawings of the facility
Certification of conformity of the equipment, signed by the RASSC
Certification of conformity of the facility, signed by the RPS/RPTU

In ……., on ……. of ……..…… of 20…..

[Signature]

[Name of the Owner or his/her representative]

The data contained in this form, needed to carry out the competences of the Ministry of Industry, Tourism and Trade, the Ministry of Health and Social Policy, the Autonomous Communities and the Nuclear Safety Council, will be processed by computer; the data shall be subjected to that established in the Organic Law 15/1999, of 13 December, on the protection of personal data.

ANNEX I.b

DESCRIPTION OF THE PROJECT AND DRAWINGS OF ROOMS OR VEHICLES

EXPOSED WORKERS:
Name, job and Spanish Identity Document of the certified Director:
Number of certified operators:
Number of exposed workers classed as A ..... and b .....
Number of contracted dosimeters: area ....., film badge ....., other .....

RADIOLOGICAL EQUIPMENT (for each System or each Generator-Tube assembly):
Equipment No.
(no. given in Annex II.2)
Type of equipment
(fixed, portable, gate, mobile vehicle)
Type of table
(fixed, remote control, dental chair, etc.)
Imaging system
(card/film, with intensifier, with RVG, Digital CR, Digital DR, etc.)

DRAWINGS AND CONSTRUCTION CHARACTERISTICS OF ROOMS OR VEHICLES:

[A 1:50 scale drawing of each room shall be attached; if there are several rooms, another smaller-scale drawing of the whole shall be attached]

The following shall be specified:
- The exact location of the equipment (generators and tubes) and each of their components (tables, buckys, supports, monitors, etc.) and that of the control station.
- The location of area dosimeters, if any.
- All the dimensions of the rooms.
- The use of each of the adjoining upper, lower and side areas (home, waiting room, street, etc.).
- The thickness and construction materials of each of the structural barriers and doors.
- The thickness of other fixed or portable shielding (control windows, partitions, etc.).
- The number, thickness and materials of the existing protective clothing (aprons, gloves, goggles, etc.).

The data contained in this form, needed to carry out the competences of the Ministry of Industry, Tourism and Trade, the Ministry of Health and Social Policy, the Autonomous Communities and the Nuclear Safety Council, will be processed by computer; the data shall be subjected to that established in the Organic Law 15/1999, of 13 December, on the protection of personal data.

ANNEX II

CERTIFICATE OF CONFORMITY OF THE EQUIPMENT FOR REGISTRATION (RASSC)

DATA OF THE FACILITY

OWNER'S NAME:
TAX IDENTIFICATION NUMBER:
TEL/E-MAIL:
ADRESS:
POSTCODE:
TOWN/CITY:
PROVINCE:
NAME OF THE FACILITY:
(If different from the owner's)

INFORMATION OF CONFORMITY

I, Mr. ....., in my capacity as Head of the RPS/RPTU, for the purpose of registering the facility,
CERTIFY:

- That the equipment acquired by the owner of the aforementioned facility is the following: (1)

EQUIPMENT No.
MAKE
MODEL
SERIAL NUMBER

(1) Specify Generators and Tubes separately, and in the case they are part of a complete integrated system, indicate its name also.

- That the origin of this equipment is:
A new acquisition
The transfer from another facility already registered as ……. [code]

- That this equipment complies with the legal requirements needed for it to be entered in the Register of medical diagnosis facilities.

- That a technical data sheet is attached to this Certificate for each piece of equipment and its components.

- That all the documentation provided in relation to the equipment corresponds to the specific equipment to be supplied and installed.

In ……., on ……. of ……..…….. of 20…..

[Name of the RASSC's representative]

The data contained in this form, needed to carry out the competences of the Ministry of Industry, Tourism and Trade, the Ministry of Health and Social Policy, the Autonomous Communities and the Nuclear Safety Council, will be processed by computer; the data shall be subjected to that established in the Organic Law 15/1999, of 13 December, on the protection of personal data.

ANNEX III

CERTIFICATE OF CONFORMITY OF THE FACILITY FOR REGISTRATION (RPS/TRPS)

DATA OF THE FACILITY

OWNER'S NAME:
TAX IDENTIFICATION NUMBER:
TEL/E-MAIL:
ADRESS:
POSTCODE:
TOWN/CITY:
PROVINCE:
NAME OF THE FACILITY:
(If different from the owner's)

INFORMATION OF CONFORMITY

I, Mr. ....., in my capacity as Head of the RPS/RPTU, for the purpose of registering the facility,
CERTIFY:

• That the arrangement of the equipment and its components and the structure shielding of the rooms, bearing in mind their adjoining areas, is appropriate for assuring that the doses to the public and exposed workers are below legal limits, considering an average workload of ..... mA.min/week per piece of equipment.
• That the Project of the facility has been developed using the following standards/guides/technical codes (UNE, ISO, DIN, IEC, NCRP, GSN 5.11, ICRP, etc.).
• That the equipment to be installed has the documentation proving it meets the legal requirements needed for it to be registered.
• That the owner has prepared and documented a Radiation Protection Programme for the operation of the facility.
• That a written contract with the owner has been established and that by means of it the legal duties relating to the definition and implementation of the **Radiation Protection Programme** and the sending of the **Periodical Report** to the **CSN** [have been transferred/have not been transferred] to this RPTU. (1)
• That the **classification** of exposed workers has been carried out.
• That the **dosimetry** of workers will be [personal/area] dosimetry and that it has been contracted with the Centre……
• That the personnel that manage and operate has **credentials** from the CSN to this end.
• That the precautions included in the project relating to radiological safety and protection have been included in the construction and assembly of the facility.

(1) Epigraph not applicable to certificates issued by a RPS

The data contained in this form, needed to carry out the competences of the Ministry of Industry, Tourism and Trade, the Ministry of Health and Social Policy, the Autonomous Communities and the Nuclear Safety Council, will be processed by computer; the data shall be subjected to that established in the Organic Law 15/1999, of 13 December, on the protection of personal data.

In ……..., on ……. of ……..…….. of 20…..

[Signature]

[Name of the Head of the RPS/RPTU]