STUK

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DENTAL X-RAY EXAMINATIONS IN HEALTH CARE

This Guide is valid as of 1 September 2014 until further notice.
It replaces Guide ST 3.1, "Dental X-ray examinations in health care", issued on 20 August 2011.

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Authorization

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

Under section 70, paragraph 2, of the Radiation Act (592/1991), STUK – Radiation and Nuclear Safety Authority (Finland) issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

Translation. In the event of any differences in interpretation of this guide, the Finnish and Swedish versions shall take precedence over this translation.

This Guide includes the requirements relating to the implementation of Council Directive 96/29/Euratom; OJ No L 159, 29.6.1996, p. 1.

1 General

This Guide presents the radiation safety requirements concerning dental X-ray practices and places of use and quality assurance of dental X-ray appliances. The Guide deals with patients' dental X-ray examinations and the appliances used in them, such as

- intraoral X-ray units
- panoramic tomography X-ray equipment and the cephalostats associated with these
- cone beam computed tomography (CBCT) devices for imaging teeth and jaws.

Provisions concerning medical uses of radiation are laid down in chapter 10 of the Radiation Act (592/1991). The Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000, hereinafter referred to as the MSAH Decree) lays down the provisions concerning the basic criteria and implementation of procedures which cause exposure to radiation.

2 A safety licence is required for dental X-ray practices

The safety of dental X-ray practices lies with the party running a radiation practice (hereafter the responsible party), who shall make sure that no dental X-ray examinations are undertaken without ensuring the radiation safety of both the patients and the staff.

Dental X-ray practices involving exposure to radiation are classified into categories I and II on the basis of risk assessments of radiation appliances and practices. The use of intraoral X-ray units, panoramic tomography X-ray equipment and cephalostats is considered to belong to category I, and the use of CBCT devices to class II. When assessing the risks of practices, special attention is paid to the magnitudes of potential radiation exposures and the likelihoods of abnormal events.

In addition to the classification categories, the use of intraoral X-ray units, panoramic tomography X-ray equipment and cephalostats are divided into conventional dental X-ray practices (item 2.1) and other use of this equipment (item 2.2).

When applying for a safety licence for dental X-ray practices, an application must be submitted to STUK – Radiation and Nuclear Safety Authority (Finland) indicating the following information:

- The information on the responsible party (name and contact details, for example)
- The information on the radiation safety officer
- The contact information on the place where radiation is used
- The X-ray equipment used
- The facilities for the use of the equipment, the placement of the equipment, and the structural radiation shielding of the facilities (item 3.4).

Any changes to the information mentioned above shall be reported to STUK without delay. The responsible party shall be responsible for the authenticity of the information.

The responsible party shall specify the duties of the radiation safety officer. The actual working preconditions of the radiation safety officer, such as his/her authorities, location of office, time allocation etc., shall be arranged as required by the work.

An appliance may be introduced for use only after STUK has granted the required safety licence.

Section 16 of the Radiation Act stipulates that the use of radiation shall be subject to licence and lays down the provisions concerning applications for safety licences. Section 18 of the Radiation Act lays down the provisions concerning the radiation user's organization and the organization description. More details are available in Guides ST 1.1 and ST 1.4. The form (in Finnish) to be used when applying for a safety licence is available on STUK's website (http://www.stuk.fi/proinfo/valvonta/lomakkeet/fi_FI/lomakkeet/).

2.1 Conventional dental X-ray practices

A dentist, doctor or hospital physicist who has received radiation protection training in accordance with Guide ST 1.7 may be nominated as the radiation safety officer for the use of intraoral X-ray equipment, panoramic tomography X-ray equipment or cephalostats in

conventional dental X-ray practices.

If the safety licence includes several locations of use at different addresses, indicating a contact person for each location together with the application is considered a good practice.

2.2 Other dental X-ray practices

Radiation safety officers shall also be nominated for X-ray practices other than conventional X-ray practices. A radiation safety officer shall have passed the radiation safety officer's examination in the field of competence of X-ray practices in health care, dental X-ray practices or the general use of radiation in the medical sector. In addition, examinations of radiation safety officers in the fields of medicine and dentistry arranged by the examining board on radiological protection*) are acceptable. A radiation safety officer may be a

- a dentist or physician
- hospital physicist.

In practices other than conventional dental X-ray practices, medical physics expertize is required mainly for expert opinions or counsel when operations are begun or essentially changed, or when problems are encountered in radiation protection, in the optimization of operations, in quality assurance or in radiation dose measurements. A medical physics expert may be a hospital physicist or another physicist approved by STUK.

When applying for a safety licence for the use of intraoral X-ray equipment, panoramic tomography X-ray equipment and cephalostats in other than conventional dental X-ray imaging, the application must, in addition to the information described above, also clearly present the purpose of the use of radiation. Other purposes may include the following:

- The use of panoramic tomography X-ray equipment for head X-rays excluding dentistry examinations.
- Any use of a portable intraoral X-ray unit. The safety licence application shall include an explanation as to why a fixed intraoral X-ray unit would not be suitable. In addition, the application shall indicate the number of examinations planned for the appliance and the radiation shielding of the person using the appliance.
- Screenings involving exposure to radiation referred to in the MSAH Decree. The conduct of any screening programme involving exposure to radiation requires the justification of the screening to be assessed by the National Institute for Health and Welfare (THL, previously STAKES). In addition, the screening programme shall be submitted to STUK for inspection before the screening begins.
- The use of dental X-ray appliances in teaching.
- Scientific research using dental X-ray appliances. Should any individuals be exposed to radiation due to the research, the safety licence application shall include a supporting statement from the respective ethical committee concerning the justification of the activity.
- Research and development of appliances and work with dental X-ray appliances in clinical test use.
- Installation, repair and service of dental X-ray appliances in practices involving radiation or affecting radiation-producing parts.

When applying for a safety licence for dental X-ray practices performed using CBCT equipment, a description of the organization of the use of radiation (organization description) shall also be submitted, and it shall indicate the responsibility arrangements applied in the use of radiation, and the training and qualifications of the staff participating in the use of radiation.

The Government Decree on Screenings (1339/2006) specifies the provisions concerning the arranging of screenings and Section 39 of the MSAH Decree specifies the provisions concerning the justification of screenings involving exposure to radiation. Valvira (National Supervisory Authority for Welfare and Health) shall be notified concerning any clinical research carried out in order to demonstrate a medical device's compliance with requirements before the device is placed on the market or put into service. Provisions concerning the obligation to notify are laid down in the Medical

*) The Government Decision (243/1958) laid down the provisions concerning the examining board on radiological protection. Passing the examination by the board was required for the qualification of a radiation safety officer referred to in the Radition Protection Decree (328/1957).

Devices Act (629/2010).

The requirements concerning medical physics expertise are laid down in section 15 of the MSAH Decree.

2.3 Product development or installation, repair and service of dental X-ray equipment

To work as a radiation safety officer in the research and development of dental X-ray appliances, or in their installation, repair or servicing, or in their clinical test use, the nominee is required to pass the radiation safety officer's examination in the field of competence of either

- the installation, repair and servicing of radiation appliances in health care
- X-ray practices in health care
- in the field of the general use of radiation in the medical sector.

The safety licence for clinical test use granted to the supplier of a device states the requirements concerning the acceptable places of use of radiation for the device and the preconditions required for the delivery of the device. A dentist or physician with patient imaging competency shall be in charge of any clinical use.

Section 25 of the Radiation Act specifies the provisions concerning the installation, repair and servicing of radiation appliances.

3 Performing a dental X-ray examination

3.1 Justification and optimization of dental X-ray examinations

The need for a dental X-ray examination must always be considered on a patient-specific basis and the examination must be of benefit to the patient. Dental imaging of a patient shall be performed on the basis of a dentist's or physician's referral only. The referring dentist or physician shall consider the justification of the dental X-ray examination when writing the referral. In addition, the dentist or physician (item 3.2.1) responsible for the procedure involving exposure to radiation shall ascertain the justification of the examination.

The referral shall clearly state the indication for examination and other necessary information so that the dental X-ray examination can be performed in the optimal manner. The indication for examination shall be recorded in patient documentation. The dental X-ray examination shall be optimized to fulfil the purpose of the examination while minimizing the radiation exposure to the examinee. This requires e.g. that

- all staff participating in the use of radiation have been trained and are competent
- the appliances available are suitable and in proper working order
- the technology has been optimized (imaging voltage, imaging current, beam limiting)
- the image quality is sufficient for interpretation or a procedure
- the dentist or physician interprets the images and records the interpretation in patient documentation.

If the referring dentist or physician himself/herself is the dentist or physician responsible for the procedure and the performer of the procedure, he/she need not write a referral for himself/herself. However, the data concerning the examination and the indication for examination shall be recorded in patient documentation.

Justification and optimization of medical uses of radiation are dealt with in chapter 10 of the Radiation Act. The report "Radiation Protection 136, European guidelines on radiation protection in dental radiology" by the EU Radiation Protection Unit presents recommendations on indications for dental X-ray examinations and minimization of patients' exposure to radiation.

3.2 Radiation user's organization and competence requirements

All staff using radiation shall be provided with sufficient radiation protection training and sufficient user training for the relevant appliances. The responsible party shall ensure that the expertise of the staff operating X-ray appliances is properly maintained. The operating staff shall have appliance-specific up-to-date user instructions as well as instructions for cases of malfunction and hazard. Should an

appliance be sold, it is a good practice to deliver documentation concerning the appliance's history (service reports, fault logs) with the appliance.

The training and qualification requirements for radiation workers are laid down in section 18 of the Radiation Act and in chapter 5 of the MSAH Decree. Sections 24 and 25 of the MSAH Decree lay down the provisions concerning the competence of the physician responsible for a procedure involving exposure to radiation and the competence of a person participating in the performance of a procedure involving exposure to radiation. More detailed instructions are available in Guides ST 1.4, ST 1.7 and ST 1.8.

3.2.1 Physician responsible for a procedure

The physician responsible for a procedure shall have basic knowledge of the health effects of ionizing radiation and of the exposure of the patient to radiation, on the basis of which he/she can assume the responsibility for the justification and optimization of the procedure, and for his/her part, the interpretation of the results. The responsible party shall be responsible for meeting the qualification requirements.

In practices of category I, the physician responsible for a procedure may be a dentist or other type of physician.

In CBCT examinations, the physician responsible for a procedure may be

- a dentist or physician specialised in radiology[**)]
- a dentist or physician who has passed a supplementary training course on CBCT examinations and the related written test offered by an educational institution providing basic education in dentistry.

The requirements for any other category II practices shall be defined specific to each case.

3.2.2 Competence required of a person performing X-ray imaging

In practices of category I, X-ray imaging may be performed by

- a dentist or physician, or
- a radiographer who may independently perform X-ray imaging according to referrals
- a health care professional (such as a dental hygienist or a practical nurse graduated from a degree programme in oral health care) with professional training in dental imaging. Such a person may perform imaging according to instructions of a dentist or physician. However, the dentist or physician responsible for the procedure (item 3.2.1) shall be available during the procedure.

CBCT imaging may be performed by

- a dentist or physician specialised in radiology
- a dentist or physician who has passed a supplementary training course on CBCT examinations and the related written test offered by an educational institution providing basic education in dentistry
- a radiographer who may independently perform CBCT imaging according to referrals
- a health care professional (such as a dental hygienist or a practical nurse graduated from a degree programme in oral health care) who has passed a supplementary training course and the related skills demonstration in CBCT imaging. Such a person may perform CBCT imaging according to instructions of a dentist or physician (item 3.2.1). However, the dentist or physician responsible for the procedure shall be available during the procedure.

The requirements for any other category II dental X-ray practices shall be defined specific to each case.

3.3 Ensuring the radiation safety of the staff

All persons who perform imaging shall protect themselves to avoid unnecessary radiation exposure. When imaging is performed with intraoral X-ray units or panoramic tomography X-ray equipment, the person performing the imaging usually does not need additional protective devices provided that he/she avoids the primary beam during imaging and stays at a distance of no less than two meters from the patient and the X-ray tube. However, it is recommended that he/she step behind a shielded wall for the duration of imaging and uses an appropriately placed mirror or lead-glass window

[**)] A dentist specialised in clinical dentistry with bias on radiology.

to observe the patient, especially if the number of images is large. This prevents extra radiation exposure to the performer of the imaging.

If the performer of the imaging is closer to the patient than two meters during the imaging, it is recommended that he/she use a separate protective shielding such a portable shield or a lead rubber apron. Imaging with CBCT devices should always be performed with the performer standing behind a shielded wall or in a separate control room so that his/her view to the patient is unobstructed, either direct or through a mirror.

During a dental X-ray examination, only those persons in addition to the patient may remain in the examination room whose presence is required for the performance of the examination or for the safety of the patient. They shall be appropriately protected by suitable protective devices and no part of them shall be exposed to primary radiation. During X-ray imaging, all unnecessary occupation of the area next to the patient and the X-ray tube should be avoided. The dentist responsible for the practice shall ensure that these procedures are complied with. When safe working practices are established, employees who perform dental X-ray imaging do not, in principle, need to be classified as workers engaged in radiation work, and it is not necessary to set up individual monitoring for them. If the responsible party can be sure that an employee is not exposed to radiation while performing dental X-ray imaging, the employee can continue dental X-ray imaging even during pregnancy.

The provisions concerning pregnant women in tasks involving exposure to radiation are laid down in section 5 of the Radiation Decree (1512/1991).

3.4 Radiation shielding of places where dental imaging appliances are used

A room in which dental X-ray imaging is performed shall have radiation shielding capable of reducing the radiation exposure of persons in any adjacent rooms as low as reasonably achievable. During imaging, the radiation exposure of persons occupying rooms adjacent to the imaging room shall not exceed 0.3 mSv per year.

The need for radiation shielding in the imaging room depends on the number of X-ray examinations, on the imaging voltage, on the product of the imaging current and exposure time (mAs), on the size and orientation of the radiation beam, on the location of the X-ray appliance in the imaging room, and on the use of the adjacent areas.

A safety licence application shall include a floor plan which shows the places of use of panoramic tomography X-ray equipment, cephalostats and CBCT devices, and the adjacent rooms, indicating the location of any X-ray equipment, the imaging directions and the radiation shielding of the rooms. A description of the structural shielding of the place of use suffices in the case of intraoral X-ray units. However, if essential information is missing, STUK may request floor plans when necessary.

The radiation shields for dental X-ray rooms shall be designed according to Guide ST 1.10. Practical examples on the specification of the shielding of imaging rooms are given in "Hammasröntgentoiminnan laadunvalvonta ja kuvaushuoneen säteilysuojaus, STUK opastaa 2011" (Quality control of dental X-ray practices and radiation shielding of imaging rooms, Advice from STUK 2011).

4 Duties of the party selling a dental X-ray appliance

After the sale or consignment of a dental X-ray appliance has been agreed upon, the party selling or consigning it shall inform STUK of the following:

- the owner/holder of the appliance
- the precise address to which the appliance is installed or delivered for installation
- information identifying the appliance uniquely (the device type and serial number)
- conformation from the party selling or consigning the appliance that the appliance fulfils the criteria presented in this Guide
- the date of the sale or consignment of the appliance.

Section 21 of the Radiation Act stipulates that it is the responsibility of the importer, manufacturer and seller

to furnish STUK with the information needed for the regulatory control of products which they have placed on the market.

5 Requirements for dental X-ray appliances

5.1 General requirements

A dental X-ray appliance shall carry a CE marking (Directive 93/42/EEC) in accordance with the Medical Devices Act (629/2010). When using these appliances, the requirements of this Guide shall be observed.

5.2 Acceptability requirements at time of use

A dental X-ray appliance shall be suited to the intended use. If it is necessary to examine children with the appliance, its functions and performance values shall be suited to examining children. The appliance and the related auxiliaries and other devices shall comply with all acceptability requirements at time of use given in Appendix B. *Acceptability requirement* refer to the minimum requirements, or acceptability limits, specified for the performance capacity of the appliance. If the acceptability requirement are not met, then one of the following actions must be taken:

- The appliance must be repaired and its performance restored to an acceptable level.
- The use of the device must be restricted so that the feature exceeding the action level does not affect examinations or treatments.
- The appliance must be decommissioned.

Acceptability requirements are not limit values for the optimal performance of the appliance. When procuring new appliances, in acceptance tests and in quality control, the applied requirements should be based on e.g. the limis values given in international apparatus standards, as these are often stricter than the acceptability requirements.

The provisions concerning STUK's authority to confirm requirements and criteria of acceptability for specific equipment functions to be considered from the point of view of radiation safety are laid down in section 30 of the MSAH Decree. More information on acceptability requirements is available in Guide ST 3.3.

6 Arranging quality assurance

The responsible party shall arrange quality assurance procedures for practices involving exposure to radiation. Therefore, a quality assurance programme is required. The programme shall define the necessary quality assurance functions, and must also include the principles for preventing errors and accidents from which radiation doses may arise unintentionally. Quality assurance practices shall be assessed regularly and, when appropriate, changed. Quality assurance can be categorized as assurance of the technical quality and assurance of the operational quality. A quality assurance programme shall include at least the requirements presented in Appendix C.

The obligation of the responsible party to arrange quality assurance is laid down in section 40 of the Radiation Act, and section 18 of the MSAH Decree sets forth the provisions concerning quality assurance programmes. More detailed instructions on quality management are available in Guide ST 3.3.

6.1 Technical quality assurance shall ensure the operating condition of appliances

Technical quality assurance consists of acceptance testing and quality control. The purpose of technical quality assurance is to ascertain the appropriate operating condition of the appliance and the sufficiency of its performance characteristics. The responsible party shall ensure that any appliance about to be commissioned is acceptance tested before the appliance is used for examining patients. Acceptance testing checks that the appliance works appropriately and safely and that the acceptability requirements at time of use presented in Appendix B in this Guide are fulfilled.

Quality control activities are performed at specified intervals, following significant repairs or servicing, and when there is cause to suspect a malfunction or a change in the operation of the appliance. The purpose of quality control is to ascertain the appropriate operating condition of the appliance and the sufficiency of its performance characteristics.

When a new X-ray appliance is commissioned, sufficient equipment (such as test phantoms) must be available for performing the required quality control tests. Appendix C presents the minimum requirements for technical quality assurance procedures by a user as well as the intervals of the tests to be performed. In addition, the user shall at specified intervals perform the tests defined by the supplier.

The quality control of intraoral X-ray units can, in principle, be covered by user testing at specified intervals as presented in Appendix C. Any deficiencies in the performance of the appliance shall be corrected.

Panoramic tomography X-ray equipment, the related cephalostats and CBCT devices shall be subject to annual technical testing and user testing at time of use. The technical tests can be performed, for example, in connection with periodic service measurements.

The conformance to acceptability requirements at time of use shall be checked annually for CBCT devices, and for panoramic tomography X-ray equipment and the related cephalostats, at intervals of no more than two years.

All failures, malfunctions and other events during the use of the appliance which have disturbed its use or endangered safety shall be recorded in a fault log. If any abnormal events are observed that are significant for radiation safety, the measures should be taken that are presented in chapter 7.

In addition to the proper operation of the X-ray appliance, the appropriate operating condition of appliances and equipment intended for image formation and viewing is important for the reaching of a correct diagnosis. Therefore, testing shall be arranged for image receptors, and quality assurance shall be arranged for monitors used to interpret the images. These tests can also be categorized as user tests and technical tests.

The duty of the responsible party to arrange acceptance testing is laid down in section 32 of the MSAH Decree. Information on acceptance testing is available in "Lääkelaitoksen julkaisusarja 2/2001, Terveydenhuollon laadunhallinta, Radiologisen laitteen vastaanottotarkastus" (Publications of the National Agency for Medicines no. 2/2002, Quality management in health care, Acceptance test of radiological equipment). Practical examples of user tests are given in "Hammasröntgentoiminnan laadunvalvonta ja kuvaushuoneen säteilysuojaus, STUK opastaa 2011" (Quality assurance of dental X-ray practices and radiation shielding of imaging rooms, Advice from STUK 2011). Examples of technical tests are available in "Terveydenhuollon röntgenlaitteiden laadunvalvontaopas, STUK tiedottaa 2/2008" (Quality control guide for health service X-ray appliances, STUK Informs 2/2008).

6.2 Operational quality assurance covers all areas of dental X-ray practices

Quality assurance of dental X-ray practices shall include:

- all instructions necessary for performing examinations
- the recording of examination data and reporting them to STUK upon request
- the determination of patient doses and comparisons to reference levels
- clinical patient image assessments
- self assessments
- clinical audits.

Clinical auditing is not required for conventional dental X-ray practices. However, the other quality assurance procedures listed above shall be performed for conventional and other dental X-ray practices. The quality assurance procedures for these practices shall be described in writing. In addition, procedural instructions shall be written to cover and prevent abnormal events (see chapter 7).

6.2.1 Instructions required for performing examinations

Written instructions for the most common X-ray procedures shall be available in the place of use of an X-ray appliance. These procedural instructions shall cover the use of protective devices for the patient. Protective devices should be used when they do not disturb the imaging. The procedural instructions shall be detailed enough to enable a retrospective inspection of a patient's radiation exposure.

The requirements concerning instructions for conventional X-ray examinations are laid down in section 14 of the MSAH Decree. The report "Radiation

Protection 136, European guidelines on radiation protection in dental radiology" by the EU Radiation Protection Unit discusses the use of protective devices in dental X-ray examinations.

6.2.2 Recording and reporting of examination data

An X-ray examination shall be recorded in patient documentation using e.g. the classification of radiological examinations and procedures. If the implementation of an examination differs essentially from the written procedure (item 6.2.1), this shall be recorded in the patient's data. Information of re-imaging, if any, shall also be recorded in the patient's data. Upon request and according to separately issued instructions, the responsible party shall provide STUK with information on the number of examinations and radiation doses; this information will form the basis for the collation and publication of national reports of examination volumes and related radiation doses.

Section 43 of the MSAH Decree stipulates that information on the number of examinations be submitted to STUK.

6.2.3 Determination of patient doses

The radiation exposure to the patient due to examinations with dental X-ray appliances shall be determined at predefined intervals. For intraoral X-ray units, the patient dose is typically determined as the surface dose, and for panoramic tomography X-ray equipment and CBCT devices, it is determined as the dose-area product.

For intraoral X-ray units it suffices that the patient dose is determined in connection with STUK's control measurements conducted by mail at regular intervals (see chapter 8). For other dental X-ray appliances, patient doses shall be determined at intervals of no more than three years.

A patient's radiation dose can be measured with a suitable dosemeter. If the device has a patient dose display, it can be used for determining the patient's dose. The reliability of the dose display shall be checked by measurements at regular intervals in connection with e.g. the technical quality assurance procedures.

The mean patient dose value for a certain imaging procedure determined in a certain place of use shall be compared to the reference level set for the particular examination. *Reference level* refers to a predetermined dose level that is not presumed to be exceeded in a procedure performed according to the standards of good practice upon a person of normal size. The reference levels for the most common examinations are issued by STUK in specific decisions, to be changed as necessary. Other reference levels in addition to those issued by STUK may be used, but their values shall not exceed the reference values set by STUK. If the mean patient dose value exceeds the reference level in a certain place of use even after an inquiry into the matter, the reason for this shall be investigated and necessary measures shall be taken to reduce patient doses. The imaging programme used for determining the patient dose, the imaging values (tube voltage, tube current, exposure time, field size) and patient dose data shall all be stored.

In addition, checks shall be made at intervals of no more than one year that all imaging values and practices have remained as specified. If the imaging practice has experienced considerable changes, the patient dose shall be redetermined.

Section 16 of the MSAH decree stipulates that reference levels shall be introduced and STUK shall be the authority to issue the reference levels for the most general examinations. The duty of the responsible party to determine the radiation dose administered to the patient in an X-ray examination is set forth in section 17 of the MSAH Decree. The current reference level decisions (most of them in Finnish) issued by STUK are available on STUK's website (http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/en_GB/stohjeet/).

6.2.4 Assessment of clinical patient image quality

Assessment of clinical image quality refers to regular, documented patient image assessments in which patient images produced during a certain period are investigated and compared to generally accepted criteria of good image. In addition to specific clinical image quality assessments, the quality of patient images is

always checked visually after each examination. During everyday work, observations are not routinely registered, neither are the related assessment criteria predefined. Such isolated visual checks are not comparable and do not, therefore, fulfil the purposes set for clinical patient image quality assessments. The assessment of clinical patient image quality forms a good item for self-assessment (item 6.2.5).

In optimizing an X-ray examination, the aim is to reach the clinical goals set for the examination while minimizing the radiation exposure to the examinee. In addition to determining patient doses (item 6.2.3), optimizing therefore always includes the assessment of clinical patient image qualities. The purpose of this assessment is to ensure that image quality suffices for examinations. The required quality varies depending on the anatomical subject of the image and the indication for examination. It is important to make sure that all examination object -specific software solutions in X-ray appliances function appropriately and all examination procedures have been optimized. In addition, it is necessary to make sure that image quality does not deteriorate due to archiving or transfer. Appropriately documented clinical image quality assessments shall be performed regularly at least once a year. If image quality deteriorates enough to disturb diagnosing, the source of the problem shall be located, when necessary, by a step-by-step analysis of the entire imaging chain. It may be necessary, for example, to conduct constancy measurements and compare test images to the reference images taken during the initial measurements. If needed, the equipment shall be serviced or repaired.

The report "Radiation Protection 136, European guidelines on radiation protection in dental radiology – The safe use of radiographs in dental practice" by the EU Radiation Protection Unit provides recommendations for image quality in intraoral, bitewing, panoramic and cephalometric radiography. Recommendations for children's dental X-ray examinations and imaging technique are dealt with in "Lasten röntgentutkimuskriteerit, STUK tiedottaa 1/2008" (Criteria for paediatric X-ray examinations, Advice from STUK 1/2008).

6.2.5 Self-assessment and clinical auditing

Conventional dental X-ray practices (catergory I) shall be subject to annual self-assessments. For a minor operation such as the practice of one dentist, sufficient self-assessment consists of monitoring and assessing the clinical image quality (item 6.2.4). Other dental X-ray practices shall have annual self-assessments and a clinical audit at least once every five years. The purpose of both the self-assessment and the clinical audit is to ensure that the unit complies with safe working practices and produces images of high diagnostic quality.

Self-assessments and clinical audits investigate all the X-ray practices from the writing of referrals to the treatment of the patients. Self-assessments consist of the staff's assessments of the operation while clinical audits are conducted by groups of independent, external experts. Self-assessments should include some of the same elements that clinical audits do.

Self-assessment activities shall be systematic and regular to enable the addressing of weaknesses, if any, in the operation. The methods and objectives of self-assessment should be defined before the assessment is started. All observations made during the self-assessment are recorded and used as the basis for conclusions and eventual corrective actions according to the objectives set. In addition, the effectiveness of the self-assessment in practice is checked by, for example, repeating the self-assessment after a suitable period of time so that its impacts upon practices and the changes, if any, can be detected. It is often seen that practices on a certain area are of high quality. It is important to record this fact and to use repeated self-assessments in the future to check that the high quality has been preserved.

Subjects to self-assessment may include, for example:

- assessments of the quality of expert opinions on X-ray examinations, comparing them to the referrals
- the determination and analysis of patient doses
- monitoring of clinical patient image quality

- the monitoring of re-imaging and the analysis of the reasons for re-imaging
- the collection and analysis of customer feedback on X-ray examinations.

The duty of the responsible party to set up self-assessment procedures in the medical use of radiation is set forth in section 19 of the MSAH Decree, and the obligation to clinical audit is set forth in chapter 4 of the MSAH Decree. Section 21 of the MSAH Decree presents issues to be included in clinical audits.

7 Abnormal events in dental x-ray examinations

An abnormal event in a dental X-ray practice may consist of, for example:

- the exposure of a patient, worker or external person to primary radiation due to a fault in the equipment
- accidental exposure of an external person (such as a wrong patient).

Should an abnormal event or a nearmiss incident take place, the dose to which the patient or the other person was subjected shall be assessed and the reasons leading to the event or incident shall be investigated. In addition, the appropriate measures shall be taken and the respective guidelines shall be checked in order to prevent similar events and incidents in the future.

Sections 13 a and 17 of the Radiation Decree lay down the provisions concerning abnormal events and notifications of observations significant for safety. Examples of abnormal events are presented in Guide ST 1.6. The Medical Devices Act (629/2010) specifies the obligation of those engaged in the professional use of healthcare installations and equipment to give notification to Valvira (the National Supervisory Authority for Welfare and Health) concerning situations involving any hazard.

8 Regulatory control by STUK

On the basis of the application and accounts received, STUK assesses whether or not the appliance, its purpose of use and its place of use fulfil the set criteria. The appliance may be commissioned after the responsible party has been informed that the decision was positive.

If the application and its appendices do not provide sufficient information, STUK may request additional information or perform an on-site inspection in order to acquire the information.

STUK conducts control measurements for intraoral X-ray units used for patient imaging through test packages it sends by post. Such control measurements ascertain the working conditions of appliances and determine the radiation exposure to which the patient is subjected due to a dental X-ray examination. A place of use will be subject to a separate inspection if the control measurement or other reasons specifically call for one.

Practices relating to the use of panoramic tomography equipment, cephalostats and CBCT devices are checked at regular intervals in connection with the on-site inspections. If the device is transferred to a different place of use later, the inspection is usually not repeated unless special reasons exist to do so.

Inspection reports are made of all on-site inspections and all observations are recorded in the reports. Any faults or deficiencies observed in an inspection are ordered to be repaired. A deadline is set for the repairs. STUK shall be notified in writing when the repairs have been conducted. The inspection report indicate whether the practice will need to be reinspected. If the appliance or its use do not meet the safety requirements in this Guide, the appliance must not be used before the faults and deficiencies are repaired.

Bibliography

1. American Association of Physicists in Medicine (AAPM). Quality control in diagnostic radiology. Report of Task Group 12. AAPM Report No. 74. MD: AAPM; 2002. http://www.aapm.org/pubs/reports/
2. European Commission. European Guidelines on Radiation Protection in Dental Radiology, Radiation Protection 136. Luxembourg: Office for Official Publications of the European Communities; 2004. http://ec.europa.eu/

energy/nuclear/radioprotection/publication/doc/136_en.pdf
3. European Comission. European guidelines on quality criteria for diagnostic radiographic images in paediatrics. Luxembourg: Office for Official Publications of the European Communities; 1996. ftp://ftp.cordis.lu/pub/fp5-euratom/docs/eur16261.pdf
4. Health Protection Agency (HPA). Guidance on the Safe Use of Dental Cone Beam CT (Computed Tomography) Equipment. HPA-CRCE-010. Oxfordshire: HPA; 2010. http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1287143862981
5. Institute of Physics and Engineering in Medicine (IPEM). Recommended standards for the routine performance testing of diagnostic X-ray imaging systems. IPEM Report No. 91. York: IPEM; 2005.
6. Knuutila J. (ed.). Terveydenhuollon laadunhallinta. Radiologisen laitteen vastaanottotarkastus. (Quality management in health care. Acceptance test of radiological equipment). Publications of the National Agency for Medicines no. 2/2001. Helsinki: National Agency for Medicines: 2001.
7. Koskinen Walter J. Hammaslääketieteellisen röntgentoiminnan itsearviointi (Self-assessment in dental radiology). University of Helsinki; 2010.
8. Radiation Protection: Cone beam CT for dental and maxillofacial radiology. Evidence based guidelines. A report prepared by the SEDENTEXCT Project; 2011. http://www.sedentexct.eu/files/guidelines_final.pdf
9. National Council on Radiation Protection and Measurements. Radiation Protection in Dentistry. NCRP Report no 145. Bethesda, MD: NCRP; 2003.
10. National Radiological Protection Board. Guidance Notes for Dental Practioners on the Safe Use of X-Ray Equipment. NRPB; 2001.
11. Lasten röntgentutkimuskriteerit (Criteria for paediatric X-ray examinations). Advice from STUK 1/2008. Helsinki: STUK; 2008. http://www.stuk.fi/julkaisut_maaraykset/fi_FI/stuk_tiedottaa/
12. Terveydenhuollon röntgenlaitteiden laadunvalvontaopas (Quality control guide for health service X-ray appliances). Advice from STUK 2/2008. Helsinki: STUK: 2008. http://www.stuk.fi/julkaisut_maaraykset/fi_FI/stuk_tiedottaa/
13. Acceptability requirements for X-ray equipment used in health care. Radiography and fluoroscopy equipment and computed tomography appliances. Decision by STUK, No. 12/310/06 (17.8.2006). http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/en_GB/stohjeet/
14. Potilaan säteilyaltistuksen määrittäminen röntgentutkimuksissa (Determining the patient's exposure to radiation in X-ray examinations). Advice from STUK 1/2004. Helsinki: STUK; 2004. http://www.stuk.fi/julkaisut_maaraykset/fi_FI/stuk_tiedottaa/
15. Reference levels for the patient's radiation exposure for conventional X-ray examinations of adults. Decision by STUK, No. 65/310/08 (15.12.2008). http://www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/en_GB/stohjeet/
16. Hammasröntgentoiminnan laadunvalvonta ja kuvaushuoneen säteilysuojaus (Quality control of dental X-ray practices and radiation shielding of imaging rooms). Advice from STUK 2011. Helsinki: STUK; 2011. http://www.stuk.fi/julkaisut_maaraykset/fi_FI/stuk_tiedottaa/
17. X-ray examinations in health care. Guide ST 3.3. STUK (20.3.2006). http://www.edilex.fi/stuklex/en/
18. Toroi P, Komppa T, Kosunen A. Annoksen ja pinta-alan tulon mittaaminen: DAP-mittarin kalibrointi röntgensäteilykeilassa (Measurement of dose-area product. Calibration of DAP meters in X-ray beams). STUK-TR 4. Helsinki: STUK; 2008. http://www.stuk.fi/julkaisut/tr/stuk-tr4.html

APPENDIX A

DEFINITIONS

Cone beam computed tomography (CBCT) device for imaging teeth and jaws
An X-ray appliance used for imaging teeth and the jaw region through the use of a cone beam to produce two-dimensional projection images from different directions for the formation of three-dimensional images.

Intraoral X-ray unit
An X-ray appliance for dental imaging using an intraoral imaging receptor.

Cephalostat
A positioning device for skull region X-ray imaging which ensures that the imaging geometry and patient positioning remain constant and enables one-plane image formation in the receptor.

Quality control
Quality assurance procedures designed to show that the equipment and their performances conform to the set criteria.

Quality assurance
All the planned, systematic measures taken in order to ensure that all methods, appliances and their use fulfil the speicified quality requirements.

Quality assurance programme
The document referred to in section 18 of the MSAH Decree, specifying in writing the quality assurance activities in the medical use of radiation.

Panoramic tomography equipment
An X-ray appliance for dental imaging which uses a narrow mobile radiation beam to form a tomographic image of the mandibular and maxillary arches in total or in part. This Guide classifies also such devices as panoramic tomography equipment which involve the use of other types of tomography programmes that use narrow radiation beams for imaging and which do not expose the patient to radiation essentially more than does panoramic tomography equipment.

Abnormal event
An event which results in a substantial safety hazard in a place where radiation is used or in its environs. An abnormal event may also consist of an exceptional observation or fact that is of substantial significance for the radiation safety of workers, the environment or patients.

Physician responsible for the procedure (involving exposure to radiation)
A physician who possesses qualifications consistent with the character of the procedure for assessing the justification and optimization thereof, and also for contributing to the interpretation of the results of the procedure.

Radiation safety officer
The person appointed by the responsible party to take charge of the practical activities to ensure the safe use of radiation, to maintain safety and to correct any defects.

Party running a radiation practice (the responsible party)
The holder of a safety licence, or any business or sole trader, enterprise, corporation, foundation or institution which uses radiation sources in its operations or any employer or self-employed person engaged in radiation practices.
Additional information: When the responsible party not a physical person (but is e.g. a limited liability company, foundation or municipality), the party responsible for the operation as a whole is the party with the highest authority in the organization.

APPENDIX B

ACCEPTABILITY REQUIREMENTS AT TIME OF USE FOR DENTAL X-RAY APPLIANCES

Performance measurement results depend on the measurement conditions and the methods used.

Test	Acceptability criterion
Focal spot to skin distance	The distance from the focal spot of an intraoral X-ray unit to the skin of the examinee must be at least 20 cm when the tube voltage is greater than 60 kV, and at least 10 cm when the voltage is 60 kV or less.
X-ray tube voltage	The measured imaging voltage of an X-ray tube may deviate from the nominal value by no more than 10%. The coefficient of variation*) of the measured tube voltage must be less than 5%. The voltage of a portable intraoral X-ray unit must not exceed 75 kV. An intraoral X-ray unit with the nominal voltage under 50 kV must not be introduced for use.
Total filtering	Total filtering of primary radiation must be equivalent to at least 1.5 mm Al when the imaging voltage is less than or equal to 70 kV, and to at least 2.5 mm Al when the imaging voltage is greater than 70 kV.
Exposure time	The measured exposure time may deviate from the set value by no more than 20% when the set time is greater than 100 ms. The coefficient of variation*) of the measured exposure time must be less than 10%.
Radiation output of an X-ray tube	When imaging is repeated five times with varied adjustments, the coefficient of variation in radiation output must be less than 10%. If the equipment contains imaging current or exposure time controls, the air kerma must be proportional to the preset current-time product Q in such a way that: $\left\lvert \frac{\bar{K}_1}{Q_1} - \frac{\bar{K}_2}{Q_2} \right\rvert \leq 0,2 \cdot \frac{\frac{\bar{K}_1}{Q_1} + \frac{\bar{K}_2}{Q_2}}{2}$, in which $\bar{K}_1$, $\bar{K}_2$ are the measured air kerma values and Q_1, Q_2 are the products of the imaging current and exposure time. Q_1 and Q_2 differ from one another by a factor which is as close as possible to factor 2 without exceeding it.
Centering and size of radiation beam	In intraoral X-ray units, the central axes of the cross sections of the radiation beam and the collimation tube (distance limiting device) must not differ from one another by more than ± 2 mm. The field size diameter at the end of the collimation tube (distance limiting device) shall not exceed 6 cm. When using panoramic tomography X-ray equipment, cephalostats and CBCT devices, the radiation beam must fall entirely on the image receptor. CBCT devices shall enable the use of field sizes suited to particular examinations.
Dose display	The error in a dose display shall not exceed 25%.
Patient-positioning accuracy (panoramic tomography X-ray equipment and CBCT devices)	Signal lights shall enable the correct positioning of the patient for the imaging.

CT image noise	The CT number deviation in the centre of the CT image shall not differ from the reference performance values by more than 25%.
Reconstruction accuracy of the image	The proportions in the image shall not significantly differ from the true measures of the object.
High contrast resolution	The resolution of the image shall not be significantly inferior to that of the reference image.
*) Coefficient of variation (relative standard deviation) = $\sigma / \bar{x}$ or standard deviation (σ) of measurement results divided by the mean value ($\bar{x}$).	

Standard deviation, or square root of measurement result variance $\sigma = \sqrt{\frac{1}{N-1} \cdot \sum_i (x_i - \bar{x})^2}$ and mean value of measurement results $\bar{x} = \frac{1}{N} \sum_i x_i$. In this case, x_i is the measurement result number i in order.

APPENDIX C

INTERVALS FOR QUALITY ASSURANCE ACTIVITIES REQUIRED OF A USER OF DENTAL X-RAY APPLIANCES

The following presents the minimum requirement for quality assurance, in addition to which quality assurance activities shall be performed following significant repairs or servicing, and when there is cause to suspect a malfunction or a change in the operation of the appliance.

In addition to the tests presented here, conformance to acceptability requirements at time of use (Appendix B) shall be checked annually for CBCT devices, and for panoramic tomography X-ray equipment and the related cephalostats, at intervals of no more than two years.

Test	**Interval**
QUALITY CONTROL – USER TESTS	
Safety tests	
Mechanical functions and emergency switches of X-ray appliances	12 months
Radiation detectors and warning lights	12 months
Condition of protective devices	12 months
Functional tests	
Imaging of the test phantom • radiation beam size check • for panoramic tomography X-ray equipment and CBCT devices, also centering of the radiation beam and orientation of signal lights	6 months
Even motion of panoramic tomography equipment	6 months
Image formation and viewing	
Films and cassettes • changing development liquids • sealing of cassettes • condition of intensifying screens • compatibility of intensifying screens and film • contact of intensifying screens and film • dark room conditions	 • at regular intervals • 12 months • 12 months • 12 months • 12 months • 12 months
Digital image receptors • condition of the image receptor • image smoothness • CR reader	 • 6 months • 12 months • 12 months
Monitors and work stations, working environment • test image check	 • 1 month
OPERATIONAL QUALITY ASSURANCE	
Determination of patient doses	intervals of 3 years; annual checks to ensure that there has been no change
Assessment of clinical patient image quality	12 months
Self assessment	12 months
Clinical audits	intervals of 5 years. As an exemption conventional dental X-ray practices (class I), which does not require clinical audit.

ST GUIDES (9.12.2014)

General guides

ST 1.1 Safety in radiation practices, 23 May 2013
ST 1.3 Warning signs for radiation sources, 9 December 2013 (in Finnish)
ST 1.4 Radiation user's organization, 2 November 2011
ST 1.5 Exemption of the use of radiation from the safety licensing, 12 September 2013 (in Finnish)
ST 1.6 Operational radiation safety, 10 December 2009
ST 1.7 Radiation protection training in health care, 10 December 2012
ST 1.8 Qualifications and radiation protection training of persons working in a radiation user's organization, 17 February 2012
ST 1.9 Radiation practices and radiation measurements, 17 March 2008
ST 1.10 Design of rooms for radiation sources, 14 July 2011
ST 1.11 Security arrangements of radiation sources, 9 December 2013

Radiation therapy

ST 2.1 Safety in radiotherapy, 18 April 2011

Diagnostic radiology

ST 3.1 Dental X-ray examinations in health care, 13 June 2014
ST 3.3 X-ray examinations in health care, 20 March 2006
ST 3.8 Radiation safety in mammography examinations, 25 January 2013

Industry, research, education and commerce

ST 5.1 Radiation safety of sealed sources and devices containing them, 7 November 2007
ST 5.2 Use of control and analytical X-ray apparatus, 26 September 2008
ST 5.3 Use of ionising radiation in the teaching of physics and chemistry, 4 May 2007
ST 5.4 Trade in radiation sources, 19 December 2008.
ST 5.6 Radiation safety in industrial radiography, 9 March 2012
ST 5.7 Shipments of radioactive waste and spent fuel, 6 June 2011
ST 5.8 Installation, repair and servicing of radiation appliances, 4 October 2007

Unsealed sources and radioactive wastes

ST 6.1 Radiation safety when using unsealed sources, 17 March 2008
ST 6.2 Radioactive wastes and discharges, 1 July 1999
ST 6.3 Radiation safety in nuclear medicine, 14 January 2013

Radiation doses and health surveillance

ST 7.1 Monitoring of radiation exposure, 14 August 2014
ST 7.2 Application of maximum values for radiation exposure and principles for the calculation of radiation doses, 9 August 2007
ST 7.3 Calculation of the dose caused by internal radiation, 13 June 2014
ST 7.4 The dose register and data reporting, 9 September 2008.
ST 7.5 Medical surveillance of occupationally exposed workers, 4 May 2007

Veterinary medicine

ST 8.1 Radiation safety in veterinary X-ray examinations, 20 March 2012

Non-ionizing radiation

ST 9.1 Radiation safety requirements and regulatory control of tanning appliances, 1 July 2013 (in Finnish)
ST 9.2 Radiation safety of pulsed radars, 2 September 2003 (in Finnish)
ST 9.3 Radiation safety during work on masts at FM and TV stations, 2 September 2003 (in Finnish)
ST 9.4 Radiation safety of high power display lasers, 28 February 2007 (in Finnish)

Natural radiation

ST 12.1 Radiation safety in practices causing exposure to natural radiation, 2 February 2011
ST 12.2 The radioactivity of building materials and ash, 17 December 2010
ST 12.3 Radioactivity of household water, 9 August 1993
ST 12.4 Radiation safety in aviation, 1 November 2013