

Act and Regulations on Radiation Protection and Use of Radiation

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Act on Radiation Protection and Use of Radiation (No. 36 of 12 May 2000)

Chapter I Purpose, scope and definitions

Section 1 Purpose of the Act

The purpose of this Act is to prevent harmful effects of radiation on human health and contribute to the protection of the environment.

Section 2 Scope of the Act

The Act applies to any production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources.

The Act also applies to human activity giving increased levels of naturally ionising radiation from the environment.

The Act also applies to planning and emergency preparedness against incidents and accidents.

Section 3 Definitions

In this Act -

- a) "radiation" means ionising and non-ionising radiation.
- b) "ionising radiation" means radiation from radioactive substances, x-ray radiation and particle radiation.
- c) "non-ionising radiation" means optical radiation, radio frequency radiation, electrical and magnetic fields or other radiation with analogous biological effects and ultrasound.
- d) "radiation sources" means radioactive substances, goods or equipment containing such substances, as well as installations, apparatus or equipment which may emit radiation.
- e) "medical use of radiation" means the application of radiation to persons for the purpose of medical examination and treatment, in research or examinations in a legal context.
- f) "waste management" means any disposal of radiation sources after completed use, including storage, release, deposition, return scheme or treatment as ordinary waste.

Section 4 Territorial scope of the Act

The King may in regulations provide that this Act shall apply in Svalbard, Jan Mayen and Norwegian dependencies, and may lay down special rules as regards local conditions.

The Act applies to devices and any installation deployed on the Norwegian part of the continental shelf and on Norwegian ships and aircraft in areas that are not subject to the sovereignty of any other State.

Chapter II General provisions

Section 5 Requirement of justification and basic principles for use of radiation

All production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources shall be justifiable to ensure that risks do not arise to those performing any such activity, to other persons or to the environment. Also human activity giving increased levels of naturally ionising radiation from the environment shall be justifiable. In the assessment of the justification, importance shall inter alia be given to whether the benefits of the activity outweigh the risks associated with the radiation, and to whether the activity is arranged in such a way as to avoid acute injury to health and to minimise the risk of late injury as far as is reasonably possible. Radiation doses shall not exceed established limits.

Apparatuses or devices that may emit radiation shall be designed and shall function properly.

Section 6 Approval and notification

The ministry may in regulations lay down requirements regarding approval or notification of any production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources. Approval or notification requirements may also include human activity giving increased levels of naturally ionising radiation from the environment. The regulations may prescribe requirements as to the content of applications and notifications.

Where an approval or notification requirement has been prescribed, an undertaking subject to such a requirement shall not be started until approval is given or notification dealt with. An undertaking may not be expanded or materially changed in relation to the existing approval or notification.

Section 7 Instruction and training

In undertakings encompassed by this Act, the employees and other associated persons shall have such instruction or training as is necessary to ensure that they have sufficient qualifications or knowledge in respect of radiation protection and safe use of radiation.

Visitors and others with access to the undertaking shall, where necessary in the interest of radiation protection, be provided with information about precautions that must be taken.

The ministry may lay down supplementary regulations concerning training, qualification requirements and instruction for persons who use or come into contact with radiation.

Section 8 Protective measures

Undertakings subject to this Act shall take necessary measures to protect the employees, other associated persons and the environment against radiation. Persons who because of low age, pregnancy or other reasons are particularly sensitive to radiation shall either be assigned tasks that do not involve exposure to radiation, or be protected by other appropriate measures.

The ministry may lay down supplementary regulations concerning factors as mentioned in the first paragraph, including a minimum age for workers exposed to radiation, as well as medical examination of persons who are exposed to radiation.

Section 9 Special provisions on radioactive waste and radiation-emitting apparatuses that are discarded

In order to ensure safe management of radioactive waste with respect to radiation protection, the ministry may lay down supplementary regulations on storage, deposition, release into the environment, return schemes and treatment as ordinary waste. The regulations may prescribe a duty for suppliers of radioactive substances to establish return schemes for radioactive waste, and likewise a duty for undertakings to establish and utilise such return schemes. The provisions of this paragraph also apply to waste, equipment or packaging that contains or is contaminated by radioactive substances.

Where apparatuses or equipment which may emit radiation are discarded or finally taken out of service, the owner or the responsible party shall prevent subsequent harmful use of such apparatuses or equipment by ensuring that they no longer emit radiation.

Section 10 Naturally ionising radiation

The ministry may lay down regulations that prescribe limitations, including dose limits, for work or periods spent in places where radiation levels from naturally ionising radiation are increased due to human activity.

Section 11 Internal control

The King may in further regulations lay down provisions concerning internal control and internal control systems to ensure compliance with requirements laid down in or pursuant to this Act.

Section 12 Regulations on satisfactory radiation protection and use of radiation etc.

In order to promote the purpose of this Act and to ensure proper radiation protection and use of radiation, the ministry may lay down regulations to supplement the provisions of this Act. Such regulations may inter alia lay down requirements with regard to:

- a) the organisation of radiation protection, including the designation of a responsible radiation protection officer, and requirements as regards the registration of information necessary for the purpose of internal control or supervision.
- b) shielding measures in the form of design and adaptation of premises and workplaces, work procedures and use of personally fitted protective equipment. Requirements may also be laid down for the design and function of radiation-emitting equipment.
- c) marking of radiation sources and information about the application, handling and storage of radiation sources. Requirements may also be laid down as to warning signs in premises or areas where radiation sources or radioactive waste are present which may entail a health risk. Requirements may also be laid down to inform involved persons and the general public about the use of radiation and radiation protection.
- d) measurement of radiation levels, including personal dosimetry.
- e) dose limits for relevant types of radiation.
- f) transport of radiation sources, including radioactive waste and equipment containing such sources.
- g) follow up of protective measures in connection with the carrying out of repairs, maintenance or alteration of a radiation source or installation.

Chapter III Special provisions for medical use of radiation

Section 13 Justification and optimisation

The medical use of radiation shall be performed in accordance with good medical examination and treatment practices, including provisions for radiation protection.

For the medical use of radiation, the professionally responsible person shall assess whether the use of radiation is justified. In the assessment account shall inter alia be taken of whether the benefits outweigh the potentially harmful effect due to the use of radiation. Account shall be taken of the benefit to the individual, the benefit to society and whether alternative techniques can be applied. The use of radiation shall be avoided in cases where the same result can be achieved by other means without material inconvenience, for example by using other methods or by obtaining results from previous examinations.

When radiation is applied, the person professionally responsible for the examination or treatment shall ensure that the applied radiation doses are as low as may reasonably be achieved, viewed in light of the purpose of the irradiation, available equipment and resources, and similar circumstances.

The undertaking shall at regular intervals verify that the emitted radiation dose matches the dose calculated. This does not apply to examination or treatment involving radioactive substances being administered to the patient.

The ministry may lay down supplementary regulations with requirements for the medical use of radiation.

Section 14 Duty to inform about radiation protection precautions

Where, in connection with the medical use of radiation, radiation protection measures are taken that require a particular conduct on the part of the person being examined or treated, the professionally responsible or the authorised person shall inform the person in question how to act in order to fully benefit from such measures. This also applies to attendants who support the person at the treatment or examination. Information as mentioned may be omitted where there is no reason to expect the person to be able to make use of it.

Where radioactive substances are administered to patients, the professionally responsible person shall inform about precautions that should be taken to protect other persons against radiation.

The ministry may make supplementary regulations concerning the duty to provide information about radiation protection precautions.

Chapter IV Planning of incident and accident management. Emergency preparedness

Section 15 Duty for planning

The ministry may in regulations or individual decisions impose on undertakings subject to this Act a duty to plan for the handling of incidents and accidents, and requirements with regard to exercises.

The decision may include a duty to notify rescue service agencies and the supervisory authority about special risks of which the rescue service and the supervisory authority should be aware in order to handle incidents or accidents.

Undertakings may be required to notify physical and legal persons in their immediate vicinity of special risks that may arise. Physical and legal persons who do not themselves conduct an activity subject to this Act, but who may be affected by past incidents or accidents, may have a separate duty imposed on them to plan for limiting harmful effects.

In the event of an accident or event at a nuclear facility or during the transport of a nuclear substance which entails an imminent threat to public health or the environment, the agency responsible for nuclear accident preparedness or the Norwegian Radiation Protection Authority shall ensure that the population immediately receives information enabling steps to be taken to prevent or reduce damage. Should conflict arise between the information requirement under this provision and the secrecy obligation of section 53 of Act No. 28 concerning Nuclear Energy Activities, the information requirement shall take precedence. In such cases the secrecy obligation shall be upheld to the extent that it does not prevent fulfilment of the information requirement. The ministry may adopt decisions regarding implementation of the information requirement.

Section 16 Emergency preparedness against nuclear accidents

The King organises an emergency preparedness against nuclear accidents.

In the acute phase of a nuclear accident the King may, notwithstanding the allocation of authority under other Acts, order state and municipal agencies to implement evacuation, area access restriction, as well as measures to safeguard foodstuffs, including drinking water and protection of animals. The King may also order private and public undertakings to perform analyses and gather information for the assessment of the situation.

The King may also, notwithstanding the allocation of authority under other Acts, delegate his authority under the second paragraph to a designated state agency for nuclear accident preparedness.

Agencies assigned functions in the field of nuclear accident preparedness are required to act according to a coordinated body of plans.

The King may order persons with central preparedness functions to be available in the event that an emergency situation arises.

Section 17 Special exemptions in rescue and civil emergency situations and with regard to national defence

The King may in regulations lay down exemptions from dose limits and other requirements laid down pursuant to this Act in situations where implementing a rescue or civil emergency operation makes it necessary. Personnel shall not be ordered to perform tasks at the risk of acute radiation injury.

The King may also make exemptions from provisions laid down in or pursuant to this Act in situations where necessary in the interest of national defence preparedness.

Chapter V Administrative provisions, penalties and commencement

Section 18 Supervision and decisions. The supervisory authority's right of access, information and to take measurements

The Norwegian Radiation Protection Authority supervises compliance with provisions laid down in or pursuant to this Act, and may for this purpose make such individual decisions as are necessary.

The King may for delimited areas provide in regulations that other state supervisory agencies or municipalities shall carry out supervision and make necessary individual decisions in pursuance of this Act. Public agencies that are assigned authority under the provision of the first sentence may apply the enforcement provisions in the Act on the conditions laid down in the particular provision.

The supervisory authority shall be given free access to perform supervision, and shall be provided with information necessary for the supervisory authority to perform its functions under the provisions of this Act.

The supervisory authority shall be given access to undertake measurements and investigations. The undertaking shall hand over samples for supervisory purposes free-of-charge. If it is demonstrated that provisions laid down in or pursuant to this Act have been infringed, the undertaking may be charged with the cost of supervision due to the infringement.

The ministry may in regulations lay down charges for the payment of particular supervisory tasks.

Section 19 Rectification and halting

The Norwegian Radiation Protection Authority may demand rectification of activity that conflicts with provisions laid down in or pursuant to this Act.

If a material risk to health exists, the Norwegian Radiation Protection Authority may halt the activity in question, confiscate substances or equipment in whole or in part, or by other means ensure discontinuation of further use. The Norwegian Radiation Protection Authority may demand the closure of an undertaking that does not possess the required licence or has not submitted the required notification.

The police are, upon request, obliged to assist the process of halting or confiscation.

Section 20 Prohibition of import and sale

The Norwegian Radiation Protection Authority may refuse the import or sale of any product or substance and any item that may involve a risk to health or environment due to radiation, provided that this is not in conflict with international agreements to which Norway has acceded.

Section 21 Coercive fine

The supervisory authority may impose a coercive fine in the form of a one-time fine or a cumulative daily fine on an undertaking that ignores a deadline for complying with an order. The coercive fine shall be fixed either at the time the order is made or when a new deadline is set for compliance.

The King may waive an imposed coercive fine when appropriate.

The ministry may lay down supplementary regulations concerning the imposition and calculation of coercive fines.

Section 22 Appeal

The Ministry of Health and Social Affairs is the appeals body for individual decisions made by the Norwegian Radiation Protection Authority under provisions laid down in or pursuant to this Act.

Appeals concerning individual decisions made under provisions laid down in or pursuant to this Act by a State supervisory agency other than the Norwegian Radiation Protection Authority are decided by the administrative agency that is the immediate superior of the supervisory agency in question.

The county governor decides appeals concerning individual decisions made by the municipality under provisions laid down in or pursuant to this Act.

Section 23 Penalties

Anyone who wilfully or through negligence violates or contributes to the violation of provisions or orders made under the provisions of or pursuant to this Act, shall be punished by fines or imprisonment not exceeding three months.

If the violation has or could have caused grave danger to health or environment, imprisonment not exceeding two years may be imposed.

If the violation has merely resulted in insignificant harm or inconvenience, public prosecution will take place only at the request of the supervisory authority.

Section 24 Commencement etc.

This Act comes into force when as the King decides.

Act No. 1 of 18 June 1938 relating to the Use of X-rays and Radium etc., will be repealed on the same date.

Regulations and other provisions and decisions made under the provisions of Act No. 1 of 18 June 1938 relating to the Use of X-rays and Radium etc., will apply also after the present Act has come into force insofar as they do not conflict with provisions laid down in or pursuant to this Act.

Section 25 Amendments to other Acts

Regulations No. 568 of 9 May 2003 on Application of the Act on Radiation Protection and Use of Radiation on Svalbard and Jan Mayen

Laid down by Royal Decree of 9 May 2003 pursuant to the Act on Radiation Protection and Radiation Use (Radiation Protection Act, No. 36 of 12 May 2000) sections 4 and 6. Introduced by the Ministry of Health

Section 1 Application of the Radiation Protection Act to Svalbard and Jan Mayen

The Act on Radiation Protection and Use of Radiation (Radiation Protection Act, no. 36 of 12 May 2000) is made applicable to Svalbard and Jan Mayen with the adjustments following from these regulations.

Other regulations made pursuant to the Radiation Protection Act do not apply on Svalbard or Jan Mayen unless so provided in such regulations.

Section 2 Notification requirement

All production, import, export, transport, transfer, possession, installation, use or handling of substances or apparatuses that emit ionising radiation (x-ray radiation or radiation from radioactive substances) shall be notified to the Norwegian Radiation Protection Authority. The same applies in connection with waste management of such sources and with activity entailing exposure to elevated levels of naturally ionising radiation from the environment.

Section 3 Delegation of authority

The ministry's authority to make individual decisions regarding the duty for planning under section 15 of the Radiation Protection Act first and second paragraph is delegated to the Norwegian Radiation Protection Authority.

Section 4 Amendment of the regulations. Dispensation

The ministry may make amendments to these regulations.

When called for by local conditions, the Norwegian Radiation Protection Authority may in special cases derogate by individual decision from the Radiation Protection Act or regulations made pursuant thereto.

Section 5 Commencement

These regulations come into force on 1 January 2004.

Regulations No. 1362 of 21 November on Radiation Protection and Use of Radiation (Radiation Protection Regulations)

Laid down by Royal Decree of 21 November 2003 pursuant to Act No. 36 on Radiation Protection and Use of Radiation sections 6, 7, 8, 9, 10, 12, 14, 15, 17 and 18. Introduced by the Ministry of Health.

Chapter I Introductory provisions

Section 1 Purpose of the regulations

The purpose of these regulations is to ensure proper radiation use, prevent harmful effects of radiation on human health and contribute to the protection of the environment.

Section 2 Scope of the regulations

The regulations apply to any manufacture, import, export, transfer, possession, installation, use, handling and waste management of radiation sources. The regulations also apply to human activity giving increased levels of naturally ionising radiation from the environment.

The regulations do not apply to electrical appliances and components that produce x-rays provided the dose in normal use does not exceed 1 $\mu\text{Sv/h}$ from accessible surfaces, or that maximal energy of the radiation produced does not exceed 5 keV.

Use of consumer articles containing weak non-ionising radiation sources is excluded from the regulations unless, as in the case of lasers and tanning appliances, they are specifically mentioned in chapter VI.

Chapters III - V of the regulations only apply to ionising radiation, while chapter VI only applies to non-ionising radiation sources. Chapters I, II, VIII and IX apply both to ionising and non-ionising radiation sources.

Chapter VII regulates medical use of radiation for the diagnosis or therapy of patients.

Section 3 Territorial scope of the regulations

Regulations No. 568 of 9 May 2003 concerning Application of the Act on Radiation Protection and Use of Radiation on Svalbard and Jan Mayen apply in respect of Svalbard and Jan Mayen. The provisions of chapter IV of the present regulations also apply to Svalbard and Jan Mayen.

Section 4 Definitions

In these regulations

- a) "radiation" means ionising and non-ionising radiation.
- b) "ionising radiation" means radiation from radioactive substances, x-rays and charged or uncharged particles.
- c) "non-ionising radiation" means optical radiation, radio frequency radiation, electrical and magnetic fields or other radiation with analogous biological effects, and ultrasound.
- d) "radiation sources" means radioactive substances, goods or equipment containing such substances, as well as installations, apparatuses or equipment which may emit radiation.
- e) "radioactive source" means a radiation source containing a radioactive substance, i.e. a substance that emits alpha, beta or gamma radiation.
- f) "sealed radioactive source" means a radioactive substance which has been encapsulated in order to prevent the diffusion of the radioactive substance to the surroundings.
- g) "open radioactive source" means a radioactive substance which is not sealed.
- h) "consumer goods" means objects, devices or appliances intended for transfer to private consumers.
- i) "radioactive waste" means discarded objects or substances which consist of or are contaminated by a radioactive substance.
- j) "tanning appliance" means an appliance with one or more ultraviolet radiation sources designed for irradiation of the skin.
- k) "radiation dose" means a measure for the amount of ionising radiation that is absorbed. The designation may be gray (Gy) or sievert (Sv).
- l) "activity" means the number of nuclear transformations (disintegrations) per second, and is therefore a measure of the strength of a radioactive source. Expressed in becquerels (Bq).
- m) "medical use of radiation" means the application of radiation to persons for the purpose of medical examination or therapy, in occupational medical examinations, in screening programmes, in forensic examinations, in insurance assessments or in research programmes.
- n) "nuclear medicine" means the application of an open radioactive source in the form of radioactive medicines which are administered to the patient for diagnostic purposes or therapy.
- o) "screening" means the systematic examination of a large group of symptom-free persons in order to identify their state of health in relation to a particular disease.

Chapter II General provisions for radiation

Section 5 Authorisation

Undertakings intending to procure, use or handle ionising radiation sources in the following contexts shall be authorised by the Norwegian Radiation Protection Authority:

- a) Industrial radiography and maintenance of industrial radiography equipment.
- b) Industrial irradiators, i.e. the use of ionising radiation to alter material or product quality.

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- c) Logging activity, i.e. characterisation of structures around bore holes.
 - d) Radiation use for research purposes.
 - e) Administration of radioactive medicines or substance to persons in connection with medical diagnostics, therapy or research.
 - f) Radiation therapy of persons.
 - g) Screening activity and use of x-ray diagnostic apparatus by specialist health services, including ordinary x-ray photography and fluoroscopy, angiography and intervention, computer tomography, mammography and dedicated child diagnostics.
 - h) Use of accelerators apart from electron microscopes.
 - i) Manufacture and import of radioactive medicines.
 - j) Addition of radioactive substances in the manufacture of products, and sale of such products. The sale of consumer goods mentioned in the annex, point 1, is exempt from the requirement of authorisation.
 - k) Manufacture of radioactive sources.
 - l) Use of open radioactive sources for tracer surveys outside the laboratory.
 - m) Use of sealed radioactive sources with activity levels greater than 10^6 times the exemption levels stated in the annex, apart from in the case of Co-60 where the activity limit is set at 10 GBq.
 - n) Use of open radioactive sources with activities requiring a type A isotope laboratory, cf. section 17.
 - o) Discharges of radioactive substances. The Norwegian Radiation Protection Authority may establish exemption and clearance levels.
 - p) Facilities for the treatment, storage or final disposal of radioactive waste.
 - q) Import and export of radioactive waste.
 - r) Distributors of radiation sources. Requirements for authorisation do not apply to radiation sources and areas of use mentioned in the annex.

Undertakings intending to procure and use magnetic resonance imaging (MRI) for medical purposes shall also be authorised by the Norwegian Radiation Protection Authority.

To obtain authorisation under the first and second paragraph, the undertaking must inter alia prove that it has an organisation with a radiation protection and radiation safety capability, that it possesses sufficient competence in the field of radiation protection, and that it has the necessary measuring equipment and other safety equipment.

In the authorisation the Norwegian Radiation Protection Authority may impose conditions regarding use, the content of internal controls, reporting, competence, physical protection, use of measuring apparatus, maintenance routines, quality control of apparatus and equipment for medical radiation use, waste disposal, return scheme for disused sources, emergency preparedness, design of premises etc.

Section 6 Notification

Undertakings wishing to procure use or handle ionising radiation sources for purposes and in contexts other than those mentioned under section 5 shall notify the Norwegian Radiation Protection Authority. Such radiation sources must not be procured, used or handled until the undertaking has received confirmation that notification has been received. The notification requirements also apply to the procurement, use and handling of class 4 laser products and to tanning appliances, cf. section 28.

The notification requirement does not apply to radiation sources and areas of use mentioned in the annex.

Section 7 Competence, instructions and procedures

Undertakings shall ensure that employees and other associated persons who install or work with radiation sources, or who may be exposed to radiation, shall have sufficient competence in the field of radiation protection and safe use of radiation sources and measuring and protective equipment.

The undertaking shall prepare instructions and work procedures in writing which ensure proper radiation protection and prevent persons from being exposed to levels which exceed limits stated in applicable standards or international guidelines.

Section 8 Requirements on the radiation protection officer

Undertakings which apply or install ionising radiation sources, except radiation sources and areas of use mentioned in the annex, shall designate one or more persons who shall be able to:

- a) Use measuring equipment and evaluate the measurement results.
- b) Guide the employees in the safe use of the radiation sources and protective and measuring equipment.

The same applies to undertakings which apply or install UVC sources, class 4 laser products or other powerful sources of non-ionising radiation which may lead to exceeding of exposure limits stated in existing norms or international guidelines.

In the case of particularly extensive use of ionising radiation, the radiation protection officer must be able to carry out or have others carry out physical, technical and radiochemical measurements and assessments in order to determine radiation doses, and must also be able to assess health risks and consequences associated with various accident situations which may arise.

Section 9 Risk assessment, physical protection and emergency preparedness

Undertakings which plan to use or handle radiation sources shall make an assessment of the risk factors associated with the use of radiation. If the assessment shows that employees, other persons or the environment are at risk or that radiation sources may be orphaned, the undertaking shall:

- a) Take all reasonable steps to avoid or reduce the likelihood of such events.
- b) Protect the radioactive sources against theft, sabotage and fire and water damage.
- c) Give the employees the necessary information and training as well as the protective equipment needed to limit exposure to radiation in connection with such events.
- d) Prepare an emergency preparedness plan which describes measures to halt, limit and remove discharges, measures to limit radiation doses and other measures to reduce the consequences of such events.
- e) Hold exercises.

Requirements as to risk assessment, physical protection and emergency preparedness do not apply to radiation sources and areas of use mentioned in the annex.

Section 10 Requirement for inventory of radiation sources

The undertaking is obliged to maintain an inventory of and control over ionising radiation sources. The same applies to UVC sources, class 4 laser products or other powerful sources of non-ionising radiation which may lead to exposure limits stated in existing norms or international guidelines being exceeded. This obligation entails inter alia that information on location, source type and temporary relocations shall be registered. In the case of radioactive sources, specification of the radioactive substances and activity shall also be registered, along with serial numbers or other information able to uniquely identify the source.

Undertakings that dispose of radiation sources which are subject to approval or notification under section 5 and section 6 shall notify such disposal to the Norwegian Radiation Protection Authority.

Section 11 Obligation to notify in the event of accidents, incidents and abnormal events

The undertaking shall immediately notify accidents, incidents and abnormal events to the Norwegian Radiation Protection Authority. A written report shall be sent to the Norwegian Radiation Protection Authority as soon as possible and within 3 days at the latest.

The terms “accident”, “incident” and “abnormal event” mean:

- a) Events which cause or may have caused unintended exposures of employees, patients or other persons that are significantly above normal levels.
- b) Loss or theft of radiation sources.
- c) Unintended discharges of radioactive substances to the environment.
- d) Events which involve irradiation of the general public whereby an individual may be exposed to more than 0.25 mSv per year.
- e) Significant technical failure at the radiation source that is of significance for radiation protection.
- f) Significant deviation from adequate dose/activity to the treated tissue of a patient.
- g) Serious radioactive contamination of an area or equipment.

Section 12 Requirements on apparatus

Radiation sources shall be designed such that risk of incidents and undesired radiation exposure of users and other persons is as low as practically possible.

Equipment shall be manufactured in accordance with the prevailing version of standards from the International Electrotechnical Committee (IEC) and the International Organization for Standardization (ISO), provided no superseding national or European standards exist.

Chapter III Provisions on ionising radiation

Section 13 Choice of radiation source, requirement as to source encapsulation

The undertaking shall assess alternatives to the use of ionising radiation, including the feasibility of techniques which do not involve ionising radiation. For non-medical use of radiation, x-ray apparatus

shall, where practically possible, be used rather than radioactive sources. Where radioactive sources must be used, their activity shall be as low as practically possible and they shall preferably be sealed.

The encapsulation shall be sufficiently sound to prevent leakage of the radioactive substance both in normal use and in the event of minor incidents, and shall comply with the requirements recommended in prevailing version of ISO 2919 (Sealed radioactive sources - classification) applying at any time. A leakage test shall be carried out at points where the source encapsulation is regularly exposed to mechanical or chemical wear and tear, and in the event of concrete suspicion that the source encapsulation is damaged.

Section 14 Technical requirements on equipment, marking

Equipment and appliances containing radioactive sources shall be marked with the standard ionising radiation warning sign together with information about source type and activities on a given date. The manufacturer and serial number shall also be stated.

Industrial nuclear gauges in permanent installations containing radioactive sources shall satisfy the requirements stated in ISO 7205 for class xx2323xxxxx as regards radiation. The equipment shall moreover be constructed in such a way as to ensure that it is not possible to open or disassemble it without using special tools, or it shall be sealed in such a manner that the radioactive source cannot be removed without breaking the seal.

Permanently positioned equipment for non-medical imaging and technical analyses shall comply with the following requirements:

- a) The equipment shall be shielded such that the dose rate on the surface does not exceed 5 $\mu\text{Sv/h}$.
- b) X-ray apparatus shall have light or sound signals indicating when radiation is generated.
- c) X-ray apparatus shall not be able to generate radiation without the use of a key or code.

Section 15 Requirement for storage

Radioactive sources which are temporarily decommissioned, sources which are temporarily stored, as well as radioactive waste in the form of sources which have been in use, shall be in proper safekeeping.

- a) The storage room/closet shall be locked and access restricted.
- b) The door shall have a standard ionising-radiation warning sign and explanatory text.
- c) The radiation level outside the storage room shall not exceed 7.5 $\mu\text{Sv/h}$.
- d) Radioactive sources shall not be stored together with explosives or highly flammable substances.
- e) An inventory of stored radioactive sources shall be present in the storage room.

Section 16 Shielding and technical safety requirements

Radiation shielding and other safety equipment such as personal protective equipment and technical safety systems shall be present where required. These items shall be designed such that the risk of incidents and accidents and radiation doses to employees and other persons is as low as reasonably achievable, cf. section 21 concerning dose limits.

The undertaking shall regularly ensure that safety equipment and operations function as intended.

The undertaking shall plan shielding and radiation use so as to prevent irradiation of members of the general public which may involve individuals being exposed to more than 0.25 mSv per year.

Section 17 Work involving open radioactive sources and classification of isotope laboratories

All work involving open radioactive sources shall take place in an isotope laboratory of type A, B or C, depending on the activities involved. Activity limits for the various types of isotope laboratories are as follows:

<i>Type of laboratory</i>	<i>(Activity) which may be used per occasion in the laboratory</i>
Type C	Up to 10 times the exemption levels for activities stated in the annex
Type B	Up to 10 ⁴ times the exemption levels level for activities stated in the annex
Type A	More than 10 ⁴ times the exemption levels for activities stated in the annex

The activity limits apply to normal chemical work. For simple work processes, for example preparation of stem solutions and diluted solutions, the stated limits may be raised by up to a factor of 10. In case of work involving particular risk, including work with dry substances, the activity limits shall be reduced by a factor of 10.

Storage of open radioactive sources shall be kept to a minimum.

In case of work with open radioactive sources, measuring equipment for control of radioactive contamination shall be present. Measuring equipment and other safety equipment such as extractor units and fans shall be inspected regularly.

Requirements for class A, B or C laboratories do not apply to work involving activities below the exemption levels stated in the annex.

Section 18 General requirements on isotope laboratories

All isotope laboratories shall be equipment and designed such that:

- a) The radiation doses to workers can be kept as low as reasonable achievable.
- b) The risk of contamination and of intake of radioactive substances is minimal,
- c) Surfaces are impervious and smooth to ease cleaning and resistant to the chemicals used in the laboratory,
- d) Recirculation of radioactive substances to the laboratory or other premises is prevented, normally by means of an extractor unit. Where necessary, it shall be possible to mount absorbent filters in the ventilation system.
- e) Personnel can wash their hands in a wash basin

Section 19 Additional requirements on type A and B isotope laboratories

A type B isotope laboratory shall be reserved for work involving radioactive substances, and shall be designed such that:

- a) There is a transition zone to the controlled area. The transition zone shall contain a contamination monitor, a suitable wash basin and an emergency shower,
- b) The laboratory has reduced air pressure in relation to the surroundings so that radioactive substances do not escape into the working atmosphere,
- c) The ventilation system for outgoing air is connected to a separate ventilation duct whose outlet is positioned such that the air is not recirculated into the working atmosphere. The fan shall be positioned close to the outlet of the ventilation duct.

Type A laboratories require approval pursuant to section 5 n).

Chapter IV Occupational exposure to ionising radiation

Section 20 Classification and marking of the workplace

The undertaking shall classify the workplace as a controlled area if employees may be exposed to radiation doses above 6 mSv per year or if the dose to the hands may exceed 150 mSv per year.

The undertaking shall classify the workplace as a supervised area if employees may be exposed to radiation doses in excess of 1 mSv per year or if the dose to the hands may exceed 50 mSv per year.

Undertakings using ionising radiation sources shall organise radiation use and shielding etc., in such a way that employees outside the supervised area cannot be exposed to radiation doses in excess of 1 mSv per year.

A controlled area shall be physically demarcated or, where physical demarcation is not possible, clearly marked by other means. A controlled or supervised area shall be marked with signs stating that it is a controlled or supervised area and giving further details of the position of the radiation sources and of the risk they may involve.

This section does not regulate the transport of radioactive sources. The requirements as to marking of the workplace do not apply in the case of elevated cosmic radiation to flight personnel, or in the case of elevated radon exposure at subsurface workplaces.

Section 21 Dose limits etc.

All radiation exposure shall be kept as low as reasonably achievable, and the following dose limits shall not be exceeded:

- a) The dose limit for workers over the age of 18 is 20 mSv per calendar year. The Norwegian Radiation Protection Authority may grant dispensation for individuals where the nature of the work makes it impracticable to set an annual limit of 20 mSv. In such cases permission may be given for a limit of 100 mSv over a continuous five-year period, on condition that the effective dose does not exceed 50 mSv in any single year.
- b) The radiation dose to the lens of the eye shall not exceed 150 mSv per year.
- c) The radiation dose to the skin, hands and feet shall not exceed 500 mSv per year.

d) For apprentices between the age of 16 and 18 years who use radiation sources as part of their training, doses of respectively 5, 50 and 150 mSv per year apply instead of the doses stated under a) to c).

e) For pregnant women the dose to the foetus shall not exceed 1 mSv for the remainder of the pregnancy, i.e. after pregnancy has been established.

Rescue work in emergency situations shall as far as possible be carried out within the general dose limits mentioned in a) to c). If the work may involve doses in excess of 50 mSv, the work shall only be carried out by volunteers who have been thoroughly informed of the risks and hazards involved. Women of fertile age may participate provided they are not pregnant. Exceeding this limit can only be accepted in order to save lives, avoid serious damage to health or prevent a dramatic escalation of the accident. Radiation doses in excess of 500 mSv shall as far as possible be avoided and can only be accepted in order to save lives, and only after a thorough assessment has been made and it is recognised that the benefits clearly outweigh the costs in the form of health risk to the rescue personnel.

Where there is reason to believe that an employee has exceeded the dose limit, the employer shall immediately carry out an investigation to identify the causes, and take steps to avoid repeats.

Section 22 Personal dosimetry etc.

Employees who work within a controlled or monitored area shall carry a personal dosimeter or ascertain their personal radiation exposure by other means.

Employers shall see to it that employees are informed of the dose readings and are obliged to store the employees' personal dose reports.

The results of dose monitoring shall be reported each year to the Norwegian Radiation Protection Authority.

Chapter V Special provisions on discharges to the environment and on waste treatment of substances which emit ionising radiation

Section 23 Regulation of discharges

Undertakings which cause discharges of radioactive substances shall have approval to do so from the Norwegian Radiation Protection Authority cf. section 5 o). The undertakings shall use the best available technology such that discharges to the environment are avoided or kept to the lowest possible level.

Section 24 Order to investigate and carry out countermeasures

The Norwegian Radiation Protection Authority may order undertakings which cause or may cause radioactive contamination or radiation in the environment to carry out investigations and take measures which may reasonably be demanded in order to:

- a) establish whether and to what extent the undertaking work activity in question leads or may lead to radioactive contamination,
- b) identify the cause for and the consequences of elevated radiation levels in the environment,
- c) identify how the radioactive contamination should be counteracted,
- d) counteract any damage or inconvenience resulting from the contamination.

Section 25 Requirements as to treatment, storage and final disposal of radioactive waste

Radioactive waste shall be dealt with in such a way as to cause the least possible damage and inconvenience. The waste treatment shall:

- a) generate minimal waste,
- b) be carried out using the best available technology. To minimise waste problems, a basis shall be taken in technology which, based on an overall assessment of current and future use of the environment and of economic factors, gives the best results.

Undertakings which procure sealed radioactive sources shall make certain that a return scheme exist so that radiation sources can be returned after use.

Radioactive sources which are permanently decommissioned shall be returned to the distributor, manufacturer or to an approved facility in Norway for disposal, cf. section 5 p).

Radiation sources and areas of use mentioned in the annex are exempt from these requirements.

Chapter VI Provisions for non-ionising radiation

Section 26 Exposure levels

All exposure shall be kept as low as reasonably achievable. Relevant guidelines from the International Commission on Non-Ionizing Radiation Protection (ICNIRP) shall as a principal rule be followed provided no superseding national or European standards exist.

Section 27 Lasers

Lasers shall be constructed, classified and marked in accordance with the prevailing version of Norwegian standard NEK-EN 60825-1.

Undertakings which use class 3B or 4 lasers for purposes where exposure of people is not intended shall ensure that personal irradiation in excess of the maximum permissible exposure (MPE) values stated in the standard cannot occur.

For all use of class 3B or 4 lasers where exposure of people is intended, section 41 c) and d) applies.

Section 28 Tanning appliances

Undertakings which offer tanning appliances for cosmetic purposes for sale, rent or use shall notify the Norwegian Radiation Protection Authority accordingly.

Tanning appliances shall be constructed and classified in accordance with the prevailing Norwegian standard EN 60335-2-27. Only tanning appliances belonging to UV type 3 are allowed to be sold or used for cosmetic purposes. Anyone who imports/sells tanning appliances is responsible for ensuring that the requirements are met and that necessary measurements are performed. Measurements confirming the classification must be carried out by a laboratory accepted by the Norwegian Radiation Protection Authority, and documentation for this shall be approved by the Norwegian Radiation Protection Authority before new models are offered for sale or put to use.

Only ultraviolet radiation sources, filters and components of significance for the radiation output for which the appliance is certified shall be used. Ultraviolet radiation sources may only be replaced with identical or biologically equivalent sources or sources resulting in correspondence with UV type 3. A specification of permitted radiation sources shall be available for each model.

Importers/distributors are responsible for ensuring that the appliances are equipped with instructions for use and marking in Norwegian in accordance with EN 60335-2-27 and marked with a warning which shall be in an easily visible position and of robust design. The warning label shall have the following text: ¹ "*Advarsel – Ultrafiolett stråling kan føre til skade på øyne og hud. Les bruksanvisningen. Bruk beskyttelsesbriller. Enkelte medisiner og kosmetikk kan øke følsomheten for UV.*" A label showing "UV type 3" shall also be affixed to the appliance. Appliances whose luminance exceeds 100 000 cd/m² shall in addition carry the following warning text²: "*Advarsel. Intens lysstyrke. Se ikke rett på lyskilden.*"

The undertaking is obliged to ensure that appliances and marking comply with applicable requirements and to inform the customer of the recommended schedule of exposure in the appliance's instructions for use. It is also obliged to inform the customer of possible health risks associated with the use of cosmetic tanning appliances and that the customer should use protective glasses when sun tanning. It must be possible to set the tanning appliances' timer in accordance with the recommended schedule of exposure. The undertaking is obliged to post a notice with a warning text and safety rules in accordance with EN 60335-2-27 in an easily visible position on the premises. The notice shall also contain the following³: "*Statens strålevern fraråder bruk av solarium for personer under 18 år.*"

Chapter VII Medical use of radiation

Section 29 Justification

New methods and applications of radiation in medicine shall be evaluated on a general basis and deemed to be justified before becoming available for general use. Existing areas of use and methods shall be reassessed when new information emerges about their effectiveness or effects.

An assessment shall be made of whether the use of radiation is justified for the individual patient's premises. If possible, previous information on the patient shall be obtained in order to avoid unnecessary radiation use. Irradiation may be justified in a particular case, even if not justified in general terms.

Section 30 Optimisation

The undertaking shall on a continual basis take care that medical use of radiation is optimised. The optimisation includes choice of method, apparatus and equipment; assessment of diagnostic information or the effect of therapy; practical implement ability of the examination or therapy, along with an assessment of work technique and radiation dose to the patient.

¹ "Warning - Ultraviolet radiation may cause damage to the eyes and skin. Read the instructions for use. Use protective glasses. Some medicines and cosmetics may increase sensitivity to UV."

² "Warning. Intense light. Do not stare at the light source."

³ "The Norwegian Radiation Protection Authority advises young people under 18 not to use tanning appliances."

Each undertaking shall establish protocols for the most usual and relevant medical procedures. The protocols shall provide information on procedures and apparatus settings for carrying out examinations and therapy. These procedures shall be reviewed on a regular basis.

Section 31 Radiation dose / activity to the patient

The undertaking shall maintain a summary of representative doses/administered activity to patients undergoing typical x-ray and nuclear medical diagnostic examinations.

Therapy with ionising radiation for curative or palliative purposes shall be in accordance with professionally proper and documented procedures as regards description of target volume, organ at risk, fractionation and doses.

Section 32 Women of fertile age

For therapy or examination of women of fertile age, special attention shall be paid to protection of the foetus if pregnancy has been declared or cannot be ruled out. In the assessment of the justification account shall be taken of the expected dose to the foetus, whether the examination or therapy can be postponed considering the state of health of the woman and whether alternative methods exist which involve less risk of damage.

Section 33 Requirements as to competence and training

Undertakings which employ radiation for the following specified purposes shall have personnel with the following competence:

- a) For x-ray diagnostics subject to an approval requirement under section 5, a medical practitioner with specialist competence in medical radiology or a dentist with specialist competence in maxillofacial radiology.
- b) For other x-ray diagnostics, a medical practitioner or dentist trained in radiation protection relevant for the apparatus in question.
- c) For high- and medium-energy radiation therapy, a medical practitioner with specialist competence in oncology.
- d) For nuclear medical examinations, a medical practitioner with specialist competence in nuclear medicine.
- e) For nuclear medical therapies, a medical practitioner with specialist competence in oncology or nuclear medicine.
- f) For dental x-rays (with tube voltage not exceeding 75 kV), a dentist or dental nurse; for special examinations, a dentist with relevant specialist competence.
- g) For skin therapy with tube voltage not exceeding 15 kV x-ray radiation, a medical practitioner with specialist competence in dermatology.
- h) For use of x-ray appliances in chiropractic activity, a medical practitioner or chiropractor trained in radiation protection relevant for the apparatus in question.
- i) For medical therapy of skin diseases with UV radiation, a medical practitioner.

Undertakings using radiation for medical purposes that require authorisation under section 5 shall have personnel with a scientific competence at the level of master's degree and additional competence in medical physics.

Permanent x-ray installations shall be operated by a radiographer or personnel with proven equivalent knowledge of radiation use and radiation protection. For radiation therapy, personnel who operate the apparatuses on an independent basis shall be professionally trained radiation therapists at bachelor's level or have further education in radiation therapy or other health care training at the same level. Medical practitioners who use x-ray apparatus for guidance during interventions, surgery etc., shall have the requisite training in the use of radiation and radiation protection. Apparatuses for nuclear medicine shall be operated by personnel with a university-level education of at least three years (radiographer, bioengineer or the like) and with further training in nuclear medicine and radiation protection approved by the Norwegian Radiation Protection Authority.

All affected personnel shall have specific training before new apparatuses and methods are put into clinical use.

Section 34 Duty to provide information

When requested by the Norwegian Radiation Protection Authority, the undertaking shall provide information on the annual number of therapies and diagnostic examinations carried out in various medical areas, as well as records of radiation doses to patients.

When requested by the Norwegian Radiation Protection Authority, the undertaking shall be able to present a technical record of measurements for each individual apparatus showing results from commissioning tests, acceptance tests and periodical tests of the equipment, as well as maintenance and service reports.

Section 35 Requirements on apparatuses

Apparatuses for medical use of radiation shall comply with relevant standards from the International Electrotechnical Committee (IEC) and the International Organization for Standardization (ISO), provided no superseding national or European standards exist.

Technical documentation on the apparatuses' performance, instructions for use, maintenance descriptions and descriptions of radiation protection and safety, shall be available in Norwegian or English, and comply with relevant IEC and ISO standards.

Apparatuses used for screening, examination of children, computer tomography and angio- and interventional radiology shall be fit for the respective areas of application.

Where x-ray apparatuses are received and prepared for use that requires authorisation under section 5, testing shall encompass all parameters and factors which may affect radiation dose and image quality. A system for periodic testing of apparatus and equipment shall also be established.

Technical documentation on the apparatuses' performance, instructions for use, maintenance descriptions and descriptions of radiation protection and safety, shall be available in Norwegian and/or English, and comply with relevant IEC and ISO standards.

New x-ray fluoroscopy apparatuses shall be equipped with at least two levels of automatic dose regulation.

Section 36 Dosimetry in connection with ionising radiation therapy

The undertaking shall have a reference instrument for dose measurement. This reference instrument shall be calibrated every second year against the national standard. Sources used for radiation therapy shall be calibrated against the reference instrument for those radiation qualities that are used clinically. Calibration of radiation sources for radiation therapy shall be performed in connection with acceptance testing, in connection with maintenance affecting the dosimetry and in accordance with planned routines, and shall be performed in accordance with international or national protocols where such protocols have been prepared.

Section 37 X-ray diagnostics

Exposure parameters this shall be recorded for all patients in the following types of examinations: computer tomography (CT), angiography and intervention, conventional x-ray examinations of the gastrointestinal tract and examinations that are specially prepared for children. New x-ray apparatus shall be equipped with a device providing a measure for the radiation dose to the patient during the examination, and these data shall accompany the medical journal for the patient or be obtainable by other means.

New x-ray apparatuses featuring fluoroscopy shall be equipped with at least two levels of automatic dose regulation.

At permanent x-ray installations, standardised protocols for use shall be developed for optimal setting of apparatuses relevant for ordinary medical issues. Such protocols are to be used as guideline; the apparatus shall be adjusted to the optimal setting for the individual patient. Gonads, retinas, breasts and thyroid gland shall be shielded from the primary radiation field provided such shielding does not hide areas of clinical interest.

Section 38 Radiation therapy

Tools shall be available for individual planning of radiation doses based on the anatomy of the patient and there shall be a professionally responsible person who is familiar with the dose calculation models and the limitations of the tools. Before therapy begins, the dose calculation shall be verified by at least two competent persons. A verification system shall exist whereby the therapy is verified against planned values. Any change in relation to the therapy plan shall be documented. Manual transfer of therapy data shall be kept to a minimum. The therapy shall be documented in order to permit reconstruction of the therapy setup, therapy path and doses administered to each individual patient. The patient is entitled to information about radiation doses and the risks attending radiation therapy.

Section 36 Dosimetry in connection with ionising radiation treatment

The undertaking shall have a reference instrument for dose measurement. This reference instrument shall be calibrated every second year against the national standard. Sources used for radiation treatment shall be calibrated against the reference instrument for those radiation qualities that are used in the clinical context. Calibration of radiation sources for radiation treatment shall take place in connection with acceptance testing, with maintenance of significance for dosimetry and in accordance with planned routines, and shall take place in accordance with international or national protocols where such protocols have been prepared.

Section 37 X-ray diagnostics

Exposure parameters shall be recorded for all patients in the following types of examination: computer tomography, angiography and intervention, conventional x-ray examinations of the gastrointestinal tract and examinations that are specially designed for children. New x-ray apparatus shall be equipped with a device providing a measure of the radiation dose to the patient during the examination, and these data shall accompany the patient's journal or be obtainable by other means.

Standardised protocols for use at permanent x-ray installations shall be developed for optimal adjustment of apparatuses to the commonest medical issues. Such protocols are of a guideline nature; the apparatus shall be adjusted to the optimal setting for the individual patient. Gonads, lenses of the eyes, breasts and thyroid gland shall be shielded from the primary radiation field provided such shielding does not hide areas of clinical interest.

Section 38 Radiation therapy

Tools shall be available for individual planning of radiation doses with a basis in the patient's anatomy, and there shall be a professionally responsible person who is familiar with the dose calculation models and the limitations of the tools. Before treatment starts, the dose calculation shall be checked by at least two specialists. A verification system shall exist whereby the treatment is checked against planned values. Any change in relation to the treatment plan shall be documented. Manual transfer of treatment data shall be kept to a minimum. The treatment shall be documented in order to permit reconstruction of the treatment setup, course of treatment and doses administered to each individual patient. The patient is entitled to information about radiation doses and the risk attending radiation treatment.

Procedures shall exist for reporting and follow-up of deviations with a separate register for the various types of deviation. The patient and any immediate family members shall be alerted in the event of deviation of significance for the therapy. A dosimetric and medical assessment of the deviation shall decide the further follow-up of the patient.

In the case of external high-energy radiation therapy, a system shall exist for dosimetric and geometric control of the therapy.

In the case of brachytherapy, the positioning of radiation sources within the patient and therapy durations shall be documented. A radiation protection monitor shall be available in the control room.

Section 39 Nuclear medicine

In the case of nuclear medical examinations, the radiation dose to the patient shall be stated in terms of effective dose.

In the case of treatment, the radiation dose to the patient shall be stated in terms of absorbed dose to the treated tissue. Administered activity may be used as an indicator of radiation dose in both cases. The activity shall be determined prior to each individual administration to the patient. Individual dose planning shall be performed prior to each therapy.

Information on applied radioactive medicines and the mean administered activities for each type of examination or therapy provides the basis for calculation of radiation doses in nuclear medicine.

Section 40 Optical radiation

Therapy with optical radiation for the purpose of curing disease or relieving symptoms shall be performed in accordance with professionally proper and documented procedures.

Light therapy for jaundice in newly born babies shall be carried out at a hospital, birth clinic or the like, using apparatus intended for the purpose and with a paediatrician professionally responsible for the therapy. The choice of apparatus, light sources and therapy method shall comply with relevant standards from the International Electrotechnical Committee (IEC) and the International Organization for Standardization (ISO), provided no superseding national or European standards exist.

Registered nurses, nursing auxiliaries and children's nurses with special training in radiation protection in the context of light therapy are entitled to operate light therapy apparatus. Control measurement of the light source shall be performed regularly.

Section 41 Lasers

Medical use of lasers is subject to the following requirements:

- a) A laser shall be constructed, classified and marked in accordance with the applicable Norwegian standard, NEK-EN 60825-1.
- b) The undertaking shall establish and maintain adequate training in handling laser risks for all workers in a controlled area.
- c) Medical use of class 3B or 4 lasers shall be under the responsibility of a medical practitioner or dentist.
- d) Irradiation with laser light in connection with eye therapy shall only be performed under the responsibility of a medical practitioner with completed specialist training in ophthalmology.

Chapter VIII Administrative provisions

Section 42 Inspection

The Norwegian Radiation Protection Authority inspects compliance with provisions laid down in or pursuant to these regulations, and may lay down individual decisions as necessary for this purpose.

The Norwegian Radiation Protection Authority shall be given free access to perform inspections, and shall be provided with the information necessary to carry out inspections and implement decisions made pursuant to these regulations. The Norwegian Radiation Protection Authority shall also be given access to undertake measurements and investigations.

The Norwegian Radiation Protection Authority's inspection powers concerning tanning appliances, and thereby its power to make the necessary administrative decisions in the individual case, is delegated to the municipalities, cf. the Act on Radiation Protection and Use of Radiation section 18.

Section 43 Rectification and halting of activity

The Norwegian Radiation Protection Authority may demand rectification of activity that conflicts with provisions laid down in these regulations.

If a material risk to health exists, the Norwegian Radiation Protection Authority may halt the activity in question, confiscate substances or equipment in whole or in part, or by other means ensure that continued use of such substances or equipment cannot take place. The Norwegian Radiation Protection Authority may demand the closure of an undertaking that does not possess the required licence or has not submitted the required notification.

The police are, upon request, obliged to assist the process of halting or confiscation.

Section 44 Coercive fine

The Norwegian Radiation Protection Authority may impose a coercive fine in the form of a one-time fine or a cumulative daily fine on an undertaking that ignores a deadline for complying with an order. The coercive fine shall be fixed either at the time the order is made or when a new deadline is set for compliance.

Section 45 Dispensation

The Norwegian Radiation Protection Authority may in special cases grant dispensation from the provisions of these regulations.

Section 46 Appeal

The Ministry of Health is the body of appeal for individual decisions made by the Norwegian Radiation Protection Authority under the provisions of these regulations.

The county governor decides appeals concerning individual decisions made by the municipality under the provisions of these regulations.

Section 47 Penalties

Anyone who wilfully or through negligence violates or contributes to the violation of provisions or orders made under the provisions of these regulations shall be punished by fines or imprisonment not exceeding three months.

If the violation has or could have caused grave danger to health or the environment, imprisonment not exceeding two years may be imposed.

If the violation has merely resulted in insignificant damage or inconvenience, public prosecution will take place only at the request of the supervisory authority.

Section 48 Prohibition of import and sale

The Norwegian Radiation Protection Authority may refuse the import or sale of any product or substance and any item that may involve a risk to health or environment due to radiation, provided that such refusal does not conflict with international agreements to which Norway has acceded.

Section 49 Amendments to the regulations

The Ministry of Health may make amendments to these regulations.

Chapter IX Final provisions

Section 50 Commencement

These regulations come into force on 1 January 2004.

Section 7, section 33, section 35 fourth and fifth paragraphs, section 37 and section 39 come into force on 1 January 2006.

Section 51 Transitional provisions

Permits and approvals granted and previous rules shall apply until they are replaced by approval under section 5 but are in no event valid after 1 January 2008. Existing undertakings that are encompassed by section 5 o) and r) shall be approved not later than 1 January 2006.

Apparatus which complies with the requirements of earlier regulations no. 741 of 8 April 1983 in respect of tanning appliances/ultraviolet lamps may continue to be used in the same undertaking until 1 January 2006.

Section 52 Revocation of regulations

The following regulations are revoked as from 1 January 2004:

- Regulations no. 1 of 23 January 1976 on supervision and use of installations, apparatus, material and substances which emit ionising or other health-hazardous radiation.
- Regulations no.4 of 2 November 1979 on the right to use x-ray apparatus for medical purposes.
- Regulations no. 155 of 1 March 1983 on the manufacture, import and sale of radioisotopes.
- Regulations no. 741 of 8 April 1983 for tanning appliances/ultraviolet lamps. Delegation of authority.

Annex to Regulations on Radiation Protection and Use of Radiation, cf sections 5, 6, 8, 9, 17 and 25

Exemption levels

1 Areas of use and types of source exempt from requirements stated in the respective sections

- a) Smoke detectors containing less than 40 kBq Am-241
- b) Welding electrodes containing thorium.
- c) Depleted uranium used as balance weights or shielding material.
- d) Sealed radioactive sources used for tuition/demonstration and testing ,provided the source activity is less than 1 MBq.

2 Radiation sources exempt from requirements stated in the respective sections

Where specified in the regulations, radioactive sources whose activity content does not exceed the levels in the table are exempt from the requirements of the regulations. The values in the table refer either to maximal activity per source or total activity (quantity) handled at any point in time by individuals. Exemption from the requirements of the regulations requires either total source strength (Bq) or activity concentration (Bq/g) to be below the level.

For work involving open radioactive sources in laboratories, the exemption levels apply to the individual laboratory. Where the work involves different nuclides at the same time, the sum of the relationship between the overall activity) for each nuclide and the corresponding exemption level must be less than or equal to 1. This is illustrated as follows:

$$\sum_k \frac{A_k}{A_{E,k}} \leq 1, \quad \text{eventuelt} \quad \sum_k \frac{C_k}{C_{E,k}} \leq 1$$

where

A_k = activity for radionuclide k

$A_{E,k}$ = exemption level for activity of radionuclide k

C_k = activity concentration for radionuclide k

$C_{E,k}$ = exemption level for activity concentration of radio radionuclide k.

Nuclide	Activity <i>Bq</i>	Activity concentration <i>Bq/g</i>	Nuclide	Activity <i>Bq</i>	Activity concentration <i>Bq/g</i>
H-3	10 ⁹	10 ⁶	Co-56	10 ⁵	10 ¹
Be-7	10 ⁷	10 ³	Co-57	10 ⁶	10 ²
C-14	10 ⁷	10 ⁴	Co-58	10 ⁶	10 ¹
O-15	10 ⁹	10 ²	Co-58m	10 ⁷	10 ⁴
F-18	10 ⁶	10 ¹	Co-60	10 ⁵	10 ¹
Na-22	10 ⁶	10 ¹	Co-60m	10 ⁶	10 ³
Na-24	10 ⁵	10 ¹	Co-61	10 ⁶	10 ²
Si-31	10 ⁶	10 ³	Co-62m	10 ⁵	10 ¹
P-32	10 ⁵	10 ³	Ni-59	10 ⁸	10 ⁴
P-33	10 ⁸	10 ⁵	Ni-63	10 ⁸	10 ⁵
S-35	10 ⁸	10 ⁵	Ni-65	10 ⁶	10 ¹
Cl-36	10 ⁶	10 ⁴	Cu-64	10 ⁶	10 ²
Cl-38	10 ⁵	10 ¹	Zn-65	10 ⁶	10 ¹
Ar-37	10 ⁸	10 ⁶	Zn-69	10 ⁶	10 ⁴
Ar-41	10 ⁹	10 ²	Zn-69m	10 ⁶	10 ²
K-40	10 ⁶	10 ²	Ga-72	10 ⁵	10 ¹
K-42	10 ⁶	10 ²	Ge-71	10 ⁸	10 ⁴
K-43	10 ⁶	10 ¹	As-73	10 ⁷	10 ³
Ca-45	10 ⁷	10 ⁴	As-74	10 ⁶	10 ¹
Ca-47	10 ⁶	10 ¹	As-76	10 ⁵	10 ²
Sc-46	10 ⁶	10 ¹	As-77	10 ⁶	10 ³
Sc-47	10 ⁶	10 ²	Se-75	10 ⁶	10 ²
Sc-48	10 ⁵	10 ¹	Br-82	10 ⁶	10 ¹
V-48	10 ⁵	10 ¹	Kr-74	10 ⁹	10 ²
Cr-51	10 ⁷	10 ³	Kr-76	10 ⁹	10 ²
Mn-51	10 ⁵	10 ¹	Kr-77	10 ⁹	10 ²
Mn-52	10 ⁵	10 ¹	Kr-79	10 ⁵	10 ³
Mn-52m	10 ⁵	10 ¹	Kr-81	10 ⁷	10 ⁴
Mn-53	10 ⁹	10 ⁴	Kr-83m	10 ¹²	10 ⁵
Mn-54	10 ⁶	10 ¹	Kr-85	10 ⁴	10 ⁵
Mn-56	10 ⁵	10 ¹	Kr-85m	10 ¹⁰	10 ³
Fe-52	10 ⁶	10 ¹	Kr-87	10 ⁹	10 ²
Fe-55	10 ⁶	10 ⁴	Kr-88	10 ⁹	10 ²
Fe-59	10 ⁶	10 ¹	Rb-86	10 ⁵	10 ²
Co-55	10 ⁶	10 ¹	Sr-85	10 ⁶	10 ²
Sr-85m	10 ⁷	10 ²	Pd-103	10 ⁸	10 ³
Sr-87m	10 ⁶	10 ²	Pd-109	10 ⁶	10 ³
Sr-89	10 ⁶	10 ³	Ag-105	10 ⁶	10 ²
Sr-90 ^a	10 ⁴	10 ²	Ag-110m	10 ⁶	10 ¹

Sr-91	10^5	10^1	Ag-111	10^6	10^3
Sr-92	10^6	10^1	Cd-109	10^6	10^4
Y-90	10^5	10^3	Cd-115	10^6	10^2
Y-91	10^6	10^3	Cd-115m	10^6	10^3
Y-91m	10^6	10^2	In-111	10^6	10^2
Y-92	10^5	10^2	In-113m	10^6	10^2
Y-93	10^5	10^2	In-114m	10^6	10^2
Zr-93 ^a	10^7	10^3	In-115m	10^6	10^2
Zr-95	10^6	10^1	Sn-113	10^7	10^3
Zr-97 ^a	10^5	10^1	Sn-125	10^5	10^2
Nb-93m	10^7	10^4	Sb-122	10^4	10^2
Nb-94	10^6	10^1	Sb-124	10^6	10^1
Nb-95	10^6	10^1	Sb-125	10^6	10^2
Nb-97	10^6	10^1	Te-123m	10^7	10^2
Nb-98	10^5	10^1	Te-125m	10^7	10^3
Mo-90	10^6	10^1	Te-127	10^6	10^3
Mo-93	10^8	10^3	Te-127m	10^7	10^3
Mo-99	10^6	10^2	Te-129	10^6	10^2
Mo-101	10^6	10^1	Te-129m	10^6	10^3
Tc-96	10^6	10^1	Te-131	10^5	10^2
Tc-96m	10^7	10^3	Te-131m	10^6	10^1
Tc-97	10^8	10^3	Te-132	10^7	10^2
Tc-97m	10^7	10^3	Te-133	10^5	10^1
Tc-99	10^7	10^4	Te-133m	10^5	10^1
Tc-99m	10^7	10^2	Te-134	10^6	10^1
Ru-97	10^7	10^2	I-123	10^7	10^2
Ru-103	10^6	10^2	I-125	10^6	10^3
Ru-105	10^6	10^1	I-126	10^6	10^2
Ru-106 ^a	10^5	10^2	I-129	10^5	10^2
Rh-103m	10^8	10^4	I-130	10^6	10^1
Rh-105	10^7	10^2	I-131	10^6	10^2
I-132	10^5	10^1	Gd-153	10^7	10^2
I-133	10^6	10^1	Gd-159	10^6	10^3
I-134	10^5	10^1	Tb-160	10^6	10^1
I-135	10^6	10^1	Dy-165	10^6	10^3
Xe-131m	10^4	10^4	Dy-166	10^6	10^3
Xe-133	10^4	10^3	Ho-166	10^5	10^3
Xe-135	10^{10}	10^3	Er-169	10^7	10^4
Cs-129	10^5	10^2	Er-171	10^6	10^2
Cs-131	10^6	10^3	Tm-170	10^6	10^3
Cs-132	10^5	10^1	Tm-171	10^8	10^4
Cs-134m	10^5	10^3	Yb-175	10^7	10^3
Cs-134	10^4	10^1	Lu-177	10^7	10^3

Cs-135	10^7	10^4	Hf-181	10^6	10^1
Cs-136	10^5	10^1	Ta-182	10^4	10^1
Cs-137 ^a	10^4	10^1	W-181	10^7	10^3
Cs-138	10^4	10^1	W-185	10^7	10^4
Ba-131	10^6	10^2	W-187	10^6	10^2
Ba-140 ^a	10^5	10^1	Re-186	10^6	10^3
La-140	10^5	10^1	Re-188	10^5	10^2
Ce-139	10^6	10^2	Os-185	10^6	10^1
Ce-141	10^7	10^2	Os-191	10^7	10^2
Ce-143	10^6	10^2	Os-191m	10^7	10^3
Ce-144 ^a	10^5	10^2	Os-193	10^6	10^2
Pr-142	10^5	10^2	Ir-190	10^6	10^1
Pr-143	10^6	10^4	Ir-192	10^4	10^1
Nd-147	10^6	10^2	Ir-194	10^5	10^2
Nd-149	10^6	10^2	Pt-191	10^6	10^2
Pm-147	10^7	10^4	Pt-193m	10^7	10^3
Pm-149	10^6	10^3	Pt-197	10^6	10^3
Sm-151	10^8	10^4	Pt-197m	10^6	10^2
Sm-153	10^6	10^2	Au-198	10^6	10^2
Eu-152	10^6	10^1	Au-199	10^6	10^2
Eu-152m	10^6	10^2	Hg-197	10^7	10^2
Eu-154	10^6	10^1	Hg-197m	10^6	10^2
Eu-155	10^7	10^2	Hg-203	10^5	10^2
Tl-200	10^6	10^1	Pa-233	10^7	10^2
Tl-201	10^6	10^2	U-230 ^a	10^5	10^1
Tl-202	10^6	10^2	U-231	10^7	10^2
Tl-204	10^4	10^4	U-232 ^a	10^3	10^0
Pb-203	10^6	10^2	U-233	10^4	10^1
Pb-210 ^a	10^4	10^1	U-234	10^4	10^1
Pb-212 ^a	10^5	10^1	U-235 ^a	10^4	10^1
Bi-206	10^5	10^1	U-236	10^4	10^1
Bi-207	10^6	10^1	U-237	10^6	10^2
Bi-210	10^6	10^3	U-238 ^a	10^4	10^1
Bi-212 ^a	10^5	10^1	U-nat	10^3	10^0
Po-203	10^6	10^1	U-239	10^6	10^2
Po-205	10^6	10^1	U-240	10^7	10^3
Po-207	10^6	10^1	U-240 ^a	10^6	10^1
Po-210	10^4	10^1	Np-237 ^a	10^3	10^0
At-211	10^7	10^3	Np-239	10^7	10^2
Rn-220 ^a	10^7	10^4	Np-240	10^6	10^1
Rn-222 ^a	10^8	10^1	Pu-234	10^7	10^2
Ra-223 ^a	10^5	10^2	Pu-235	10^7	10^2
Ra-224 ^a	10^5	10^1	Pu-236	10^4	10^1

Ra-225	10 ⁵	10 ²	Pu-237	10 ⁷	10 ³
Ra-226 ^a	10 ⁴	10 ¹	Pu-238	10 ⁴	10 ⁰
Ra-227	10 ⁶	10 ²	Pu-239	10 ⁴	10 ⁰
Ra-228 ^a	10 ⁵	10 ¹	Pu-240	10 ³	10 ⁰
Ac-228	10 ⁶	10 ¹	Pu-241	10 ⁵	10 ²
Th-226 ^a	10 ⁷	10 ³	Pu-242	10 ⁴	10 ⁰
Th-227	10 ⁴	10 ¹	Pu-243	10 ⁷	10 ³
Th-228 ^a	10 ⁴	10 ⁰	Pu-244	10 ⁴	10 ⁰
Th-229 ^a	10 ³	10 ⁰	Am-241	10 ⁴	10 ⁰
Th-230	10 ⁴	10 ⁰	Am-242	10 ⁶	10 ³
Th-231	10 ⁷	10 ³	Am-242m ^a	10 ⁴	10 ⁰
Th-nat (incl. Th- 232)	10 ³ 10 ⁵	10 ⁰ 10 ³	Am-243 ^a	10 ³	10 ⁰
Th-234 ^a	10 ⁶	10 ¹	Cm-242	10 ⁵	10 ²
Pa-230	10 ³	10 ⁰	Cm-243	10 ⁴	10 ⁰
Pa-231			Cm-244	10 ⁴	10 ¹
Cm-245	10 ³	10 ⁰	Cf-252	10 ⁴	10 ¹
Cm-246	10 ³	10 ⁰	Cf-253	10 ⁵	10 ²
Cm-247	10 ⁴	10 ⁰	Cf-254	10 ³	10 ⁰
Cm-248	10 ³	10 ⁰	Es-253	10 ⁵	10 ²
Bk-249	10 ⁶	10 ³	Es-254	10 ⁴	10 ¹
Cf-246	10 ⁶	10 ³	Es-254m	10 ⁶	10 ²
Cf-248	10 ⁴	10 ¹	Fm-254	10 ⁷	10 ⁴
Cf-249	10 ³	10 ⁰	Fm-255	10 ⁶	10 ³
Cf-250	10 ⁴	10 ¹			
Cf-251	10 ³	10 ⁰			

Substances marked ^a in the above table represent radioactive substances in equilibrium with the daughter products listed below. The activity level in the table refers to the parent nuclide alone, although the radiation contribution from the daughter products is taken into account when establishing the parent nuclide's activity level.

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144

Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Bi-210, Pb-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239.

Guidance on the Regulations on Radiation Protection and Use of Radiation

The following comments expand on the content of each provision. They are not binding, but are intended to serve as a guide.

To section 1: The purpose refers both to protection of human health and protection of the environment. The term "prevent" entails both preventing harmful effects and limiting possible further damage. The term "harmful effects" refers only to undesired effects.

To section 2: Radioactive substances which occur naturally in the environment and which have not become concentrated as a result of human activity, along with naturally occurring non-ionising radiation, are not regulated in these regulations. Examples of increased concentration of naturally occurring radioactive substances that are regulated by the regulations are: radon exposure at subterranean workplaces (mines), cosmic radiation to flight personnel and handling of scale (low radioactive deposits from the oil and gas sector).

Criteria for exempting an ionising radiation source from specified sections of the regulations in accordance with the annex are established with a basis in the following principles:

- a) The radiation dose to individual members of the population from the radiation source in question shall not exceed 10 μ Sv in the course of a year.
- b) The collective radiological impact to the population in the form of the individual dose multiplied by the number of exposed individuals shall not exceed 1,000 inhabitants x mSv in the course of a year.
- c) The exempted practice is such that there are no natural scenarios in terms of accidents which can lead to the above criteria being breached.

X-ray producing electrical appliances and components which are exempted may typically be cathode-ray tubes for displaying images and electrical components in high-voltage installations.

For non-ionising radiation sources the regulations will typically encompass light-treatment equipment, fields from radar, radio transmitters, mobile transmitters, power lines etc., in addition to tanning appliances and lasers which receive special mention.

To section 3: Reference is made to a report prepared by an inter-ministerial working group which assesses the application of radiation protection legislation on Svalbard, Jan Mayen and Norwegian dependencies.

Regulations on work involving ionising radiation have been laid down in pursuance of the Working Environment Act and therefore apply to Svalbard and Jan Mayen. Parts of these regulations are incorporated in the Regulations on Radiation Protection and Use of Radiation. These regulations are continued for Svalbard and Jan Mayen. Hence section 3 second sentence provides that chapter IV of the regulations applies to Svalbard and Jan Mayen.

To section 4:

b) Ionising radiation is defined in purely physical terms as the transfer of energy in the form of particles or electromagnetic radiation capable of forming ions in biological material, i.e. radiation with energy exceeding 12.6 eV corresponding to a wavelength of 100 nm or less. Typical examples of ionising radiation are x-ray radiation, gamma radiation, cosmic radiation, neutron radiation, radiation from radon etc.

c) Non-ionising radiation is defined in purely physical terms as radiation with energy below 12.6 eV, and electrical and magnetic fields. Examples of non-ionising radiation are optical radiation, radio frequency radiation, low-frequency and static and electrical and magnetic fields. The Radiation Protection Act also includes ultrasound in the sense of non-ionising radiation. Radiation from tanning appliances and lasers is an example of non-ionising radiation.

k) The term "radiation dose" may, depending on the context, refer to various dosimetric quantities such as organ dose, effective dose, ambient dose equivalent etc., expressed in units of Sv or Gy, or decadic prefixes of the latter such as milli or micro. Dose rate can be expressed in the unit Sv/h or Gy/h, or decadic prefixes of the latter such as mSv/h or µSv/h.

m) Medical use of radiation includes radiation used for odontological purposes.

To section 5: Approval of undertakings includes approval of the premises to be used. This means that plans and descriptions should be sent to the Norwegian Radiation Protection Authority at the planning stage. The same applies in the event of major changes to existing laboratories and radiation rooms.

a) "Industrial radiography" means the use of ionising radiation sources for the purpose of non-destructive testing (NDT). This term does not include the use of radiation sources for the purpose of technical analysis, or for detecting foreign bodies or identifying material composition.

b) See also Regulations no. 504 of 20 March 2001 on treatment of foodstuffs with ionising radiation section 7.

d) Radiation use for research purposes is particularly relevant at research institutions, universities, university colleges, enterprises carrying on research etc. Use of ionising radiation in the context of teaching and routine analysis does not require approval.

e)-g) In practice the requirement as to approval of radiation use for medical purposes encompasses the more advanced areas of use at hospitals and x-ray institutions, i.e. all radiation therapy and nuclear medicine, as well as x-ray diagnostics requiring specialist competence or special safety precautions. When approval is sought for medical use of radiation, emphasis is given to the undertaking's need for a quality assurance system which covers, but is not confined to:

- How responsibility for radiation protection and radiation is attended to, organised and distributed, including a description of areas of responsibility of professionally responsible officers is at various levels of the undertaking.
- What reporting paths and communication channels exist between hospital management, professionally responsible officers and other affected personal.
- Designation of a radiation safety officer, who must be an identified individual responsible for the Norwegian Radiation Protection Authority's contact with the undertaking.
- A copy of permits and an overview of apparatuses for medical radiation use that have been notified to the Norwegian Radiation Protection Authority.

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- A system for education, training and maintenance of competence for affected personal in radiation protection, work methodology and apparatuses for medical use of radiation.
 - Routines for maintenance and quality control of apparatuses for medical use of radiation.
 - Protocols for the commonest medical procedures in x-ray diagnostics and nuclear medical diagnostics.
 - Routines for determining representative values for doses or administered activity in connection with diagnostic and nuclear medical examinations.
 - Necessary dosimetry functions for radiation treatment and diagnostics.
 - A description of target volume in radiation treatment with determination of doses and fractioning.
 - Procedures for planning and implementing radiation treatment that ensure geometric and dosimetric precision, as well as procedures for clinical follow-up of the patient after treatment.
 - Measures for limiting radiation doses to relatives or any third person when patients with residual activity are discharged from hospital or die.
 - Instructions for internal transport of radioactive material.
 - Plan for handling radiation protection in connection with unplanned events and incidents.

i) Cf Regulations no. 635 of 30 June 1995 on the manufacture and import of medicines.

m) For the most commonly used gamma emitters, 10^6 times the exemption level means 10 GBq.

n) Type A isotope laboratories are intended for work involving large quantities of radioactive substances, such as for example isotope production laboratories where requirements as to equipment and design are set by the Norwegian Radiation Protection Authority in each case.

o) This includes establishing exemption levels for discharges to the environment and clearance levels for previously regulated material.

p) Waste facilities do not include radiation users' facilities for intermediate storage of spent sources destined for discharge or waste treatment.

q) Radioactive waste means inter alia radioactive scrap metal and low-level radioactive waste from the production of oil and gas (LRA).

r) Distributors of radiation sources also include undertakings which import with a view to resale. Importers and distributors seeking approval will be required by the Norwegian Radiation Protection Authority to maintain an overview of imports and sales of radionuclides. Such overviews must contain information on the type of nuclide, level of activity along with the date of sale and the purchaser's name and address. Distributors must also provide the necessary information to buyers on any risk factors associated with use of the sources.

To section 6: Handling of radiation sources consisting of contaminated scrap metal, radioactive deposits etc., is also subject to notification under this section. Examples of medical x-ray diagnostics that are only subject to notification are ordinary dental x-rays (tube voltage below or equal to 75 kV), OPGs, cephalostats, x-rays in primary health services (imaging of extremities), osteoporosis apparatuses etc. Nor do veterinarians need approval. Advice to user categories which are only subject to a notification requirement will be amplified in separate guides. Report forms will be posted on the Norwegian Radiation Protection Authority's web pages. Section 28 regulates notification for sunbed salons.

To section 7: Instructions and procedures may for example be required in the following situations:

- a) Where radioactive sources are to be manipulated in and out of a shielded position.
- b) Where there is a risk of spillage from open radioactive sources.
- c) Maintenance of marking etc.
- d) Where there is a risk of exposure to powerful class 3B or 4 industrial lasers.
- e) Where UVC is used for disinfection in the food industry.
- f) In connection with the use of radar installations on small vessels.
- g) In connection with the use of other powerful sources of non-ionising radiation.
- h) When adjusting apparatus parameters etc., with a bearing on image quality and patient doses in medical radiation use.

To section 8: This section describes the function of, and technical requirements on, the radiation safety officer. The designation of a radiation safety officer does not affect the owner's or employer's overarching responsibility for all conditions within the undertaking, but must ensure that the undertaking's radiation protection functions satisfactorily. The radiation safety officer is also a contact person for the supervisory authority. The number of radiation safety officers and their organisational setup will necessarily depend on the undertaking's structure and the complexity of radiation use. At large undertakings a single central, and several local, radiation safety officers may be expedient. The radiation safety officer(s) attends to health, environment and safety aspects, i.e. radiation safety for the employees and any third persons (visitors, neighbours etc). Requirements as to patient safety are contained in chapter VII.

To section 9: The emergency preparedness plan should detail notification routines, organisation of preparedness, responsibilities, preplanned routines for handling given situations, routines for identifying the scope of an event, communication routines, description of relevant protective equipment, routines for follow-up of involved personnel, routines for information to the population etc.

To section 10: Disposal includes the scrapping of radiation sources. Where open radioactive sources are concerned, this requires the undertaking to ensure that it has updated lists of nuclides and activity that have been procured, are in use, are in storage or have been sent to a waste facility.

To section 11: Examples of incidents and events which must be reported under this section:

- A defect in an x-ray apparatus that has resulted in a significantly raised dose to a patient or the operator, or any fault in its operation - such as failure of the timer to halt the exposure in the usual manner, failure of the automatic dosage system, etc (a)
- Inadvertent entry of employees into the primary radiation field of industrial radiation sources (a)
- Inadvertent entry of passers-by into a controlled area who may have received doses in excess of 0.25 mSv, for example persons who have entered a cordoned-off area used for industrial radiography or who have cleaned tank interiors with the radiation source (level gauge) in the open position (d)
- Spillage of radioactive solutions (contamination) that cannot be removed by simple means (g)

To section 12: This requirement is directed at owners, distributors and manufacturers, all of whom are obliged to satisfy themselves that equipment is suitably designed with a view to radiation safety.

To section 14: These requirements refer to apparatuses for imaging and analysis in the field of industrial and research use, and do not encompass medical x-ray equipment, etc. Apparatuses for medical diagnostics are regulated in chapter VII. Equipment and devices containing radioactive sources must, in addition to meeting the requirements of these regulations, carry a standard warning sign against ionising radiation, cf regulations no. 972 of 6 October 1994 on safety signs and signals at the workplace.

The term “industrial gauge” means a device for measurement or process control that is activated by radiation from one or more sealed radioactive sources. The gauge normally includes a source container and a detector. ISO class xx2323xxx means that the source container must be designed such that the radiation level does not exceed 500 µSv/h at a distance of 5 cm from the source container. The remaining numerical and alphabetical references in the ISO classification refer to other technical and physical characteristics of the source container, and may have different values.

To section 16: Other safety equipment may for example include:

- a) Personal protective equipment such as lead-rubber aprons, transportable shields etc.
- b) Technical safety systems which interrupt the radiation if a door or barriers are opened.
- c) Emergency stop switches and warning signs with text explaining that radiation is being generated.
- d) Radiation protection monitors etc.
- e) Special tools, shielded containers etc.

Checking of safety equipment may for example include fluoroscopy of lead-rubber aprons to test their shielding capacity.

Technical requirements as to shielding and other safety equipment do not apply in relation to patient radiation safety, which is dealt with in section 35.

To section 17: Use of open radioactive sources in activity requiring a type A laboratory requires approval under section 5 n). As part of the approval process, requirements are also set in terms of design and equipment.

To section 18: Cleaning after contamination should continue for as long as it effectively reduces activity. Extractor units in isotope laboratories should be checked in accordance with the relevant standards before being put into use, when fixtures are changed and thereafter at least once every three years. Floor surfaces in isotope laboratories should preferably consist of a complete covering with no joints, and any joints should be all-welded. The edges of the floor covering should be bent up walls, piping and column bases. Benches and tables should preferably be jointless. Where joints are unavoidable they must be located in places where there is little risk of spillage or spray. Joints in tables and benches that are permanently fixed or not removable must be filled with an impervious material. In the same cases joints to an adjoining wall or other permanent fixture must be filled with an impervious material, or a rounded-off moulding should be fitted. Joints in tables and benches which are not permanently fixed and which are easily removable need not be filled with impervious material. Textile chairs and ordinary

curtains are not suitable for use in isotope laboratories. Relevant standards for control of extractor units in isotope laboratories are DS 457 (Danish standard) or similar standards.

To section 19: The laboratory should be separated from adjoining rooms by an anteroom or the like for changing coat and shoes. The anteroom functions as a transition zone between inactive and active areas, and the transition zone to the active area must be clearly marked (for example by painting a strip on the floor or installing a physical barrier). It must be possible to install absorbent filters in the ventilation systems, depending on what nuclide types and activity are employed. The filters should be placed in the part of the ventilation system/duct that is located inside the laboratory, and should be easily replaceable. Laminar air flow benches with horizontal airflow in which air is blown towards the personnel are not suitable for work involving radioactive substances.

To sections 20 – 22: Regulations no. 1157 of 14 June 1985 on work with ionising radiation, laid down pursuant to the Working Environment Act, will be amended with the same commencement date as the radiation protection regulations. The regulations will contain requirements as to medical examinations and relocation of pregnant employees.

To section 20: Cf Regulations no. 972 of 6 October 1994 on safety signs and signals in the workplace. Classification of the area in question depends primarily on what doses can be exceeded, and not on the average doses to which employees are exposed. Inside the controlled and monitored area a number of work tasks may be performed that result in exposure to radiation below 1 mSv per year and that are predictable in the sense that the risk of incidents is negligible. Such work tasks can also be performed by pregnant employees, cf section 21 which contains the dose limit for pregnant employees.

Where transport is concerned, requirements as to labelling, radiation levels etc., are set out in Regulations no. 1264 of 11 November 2002 on transport of hazardous goods by road and rail. In this context transport includes all operations and conditions connected with and involved in moving radioactive material, including intermediate storage en route.

To section 21: The dose limits refer to the contribution over and above the normal level of natural radiation. For workplaces exposed to radon it may be relevant to convert from radon concentration to annual dose, taking into account time spent on site and possible other modifying factors. As regards intake of radioactive substances, the same limits apply, i.e. the sum of the dose from intake of radioactive substances (internal dose) and the dose from external sources should not exceed the specified limits. Derived values in the form of annual limits of intake (Bq per year) for various radioactive substances are obtainable upon application to the Norwegian Radiation Protection Authority.

- a) The limit applies to irradiation of the entire body or large parts of it, and refers to the effective dose.
- c) The skin dose limit refers to the average dose to an area of 1 cm² irrespective of the size of the skin area exposed.

In the case of rescue work, employees who are involved in a lifesaving effort should as far as possible avoid doses exceeding 500 mSv, which is the threshold value for acute radiation injuries. These employees should be informed of the health risks in advance and must be trained in the requisite measures. They must also be equipped with adequate protective equipment, and the doses must be

monitored. They must be trained for such action and understand the risks associated with radiation. Measures of a more long-term nature such as removal of contamination, waste treatment etc., should be planned and optimised in advance, such that their implementation is as far as possible identical with normal practice, and the normal regime for occupational exposure should be applied. Where an accident results in pollution of the environment, doses to persons whose normal work is performed in this environment will increase. This may apply to farmers, forestry workers etc. Such work is not associated with the accident, and these persons are therefore not regarded as occupationally exposed. Hence the general dose limits will apply.

While the dose limit might be exceeded as a result of technical failure of a radiation apparatus, the reason will normally be inadequate training and unsuitable work techniques. The employer's investigation in the event that the dose limits are exceeded may for example entail:

- Reviewing work techniques and routines, particularly in cases where changes have been made. Can the distance to the source/radiation field be increased? Can the employee be provided with better shielding?
- Reviewing settings on the apparatus such as collimators, kV/mA etc., and checking optimisation in terms of radiation protection. Is there any fault in the apparatus itself which may affect the dose?

The employer should also investigate possible reasons that are not related to the work itself, for example the personal dosimeter may have been stored close to a radiation source or the employer may have attended an x-ray examination or radiation treatment without removing his/her dosimeter.

To section 22: The Norwegian Radiation Protection Authority is responsible for maintaining an overview of occupational doses to employees etc., (national dose register). The Norwegian Radiation Protection Authority regularly receives inquiries from the United Nations (UNSCEAR), the European Union and similar organisations regarding the reporting of annual doses for occupationally exposed persons and the like. In order for this job to be manageable, the Norwegian Radiation Protection Authority needs annual reports from the players in the field.

To section 23: The Norwegian Radiation Protection Authority may stipulate exemption levels providing exemption from the approval requirement, cf section 5 o) and clearance levels for previously regulated material. "Discharges to the environment" means the release of radioactive substances to the environment, including exposure of people.

Very short-lived radioactive substances destined for discharge must be placed in intermediate storage for radioactive decay before being released. Release to the environment should take place in such a way as to minimise elevated concentrations of radioactive substances. When the Norwegian Radiation Protection Authority determines whether to grant a discharge permit and sets the associated conditions, emphasis will be given to the pollution-related drawbacks of the discharge compared with the advantages and disadvantages that the measure otherwise entails. Any discharge permit will require use of the best available technology (BAT) for the purpose of minimising discharge. In this context reference is made to the Oslo Paris Commission's definition of BAT. To avoid elevated concentrations, only water-soluble substances may be released to the sewerage system.

To section 25: For approval of waste facilities under section 5, the Norwegian Radiation Protection Authority may require impact and safety analyses containing a description of the facility, waste, barriers to the environment and relevant scenarios for possible events and pollution in the period after termination of operations. An undertaking which operates a waste facility must have a detailed accounting system showing nuclides, activity, chemical/physical form, treatment etc. It must also require suppliers to specify the content of the waste. The undertaking should designate a radiation safety

officer. When a waste facility is established, a plan should exist for terminating active operation of the facility and for closing it down. As regards final disposal sites the plan should contain a description of monitoring, where applicable, in the period following closure. The application should specify what type of radioactive waste is involved. It should also contain a description of the accounting system (nuclides, activities chemical/physical form etc.), the internal control system, and the tasks and functions of the radiation safety officer etc.

To section 26: The provision requiring all exposure to be kept as low as reasonably achievable also requires other factors to be taken into account: the environment, aesthetics, costs etc. Little is currently known about long-term effects of weak fields. Hence it is important to maintain the precautionary principle and strive for fields that are as weak as possible. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) provides guidelines both for the population in general and for the occupationally exposed. The guidelines are set in such a way that acute injury cannot arise if the levels are not exceeded.

Work under voltage which may result in greater exposure than allowed for in the guidelines could, for example, be performed if deemed necessary from an emergency preparedness, financial or practical point of view. The regulations do not make the guidelines applicable to short-term exposure, for example when passing under power lines.

Section 3 of Regulations on environmentally-targeted health care (No. 486 of 25 April 2003) provides that where other legislation establishes health-based requirements or norms, these requirements or norms should be applied when assessing compliance with the regulations' requirement that operations should be satisfactory from the point of view of health. The Radiation Protection Regulations section 26 - together with the management strategy set out in Norwegian Official Reports (NOU) 1995:20 and Proposition to the Storting No. 65 (1997-1998) as subsequently updated in light of any new knowledge in the area - will constitute such a norm.

As regards electrical installations and electrical equipment, reference is also made to the Act on supervision of electrical installations and electrical equipment (No. 4 of 24 May 1929) with associated regulations. The purpose of that act is to ensure that all electrical installations are constructed, run and maintained in such a way that they do not pose a danger to human life and health or material assets, cf section 2 of the act. A number of technical regulations have been laid down in pursuance of the act that regulate various aspects of electrical installations and electrical equipment, among them requirements as to the construction of installations, technical requirements on installations, distances to the electrical mains network and how work at installations, and their operation, should be carried out.

References/standards:

- "Guidelines on limiting exposure to non-ionizing radiation" 7/99, Munich, 1999, issued by the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

To section 27:

References/standards:

As regards lasers, reference is made to the European Standard at any time in affect. As of 2003 the relevant standard is entitled NEK EN 60825-1:1994 Safety of laser products – Part 1: Equipment, classification, requirements and user's guide, with amendments.

To section 28: The notification requirement also applies to undertakings already in existence when the regulations enter into force. New undertakings should be notified to the supervisory authority ahead of start-up. Tanning appliances are also regulated by Regulations on hygiene requirements for hairdresser, skin care, tattooing and piercing activity etc. Undertakings coming under the present regulations require municipal approval. Hence there is no need for the Radiation Protection Regulations to include a separate arrangement for notifying municipal authorities.

References/standards:

As regards tanning appliances, reference is made to the European standard at any time in affect. As of 2003 the relevant standard is entitled NEK EN 60335-2-27:1997 Safety of household and similar electrical appliances – Part 2: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation, with amendments.

To section 29: Use of radiation for diagnostic or treatment purposes is justified provided the radiation use is predominantly beneficial to the patient in terms of the expected diagnostic outcome or treatment outcome and the damage that may result from the radiation. The assessment may also include the expected quality and effectiveness of the outcome, as well as advantages and risks associated with alternative methods that entail smaller radiation doses or that do not utilise ionising radiation. The patient's "individual premises" refers to his or her diagnosis, state of ill-health, symptoms, age, gender etc.

To section 30: Optimisation entails an assessment where apparatus and procedures are selected with a basis in technical, practical, financial and social conditions such that:

- Diagnostic examinations are performed at the lowest possible radiation dose while at the same time securing the desired diagnostic information.
- Examination or treatment of pregnant women with ionising radiation entails the lowest possible radiation dose to the foetus.
- Where radiation treatment is concerned, an adequate radiation dose to the target volume is striven for at the same time as an effort is made to achieve the lowest possible dose to tissue outside the target volume. "Target volume" means a delimited region within the patient at which a suitable dose is aimed based on the clinical objective of the radiation.

"Protocols" means method manuals or procedure manuals. Revision of such manuals entails systematic examination of protocols and procedures either by means of an internal audit system and/or by means of external clinical audits performed by auditing teams. Audits must be documented in a report archived by the undertaking.

To section 31: This requirement is a result of the increased focus on the patient's right to information about radiation doses received in x-ray diagnostic and nuclear medical examinations. In x-ray diagnostics there are several methods of measuring or calculating radiation doses, while in nuclear medicine administered activity is used as a measure of radiation dose. The phrase "representative value of dose or activity" means the undertaking's own ascertained value for a given examination at a given laboratory based on an average of a selection of patients. This value must be collated with diagnostic reference values issued by the Norwegian Radiation Protection Authority. Where the undertaking's representative value for a given examination is higher than the Norwegian Radiation Protection Authority's reference value, the reason for this must be identified and action taken to reduce the value in question.

To section 32: This provision is particularly important in cases where the uterus will be within the primary radiation field. It will also be relevant in other cases to provide information on doses and risks associated with exposure of the patient's foetus. While it is the requisitioning doctor in consultation with the ward who is responsible for retrieving information on pregnancy, extra security is afforded if this responsibility is followed up by the personnel carrying out the treatment or examination. In x-ray diagnostic examinations there is little risk of harm to the foetus, and the focus on radiation doses must not prevent life-threatening conditions from being assessed. Provided the pelvis is not covered by the primary radiation field, X-ray examinations of pregnant women, including imaging of the head and extremities, dental x-rays, mammography and computer tomography of the thorax (only during early pregnancy) can be carried out without taking special precautions.

To section 33: As regards radiation therapy and nuclear medicine (section 5 e) and f)), scientific personnel should be permanently attached to the undertaking in a number commensurate with the scale of the undertaking, such that professionally responsible persons can be designated, cf the comments to section 38, to attend to radiation protection and radiation use and to dosimetric measurements and quality control of apparatus and equipment. "Scientific personnel" usually means a physicist with three years' theoretical and practical in-depth study of medical physics, with at least one of these years spent in clinical practice. Scientific personnel with professional responsibility must have a further two years' clinical experience. As regards x-ray diagnostics requiring approval under section 5, such personnel should be associated with the organisation in order to facilitate necessary consultation on corresponding conditions, including dosage and image quality assessments, in connection with the development of examination protocols.

The undertaking should also have engineering competence or services, commensurate with the scale of the undertaking, to take care of necessary technical maintenance. Where radiation therapy is concerned, it is recommended that a minimum of two radiation therapists should carry out patient treatment on a joint basis in order to ensure correct use in accordance with procedures applying at any time.

Doctors who use x-ray apparatus for guidance in connection with operations, interventions, endoscopy etc., must have the training needed to give them an understanding of parameters that affect image quality and radiation doses to patients and personnel. Such training must include purely technical aspects of the apparatus as well as work technique (distance, apparatus geometry etc).

To section 35: Requirements as to maintenance and quality control of apparatus used in radiation medicine also apply to apparatuses that are subject to notification. Apparatus for medical radiation use should be checked in accordance with applicable international guidelines provided no national recommendations exist in the field. Initial values are established in connection with the setting up and acceptance testing of new apparatuses. In the event of technical changes to apparatuses or to associated peripheral equipment which may conceivably affect the initial values, new values must be established. These values should be monitored over time, and routines must exist for action to be taken in the event of observed deviations. Tolerances to deviations should be defined such that defects in or faulty use of apparatus and equipment are captured before they affect the clinical result of the examination or treatment.

To section 36: The term "dosimetry" means the definition, measurement and calculation of ionising radiation. "Calibration" means establishing the connection between the relative value from a measuring instrument and a known unit of measurement in the SI system. In this system the unit of measurement will be dose in grays per charge in coulombs (Gy/C). The protocol "Absorbed dose determination in external beam radiotherapy TRS 398" from the IAEA in Vienna is currently the Norwegian protocol for

calibration of radiation sources for external treatment and "IAEA TECDOC-1274" for brachytherapy. The radiation sources used in radiation treatment will be radioactive sources that are used in brachytherapy and x-ray apparatuses/linear accelerators for external treatment.

To section 37: New x-ray apparatuses are delivered with devices showing a measure of the radiation dose to the patient after completion of an examination. This provision is designed to ensure that such information is retained. On older apparatuses that lack such systems, the radiation dose can be calculated afterwards provided the exposure parameters are recorded. In the case of x-ray imaging and fluoroscopy the dose will typically be stated as the entrance dose at the skin surface or as the dose-area product. In the case of computer tomography (CT) the dose will be stated as the weighted CT dose index and dose-length product (DLP). Organ doses and effective dose can be calculated from such dose values using available software. On this basis representative dose values based on a selection of patients can be calculated and collated with diagnostic reference values issued by the Norwegian Radiation Protection Authority as an aid to optimisation in the field of x-ray diagnostics.

The dose to the patient's gonads can in some cases be significantly reduced by shielding them with lead. Shielding the testicles is recommended in the case of men below 50 if the testicles are within the primary radiation field or closer than 5 cm from the edge of field. Shielding is recommended in the case of women below 45 if the ovaries are within the primary radiation field in AP projection, but not if it covers structures of clinical interest. Exposure in PA projection is recommended where clinically possible. This technique significantly reduces the dose to women's gonads and mammary tissue.

To section 38: The term "professionally responsible" denotes a function held by a person with the competence described who is professionally responsible within his/her area for justification and optimisation, work methods and personnel competence, and who collaborates with persons who are professionally responsible for other areas or specialities in the assessment of clinical results.

The term "brachytherapy" denotes intra-cavity, intravascular and interstitial treatment using encapsulated radioactive sources (including iridium 192 needles and threads), as well as treatment using eye applicators.

To section 39: The phrase "individual dose planning" in nuclear medicine entails taking account of the patient's age, gender, weight, state of ill-health etc., in order to be able to estimate the dose to the treated tissue before treatment starts.

To section 42: Section 42 first and second paragraph corresponds to section 18 of the Radiation Protection Act. The Norwegian Radiation Protection Authority has been empowered to make necessary individual decisions. Requirements imposed in Act of 10 February 1967 relating to procedure in cases concerning the public administration (Public Administration Act) apply to individual decisions made. The obligation of the second paragraph to disclose information to the supervisory authority is confined to information that is necessary for supervisory purposes.

The provision of the third paragraph establishes a legal basis for municipalities, in addition to the Norwegian Radiation Protection Authority, to oversee radiation protection in tanning salons, cf section 28. Municipal authorities are also empowered to apply the enforcement provisions and sanctions contained in the act and the regulations. Municipalities are already responsible for overseeing hygiene in tanning salons pursuant to regulations no. 581 of 6 May 1998 on hygiene requirements for hairdresser, skin-care, tattooing and piercing undertakings etc.

To section 43: This provision corresponds to section 19 of the Radiation Protection Act. Rectification may be demanded in the event of failure to comply with requirements laid down in or pursuant to these regulations, for example conditions for approval. Where an order is made for rectification, a reasonable period should be allowed for compliance, depending on the scale of the rectification that is required.

Where a material risk to health exists, a halt may be ordered. Ordering a halt is a highly interventionary instrument which requires the presence of a substantial degree of risk. Besides ordering a halt, the supervisory authority may confiscate substances or equipment if there is a material risk to health. This may be appropriate in cases where the undertaking itself lacks the knowledge needed to avert further risk to health. Where the undertaking lacks approval a halt may be ordered even if there is no material risk to health. Ordering a halt on this basis is motivated by the need for all parties to square up to the obligation to obtain approval. The supervisory authority decides whether or not a halt should be ordered. For example, rectification may also be required where approval is lacking, such that the undertaking does not have to halt in order to start up again.

Should it prove necessary to physically force a halt to operations or confiscation in order to avert further risk, this will constitute an action which the police are legally authorised to assist. Representatives of the supervisory authority may also physically halt operations if this appears to be absolutely necessary.

To section 44: This provision corresponds to the Radiation Protection Act section 21 first paragraph. The supervisory authority may impose a coercive fine on an undertaking that fails to bring operations into line with requirements set forth in or pursuant to legislation within a deadline stipulated for compliance with an order. A coercive fine may be imposed in the form of a one-time fine or a cumulative daily fine, and may be appealed in the same way as other administrative decisions, cf the Public Administration Act.

To section 45: This provision authorises the Norwegian Radiation Protection Authority to grant dispensation from the provisions of the regulations in concrete cases. The power to grant dispensation is confined to special cases. Such cases may, for example, be where applying the general rules would come across as highly unreasonable. The provision is to be regarded as a safety valve, and the premise is that it should be applied with great caution. Decisions in dispensation cases are individual decisions which may be appealed under the provisions of the Public Administration Act, cf sections 28 et seq., of that act.

To section 46: This provision corresponds to be Radiation Protection Act section 22. The Ministry of Health is the appeals body for individual decisions made by the Norwegian Radiation Protection Authority, cf the Public Administration Act section 28. For decisions made by a municipality under section 42 third paragraph, the appeals body is the county governor. The Norwegian Radiation Protection Authority may provide expert assessments when appeals are dealt with. Expert assistance is available both when a case is dealt with by the appeals body and by the subordinate body.

To section 47: This provision corresponds to be Radiation Protection Act section 23. The ordinary prescribed penalty scale for violations is fines or imprisonment of up to three months. Complicity is a criminal offence. The culpability requirement is intent or negligence. A severer penalty is available whereby up to two years' imprisonment can be imposed where the violation has or could have resulted in grave damage to health and environment. The two-year penalty scale means that violation of the second paragraph is regarded as a criminal offence. A procedural consequence of a violation being a criminal offence is that it is the public prosecutor who decides the issue of prosecution, cf The General Civil Penal Code section 66. In order to curb or prevent violations of a less serious nature – for example

violations of public order provisions or violations which have not had serious consequences – from being prosecuted without good cause, public prosecution may only take place upon petition from the supervisory authority, provided the violation has only resulted in insignificant damage or inconvenience. Against the background of its special competence, the supervisory authority will be best placed to decide this matter, and it is empowered to apply its administrative instruments instead. i.e. a rectification order, coercive fine etc. Reference is also made to a special rule of prosecution, The General Civil Penal Code section 229, which requires the prosecuting authority, where it assumes that a criminal offence has been committed, to immediately bring the details to the knowledge of the supervisory authority to enable the latter to decide whether or not to petition for prosecution.

In many cases violation could be due to inadequate organisation, training, cumulative errors or other so-called system faults. Where a violation is due to factors for which the undertaking as such must assume responsibility, a natural response is to apply the general provisions on corporate penalties in The General Civil Penal Code section 48a and section 48b, even where specific actions leading to the violation can be identified.

To section 48: This provision corresponds to the Radiation Protection Act section 20. It refers to any product which may entail a health risk due to radiation. Prohibition can be targeted at any stage of the import or sales chain. Imports or sales may be prohibited by individual decision or by regulations. The Customs Act entitles the Customs Service to enforce an import ban established pursuant to the radiation protection legislation. Where an import of sales ban conflicts with agreements concerning the free movement of goods, cf the EEA agreement, the principles established by the EEA agreement must be taken into account. In the case of other agreements to which Norway is a party, for example the WTO Agreement, the principles of such agreements must similarly be taken into account to ensure that prohibitions are not instituted in conflict with international agreement. By its wording, the legal basis refers to any product or merchandise, but is not intended to be applied in cases where other legislation exists. For example, a ban on the sale of foodstuffs contaminated with radioactivity is regulated by the food legislation. Similarly, where medicines are concerned, a necessary assumption is that the right to impose a ban on sales is exhaustively regulated in the medicines legislation.

To section 52: The present regulations replace not only the four existing regulations in the field, but also 18 bodies of rules/provisions that have been used as a guide and basis for management. In addition to new regulations establishing formal requirements for all types of undertakings, the Norwegian Radiation Protection Authority will draw up specific guides for various areas of activity which will provide information and guidance on how the respective types of undertakings can meet the requirements of the regulations. The regulations, together with guides, will replace the previous provisions. The Norwegian Radiation Protection Authority has initiated the development of new guides which will be published as and when they are completed.

Regulations relating to Systematic Health, Environmental and Safety Activities in Enterprises

(Internal Control Regulations)

Laid down by Royal Decree of 6 December 1996 in pursuance of section 16a, cf. section 2, subsection 8, of Act No. 4 of 4 February 1977 relating to Worker Protection and Working Environment etc.; section 14 of Act No. 47 of 21 May 1971 on Inflammable Goods and Liquids and Gases under Pressure; section 14 of Act No. 39 of 14 June 1974 on Explosives; section 4 of Act No. 26 of 5 June 1987 on Fire Prevention etc.; section 52b of Act No. 6 of 13 March 1981 on Protection against Pollution and on Waste; section 8 of Act No. 79 of 11 June 1976 on Control of Products and Consumer Services; section 41, cf. section 48, of Act No. 9 of 17 July 1953 on Civil Defence; section 3, cf. section 9, of Act No. 4 of 24 May 1929 on Supervision of Electrical Installations and Electrical Equipment and section 17, second paragraph, of Act No. 38 of 2 April 1993 relating to the manufacture and use of genetically modified organisms (Gene Technology Act). Amended by Act No. 1352 of 17 December 1999, Act No. 270 of 9 March 2000, Act No. 127 of 1 February 2002, Act No. 1599 of 19 December 2003, Act No. 1395 of 8 October 2004 and Act No. 51 of 28 January 2005.

Section 1 · Object

Through requirements as to systematic implementation of measures, these regulations shall promote efforts to improve conditions in enterprises in regard to

the working environment and safety

prevention of damage to health or disturbances to the environment from products or consumer services

protection of the external environment against pollution and improved treatment of waste

so as to ensure that the objectives of the health, environmental and safety legislation are achieved.

Section 2 · Scope and extent

This regulation applies to enterprises encompassed by

Act relating to inspection of electrical installations and electrical equipment (Act No. 4 of 24 May 1929)

Section 48, cf. section 41, of the Civil Defence Act (enterprises required to maintain safety and emergency preparedness measures) (Act No. 9 of 17 July 1953)

The Product Control Act (Act No. 79 of 11 June 1976)

The Working Environment Act (Act No. 4 of 4 February 1977)

The Pollution Control Act, where the enterprise employs staff (Act No. 6 of 13 March 1981)

The Gene Technology Act (Act No. 38 of 2 April 1993)

Act on radiation protection and use of radiation (Act No. 36 of 12 May 2000)

Act relating to fire and explosion prevention (Act No. 20 of 14 June 2002)

This regulation is not applicable in Svalbard or to enterprises as mentioned in section 2, subsection 3, of the Working Environment Act, cf. Royal Decree of 27 November 1992 on Worker Protection and Working Environment in Petroleum Activities.

Section 3 · Definitions

In this regulation the following definitions apply:

Internal control

Systematic measures designed to ensure that the activities of the enterprise are planned, organised, performed and maintained in conformity with requirements laid down in or pursuant to the health, environmental and safety legislation.

Health, environmental and safety legislation

The statutes mentioned in section 2, first paragraph, and regulations laid down in pursuance thereof.

Section 4 · Obligation to maintain internal control

The person responsible for the enterprise shall ensure that internal control is introduced and performed in the enterprise and that this is done in collaboration with the employees and their representatives.

The employees shall participate in the introduction and performance of internal control.

Section 5 · Content of systematic health, environmental and safety activities.

Documentation requirements

Internal control shall be adapted to the nature, activities, risks and size of the enterprise to the extent required to comply with requirements set out in or pursuant to the health, environmental and safety legislation.

Internal control entails that the enterprise shall:		Documentation
1.	ensure that those Acts and regulations in the field of health, environmental and safety legislation that apply to the enterprise are accessible, and have an overview of requirements of particular importance for the enterprise.	
2.	ensure that the employees have sufficient knowledge of and proficiency in systematic health, environmental and safety activities, including information on changes made	
3.	ensure employee participation so as to utilise overall knowledge and experience	
4.	establish health, environmental and safety objectives	must be documented in writing
5.	have an overview of the enterprise's organisational set-up, including allocation of responsibilities, duties and authority in regard to the work on health, the environment and safety	must be documented in writing
6.	identify dangers and problems and against this background assess risks; draw up appurtenant plans and measures to reduce such risks	must be documented in writing
7.	implement routines to uncover, rectify and prevent breaches of requirements established in or pursuant to the health, environmental and safety legislation	must be documented in writing

8.	carry out systematic surveillance and reviews of the internal control system to ensure that it functions as intended	must be documented in writing
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Internal control shall be documented in the form and to the extent necessary in the light of the nature, activities, risks and size of the enterprise. Documentation resulting from requirements set out in or pursuant to the health, environmental and safety legislation, for example instructions, authorisations, proof of qualifications, certifications and the like, shall be included.

Written documentation pursuant to this regulation shall encompass at least the second paragraph, subparagraphs 4 to 8 inclusive, of this section.

Voluntary certificates may also form part of the documentation.

Section 6 · Coordination

Where two or more enterprises perform work on the same worksite, they shall, where necessary, agree in writing which of them is to be responsible for co-ordinating the internal control of their joint activities or areas. Failing such agreement, the supervisory authorities may decide which of them shall have this responsibility. If considerations of health, environment or safety indicate a different allocation of responsibility, the supervisory authorities may reverse an agreement that has been entered into.

Where an enterprise engages an independent contractor to carry out assignments on the enterprise's own premises or site, the contractor's internal control shall as far as possible be made the basis for the work encompassed by the assignment. This applies where the assignment is performed by the contractor in person, by the latter's own employees or by others. The enterprise shall furnish information on joint rules and the like and see to it that any defects are rectified or necessary adjustments made in its own internal control or that of the contractor.

Section 7 · Supervisory authority

The supervisory authority pursuant to the health, environmental and safety legislation shall supervise and provide guidance on implementation of and compliance with these regulations.

Section 8 · Exemptions

The Ministry of Labour and Social Affairs may after consulting the Ministry of Environment, the Ministry of Justice and the Ministry of Health*, grant exemption from this regulation when special conditions obtain.

* now Ministry of Health and Care Services

Section 9 · Appeal

Individual decisions made pursuant to these regulations may be appealed to the administrative agency that is immediately superior to the administrative agency which made the decision, cf. the Public Administration Act.

In the case of individual decisions made pursuant to the health, environmental and safety legislation, provisions of the Acts mentioned that govern the right to appeal apply.

Section 10 · Sanctions

The provisions on penalties and other sanctions set out in the health, environmental and safety legislation are applicable in the event of contravention of the provisions of these regulations.

Section 11 · Commencement

These regulations come into force on 1 January 1997.

As from the same date the regulations on internal control laid down by Royal Decree of 22 March 1991 shall be repealed.

Comments on the Regulations relating to Systematic Health, Environmental and Safety Activities in Enterprises

(Internal Control Regulations)

Re Section 2 · Scope

The regulations apply to enterprises covered by the Acts mentioned in this section. They cover public and private sector enterprises of all kinds and all types of commercial activity, including consumer services. The public administration and public services are also included. Private individuals/consumers, on the other hand, are not covered by the regulations. For closer definition of how the term «enterprise» should be understood, attention is drawn to the individual Acts. Any doubt as to the scope of the regulation may be clarified by contacting the supervisory authority in question.

In order for the regulations to apply in the area covered by the Pollution Control Act, the enterprise must have employees. As a general rule the same is true in regard to the Working Environment Act. Hence one-man enterprises are not expressly required to establish internal control for compliance with the Pollution Control Act or with regulations pursuant to the Working Environment Act. Such businesses may however come under a co-ordinated internal control system if they perform work together with other firms at the same workplace; cf. section 6 of the regulation.

In the area covered by the legislation on electricity, fire prevention, product control, gene technology and radiation protection, the fact that an enterprise has or does not have employees has no bearing on the application of the regulations. This has to do with the purpose of the particular legislation. All businesses, including one-man enterprises, coming under the provisions of electricity, fire prevention, product control, gene technology and radiation protection legislation are encompassed by the internal control regulations unless it is specifically stated that the regulation is not applicable.

The obligation to maintain internal control also applies to any enterprise that engages independent contractors to carry out construction assignments. Such enterprises must have internal control encompassing the health, environmental and safety requirements imposed on them by virtue of their construction activities and their relationship with the contractors. They are accordingly required to incorporate in their internal control systematic measures to satisfy the requirements of the Regulation concerning Minimum Safety and Health Requirements at Temporary or Mobile Construction Sites (otherwise called the Construction Sites Safety and Health Regulations (Construction Client Regulations), laid down by Royal Decree of 21 April 1995.

In regard to the Product Control Act, the regulation applies to enterprises which manufacture, process, import, market or utilise a product or treat a product in any other way, and enterprises which offer a service to consumers. Enterprises which offer the use of products or services are subject to the regulations regardless of whether or not they receive payment for doing so.

Municipalities offering for example the use of goalposts, playground equipment etc., are subject to the regulations.

The regulations also encompass the municipalities' obligations under the Act relating to fire and explosion prevention to ensure the establishment and operation of a fire service. Internal control as a principle of management and supervision has been introduced in several areas. Hence many enterprises are required to operate internal control encompassing several different acts and associated regulations, among them the food and fisheries industry and schools and day care institutions. Enterprises coming under several different internal control provisions must consider the most appropriate way of complying

with the requirements. In many cases a practical approach would be to draw up an overall system which takes all the relevant legislation into account.

Re Section 4 · Obligation to maintain internal control

The obligation to introduce and operate internal control rests with «the person responsible» for the enterprise. By this is meant the management or owner of the enterprise. Who, or which functions may be entailed, varies according to the enterprise's organisational set-up. Although internal control must be performed at all levels of the enterprise, the main responsibility for initiating the system (i.e. for «introducing» internal control) and for maintaining it (i.e. for «performing» it) is vested in top management of the enterprise. This section makes clear, however, that internal control must be introduced and operated in collaboration with the employees, the working environment committee, safety delegate(s) and/or employee representatives where such exist.

Who is «responsible» for the enterprise will depend on the various acts underlying the regulation. Examples of persons responsible for implementing the regulation are:

the employer (under the Working Environment Act)

the management as shown in the enterprise's organisational set-up or structure (under the Pollution Control Act)

anyone in charge of the manufacture, storage, transport (including loading and unloading), procurement, use and import and export of explosives and trade with such goods (under the Product Control Act)

owners and users (under section 48 of the Norwegian Civil Defence Act, cf. section 41)

undertakings (under the Act relating to fire and explosion prevention)

owners and users of electrical installations and electrical equipment; producers, as well as importers and other distributors, of electrical equipment; electro-fitters and the like (under the Supervision of Electrical Installations and Electrical Equipment Act)

the management of undertakings as shown by the undertakings' organizational or company structure (under the Gene Technology Act)

the management of undertakings as shown by the undertakings' organizational or company structure (under the Act on radiation protection and use of radiation)

It is implicit in section 4 that the person responsible for the enterprise is obliged to see that internal control is monitored and reviewed to ensure that it functions as intended. This requires continual assessment of internal control activities to enable shortcomings to be identified. It also entails a complete review at regular intervals, i.e. a review of the entire internal control system; cf. section 5, subsection 8.

Section 4, second paragraph, expressly states that employee participation is obligatory. This is also a general condition of employment contracts. Hence participation in internal control activities is a requirement. Sections 24 and 26 of the Working Environment Act expressly require safety delegates and members of working environment committees to participate in establishing and maintaining internal control. Moreover, under section 12, subsection 3, of the same Act employees and their union representatives are entitled to be consulted in connection with management and planning systems. Indeed, internal control is regarded as a management and planning system coming under section 12, subsection 3, of the Act. For firms which are bound by a collective pay agreement the same provisions are set out in chapter IX of the Main Agreement between the main worker and employer organisations.

It is absolutely essential that internal control be integrated in the overall management and planning of the enterprise. More and more enterprises are now concerned to integrate their relationship to the external environment into their organisation strategy and profile, and internal control is an instrument suited to strengthening this work within the enterprise. Employees too will be interested in giving their enterprise an environmental profile and in contributing to a more environment-friendly community. Internal control must also incorporate requirements in regard to the external environment, and is therefore an instrument which the employees and their elected representatives can use to influence dispositions by the enterprise affecting the environment. Moreover, it is clearly essential to turn employees' experience to account to ensure that internal controls function properly. Their familiarity with, for example, various inputs in production, procurement, waste treatment etc., represents valuable knowledge which can contribute to a systematic review of all aspects of the enterprise that affect the external environment. The scope for conflicts of interest would appear to be limited inasmuch as consideration for the working environment and the external environment generally pull in the same direction.

Enterprises encompassing both employees and customers/users - e.g. hospitals, schools, day care institutions and hotels - have a responsibility for the health, environment and safety of both groups. Where this type of activity is concerned it is important to keep in mind that the legislation can impose requirements directed at one of the above groups - employees or users - or at both groups. The Product Control Act deals with the safety of the pupils etc., while the Working Environment Act covers the employees. The Act relating to fire and explosion prevention sets requirements concerning the safety both of hotel guests and the hotel staff. In the latter case the internal control system must include all the acts making up the legal basis for the regulations to ensure that it encompasses both employees and users.

Re Section 5 · Content of systematic health, environmental and safety activities. Documentation requirements

Section 5 sets requirements as to the content and documentation of internal control. Subsection 2 requires all employees to possess the knowledge and skills they need to perform their work in a safe and, from a health and environment angle, proper manner. Hence they also have to be aware of changes made to the internal control system. Some knowledge requirements are fixed by rules or collective agreement, for example in the case of safety delegates, industrial safety personnel, etc. Other requirements naturally follow from the nature of the enterprise, its activities and inherent risks.

Subsection 3 requires the collaboration and involvement of the employees in regard to drawing up, performing and making changes to the internal control system; cf. also section 4.

The enterprise must have an objective for its health, environment and safety activities in the same way as for other areas of its operations. This is set out in subsection 4. Objectives are an important precondition for plans and activities and should be cast in as concrete a form as possible. Overall objectives must also be established. Objectives must be documented in writing.

The third paragraph points out that documentation of internal control will vary according to the nature, activities, inherent risks and size of the enterprise concerned. Some enterprises will make thoroughgoing risk analyses, while others will make do with simpler documentation. Internal control requires good order and a carefully prepared system. Implicit here is the need for all employees to be familiar with the enterprise's practice of internal control in regard to health, environment and safety, and the supervisory authorities must be given a clear view of the enterprise's policy and practice as regards health, environmental and safety activities.

Where routines and procedures in regard to health, the environment and safety already exist, the enterprise will be required to further develop such routines and procedures into a coherent system. This will include systematising work routines, instructions and the like that already exist in writing in such a

way that they can be incorporated in an internal control system. Where regulations impose requirements as to certification, certificates must be subject to internal control. It may also be useful and expedient for other documentation obtained by the enterprise - e.g. voluntary certificates confirming that a product, a service or an activity, or a person's competence, are in conformity with specified requirements - to be included in the documentation

Re Section 6 · Co-ordination

This provision applies in situations where two or more enterprises perform work/activity together, or for each other, at the same workplace. The first paragraph covers, among other things, situations mentioned in section 15 of the Working Environment Act, while the second paragraph covers situations where an enterprise engages independent contractors to perform work on its behalf - e.g. maintenance or construction work.

Under the first paragraph, enterprises which perform work at one and the same workplace simultaneously must agree in writing which of them is to be responsible for co-ordinating internal control of joint activities or areas. This provision is grounded in the obvious need for someone with responsibility for, and an overview of, the overall health, environmental and safety situation at such workplaces. The requirement is confined to cases where co-ordination is considered necessary. Co-ordination is mandatory where two or more enterprises together have more than 10 employees working at the same workplace at the same time, cf. section 15 of the Working Environment Act. Also in cases where the number of employees is smaller than 10, situations are conceivable where the risk associated with having two or more enterprises at the same workplace is considered great enough to warrant co-ordinating the enterprises' internal control systems.

In addition to establishing which enterprise has co-ordinating responsibility, the agreement should also specify the areas and/or activities to which this responsibility applies. Which enterprise singles itself out to take care of co-ordination will vary from case to case. In some cases it will be the one that contracts out an assignment, while in others a particular enterprise may be required to assume responsibility for co-ordination by virtue of the terms of its licence.

Rules governing co-ordination of two or more enterprises are set out in section 15 of the Working Environment Act and in the Construction Sites Safety and Health Regulations (Construction Client Regulations), among others. An enterprise assigned main co-ordinating responsibility under section 15 of the Working Environment Act will as a rule also have such responsibility under the Internal Control Regulation. According to the Construction Sites Safety and Health Regulations, the enterprise for which building operations are carried out and/or the project supervisor is/are responsible for designating a health, environment and safety co-ordinator at the building or construction site. The assumption is that the interests of co-ordinated internal control and health, environment and safety are best taken care of if one and the same enterprise bears responsibility for all the statutory obligations involved. Where there are two or more enterprises, each discharging obligations pursuant to different bodies of rules, they must co-ordinate operations to ensure that the overall result is in conformity with the law. At enterprises operating at e.g. shopping centres, industrial parks and the like, it may in many cases be natural for the operating company or holding company to assume co-ordinating responsibility. The enterprise in question must in all cases have the necessary overview, competence and authority.

If no agreement has been reached, the authorities may decide which of the enterprises shall be responsible for co-ordination. In special cases the supervisory authorities can also reverse an already formalised agreement. The precondition is that an enterprise assigned responsibility for co-ordinating internal control on a site where two or more different enterprises are working simultaneously must have the necessary overview, competence and authority to assume such responsibility. If the supervisory

authorities find that the enterprise that has formally agreed to take on such responsibility is unfit to do so, the agreement may be cancelled.

The second paragraph deals with internal control in relation to independent contractors. This provision only applies to contract work done in connection with assignments on the commissioning enterprise's own site or installation.

The point of departure is that an enterprise carrying on activities connected with a physical installation etc., is obliged to ensure that all activities on the site are encompassed by internal control, regardless of whether or not those performing the activities are employed by the commissioning enterprise. The reason for this is that it is often immaterial whether the persons exposed to risk while working are employed by the enterprise or not. The same will naturally apply where there is a risk of polluting the external environment, and otherwise in connection with safety and protection measures needed to prevent dangerous or harmful situations from arising as a result of an enterprise's own activities. The internal control employed will be that of the contractor who performs the contract. This entails that the commissioning enterprise has to assess the risks arising when suppliers and contractors carry out activities on its site. Where contractors are engaged as a standing arrangement or on a frequent basis, fixed routines for this may need to be included in the enterprise's own internal control system. Where contractors are engaged only by way of exception, risks must be assessed on a case-by-case basis. What is essential is to assess any environmental or other hazards associated with the assignment.

According to the rules the person responsible for the enterprise must investigate whether the contractors engaged by the enterprise operate satisfactory internal control. In many cases it will be necessary to assess whether the enterprise's own internal control includes general routines and measures dealing with, say, the working environment, use of fire, protective equipment or pollution risks.

The degree of mutual modification and/or correction of the internal control of the commissioning enterprise and the contractor respectively will vary both with the type and scale of the contract, the enterprise's size and inherent risk factors and how satisfactory the contractor's internal control is considered to be. The aim throughout must be to ensure that internal control is co-ordinated to the degree required to ensure that the result is in conformity with the legislation.

As a rule no co-ordination of internal control will be called for where the enterprise purchases components, parts and equipment from another enterprise.

Re Section 7 · Supervisory authority

This provision establishes who is responsible for supervising compliance with the regulations. The following bodies are supervisory authorities pursuant to the regulation:

Norwegian Labour Inspection Authority (Working Environment Act)

Directorate for Fire and Electrical Safety - municipal fire prevention authorities (the Act relating to fire and explosion prevention)

Directorate for Fire and Electrical Safety - local inspections (Supervision of Act relating to inspection of Electrical Installations and Electrical Equipment, and parts of the Product Control Act as regards consumer services and the physical, thermal, mechanical and fire prevention properties of the products)

Norwegian Pollution Control Authority (Pollution Control Act and Product Control Act)

County governors (Pollution Control Act and certain regulations in pursuance of the Product Control Act)

Industrial Safety and Security Organisation (Civil Defence Act)

Norwegian Maritime Directorate (Regulations relating to pleasure boats issued pursuant to the Product Control Act)

Directorate for Nature Management (Gene Technology Act; release of genetically modified organisms)

Norwegian Directorate for Health and Social Welfare (Gene Technology Act; contained use of genetically modified organisms)

Norwegian Radiation Protection Authority (Act on radiation protection and use of radiation)

The supervisory authorities utilise systems-based audits and verifications to assess the health, environmental and safety status at enterprises, placing the emphasis on preventive health, environment and safety work. The supervisory authorities do not confine themselves to assessing directly negative events such as injuries, emissions and absence from sickness. They also provide guidance on understanding the regulation's requirements and the principles of internal control. The scope of their obligation to provide guidance is regulated in the Public Administration Act. Trade organisations etc. can also give affiliated enterprises guidance on solutions appropriate to the branch of industry in question.

Re Section 8 · Exemptions

Assessments must take into account the consequences of exemption for health, environmental and safety activities at the enterprise.

Re Section 9 · Appeals

The supervisory authorities may make various types of decision to enforce this regulation. They may for example order an enterprise to comply with the requirement to establish internal control. Another example could be ordering an enterprise to comply with the requirements as to documentation of internal control. Such orders will normally take the form of «administrative decisions» which can be appealed to the immediate superior agency (see overview below). Orders to rectify breaches of an enterprise's internal control system and the like are issued pursuant to the internal control regulations. Orders to rectify concrete contraventions of the underlying body of laws and regulations are made in pursuance of the latter. Both types of order can be appealed to the agency superior to the agency which issued the order.

Decisions/orders made by the local Labour Inspectorate may be appealed to the Directorate of Labour Inspection. Decisions/orders made by the Directorate of Labour Inspection at first instance may be appealed to the Ministry of Labour and Social Affairs.

Decisions/orders made by the Municipal Council or County Governor may be appealed to the Directorate for Civil Defence and Emergency Planning. Section 28 (2) of the Public Administration Act shall apply to other municipal decisions.

Decisions made by the local electrical safety inspection authority may be appealed to the Directorate for Civil Defence and Emergency Planning.

Decisions/orders made by the Directorate for Civil Defence and Emergency Planning at first instance, may be appealed to the Ministry of Justice and the Police.

Decisions/orders made by the county governor at first instance may be appealed to the Norwegian Pollution Control Authority.

Decisions/orders made by the Norwegian Pollution Control Authority at first instance may be appealed to the Ministry of the Environment.

Decisions/orders made by Industrial Safety and Security Organisation may be appealed to the Directorate for Civil Protection and Emergency Planning.

Decisions made by the Norwegian Maritime Directorate as regards pleasure boats may be appealed to the Ministry of Trade and Industry.

Decisions/orders made by the Directorate for Nature Management may be appealed to the Ministry of the Environment.

Decisions/orders made by the Norwegian Directorate for Health and Social Welfare may be appealed to the Ministry of Health and Care Services.

Decisions made by the Norwegian Radiation Protection Authority may be appealed to the Ministry of Health and Care Services.