Survey on the implementation of the "justification", "optimisation" and "limitation of doses" radiological principles in national regulations in Europe

NORWAY

1 The implementation of European Directives

1. *Since when have the European Directives 96/29 and 97/43 been implemented in your country?*

Norway is not member of EU and do not have to implement these directives. However, our revised radiation protection act was issued 12. May 2000 and include many of the requirement in the directives.

2. *If they are not implemented, is it expected and when?*

2 Justification principle

1. *What is the exact wording of the justification principle in the Law?*

See annex Chapter II, Section 5 and Chapter III, Section 13.

2. *Which practices are explicitly named as unjustified or forbidden?*

None explicitly.

3. *Which regulatory body(ies) is (are) responsible to determine if a practice is justified or not? NRPA (other regulatory bodies might be consulted)*

3 Optimisation principle

1. *Could you give is the exact wording (citation) of the optimisation principle (ALARA) as defined in the Law or national regulation?*

See annex Chapter II, Section 5 and Chapter III Section 13.

And additionally described in Regulation No 1362 of 21 November 2003 on Radiation protection and use of radiation.

2. *Does the national regulation give a description on the practical way to implement the optimisation principle (e.g. need to perform dose prediction and to establish dose objectives, need to perform real-time dose follow-up, need to write feedback experience report, etc)?*

Yes, both in regulations and in specific requirements specified in authorizations.

3. *Does it exist a specific guidance to help operators / end-users in implementing the optimisation principle?*

Yes, guidelines are issued for specific user groups. So far 7 guidelines are published (only in Norwegian)

4 Dose limits

1. *Can you provide us with present regulatory dose limits established to reduce the probability of occurrence of stochastic effects?* [please separate public and occupational dose limits, permanent and interim workers, males and females, and other specific cases: pregnant women, post-accidental intervention limits, life dose, etc]

See text from regulations Section 21 below.

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.

2. *What are the legal dose limits to prevent public and workers from deterministic health effects?*

See annex Section 21.

5 Dose constraints

1. *Here again, could you give is the exact wording (citation) of the Law or regulations where the concept of dose constraint is mentioned.*

The direct concept dose constraint is not used but indirectly some sections in the regulations are connected to dose constraint. We think that a constraint is an instrument to be used in the optimisation process.

Examples:

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 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.

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The representative doses mentioned in Section 31 shall be compared with reference doses (constraints) given by the authority (NRPA).

2. *In which domain (e.g. public dose, occupational dose, patient dose, etc) and by whom (regulatory body, operators, etc) are dose constraints implemented in your country?*

All domains are planned for. The date for implementation with regard to patient constraints is 1, January 2008

3. *What are the corresponding values and rationales behind these values?*

Practical experience.

4. *What is(are) the status(es) of dose constraint(s)?*

Yes these are in practice mandatory because they are used as requirements and conditions in the authorisation/ licensing process.

5. *What is effectively done if a constraint is exceeded?*

Ordering improvements if observed in inspections/ or through self-assessments.

ANNEX

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

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 can 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 havebeen 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
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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 non-recurring fine or a 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 repealedon 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
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