III. OTHER PROVISIONS

THE NUCLEAR SAFETY COUNCIL

15594

The Nuclear Safety Council's Instruction IS-28, of 22nd September 2010, on the technical specifications that second- and third-category radioactive facilities must observe.

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, confers on this Public Body the faculty to "prepare and approve Instructions, Circulars and Guides of a technical nature relating to nuclear and radioactive facilities and nuclear safety- and radiological protection-related activities".

The aspects included in Article 7 of Royal Decree 1836/1999 approving the Regulation On Nuclear and Radioactive Facilities must figure in the authorisations granted by the Ministry of Industry, Tourism and Trade or the competent body of the corresponding Autonomous Community – in the case the functions and services with regard to second- and third-category radioactive facilities have been transferred to the latter – following the Nuclear Safety Council's mandatory report. Sections j) and k) of said Article 7 concern the limits and conditions as regards radiological protection and safety as well as other conditions that might apply to each case.

The approval of this Instruction arises from the need to develop the aspects contained in said Sections j) and k) as well as to regulate and unify the criteria applied by the Nuclear Safety Council when requiring the radiological protection and safety limits and conditions to which the operation of second- and third-category radioactive facilities must be subjected and which up to now were being included in the authorisations thereof on a case by case basis.

Some of these specifications refer to regulatory aspects required by current legislation as regards radiological protection and safety and are included in the present Instruction in order to highlight the most relevant aspects for the safe operation of the facilities. Other specifications concern more technical issues that depend on the activity carried out and the radioactive material and/or equipment being used at each facility.

The experience accumulated over more than thirty years of application of the licensing regime envisaged in Law 25/1964, of 29 April, on Nuclear Energy for radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes, which was initially developed in the Regulation On Nuclear and Radioactive Facilities from 1972 and given continuation on successive revisions thereof, has allowed to correctly define the technical requirements applicable to the operation of those facilities that guarantee an appropriate level of radiological protection and safety and ensure that licensees prepare and, where appropriate, send to the competent bodies the reports and records needed for the proper exercise of the control function assigned to those bodies in the legislation currently in force.

By means of means of the present Instruction, the technical specifications on radiological protection and safety which are required of second- and third-category radioactive facilities are made public.

By virtue of all the above and in accordance with the legal authorisation envisaged in Article 2, Sections a) and j), of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, prior consultation of the affected sectors and after the appropriate technical reports, this Council, in its meeting of 22nd September 2010, has agreed the following:

First. *Object and Scope of Application.*—The purpose of the present Instruction is to establish the technical specifications as regards radiological protection and safety to which the operation of second- and third-category radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes must be subjected.

Second. *Definitions.*—The definitions of the terms and concepts used in the present Instruction match those contained in the following legal documents:

Law 25/1964, of 29th April, on Nuclear Energy.

Law 15/1980, of 22nd April, creating the Nuclear Safety Council.

Royal Decree 1838/1999, of 3rd December, approving the Regulation On Nuclear and Radioactive Facilities.

Royal Decree 783/2001, of 6th June, approving the Regulation on Sanitary Protection against Ionising Radiations.

Royal Decree 229/2006, of 24th February, on the Control of Sealed, High-Level Radioactive Sources and Orphan Sources.

Third. *Fields of Application.*—For the purposes of the practical application of this Instruction, the following fields of application are established for facilities:

Nuclear Medicine.—Facilities where unsealed radioactive sources are applied for patient diagnosis or therapeutic purposes.

Radiotherapy.—Facilities where the ionising radiations from a generating device or a radioactive source – usually sealed – are used for therapeutic purposes.

Laboratories with unsealed sources.—Facilities other than Nuclear Medicine facilities where unsealed radioactive material is handled.

Industrial Radiography and Gammagraphy.—Facilities where equipment that generates radiation or is equipped with sealed radioactive material – fixed or portable – is used in non-medical radiography or radioscopy.

Other fields of application:

a) Soil testing using nuclear moisture-density gauges .

b) Industrial processes control with sealed radioactive sources.

c) Industrial processes control with X-rays.

d) Instrumental analysis (spectrometry and fluorescence).

e) Commercialisation and Technical Assistance.

There might be other fields of application not specifically contemplated in this Instruction to which the latter shall apply depending on the radioactive material or equipment the facility is provided with to carry out its activity.

Fourth. *Radiological protection and safety technical specifications.*—In the present Instruction, radiological protection and safety technical specifications are organised into the following three Annexes:

Annex I.—Regulatory and generic specifications that are applicable to and binding on all radioactive facilities regardless of their field of application.

Annex II.—Technical specifications organised according to the characteristics of the facility:

A. Facilities where unsealed radioactive material is produced, used, owned, processed, handled or stored.

B. Facilities where sealed sources are produced, used, owned, processed, handled or stored.

C. Facilities where radioactive or radiation generating equipment is produced, used, owned, processed, handled or stored.

D. Facilities with shielded enclosures.

E. Facilities with mobile radioactive equipment.

Annex III.—Technical specifications applicable to specific practices:

A. Positron Emission Tomography (PET).

B. Therapy with unsealed radioactive material.
C. Brachytherapy.
D. Industrial Radiography and Gammagraphy.
E. Industrial processes control with radioactive sources.
F. Soil testing using nuclear moisture-density gauges.
G. The commercialisation or Technical Assistance of radioactive or radiation generating material or equipment.

According to its field/s of application, the licensee of the radioactive facility shall be obliged to observe, in addition to the specifications included in its Authorisation Resolution, the appropriate technical specifications of Annex I and the appropriate technical specifications of Annexes II and III according to the characteristics of the facility and the activities carried out therein, in accordance with that stated in the following Section.

Fifth. *Distribution of technical specifications by field of application.*—In order to make it easier to observe the present Instruction in practice, the radiological protection and safety technical specifications of second- and third-category radioactive facilities are established, organised by field of application.

If more than one field of application is implemented at the radioactive facility, all specifications corresponding to each field of application must be observed. In addition, the specifications corresponding to the main field/s of application to which the facility is dedicated and all those specifications included in Annexes II and III that might be applicable to it according to the different activities that might take place therein and the radioactive materials and/or equipment that might be available shall have to be observed in each case.

In all those facilities where, regardless of their field/s of application, there are non-excepted sealed radioactive sources for calibration or verification purposes, the specifications included in Annex II (Section II.B) applicable to said sources must be observed.

1.1. Field of application of Nuclear Medicine.

All specifications included in Annex I.

Section II.A of Annex II in all cases and, in addition, Section II.B if there are sealed radioactive sources in the facility, Section II.C if there is radioactive or radiation generating equipment in the facility, and Section II.D if there are shielded enclosures in the facility.

Section III.A of Annex III if positron emission tomography (PET) activities take place in the facility, and Section III.B of the same Annex if therapeutic activities with unsealed radioactive material take place in the facility.

1.2. Field of application of Radiotherapy.

All specifications included in Annex I.

Section II.B of Annex II if there are sealed sources in the facility.

Section II.C of Annex II if there is radioactive equipment and/or radiation generating equipment.

Section II.D of Annex II when there are shielded enclosures for housing radiation emitting sources and/or equipment.

Section III.C of Annex III when Brachytherapy activities take place in the facility.

1.3. Field of application of Laboratories using unsealed radioactive sources.

All specifications included in Annex I.

Section II.A of Annex II.

1.4. Field of application of Industrial Radiography and Gammagraphy.

1.4.1. Fixed Industrial Radiography and Gammagraphy.

All specifications included in Annex I.

Sections II.B (Gammagraphy) and II.C of Annex II in all cases and, in addition, Section II.D if the facility has a shielded enclosure.

1.4.2. Mobile Industrial Radiography.

All specifications included in Annex I.

Section II.C of Annex II in all cases and, in addition, Section II.E, which applies to mobile equipment.

1.4.3. Mobile Gammagraphy.

All specifications included in Annex I.
Sections II.B and II.C of Annex II in all cases and, in addition, Section II.E pertaining to mobile equipment.
Section III.D in all cases.

1.5. Field of application of Soil testing using nuclear moisture-density gauges.

All specifications included in Annex I.
Sections II.B and II.C of Annex II in all cases and, in addition, Section II.E pertaining to mobile equipment.
Section III.F in all cases.

1.6. Field of application of Industrial processes control with sealed radioactive sources.

All specifications included in Annex I.
Sections II.B and II.C of Annex II in all cases.
Section III.E in all cases.

1.7. Field of application of Industrial processes control with X-rays.

All specifications included in Annex I.
Section II.C of Annex II.

1.8. Field of application of Instrumental Analysis (Spectrometry/Fluorescence).

All specifications included in Annex I.
Section II.C of Annex II.

1.9. Field of application of Commercialisation or Technical Assistance.

All specifications included in Annex I.
Section II.A of Annex II if unsealed radioactive sources are stored or handled, Section II.B if sealed radioactive sources are stored or handled, and Section II.C if radioactive or radiation generating equipment is stored or handled.
Section III.G of Annex III.

Sixth. *New practices, singular facilities and specific requirements.*—The specifications applicable to new practices with radiations or to singular facilities that cannot be classed as being part of any of the fields of application defined above, as well as the specific requirements for facilities placed within them, shall be established in the licence proper.

Seventh. *Infractions and sanctions*.—The present Nuclear Safety Council Instruction is binding in accordance with that established in Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, such that the failure to comply with it shall be punished in accordance with the provisions of Articles 85 to 93 of Law 25/1964, of 29th April, on Nuclear Energy.

First Additional Provision.

This Instruction shall be applicable to all second- and third-category radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes that obtain an operating licence from the moment the latter comes into force, as well as to facilities already in operation, in all aspects that do not oppose the current Authorisation Resolutions of said facilities; otherwise, the content of said Resolutions shall prevail.

Second Additional Provision.

The Nuclear Safety Council may send the pertinent complementary instructions directly to facility licensees in order for them to better observe and verify the safety conditions of the radioactive facility.

Sole Repealing Provision.

Any rule of equal or lower level that opposes the present Instruction is repealed.

Sole Final Provision.

The present Instruction shall come into force on the day following that of its publication in the “Official State Gazette”.

In Madrid, on the 22nd of September of 2010.—Carmen Martínez Ten, the President of the Nuclear Safety Council.

ANNEX I

Regulatory and Generic Specifications

I.1 The areas of the facility shall be signalled in accordance with Annex IV of the Regulation on Sanitary Protection against Ionising Radiations.

I.2 The dose control and health monitoring of the exposed workers of the facility must be carried out and the corresponding dose and medical records must be kept updated in accordance with that established in Title IV of the Regulation on Sanitary Protection against Ionising Radiations.

The licensee of the facility shall arrange personal dosimetry with a Personal Dosimetry Service expressly authorised by the Nuclear Safety Council.

Health monitoring shall be conducted by Occupational Risk Prevention Services that perform the function of monitoring and controlling worker’s health or by authorised, Specialised Medical Services.

I.3 Within the first quarter of every calendar year, the licensee of the facility shall send to the Directorate-General of Energy Policy and Mines or the executive body of the Autonomous Community that authorised the facility and to the Nuclear Safety Council a yearly Report, in accordance with Article 73.2a) of the Regulation On Nuclear and Radioactive Facilities, where a summary of each of the Operation Logs available at the facility during the previous year, the inventory of radioactive equipment and materials present at the facility – indicating their location and operating state – and the statistical results of the dose controls performed on facility personnel during said period are included.

I.4 Radioactive equipment and material may only be purchased from entities authorised to sell them in Spanish territory. Should the licensee import them directly, the legally established formalities must be followed.

The transfer of radioactive equipment and/or materials between authorised facilities shall be subject to that established in the Regulation On Nuclear and Radioactive Facilities.

Shipments of radioactive material from or to member countries of the European Union may only be carried out after the requirements set in the Regulation EURATOM 1493/1993 are fulfilled.

I.5 The licensee must have those of the following documents that are applicable to it:

The certificates approving the design of the prototypes corresponding to radiation emitting equipment or, failing that, the mandatory documentation that is equivalent in the country of origin.

The CE marking and, in the case of equipment for medical use, the CE declaration of conformity as a health product, in accordance with Directive 93/42/CEE.

The equipment quality control certificate.

The certificates of sealed radioactive sources in accordance with Standard ISO 2919/1999.

The certificates of unsealed radioactive sources in accordance with Standard UNE 73310/1999 or its equivalent Standard ISO 3925.

The certificates of approval of sources as special form radioactive material, when this is required by transport regulations.

The certificates approving the containers used for the transport of radioactive equipment or material as type B(U) package models and their validation in Spain, when this is required by transport regulations.

The documents proving that the design of the transport package fulfils the applicable provisions, when this design does not require a certificate of approval from the competent authority.

The operating manuals and maintenance programmes of the radioactive or radiation generating equipment.

The certificates of the removal of radioactive equipment or material.

Pictures of high-level sources, their containers and packaging for transport, and the equipment where they will be encased, in accordance with Royal Decree 229/2006.

I.6 The radiation monitoring of the facility shall be conducted by means of suitable radiation/contamination detectors.

A programme for calibrating and checking radiation detection and measurement systems shall be set up taking into account aspects such as the manufacturer's recommendations, the recommendations from the calibration laboratory that conducts the calibrations, the results of the periodic checks, the range and severity of usage, the environmental conditions, the expected measurement accuracy, etc. The recommendations contained in Standard UNE EN 30012-1 or its equivalent Standard ISO 10012-1 may be taken as the basis for setting up this programme.

The programme of periodic calibrations and checks, as well as the criteria applied when setting it up, shall be reflected in a procedure. Calibrations shall be carried out by a legally accredited laboratory.

I.7 The personnel of the facility shall know and observe that established in the Operating Handbook and the On-Site Emergency Plan thereof.

Every two years, the licensee shall require all exposed workers of the facility to take part in a training programme on radiological protection at a level appropriate to their responsibility and to the risk of exposure to ionising radiations of their job, where sessions relating to the content of the aforementioned documents, their practical application and, where appropriate, the execution of emergency drills shall be included. Records of the training programs given, their contents and the people that take part in them shall be kept.

I.8 An Operation Log must be kept, in accordance with that established in Articles 69, 70 and 71 of the Regulation On Nuclear and Radioactive Facilities, where the following data shall be recorded:

Relevant data of the operation of the facility, including, where appropriate, the shifts of supervisors and operators, any type of incident that takes place in the facility, and the name and signature of the supervisor in charge.

Purchases, removals and transfers of radioactive equipment and material, discharges of radioactive effluents, and storage and disposal of solid radioactive waste.

I.9 The licensee must keep records, which might be included or referred to in the Operation Log, of the following aspects that might be applicable to it:

The inventory of radioactive equipment and material.

The results of the calibrations and checks on radiation detection and measurement equipment.

The results of the checks on radioactive equipment safety systems.

The results of the tests to ascertain the tightness of sealed radioactive sources.

The data relating to the control of radiation and contamination levels at the premises of the facility.

The checks on the suitability of the biological shielding and safety systems of the facility under normal operating conditions.

The replacement of sealed radioactive sources, indicating the destination of disused sources and the origin of the new ones.

The maintenance operations on radioactive equipment, or their accessories, that affect radiological safety. The authorised entity or persons that carry them out.

The plan for the continuous training of the operations personnel of the facility, its contents and the people that take part in it.

Emergency drills.

Dosimetry.

I.10 Documents and records of radioactive facilities shall comply with that established in the Nuclear Safety Council's Instruction IS-16, of 23rd January 2008, regulating the periods which the documents and records of radioactive facilities must remain filed for (BOE No 37, 12th February 2008).

I.11 Radioactive equipment and materials must remain duly controlled at all times so as to prevent their possible handling by unauthorised personnel; to this end, the facility shall be fitted with means guaranteeing the security of the facility.

I.12 In case of any event entailing radiological risks for exposed workers or members of the public, the On-Site Emergency Plan shall be applied.

As for the notification of and reports on what happened, the provisions of the Nuclear Safety Council's Instruction IS-18, of 2nd April 2008, on the notification of radiological events and incidents (BOE No 92, 16th April 2008), shall be followed.

I.13 The licensee shall be responsible for the presence of fire extinguishing means in the rooms intended for the storage of radioactive material, which shall be located in easy-to-reach places and must be operational at all times; all personnel shall know how to use them. There shall be no flammable or explosive products inside radioactive equipment or material storage enclosures.

I.14 The transfer of radioactive material between the premises that make up the facility shall be done with the supervisor's prior knowledge and must be carried out with the appropriate radiological protection and safety measures according to the type of radioactive material to be moved and on the basis of the route to be taken, the presence of people not belonging to the radioactive facility being taken into account. The control of all radioactive material and waste of the facility will fall under the supervisor's responsibility.

I.15 The transport of radioactive material throughout Spanish territory shall be carried out in accordance with Law 25/1964 on Nuclear Energy and the applicable regulations on the transport of dangerous goods by road, rail, sea and air.

I.16 In order to transport radioactive material, the civil liability for the nuclear damages that might be caused by the activity must be covered in the terms established in the applicable specific regulations.

ANNEX II

Specifications applicable according to the Characteristics of the Facility.

II.A *Facilities where unsealed radioactive material is produced, owned, processed, handled or stored*

II.A.1 Unsealed radioactive sources must be identified in accordance with Standard UNE 73310 or its equivalent Standard ISO 3925.

II.A.2 The facility must be fitted with systems suitable for the management and temporary storage of radioactive waste.

II.A.3 The management of solid waste materials with radioactive content shall be carried out in accordance with the provisions of the Ministry of Economy's Ministerial Order of 21st May 2003 and the CSN's Safety Guide 9.2.

The collection of solid waste materials which must be managed as radioactive waste due to their activity concentrations or levels shall be agreed with an authorised entity.

II.A.4 The licensee must be expressly authorised before disposing of radioactive effluents from the facility, in accordance with to that envisaged in Article 51 of the Regulation on Sanitary Protection against Ionising Radiations.

Controlled discharges of liquid radioactive effluents into the public sewer system must fulfil the following requirements:

The material released shall be in water-soluble form or easily dispersible biological material.

The activity concentration at the end point of discharge into the general sewer system shall not exceed, in each discharge, the concentration levels obtained by dividing the limits of intake by ingestion for the "older than 17 years-old" age group by the yearly water ingestion rate for an adult individual (600 l).

If more than one radionuclide is discharged, the sum of the fractions obtained by dividing the concentration value of each radionuclide by the corresponding concentration level shall not exceed one.

The total activity of radioactive material discharged into the public sewer system in one year shall not exceed 10 GBq of 3H and 1 GBq of 14C; the sum of the activities of the other radionuclides shall be below 1 GBq.

II.A.5 The radiological monitoring of contamination must be carried out, the absence of surface contamination at the end of the workday being ensured, for which the facility shall be fitted with equipment of the appropriate type and sensitivity. For those radionuclides for which detection by direct measurement with the monitors available at the facility is not feasible, indirect methods (frotis) must be used.

II.A.6 Means suitable for the radioactive decontamination of people and surfaces must be available. The location of the means and instructions of use must be known by all facility personnel.

II.A.7 Those rooms where radioactive gases or aerosols might be produced there will be equipped with an appropriate ventilation system, which must be kept operational at all times.

II.B Facilities where sealed sources are produced, used, owned, processed, handled or stored

II.B.1 Sealed radioactive sources must meet the marking requirements included in Standard ISO 2919:1999 (E).

II.B.2 In accordance with the CSN's Safety Guide 5.3, tests guaranteeing the tightness of sealed radioactive sources and the absence of surface contamination shall be conducted by an authorised entity with a periodicity no greater than one year, with the exception of the following cases (these exceptions do not apply to high-level sources):

Static sources included in fixed equipment, the tests on which shall be conducted with a periodicity no greater than two years.

Sources included in disused equipment, the tests on which shall be conducted when said equipment is to be returned to operation.

Sources that are replaced in periods of time greater than one year and shorter than two year, in which case a surface contamination absence test shall be conducted upon the source being replaced.

In addition, tightness tests must be conducted after any incident that might affect the integrity of radioactive sources.

II.B.3 Rooms housing sources in gaseous state shall be fitted with an appropriate ventilation system that must be kept operational at all times.

II.B.4 The licensee shall return all disused sources to the vendor, for which it will have to arrange with the latter the appropriate agreements, or transfer them to another licensee authorised to have possession of them. Whenever the previous alternatives are not feasible, the sources shall be transferred to an entity authorised to manage them as radioactive waste. These transfers shall be made without undue delays.

In the case of high-level sealed sources, and in accordance with Royal Decree 229/2006, of 24th February (BOE, 28th February), on the control of high-level sealed radioactive sources and orphan sources, in addition to the previous specifications, the following specifications shall apply:

II.B.5 The licensee shall prepare an inventory sheet on each of the high-level sealed sources available at the facility, where their location and transfers shall be recorded. These sheets shall be in keeping with the model included in Annex II of Royal Decree 229/2006.

The licensee shall send, within the first quarter of each calendar year, a written or electronic copy of these inventory sheets to the Nuclear Safety Council and the Ministry of Industry, Tourism and Trade or the competent body of the corresponding Autonomous Community. Likewise, it shall send an updated copy of the inventory sheets corresponding to the affected sources in the following cases:

Immediately after it is supplied with a new high-level sealed source.

Whenever the usual location of use or storage of the previously declared source is changed (transfers outside the authorised rooms for periods of time greater than seven days (industrial gammagraphy facilities) or storage for periods of time greater than seven days (commercial facilities)).

Immediately after the source is transferred to another licensee authorised to have possession of it, the supplier, or an entity authorised to manage it as radioactive waste.

The licensee must keep the inventory sheets at the disposal of the Nuclear Safety Council Inspection.

II.B.6 The licensee shall verify on a monthly basis that the high-level sealed sources and the equipment that encase them are located in the locations planned for them to be used or stored and in good state, it being obliged to keep a documentary record of these verifications.

II.B.7 The biennial training plan to which Specification I.7 refers to shall include sessions on the safe management of radioactive sources and the possible consequences of the loss of control over them and the way to proceed in each case.

II.B.8 The licensee must set up a financial guarantee to deal with the safe management of disused high-level sealed sources, even in case of insolvency, cessation of activity or any other contingency. This guarantee may consist in an insurance policy, a blocked bank account or any other financial guarantee agreed with a duly authorised financial entity. Publicly-owned facilities (by the State, an Autonomous Community or a local authority) are exempt from setting up this financial guarantee.)

II.B.9 The measures to prevent and ensure the rapid detection of situations entailing the loss, theft and unauthorised use or transfer of radioactive equipment or materials according to that indicated in the documentation on security submitted by the licensee must be kept operational at all times.

II.C *Facilities where radioactive or radiation generating equipment is produced, used, owned, processed, handled or stored.*

II.C.1 The name of the vendor and the basic symbol included in Standard UNE 73-302 shall appear on the outside of the equipment.

Likewise, it shall bear the name of the manufacturer, the model, the serial number, the production date, and the technical characteristics (voltage, current, maximum power) or the maximum authorised radioactive content (nature and activity), as appropriate, in an indelible, accessible and readable manner.

II.C.2 The Technical Assistance of the equipment must be carried out by an authorised entity in accordance with the provisions of the Regulation On Nuclear and Radioactive Facilities.

When the Technical Assistance is to be conducted by a foreign company in Spanish territory, the licensee of the facility shall be responsible for ensuring that the personnel that perform it have the corresponding qualification, for which they must have a certification issued by the manufacturer of the equipment or an equivalent one. Likewise, the licensee shall be responsible for the performance of the operations in accordance with all regulations on radiological protection and safety applicable in Spain. Both points must be expressly established by means of a written contract, which the licensee must have available at all times for it to be reviewed by the CSN.

No radioactive equipment that has been in disuse for over one year may be returned to operation without it having been checked in the last period of six months in order to guarantee that it works properly from the point of view of radiological protection.

II.C.3 In order to proceed to disassemble equipment whose materials may be activated, a plan to manage said waste materials that includes a radiological characterisation study and the planned, subsequent management channels must be in place.

The management of said waste materials may be carried out through conventional channels (declassification) after it has been verified that the technical requirements set by the Nuclear Safety Council have been met and the proper authorisation has been obtained.

II.C.4 When appropriate, the licensee shall have set up the appropriate agreements for returning parts or containers made of depleted uranium to the supplier or manufacturer of origin.

II.D *Facilities with shielded operation enclosures*

II.D.1 Checks of the suitability of biological shielding must be conducted in actual operating conditions of the facility at least once a year. The results shall be recorded and included in the yearly reports.

II.D.2 Periodic checks of the safety systems and signalling of each shielded enclosure must be conducted. A record of the results obtained shall be kept.

II.D.3 Should the conditions of occupation of the rooms adjacent to any of the shielded rooms that house the radioactive or radiation generating equipment change throughout the life of the facility, a safety study that takes the new conditions into account must be previously carried out and reported to the Nuclear Safety Council.

II.E *Industrial facilities with mobile equipment*

II.E.1 During the execution of operations, operators must step up the monitoring of radioactive equipment, for which they must keep at a distance therefrom that allows them to have visual control both during the performance of measurements and in those periods of time when the equipment is not being used by them.

II.E.2 During the execution of operations, radiation levels shall be monitored by using appropriate radiation monitors. Personnel using radioactive equipment must use individual dosimeters.

II.E.3 The dose intensity on the surface of the areas adjacent to both central and temporary radioactive equipment storage enclosures shall be such that these areas are classed as being free-access areas according to the Regulation on Sanitary Protection against Ionising Radiations.

II.E.4 When work with radioactive equipment is to be carried out at the premises of the licensee's customers, appropriate agreements shall be arranged so that the authorised personnel of Nuclear Safety Council have free access thereto.

II.E.5 In radioactive equipment storage enclosures located in places where there are usually no facility personnel, the maintenance of security conditions must be checked at least on a weekly basis. A record of said checks shall be kept, which shall remain at the storage enclosure itself.

II.E.6 In addition to the general Operation Log, one log per piece of equipment shall be kept where the data relating to the operations that are carried out shall be recorded: date, place, involved personnel, and incidents.

In the case the radioactive equipment has to be away for periods of time greater than one working day, it must be accompanied by its Operation Log. Personnel with Operator licence who perform the operations when the equipment is to stay at a different location for long periods of time are allowed to sign its records. In such case, the records must be approved and signed by a Supervisor with a periodicity no greater than three months.

ANNEX III

Specifications Applicable to Specific Practices.

III.A *Positron Emission Tomography (PET)*

III.A.1 Personnel handling radioactive material shall carry, in addition to whole-body dosimeters, ring dosimeters so as to estimate hand doses.

III.A.2 Procedures aimed at reducing radiation doses that might be received by personnel, particularly on the hands, during radiopharmaceutical preparation and injection processes shall be defined. To that end, rotating shifts of the personnel that might take part in the handling of radioactive material must be clearly set up.

III.B *Therapy with unsealed radioactive material*

III.B.1 Patients subjected to treatments with radiopharmaceuticals may leave the hospital when it is possible to assert that, according to the dose rate measured at a distance of one meter, the estimates of the activity that will be eliminated by urine, and the analysis of the specific conditions of the family and social environment of each patient, the yearly dose values established for each group of people of said environment shall not be exceeded. Until then, if radiological conditions require it, the patients shall remain in specially fitted rooms.

III.B.2 Upon leaving the hospital environment, written instructions shall be given to patients subjected to treatments with radiopharmaceuticals and their relatives that shall consider the circumstances of each case and be designed to reduce the radiological risks.

III.C *Brachytherapy*

III.C.1 Suitable radiological protection measures shall be adopted during the preparation and implantation of radioactive sources according to the associated risk. Such measures shall include tracking after every implantation or removal of radioactive material by monitoring the patient, the personnel and the areas involved so as to prevent the loss or misplacement of sources, the movements thereof being recorded.

III.C.2 Personnel preparing and carrying out hand implants shall carry dosimeters suitable for estimating hand doses.

III.C.3 Upon leaving the hospital environment, written instructions shall be given to patients with permanent radioactive source implants and their relatives that shall consider the circumstances of each case and be designed to reduce the radiological risks.

III.D *Industrial Gammagraphy Facilities*

Mobile equipment.

III.D.1 Onsite enclosures for the temporary storage of equipment provided with radioactive material must be in keeping with the provisions of the CSN's Safety Guide 05.14 in this respect.

III.D.2 Whenever there is radioactive equipment in any of the facility's authorised or temporary storages, the latter will be furnished with at least one suitable radiation detector. Likewise, whenever a gammagraphy device is running there must be a radiation detector present.

III.D.3 When gammagraphy devices are used, all exposed workers must carry their personal dosimeter (TLD), a direct-reading diameter (DLD) with an acoustic alarm and, in addition, a piece of radiation detection equipment independent from the DLD.

III.D.4 The licensee must implement the Inspection Programme foreseen in the Operation Handbook of the facility in order to check that radiography operators and their assistants perform their functions fulfilling the requirements established in the conditions of the facility's licence and the operation and emergency procedures included in the facility's Operation Handbook and the Emergency Plan.

III.D.5 The supervisor must plan, in accordance with that foreseen in the Operation Handbook, the different types of work (piping, gas pipelines, spheres, etc.) to be carried out by operations personnel in order to optimise the doses.

III.D.6 The training programme which Specification I.7 refers to may be given by the supervisor of the facility and its content shall be based on that established in the CSN's Safety Guide 5.12 "Validation of Training Courses for Radioactive Facility Supervisors and Operators", for the field of application of industrial radiography.

The credentials proving this training has been received must be submitted together with the application for the renewal of the operator licence.

III.D.7 Records of the aspects listed below shall be kept:

The planning of tasks, doses and the subsequent actions carried out by the supervisor.

The inspections conducted by the supervisor on field gammagraphy operations carried out by operators and assistants. The inspected personnel, the results, and the corrective actions.

The location of mobile equipment at all times, indicating which operations personnel are in charge of the equipment that has been transferred.

III.D.8 Once the risks entailed by the execution of works with mobile gammagraphy equipment are known, the commitment undertaken by the licensee to perform then in safe conditions from the point of view of the radiological protection of the workers of the customer company and the members of the public must be clearly stated. The customer must be informed of its obligation to provide all means necessary for the execution of the works in said safe conditions, in accordance with the provisions of the applicable regulations and the Law for the Prevention of Occupational Risks.

III.D.9 In each of the facility's authorised rooms where there are enclosures for the storage of equipment there will be means to deal with operational accidents with gammagraphy equipment.

III.D.10 Mobile gammagraphy operations shall be carried out by one operator or supervisor accompanied by another person, who may either be licensed personnel (operator or supervisor) or unlicensed personnel who may act as an assistant provided that the fulfilment of the requirements included in the Operation Handbook for this type of personnel is ensured.

III.D.11 When operations are to be carried out inside a customer's bunker, a Safety Study thereof must be conducted that proves that the requirements established in Point 4 of the CSN's Safety Guide 5.14 "Radiological Protection and Safety of Industrial Gammagraphy Radioactive Facilities" are observed, the following considerations being made:

The interlocks of all the accesses of the bunker must physically prevent people from getting inside of it.

In those bunkers whose use is shared with other gammagraphy facilities, it has to be taken into account that the maximum dose outside shall not exceed the fraction of the dose limit for the public – set in the Regulation on Sanitary Protection against Ionising Radiations – corresponding to the amount of time the bunker is used.

In addition, if the estimated duration of the operations is greater than one month, the following information shall be sent to the Nuclear Safety Council before that bunker starts being used:

The address and location of the bunker.

The conclusions of the Safety Study that has been conducted, on the basis of the particular considerations of bunker usage (if any).

The safety devices of that bunker must be checked with a periodicity no greater than three months. Likewise, before the commencement of the activities, the radiation levels outside the bunker shall be measured and its safety devices shall be checked. A record of the results of the checks and measures taken shall be kept.

In the event the estimated duration of the use of said bunker exceeds one year, this enclosure must become part of the facility's authorised premises, for which the appropriate authorisation formalities must be carried out.

If there is Co-60 equipment.

III.D.12 Gammagraphy works with equipment equipped with Co-60 sources shall always be carried out inside shielded enclosures that have the appropriate safety systems, designed and built in accordance with the requirements established in Point 4 of the CSN's Safety Guide 5.14 "Radiological Protection and Safety of Industrial Gammagraphy Facilities".

III.D.13 In order to perform a gammagraphy job outside the premises of the radioactive facility with a piece of equipment equipped with a Co-60 source, the Nuclear Safety Council must be notified at least seven days in advance, where both the justification for the use of said source and the planning made by the supervisor for that specific job – where the radiological protection measures and means to be used as well as the expected doses to the personnel that are going to carry it out shall be established – must be attached to the notification.

Equipment in shielded enclosures.

III.D.14 When accessing any shielded irradiation enclosure after an operation, people must carry a portable radiation detector.

Mobile and Fixed Gammagraphy.

III.D.15 The following must be recorded in the Operation Log of every piece of equipment: the type of operation, the activity of the source, the lengths of exposure, and the doses recorded by direct-reading dosimeters.

III.D.16 Both the areas for storing radioactive equipment and the areas where operations with this equipment take place shall be signalled in accordance with Annex IV of the Regulation on Sanitary Protection against Ionising Radiations. In addition, access to these areas shall be controlled, work areas being cordoned off and marked.

III.E Industrial processes control *with sealed radioactive sources.*

III.E.1 Whenever the radioactive heads of the equipment have to be taken out of their place of operation, they shall be stored in an enclosure authorised for such purpose, where radiation levels shall be measured on a monthly basis. A record of such checks shall be kept, which shall be kept at the storage enclosure itself. Access to said enclosure shall be controlled and the enclosure must be signalled according to regulations.

III.E.2 Operations carried out in the controlled area or affecting radioactive heads must be conducted by personnel with operator or supervisor licence or at least in the presence and under the direction of licensed personnel.

The replacement or removal of the radioactive sources of emitter heads must be performed by an authorised entity.

III.F Soil testing using nuclear moisture-density gauges

III.F.1 The areas where operations with the equipment are carried out shall be signalled in accordance with Annex IV of the Regulation on Sanitary Protection against Ionising Radiations. Likewise, access to these areas shall be controlled, work areas being cordoned off and marked with devices that emit light flashes.

III.F.2 Moisture-density gauges must be checked and subjected to routine maintenance operations with the frequency that is deemed necessary, which shall never exceed six months, in order to ensure that they work properly from the point of view of radiological protection.

The weekly check of the equipment must be carried out by an authorised after-sales service company. It may be conducted by personnel of the radioactive facility having a supervisor or

operator licence when the licensee has procedures approved by the CSN for such purpose. In this case, the equipment must be checked by an authorised entity with a periodicity no greater than two years.

Facility personnel are not allowed to perform any inspection or maintenance operation on the equipment that requires detaching the radioactive source or the probe rod from the piece of equipment. These operations may only be performed by the authorised Technical Assistance company.

(In the case of Troxler equipment having a probe rod, no radioactive piece of equipment may be used if no checks have been conducted on the probe rod or its weld by an authorised entity in the last five years; in the case of equipment belonging to model 2401, in the last two years.)

III.F.3 Onsite enclosures for the temporary storage of equipment provided with radioactive material must be in keeping with that established in the CSN's Safety Guide 5.14 in this respect.

III.F.4 Whenever there is radioactive equipment in any of the facility's authorised or temporary storages, the latter will be furnished with at least one suitable radiation detector. Likewise, whenever a piece of equipment is running there must be a radiation detector present.

III.F.5 Radioactive equipment must remain inside their transport packaging, only being taken out when they are going to be used.

III.G *Commercialisation and/or* Technical Assistance *of radioactive material and/or equipment or radiation generating equipment.*

III.G.1 The sale or distribution of *radioactive material and/or equipment or radiation generating equipment* included in the licence of the commercial facility may only be made to companies or people legally authorised to have possession of and use them. Supplied activities may never exceed those authorised in radioactive facilities.

III.G.2 The licensee shall keep a record of the sales or supplies, Technical Assistance activities, and removals that are carried out (these records can be referenced in or be a part the Operation Log), where the following data must figure:

The date of the operation (supply, assembly and reception by the customer, Technical Assistance, or removal of radioactive or activated material).

The identification of the radioactive equipment or material which is the object of the operation.

The reference of the radioactive facility or, failing that, the name and address of the buyer or user of the radioactive material.

The details of the operation (installation, loading and unloading of radioactive sources, acceptance tests, preventive maintenance, corrective maintenance, management of waste material or sources); likewise, when applicable, its results and the personnel that have carried it out.

III.G.3 The licensee must send to the Nuclear Safety Council within the first ten days of each calendar quarter a report on the sales or supplies, Technical Assistance activities and removals that it has carried out and have taken place during the preceding quarter (Quarterly Report).

III.G.4 The packaging containing the radioactive material shall be marked according to Standard UNE 73-302.

III.G.5 Until the delivery note is not signed by the customer, the commercial facility shall be responsible for the radioactive equipment or material that it supplies.

III.G.6 Licensees of radioactive facilities authorised to commercialize and distribute radioactive material, by acting as senders of the shipments, must guarantee that the necessary personnel and means are available to help the competent authorities to face up to any incident that could take place during transport, in order to comply with that established in Article 4 of Royal Decree 387/1996, of 1st March, approving the Basic Directive of Civil Protection Planning against the risk of accidents in the transport of dangerous goods by road and rail. These capabilities must be maintained whenever the facility is in operation or the transfer of radioactive material to the final recipients or users is taking place; likewise, they will be described and updated in the facility's Emergency Plan.

III.G.7 The information on the persons in charge and the contact phone numbers for transport incidents must be reported to the Nuclear Safety Council's Emergency Room (SALEM) so that this people can be quickly located in the event said incidents occur. This information must be kept permanently updated, SALEM being notified of the changes that take place.

Unsealed radioactive material.

III.G.8 With every unsealed radioactive source, the licensee must provide its customers a certificate whose content is in accordance with Standard UNE 73310 or its equivalent Standard ISO 3925 (E). Likewise, the unsealed radioactive sources that are supplied must be identified in accordance with that required in said Standards (it does not apply to either radiopharmaceuticals or standard sources).

III.G.9 Every consignment of radiopharmaceuticals to be commercialized shall be accompanied by the documentation established by the legislation that regulates them and is applicable thereto. The supplied activity must be shown in Becquerels.

The absence of surface contamination will always be checked in every radiopharmaceutical consignment that is supplied.

III.G.10 The licensee shall establish written agreements with the licensees of the receiving radioactive facilities where the procedures to be followed in relation to the supply of radioactive material and, where appropriate, the collection of handled material shall be included.

III.G.11 Records of the orders and delivery notes – duly filled in and signed by the persons in charge of the consumer centres – must be kept at the facility. In them there will be a section reserved for possible observations by the recipients. In the event such observations have an impact on radiological protection, they must be reflected in the Operation Log and the Yearly Report.

III.G.12 The radionuclide generators that are supplied must be accompanied by the following documentation:

A user manual and the maximum dose intensity in contact with the surface of the generator one meter therefrom.

Information on the decay of the radionuclides present in the column.

The procedure to be followed by the user if he wants to return the used generators to the supplier.

These generators shall bear an accessible and readable label where the maximum activity of the loaded mother radionuclide at the time of its production and the date thereof shall appear, regardless of whether the calibration date and the activity corresponding to that date are shown. Generators shall bear on the outside a mark or label with the name of the vendor .

Sealed sources.

III.G.13 The sealed radioactive sources that are supplied must be labelled and marked, showing at least the information that is indicated in Point 8 of Standard ISO 2919/1999 (E).

III.G.14 The licensee must attach to every source its corresponding certificate as a sealed radioactive source, the content of which shall be in accordance with Point 9 and Annex B of Standard ISO 2919/1999. In the event this certificate is older than 6 months, a recent certificate – issued by an entity recognised for this purpose – proving its tightness and absence of surface contamination must be provided.

Sources for medical implants must be accompanied by the CE marking and the CE declaration of conformity, in accordance with Royal Decree 634/1993, of 3rd March, and Royal Decree 1616/2009, of 26th October.

III.G.15 The commercial facility shall have established the appropriate agreements with the manufacturer or vendor of origin for the return of the disused radioactive sources that it has collected from its customers. When this is not possible, it shall transfer the sources to an entity authorised to manage them as radioactive waste. These transfers shall be made without undue delays.

If in possession of an authorisation for the commercialisation of high-level sealed sources in accordance with Royal Decree 229/2006, of 24th February (BOE, 28th February), on the control of high-level sealed radioactive sources and orphan sources, in addition to the previous specifications, the following specifications shall apply:

III.G.16 Before proceeding to import high-level sealed radioactive sources, the appropriate agreements must be established with the consignee in order to facilitate the direct reception thereof at the radioactive facility of the final holder, and the same will be done to return a source of said characteristics to its country of origin after it is removed. In the event that, due to any exceptional circumstance, the high-level radioactive source or sources must be stored at the premises of the commercial radioactive facility for a period exceeding seven days, the licensee must prepare an inventory sheet on each of the sources, where it shall record its location and

subsequent transfer. These sheets shall be in keeping with the model included in Annex II of the aforementioned Royal Decree 229/2006.

The licensee shall send to the Nuclear Safety Council and the Ministry of Industry, Tourism and Trade or the competent body of the corresponding Autonomous Community a written or electronic copy of those inventory sheets as soon as it receives the high-level source, when it changes its warehouse location and immediately after the source is transferred to other authorised holder, the supplier of origin or a recognised facility.

The licensee must keep the inventory sheets at the disposal of the Nuclear Safety Council Inspection.

III.G.17 Upon the arrangement by the commercial facility of the supply of sealed sources of category 1, in accordance with the IAEA's classification of radioactive sources (Safety Guide RS-G-1.9), the commercial facility shall report the supply to the Nuclear Safety Council, to which it shall send, at least 15 days in advance, a report including exact information on: the activity, nature, and marking of the source, the identification of the receiving facility, the planned place for the reception of said source, the conveyance, the packaging model to be used until installation, and the equipment loading date that is appropriate in each case. Likewise, the loading/unloading procedure shall be included.

III.G.18 With each high-level sealed radioactive source, a picture of its prototype and its usual container shall be provided, and this information shall accompany the source in all of its travels.

III.G.19 Whenever possible, the identification number shall be marked on the source by engraving or embossing. Likewise, the identification number of the source shall be marked on its container; if the container is reusable, it will at least bear the identification, nature and activity of the source.

Radioactive or radiation generating equipment.

II.G.20 The name of the vendor and the basic symbol included in Standard UNE 73-302 shall appear on the outside of the equipment that is supplied.

Likewise, it shall bear the name of the manufacturer, the model, the serial number, and the technical characteristics (voltage, current, maximum power) or the maximum authorised radioactive content (nature and activity), as appropriate, in an indelible, accessible and readable manner.

Equipment with type approval shall be marked and labelled in accordance with its Type Approval Resolution.

III.G.21 The licensee shall keep copies of the Technical Manuals of each piece of equipment supplied in the official language of the State at all times.

III.G.22 The licensee must provide the following documentation to its customers:

a) The certification of approval of the design of the prototype or the equivalent documentation mandatory in the country of origin for the type of equipment that it commercializes.

b) A quality assurance certificate where it is stated that the piece of equipment that is supplied has passed the checks foreseen in the Quality Control Programme.

c) The documents that must accompany the piece of equipment and include the standards that apply to it:

An operation manual, in Spanish.

A full description of the piece of equipment.

A functional description of all safety interlocks and systems.

Instructions of use; the radiological protection measures to be followed by the user under conditions of normal operation and during possible failures that might change its radiological safety.

A maintenance and service programme that includes the periodic checks recommended by the manufacturer in order for the radiological safety of the piece of equipment not to decrease.

d) The CE marking and, in the case of equipment for medical use, the CE declaration of conformity as a health product, in accordance with Royal Decree 1591/2009 or Directive 93/42/CEE, modified by Directive 07/47/CEE.

e) The certificate and information required in its corresponding Type Approval Resolution, when it is a piece of equipment with type approval.

f) The certificate of approval as a type B(U) package model and validation in Spain when required by transport regulations or, where appropriate, a special form radioactive material certificate.

III.G.23 Once the assembly of each piece of equipment has finished, and before it is delivered to the customer, the supplier company must verify the proper operation of the safety interlocks and systems and perform the appropriate acceptance tests aimed at guaranteeing its compliance with the standards that apply thereto. A written record of the performance of said tests must be kept, signed by qualified representatives of both parties.

III.G.24 The licensee shall guarantee its customers the Technical Assistance of the equipment it commercializes.

Every time Technical Assistance activities are carried out on said equipment, the licensee shall issue a certificate where the following shall be included:

The name and address of the user of the piece of equipment.
The identification of the piece of equipment and the elements thereof that are checked.
The identification of the checks that are made.
The obtained results.
The signature of the personnel that have carried them out.

Said certificate must be provided immediately after the work on the piece of equipment in question is deemed completed and handed over.

The loading and unloading of sealed radioactive sources shall be carried out by personnel specially qualified for this purpose.