

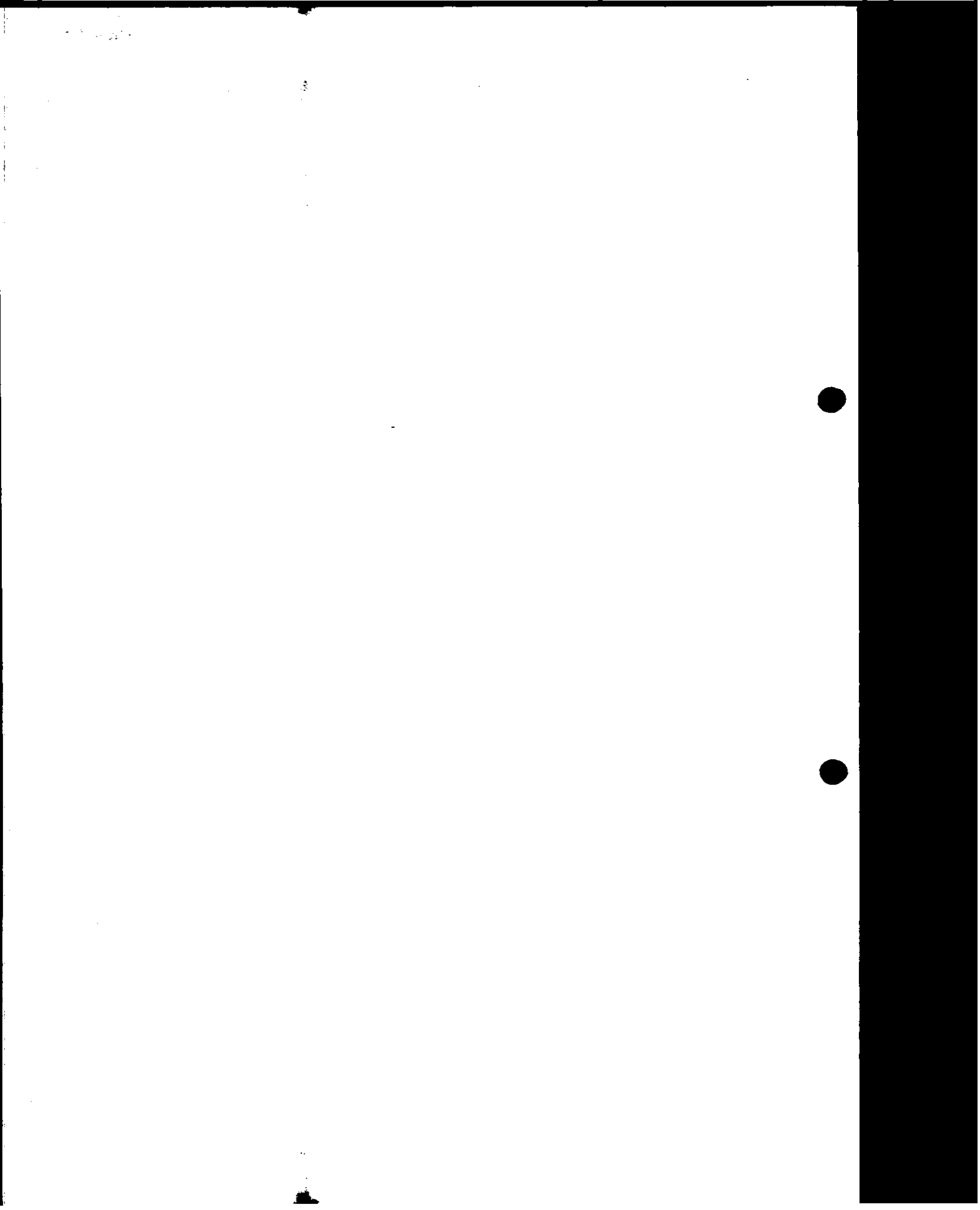
NUCLEAR LAW

Bulletin

S U P P L E M E N T T O N ° 1 2

	<u>Page</u>
1. <u>GERMANY</u> : ORDINANCE CONCERNING PROTECTION FROM DAMAGE BY X-RAYS (X-RAY ORDINANCE)	3
2. <u>FRANCE</u> : DECREE N° 63-1228 OF 11TH DECEMBER 1963 CONCERNING NUCLEAR INSTALLATIONS, AS AMENDED BY DECREE N° 73-405 OF 27TH MARCH 1973	30

November 1973



G E R M A N Y

ORDINANCE CONCERNING PROTECTION FROM DAMAGE BY X-RAYS*

(X-RAY ORDINANCE)

1st March, 1973

(Bundesgesetzblatt 1973, I, p. 175)

PART I

GENERAL PROVISIONS

Section 1. Field of application

(1) This Ordinance applies to X-ray installations and incidental sources of radiation, where X-rays of a threshold energy of not less than 5 keV can be produced by accelerating electrons, and where the electrons cannot be accelerated to an energy greater than 3 MeV.

(2) This Ordinance does not apply to the operation of X-ray apparatus in connection with education in schools, insofar as the schools come under the Second Radiation Protection Ordinance of 18th July, 1964 (Bundesgesetzblatt I, p. 500), as amended by the Second Ordinance amending and supplementing the First Radiation Protection Ordinance of 12th August, 1965 (Bundesgesetzblatt I, p. 759).

Section 2. Definitions

For the purposes of this Ordinance:

1. Occupationally exposed persons means: persons who are normally in a controlled area as a consequence of their employment;

* Unofficial translation prepared by the Secretariat.

2. X-ray installation means: equipment, apparatus or appliances which are operated for the purpose of generating X-rays;
3. X-ray generator means: an X-ray tube and the protective housing of the tube and, in the case of an "all-in-one" unit, the high voltage generator;
4. incidental radiation source means: equipment, apparatus, or appliances in which X-rays are generated, but which are not operated for this purpose;
5. X-ray diagnosis means: fluoroscopy, X-ray photography or other diagnostic methods using X-rays;
6. fluoroscopy means: the irradiation by means of X-rays of a living being, human or animal, or of an object, in order to make its state, condition or functions directly visible;
7. X-ray photography means: the presentation of a living being, human or animal, or of an object by means of X-rays in order to make its state, condition or functions visible for observation at a later time;
8. X-ray treatment means: the irradiation of a living being, human or animal, or of an object in order to affect its state, condition, or functions.

PART II

CONDITIONS FOR USE

OBLIGATION TO HAVE AN AUTHORISATION

Section 3. Authorisation to operate X-ray installations

- (1) Any person operating an X-ray installation must have an authorisation from the responsible authority.
- (2) An authorisation shall be granted:
 1. if nothing is known which could throw doubt on the reliability of those responsible for radiation protection;
 2. if those responsible for controlling or supervising the proposed operation of the X-ray installation have the specialised skills required for radiation protection and if these responsible personnel are available in sufficient numbers for the safe operation of the X-ray installation;
 3. if it is ensured that other personnel involved in the proposed operation of the X-ray installation have the necessary knowledge of the possible hazards of radiation and of the protective measures to be taken; and

4. if it is ensured that, in the proposed operation of the X-ray installation, such devices are made available and measures taken as are necessary, in the light of present levels of knowledge and technology, to provide adequate protection of individuals and the public in general against radiation damage to life, health and property.

(3) Sub-sections 1 and 2 shall apply accordingly if the X-ray installation or its operation is substantially modified. Any modification that may affect radiation protection shall be regarded as substantial.

Section 4. Operation of X-ray installations without authorisation

(1) A person operating an X-ray installation, the X-ray generator in which is of an approved design in accordance with Section 7(2), does not require an authorisation as laid down in Section 3, provided that the conditions set out in Section 3(2), paragraphs 2 and 3 are satisfied and that before the X-ray installation is first commissioned a specialist appointed by the responsible authority has inspected it and issued a certificate:

1. describing the X-ray installation and its proposed operation, and
2. stating that (a) the X-ray generator is of an approved design, and (b) that such devices are made available and measures taken as are necessary to provide adequate protection against radiation damage to life, health and property.

Should the specialist decline to issue the certificate, a decision will be taken, on request, by the responsible authority.

(2) For X-ray installations referred to in sub-section 1 operated for medical, dental or veterinary purposes, evidence of the specialised skills required for radiation protection on the part of the doctors, dentists or veterinarians responsible for the control or supervision of the proposed operation shall take the form of the production of a certificate issued by the authority competent under the law of the Land and proving that the person in question has attended a course on radiation protection in connection with X-ray applications. This certificate shall not be required of medical practitioners, dentists or veterinary surgeons who can show that they have obtained:

1. the doctor's degree based on Sections 4 or 6 of the Ordinance on the qualification of medical practitioners of 28th October, 1970 (Bundesgesetzblatt I, p. 1458) or
2. the dentist's degree based on the Ordinance on the qualification of dentists referred to in Section 48 of this Ordinance, or
3. the veterinary surgeon's degree based on Sections 2 or 6 of the Ordinance concerning the qualification of veterinarians dated 23rd March, 1967 (Bundesgesetzblatt I, p. 360).

(3) Any person proposing to operate the X-ray installation referred to in sub-section 1 shall so notify the responsible authority at least two weeks before putting it into operation. This notification shall be

accompanied by evidence that the conditions set out in Section 3, sub-sections 2 and 3 are fulfilled. A copy of the specialist's certificate referred to in sub-section 1 and of the design approval shall also be joined to the notification.

(4) Sub-sections 1 to 3 shall similarly apply if the X-ray installation or its operation is substantially modified. Any modification which may affect radiation protection is to be regarded as substantial.

(5) A person operating an apparatus which is highly or completely protected within the meaning of Sections 2 and 3 of Appendix II*, shall not require the authorisation referred to in Section 3, if the highly or completely protected apparatus is of an approved design and if the persons responsible for controlling or supervising the operation of the highly protected apparatus have the specialised skills required for radiation protection. The responsible authority shall be notified at least two weeks before the highly or completely protected apparatus is put into operation. To the notification shall be joined a copy of the authorisation and, in the case of highly protected apparatus, the name and address of the person responsible for controlling or supervising the operation of the highly protected apparatus.

(6) The responsible authority may prohibit the operation of X-ray installations not requiring authorisation under sub-sections 1, 4 or 5 if anything is known which could throw doubt on the reliability of any one of the persons responsible for radiation protection or if it should appear that one of these responsible persons has not or no longer has the specialised skills required for radiation protection.

Section 5. Operation of incidental radiation sources

(1) Any person operating an incidental source of radiation requires authorisation from the appropriate authority. Section 3(2) shall apply accordingly.

(2) Any person operating an incidental source of radiation where the voltage used for electron acceleration does not exceed 20 kV, shall not require the authorisation referred to in sub-section 1, provided that:

1. the local dose rate at a distance of 5 centimetres from the surface does not exceed 36 picoamperes per kilogramme (pA/kg) (0.5 milliroentgen per hour), and
2. sufficiently clear indication is given on the radiation source that:
 - (a) X-rays are generated, and
 - (b) the voltage for electron acceleration must not exceed the maximum value shown.

* As the Appendices of this Ordinance are mainly of a technical nature, they are not reproduced in the Bulletin.

(3) Any person operating an incidental source of radiation where the voltage used for electron acceleration exceeds 20 kV, shall not require the authorisation referred to in sub-section 1, provided that:

1. the design of the radiation source is of an approved type, and
2. sufficiently clear indication is given on the radiation source that:
 - (a) X-rays are generated,
 - (b) a system (to be described) ensures that the highest local dose rate allowed for the approved design is not exceeded, and
 - (c) the voltage used for electron acceleration must not exceed the maximum value - which shall also be indicated.

(4) The manufacturer or importer shall supply incidental radiation sources for use without an authorisation to other persons only if they are designed in accordance with the conditions set out in sub-sections 2 or 3. Incidental radiation sources requiring authorisation shall be supplied by the manufacturer or importer only if the source bears a clearly visible indication that authorisation is required.

Section 6. Maintenance and repair of X-ray installations and incidental radiation sources

(1) Any person whose trade is the maintenance and repair of X-ray installations or incidental radiation sources shall so notify the responsible authority in writing forthwith. Sections 3 to 5 shall not apply to the operation of X-ray installations or incidental radiation sources for purposes of repair and maintenance.

- (2) The responsible authority may prohibit maintenance or repair:
1. if the persons controlling or supervising maintenance or repair are unreliable or do not have the specialised skills required for radiation protection, or
 2. if the necessary radiation protection is not ensured during maintenance or repair.

DESIGN APPROVAL

Section 7. Design approval

(1) On application by the manufacturer or importer, the Physikalisch-Technische Bundesanstalt (Federal Physics and Technology Institute) shall verify:

1. X-ray generators for compliance with the provisions of Appendix I* or of Appendix II, Section 1 ;

2. highly protected apparatus for compliance with the provisions of Appendix II, Section 2 ;
3. completely protected apparatus for compliance with the provisions of Appendix II, Section 3 ;
4. incidental radiation sources for compliance with the provisions of Appendix II, Section 4 .

The application shall be accompanied by the drawings necessary for the verification and by a description of the design and method of operation. If requested, a specimen necessary for the verification shall be supplied to the Physikalisch-Technische Bundesanstalt. The Physikalisch-Technische Bundesanstalt shall notify the result of its verification to the responsible authority.

(2) The responsible authority shall decide, on application, whether to approve an X-ray generator, highly or completely protected apparatus, or incidental radiation source which has been verified in accordance with sub-section 1. Approval shall be granted if the X-ray generator, highly or completely protected apparatus, or incidental radiation source complies with the provisions referred to in sub-section 1. If this is not so approval shall not be granted.

Section 8

(1) Approval shall be granted on condition that the person to whom it is granted:

1. (a) verifies each approved X-ray generator, highly or completely protected apparatus, or each incidental radiation source for compliance with the essential radiation protection characteristics given in the design approval, and ensures that the manufacture and individual verification of each installation is supervised by one of the specialists appointed by the responsible authority;
- (b) provides the approved X-ray generator, highly or completely protected apparatus, or incidental radiation source with characteristics and data specified by the responsible authority;
2. delivers to the purchaser of an X-ray generator, highly or completely protected apparatus, or incidental radiation source, two copies of the approval certificate and indicates on them the result of the individual verification referred to in sub-section 1(a); and
3. supplies with the approved X-ray generator, highly or completely protected apparatus or incidental radiation source, a set of instructions for operation with special reference to the steps taken for radiation protection.

(2) Approvals of X-ray generators, highly or completely protected apparatus or incidental radiation sources shall remain valid for a maximum of ten years. On application, approvals may be renewed, any number of times, for a like period. X-ray installations and incidental radiation sources which are offered for sale prior to the expiry of the approval period may continue to be operated under the provisions of Sections 4 and 5 unless the responsible authority establishes that adequate protection against radiation damage is not ensured.

Section 9. Approval certificate

If the design is approved in accordance with Section 7(2), the approving authority shall issue an approval certificate which shall state:

1. the essential radiation protection characteristics for the X-ray generator and additionally, in the case of highly and completely protected apparatus and incidental radiation sources, the identification of the systems providing the radiation protection;
2. limitations, instructions, conditions and time limits; and
3. the characteristics and data with which the X-ray generator, highly or completely protected apparatus, or incidental radiation source is to be provided or marked.

Section 10. Publication in Bundesanzeiger (Official Journal)

The grant, suspension and renewal of design approvals and the findings of the responsible authority in accordance with Section 8(2), third sentence, shall be published in the Bundesanzeiger.

PART III

PROVISIONS REGARDING USE

GENERAL PROVISIONS

Section 11. Responsibility for radiation protection

- (1) Responsibility for radiation protection shall lie with:
1. any person operating an X-ray installation or an incidental radiation source requiring authorisation;
 2. those appointed by such a person to be responsible for controlling or supervising the operation of the X-ray installation or of the incidental radiation source requiring authorisation. The responsible authority shall be notified immediately of their appointment, with details of their competence within

the enterprise, and of their dismissal; to the appointment notifications shall be joined evidence of the necessary specialised skill. A copy of the notification shall be given to the responsible person.

(2) The duties of the persons referred to in sub-section 1, paragraph 2, under these regulations are confined to their competence within the enterprise. They shall immediately report all defects in radiation protection to the person operating the X-ray installation or incidental radiation source requiring authorisation.

(3) Should the competence in the enterprise of any of the persons referred to in sub-section 1, paragraph 2, be inadequate, especially as regards the taking of immediate steps to avert danger, then the responsible authority shall rule that for the purposes of this Ordinance, such a person may not be regarded as responsible for radiation protection.

Section 12. General protective measures

For the purpose of providing protection against radiation damage to life, health and property, those responsible for radiation protection shall ensure, by means of appropriate protective measures, and in particular by providing suitable premises, protective arrangements, equipment and personal protective gear and instituting suitable operating control procedures, and by providing sufficient and suitable staff, that, in the operation of the X-ray installation or incidental radiation source requiring authorisation:

1. the protection provisions set out in Sections 13 to 35 and 39 to 41 are complied with; and
2. the radiation doses received by individuals or the public in general are kept to a minimum and in any case below the levels indicated in Sections 32 to 34.

Section 13. Measurement of the dose rate from X-ray installations operated for therapeutic purposes

(1) If an X-ray installation is used for medical treatment, then without prejudice to Section 4(1), paragraph 2(b), the dose rate shall be measured in normal conditions of use when the X-ray installation is installed or when modifications are made which could affect the intensity of the working beam produced and the findings shall be recorded. Measurement shall be made at least every six months to check that the dose rate in the working beam still agrees with the recorded figure; the result of such tests shall be recorded. The measurements referred to in the first and second sentences are unnecessary if the dose rate is monitored continually during operation.

(2) Measurements in accordance with sub-section 1 shall be made with a dosimeter connected directly to a measuring instrument specified by the Physikalisch-Technische Institut or an equivalent instrument approved by the responsible authority. Such measurements shall be repeated whenever the dosimeter has been the subject of any action that may affect the accuracy of the reading, and in any case at least every two years. The results of initial and repeated measurements shall be recorded.

(3) These records shall be kept available for inspection. They shall be retained for thirty years and produced to the responsible authority on request. When the X-ray installation is taken out of service they shall be transferred to the responsible authority.

Section 14. Further duties of persons operating an X-ray installation or an incidental radiation source

- (1) A person operating an X-ray installation shall in addition:
1. have available where the X-ray installation is located a copy of the authorisation document (Section 3) or, in cases where design approval is granted under Section 7(2), a copy of the approval certificate (Section 9) and the instructions for operation ~~Section~~ 8(1), paragraph 37; and
 2. have a copy of this Ordinance available or displayed for inspection.

(2) Any person operating an X-ray installation or an incidental radiation source of an approved design under Section 7(2), shall cease operating it if the suspension of the approval or a ruling of the authority under Section 8(2), third sentence is published in the Bundesanzeiger, or if the X-ray installation or incidental radiation source ceases to match the characteristics set out in the approval certificate.

Section 15. Controlled and supervised areas

(1) Any area within which persons may receive a dose equivalent exceeding 15 millijoule per kilogramme (mJ/kg) (1.5 rem) in a year (controlled area) shall be marked off. During the time, the installation is energised, this area shall be identified. On this identification at least the words "no entry - X-rays" shall be clearly visible; it must also be displayed whilst the installation is being made ready.

(2) The area adjoining a controlled area, within which persons may receive a dose equivalent exceeding 1.5 mJ/kg (0.15 rem) in a year (supervised area) shall be defined and monitored in accordance with Section 39.

(3) Local doses arising from other radiation sources shall be taken into account when establishing the limits of the controlled and supervised areas.

(4) The responsible authority may rule that other areas are to be considered as controlled or supervised areas if this is necessary for the protection of individuals or of the public in general.

(5) The areas referred to in sub-sections 1, 2 and 4 constitute controlled or supervised areas only when the installation is energised.

Section 16. X-ray rooms

(1) An X-ray installation may only be operated in the totally enclosed room (X-ray room) specified in the authorisation or specialist's certificate.

(2) Sub-section 1 notwithstanding, an X-ray installation may be operated for diagnosis outside the X-ray room, if the condition of the person or animal concerned or the latter's size so dictates. X-ray diagnosis shall be carried out in such a manner that the working beam cannot impinge upon any person or animal other than those under diagnosis.

(3) Sub-section 1 shall not apply to X-ray installations:

1. for mass X-ray examinations;

2. for technical purposes, as described in the provisions of Appendix II, Section 2 (highly protected equipment) or Section 3 (fully protected equipment); and

3. in other cases:

(a) if it is expressly stated in the authorisation that the X-ray installation is intended for operation outside an X-ray room, or

(b) if the responsible authority gives permission for the operation of the X-ray installation outside an X-ray room,

and if it is absolutely essential in a particular case for the X-ray installation to be operated outside an X-ray room.

Section 17. Special provisions for controlled and supervised areas

(1) Permanent installations whose purpose is to protect persons exposed to X-rays at work, in particular by screening or keeping them at a distance, shall be so designed that the dose equivalent absorbed from an X-ray installation or an incidental radiation source cannot exceed an average of 1 mJ/kg (0.1 rem) in a week.

(2) No work station, passages or changing room shall be located within the controlled area of X-ray installations operated in an X-ray room. This does not apply to the work-stations necessary solely for the manning the installation, and which, for reasons bound up with the proper use of the X-rays, cannot be located outside the controlled area.

(3) Rooms other than the X-ray room and rooms outside the controlled area in which there may be radiation due to the operation of an X-ray installation or of an incidental radiation source requiring authorisation, shall be so constructed that persons cannot receive a dose equivalent exceeding 5 mJ/kg (0.5 rem) in a year.

(4) Sub-sections 2 and 3 do not apply to rooms in which it is ensured that there is no-one during the time that the installation is energised.

(5) In areas where persons live or stay continuously without being employed in connection with the operation of an X-ray installation or a source of incidental radiation, it shall be ensured that persons cannot receive a dose equivalent greater than 1.5 mJ/kg (0.15 rem) in a year.

Section 18. Presence in controlled areas

(1) During X-ray diagnosis of human beings, only the following persons, apart from the person under diagnosis, may remain within the controlled area to the extent that this is necessary for performing the X-ray diagnosis:

1. the doctors or dentists engaged in the X-ray diagnosis;
2. persons engaged in the X-ray diagnosis who are not doctors or dentists but are qualified to do medical or dental work;
3. persons defined in Section 20(1), paragraphs 3 and 4;
4. other persons whose presence is necessary for the continuing operation of the installation (e.g. physicists);
5. other persons, whose presence is necessary, under the supervision of the persons referred to in paragraph 1 above, for training, further training, or advanced training purposes or for the acquisition of knowledge regarding radiation protection;
6. other persons whose presence is strictly necessary for purposes of the X-ray diagnosis, under the direct supervision of one of the persons defined in paragraph 1 above.

(2) During X-ray therapy on live human beings, apart from the person being treated only those whose presence is strictly necessary for performing the limited X-ray therapy shall remain in the controlled area.

(3) During the X-ray diagnosis of animals, only the following persons shall remain in the controlled area, to the extent that this is necessary for the purposes of the X-ray diagnosis:

1. persons qualified to practise as veterinarians;
2. persons qualified to practise as doctors or dentists;
3. the persons referred to in Section 30(2);
4. assistants employed, under supervision of the persons referred to in paragraphs 1 to 3 above, provided they have the necessary radiation protection knowledge for this application;
5. other persons, whose presence is necessary, under the supervision of the persons referred to in paragraphs 1 to 3 above, for training, further training or advanced training purposes or for the acquisition of knowledge regarding radiation protection;
6. other persons whose presence is strictly necessary for purposes of the X-ray diagnosis, under the direct supervision of one of the persons defined in paragraph 1 above.

- (4) During X-ray treatment of animals, no person shall remain in the controlled area.
- (5) If the X-rays are used in cases other than those referred to in sub-sections 1 to 4, only persons qualified in accordance with Section 31 and, under their supervision, assistants, shall remain in the controlled area to the extent that this is necessary with regard to the operation of the installation.
- (6) Persons possessing the necessary knowledge of radiation protection may be in the controlled area for the purpose of carrying out measurements and tests on the X-ray installation or incidental radiation source requiring authorisation.
- (7) Persons may be in the controlled area of incidental radiation sources requiring authorisation only if their presence is necessary for the operation of the installation or for training purposes.
- (8) The responsible authority may allow those responsible for radiation protection during X-ray diagnosis, or during the operation of an incidental radiation source requiring authorisation, to admit other persons to a controlled area.
- (9) Persons under 18 years of age may not be employed in a controlled area. Pregnant women shall not be allowed in a controlled area, except for purposes of diagnosis or therapy.

Section 19. Protective clothing

All persons in a controlled area shall wear clothing giving adequate protection against X-rays where adequate protection is not provided by permanent devices in accordance with Section 17(1). This does not apply to the person under diagnosis or therapy.

THE USE OF X-RAYS ON LIVE HUMAN BEINGS

Section 20. Persons authorised to use X-rays

- (1) Only the following persons may use X-rays on live human beings in the practice of their profession:
1. persons qualified to practise medicine or dentistry;
 2. persons other than those referred to in 1 above, if they are qualified to do medical or dental work and have proved they have the necessary radiation protection knowledge for this application in an examination set by the responsible authority;
 3. persons qualified as one of the following: medical radiographer or technical medical assistant;
 4. assistants acting under the continuous supervision and responsibility of one of the persons referred to in 1 above, provided that they have the necessary radiation protection knowledge for this activity.

(2) In addition to the persons referred to in sub-section 1, assistants employed under the supervision of and responsible to one of the persons referred to in sub-section 1, paragraph 1, may use X-ray installations for mass X-ray examinations, provided that they have the necessary radiation protection knowledge for this activity.

Section 21. Limitations on the use of X-rays

(1) X-rays may be used on human beings only in medical and dental practice or in such other cases as the law provides or permits.

(2) The decision on whether and how X-rays are to be used for diagnosis or therapy on human beings shall be taken only by a qualified medical practitioner, or, insofar as the X-rays are to be used for dental purposes, a qualified dental practitioner.

(3) Apart from the purposes set out in sub-section 1, X-rays may be used on human beings only after special approval valid for a specific time has been given by the responsible authority. The approval shall be refused if the applicant fails to show that protection is ensured against radiation damage to life and health, and to the gonads in particular, and that the provisions of this Ordinance in connection with the use of X-rays in medical practice are observed.

Section 22. General principles in relation to the use of X-rays on live human beings

In medical or dental practice X-rays shall be used on live human beings in conformity with scientific and technical knowledge, only if necessary in accordance with the principles of good practice in medicine or dentistry. The use of X-rays shall be such that the radiation dose to the person under diagnosis or therapy is kept as low as possible. In X-ray diagnosis X-ray photography shall be preferred to fluoroscopy. There shall be no departure from the provisions of Sections 23 to 25, 27(1) and (2) and Section 28 except on imperative medical grounds.

Section 23. Protection of the gonads and of the embryo

(1) X-ray diagnosis of persons who are not permanently unable to procreate or bear children shall be carried out in such a manner that the gonads are not subjected to direct radiation, provided that this does not affect the clarity of the diagnosis.

(2) In the case of women of child-bearing age, X-ray diagnosis of the pelvic region shall not be carried out unless pregnancy is unlikely.

Section 24. General principles in relation to fluoroscopy

(1) Fluoroscopy shall not take place until the eyes of the fluoroscopist are fully adapted to obscurity, unless electronic amplification equipment is used. The X-rayed area shall be restricted to the area to be examined.

(2) For fluoroscopy with non-stationary apparatus electronic amplification shall be used. The X-ray apparatus shall be switched on only for purposes of fluoroscopy or photography.

Section 25. General principles for X-ray diagnosis of the head and limbs

(1) For all X-ray examinations in the region of the head with the working beam directed towards the body, and or X-ray photography of the teeth or jaws a protective screen of at least 0.4mm of lead equivalent is to be positioned so as to protect the remainder of the body from radiation.

(2) During any examination of the limbs where there is a risk of radiation reaching parts of the trunk, the patient shall be provided with a device of at least 0.4 mm lead equivalent to protect the trunk against X-ray irradiation.

Section 26. General principles for X-ray treatment

(1) For X-ray treatment on human beings, the course of radiation treatment shall be set out in writing, together with particulars of how it is to be applied, before the treatment is commenced, and shall be under the control of a person qualified to practise medicine or dentistry. The treatment plan shall give all necessary details concerning the X-ray treatment, and in particular dose, exposure time and schedule, skin and target dosages, locations and limits of the radiation field, choice of filter, tube current, tube voltage and focal spot skin distance, and details of the protection against scattered radiation.

(2) The position of the radiation field and compliance with the other requirements referred to in sub-section 1 shall be verified by a person qualified to practise medicine or dentistry, before each individual treatment of a person is commenced.

Section 27. Use of X-rays in cases of pregnancy

(1) In the case of pregnancy no X-ray diagnosis or therapy shall be carried out.

(2) Where X-ray diagnosis is imperative for medical reasons during pregnancy, every endeavour shall be made to reduce the dose of radiation, in particular by limiting the number of X-ray photographs and by using the shortest possible exposure times and the smallest possible X-ray beam, in order to protect the embryo.

(3) The dose equivalent to the embryo during the first two months of pregnancy must not exceed 10 mJ/kg (1 rem). This dose shall be exceeded only when shown to be absolutely vital.

Section 28. Use of X-rays on babies, children and adolescents

- (1) In the case of babies, children and adolescents, age, weight and surface area shall be taken into account in determining the physical characteristics of the X-ray beam and of the dose.
- (2) In X-ray therapy on babies, children or adolescents, the gonads, bone-marrow, dental system, bone growth areas and glands and gland systems shall be protected from direct exposure to the X-ray beam.
- (3) During X-ray diagnosis on babies, children and adolescents, the X-ray beam is to be focused only on the immediate object of the examination. In fluoroscopy and X-ray photography (including photofluorography of the chest), the pelvis shall be excluded from the X-ray beams. The gonads shall be shielded from the X-rays.

Section 29. Records

- (1) Prior to any X-ray examination or X-ray treatment, enquiries shall first be made concerning any previous use of ionizing radiation. With regard to mass X-ray examinations, it is sufficient to ask the patient the date of his or her last chest X-ray. Women of child-bearing age shall also be asked whether they are pregnant. The information referred to in the above three sentences shall be recorded.
- (2) A record shall be kept of X-ray examination or treatment. The record of an X-ray examination shall show the date, the type of examination, the area examined and the particulars from which the radiation dose may be derived, including the number of plates and data relating to current and voltage together with exposure times of fluoroscopy. Records of X-ray treatment must, in addition, show all necessary data concerning the X-ray treatment, and in particular the determination of the dose rate, exposure time and schedule, surface and depth dose, position and limits of the radiation field, choice of filter, X-ray tube current and voltage and the skin-focal spot distance, together with the nature of the protection from scattered radiation.
- (3) On request, the person to be examined or treated shall be given a copy of the record referred to in sub-section 2.
- (4) Any person operating an X-ray installation in the practice of medicine or dentistry shall retain these records for a period of thirty years after the last treatment in the case of X-ray therapy, and for a period of ten years from the last examination in the case of X-ray diagnosis. The responsible authority may require, where a practice is discontinued, that the records shall be transferred to a place designated by the authority; the necessary steps shall be taken to preserve medical secrecy.
- (5) Any person who has examined or treated another person by means of X-rays or other ionizing radiations, shall give to those persons who undertake any subsequent X-ray examination or treatment on their request, the information in the records referred to in sub-sections 1 and 2, and must transmit provisionally the relative file to them. If the file is kept by another person, this person must hand over this file to them provisionally.

USE OF X-RAYS IN OTHER CASES

Section 30. Use of X-rays on animals

- (1) Only the following persons shall use X-rays on animals:
 1. persons authorised to practise as veterinary surgeons;
 2. persons qualified to practise medicine or dentistry;
 3. assistants working under the supervision of the persons referred to in 1 and 2 above, provided that they have the necessary knowledge of radiation protection.
- (2) Other persons shall use X-rays on animals only if they have the authorisation of the competent authority, provided they have shown that they have necessary radiation protection knowledge for such use.
- (3) The use of X-rays on animals in no way affects the regulations regarding animal protection.

Section 31. Persons authorised to use X-rays in any other cases

In cases other than their use on living human beings or animals, X-rays shall be used only by such persons as possess the necessary radiation protection knowledge.

PROVISIONS REGARDING RADIATION EXPOSURE

Section 32. Maximum permissible doses for occupationally exposed persons

- (1) The dose equivalent absorbed by an occupationally exposed person from an X-ray installation or from an incidental radiation source requiring authorisation, must not exceed the permissible values given in subsections 2 to 6 below.
- (2) The dose equivalent absorbed up to a given age must not exceed 50 mJ/kg (5 rem) multiplied by the number of years of age minus 18 (maximum permissible dose in relation to age).
- (3) The total dose equivalent during a period of 13 successive weeks must not exceed 30 mJ/kg (3 rem), nor must it exceed 50 mJ/kg (5 rem) in a year.
- (4) If the dose equivalent absorbed as a consequence of the operation of an X-ray installation or of an incidental radiation source requiring authorisation is known, then the dose equivalent received, distributed over each period of 13 successive weeks may be as much as 30 mJ/kg (3 rem) for each such period until the maximum dose in relation to age is reached.

(5) In the case of a female occupationally exposed person and whose child-bearing ability is not permanently excluded, the dose equivalent received in any period of 13 successive weeks shall not exceed 15 mJ/kg (1.5 rem).

(6) If an occupationally exposed person has received a dose equivalent exceeding 30 mJ/kg (3 rem) but not more than 250 mJ/kg (25 rem) as a result of an accidental and exceptional exposure to radiation, this accidental exceptional radiation dose is to be taken into account in the accumulated dose equivalent in determining whether the maximum permissible dose in relation to age has been reached. If the value determined exceeds the maximum permissible dose in relation to age, no account is taken of the extent to which it does so; this is permissible once only during the lifetime of any person.

Section 33. Maximum permissible doses in respect of exposure of parts of the body of occupationally exposed persons

(1) The dose equivalent during any 13 consecutive weeks to the hands, forearms, feet and ankles of an occupationally exposed person may amount to 150 mJ/kg (15 rem) with a maximum of 600 mJ/kg (60 rem) in a year, provided the permissible values given in Section 32 for the other parts and organs of the body are not exceeded.

(2) If an occupationally exposed person has received a dose equivalent exceeding 150 mJ/kg (15 rem) but not more than 600 mJ/kg (60 rem), the amount by which it exceeds 150 mJ/kg (15 rem) may be disregarded once during the lifetime of this person. The competent authority, having taken medical advice, may allow the exceeding of this dose to be disregarded more than once, provided that there is no fear that the health of the person concerned is endangered.

Section 34. Maximum permissible doses to other persons

(1) The dose equivalent set out in sub-sections 2 to 4 shall not be exceeded in the case of non occupationally exposed persons.

(2) In the case of a person who stays in a controlled area from time to time in the course of his employment, though not engaged in the use of X-rays or of an incidental radiation source requiring authorisation, the dose equivalent in one year shall not exceed 15 mJ/kg (1.5 rem).

(3) In the case of a person staying in a controlled area, not in the course of his or her employment but for training purposes, the dose equivalent absorbed in one year shall not exceed 5 mJ/kg (0.5 rem) before the completion of his or her 18th year, or 15 mJ/kg (1.5 rem) thereafter.

(4) In the case of a person staying in a supervised area, the dose equivalent received in one year shall not exceed 5 mJ/kg (0.5 rem).

Section 35. Other exposure to be taken into account

Any other exposure to ionizing radiations in the course of a person's occupation shall be taken into account in determining whether the permissible doses set out in Sections 32 to 34 have been reached.

Section 36. Duty to report over-exposure

(1) Any person operating an X-ray installation or an incidental radiation source requiring authorisation must notify the competent authority without delay:

1. if in the case of occupationally exposed persons the maximum permissible radiation dose in relation to the age of the operator, or the permissible dose equivalents set out in Section 32(4), Section 33(1), have been exceeded, as a consequence of the operation of an X-ray installation or of an incidental radiation source requiring authorisation;
2. if an occupationally exposed person has been exposed to the radiation doses specified in Sections 32(6) or 33(2);
3. if, in the case of other persons, the permissible dose equivalents set out in Section 34(2), (3) or (4) have been exceeded, as a consequence of the operation of an X-ray installation or of an incidental radiation source requiring authorisation.

(2) The persons responsible for radiation protection as defined in Section 11(1), paragraph 2, must notify those operating the X-ray installation or incidental radiation source requiring authorisation as soon as they become aware of facts of the nature referred to in sub-section 1 above.

Section 37. Protective measures directed by the competent authority

(1) The competent authority is empowered to decide upon such protective measures as are necessary for the implementation of Sections 11 to 19, and 32 to 36.

(2) When the object of the protective measures is not to avert an imminent threat to life or health, reasonable delay shall be allowed for compliance with the direction.

(3) The direction shall be carried out by those who operate the X-ray installation or incidental radiation source requiring authorisation. In urgent cases the direction may also be addressed to the persons referred to in Section 11(1), paragraph 2. These persons must immediately inform the operator of the X-ray installation or of the incidental source requiring authorisation.

Section 38. Verification ordered by the authorities

The competent authority may, on stating its reasons, require any person operating an X-ray installation or an incidental radiation source requiring authorisation to verify the radiation protection devices by a body to be specified, and to have the verification repeated at specific intervals of time. The results of the verification shall be produced to the authority on request.

Section 39. Measurement of local dose or local dose rate

(1) Whenever this is necessary for radiation protection reasons, the local dose or local dose rate in controlled and supervised areas associated with an X-ray installation or an incidental radiation source requiring authorisation shall be measured. In justified exceptional cases the competent authority may specify the body which shall make the measurements.

(2) The date and results of the measurements referred to in sub-section 1 shall be recorded. The records shall be retained for 30 years and produced to the competent authority on request. The records shall be transferred to competent authority when the operation of the X-ray installation or incidental radiation source requiring authorisation is discontinued.

Section 40. Measurement of personal dose

(1) Persons staying in the controlled area shall be submitted to radiation dose measurements; in the case of use of X-rays on human beings this does not apply to persons under X-ray diagnosis or therapy. The measurements must be taken on the trunk, and underneath protective clothing if this is worn. If individual parts of the body are particularly exposed to radiation, measurements must also be taken at these parts, except where this is not possible in the case of X-rays used on human beings without unreasonable risk to the patient under diagnosis or treatment.

(2) Measurements on the body shall be carried out by two independent procedures. One shall enable the dose to be determined on each occasion and the daily doses measured by this procedure shall be recorded. In the cases referred to in Section 18(5), the necessity of the person's presence in the controlled area shall be justified in the records. The other measurement shall be made by dosimeters, obtained from the competent body (weights and measures body) under Land law and returned to that body at intervals not exceeding one month. The weights and measures body shall establish the dose, record the results of measurement, and give this information in writing to the person handing in the dosimeter. The body shall retain its records for 30 years.

(3) In the case of persons referred to in Section 34(2) and (3), measurements need be made only by one of the procedures specified, but otherwise sub-section 2 above shall apply.

(4) Persons whose personal dose has to be measured shall allow the necessary measurements to be taken.

(5) Any person operating an X-ray installation or an incidental radiation source requiring authorisation shall retain the results communicated by the weights and measurements body and the records referred to in sub-section 2, second sentence, for 30 years, and shall hand them over, on request, to the competent authority. The above mentioned person shall inform those concerned of the measurement results on request, and in any case immediately if the highest permissible dose equivalent as defined in Sections 32 or 33 is exceeded.

(6) On application, the competent authorities may grant exceptions to the provisions of sub-sections 1 to 3 above, provided that no risk is incurred by the persons referred to therein. Should any special risk appear possible because of the way in which the X-ray installation or incidental radiation source requiring authorisation is used, the authority may rule that the dosimeters shall be returned for computation to the weights and measurements body at intervals of less than one month.

(7) In the event of faulty dosimeter measurements should the dosimeter fail, the weights and measurements body may adopt a substitute dose level.

Section 41. Information

(1) Persons who by virtue of their occupation under the provisions of this Ordinance have to be in a controlled area or use X-rays, shall be advised beforehand of the working methods, possible dangers, protective measures to be taken, and insofar as an authorisation is granted, its content and coverage significant to their jobs. This information shall be given to them every six months; the competent authority may decide upon shorter intervals.

(2) Records shall be kept of what information is given and when, and shall be signed by the person advised. The records shall be retained for five years and produced on request to the competent authority.

PART IV

MEDICAL SUPERVISION

Section 42. Medical examination of occupationally exposed persons

(1) Any person operating an X-ray installation or a source of incidental radiation requiring authorisation may employ a person in a controlled area who would normally remain within such an area in the course of his employment, only if such employed person has, within the two months preceding the first day of such employment, been examined by a medical practitioner approved by the competent authority, and has a certificate issued by this doctor, to the effect that there are no objections on health grounds to such employment. A decision by the competent authority in accordance with Section 44 may take the place of the certificate.

(2) Any person operating an X-ray installation or a source of incidental radiation requiring authorisation may continue to employ an occupationally exposed person after the expiry of one year from the last

examination under the provisions of sub-section 1, only if this person has been re-examined by an approved doctor and has a certificate issued by such doctor to the effect that there are no objections on health grounds to continued employment in the controlled area. Sub-section 1, second sentence, shall apply accordingly.

(3) Any person operating an X-ray installation or an incidental radiation source requiring authorisation shall make the results of the personal dose measurements available to the examining doctor.

Section 43. Medical certification

Any person operating an X-ray installation or an incidental source of radiation must keep the medical certificates referred to in Section 42(1) and (2) for 30 years. They shall be produced to the competent authority on request. If an occupationally exposed person terminates his employment, certified copies of this medical certificate shall be given to him forthwith. If the certificate is necessary for taking up a new employment, then on request the certificate itself shall be provided instead of the copy.

Section 44. Decision by the authority

If it is stated in the medical certificate that there are objections to employment on health grounds under Section 42, then on application by the person operating the X-ray installation or incidental radiation source, or by the person examined, the competent authority shall decide whether and under what conditions this latter person may be employed. The competent authority may permit employment only where, on the basis of medical expertise, there is no risk that the health of the person examined will be endangered thereby.

Section 45. Immediate measures in case of a single high dose of radiation

(1) If there is any reason to fear that any person - other than the person under diagnosis or treatment - has, in connection with any activity referred to in the provisions of this Ordinance, received a single dose equivalent of more than 250 mJ/kg (25 rem) or, in the cases referred to in Section 33, over 600 mJ/kg (60 rem), then the person operating the X-ray installation or source of incidental radiation requiring authorisation shall ensure that the person concerned is taken immediately to a qualified doctor. The person operating the X-ray installation or incidental source of radiation requiring authorisation shall immediately cause the facts of the case to be established, and inform the competent authority. In the cases of persons where the personal dose has to be measured in accordance with Section 40(2), fourth sentence, he must immediately cause the measures set out in Section 40(2), fifth sentence, to be taken.

(2) Any person operating an X-ray installation or an incidental source of radiation requiring authorisation, may employ, in controlled areas a person who has received a radiation dose as referred to in sub-section 1, only if permission is given by the competent authority. This authority may permit employment only when on the basis of medical expertise there is no risk that the health of the person will be endangered.

The competent authority may, given the conditions set out in the second sentence above, allow the provisions of Section 32(2), to be disregarded.

Section 46. Medical examination by order of the competent authority

(1) Any person who is or who has been employed as an occupationally exposed person in a controlled area during the operation of an X-ray installation or of a source of incidental radiation requiring authorisation shall submit to examination by a qualified doctor on being so required by the competent authority, if a report under Section 36 has been made or should have been made.

(2) If there is a risk that the health of an occupationally exposed person is endangered if that person continues in one of the occupations referred to in sub-section 1, the competent authority may order that the person concerned shall no longer be employed in the controlled area, or else only to a limited extent.

(3) Sub-sections 1 and 2 shall similarly apply to persons, other than occupationally exposed persons, who are or have been in a controlled area. They are not applicable to persons who have been in a controlled area for the purposes of diagnosis or treatment.

Section 47. General notification of accidents

Any person responsible for radiation protection must immediately inform the competent authority of any accident or case of damage which may lead to radiation damage, during the operation of an X-ray installation or an incidental source of radiation requiring authorisation.

PART V

SUPPLEMENTARY PROVISIONS

Section 48. Change in regulations concerning dentists' qualifying examinations

The regulations for the examination of dentists dated 26th January, 1955 (Bundesgesetzblatt I, p. 37) as amended by the Second Ordinance amending the regulations for the dentists' qualifying examination dated 22nd April, 1971 (Bundesgesetzblatt I, p. 379) are hereby amended as follows:

1. In Section 36(1)(b), amend the words "at an X-ray course" to read "at a radiology course with special reference to radiation protection".
2. In Section 48(3), add the following sentence: "Further, the candidate must demonstrate his knowledge of radiology as necessary for a dentist, and of the protective measures to be taken in connection with the use of ionizing radiations on human beings."

Section 49. Transitional provisions for the continued operation and regarding the design approval of X-ray installations and sources of incidental radiation

(1) For X-ray installations in use for medical and veterinary purpose at the moment this Ordinance enters into force, Section 4 shall be applied in the manner set out in the following sentences. A design approval in accordance with Section 7(2) shall not be required. Proof of compliance with the conditions of Section 3(2), paragraphs 2 and 3 shall be furnished within six months of this Ordinance's entry into force; the competent authority may extend this period. The certificate referred to in Section 4(1) shall be produced within three years of the entry of this Ordinance into force. Within six months of this Ordinance's entry into force the use of the X-ray installation shall be reported on a form as shown in Appendix III .

(2) Should any X-ray installation be in use when this Ordinance comes into force for purposes other than the cases referred to in subsection 1, then Section 4(1) and (5) shall be applied in the manner set out in the following sentences: Design approval for the X-ray generator in accordance with Section 7(2), is not required, if its design is authorised under previously applicable law. Proof of compliance with the conditions of Section 3(2), paragraphs 2 and 3, shall be produced within six months of this Ordinance's entry into force; the competent authority may extend this period. The certificate under Section 4(1), must be produced within three years of the entry into force of this Ordinance. Within six months of this Ordinance's entry into force use of the X-ray installation shall be reported on a form in accordance with Appendix III .

(3) If any incidental radiation source within the meaning of Section 5 operating at less than 20 kV is in use when this Ordinance enters into force it may continue to be used without authorisation as specified in Section 5(1), even if the conditions of Section 5(2) are not met. This also applies to television apparatus, operated at up to 30 kV. In addition, sources of incidental radiation, operated at over 20 kV may continue to be used without authorisation provided that their operation is reported within six months of the entry into force of this Ordinance, on a form in accordance with Appendix III .

(4) Any person operating an X-ray installation that requires an authorisation in accordance with Section 3 when this Ordinance enters into force shall apply for such authorisation within six months of the date when this Ordinance enters into force. If such application is made within the correct time laid down, the X-ray installation may continue to be operated without authorisation until a decision is reached on the application.

(5) If an application for design approval of an X-ray installation is necessary under previously applicable law and is made before this Ordinance comes into force, the design verification may be carried out in accordance with such previously applicable law and the design approval

granted. The provisions of Section 8(2), first and third sentences, shall apply as appropriate. The first sentence shall apply, as appropriate, to the verification carried out or begun in accordance with previously applicable law under Section 4(1), paragraph 2(b).

(6) Design approval granted under previously applicable law shall be treated as approval under Section 7(2) for ten years after this Ordinance enters into force; Section 8(2), third sentence shall apply as appropriate.

(7) Insofar as medical examination of occupationally exposed persons was not required by previously applicable law, Section 42 shall be applied only one year after this Ordinance enters into force. Section 46 remains unaffected.

Section 50. Transitional provisions regarding the changes in the regulations for dentists' qualifying examinations

Dental students who have already completed, when this Ordinance comes into force, three semesters at German science universities after passing the preliminary dentists' examination in full, may take the qualifying examination for dentistry in accordance with the previously applicable provisions provided application to take the examination is made within two years of the date when this Ordinance enters into force.

Section 51. Provisions for the Federal armed forces sector

As regards reporting X-ray installations and sources of incidental radiation under Section 49(1) to (3), the Federal Minister for Defence or the agency appointed by him may rule that a form different from that in Appendix III shall be used for the armed forces.

PART VI

PROVISIONS REGARDING FINES, AND FINAL PROVISIONS

Section 52. Infringements

An infringement of the provisions within the meaning of Section 46(2) of the Atomic Act shall be committed by any person who, intentionally or negligently:

1. fails to comply with the provisions regarding operation (Sections 3 to 10) in that he or she
 - (a) operates an X-ray installation or an incidental source of radiation without the authorisation required under Section 3(1) or Section 5(1), first sentence;

- (b) substantially modifies an X-ray installation or an incidental source of radiation or its operation without the authorisation required under Section 3(3) or Section (5)1 second sentence, taken in conjunction with Section 3(3);
 - (c) fails to report, reports incorrectly or incompletely, or does not report within the proper time, as required under Section 4(3), paragraph 4 and paragraph 5, second and third sentences, or Section 6(1), first sentence;
 - (d) operates an X-ray installation in violation of an enforceable prohibition under Section 4(6);
 - (e) permits, in violation of Section 5(4), another person to operate an incidental source of radiation;
 - (f) maintains or repairs, in violation of an enforceable prohibition under Section 6(2), an X-ray installation or incidental sources of radiation;
2. does not comply with the provisions regarding operation (Sections 11 to 41) in that he
- (a) fails to report, reports incorrectly or incompletely or does not report within the right time as required under Section 11(2), paragraph 2, second sentence;
 - (b) fails, in violation of Section 11(2), second sentence, to report a defect or does not report it within the proper time;
 - (c) fails to comply with the provisions regarding the observance of protective measures as laid down in Section 12 in conjunction with Sections 13, 15(1) to (3), 16(2), second sentence, 17(1) to (3) and (5), 18(1) to (5), (7) and (9), 19 to 21(1), (2) and (3), first sentence, 30(1) and (2), 31 to 33(1) and (2), second sentence, 34, 35, 39(1), first sentence and (2), 40(1) and (2), first to fourth sentence and 41;
 - (d) fails to have available, in violation of Section 14(1), paragraph 1, a copy of the authorisation document, a copy of the approval certificate or the instructions for operation;
 - (e) fails to have a copy of this Ordinance available or displayed, in violation of Section 14(1), paragraph 2;
 - (f) fails to discontinue, in violation of Section 14(2), the operation of an X-ray installation or of a source of incidental radiation;
 - (g) operates an X-ray installation outside the X-ray room in violation of Section 16(1);
 - (h) uses X-rays without being so authorised under Sections 20, 30(1) or (2) or 31;
 - (i) uses X-rays on live human beings for purposes other than those laid down in Section 21(1), or without being so

- authorised in accordance with Section 21(3), sentence 1, or causes X-rays to be used without being so authorised in accordance with Section 21(2);
- (j) fails to comply with the provisions of Section 29(1), (2) or (4) regarding the enquiries to be made of patients, and regarding records and the keeping and transferring of records;
 - (k) fails to give information or gives incorrect or incomplete information concerning records, or fails to furnish the documents or furnishes them incompletely, in violation of Section 29(5);
 - (l) fails to report, or does not report within the proper time, any exceeding of the permitted dose equivalent or any abnormal radiation dose, in violation of Section 36(1), or fails in his obligation under Section 36(2) or Section 38(3), third sentence, to provide the required information;
 - (m) fails to carry out, carries out incorrectly, or does not carry out within the proper time, an enforceable direction from the competent authority under Section 37(1) or Section 40(6) second sentence;
 - (n) fails to have an X-ray installation or an incidental source of radiation verified, in disregard of an enforceable direction under Section 38, first sentence, or fails to produce or incompletely produces the results of the verifications in disregard of an enforceable direction under Section 38, second sentence;
 - (o) refuses to allow the personal dose to be measured, in violation of Section 40(4);
 - (p) fails to keep or produce reports or records, in violation of Section 40(5), first sentence, or fails to report or does not report in due time to the persons concerned, the results of the measurements or the fact that a person's maximum permissible dose equivalent has been exceeded, in violation of Section 40(5), second sentence.
3. fails to comply with any of the provisions regarding medical supervision (Sections 42 to 47) in that he
- (a) employs a person in a controlled area in violation of Section 42(1), first sentence, or Section 45(2), first sentence or continues to employ a person within the controlled area in violation of Section 42(2), first sentence;
 - (b) fails to produce to the doctor the results of the personal dose measurements, in violation of Section 42(3);
 - (c) fails to retain or produce a medical certificate in violation of Section 43, first or second sentence, or fails to provide certified copies or medical certificates in violation of Section 43, third or fourth sentence;

- (d) in violation of Section 45(1), first sentence, fails to cause any person referred to therein to attend a qualified doctor, or does not do so at the proper time; fails to have the facts established or a report made or does not do so at the proper time, in violation of Section 45(1), second sentence, or fails to take the necessary steps under Section 40(2), fifth sentence, or does not do so at the proper time, in violation of Section 45(1), third sentence;
- (e) fails to submit, on enforceable request, to medical examination in violation of Section 46(1), or (3), first sentence;
- (f) employs a person within a controlled area, in disregard of an enforceable direction from the competent authority in accordance with Section 46(2), or (3), first sentence;
- (g) fails to report an accident or other damage during the operation of an X-ray installation or an incidental source of radiation, or does not do so at the proper time, in violation of Section 47.

Section 53. Provisions relating to Berlin

This Ordinance shall also be applicable to Berlin under Section 14 of the Third Control Act of 14th January, 1952 (Bundesgesetzblatt I, p. 1), taken in conjunction with Section 58 of the Atomic Energy Act and Section 21 of the Act concerning the practice of dentistry.

Section 54. Entry into force

- (1) This Ordinance shall enter into force on the first day of the sixth calendar month after its publication.
- (2) The Ordinance concerning protection against damage caused by X-rays and radioactive material in non-medical applications of 7th February, 1941 (Reichsgesetzblatt I, p. 88) shall cease to have effect as from the date when this Ordinance enters into force.

F R A N C E

DECREE N° 63-1228 OF 11TH DECEMBER 1963
CONCERNING NUCLEAR INSTALLATIONS, AS AMENDED BY
DECREE N° 73-405 OF 27TH MARCH 1973*

Section 1

The provisions of the present Decree shall apply to large nuclear installations as defined in Section 2 which are operated by any natural or legal person, public or private, civil or military.

Section 2

Large nuclear installations are:

- (1) Nuclear reactors, with the exception of those comprised in a means of transport;
- (2) Particle accelerators, the characteristics of which are specified by joint Order of the Minister for Education, the Minister for Industrial and Scientific Development and the Minister of Health;
- (3) Plants for manufacture, processing or conversion of radioactive substances, i.e. all natural or artificial substances emitting radiations which are directly or indirectly ionizing, namely: plants for manufacture of nuclear fuels, isotopic separation of nuclear fuels, reprocessing of irradiated nuclear fuels or processing of radioactive wastes;
- (4) Facilities for the storage, deposit or use of radioactive substances, including wastes and notably those intended for irradiation.

* This text incorporates the amendments made by the amending Decree. The passages underlined represent amendments to the original text. This text is an unofficial translation prepared by the Secretariat.

The plants and installations defined in paragraphs 3 and 4 above shall be deemed large nuclear installations when the quantity or total activity of the radioactive substances that may be held in them exceeds the minimum laid down, according to the type of installation and the radioisotope in question, by joint Order of the Minister for Industrial and Scientific Development, the Minister of Health and the Minister responsible for Protection of Nature and the Environment.

All equipment contained within the perimeter referred to in Section 3 shall be deemed part of the large nuclear installation.

Section 3

The setting up of large nuclear installations shall be subject to prior authorisation; the application for authorisation shall state the characteristics of the large nuclear installation or installations and of the establishments referred to in Section 6bis which are the subject of the application; it shall include a plan showing the perimeter of the installation within the nuclear site. A nuclear site may comprise several large nuclear installations having the same operator and constituting an organic whole; on the same conditions it may also offer possibilities for the creation of new installations.

The application for authorisation shall be submitted to the Minister for Industrial and Scientific Development and, where necessary, to the Minister responsible for the establishment. The Minister for Industrial and Scientific Development shall give notification of this application to the Minister for the Interior, the Minister for Territorial Development, Equipment, Housing and Tourism, the Minister for Cultural Affairs, the Minister responsible for Protection of Nature and the Environment, the Minister for Agriculture and Rural Development, the Minister of Health and the Minister of Transport.

The application shall be subject to a local enquiry. The local enquiry shall not be compulsory:

- (a) for a large nuclear installation which has already been the subject of an enquiry prior to being declared of public interest, provided that the installation is in conformity with the project submitted at that enquiry or that any alterations made do not substantially affect the size or purpose of the installation or increase the hazards constituted by such installation;
- (b) in the case of alterations made to an installation or projected installation which has already been the subject of a local enquiry, if such alterations satisfy the conditions laid down in the previous sub-paragraph;
- (c) for applications for authorisation of a change of operator submitted under Section 6.

Joint Orders of the Minister for the Interior, the Minister for Territorial Development, Equipment, Housing and Tourism, the Minister responsible for Protection of Nature and the Environment, the Minister for Industrial and Scientific Development and the Minister of Health shall determine the procedures for conduct of the local enquiry.

The authorisation shall be granted, subject to the opinion of Committee referred to in Section 7, by Decree made on the report of the Minister for Industrial and Scientific Development and, where applicable, the Minister under whom the establishment comes, and subject to the concurrence of the Minister of Health.

If the Minister of Health has not given his opinion within three months from the date on which it is requested, the authorisation may be granted by Decree made in the Council of Ministers.

A list of large nuclear installations shall be established and kept up to date by the Minister for Industrial and Scientific Development.

Section 3 bis

(a) Notwithstanding the provisions of Section 3, the setting up of certain large nuclear installations with activity levels below those fixed by joint Orders of the Minister for Industrial and Scientific Development, the Minister responsible for Protection of Nature and the Environment and the Minister of Health may be authorised on the conditions laid down in the present Section.

(b) The large nuclear installations defined in paragraph (a) may be authorised, for a non-renewable period of less than six months by Order of the Minister for Industrial and Scientific Development, without a local enquiry, subject to the opinion of the Préfet or Préfets concerned and of the Permanent Unit provided for in Section 10.

(c) The large nuclear installations defined in paragraph (a), when built to a standard specification, may be authorised on the following conditions:

- a Decree made on a report by the Minister for Industrial and Scientific Development, subject to the opinion of the Committee referred to in Section 7 and with the concurrence of the Minister of Health shall give approval in principle for the type of installation;
- an Order of the Minister for Industrial and Scientific Development, made after the local enquiry provided for in Section 3 and subject to the opinion of the Permanent Unit referred to in Section 10, shall authorise operation within a certain perimeter.

(d) Mobile large nuclear installations in the category defined in paragraph (a) may be authorised on the following conditions:

- a Decree made on the report of the Minister for Industrial and Scientific Development, subject to the opinion of the Committee referred to in Section 7 and with the concurrence of the Minister of Health, shall approve the installation in principle;
- an Order by the Minister for Industrial and Scientific Development, made without a local enquiry, subject to the opinion of the Préfet or Préfets concerned and of the Permanent Unit referred to in Section 10, shall authorise parking of the installation within one or more specified perimeters, and shall fix the maximum length of time;
- the operation of moving an installation from one perimeter to another shall fall within the scope of the regulations concerning carriage of dangerous substances.

Section 3 ter

Certain categories of nuclear installations of lesser importance may be placed outside the scope of application of the present Decree by joint Order of the Minister responsible for atomic affairs, the Minister for Industry and the Minister of Health, without prejudice to possible application of the Act of 19th December 1917.

Section 4

The authorisation for the setting up of an installation shall specify the perimeter and the characteristics of the installation and the special requirements with which the operator must comply, notwithstanding application of the general technical rules referred to in Section 10 bis. It shall in particular lay down the conditions for commissioning the installation.

These conditions may, if necessary, be amended by Decrees made according to the procedure specified in Section 3.

These conditions do not prevent application of the provisions laid down in Book II of the Labour Code and by enactments made in implementation thereof in the interests of the health and safety of workers.

Section 5

The authorisation for construction shall also specify the period within which the installation is to be commissioned, according to its nature.

If the installation has not been commissioned within the period laid down or if it is not operated for a consecutive period of two years, a fresh authorisation, granted under the same procedure, shall be required.

Section 6

A further authorisation, granted under the procedure specified in Section 3, must be obtained :

- when the operator wishes to add another large nuclear installation to an existing installation;
- when there is a change of operator of an authorised large nuclear installation;
- when a large nuclear installation is moved;
- when a large nuclear installation is to undergo alterations of a nature such as to lead to non-compliance with the requirements previously imposed;

- when a large nuclear installation is destroyed or shut down for a period of more than two years as the result of fire, explosion or any other incident;
- when the perimeter of a large nuclear installation is modified.

Section 6 bis

Establishments falling within the scope of application of the Act of 19th December 1917 which are situated within the perimeter referred to in Section 3 above shall be subject to the following requirements notwithstanding the provisions laid down in the said Act and its implementing enactments:

- (a) the Minister for Industrial and Scientific Development shall act in place of the Préfet or Préfets concerned for any administrative action concerning these establishments. He shall keep the Préfet or Préfets informed of any such action;
- (b) applications for authorisation of Category 1 and 2 establishments included in the application for authorisation of a large nuclear installation do not require a separate enquiry; the enquiry must satisfy the conditions laid down in Sections 7 and 9 of the Act of 19th December 1917. These establishments shall be authorised by the Decree authorising the large nuclear installation within the perimeter of which they are situated;
- (c) the Minister for Industrial and Scientific Development shall inform the operator, subject to the opinion of the Inspector of Large Nuclear Installations referred to in Section 11, of the technical requirements with which he must comply.

Section 7

An Interministerial Committee for large nuclear installations shall be set up, composed as follows:

One member of the Council of State having at least the rank of Counsellor, as Chairman;

The High Commissioner for Atomic Energy or his representative as Vice-Chairman;

A representative of the Minister for Defence;

A representative of the Minister of Labour;

Two representatives of the Minister for the Interior;

One representative of the Minister for Economic Affairs and Finance;

One representative of the Minister for Education;

One representative of the Minister for Territorial Development, Equipment, Housing and Tourism;

One representative of the Minister for Cultural Affairs;

One representative of the Minister responsible for Protection of Nature and the Environment;

One representative of the Minister for Agriculture and Rural Development;

Three representatives of the Minister for Industrial and Scientific Development;

Two representatives of the Minister of Health;

One representative of the Minister of Transport;

Two representatives of the Atomic Energy Commission ;

One representative of the National Centre for Scientific Research;

Two representatives of Electricité de France;

One representative of the National Institute for Health and Medical Research;

One representative of the Central Service for Protection against Ionizing Radiations;

One representative of the National Institute for Agricultural Research;

Three members chosen for their special competence in the nuclear field, being proposed by the Minister for Industrial and Scientific Development and one by the Minister of Health.

Deputy members shall be nominated, their number being equal to that of Members.

The Chairman, Members and Deputies shall be appointed by Order of the Prime Minister for a period of five years.

The Committee shall also include a Permanent Secretary, who is entitled to speak and vote, appointed by Order of the Prime Minister on the proposal of the Minister for Industrial and Scientific Development. A Deputy permanent secretary shall be nominated by the same procedure.

The Committee may call on the assistance of technicians or other persons specially competent for the study of a given question and may undertake any technical consultation which it deems necessary.

Section 8

The Committee shall give its opinion concerning requests for authorisation to set up or modify large nuclear installations, and concerning the special requirements applicable to individual installations. The Committee must give its opinion within two months after the matter has been referred to it by the Minister for Industrial and Scientific Development.

The Committee shall give its opinion and make proposals on other questions relating to large nuclear installations, and in particular:

In this connection draft regulations for protection of workers, the public, nature and the environment must be submitted to the Committee when they concern large nuclear installations.

Section 9

The Committee shall meet at least once per year, and whenever convened by its Chairman.

Decisions are taken by majority vote. Where votes are equal the Chairman shall have the casting vote.

The Committee shall draw up its standing orders. Applications for authorisation and requests for opinions shall be sent to the Secretariat of the Committee by the Minister responsible for Atomic Energy*. They shall be the subject of a report by the Permanent Secretary.

Section 10

A Permanent Unit shall be set up within the Committee, consisting of the Chairman, Vice-Chairman and Permanent Secretary of the Committee and the following members designated by the Chairman among the Members or Deputy Members of the Committee:

The representative of the Minister of State for Social Affairs;

A representative of the Minister for the Interior;

The representative of the Minister for Protection of Nature and the Environment;

The representative of the Minister for Territorial Development, Equipment, Housing and Tourism;

A representative of the Minister for Industrial and Scientific Development;

A representative of the Minister of Health;

The representative of the Central Service for Protection against Ionizing Radiations;

* Note by the Secretariat: when the present Decree was drafted in 1963, the Minister responsible for Atomic Energy was primarily competent regarding authorisations for large nuclear installations. In 1973, those same powers lie with the Minister for Industrial and Scientific Development, which explains why both appellations are to be found here, according to whether the 1963 or the 1973 texts are referred to.

A representative of the Atomic Energy Commission;

A representative of Electricité de France.

The Chairman may designate Deputy Members, their number being equal to that of Members.

The Permanent Unit shall invite a representative of the Minister responsible for the installation under examination, when the latter does not come under the Minister for Industrial and Scientific Development.

In the event of equal voting, the Chairman shall have a casting vote.

The Permanent Unit shall be competent ipso jure to express, on behalf of the Committee, the opinions provided for in Section 3 bis, and opinions on applications for authorisation which are necessary under Section 6, in case of a change of operator, alterations likely to lead to non-observance of the requirements imposed or changes in the perimeter.

The Committee may also refer to the Permanent Unit, to express an opinion on its behalf, other applications submitted to it which present no special difficulties.

Section 10 bis

General technical rules concerning safety of large nuclear installations shall be issued in the form of an Order by the Minister for Industrial and Scientific Development.

Section 11

Supervision of large nuclear installations, shall be carried out by inspectors of large nuclear installations chosen from among persons responsible for the supervision of classified establishments and designated jointly by the Minister responsible for the Protection of Nature and the Environment and the Minister for Industrial and Scientific Development, and placed under the latter's authority. These inspectors shall supervise application of the general technical rules concerning large nuclear installations, the provisions contained in the Decree authorising construction and any requirements imposed later on the operator in application of such Decree of authorisation or under Section 6 bis.

The inspectors of large nuclear installations shall also be responsible for the supervision provided for in the Act of 19th December 1917 as amended, as regards establishments referred to in Section 6 bis of this Decree.

The inspectors appointed must take an oath of office and shall be bound by professional secrecy, as laid down in Section 28 of Decree No. 64-303 of 1st April 1964.

Officials of the Central Service for Protection against Ionizing Radiations, in their capacity as commissioned and sworn officials shall be responsible for supervising application of the regulations concerning discharge of radioactive effluents, with a view to protection of public health.

In the exercise of their functions the inspectors of large nuclear installations and officials of the Central Service for Protection against Ionizing Radiations shall keep in close contact with the departmental services concerned. They may enlist the assistance of technicians.

The above provisions shall not prevent application of other supervisory measures provided for in the legislation in force. This is, for example, the case as regards labour inspection and technical checks on construction and operation of nuclear installations intended for electricity generation, carried out by Government supervisory engineers; inspections must be carried out in liaison with the inspectors of large nuclear installations and officials of the Central Service for Protection against Ionizing Radiations.

Section 12

Infringement of the provisions of Title I of the Act of 2nd August 1961, referred to above, with regard to radioactive pollution from the installations referred to in Section 2 of the present Decree, and of the regulations made thereunder shall be punishable by a fine of Frs. 400 to Frs. 2,000.

Section 13

In case of emergency the Minister for Industrial and Scientific Development, and whether or not on the proposal of the Minister of Health or the Minister under whom the establishment comes, shall take on his own authority all executive measures necessary to bring the incident to an end and guarantee safety; he may in particular suspend operation of the installation, if necessary by placing it under seal.

Section 14

Large nuclear installations listed in Section 2 which existed prior to publication of the present Decree shall not be subject to authorisation but shall be subject to the inspection provided for in Section 11.

Within a period of two months from publication of the present Decree, such installations must be notified to the Minister responsible for Atomic Energy.

When the operation of these installations gives rise to hazards the operator may be required to take the necessary remedial measures as provided in Section 4(2).

Section 15

Within one year from the publication of the present Decree the operators of large nuclear installations existing at the date of publication shall forward to the Minister for Industrial and Scientific Development a file defining in particular the site and perimeters referred to in Section 3 of the Decree of 11th December 1963 mentioned above, as amended by the present Decree.

The Minister shall notify to the operator the perimeter authorised for the installations. Such notification shall be equivalent to approval within the meaning of Section 3 and completion of the formalities required under this Decree.

The establishments referred to in Section 6 bis of the Decree of 11th December 1963 referred to above, amended by the present Decree, which existed prior to publication of the present Decree, shall be notified, if they have not already been so notified, to the Minister for Industrial and Scientific Development within one year from publication of the present Decree.

They shall be subject to the provisions of Section 6 bis of the Decree of 11th December 1963 referred to above, as amended by the present Decree. However, when they have already been authorised, no further authorisation is needed under the procedure provided for in these Sections.

Section 16

When an installation not covered by Section 2 of the present Decree and not subject to the Act of 19th December 1917 is a source of hazard due to production, use or possession of radioactive substances, the Minister responsible for Atomic Energy and, where applicable, the Minister under whom the establishment comes, with the concurrence, or on the proposal of the Minister responsible for Health and Population or the Minister of Labour or again the Minister responsible for Industry, shall jointly require the operator of that installation to take the necessary measures to eliminate any hazards that have been found to exist and at the same time to have the installation classified.

In an emergency the Minister responsible for Atomic Energy, subject to the opinion or, where appropriate on the proposal of the Minister of Health or the Minister under whom the establishment comes, shall have full authority to take any executive measure necessary to put an end to the incident; he may for example suspend operation of the installation, if need be by placing it under seal.

Section 17

Large nuclear installations connected with national defence and classified as secret by the Prime Minister on the proposal of the Minister for the Armed Forces and the Minister responsible for Atomic Energy shall no longer be subject to the provisions of the present Decree as from the date of the decision so classifying them.

Section 18

Joint Orders by the Minister responsible fo Atomic Energy, the Minister of Health and Population and, where necessary, the other Ministers concerned, made after obtaining the opinion of the Committee referred to in Section 7 above, shall determine procedures for the application of the present Decree.