Regulations in the Nordic countries concerning oral and maxillofacial radiographic imaging technologies and their use

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The first national recommendations for radiation protection were given by the British Roentgen Society (1915) and American Roentgen Society (1922). The basis for modern radiation protection was given in the recommendations of International Commission on Radiological Protection (ICRP 26) in 1977.

Dental education in all Nordic countries takes five years and leads to the competence of performing intraoral radiography in Sweden and intraoral standard and panoramic radiography in Norway and dento-maxillo-facial radiography in Denmark and Finland. There is obligatory special training before using standard panoramic units in Sweden.

For performing cone beam CT examinations and interpreting the images, a specialist degree in maxillofacial radiology is required in Sweden and Norway.

Dental assistants and hygienists can perform intraoral radiography under the responsibility of a dentist. In Sweden, Norway and Denmark dental hygienists may also record caries lesions and periodontal disease, although in Sweden and Finland all radiographs must be shown to the dentist. In Denmark and Norway the dental hygienists may be responsible for a dental x-ray unit, and they can refer the patient for a radiographic examination.

Updating education is mandatory only in Finland according to EU guidelines.

The demands for dental radiographic units are very similar in all countries.

Quality assurance programmes are regulated by law in Finland, Sweden and Denmark. The programmes comprise daily, monthly or yearly checks of radiographic procedures. Regulations for digital dental radiography are still under construction, though some are available in Denmark.

The use of radiation as a method for medical examination and therapy started soon after Wilhelm Conrad Röntgen discovered x-rays in November 1895. The side effects of radiation were found rather soon on the hands of users and on the skin and eyes of the examined patients. As early as in 1896, warnings of radiation-induced injuries were published. Greater interest to radiation protection started just after several reports of amputated hands and fingers and cancers due to radiation (1).

The first national recommendations for radiation protection were given by The British Roentgen Society (1915) and American Roentgen Society (1922). The genetic side effects of radiation were found at that time. The first international congress of radiology was held in the year 1925. The main topics were radiation protection and standard measures for radiation. The largest problem was the lack of measurement standards, which were considered even more important than radiation protection (2). At the second international congress in Stockholm (1928), the International Commission on Radiological Units (ICRU) and the International Commission on Radiological Protection (ICRP) were founded. The task for ICRP was to give recommendations for safe use of x-rays and radium. At first these recommendations were given only for the safety of the workers. It is noteworthy that the societies of physicians started radiation protection. The International Association of Radiology sponsored both ICRP and ICRU (2).

The basis for modern radiation protection was established by the recommendations of ICRP (ICRP 26) in 1977. The recommendations were updated in 1990 (ICRP 60); recent recommendation came in 2007. The basic idea is that people must be protected, but the practical application of radiation must be accepted. In recommendation of ICRP 60 the principles, which are valid today were ratified: justification, optimization and individual protection. The largest radiation dose for workers was set to be 20 mSv/year calculated as a mean average over five years. The largest dose in each individual year was 50 mSv. The largest radiation dose for the whole population is 1 mSv/year (2).

Radiation protection

Finland

The use of radiation has needed a licence since the year 1957, and it has been supervised according to regulations prepared by international agreements, recommendations and standards. The Radiation Act was implemented in 1957 – much later than some other countries comparable to Finland. The law was prepared thoroughly the previous six years. Some supervision was initiated already before

the radiation protection law. So for the import of radioactive substances »The Poison Act« was applied, although it did not directly concern radioactive substances. The technical demands concerning x-ray units was given applying The Electricity Act from the year 1945 (3).

»The Radiation Act« (174/1957), which gave a common basis for the control of radiation equipment and radioactive substances is still in use, although it has been updated a few times after 1957. At the end of the 1990s Finland joined the EU, and at the same time acts and decrees (Radiation Act (592/1991), Radiation Decree (1512/1991)) were prepared to comply with EU legislation. In Finland the use of radiation is supervised and directed by The Finnish Radiation and Nuclear Safety Authority (STUK) with authorization given by The Radiation Act (2). Today the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000) regulates patient safety, too.

The Finnish Radiation and Nuclear Safety Authority (STUK) started its function as a small research institute in 1958. Today, it is the authority in radiation and nuclear safety, research and expertise institute with extensive international contacts (2). In the 1960s the dose control of people working with radiation started. During the 1970s the testing methods for testing the functional conditions and accuracy were developed by STUK. In the 1980s the development lead to improving the technical quality control of the x-ray establishments; later on the obligation for quality control was incorporated in the law. The responsibility for the users of radiation was emphasized and quality control now includes self-evaluation and audit (2).

The use of radiation in Finland is rather wide-ranging. In the beginning of year 2003 there were in the register of STUK 1820 safety permissions. The number of items of registered radiation equipment was 14,120, of which almost 6,800 were in health care. The number of radiographic equipment in health care per capita is the fifth largest in the world (2).

Sweden

The Swedish Radiation Protection Authority (SSI) is a central regulatory authority charged with promoting effective radiation protection for people and the environment today and in the future. SSI sets limits on radiation doses to the public and to those who work with radiation. SSI produces recommendations and regulations on general obligations in dental practices using ionising radiation.

Norway

The Norwegian Radiation Protection Authority (NRPA) is the national authority in the area of radiation protection and nuclear safety in Norway and has the administrative control of medical use of ionising radiation for diagnosis and therapy (4).

Radiation protection is today regulated by the »Act on Radiation Protection and Use of Radiation« (2000) (5) replacing »Act on the use of x-rays and radium« (No. 1, 18th of June 1938). NRPA previously named »Statens Institutt for Strålehygiene« (SIS) produced two recommendations, one in 1973 (6) and one in 1988 (7), on the use of x-ray in dental practices. General recommendations from SIS were in accordance with those given by ICRP with modifications applicable to the Nordic countries (8).

As Norway is not a member of the EU, the Euratom directives of 13th of May 1996 and 30th of June 1997 were not implemented in the new Norwegian »Act on Radiation Protection and Use of Radiation«. Norway in 1961 ratified the ILO convention no. 115 on radiation protection of workers. This convention and updated recommendations from ICRP were incorporated in the new act. Radiation protection and quality assessment in Norway is further regulated by several laws such as the »Health Personnel Act«, the »Patient's Rights Act«, the »Specialist Health Care Services Act« and the »Patient Injury Act«. »Health, Safety and Environment« (HSE), or »Helse, Miljø og Sikkerhet«, is the code for a collection of fundamental concepts and methods related to the working environment, safety and external environment that also addresses the subject of radiation protection.

Requirements regarding approval or notification of radiological equipment: »Act on Radiation Protection and Use of Radiation«, Section 5 lists all types of installations that need approval. Section 6 deals with other radiation sources like dental x-ray installations that need only to be notified to the NRPA.

Due to this distinction, dental x-ray installations are not regulated in detail as in Sweden and Denmark, but the user of such equipment must keep the basic rules for radiation protection in mind at all times; that is that an assessment must be made of whether the use of radiation is justified on the individual patient's premises, and that the use of radiation is optimised (9).

Denmark

The Danish Radiation Protection Authority (SIS, »Statens Institut for Strålebeskyttelse«) is a central regulatory authority charged with promoting effective radiation protection for people and the environment. SIS sets limits on radiation doses to the public and to those who work with radiation. SIS issues recommendations and regula-

tions on general obligations in dental practices using ionising radiation.

Requirements for dentists who perform radiographic examinations

Finland

The dental education in Finland takes five years, and it leads to the competence of using dental radiographic equipment. The Finnish Radiation and Nuclear Safety Authority (STUK) have made the responsibility of giving permission to use dental x-ray equipment over to Dental Schools. Thus, Helsinki has a special Radiation Protection Examination before the students can pass the final examination in Oral Radiology.

The curriculum in Oral Radiology equals 6 ECTS-points, and it includes radiographic techniques, equipment, radiation biology and protection and also diagnostics of oral diseases, anomalies, cysts and tumours. After graduation the dentist is accredited to interpret all kinds of oral radiographs (10,11).

Sweden

The dental education in Sweden takes five years, and it leads to the competence of using intra-oral radiography. The regulation *SSI FS 2000:2* (12) states that the radiological leadership for practices with dental x-ray equipment with a maximum tube voltage not exceeding 75 kV and intended for use of intraoral image receptors must be held by a registered dentist. Radiographic examinations must be based on individual selection criteria and screening must not exist (13).

Norway

The dental education in Norway takes five years, and it leads to the competence of using intraoral and panoramic radiography. The NRPA regulations Section 33: »Requirements as to competence and training« (14) state that: 1) For x-ray diagnostics, subject to an approval requirement under section 5 requires a medical practitioner with specialist competence in medical radiology or a dentist with specialist competence in maxillofacial radiology. This concerns for instance all types of electronic data-assisted tomographic equipment such as CT equipment, including CBCT-scanning; 2) For other x-ray diagnostics, a medical practitioner or dentist trained in radiation protection relevant for the apparatus in question is required; 3) For dental x-rays (with tube voltage not exceeding 75 kV), a dentist or dental nurse (dental hygienist); 4) For other special examinations, a dentist with relevant competence.

Denmark

The dental curriculum in Denmark lasts five years, and it leads to the competence in examining the teeth, jaws and skull using ionising radiation, i.e. dento-maxillo-facial radiography. Oral radiology equals 7-8 ECTS-points (in some semesters it is counted together with other disciplines). A dentist may be responsible for dental x-ray units and extraoral units used for dento-maxillo-facial examination and may perform all examination types with these units. The name of the person responsible (a licence-holder) for an x-ray unit must be submitted to and registered by SIS. Radiographic examinations must be based on individual selection criteria and screening must not exist.

There are two main publications issued by SIS, which regulate dento-maxillo-facial radiographic examinations, 1)»publication on dental x-ray units for intraoral examination using voltage up to 70 kV« (15) and 2)»publication on larger dental x-ray units« (16). Currently, the exception is cone beam CT scanners (CBCT), which is categorized under the medical regulation for CT scanners (17) meaning that special education is needed to be allowed the control of such equipment, and a radiation physicist must be called on. Particular regulations for CBCT will soon be released, however, probably requiring the dentist to take courses and an exam before working with CBCT while categorizing the equipment under less strict requirements.

Requirements for dental nurses and radiographers who perform oral radiography

Finland

The radiographers have their own school, and the education takes 3.5 years (210 ETCS-points), after which they can perform radiography to a doctor's referral. A radiologist must interpret the images.

The curriculum of dental assistants takes three years; it includes oral radiography, which may be performed by a dental assistants under guidance of the dentist. All radiographs must be interpreted by the dentist.

Sweden

The nursing radiology (radiographer) programme consists of three years, and the students learn to be well prepared to develop and improve methods and techniques within medical radiology. They usually work in radiology departments, but are often included in the staff of a radiology department in a dental school.

The National Board of Health and Welfare has regulated that a dental hygienist in Sweden has the competence to diagnose caries and periodontal disease. The dental

hygienist education is two years and radiography is part of the education, including the competence to take intraoral radiographs. The radiological leadership, however, must be held by a registered dentist, and all radiographs must be evaluated by a dentist when diagnosing other conditions than caries and periodontal disease.

Norway

The medical radiographer education in Norway is three years and additional subspecialisation may be obtained. The employment is usually in radiology departments in radiology in hospitals or private institutions. At the universities in Oslo and Bergen radiographers are included in the staff of the radiology departsments in the dental schools.

The dental hygienist education is three years including a radiography education, focusing particularly on radiation protection. The Norwegian Radiation Protection Authority (4) regulates that a dental hygienist has the competence to be the responsible owner of a dental x-ray unit and hold the leadership for their practice recording caries and periodontal disease. This implies that they also have the competence to refer a patient for further examination.

The dental assistant education in Norway is one year including radiography. They have the competence to take intraoral radiographs. All radiographs must be submitted to a dentist for diagnosis. As in Denmark all dental auxiliary personnel may take radiographs and perform other dental procedures under the responsibility of a dentist (18).

Denmark

The radiographer curriculum is 3½ years in the School of Radiographers. Their employment is traditionelly in radiology departments in hospitals or larger private clinics. However, it may be beneficial to a radiology department in a dental school to include a radiogarpher in the staff. A radiographer is employed in the School og Dentistry in Århus.

A dental hygienist in Denmark may be recognized by SIS to be responsible for a dental x-ray unit and has the competence to refer a patient for radiographic examination. The dental hygienist education is 2½ years and radiography is included in the education. The dental hygienist has the authority to diagnose caries lesions and periodontal disease.

A dental assistant has a two-year education and may take radiographs and perform other dental procedures under the responsibility of a dentist (19). The dental assistant may not be asked by the dentist to assist in holding the film in the patient's mouth during exposure.

Mandatory updating education

Finland

The government regulation no. 423/2000 and STUK directive ST 1.7 (following the EU directives) assign that all dentists and dental assistants who take radiographs must take part in updating training. The need for this training is 0.75 ECTS-points during every five-year period.

In *Sweden*, *Norway* and *Denmark* there is at current no mandatory updating training. The Norwegian Dental Association arranges a highly recommended, systematic updating training for its members, »Tannlegenes systematiske etterutdanning« (TSE), which also includes a theoretical and practical course in oral and maxillofacial radiology (together with oral surgery and oral medicine). TSE courses are partially net-based.

In Denmark, mandatory yearly updating for all dentists will be initiated in 2009.

Demands for radiographic units and their users

Intraoral radiographic units

Finland

STUK has issued requirements for the functional conditions of intraoral x-ray units. They include for example the width of the radiation beam on the tip of the cone, the thickness of the aluminium filter, the range of the timer, kV and mA in successive exposures and so on. The units do not need a safety licence if they are manufactured after 01-01-1984, but they must be reported to the index held by STUK with necessary information for the authorities to decide that the unit can be used safely. The units manufactured after 14-06-1998 must have a CE-marking (93/42/ETY) and shielding of the room must be according to the STUK directive ST- 3.1. The radiological leadership must always be held by a registered dentist or MD (*www.stuk.fi*).

Sweden

In Sweden there is a new regulation on the demands of the radiographic units. The requirements for the x-ray unit are given in detail and the unit must be CE-marked (98/34/EG). The aim is to reduce the radiation dose to the patient as much as possible. Examples from the regulation are demand on individual selection criteria, use of thyroid shielding (0.25 mm Pb), use of film with high sensitivity or digital receptors, use of receptor holders and rectangular collimation. The shielding of the room is regulated in *SSI FS 2005:6* (20), and in general the demand is 0.5 mm Pb shielding. The radiological leadership must always be held by a registered dentist.

Norway

The NRPA regulations Section 12: »Requirements on apparatus« regulates the radiographic units (6). Equipment must be manufactured in accordance with the prevailing version of standards from the International Electro-technical Committee (IEC) and the International Organization for Standardization (ISO). Thus, according to NRPA, no CE-marking of dental x-ray units is required in Norway.

»Act on Radiation Protection and Use of Radiation«, Section 5, lists all types of installations that need approval. Section 6 deals with other radiation sources like dental x-ray apparatus that need only to be notified to the NRPA.

NRPA regulations on users of radiographic units state: For dental x-rays (with tube voltage not exceeding 75 kV), a dentist or a dental nurse/hygienist; for special examinations, a dentist with relevant competence.

Denmark

A separate publication regulates dental x-ray units for intraoral examination at or below 70 kV (15); dental film with a sensitivity equalling at least E-speed (standard DS/ISO 3665) or digital receptors must be used. Recent publications regulate quality control when working with digital imaging plates (21) or sensor systems (22). A tube of at least 10 cm in length must be used. If a circular tube is used, the skin radiation field may be no more than 6 cm in diameter; if a rectangular tube is used, this field may be no more than 4 cm x 5 cm. The dental unit must not be used for examination of the skull. The dental unit may be used for some examination projections of the TMJ (not transcranial) and for hand-and-wrist radiographs. If on average fewer than 25 exposures are performed in the clinic per day, the person who performs the examination may stand unprotected in the room during exposure if the distance to the primary radiation field is at least 2 m. If more than 25 exposures are performed per day, the person must be protected by a shielding, and the x-ray unit placed in a separate room. The shielding of the room is regulated in detail and in general the demand in buildings where persons are working in neighbouring rooms is 1 mm Pb shielding.

Extraoral radiographic units

Finland

Regular panoramic and cephalometric skull radiographic units do not need a security licence, but they must fulfil requirements for conditions of function given by STUK like intraoral x-ray units.

Panoramic units with cross-sectional tomography and other modalities and CBCT units need a security licence from STUK and cannot be used before the permission from STUK has been received (*www.stuk.fi*).

The user must be a dentist or radiographer if the clinic takes these radiographs of patients on referral. Dental nurses can take extraoral radiographs under the guidance of a dentist.

Sweden

In Sweden *SSI FS 2000:2* (12) regulates the use of extraoral radiography. The radiological leadership for practices with dental panoramic examinations must be held by a registered dentist with special training for panoramic examinations. The training for panoramic radiography does not include the use of tomography. A dentist with special training for panoramic examinations must cooperate with a specialist in oral radiology in order to use the tomographic functions and interpret the tomographic images. For practices with specialised examinations in dental x-ray diagnostics (for example CBCT) the radiological leadership must be held by a registered dentist with specialist competence in oral radiology.

Norway

In Norway the NRPA regulations Section 33 apply to the use of advanced imaging. The use of extraoral radiography, not subject to an approval such as standard panoramic and cephalographic units, may be performed by a dentist trained in radiation protection relevant for the apparatus in question and with relevant competence to undertake special examinations.

Advanced imaging equipment subject to an approval by the Norwegian Radiation Protection Authority (NRPA) may be performed only by dentists with specialist competence in maxillo-facial radiology (or a medical radiologist). This concerns for instance all types of CT equipment, including the responsibility of making diagnosis with CBCT examinations. The medical regulation of CT scanners states that such scanners are operated by medical radiographers, and a radiation physicist must be on hand.

Denmark

A separate publication regulates the use of »larger« dental radiographic equipment, including panoramic radiography, other tomography, skull radiography and dental units with kV above 70 (16). All extraoral examinations must be performed with film in a cassette with intensifying screens or with digital receptors.

There are no particular educational demands for dentists who work with extraoral equipment. The shielding of the room is regulated and in general the demand in buildings where persons are working in neighbouring rooms is 2 mm Pb shielding at voltages 70-100 and 2.5 mm above 100 kV. This may be reduced to 1 mm Pb for panoramic units where the primary radiation is absorbed in the cassette holder. The person who performs the examination must be shielded during exposure, usually standing outside the room. New regulations will soon be published for CBCT units worked by dentists.

New regulations regarding patient protection in connection with dento-maxillo-facial radiography were published in 2007 (23,24). After this, no patient protection is obligatory, neither for adults nor children.

Quality assurance

Finland

Quality assurance for intraoral x-ray units includes 1) examination of the quality of the radiograph, which is done with a phantom, 2) accuracy of the exposure time (radiation output), 3) measurement of the width of the beam (< 6 cm) and its centring, 4) measurement of kV and mA, 5) inspection of the shaft of the unit, electric cables and warning lights and sounds.

Quality assurance for panoramic x-ray unit includes 1) examination of the quality of the radiograph, which is done with a phantom, 2) accuracy of the beam in the secondary slot and exposure area on the film, 3) steadiness of rotation and film holder movement, 4) accuracy of the sharply depicted layer (with metal ball phantom), 5) the exact place of the lights for patient positioning (sharply depicted layer, central sagittal plane, Frankfort horizontal), 6) inspection of the cassettes, electric cables and warning lights and sounds.

Quality assurance for automatic developers of film radiographs includes examination of the quality of the radiograph, which is done with a phantom. If the clinic takes more than 50 panoramic radiographs in a month, they must use a sensitometer-densitometer system. The safety light in the darkroom must be examined using the coin test.

All view boxes must have neon tubes of the same light temperature and the same age.

Radiation chaperons and shields are inspected by eye.

The quality assurance instructions for digital imaging, when they differ from those of film-based imaging, are under construction and they are to be issued this autumn.

Most quality assurance procedures are made once a year, although quality of the radiograph must be checked from two to 12 times a year. Automatic developers must be examined from 1 to 7 times a week (*www.stuk.fi*).

Sweden

The Swedish regulations state that the licence-holder shall have an established quality assurance program, which comprises checks of the equipment as well as of the working methods (12). Dental x-ray equipments intended for intraoral image receptors must be checked annually together with the radiation protection devices, instructions and a review of the film processing procedure. Dental panoramic equipments must be checked annually regarding the x-ray system, image receptor system and x-ray stand. The check is technically advanced, and it is not possible for the dentist to perform the check. The consistancy of the film processing must be checked weekly.

Instructions for quality assurance of digital systems are lacking in Sweden.

Norway

In contrast to medical x-ray equipment that needs approval, no regulations exist with regard to quality assurance program for use of dental x-ray equipment at the present time in Norway.

Denmark

The regulations state that the licence-holder must have an established quality assurance program, which comprises daily, monthly or yearly checks of film and cassettes, the film development process, the darkroom or semi-automatic developing machines, the x-ray equipment and the light box luminance as well as of the working methods (15,16). A reference film of a patient displaying teeth with fillings must be placed visible at all light boxes used for checking the quality of each newly developed film. Reference films of a step-wedge phantom must be saved to control for image density and contrast over time.

Dental panoramic equipments must be checked monthly regarding the x-ray and image receptor system. There are so far only limited regulations for quality assurance of digital systems in Denmark (21,22).

Dansk resumé

De første nationale retningslinjer for strålebeskyttelse blev udgivet af »British Roentgen Society« (1915) og »American Roentgen Society« (1922). Baggrunden for nutidige regler for strålebeskyttelse ligger i anbefalingerne fra »The International Commission on Radiological Protection« (ICRP 26), som er fra 1977.

Tandlægeuddannelsen tager fem år i alle de nordiske lande og medfører, at tandlægen har kompetence til at udføre intraorale røntgenundersøgelser i Sverige, intraorale og standard panoramaundersøgelser i Norge og dentomaksillo-faciale undersøgelser i Danmark og Finland. Speciel træning og uddannelse er krævet for at udføre standard panoramaundersøgelser i Sverige. For at kunne udføre »cone beam« CT-scanning og tolke billederne kræves en specialistgrad i maksillo-facial radiologi i Sverige og Norge.

Klinikassistenter og tandplejere har lov at udføre intraorale røntgenundersøgelser under tandlægens ansvar i de andre lande, mens tandplejere har selvstændigt virke i Danmark og Norge. I Sverige, Norge og Danmark må tandplejere selvstændigt diagnosticere carieslæsioner og parodontale sygdomme, dog skal i Sverige og Finland alle røntgenbilleder optaget af en tandplejer ses af en tandlæge. I Danmark og Norge kan tandplejere være ansvarlige for et dentalapparat, og de kan henvise en patient til røntgenundersøgelse.

Løbende efteruddannelse er obligatorisk i Finland efter EU's regelsæt.

Kravene til røntgenapparater og -enheder er meget ensartede i de nordiske lande.

Kvalitetssikring er reguleret ved lovgivning i Finland, Sverige og Danmark. Disse programmer foreskriver daglig, månedlig eller årlig kontrol af røntgenprocedurer og -apparater. Regelsæt for brug af digitale røntgensystemer er ikke færdigudviklede, og Danmark er det eneste land, hvor der findes bekendtgørelser.

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