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CONE-BEAM COMPUTED TOMOGRAPHY EXAMINATIONS OF THE HEAD AND NECK REGION IN FINLAND: INDICATIONS AND PATIENT RADIATION DOSE

Master of Science thesis

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ABSTRACT

SONJA TURNBULL-SMITH: Cone-Beam Computed Tomography Examinations of the Head and Neck Region in Finland: Indications and Patient Radiation Dose
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Diagnostic reference levels (DRLs) are pre-determined dose levels employed for patient dose management in diagnostic radiology. Cone-beam computed tomography (CBCT) has gained significant popularity in the imaging of the head and neck region eliciting the need for DRLs for CBCT examinations.

The main objective of the study was to collect dose data for the establishment of indication-based national DRLs for CBCT examinations of the head and neck region in Finland as well as to form proposals for the prospective DRLs. In addition, examination frequencies, the use of optimised imaging parameters and the effect of manufacturer and model of the CBCT device on dose were studied.

The study was conducted as a nation-wide dose survey among the Finnish facilities conducting CBCT examinations of the head and neck region. The response rate was 56% in terms of registered devices and 57% in terms of listed places of use.

DRL proposals were made for seven indications. The values for the proposals were derived from the 75th percentile values of the indication-specific dose distributions. Very wide dose ranges were observed within all seven indications. The most common indication was pre-surgical imaging of implant treatments. A significant portion of the respondents had used default factory settings instead of optimising the imaging parameters. No particular manufacturer or device model stood out as producing exceptionally high or low doses regardless of the user. The Finnish DRLs for CBCT examinations will be issued based on the results of this study.

TIIVISTELMÄ

SONJA TURNBULL-SMITH: Pään ja kaulan alueen kartiokeilatietokonetomografiatutkimukset Suomessa: indikaatiot ja potilasannokset
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Vertailutasot ovat ennalta määrättyjä annostasoja, joita käytetään diagnostisessa radiologiassa potilasannosten hallintaan. Kartiokeilatietokonetomografia (KKTT) on saavuttanut merkittävän suosion pään ja kaulan alueen kuvantamisessa aikaansaaden tarpeen vertailutasoille KKTT-tutkimuksissa.

Tutkimuksen päätavoitteena oli kerätä annosdataa kansallisten indikaatiopohjaisten vertailutasojen muodostamiseksi pään ja kaulan alueen KKTT-tutkimuksille Suomessa sekä tehdä ehdotukset tuleville vertailutasoille. Lisäksi selvitettiin tutkimusmääriä, optimoitujen kuvausparametrien käyttöä sekä KKTT-laitteen valmistajan ja mallin vaikutusta annokseen.

Tutkimus toteutettiin valtakunnallisena annoskyselynä suomalaisille käyttöpaikoille, joissa tehdään pään ja kaulan alueen KKTT-tutkimuksia. Vastausprosentti oli 56 % rekisteröityjen laitteiden ja 57 % listattujen käyttöpaikkojen suhteen.

Vertailutasoehdotukset tehtiin seitsemälle indikaatiolle. Ehdotusten arvot johdettiin indikaatiokohtaisten annosjakaumien 75. persentiilejä vastaavista arvoista. Kaikissa seitsemässä indikaatiossa annosten vaihteluväli oli todella laaja. Yleisin indikaatio oli implanttihoitojen preoperatiivinen kuvantaminen. Huomattava osa vastaajista oli käyttänyt tehtaalla esiohjelmoituja arvoja kuvausparametrien optimoinnin sijaan. Mikään valmistaja tai laitemalli ei erottunut muista tuottamalla poikkeuksellisen korkeita tai matalia annoksia käyttäjästä riippumatta. Suomalaiset vertailutasot KKTT-tutkimuksille julkaistaan tämän tutkimuksen tulosten perusteella.

PREFACE

The study was partly conducted in the Department of Radiation Practices Regulation at the Finnish Radiation and Nuclear Safety Authority (STUK). I would like to thank STUK for the opportunity and for the interesting topic of the thesis. I would also like to thank my former colleagues at STUK for the warm and inspiring working environment.

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Helsinki, 25th August 2016

Sonja Turnbull-Smith

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LIST OF ABBREVIATIONS AND SYMBOLS

AD	Achievable Dose
ALARA	As Low as Reasonably Achievable
BSS	Basic Safety Standards
CBCT	Cone-Beam Computed Tomography
CCD	Charge-Coupled Device
CMOS	Complementary Metal Oxide Semiconductor
CT	Computed Tomography
$CTDI_W$	Weighted CT Dose Index
DAP	Dose Area Product
DDM2	Dose Datamed 2
DLP	Dose Length Product
DRL	Diagnostic Reference Level
EC	The European Commission
EFTA	European Free Trade Association
ESD	Entrance Surface Dose
EU	The European Union
FOV	Field of View
FPD	Flat Panel Detector
HD	High Definition
HPA	The Health Protection Agency
ICRP	International Commission on Radiological Protection
II	Image Intensifier
KAP	Kerma Area Product
kV_p	Tube Peak Voltage
mA	Milliampere
MED	Medical Exposure Directive
MSAH	Ministry of Social Affairs and Health
MSCT	Multi-Slice Computed Tomography
PC	Personal Computer
ROI	Region of Interest
ST Guide	Radiation Safety Guide (*in Finnish ST-ohje*)
STO	Department of Radiation Practices Regulation
STUK	Radiation and Nuclear Safety Authority in Finland (*in Finnish Säteilyturvakeskus*)

TFT	Thin-Film Transistor
TMJ	Temporomandibular joint
2D	Two-Dimensional
3D	Three-Dimensional

1. INTRODUCTION

Radiographic examinations have an essential role in today's medicine as an important part of diagnostics, treatment planning and follow-up on patients [25, p. 9]. Computed tomography (CT) has revolutionised medical radiographic imaging by enabling three-dimensional (3D) visualisation of structures that previously could only be depicted in two dimensions (2D) [5]. However, the application of CT to dental imaging has been strongly hampered by its high dose compared to conventional two-dimensional (2D) methods, large physical size and high costs. Relatively recently, the afore-mentioned issues were solved by the adoption of cone-beam computed tomography (CBCT) to dental imaging. CBCT is a radiographic imaging modality that is capable of providing 3D images with a lower dose and cost than conventional CT. Moreover, for the physical size of CBCT units is small compared to CT devices, allowing CBCT units to be placed in dental offices. [101] Currently, CBCT is highly popular in the imaging of the head and neck and also has various applications outside the traditional dental applications [15; 26, pp. 45–88; 30; 60; 106].

Despite the indisputable benefits of radiographic imaging in medicine, each radiographic examination should be carefully considered because the employment of ionising radiation always entails a risk of detrimental effects to the patient. The potential adverse consequences caused by radiation comprise two types: deterministic and stochastic effects. Deterministic effects are tissue reactions that occur above a certain dose threshold. [98, pp. 37–38] When the threshold is exceeded, the occurrence of the effects is certain and the severity of the effects is dose-dependent [66, p. 46]. Deterministic effects encompass reactions and conditions, such as erythema, cataract, infertility and foetal abnormalities [66, pp. 44, 46; 98, pp. 37–38]. Stochastic effects include cancer and heritable effects. In contrast to deterministic effects, stochastic effects take place without a threshold. Thus, the risk of stochastic effects is ever-present in radiographic imaging, even at very low doses. [98, pp. 37] Dose does not affect the severity of stochastic effects but the probability of the effects

increases with dose [66, p. 45].

Deterministic effects are associated with high single radiation doses [66, p. 44] and are thus not common in diagnostic radiology [98]. For stochastic effects, the total risk is determined by the cumulative dose of lifetime exposures to ionising radiation. For an individual, the risk of stochastic effects can be regarded as relatively small even in the case of relatively high cumulative doses. [66, p. 45] However, stochastic effects can lead to a significant health risk at population level if the amount of people exposed is large, even if the individual doses are low [55; 66, p.45]. This is the case in dental imaging, where the number of radiographic examinations and patients is vast [55].

To protect patients from the deleterious effects of radiation, radiographic imaging practices should always be based on the principles of justification and optimisation. The afore-mentioned principles essentially state that the benefits of the examination should outweigh the potential detriment caused by the examination as well as that the dose to the patient should be as low as can be achieved using reasonable measures and without losing the required diagnostic information [43, pp. 9–16]. To aid dose management and to initiate the process of optimisation, the concepts of diagnostic reference levels (DRLs) has been introduced. DRLs are pre-defined dose levels derived from national dose distributions that should not be repeatedly exceeded under normal circumstances. [43, p. 23–24; 44; 111] The obligation to apply DRLs to radiographic imaging is laid down in the Finnish and European legislation [19,111]. In Finland, the DRLs for the most common examination types are issued by the Radiation and Nuclear Safety Authority (STUK) [19].

The study described in the work at hand was triggered by the need to issue DRLs for CBCT examinations of the head and neck region in Finland. The study succeeded in collecting the required nationwide dose data for STUK to establish the Finnish DRLs for CBCT examinations. To further aid the establishment of DRLs, proposals compliant with international guidelines were formed for the prospective DRLs. Moreover, the study revealed new and important information concerning radiation safety practices, such as the prevalence of optimisation, in CBCT imaging in Finland.

The following two chapters of the thesis present the theoretical background of the study. Chapter 2 Cone-Beam Computed Tomography introduces CBCT as an imaging technique and compares it with other modalities employed for the imaging of

the head and neck region. The chapter also examines the imaging parameters of CBCT scanners as well as their effect on dose and image quality. Furthermore, the indications for CBCT examinations are discussed. Chapter 3 Radiation Safety explores the fundamental principles governing the use of ionising radiation for medical imaging as well as important pieces of Finnish and international legislation regarding radiation safety. The role of STUK is also elucidated. Moreover, the concept of DRLs is presented and DRLs are considered by looking at their adoptions in Europe and Finland as well as at their establishment and application. Chapter 4 Materials and Methods explains how the survey was conducted and how the obtained data was processed. Chapter 5 Results and Analysis both presents and analyses the results of the study. Finally, Chapter 6 Conclusions concludes the study and discusses the importance of the results.

2. CONE-BEAM COMPUTED TOMOGRAPHY

CBCT is a 3D radiographic imaging technology that arrived at dental offices in the late 1990's. The first commercial CBCT device designed for dental imaging was the NewTom DVT 9000, which entered the European market in the year 1999. [5] Since then the technology has rapidly gained major popularity in dental imaging [67] and at present, there are various models from several manufacturers available on the market [64]. Furthermore, the applications of CBCT in the head and neck region have extended widely beyond the traditional dental indications [15; 26, pp. 45–88; 30; 60; 106]. Despite being a rather recent imaging modality in the imaging of the head and neck region, the technology was already developed in the early 1980's but was originally used for angiography [5], i.e. for the radiographic imaging of blood vessels [54, p. 34]. The adoption of CBCT into the imaging of the head and neck region required technical advancements in computer, X-ray tube and detector technology, which explains the delay between the its invention and adoption [101].

The first three sections of the chapter introduce the basics of CBCT in terms of the principle of operation, the process of image production and the main components of the imaging system. Thereafter, the imaging parameters of CBCT devices are explored and their effect on dose and image quality are studied. Furthermore, the adjustability of the parameters is discussed. The chapter also compares CBCT to other radiographic modalities applied to diagnostic imaging of the head and neck region. Lastly, the recommended indications for CBCT examinations are examined.

2.1 Principle

At its most fundamental level, the imaging system of a CBCT unit comprises an X-ray tube and a detector that rotate around the head of the patient [101]. As in other imaging modalities employing X-rays, the X-ray tube produces a beam of radiation that is directed at the patient and the radiation that traverses the patient is registered by the detector [28]. The key to CBCT technology is the shape of the

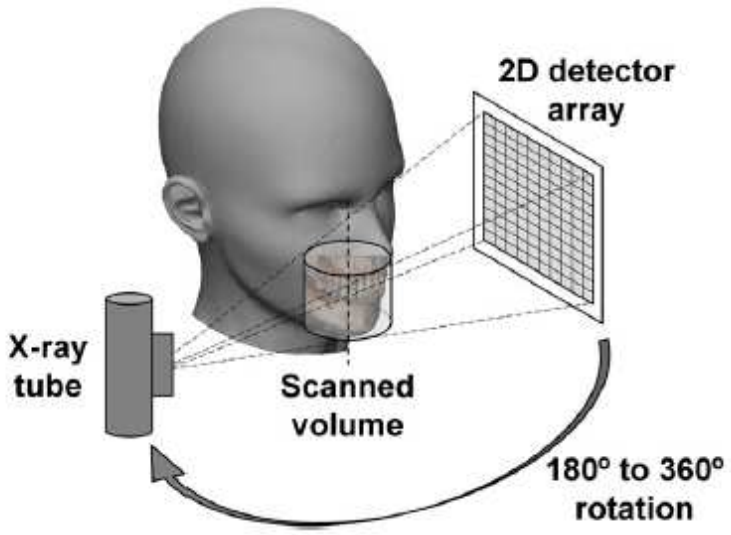


Figure 2.1 *The principle of cone-beam computed tomography. Reproduced with permission of British Institute of Radiology from [67] in the format Republish in a thesis via Copyright Clearance Center.*

X-ray beam, which is that of a cone or a pyramid [101]. Owing to the geometry of the beam, the entire area desired to be imaged, i.e. the region of interest (ROI), can be enclosed within the beam. [28, 101] From the foregoing it also follows that only a 180- to 360 -degree rotation of the tube-detector pair is sufficient to capture the data required for the reconstruction of final the image [67]. The volume of the object scanned by the X-ray beam is denoted by the term field of view (FOV) [63, p. 148]. The size of the FOV should be as close to that of the ROI as possible to avoid unnecessary radiation exposure to the patient [98, p. 89].

The above-discussed principle of CBCT imaging is depicted in Figure 2.1. The figure shows the X-ray tube and the detector as well as their position on the opposite sides of the patient. The rotation of the tube-detector pair about a vertical axis around the head of the patient is demonstrated by the arrow. Figure 2.1 also illuminates the beam geometry examined in the previous paragraph. The volume referred to as scanned volume in the figure, depicts the FOV.

2.2 Image Production and Display

As the tube-detector pair rotates around the patient, a series of sequential 2D images is captured by the detector [101]. The series consists of 128–1024 images, which

are referred to as basis images [51]. The series of basis images is also called the projection or raw data [67]. After acquiring the basis images, the images are processed by correcting inhomogeneities originating from non-idealities in the operation of the detector, such as pixel defects. The final image is generated from the corrected raw data by applying a reconstruction algorithm to each of the basis images and then combining the reconstructed images into a single 3D volume. A popular reconstruction algorithm used in CBCT is the Feldkamp-Kress-Davis algorithm that employs filtered backprojection. [67, 101] The 3D volume is comprised of voxels, i.e. small volume elements that can be considered the 3D equivalent of 2D pixels [28]. In CBCT, the voxels of the resulting 3D volumes are isotropic, meaning that the voxel dimensions are equal in all directions [51].

The resulting CBCT images can be viewed in numerous formats, including 3D visualisations, 2D images in different planes as well as images simulating those obtained from conventional 2D dental radiography [67]. In 2D, CBCT images can be visualised in the three anatomical orthogonal planes (axial, coronal and sagittal) [1]. It is also possible to display images in non-orthogonal, such as oblique, planes [67]. Examples of the simulated images include visualisations mimicking pantomographic and cephalometric images [5, 12]. Pantomographic and cephalometric imaging are discussed in Section 2.5 Comparison to Other Imaging Modalities.

2.3 Components of the Imaging System

As described above, CBCT units include an X-ray tube and a detector that revolve around the patient's head. The tube-detector pair is attached to a gantry. [101] In the case of most CBCT units designed for the imaging of the head and neck, the patient is in a standing position. In many of the afore-mentioned units, the height of the tube-detector pair can be adjusted making it possible to image patients in a wheelchair. Some CBCT systems include a built-in patient chair and the patient is imaged in a seated position. [51] Examples of the afore-mentioned types of CBCT units are presented in Figure 2.2. Moreover, there are also CBCT systems, in which the patient is supine, but such systems are uncommon among those dedicated to the imaging of the head and neck [51].

The X-ray tubes used in CBCT operate at a rather low power [61] with tube peak voltages (kV_p) and currents in the range of 40–120 kV_p and 1–32 milliamperes (mA), respectively [51]. The X-ray sources of CBCT devices generate X-rays in either a

(a) An example of a CBCT unit, in which the patient is imaged in a standing position [73].

(b) An example of a CBCT unit with a built-in patient chair [49].

Figure 2.2 *Examples of CBCT units designed for the imaging of the head and neck region.*

pulsed or continuous fashion. In the case of continuous X-ray production, X-rays are generated ceaselessly during the whole scanning time. [67, 101] However, the detector is not capable of continuous detection because time is also required to collect and forward the detected signal [1]. Moreover, the detector needs to move to the position, from which the subsequent basis image is taken [100]. Thus, when X-rays are generated continuously, the patient is exposed to radiation that does not contribute to image production [101]. Frame rate is a measure that describes the number of images the detector can produce per second [100]. In pulsed X-ray production, the generation of X-rays is intermittent and synchronised with the frame rate of the detector so that exposures are not made during the time the detector is unavailable for detection [1,67,101]. Consequently, the dose to the patient is reduced compared to continuous X-ray production [101].

Important components of the CBCT imaging system associated with the X-ray tube are the collimators. Collimators refer to lead-alloy shields that allow the beam to be focused onto a limited area, enabling the FOV to be smaller than the entire head of the patient. The collimators form openings that direct the beam. Most CBCT

units have more than one pre-defined opening size and thereby, provide more than one FOV size. [67]

CBCT systems employ area detectors of two alternative types: detectors consisting of image intensifiers (II) combined with charge-coupled devices (CCDs) and flat panel detectors (FPDs) containing arrays of hydrogenated amorphous silicon thin-film transistors (TFTs) or complementary metal oxide semiconductors (CMOSs) [5]. II/CCD detectors are found in older CBCT units, whereas FPDs are used in the majority of modern CBCT devices [51]. The basic principle of operation is the same for both FPD detector types. The detectors include a scintillator material that converts the detected X-rays to visible light photons. The light photons, in turn, are converted into electrical charge by photodiodes incorporated into the detectors. The produced charge is then collected and read out to produce the output signal of the detectors. [5]

CBCT units typically employ a separate computer for image acquisition, from which the data is sent to another computer to be processed. The reconstruction and display of images can be performed on a personal computer (PC). Thus, no specialised workstations for image processing are needed. [101]

2.4 Imaging Parameters

The purpose of diagnostic radiographic imaging is to gain information to answer the clinical question, for which the imaging examination has been prescribed. In acting to achieve the foregoing objective, the following two aspects should be considered: the quality of the images obtained through the imaging examination as well as the radiation dose received by the patient. The quality of the resulting images should be such that sufficient diagnostic information is provided. However, at the same time, the ALARA principle should be abided by. [14] ALARA stands for ”as low as reasonably achievable” and accordingly, the principle states that the patient radiation dose should be as low as can be achieved using reasonable measures and without the required diagnostic information being lost [111]. The ALARA principle is addressed in more detail in the next chapter. Both the patient dose and image quality are influenced by the choice of imaging parameters, such as the FOV size and tube current [67]. The main imaging parameters and their effect on dose and image quality are summarised in Table 2.1 and further discussed in the first subsection. The second subsection explores the possibilities of the user to adjust and optimise

the parameters.

2.4.1 Effect on Dose and Image Quality

Image quality can be regarded as an entity composed of several components, some of which are inter-related. The afore-mentioned components include spatial resolution, contrast, noise and artefacts. Spatial resolution indicates the ability to discern small details from each other. Contrast describes how well distinction between regions of different density can be made. Noise and artefacts, in turn, are undesired components introduced into the image. Noise refers to unwanted random variation in the image signal, whereas artefacts are non-random elements seen in the image that do not have a counterpart in the actual object that is imaged. An important source of artefacts in CBCT is scattered radiation from the patient that reaches the detector and thereby, contributes erroneously to the detected signal. Due to their inter-relatedness, the afore-mentioned components should be considered together when assessing image quality. In radiological imaging, image quality is influenced by the following imaging parameters: FOV size, tube current and voltage as well as voxel size. [67]

Table 2.1 *The effect of imaging parameters on patient dose and the components of image quality. Adapted from [67]. ↑ denotes an increase and ↓ a decrease in an imaging parameter or in an effect on the components of image quality.*

Imaging Parameter	Spatial resolution	Contrast	Noise	Artefacts	Patient Dose
FOV size ↑	-	↓	↑	↑	↑
Tube current ↑	-	-	↓	-	↑
Tube voltage ↑	-	↓	↓	-	↑
Voxel size ↓	↑	-	↑	-	-

By increasing the tube current, noise in the resulting image can be reduced. However, the magnitude of the tube current is directly proportional to the number of X-ray photons that are produced in the X-ray tube. Thus, the tube current has a direct effect on radiation dose, and the noise reduction achieved by increasing the tube current comes with the cost of an increased patient dose. Noise reduction can also be accomplished by increasing the tube voltage. However, at the same time, an increase in tube voltage results in decreased contrast. Furthermore, as in the case of the tube current, increasing the tube voltage leads to a higher patient dose. [67]

In contrast to the parameters discussed above, increasing the FOV size does not provide benefits in terms of image quality. On the contrary, the employment of large FOV sizes results in decreased contrast as well as added noise and more artefacts due to an increase in scattered radiation captured by the detector. Additionally, large FOVs entail high patient doses. It has to be noted though, that the use of small FOV sizes also causes the formation of certain types of artefacts. This is because in the case of small FOVs, a large portion of the patient's head is left outside the FOV and the mass corresponding to that portion interferes with the generation of the projection data, from which the eventual image is reconstructed. However, in many cases the foregoing artefacts can be regarded as being of only minor practical importance in CBCT imaging. [67]

The effect of voxel size on image quality is that spatial resolution is improved when the voxel size is decreased. However, the reduction in voxel size simultaneously causes the image to become noisier. The voxel size *per se* does not influence the dose. Yet, in some CBCT units, the adjustment of voxel size is incorporated into resolution settings or protocols, which alter the tube current according to the voxel size. Such resolution settings or protocols employ higher tube currents to compensate for the added noise caused by voxel size reduction. As a consequence of the increase in tube current, the patient dose becomes higher. [67]

2.4.2 Adjustability and Optimisation

The technical specifications, including the imaging parameters, of 45 different dental CBCT units were recently reviewed by Kiljunen et al. [51]. According to the review, the adjustability of imaging parameters varies significantly between different CBCT models. There are differences in which parameters and to which degree they can be adjusted by the user. [51] Thus, the possibilities of the user to influence the imaging parameters is highly dependent on the CBCT device at hand.

The user can modify the tube current almost without exception in all CBCT devices reviewed by Kiljunen et al. However, the range of available adjustment offered by some units is only a few milliamperes, whereas in some devices the range covers over 30 mA. The review shows that there are several CBCT units on the market that have a fixed tube voltage. An adjustable tube voltage is, nevertheless, more common and a typical range of adjustment is 60–90 kV_p. In most of the reviewed scanners

the user can choose between pre-defined FOV size options. The number of the pre-defined FOV sizes is highly variable between different CBCT models, ranging from only one option up to 20 options. The FOV sizes extend from 4 cm x 4 cm/5 cm x 5 cm (diameter x height) to 23 cm x 26 cm. The sizes within the foregoing range do not, however, follow any standard but every manufacturer has their own sizes. The exact sizes also differ between the models of the same manufacturer. The possibility to freely adjust the dimensions of the FOV within certain limits is rare, with such a feature being available in only one of the reviewed CBCT devices. Voxel size options are also provided in most CBCT units. [51]

Most CBCT units also have pre-defined protocols or programmes that provide default values for imaging parameters according to the imaging task and/or the size of the patient entered by the user [64, 68]. Studies have reported, however, that sufficient image quality is attainable with lower tube currents and/or voltages than those of the default settings [18,31,52,68,108]. Thus, in conformity with the ALARA principle, users should not settle for the default values provided by the CBCT devices but optimise the values to reduce the patient dose within the limits of adequate image quality required by the clinical question.

With regard to optimising imaging parameters to achieve the best compromise between patient dose and image quality, the FOV size can be considered the most straightforward parameter. That is because the use of an unnecessarily large FOV size not only increases the dose to the patient but also degrades image quality, as discussed earlier in the section. The optimisation of the tube current and tube voltage is more complicated because an increase in the foregoing parameters results in better image quality in terms of less noise but in higher patient dose. [67] However, the effect of tube current reduction is more prominent on dose than on image quality. The foregoing is explicable by the inverse square law for dose and noise, which states that dose is inversely related to the square of noise. [51] Thus, the adjustment of tube current is an important means of lowering patient dose without causing unacceptable deterioration of image quality. The reduction of tube voltage has been found to degrade image quality more than the lowering of tube current [69]. Efforts should, however, be made to adjust the tube voltage according to the size of the patient, especially when imaging children [51].

2.5 Comparison to Other Imaging Modalities

Besides CBCT, other radiographic imaging modalities applied to the examinations of the head and neck region include intra-oral radiography, panoramic tomography, cephalometric imaging and multi-slice computed tomography (MSCT) [12]. Additionally, plain 2D radiography is used in the head and neck region but only to a minor extent [17]. Intra-oral radiography and panoramic tomography comprise the traditional 2D radiographic methods in dental imaging [26, p. 72]. They are the main and in many cases, the only modalities needed for dental imaging purposes [107].

2.5.1 Two-Dimensional Radiography

Intra-oral radiography refers to an imaging technique, in which the X-ray tube is outside the patient but the image receptor is placed inside the patient's mouth [109, p. 50]. The technique incorporates the possibility of obtaining three projection types. The projections differ from each other by depicting different parts of the tooth and different amounts of bone around the tooth. [72, p. 109] Intra-oral radiography provides high spatial resolution [12] and can be used for the imaging of a single tooth or a few adjacent teeth [79; 109, p. 50]. In addition to high spatial resolution, the advantages of intra-oral radiography encompass low dose, low cost and the simplicity of the examinations. However, a significant limitation to the use of intra-oral radiography is that 3D structures are depicted in 2D resulting in superimposition of structures, which in turn can lead to structures and lesions not being visible in the images. [62] Furthermore, the 2D representation of 3D structures can cause misinterpretations on the dimensions of lesions. For example, bone defects may appear smaller in the images than they are in reality. [7, 62]

Panoramic tomography is an imaging modality that has been on the market since the 1960's and was developed by a Finnish professor, Yrjö Paatero. Similar to CBCT, also panoramic tomography employs an X-ray tube and detector that are located on opposite sides of the patient's head and that rotate around the head about a vertical axis of rotation. In contrast to CBCT, in panoramic tomography, the beam is narrow in the vertical plane and is of the shape of a fan. The movement of the X-ray tube occurs behind the head of the patient and covers a trajectory slightly longer than a semicircle. [109, pp. 73–75] Panoramic tomography produces a single 2D image covering a large area, including the jaws, the teeth, the temporomandibular joints

(TMJ) and maxillary sinuses [107]. TMJ is the joint between the lower jaw bone and the skull [54, p. 386]. Maxillary sinuses refer to the air-filled cavities located in the maxillary bone on both sides of the nose [54, pp. 568, 656]. The spatial resolution in pantomographic images is, however, poorer than in intra-oral radiography [12]. As a 2D modality, also panoramic tomography suffers from superimposition of structures, with overlap of oral structures and the cervical spine being projected onto the images. Due to reasons arising from technique, only one image layer or plane can be brought into focus in pantomographic imaging. At the centre of the afore-mentioned layer structures are sharply depicted in the resulting image, whereas the visualisation of objects located elsewhere is hampered by blurring and distortion. [107] Thus, panoramic tomography is applicable to imaging tasks, in which a broad view is desired but the requirements for resolution or anatomical detail are not high [56, p. 175]. Besides covering an extensive area, the advantages of panoramic tomography include low dose and convenience of performing the examinations due to their short duration and them being extraoral [56, p. 175; 107].

Panoramic imaging devices can also be fitted with an additional piece of equipment, a cephalostat, to enable cephalometric imaging [79]. Cephalometric imaging is concerned with the assessment of relations between specific points in the skull and is utilised in orthodontics. The cephalostat is used for positioning the patient's head in order to conduct the skull assessment in a standardised manner. Besides panoramic units fitted with cephalostats, also separate X-ray devices dedicated to cephalometric imaging only are available. [113, pp. 161–162, 166–168]

Plain 2D radiography has been superseded by other imaging modalities for most indications in the head and neck region [17]. However, plain radiography still has a role in the imaging of paranasal sinuses in Finland [114]. Paranasal sinuses refer to the normally air-filled cavities located in the bone surrounding the nasal cavity, including the previously mentioned maxillary sinuses. [54, pp. 568, 656]. According to the current Finnish care guidelines regarding inflammations of the paranasal sinuses, plain radiography often provides sufficient information if radiographic imaging is required for recurrent acute inflammations [114]. In favour of using plain 2D radiography is also that the examinations are easy and rapid to perform. Moreover, the costs and dose are relatively low. [17] However, the employment of plain radiography for the imaging of sinuses has also received heavy criticism, stating, among others, that it has a low diagnostic value due to projection effects in the images [17] as well as that it produces a significant amount of false positive and negative results

when applied to the diagnostics of sinus inflammations [17, 29].

2.5.2 Three-Dimensional Imaging Modalities

Both CBCT and conventional CT produce 3D images and thereby, provide a solution to the problems inherent to 2D radiography that result from 3D structures being depicted in 2D. However, the technique underlying image production as well as the components of the imaging systems differ between the afore-mentioned modalities. The differences result in the physical size, cost, dose and image quality of CBCT and conventional CT devices being distinct from each other. [5]

The principle of conventional CT imaging is shown in Figure 2.3. As seen in the figure, a fundamental difference between CBCT and CT is the shape of the X-ray beam. In contrast to the cone- or pyramid-shaped beam employed in CBCT, the beam in CT is the shape of a fan. [101] Similar to CBCT, the X-ray source rotates around the patient with detectors on the opposite side of the patient. However, unlike in most CBCT devices, the patient is supine on a patient table and the rotation of the X-ray source and detectors takes place about a horizontal axis. [5] Due to the imaging system incorporating a patient table, the footprint of the device is larger than that of a CBCT device [5], in most of which the patient is imaged in a standing or a seated position [51].

Following from the shape of the beam in CT, the beam only covers a slice of the patient instead of the entire ROI, like in CBCT. Consequently, the patient has to be imaged slice by slice. [101] The foregoing requires several rotations of the X-ray source as well as translational motion of the patient table. In former generations of CT devices, only one image slice was captured during a rotation of the X-ray source, whereas the multi-slice technology employed by the modern CT devices, i.e. MSCT systems, enables multiple slices to be acquired per rotation. Furthermore, because the 3D image volume in conventional CT is assembled by stacking the afore-mentioned axial image slices, the FOV cannot be restricted to a small area within the patient's head like in CBCT. [5]

Due to the different beam geometry, also the detector types employed by CBCT and MSCT differ from each other. Instead of area detectors used in CBCT units, CT systems incorporate arrays of small detectors arranged in an arc configuration. In the multi-slice technology, there are several rows of detector arrays adjacent to

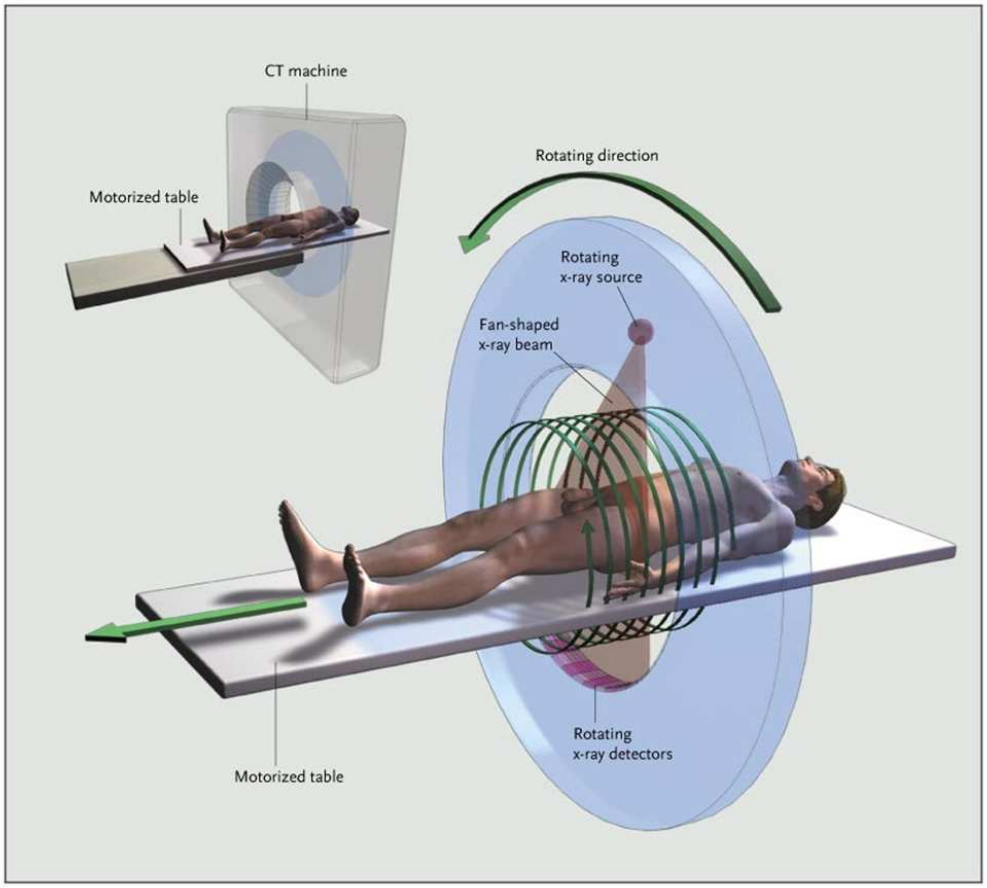


Figure 2.3 *The principle of computed tomography. Reproduced with permission from [13], Copyright Massachusetts Medical Society.*

each other. The detectors are either xenon gas detectors or detectors composed of a scintillator medium and a photon detector. [5]

Besides the detector types, also the requirements for tube power and image processing software are dissimilar between CBCT and MSCT. The X-ray tubes of MSCT units typically operate at a higher power than those of CBCT systems, with especially the tube currents being higher than those used in CBCT. MSCT requires more of the software used for image processing than CBCT. Thus, unlike in CBCT, a PC is not sufficient for image reconstruction in MSCT and accordingly, a special workstation for image processing is a part of the MSCT imaging system. [5]

It is possible to assess both bone and soft tissues in 3D using MSCT and thus, in that respect MSCT is applicable to the evaluation of almost all pathologies of the head and neck region. [12] However, especially in dental imaging, the use of MSCT is

problematic due to issues concerning dose, cost and availability [101]. The effective dose of MSCT is substantially higher than that of the conventional 2D radiographic methods [26, p. 31]. Furthermore, due to the high cost and large physical size of MSCT devices, the availability of MSCT for dentists is very restricted [101].

The CBCT technology has, however, succeeded in overcoming the above-mentioned problems regarding CT and dental imaging and thereby, also enabled the use of 3D imaging for dental applications. MSCT systems require a large physical space, whereas space available in dental office settings is sufficient for CBCT units due to their smaller footprint. The smaller size and the above-discussed differences in the technology and components of the imaging system result in CBCT units being affordable compared to MSCT devices. In effect, the price of a CBCT unit is approximately 1/4–1/5 that of a MSCT device. Furthermore, in comparison to MSCT, significant dose reductions can be achieved by using CBCT. [101] However, the range of effective doses for CBCT is extensive, including effective doses of the same magnitude as those of MSCT [70]. A key factor influencing the dose of CBCT is the selection of an appropriate FOV size [98, p. 89]. It is also to be noted that the effective doses of CBCT are, nevertheless, higher than those of conventional 2D methods [26, pp. 30–31].

A major limitation to the use of CBCT is its poor contrast resolution, rendering the modality unsuitable for imaging tasks involving soft tissues. Moreover, the images produced by CBCT contain more noise than those produced by MSCT. The main causes for the poor contrast resolution and noise in CBCT are the shape of the beam causing a significant amount of scatter radiation as well as the lower tube voltages and currents compared to MSCT. [5] Consequently, when information on soft tissues is required, the radiographic imaging modality of choice is MSCT in the head and neck region [5]. The spatial resolution, however, has been stated to be higher in CBCT than in MSCT [12].

2.6 Applications of Cone-Beam Computed Tomography in the Head and Neck Region

In literature, an extensive number and variety of applications of CBCT can be found [15; 26, pp. 45–88; 30; 60; 106]. However, despite having several potential applications, CBCT is not always the most appropriate imaging or examination method for those. For example, in dental and maxillofacial imaging, the information

provided by CBCT may not alter the diagnosis or treatment plan proposed based on conventional radiography but often entails higher costs and patient dose. [26] To identify the situations where CBCT offers benefit for both the dentist or physician and the patient, recommendations and guidelines have been issued [26, 36]. The section explores the guidelines and recommendations issued on the clinical use of CBCT as well as the applications of CBCT in the head and neck, with the emphasis on the indications suggested by evidence-based guidelines.

2.6.1 Guidelines and Recommendations

A recent review by Horner et al. [36] found 11 publications that specifically pertained to CBCT imaging and contained guidelines or recommendations on the clinical use of CBCT. Furthermore, an additional 15 publications were identified that also included guidelines and recommendations on the clinical employment of CBCT but the foregoing publications were not specific to CBCT. Out of the afore-mentioned sets of guidelines, only two were rated as evidence-based by the authors of the review: those issued by the SEDENTEXCT consortium [102] and the national guidelines for CBCT of Germany [20].

The guidelines by SEDENTEXCT were issued in 2011 [102]. The afore-mentioned guidelines were also published in 2012 in the publication "Radiation Protection No 172" by the European Commission (EC) [26]. The SEDENTEXCT guidelines were prepared by a multidisciplinary team of experts, including medical physicists, dentists and dental radiologists [102]. The current version of the national guidance of Germany is from the year 2013 [20].

2.6.2 Indications according to SEDENTEXCT Guidelines

In general, according to the SEDENTEXCT guidelines, CBCT is indicated when the information obtained from conventional radiography is insufficient or is in contradiction with clinical findings. Furthermore, CBCT is a justified alternative for MSCT when its dose has been demonstrated to be lower and information on soft tissues is not needed. The foregoing guidelines propose indications for CBCT that comprise three main categories: the developing dentition, restoring the dentition and surgical applications. [26]

The category developing dentition contains indications pertaining to children. The children's indications, for which CBCT may be used according to SEDENTEXCT are the following: the assessment of impacted teeth and potential resorption, i.e. breakdown of adjacent teeth, associated with the impaction, the evaluation of cleft palates as well as the planning of management and surgery in complicated orthodontic cases. [26] An impacted tooth is a tooth that has failed to erupt normally [38]. Cleft palate refers to a birth defect, in which the oral development is abnormal resulting in a gap in the roof of the mouth. Cleft palates are corrected surgically. [16] Orthodontia is concerned with problems related to the teeth and jaw, such as abnormal bite, gaps between teeth as well as crooked and misaligned teeth [65].

The category restoring the dentition includes endodontics, periodontal and periapical diseases as well as dental trauma [26]. Endodontics deals with the inside of the tooth, i.e. the dental pulp and the root canals of the tooth [3; 54, p. 139]. In endodontics, possible indications for CBCT include planning of endodontic surgery as well as the evaluation of root canal morphology and root resorption [26], i.e. the loss of structures of the tooth root [3]. Periodontal diseases refer to diseases of the tissues that surround the teeth and to which the teeth are attached [54, p. 547]. Periodontal diseases can cause loss of bone around the teeth, for the assessment of which CBCT may be useful [2, 26]. Periapical diseases result from an infection in the dental pulp that spreads through the root canal to affect the areas at the tip and around the tooth roots [37, 115]. The use of CBCT may be advisable in situations where symptoms and clinical findings suggest periapical disease but conventional radiography reveals no signs thereof [26]. Regarding dental trauma, the SEDENTEXCT guidelines mention suspected root fractures as a possible indication for CBCT [26].

Surgical applications of CBCT proposed by the SEDENTEXCT guidelines encompass pre-surgical imaging for the removal of wisdom teeth as well as for implant dentistry. Regarding wisdom tooth extraction, the use of CBCT may be appropriate in cases where conventional radiography has shown that the tooth to be removed is in close vicinity of the mandibular canal. The mandibular canal contains nerves, which are at risk for damage during surgical extraction if the tooth is closely related to the canal. In implant dentistry, CBCT may be indicated for obtaining information on the amount and quality of bone at the prospective implant site as well as on the location of other anatomical structures in relation to the implant site prior to surgery. Other surgical applications suggested by the afore-mentioned guidelines

include the assessment of jaw bone defects caused by cancer as well as changes and abnormalities in the bony structures of the TMJ. Additionally, planning of orthognathic surgery is also on the list of surgical applications for CBCT. [26] Orthognathic surgery deals with the correction of skeletal abnormalities of the lower or upper jaw bone or both [4].

2.6.3 Other Indications

The SEDENTEXCT guidelines are mainly focused on the dental applications of CBCT, whereas the previously mentioned national guidelines of Germany are broader with respect to other indications in the head and neck area [20, 26]. An important indication for CBCT not included in the SEDENTEXCT guidelines but covered by the German ones, is the imaging of paranasal sinuses. CBCT has emerged as a substitute for MSCT in the imaging of paranasal sinuses and its use for the imaging of sinuses has become common [15, 30, 106]. The German guidelines state that CBCT should be used to detect and differentiate pathologies of the sinuses when the foregoing is not possible with 2D radiographic methods. Moreover, CBCT may be indicated for the pre-operative imaging of the sinuses in individual cases, where surgery involving the sinuses is planned, and there are grounds for the assessment of the status of the sinuses based on the medical history and clinical situation of the patient. A suspected inflammation in the sinuses is an example of the latter. [20]

Other indications for CBCT in the head and neck area included in the German guidelines encompass the following: salivary stones, fractures of the facial bones, the localisation of foreign bodies as well as the assessment of the upper airways. According to the guidelines, the use of CBCT may be indicated in individual cases for the exact localisation of salivary stones but not for the assessment of other pathologies of the salivary glands. Regarding the fractures of the facial bones, CBCT can be employed to determine the precise location of the fracture fragments. However, in case of suspicion that also the brain is affected or that the soft tissues are damaged, MSCT should be preferred over CBCT. The localisation of foreign bodies in the mouth, jaw and face area is regarded as a possible indication for CBCT in the guidelines. Concerning the assessment of the upper airways, the guidelines state that CBCT imaging may be indicated in special cases, such as with patients with proven sleep apnoea symptoms. [20]

Besides the above-discussed indications for CBCT found in the SEDENTEXCT and

the national German guidelines, other applications reported in literature include the imaging of the cervical spine, the evaluation of the position of inner and middle ear implants and computer-aided surgical planning [60,106]. Implant treatments are an example of a branch of dentistry, to which computer-aided surgical planning employing CBCT has been applied [9,106]. The data obtained through CBCT imaging can be imported to a surgical planning software, which allows the implant procedure to be virtually planned and simulated [8]. In addition to producing virtual simulations and models, CBCT data in conjunction with surgical planning programmes can be utilised to fabricate physical 3D models and surgical guides by rapid prototyping [8, 9, 106]. Surgical guides are templates that are used in implant surgery to assure that the implants are placed in the exact correct location and orientation [97].

3. RADIATION SAFETY

The core of radiation safety in medical radio-diagnostic imaging is that the benefits of the examinations exceed the detriment caused to the patient and that the patient is not exposed to any excessive radiation. To ensure and contribute to radiation safety in medical imaging, principles, recommendations and pieces of legislation have been issued. Furthermore, several international, regional and national bodies are involved in promoting and regulating radiation safety. The chapter examines the fundamental principles governing radiological protection as well as the national and international bodies acting in the field. Moreover, the European and Finnish legislation and requirements regarding the medical use of radiation are explored. Also the concept of DRLs is introduced and discussed in depth from several viewpoints.

3.1 Radiological Protection

The principles of justification and optimisation are the fundamental principles governing radiological protection in medical imaging. The principal international body in the field of protection against ionising radiation is the International Commission on Radiological Protection (ICRP) [46, p. 6].

3.1.1 International Commission on Radiological Protection

ICRP is a non-profit, non-governmental organisation founded in 1928 to promote radiological protection. ICRP issues recommendations and guidelines aimed at people, organisations and agencies functioning in the field. The foregoing include advisory and regulatory agencies responsible for radiation safety, such as national authorities. ICRP reaches its audience through the journal *Annals of ICRP*, which is published four times a year. [46, pp. 6, 38] In addition to recommendations and guidelines, the publications by ICRP encompass supplementary information to the recommendations, reviews on topical issues pertaining to radiation and radiological

protection, compendiums of reference data and coefficients as well as symposium proceedings [40].

The recommendations by ICRP are broad in nature and cover radiological protection at a fundamental level. The role of the other publications, in turn, is to focus on specific topics and delve deeper into them. The recommendations and guidelines of ICRP enjoy an eminent status and form the basis for national legislation on radiation protection globally as well as for the European directives concerning the field. [46, pp. 3, 36–37] In their current form, the recommendations of ICRP have been published since 1959 [46, p. 3], when the recommendations adopted in 1958 were presented in Publication 1 [41]. Thereafter, the recommendations have been revised three times. The latest version of the recommendations dates back to 2007. [46, p. 3]

The approach to radiological protection employed by ICRP relies on three fundamental principles: justification, optimisation and the application of dose limits [46, p. 1]. Dose limits or constraints are not applied in medical exposures [46, p. 14] and therefore, the third principle on the list is not discussed in the study. The next subsection is dedicated to the exploration of the principles of justification and optimisation.

3.1.2 General Principles

The principle of justification and the principle of optimisation form the basis for the safe use of radiation in medicine [47, p. 5]. The principle of justification deals with the balance between the expected benefits entailed by the use of radiation and the potential deleterious consequences caused by the exposure to radiation. The principle of optimisation, in turn, is concerned with the radiation dose the patient is exposed to during a medical examination or procedure. [111]

Medical examinations and procedures that employ ionising radiation, including radiographic imaging, pose the patient at risk of adverse health effects, such as cancer and radiation damage [47, p. 5]. In many cases, the risk can be considered relatively low, but it is nevertheless existent. Therefore, imaging using X-rays should never be performed unnecessarily or as a routine examination. [25, pp. 9, 14–16, 18] However, on the flip side, radiographic imaging is a fundamental tool in obtaining the correct diagnosis, in deciding on the most appropriate treatment as well as in following up on the patients [25, p. 9]. Thus, the employment of radiographic imaging can provide significant benefits despite the risks and thereby, it neither can, nor should,

always be avoided [46, p. 41; 47, p. 6]. According to the principle of justification, the medical use of radiation is justified, when the expected benefits thereof to the patient and the society outweigh the potential harm caused to the patient [111]. In assessing the justification of the examination, the following aspects should be considered: the purpose, the aims and the information value of the examination, information on the patient obtained from medical records and by means of clinical examination as well as alternative examination options available [19; 25, p. 18; 47, p. 7; 111]. In essence, the examination should be appropriate for its purpose and the patient suited for the examination [47, p. 7]. Unjustified examinations must not be conducted [43, p. 9].

The premise of the principle of optimisation is to avoid unnecessary radiation exposure to the patient being examined [19]. The foregoing involves the application of the ALARA principle. The ALARA principle implies that the patient dose should be the lowest that can be attained using reasonable measures, on the condition that the needed diagnostic information is acquired. In this context, the term ”reasonable” refers to considering financial and social factors involved in the measures taken to protect the patient from radiation. In other words, dose reduction should not be conducted at the cost of unduly high expenses or disproportionate deterioration of image quality, nor should it render performing the examination too complex. [43, pp. 13–16] Thus, complying with the principle of optimisation does not necessarily equal minimising the dose [46, p. 92]. Instead, optimisation is a weighing process between the exposure, the resulting image quality and the investment of resources, where the most beneficial combination of the afore-mentioned factors is sought [43, p. 14]

Optimisation is rated as the most effective means of radiological protection by ICRP in Publication 73 that is concentrated on safety in medical exposures [43, p. 13]. Also the latest recommendations of ICRP underline the role of optimisation in radiation safety [46, p. 14, 44]. Optimisation should cover the entire examination process: both the equipment and the courses of action, i.e the methods and protocols employed. In medical exposures, the significance of the courses of action is pronounced since they directly affect the patient. [43, p. 13] In conjunction with optimisation in medical exposures, ICRP mentions DRLs a method for controlling the dose received by the patient. [43, p. 15; 46, p. 128] DRLs are examined in depth in the last section of the chapter.

3.2 Regulation

From the European and Finnish perspective, important pieces of legislation concerning radiation safety in medical imaging include the Basic Safety Standards (BSS) Directive and its predecessor the Medical Exposure Directive (MED) as well as in the Finnish legislation, the Radiation Act and the Decree of the Ministry of Social Affairs and Health (MSAH) on the medical use of radiation. In Finland, the regulatory body in the field of radiation safety is STUK. STUK is also responsible for issuing DRLs for the most common examination types in Finland.

3.2.1 Legislation

The general principles explored above are also legally binding in the European Union (EU) since they are laid down in the Council Directive 2013/59/Euratom, also referred to as the BSS Directive [112], that is concerned with protection against ionising radiation. The directive also requires the establishment and use of DRLs in radiodiagnostic examinations. As a member of the EU, Finland must transfer the council directives into national law [22]. However, the afore-mentioned directive being relatively recent, the current Finnish legislation on radiation protection is still based on the predecessors of the directive. The Directive 2013/59/Euratom is to be implemented into the national laws of the EU member states by 6th February 2018 [23]. Of the predecessors, the MED directive, i.e. the Council Directive 97/43/Euratom, pertains to medical exposures and contains the above-discussed general principles as well as the requirement of adopting DRLs [111]. Furthermore, the European Commission (EC) gives further clarification on the concept of DRLs as well as advice on the determination and employment of DRLs in its publication "Radiation Protection 109". However, the purpose of the afore-mentioned publication is advisory and thus, the guidance provided in the publication is not binding. [24]

In the current Finnish legislation, the principles of justification and optimisation are found in the Radiation Act [78] and the Decree of MSAH on the medical use of radiation [19]. The obligation to apply DRLs is included in the afore-mentioned decree of the MSAH. The decree also stipulates that DRLs are established by STUK. [19] Moreover, by the Radiation Act, STUK is authorised to issue general instructions that enable compliance with the act [78]. The instructions are provided in Radiation Safety Guides (ST Guides), each of which contains safety requirements for a specified area of radiation practices [77, p. 299; 83; 85]. The role of STUK is discussed

more closely in the following subsection. Due to the implementation of the new BSS Directive, the Finnish legislation on radiation protection will be completely revised by February 2018. All the afore-mentioned pieces of Finnish legislation as well as the ST Guides will be affected by the law reform. [10]

3.2.2 Radiation and Nuclear Safety Authority in Finland

The authority responsible for supervising the use of radiation in Finland is STUK. In matters concerning the medical use of radiation, STUK acts under the MSAH. [78] The role of STUK in radiation protection is stipulated in the Finnish legislation. The responsibilities of STUK include controlling the use of radiation and radiation practices with respect to safety, conducting research and development activities, providing expert services, supplying information and producing publications as well issuing general instructions pertaining to radiation safety and participating in international co-operation within the field of radiation protection. In addition, STUK monitors radiation levels across Finland, sustains preparedness for abnormal situations involving radiation as well as maintains a measurement standard laboratory. [6]

As an organisation, STUK comprises three regulatory departments and one department concerned with monitoring environmental radiation and maintaining emergency preparedness as well as departments of administration and public affairs [81]. One of the regulatory departments is focused on the regulation of radiation practices, namely the Department of Radiation Practices Regulation (STO), whereas the other two are responsible for matters related to nuclear energy [81], which is out of the scope of this work. The regulatory operations of STO encompass granting safety licences, conducting regular inspections at facilities employing radiation, receiving and processing reports on abnormal events related to the use of radiation, publishing and updating ST Guides as well as issuing DRLs [11, pp. 3, 5, 9].

3.2.3 Safety Requirements for Cone-Beam Computed Tomography

As mentioned previously, STUK issues safety requirements in the form of ST Guides [85]. The requirements concerning CBCT examinations are laid down in ST 3.1: Dental X-ray examinations in health care [93]. For the study at hand, the most

relevant aspects of ST 3.1 are the following: the requirement of a safety licence as well the specific requirements imposed on the qualifications of the people responsible for CBCT examinations and of those performing the examinations.

The use of CBCT devices is subject to licence. The required licence is a safety licence (*In Finnish Turvallisuuslupa*) granted by STUK. A CBCT device can be put into operation only after a licence has been obtained. To acquire a licence, the place of use must submit an application to STUK with information on the radiation user and the place of use. The information regarding the place of use should encompass contact details as well as descriptions of the CBCT device or devices as well as the facilities and their structural radiation protection. [93] Furthermore, each place of use must assign a radiation safety officer that is in charge of ensuring the safety of the radiation practices of the facility in question [89]. The radiation safety officer must also be named in the application for the safety licence [93]. Based on the granted safety licences, STUK maintains a register of all CBCT and other medical X-ray devices in Finland.

In ST 3.1 STUK also sets specific requirements for the dentists and physicians responsible for CBCT examinations as well as for the personnel performing the examinations. Of the dentists and physicians in charge of the examinations, it is required that they are specialists in oral radiology or radiology. Moreover, dentists (licentiates of dentistry) and physicians (licentiates of medicine) without the foregoing specialities can serve as dentist- or physician-in-charge after completing a supplementary training course concerning CBCT examinations and passing a written examination based on the course contents. To be allowed to conduct CBCT examinations, one must either be a specialist in radiology or oral radiology, or a radiographer. Additionally, dentists, physicians as well medical and dental specialists with a speciality other than radiology or oral radiology who have the afore-mentioned supplementary training in CBCT can perform CBCT examinations. [93] Furthermore, dental hygienists and dental assistants become eligible to conduct CBCT examinations by taking a supplementary training course on CBCT aimed at the foregoing occupational groups and successfully completing a skills test associated with the course [80, 93]. As an additional requirement, the dentist- or physician-in-charge has to be available during an examination performed by a dental hygienist or dental assistant [93].

The requirement of supplementary training in CBCT concerning the dentists and physicians responsible for the examinations as well as the dental hygienists and

assistants conducting the examinations was introduced in 2011 in ST 3.1 of that time. A transition period of two years was given to enable the implementation of the requirement. The transition period ended 1st October 2013. [90]

3.3 Diagnostic Reference Levels

The first priority in medical examinations is to fulfil the medical purpose, for which the examination has been prescribed [44, p. 35]. Thus, restricting patient dose by means of strict dose constraints or limits is not appropriate and can even entail harmful consequences if obtaining the required diagnostic information is compromised [46, pp. 87, 126]. Having said that, the patient should not be exposed to any extra radiation that is not necessary for attaining the diagnostic information [111]. Hence, there are grounds for monitoring and managing the dose received by patients [43, p. 15].

To aid the management of patient dose, ICRP has created the concept of DRLs [44, p. 35]. ICRP took preliminary steps towards DRLs in its recommendations of 1990, in which considering the use of dose constraints or investigation levels for some common diagnostic procedures was suggested. Although the term ”constraint” was used, the recommendations allowed the constraints or levels to be exceeded if such doses were clinically justifiable. [42] The actual concept of DRLs was introduced by ICRP in Publication 73 in 1996 [43]. In 2002 ICRP published supporting guidance to elucidate the purpose and the possible uses of DRLs [44]. Additionally, ICRP Publication 105 provides a summary of the guidance on DRLs given by the earlier publications [45]. Moreover, DRLs are included in the ICRP 2007 recommendations [46]. Different aspects of DRLs are examined in the following subsections.

3.3.1 Concept and Uses

The ICRP outlines that the objective of DRLs is to protect patients from radiation that is of no benefit for fulfilling the medical purpose of the examination or procedure. The application areas of DRLs are diagnostic radiology and nuclear medicine. Rather than providing a rigid definition of the term DRL, the ICRP publications give a concept or a framework that allows for latitude in implementation. [44, pp. 34–35, 48]

DRLs are numerical values that represent a percentile point in a patient dose distribution based on national, regional or local data [44, pp. 36, 48, 51]. DRLs should be issued for common examination types [43, p. 24]. The idea of DRLs is to enable the detection of unusually high dose values. To achieve the foregoing, the facilities using radiation for medical purposes should monitor their patient doses and compare a set of dose values to the DRLs. If the mean value or other appropriate reference value derived from the set of dose values is consistently higher than the DRL for the examination type in question, the place of use should evaluate their equipment and the methods employed with respect to optimisation. If shortcomings are found, pertinent measures should be taken to rectify them. [43, p. 23] It is important to note that DRLs are not applied to individual patients and thus, the value being compared to the corresponding DRL is always based on dose values from a group of patients, as described above [44, p. 48].

According to ICRP, also unusually low dose values should be identified because they can indicate unsatisfactory image quality. Yet, the ICRP acknowledges that the foregoing is not straightforward since dose is not the only factor contributing to image quality. Therefore, the formation of DRLs that would detect too low doses for sufficient image quality can be challenging. However, it is still stated in the ICRP recommendations that if the observed doses consistently lie considerably below the DRLs, the assessment of image quality should be triggered. [43, p. 24]

In general, DRLs are intended to be used in an advisory manner and not for regulatory purposes, for example. The ICRP describes three types of uses, for which DRLs can be employed. At national, regional or local level, DRLs can be used to shape dose distributions by removing doses from the top and low ends of the distributions. In the case of medical examinations, for which the clinical purpose is exactly specified and the technique employed is defined at a general level, DRLs can contribute to narrowing the dose range that is regarded as representative of good practice. Finally, at the most specific level, DRLs can advance the achievement of an optimum dose range for an imaging protocol that has explicit specifications and is employed at a particular place of use. [44, pp. 36, 48–50]

3.3.2 Adoptions in Europe

The ICRP recommends the application of DRLs and provides a framework for them. However, the task of further specifying the concept of DRLs as well as implement-

ing the DRLs is delegated to regional, national and local authorised bodies. [44, pp. 33–35] At regional level in Europe, DRLs have been adopted in the MED directive. For diagnostic radiology, the afore-mentioned directive defines DRLs as "dose levels in medical radiodiagnostic practices [...] for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied" [111]. The afore-mentioned definition has been transferred with slightly different wording but with essentially the same content to the Finnish legislation in the decree of MSAH discussed previously [19].

To aid the establishment and implementation of DRLs in Europe, the EC provides advisory guidelines in its publication "Radiation Protection 109". According to the guidelines of EC, DRLs should be prepared by professional medical bodies and the DRL values should be based on patient dose data originating from hospitals, clinics and practices of different types. Each procedure type should receive its own DRL due to differences between procedures. The DRL value should exceed the mean or median of the dose distribution, based on which the DRL is set. A proposed approach is to derive the DRLs from the 75th percentile values of the dose distributions. The rationale behind the proposal for using the 75th percentile is that patient dose distributions are typically skewed with a 'tail' towards the higher doses. Thus, the idea with the use of the 75th percentile is to target the 'tail' of the distribution. The DRLs are recommended to be given as dose area product (DAP) or entrance surface dose (ESD) or in the case of CT, as weighted CT Dose Index ($CTDI_W$) and dose length product (DLP). [24, pp. 8, 11]

Regarding the appropriate use and interpretation of DRLs, the EC guidelines state that DRLs do not separate practices into good and bad or examinations into those conducted well and badly. Thus, exceeding the DRL does not necessarily imply that the examination was performed badly. Neither does the dose being lower than the DRL mean that good practice was applied, because the image quality may be insufficient. DRLs should be reviewed at such intervals that allow for stability but that are also frequent enough to react to changes in the dose distributions. The DRL values are expected to become lower over the course of revisions, since DRLs should be derived from dose distributions and the application of DRLs should remove the highest doses from the distributions. [24, pp. 6,8, 9–10]

According to the results of surveys conducted in the years 2007–2010 in conjunction with the EU project Dose Datamed 2 (DDM2), DRLs have been taken widely into use throughout Europe. Based on the data of DDM2, 72% of European countries have issued DRLs for adult X-ray examinations. When examining the countries of the EU and the European Free Trade Association (EFTA), i.e. Iceland, Norway, Switzerland, the corresponding percentage is 81%. However, DRLs for paediatric X-ray examinations are significantly less common, with paediatric DRLs being established in only 39% of European countries and in 45% of EU and EFTA countries. The majority of the DRLs are based, at least in part, on national dose surveys, whereas in some countries published values, recommendations or European DRLs have served as a base for the DRLs. The 75th percentile approach had been employed for the derivation of the DRL values by all of the respondents, who had used national dose data and who had reported their methods. [27, pp. 3, 7]

3.3.3 Diagnostic Reference Levels in Finland

The application of DRLs is a well established practice in Finland. The first Finnish DRLs came into effect in the year 2000 [86] and to date, STUK has issued DRLs for six different examination or procedure types [84]. The foregoing examination or procedure types comprise cardiac radiology [88], nuclear medicine examinations [95], CT examinations and conventional X-ray examinations of adults [91, 92] as well as paediatric CT examinations and conventional X-ray examinations [87, 96]. The list will be complemented by the DRLs for CBCT examinations of the head and neck region subsequent to the publication of this study.

The DRLs for adult CT and conventional X-ray examinations as well as those for nuclear medicine examinations have undergone rounds of revision after their initial establishment [91,92,95]. When comparing the DRLs for conventional X-ray and CT examinations from 2000 to the current ones, significant decreases in the DRL values are observed [86,91,92]. In the case of conventional X-ray examinations of adults, the current DRL values are 40–56 % lower than the ones issued in 2000 when examining values for comparable imaging projection types [86, 92]. The only exception to the foregoing is the DRL value for panoramic tomography of the teeth and jaws, which has stayed the same. Regarding adult CT examinations, the decrease in DRL values ranges from 24 to 55% when DRL values for the examinations of certain body parts expressed in DLP are considered. In addition to the body-part-specific values, the current DRLs for adult CT examinations include indication-based DRL values,

which were not in use when the first DRLs were issued and accordingly, cannot be compared. [86, 91]

As indicated by the discussion above, the Finnish DRL values for adult CT and conventional X-ray examinations have decreased substantially during the course of revisions. The current DRLs for the foregoing imaging modalities are based on dose distributions obtained through national dose surveys [11, p. 9; 53; 32]. The DRL values for CT examinations correspond to the 75th percentiles of the distributions consisting of single patient dose values for each examination type (a particular body part or indication) [53]. The 75th percentile was also used in forming the current DRLs for conventional X-ray examinations but the values were derived from distributions containing mean patient dose values for each X-ray device instead of doses of individual patients [32]. The DRLs from 2000 considered above were not directly deduced from Finnish patient dose data. Instead, the first DRLs for adult CT examinations were based on literature and DRLs from other countries and those for conventional X-ray examinations were established by comparing Finnish dose data with European and Nordic DRLs. [50,53] Thus, it is not known how the introduction and application of DRLs for X-ray examinations has affected dose distributions in Finland, or whether the observed fall in DRL values has been accompanied by an actual removal of high dose values from the distributions.

3.3.4 Cone-Beam Computed Tomography

The ICRP has recently, in 2015, published a publication dedicated to radiological protection in CBCT. The publication dictates that DRLs should be issued for CBCT examinations. However, it is also noted that, thus far, advances towards the realisation of DRLs for CBCT have been modest and hence, international DRLs for CBCT have not been established. [98, pp. 42, 100] To the knowledge of the author, national DRLs for CBCT have not yet been issued by any country either. Also the afore-mentioned ICRP publication states that present data available pertaining to DRLs for CBCT is scarce [98, p. 100].

At the time of writing, Finland is close to issuing DRLs for CBCT examinations of the head and neck region. The Finnish DRLs are currently being prepared by STUK based on the data and information obtained through this study. Some preliminary approaches to DRLs were also found in literature. The foregoing approaches include patient dose studies conducted in Japan [21] and Korea [33] as well as notably,

an achievable dose (AD) set by the British Health Protection Agency (HPA) [35]. The AD issued by HPA is of particular significance because it was adopted in the guidelines of the SEDENTEXCT consortium [102].

The HPA measured and collected patient dose data for 41 CBCT scanners in total in conjunction with a project conducted to issue recommendations for the facility design and the quality assurance of CBCT devices. The recommendations resulting from the project were published in 2010. As a part of the recommendations, an AD of 250 mGy·cm^2 was issued for the placement of a single-tooth implant (upper first molar implant) in adults. The AD was recommended to be employed as a base for dose optimisation. The AD was determined based on the above-mentioned dose data. However, the derivation of the AD differed from that of DRLs in that normalised dose values were used instead of the actual data. The actual data had been measured using different FOV sizes and had a dose range of over 2 000 mGy·cm^2. The original dose values were normalised to an area corresponding to a FOV of 4 cm x 4 cm, which was regarded as a FOV size commensurate with the indication, i.e. imaging for single-tooth implant treatments. To the attain the AD, the 75th percentile for the distribution consisting of the normalised values was determined. The AD corresponds to the 33rd percentile of the non-normalised data. Due to lack of data, an AD was not established for child examinations. However, the HPA recommendations stipulate that children should receive their own DRLs and that in the case of paediatric CBCT examinations, DRLs should be issued for the imaging of a single impacted tooth (maxillary canine) in 12-year-old males. [35, pp. 1, 9–12]

Similar to the ICRP publication on CBCT, also the guidelines of the SEDENTEXCT project state that DRLs should be applied to CBCT examinations. However, it is also noted that extensive studies are still needed for the establishment of those. As mentioned, the AD for the placement of a single-tooth implant proposed by the HPA is included in the SEDENTEXCT guidelines. The guidelines promote the application of the afore-mentioned AD until European or national DRLs for CBCT examinations are available. [102, pp. 93–94]

In the Japanese study, the DAP doses of 21 CBCT scanners housed in dental offices in Tokyo and nearby regions were investigated. The scanners were from five different manufacturers. For the DAP measurements, the imaging parameters and settings were set assuming the purpose of the examination was the imaging of an impacted mandibular third molar, i.e. a wisdom tooth, and the patient was assumed to be a

standard-sized adult. The obtained DAP values varied between 126.7 mGy·cm^2 and 1 476.9 mGy·cm^2. No suggestions for DRLs were given based on the study. Instead, it was concluded that the establishment of DRLs still required more studies and that future studies should examine different diagnostic questions and the appropriate choice of imaging parameters for each diagnostic question. [21]

In the Korean study, dose measurement data was gathered from 14 CBCT units used in university hospitals across Korea. For the measurements, the largest FOV size capturing both the mandible and the maxilla was chosen from each device. The resulting DAP doses ranged from 476 to 3 960 mGy·cm^2 with the mean being 1 972 mGy·cm^2. The dose corresponding to the 75th percentile of the obtained distribution was 3 203 mGy·cm^2, which was proposed as a DRL value for CBCT examinations by the authors. The authors stated that DRLs should be provided in such form that both the dose value and the FOV size are given. The suggested DRL value was acquired using the FOV size 16 cm x 18 cm. [33]

3.3.5 Dose Quantity

The HPA recommends that DRLs for CBCT are given as DAP [35, p. 9], or kerma area product (KAP) as the quantity is currently recommended to be referred to as [99]. Additionally, the AD for CBCT examinations issued by the HPA is given as DAP [35, p. 12]. Furthermore, the SEDENTEXCT guidelines state that dental CBCT devices should display dose as DAP [26, p. 103].

DAP/KAP is a dose quantity that describes the energy transferred from the X-ray beam to the patient [105]. The quantity was previously defined in terms of absorbed dose in air, which in turn, refers to absorbed energy per mass unit of air at a certain point. However, the absorbed dose in air cannot be measured experimentally. What is actually detected, is the air kerma and therefore, the quantity has been redefined in terms of air kerma. [99] Ionising radiation results in the formation of charged particles that receive kinetic energy. Air kerma is the kinetic energy received by the charged particles in conjunction with their formation divided by unit mass of air. [57, pp. 69–70; 99] That said, at beam energies employed in diagnostic radiology, the energy of the charged particles is absorbed near the place of their formation [34, p. 115]. Consequently, the absorbed dose in air and air kerma are very close to equal at those energies. Thus, in the context of diagnostic radiology, DAP and KAP can be considered being the same quantity. [109, p. 123]

In addition to air kerma, KAP takes into account the size of the X-ray beam. KAP is obtained by integrating air kerma over the cross-sectional area of the X-ray beam, as shown by Equation (3.1):

$$KAP = \int_A K_a(x, y)\, dx\, dy \ , \tag{3.1}$$

in which K_a is the air kerma at point (x, y) and A the cross-sectional area of the beam. [110] The unit of KAP is Gy·cm^2 [105].

4. MATERIALS AND METHODS

The study was conducted as a survey among parties conducting CBCT examinations of the head and neck region in Finland. The chapter describes how the survey was performed as well as how the obtained data was processed.

4.1 Collection of Data

The data for the study was collected employing a self-designed and formulated questionnaire, which was in the form of an Excel sheet. The target group of the survey was the facilities performing CBCT examinations of the head and neck region in Finland. The questionnaire was sent and responses were received by email. Detailed descriptions of the target group and the questionnaire are provided in the following subsections. Moreover, the schedule concerning the sending out and the response period of the survey as well as the response rate are discussed in the first subsection.

4.1.1 Target Group, Schedule and Response Rate

The study targeted Finnish facilities performing CBCT examinations of the head and neck region. The target group was further specified to only include the facilities conducting CBCT examinations with a CBCT scanner or scanners registered by STUK as the type "Other dental X-ray device with the qualifier CBCT" (*in Finnish Muu hammasröntgenlaite, tarkenne kartiokeilatietokonetomografia (KKTT)*). Thus, among others, so called extremity CBCT scanners also applied to imaging of areas other than the extremities (including Planmed Verity® and equivalent scanners) were excluded from the study.

For the survey, a listing of the safety licences containing dental CBCT devices in Finland was retrieved from the register maintained by STUK. At the time of retrieval, in April 2015, the aforementioned listing encompassed in total 73 places of

use and 78 CBCT devices. Regarding one of the devices on the listing, there was information available that the 3D imaging modality was not in use and therefore, the device and its safety licence holder were removed from the listing. The questionnaire was sent by email under the name of STUK to the radiation safety officers of the safety licences included in the above-mentioned listing. The questionnaire was accompanied by a cover letter with an explanation of the purpose of the study as well as with detailed instructions for the completion of the questionnaire. The questionnaire and the cover letter are discussed in more detail in the next subsection.

The survey was sent out on 6th May 2015 and the completed questionnaires were asked to be returned by 22nd May 2015. A reminder about the survey was sent on 22nd May 2015 to those who had not responded by then. Due to several requests for additional time and a considerable amount of responses being submitted after the end of the initial response period, eventually all completed questionnaires received by the end of June 2015 were included in the study.

Completed questionnaires were received from 41 places of use and for 43 CBCT devices out of the 72 and 77, respectively, found on the listing, based on which the questionnaires were sent. Thus, the response rate, in terms of listed places of use that returned a completed questionnaire or questionnaires, was 57% and that, in terms of completed questionnaires per listed devices, was 56%. Furthermore, regarding six of the listed devices, it was informed that the device was either only employed for imaging phantoms, the device had not been installed or that no or only a few images had been taken using the device and therefore, no survey forms had been completed for those devices.

Additionally, completed survey forms concerning five CBCT devices outside the listing were received. One of the devices was an extremity CBCT scanner and thus, the information regarding that device was excluded from the study. The remaining four devices were dental CBCT scanners and were accordingly included in the study. Despite being of the desired type for the study, the last-mentioned CBCT devices had not appeared on the listing retrieved for the survey because one of the scanners had been mistakenly registered as another type of device, whereas the rest were trial devices owned by the manufacturers and included in their safety licences. Thus, considering the foregoing, completed survey forms were acquired altogether from 43 places of use and for 47 CBCT scanners regarded as falling within the intended scope of the study.

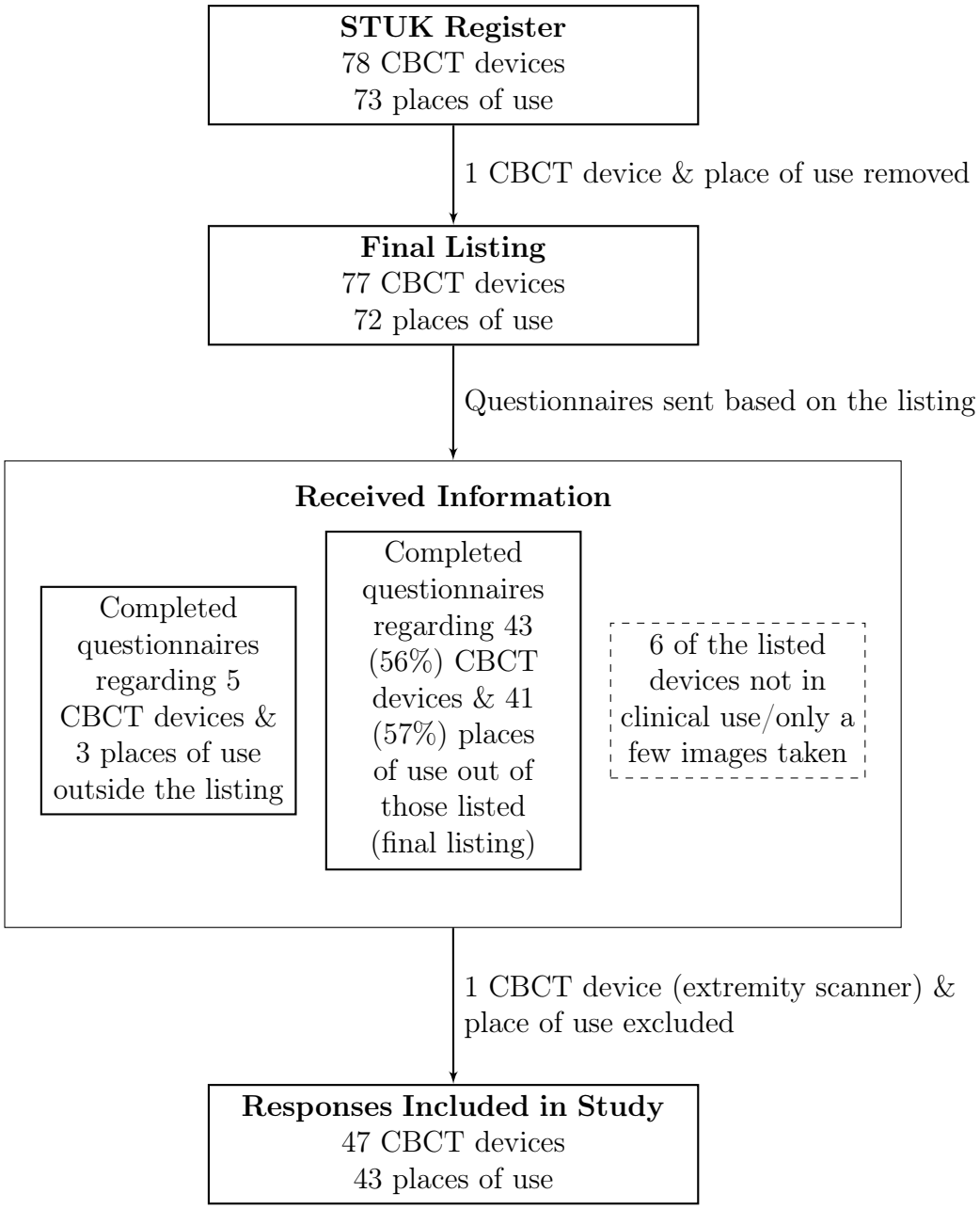


Figure 4.1 *The process of data collection from retrieving the listing of the CBCT devices and places of use of interest to determining the survey responses included in the study.*

The flowchart in Figure 4.1 summarises the above-discussed process of data collection from the retrieval of the listing of the CBCT devices and places of use to be studied, through categorisation of the received information, to the determination of the survey responses accepted for the study. Furthermore, the exact numbers of the CBCT devices and places of use at each stage are illuminated.

4.1.2 Questionnaire

The aim of the questionnaire was to obtain data for indication-based DRLs. Besides the actual dose data, examination frequencies per indication and the use of optimised imaging parameters were of interest. Furthermore, the qualifications of both the dentists or physicians responsible for the imaging examinations and the personnel performing the examinations were surveyed. The questionnaire was in the form of an Excel sheet and consisted of two sections elaborated below. The English translation of the questionnaire is presented in Appendix A. Questionnaire. The language of the original questionnaire was Finnish.

The questionnaire was sent with a cover letter containing information on the obligation to apply DRLs to medical X-ray examinations and on the aims of the survey. Moreover, instructions for the completion of each field of the questionnaire form and contact information for questions were included in the letter. The English translation of the letter is provided in Appendix B. Cover Letter.

The respondents were asked to complete a separate questionnaire form for each CBCT device. In the first section of the questionnaire, the following information regarding the respondents and their CBCT devices was requested: the safety licence number, the place of use, the manufacturer and model of the CBCT device, the filtration of the device and information on the qualifications mentioned above. The second and main section of the questionnaire comprised a table for the dose data.

The above-mentioned table contained a pre-filled list of indications for CBCT examinations of the head and neck region. The list is further discussed below. The respondents were requested to complete the table with respect to the indications, for which imaging was performed at their place of use. Concerning each indication, the table included fields where the reading of the dose display of the CBCT scanner and the error of the display were to be filled in. The dose reading was to be given as DAP. In addition, the table encompassed fields for the imaging parameters and settings that had been employed to obtain the given dose reading. The afore-mentioned imaging parameters and settings are specified later in the subsection. The information regarding the dose as well as the imaging parameters and settings was asked to be filled in assuming the patient was an average-sized male with the exception of the indications marked with the text ”children” in parentheses. Regarding the last-mentioned indications, the afore-mentioned information was to be given for a patient typical of the indication in question. Also the age of the typical patient

was asked to be provided. Moreover, the respondents were requested to report the estimated number of examinations per month for each indication.

The formation of the list of indications was a two-phase process. A preliminary list of indications was formed through searching the literature and the websites of Finnish dental clinics performing CBCT examinations. The preliminary list serving as a basis, the final list was compiled by two experts: a specialist in oral radiology and a specialist in dentomaxillofacial radiology. The final list encompassed 26 indications in total. The indications are listed in Table 4.1. In the questionnaire form, the indications were classified into five groups: 1) dentition and jaw area, 2) paranasal sinuses, 3) cervical spine area, 4) temporal bone and 5) others. In the Excel table, the classification was indicated by colour coding.

Information on the imaging parameters and settings employed was collected to enhance the assessment and analysis of the dose data. The imaging parameters requested in the questionnaire were the following: the tube voltage, tube current, the voxel size or resolution setting, FOV size and the scanning or exposure time. The FOV size was asked to be given in the form FOV diameter times FOV height. The imaging settings to be provided included the patient size setting and the name of the employed imaging programme of the device. Furthermore, regarding the imaging parameters and settings, it was enquired, whether those used were optimised or factory default settings.

4.2 Data Analysis

The data received in the form of the questionnaire responses was manually transferred and compiled into an Excel file in an indication-specific manner. The compiled file comprised the places of use, where imaging was performed for each indication and the dose readings reported by the afore-mentioned facilities. Furthermore, regarding each dose reading, the following data was included in the file: error of the dose display, the diameter and height of the FOV used, the manufacturer and model of the CBCT device as well as information on whether optimisation was conducted. In cases of the returned questionnaires being incomplete or containing equivocal information, the respondents were contacted by email or telephone to request the missing data or to ask clarifying questions. However, not everyone responded, and consequently, some data was excluded from the data compilation. Cases leading to the exclusion of data are discussed in the first subsection below.

The compiled data was read into the technical computing software MATLAB R2015b for analysis. First, the reported dose readings were corrected for display error in a manner described in Subsection 4.2.2. To form the proposals for the DRLs, the data on each indication was to ideally contain one dose value per CBCT device. However, within some indications, some places of use had given more than one dose reading or a dose range due to imaging being conducted with several protocols, including different FOV sizes and resolutions. In most such cases, a selection was made between the given alternatives. The selections and the rationales behind them are explained in Subsection 4.2.3. The dose values corresponding to the non-selected alternatives were excluded from the further data analyses. The latter comprised examining dose as a function of the manufacturers of the CBCT devices as well as studying the effect of optimisation on dose. The afore-mentioned analyses are described in Subsection 4.2.5. Furthermore, the indication-specific estimations of the number of examinations, i.e. the examination frequencies, as well as the qualifications of the people in charge and the personnel conducting the examinations were collected from the completed questionnaires and analysed separately. Subsections 4.2.6 and 4.2.7 present how the afore-mentioned information was registered.

4.2.1 Discarded Data

As mentioned previously, unclarity in the received information was one of the causes resulting in exclusion of data from the results. This was the case with some of the dose readings reported for the indication ”Presurgical imaging of implant treatments”, which consisted of two subindications: ”imaging of areas with a single missing tooth” and ”imaging of the maxilla or mandible”. The subindications were intended to be treated separately when completing the questionnaire form. However, for the afore-mentioned indication, several respondents only gave one dose value with its concomitant information on the imaging settings and parameters without indicating, which of the subindications was in question. In those cases, the respondents were asked to specify their answers. However, not everyone responded, which lead to exclusion of the dose values, for which there was no information regarding the subindication. On account of the foregoing, one dose interval and two dose values were discarded.

Another reason for discarding data was that some of the reported dose data was considered unreliable. The foregoing applied to dose values for two CBCT scanners that lacked a DAP display. Because the eventual proposals for DRLs were to be

given as DAP, also the calculations forming the basis for the proposals were to be conducted using DAP values. Despite the lack of a DAP display, the dose values for both of the afore-mentioned devices were reported as DAP. However, in one of the cases, the reported DAP values were approximations derived from another dose quantity using a method failing to conform with the definition of DAP. In the other case, there was no information on how the DAP values were determined and additionally, the values differed significantly from those previously measured by STUK. Therefore, all the dose data for the afore-mentioned two CBCT units was excluded from the study.

4.2.2 Dose Calculations

In the questionnaire, the respondents were asked to report the radiation dose as indicated by the dose display of the CBCT scanner. Due to error present in dose displays, the dose readings from the scanners do not fully represent the true dose. Hence, to better approximate the true dose, the reported dose readings were corrected utilising information on the error of the dose displays. The corrected doses were calculated using Equation (4.1):

$$dose_c = \frac{dose_d}{error_d + 1} \ , \tag{4.1}$$

in which $dose_c$ is the corrected dose, $dose_d$ the dose reading of the scanner display and $error_d$ the error of the dose display. The variable $error_d$ is a signed value: a positive sign implying that the dose reading of the display is higher than true or measured dose and a negative sign implying the opposite. Information on the error of the display was acquired from the completed survey forms as well as from logbooks of measurements conducted by STUK. Sources for the error data reported by the respondents included data from measurements performed by maintenance companies, device suppliers and STUK.

For the data on the error of the display to be applicable, it was required that the error had been measured using the same tube voltage and FOV size as was used when the dose given in the survey response was determined. If error data measured by STUK was available and it differed from the error values provided by the respondents, the data of STUK took precedence. Moreover, the error values determined with a resolution matching the one used by the respondents to obtain the reported dose,

were preferred. However, the foregoing was not a requirement. Thus, if no error data for the desired resolution was available or the data was unreliable, an error value measured with a non-matching resolution was employed, provided that the tube voltage and FOV size conformed with those required. If no information on the error of the display was available or the error data failed to fulfil the afore-mentioned requirements for the tube voltage and FOV size, the error was recorded as 0%, i.e. the corrected dose was equal to the dose reading of the display.

4.2.3 Selection between Dose, Field of View Size and Resolution Alternatives

As discussed previously, in cases where more than one dose value was provided for a CBCT device within an indication, selections between the alternatives were made. The alternative dose values mainly resulted from the employment of different FOV sizes and resolution settings within indications. The selections were made in two steps. First, from among the FOV sizes given for a CBCT device within an indication, the one closest to those most commonly used within that indication was chosen. The dose values corresponding to the selected FOV sizes were retained in the file containing the compiled data, whereas those corresponding to the other FOV sizes were removed from the compilation. Thereafter, all the other selections were made. The principles according to which the most common FOV sizes were determined as well as those underlying the other selections are described below.

The data collected regarding the FOV size comprised two variables: the FOV diameter and height. However, the exact combinations of the FOV diameter and height in the FOV size options of CBCT scanners vary considerably between manufacturers and even between different models of the same manufacturer. Hence, the FOV data in the form it was collected was not directly applicable to determining the FOV sizes most commonly used. The problem was addressed by calculating the volumes of the reported FOVs. Thereby, a single-value representation for the FOV size was obtained, providing a means of comparison.

Based on manuals of the CBCT devices and other material acquired from the manufacturers, the vast majority of the FOVs in the compiled data had the shape of a cylinder. The remainder of the FOVs were spherical and originated from a single device. Accordingly, the volumes of the FOVs, with the exception of the spherical FOVs, were calculated using the volume formula for a cylinder. The spherical FOVs

were not perfect spheres, but to obtain an approximation of their volumes, the volume formula for a sphere was utilised. Additionally, prior to the calculations, all the FOV sizes reported by the respondents were reviewed for errors and corrected using manufacturer-provided information on the FOV sizes available on each device. The erroneous FOV sizes mainly resulted from the sizes being reported in the form "height times diameter" instead of the requested "diameter times height".

To find the most common FOV sizes within each indication, indication-specific histograms of the FOV volumes were produced in MATLAB. In cases where the aforementioned histograms did not provide a clear distinction between the alternatives being considered, also other size parameters were examined. More specifically, the FOV diameters and heights were analysed as separate values, and also the numbers of their exact combinations were studied.

The other selections included choosing between resolution alternatives. Due to wide diversity in the resolution options and in their implementation between manufacturers and models [71], the resolution settings *per se* were considered incomparable. Therefore, instead of the reported resolution settings, the dose values corresponding to those were examined. Additionally, in one response alternative dose values were given due to the use of different tube currents. To conduct the selections, indication-specific dose distributions were plotted in MATLAB. The alternative dose values were included in the distributions.

The selections based on the above-mentioned dose distributions were made according to the following principles:

- Alternatives located at the edges of the dose distribution and clearly differing from the dose values in the middle parts of the distribution were excluded from the results.
- If the foregoing applied to none of the alternatives being considered, all of the alternatives were included in the results.

In all cases there were two dose alternatives. The latter principle on the list above applied to all except for one case. There were no instances where both of the dose alternatives would have been situated at the edges of the distribution.

Furthermore, some respondents had given a dose range covering alternative imaging

protocols with different imaging parameters and settings as well as their combinations. The dose ranges were addressed by taking the endpoints of the intervals and handling them as separate values. The endpoints were then mirrored against the afore-mentioned dose distributions. The endpoint of each range with a value closer to the dose values forming the middle region of the distribution was included in the results.

4.2.4 Proposals for Diagnostic Reference Levels

Proposals for the indication-based DRLs in CBCT examinations were formed based on the obtained dose data that was corrected for display error, as described in Subsection 4.2.2. In forming the proposals, the following aspects were considered: the number of data points and the imaging frequency of each indication, the form of the indication-specific dose distributions as well as the convention of applying percentiles of dose distributions to the establishment of DRLs [27, 59]. Additionally, desired characteristics of the eventual DRLs included that all the DRLs were to correspond to the same percentile.

First, the data for each indication was assessed with respect to the number of data points. Thereafter, the dose distributions of the indications with a sufficient amount of data points were visualised in MATLAB. Lines indicating three different percentiles of each dose distribution, the 75th, 80th and 85th percentile, were also incorporated into the afore-mentioned plots. The values corresponding to the percentiles were determined by applying the function `prctile` in MATLAB to the indication-specific dose data. The algorithm behind the function is explained below.

The function `prctile` sorts the given input data values in ascending order and assigns the following percentiles:

$$100\frac{0.5}{n}th, 100\frac{1.5}{n}th, ..., 100\frac{n-0.5}{n}th, \tag{4.2}$$

in which n is the number of the input data values. The sorted input data values are the percentile values corresponding to the percentiles presented in (4.2). To determine percentiles lying between those given in (4.2), the function employs linear interpolation according to Equation (4.3):

$$y = f(x) = y_1 + \frac{x - x_1}{x_2 - x_1}(y_2 - y_1) \ , \tag{4.3}$$

in which (x_1, y_1) and (x_2, y_2) refer to data points, for which $y_1 = f(x_1)$, $y_2 = f(x_2)$, and x is a value located between x_1 and x_2. The values corresponding to the percentiles falling outside the range of those presented in (4.2) equal the minimum and maximum values of the input data. [58]

The graphs of the dose distributions with the above-described percentiles were evaluated by visual inspection. Based on the visual inspection and considering the above-discussed aim of using the same percentile for all indications, the 75th percentile was deemed the most applicable to the DRL proposals being prepared. To form the final proposals for the DRLs, the values corresponding to the 75th percentiles were rounded up to the nearest ten. Finally, it was assured that the imaging frequencies of each of the selected indications were sufficient for the establishment of DRLs to be reasonable.

4.2.5 Further Analyses on Dose

Further analyses on the dose data encompassed examining the effect of optimisation and the manufacturer of the CBCT device on the dose produced. It was also studied, whether differences existed between different models of the same manufacturer with respect to dose.

Regarding optimisation, a dichotomous response option (O/F) was given in the questionnaire: O implying optimisation of the imaging settings and F referring to the use of factory default settings. Based on the answers, the letter indicating the chosen optimisation option was added for each dose value in the data compilation file. Due to responses where information on optimisation was absent or the answers differed from the pre-defined response options, a third category, namely "U = undefined", was adopted for analysis purposes. In the case of one CBCT device included in the study, the question on optimisation was considered irrelevant since the device employed automatic exposure control. Accordingly, the optimisation information concerning the foregoing device was entered as U in the data compilation. The same three categories are used in presenting the results regarding optimisation in Section 5.3.1 Effect of Optimisation on Dose.

The effect of the manufacturer and model on dose was inspected in a manner akin to that used for optimisation. The information on the manufacturers and models of the CBCT scanners used by the respondents was collected from the completed questionnaire forms. The afore-mentioned information was then registered alongside each dose value in the file comprising the compiled data.

4.2.6 Examination Frequency

The examination frequencies were requested to be reported as the estimated number of examinations per month for each indication. The frequencies were also registered and compiled for analysis in the same form. In cases where the respondents had given the frequencies in another form than that requested, the frequencies were converted to the desired form. Deviations from the requested form and the principles according to which the conversions were made are listed below.

- Examination frequencies given in the form ”less than x”, where x is an integer, were set to x.
- Frequencies reported in the form ”approximately x”, where x is an integer, were registered as x.
- When a range was provided, the mean value of the endpoints of the range was taken.
- When a frequency was reported as the number of examinations per year or per two years, the reported frequency was divided by 12 or 24, respectively.

Additionally, there were three respondents whose answers concerning the examination frequencies were such that the above-listed principles were not applicable and the answers were thus assessed individually. One of the afore-mentioned respondents reported some of the examination frequencies qualitatively using the word ”sometimes”. The foregoing frequencies were registered as 0 in the data compilation. Yet, the place of use in question was taken into account when examining the places of use where imaging was performed for each indication, which is discussed at the end of the subsection.

One of the individually assessed survey responses was completely devoid of examination frequencies but they were obtained on request. However, the acquired frequencies were not given indication-specifically but for three categories: ear, sinuses and dentition. In the survey response, the respondent had completed information regarding one ear- and one sinus-related indication as well as regarding two indications pertaining to the dentition. The frequencies provided for the categories ear and sinuses were directly assigned to the ear- and sinus-related indications, respectively. Since no information was available on how the examination frequencies were distributed between the two dentition-related indications, the frequency given for the category dentition was divided half and half between the indications.

In the third case, the respondent had given a total examination frequency (6 examinations per month) covering four indications. Accompanying the frequency was information that for one of the indications, imaging was performed less frequently than for the other three indications. Due to lack of better information, the following arbitrary frequencies were allocated to the indications: 0.75 examinations per month to the less frequent indication and 1.75 examinations per month to each of the remaining three indications (adding up to the reported total frequency of 6 examinations per month).

If indication-specific examination frequencies were provided in the responses, they were included in the results even if other information concerning the indication, i.e. the imaging parameters and settings, and dose, was missing or incomplete. In cases, where dose values had been discarded, the examination frequencies were accepted for the results nevertheless.

The combined number of examinations per month was calculated for each indication separately. However, individual examination frequencies were not determined for the subindications constituting the indication ”Presurgical imaging of implant treatments” because all respondents did not itemise the frequencies between the subindications within that indication. Examination frequencies reported as decimals and non-integer frequencies resulting from the above-described conversions were included in the calculations without rounding. The computed sums were then rounded to nearest integers to obtain the indication-specific total numbers of examinations presented later in the results.

In addition to the examination frequencies, the number of the places of use where imaging was performed, was registered for each indication. There were two survey

responses where the examination frequency of an indication/indications was marked as 0 or was missing although dose and the other requested information had been completed concerning those indications. Regarding the foregoing responses, it was assumed that imaging was performed for the indications in question but the frequency was less than one examination per month or that no examinations had been conducted thus far but the place of use was planning or at least had the preparedness to do so. Hence, in the afore-mentioned cases, the places of use were included in the number of facilities performing examinations for that indication/indications. Moreover, as noted previously, in the case of one respondent, qualitatively reported examination frequencies were registered as 0 but the place of use in question was included when determining the number of the places of use.

4.2.7 Qualifications

The respondents were requested to report the qualifications of the people in charge of the imaging examinations as well as those of the personnel performing the examinations. The information regarding the qualifications was analysed by examining the occupational groups mentioned in the survey responses. From the reported occupational groups, categories were formed based on the assumed radiological knowledge of each occupational group. The aim was that within each category, the level of radiological knowledge between the members would be approximately the same. Some categories were composed by combining occupational groups, whereas some categories comprised a single occupational group.

The categories regarding the people responsible for the examinations are listed below:

- specialists in radiology or oral radiology (*In Finnish radiologit/radiologian erikoishammaslääkärit*)
- dentists (licentiates of dentistry), physicians (licentiates of medicine), medical and dental specialists with a speciality other than radiology or oral radiology.

The corresponding categories for the personnel performing the examinations were the following:

- specialists in radiology or oral radiology (*In Finnish radiologit/radiologian erikoishammaslääkärit*)
- dentists (licentiates of dentistry), physicians (licentiates of medicine), medical and dental specialists with a speciality other than radiology or oral radiology
- radiographers (*In Finnish röntgenhoitajat*)
- dental hygienists (*In Finnish suuhygienistit*)
- dental assistants (*In Finnish hammashoitajat*).

It was assessed how the different categories were represented among the people in charge as well as among those conducting the examinations. The assessments were performed by determining the prevalences of the categories. In determining the prevalences, each category was included only once per place of use, regardless of the number of people belonging to that category.

Table 4.1 *Pre-filled list of indications used in the questionnaire.*

Dentition, jaw area, airways and cephalometry	
	Presurgical imaging of implant treatments a) imaging of areas with a single missing tooth b) imaging of the maxilla or mandible
	Assessment of the relationship between a wisdom tooth and the mandibular canal
	Jaw cysts and tumours
	Tooth fractures
	Alveolar fractures
	Jaw or condylar fractures
	Dysfunction of the masticatory system (TMJ area)
	Orthognathic surgery
	Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)
	Cleft palate (children)
	3-dimensional cephalometry
	3-dimensional cephalometry (children)
	Airway assessment
	Obscure pain conditions
	Assessment of the periapical region and the root canal morphology of the tooth
	Periodontal diseases
Paranasal sinuses	
	Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus
	Trauma of the paranasal sinuses (including orbital floor)
Cervical spine area	
	Fractures of the cervical spine
	Spondyloarthropathy of the cervical spine
Temporal bone	
	Anomalies and changes of the outer auditory canal as well as of the inner and middle ear
	Otomastoiditis
	Assessment of inner or middle ear implant positioning
Others	
	3D modelling
	Computer-aided surgical planning
	Manufacturing of customised implants

5. RESULTS AND ANALYSIS

The chapter presents the results of the study. Analysis of the results as well as discussion on the importance of the findings are also included in the chapter. The chapter is divided into four main parts. The first part presents the results pertaining to the indications for CBCT examinations and the examination frequencies. Thereafter, the findings on patient radiation dose are explored and the DRL proposals for CBCT examinations of the head and neck region are presented. In the third part, the effects of manufacturer and model as well as that of optimisation on dose are discussed. Lastly, the results regarding the qualifications of the people responsible for CBCT examinations as well as the qualifications of those performing the imaging are examined.

5.1 Indications and Examination Frequency

The respondents of the dose survey were asked to estimate the number of examinations performed at their place of use. The examination frequencies were requested to be given as the number of examinations per month and for each indication separately. The sums of the reported monthly examination frequencies are shown in Table 5.1. The table presents the frequencies in an indication-specific manner. All the indications found on the pre-defined list of the questionnaire are included. The indications are ordered according to their examination frequencies, with the most popular indication at the top. The number of places of use, at which imaging is conducted for each indication is also provided in the table. Furthermore, the examination frequencies are visualised by a bar chart in Figure 5.1. The indications with monthly examination frequencies of 47 or more, i.e. the nine most popular indications, are presented in individual bars, whereas the bar entitled ”Others” represents all of the remaining 17 indications.

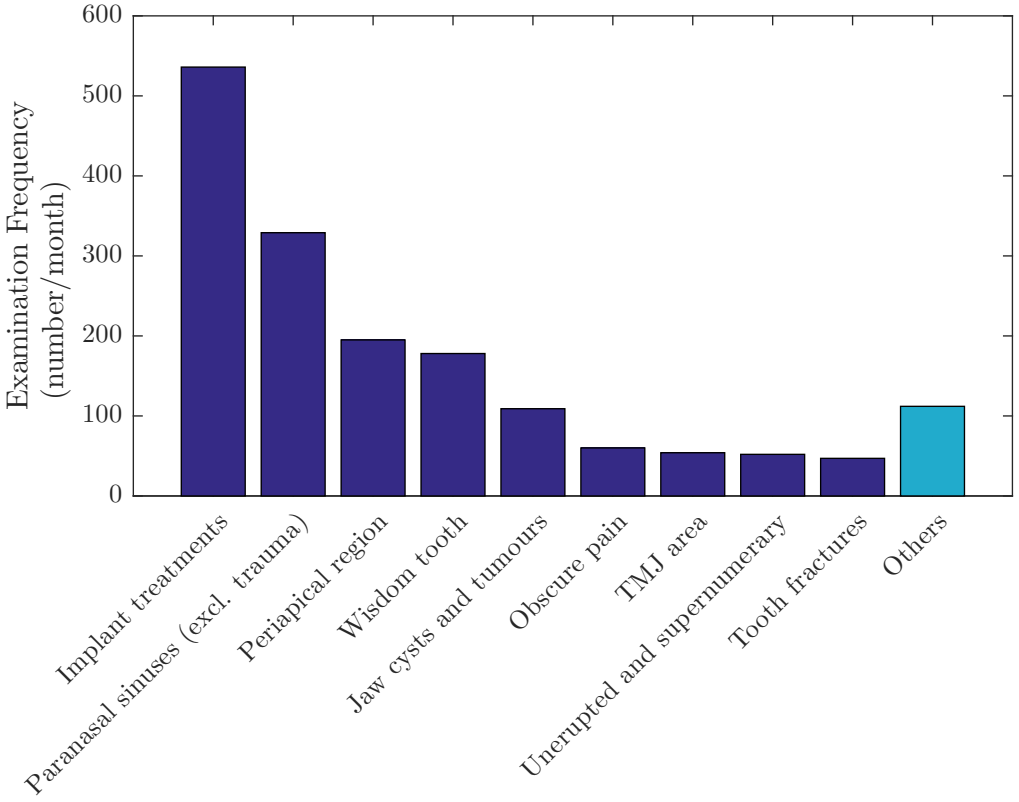


Figure 5.1 *Examination frequencies. The names of the indications are presented in abbreviated form. The correspondence between the abbreviated forms and the full titles of the indications is the following: Implant treatments = presurgical imaging of implant treatments, a) and b) together; Paranasal sinuses (excl. trauma) = inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus; Periapical region = assessment of the periapical region and the root canal morphology of the tooth; Wisdom tooth = assessment of the relationship between a wisdom tooth and the mandibular canal; Obscure pain = obscure pain conditions; TMJ area = dysfunction of the masticatory system (TMJ area); Unerupted and supernumerary = localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children). The bar entitled "Others" represents the other indications of the pre-defined list used in the dose survey.*

5.1.1 Indications

Table 5.1 shows that out of the 26 indications on the pre-defined list of the survey, there are only two indications, for which none of the respondent facilities reported having performed examinations. However, the examinations are by no means spread evenly across the indications. In terms of the number of examinations conducted, only nine of the 26 indications account for 93% of all of the reported CBCT exami-

nations of the head and neck region. There are also considerable differences between the foregoing top nine indications, with four indications dominating over the others.

The nine most important indications in terms of examination frequency were, starting from the most frequent, the following: 1) presurgical imaging of implant treatments, 2) inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus, 3) assessment of the periapical region and the root canal morphology of the tooth, 4) assessment of the relationship between a wisdom tooth and the mandibular canal, 5) jaw cysts and tumours, 6) obscure pain conditions, 7) dysfunction of the masticatory system (TMJ area), 8) localisation of unerupted and supernumerary teeth (excluding wisdom teeth) and 9) tooth fractures. Among the foregoing, the first four indications were dominant in that their examination frequencies ranged from close to 200 to several hundreds per month, whereas those of the remaining five were for the most part well below 100 per month.

The list of the most common indications can be interpreted so that the most significant application areas of head and neck CBCT in Finland are presurgical imaging of the dentition (for implant treatments and for wisdom tooth extraction), imaging of non-traumatic conditions of the paranasal sinuses and the nasal meatus as well as the assessment of the tooth root canal and the areas surrounding the apex of the root (the periapical region). It is also noteworthy that the indication ”localisation of unerupted and supernumerary teeth” is among the most common indications because it only pertains to children and thus, its prevalence shows that children also constitute an important patient group for CBCT examinations in Finland.

Examinations were conducted for almost all indications on the pre-defined list of the survey. Moreover, no complaints regarding missing indications were received from the respondents of the study. The foregoing aspects suggest that the pre-defined list succeeded in comprehensively covering the application field of head and neck CBCT in Finland.

5.1.2 Examination Frequencies

The total number of CBCT examinations per month was found to be approximately 1 670, which translates into roughly 20 000 examinations per annum. Because over 40% of the facilities conducting CBCT examinations did not respond to the dose survey and the variation between the facilities in terms of indications and

numbers of examinations performed was found to be considerable, it is impossible to extrapolate any estimates of the total nationwide number of examinations from the values obtained through this study. However, it can be said that the order of magnitude of the nationwide number of CBCT examinations appears to be tens of thousands examinations per year.

STUK surveys periodically the annual numbers of radiological examinations and procedures in Finland [48, p. 3]. The latest of the afore-mentioned surveys pertains to the examinations and procedures performed in 2015, i.e. the same year the data for this study was collected. Also CBCT examinations are included in the foregoing survey. The survey is still ongoing and thus, the data for the study is not published but preliminary data is available. At the time of writing, the response rate is approximately 80% in terms of places of use with a licensed CBCT device or devices. In the current preliminary data, the annual total number of dental CBCT examinations as well as those of other parts of the head is 9 556. The foregoing equals approximately 800 examinations per month.

The survey of STUK employs a different categorisation of the indications than this study and therefore, indication-specific comparison of examination frequencies cannot be made. However, one of the categories in the study of STUK, namely the imaging of sinuses, is similar enough to enable comparison. The current preliminary total number of examinations for the imaging of the sinuses in adult patients is 1 067 per year, i.e. roughly 90 examinations per month. Thus, according to the preliminary data, the portion of sinus examinations is 11% of all CBCT examinations. [82] In the study at hand, combined number of examinations for the indications ”inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus” and ”trauma of the paranasal sinuses (including orbital floor)” account for 20% of all CBCT examinations.

As seen in the numbers presented above, the total number of CBCT examinations in the study of STUK is approximately half of that reported by the respondents of this study. Considering that the current response rate of the survey of STUK is approximately 80%, whereas that of this study was less than 60%, the actual difference between the results of the two studies is even more substantial than the presented numbers of examinations suggest. For the imaging of sinuses, the difference in examination frequency is even larger, with the frequency found by this study being nearly 4-fold compared to the frequency obtained through the study of STUK. Also

the relative amount of sinus examinations was approximately 9 percentage points higher in this study than in that of STUK.

No clear reason can be identified for the substantial differences in the results of the two surveys. Because the numbers of examinations acquired through this study are based on estimations, overestimation is a possible explanatory factor. Furthermore, monthly examination frequencies may vary significantly between months during the year, which might not have been taken into account by the respondents of this study. Thus, the reported monthly examination frequencies may not correspond to frequencies that would be obtained by averaging annual frequencies by month but rather represent frequencies of a particular month or months. Additionally, some respondents might have accidentally provided annual examination frequencies instead of monthly frequencies in the survey forms of this study. Based on the completed questionnaires for this study, the places of use employing CBCT exhibit large diversity in the numbers of examinations and imaging indications, which can contribute to the observed difference in the relative frequencies of sinus examinations.

Table 5.1 *Indication-specific examination frequencies and the number of places of use, at which imaging is performed for each indication. The total number of CBCT examinations per month is given at the bottom of the table.*

Indication	**Examination Frequency**	**Places of Use**
Presurgical imaging of implant treatments	536	38
Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus	329	21
Assessment of the periapical region and the root canal morphology of the tooth	195	30
Assessment of the relationship between a wisdom tooth and the mandibular canal	178	38
Jaw cysts and tumours	109	28
Obscure pain conditions	60	22
Dysfunction of the masticatory system (TMJ area)	54	12
Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)	52	18
Tooth fractures	47	20
Jaw or condylar fractures	20	9
Cleft palate (children)	19	2
Alveolar fractures	18	12
Trauma of the paranasal sinuses (including orbital floor)	10	5
Anomalies and changes of the outer auditory canal as well as of the inner and middle ear	9	5
Computer-aided surgical planning	8	5
Spondyloarthropathy of the cervical spine	6	3
3D modelling	5	4
Assessment of inner or middle ear implant positioning	5	1
Manufacturing of customised implants	4	2
Periodontal diseases	3	3
Orthognathic surgery	2	2
Fractures of the cervical spine	2	1
Otomastoiditis	2	2
Airway assessment	1	1
3-dimensional cephalometry	0	0
3-dimensional cephalometry (children)	0	0
Total	**1674**	

5.2 Patient Radiation Dose and Proposals for Diagnostic Reference Levels

The section explores the results regarding the patient dose collation and presents the DRLs proposals formed based on the collected data. The amount of the collected data was sufficient for analysis in the case of seven indications, one of which consists of two subindications. The indication comprising two subindications is the ”Presurgical imaging of implant treatments” with the subindications ”imaging of areas with a single missing tooth” and ”imaging of the maxilla or mandible”.

5.2.1 Patient Radiation Dose

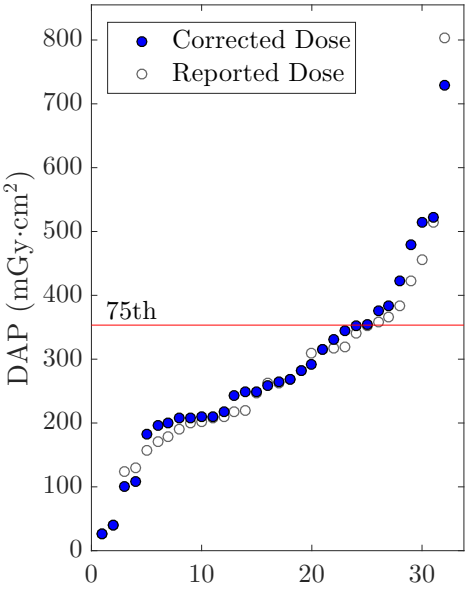
The patient dose data for the afore-mentioned seven indications is illustrated in Figures 5.2 and 5.3. In the graphs of Figures 5.2 and 5.3, each blue circle represents a single dose value corrected for display error in the manner described in Subsection 4.2.2. The empty circles in the graphs correspond to the reported dose values, i.e. non-corrected dose values provided by the respondents of the survey. Both the corrected and non-corrected dose values are arranged in ascending order. In each graph, a red horizontal line denotes the level of the 75th percentile of the corrected data. The level of the 75th percentile is shown in the figures because the DRL proposals provided in the study are derived from the foregoing percentile, as discussed in the next subsection. Furthermore, descriptive statistics of the afore-mentioned seven indications are given in Table 5.2. The values in Table 5.2 were computed based on the error-corrected data.

Figures 5.2 and 5.3 show that the dose range is very wide for all of the explored indications with maximum-to-minimum dose ratios ranging from 7 to an extreme of 50. Of the foregoing maximum-to-minimum dose ratios, the lowest pertained to the indication ”Assessment of the periapical region and the root canal morphology of the tooth” and the highest to the indication ”Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus”. In the case of all but one (”Localisation of unerupted and supernumerary teeth (excluding wisdom teeth)”) of the indications and subindications, the mean was higher than the median. The foregoing implies that the dose distributions contain a few values that are very high in relation to the rest of the values, which is also seen in the graphs of Figures 5.2 and 5.3.

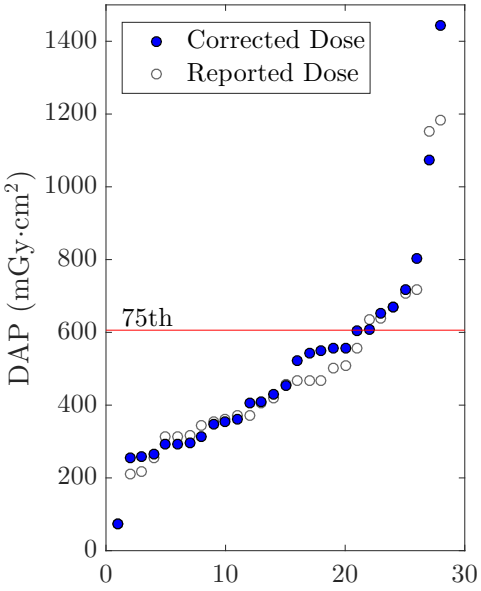
As described in Chapter 4 Materials and Methods, as a rule, the dose data included in the study for each indication consists of one dose value per CBCT scanner (with few exceptions due to accepting multiple values corresponding to different resolutions). Furthermore, the majority of the respondent facilities possess only one CBCT unit. Hence, the dose range observed in Figures 5.2 and 5.3 can also be seen as the dose variation between the places of use. Thus, the results show that the indication-specfic dose the patient is exposed to can vary significantly depending on, where the examination is performed. Such dose variation between facilities is not acceptable and shows that there is an effective need for DRLs.

To evaluate the significance of the display error correction, the values corresponding to the 75th percentiles of the corrected and non-corrected data were compared. It was calculated, how much higher or lower the percentile values derived from the non-corrected data were compared to those derived from the corrected data. At its maximum, the difference was approximately 7% and it was in the direction of the percentile value calculated from the non-corrected data being higher than that of the corrected data. Also differences in the opposite direction were observed.

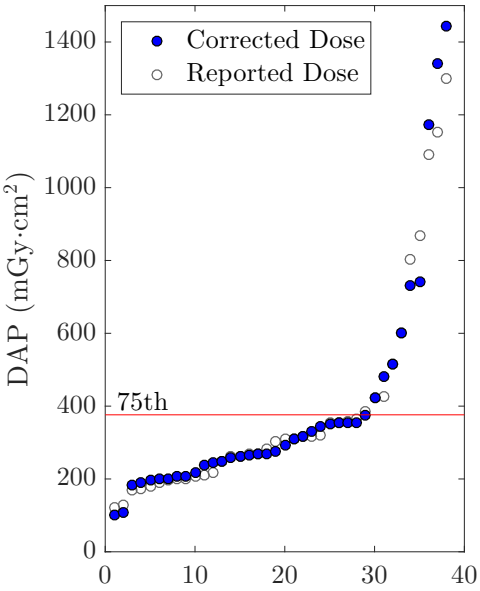
The order of magnitude of the above-described differences is such that the error is of very small practical significance when considering the establishment of DRLs since other error sources and factors are likely to have an considerably larger effect on the eventual values for DRLs. The foregoing error sources and other factors include errors in the dose readings provided by the respondents as well as the influence of the selections that were made in cases, where the place of use had reported multiple dose values within an indication. Moreover, most importantly, the determination of the values for DRLs is not an exact science since the choice of the percentile is mostly based on convention instead of the actual characteristics of the data and the eventual DRLs are often obtained by rounding the exact values corresponding to the chosen percentile.



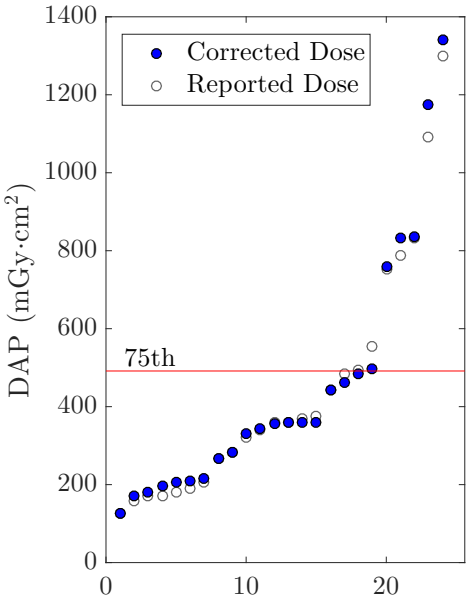
(a) Presurgical imaging of implant treatments: imaging of areas with a single missing tooth



(b) Presurgical imaging of implant treatments: imaging of the maxilla or mandible

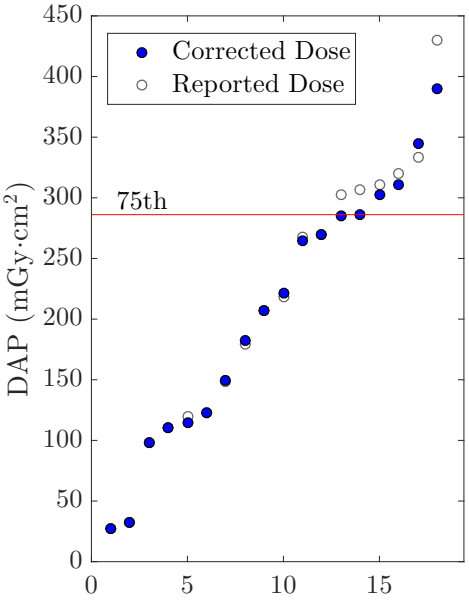


(c) Assessment of the relationship between a wisdom tooth and the mandibular canal

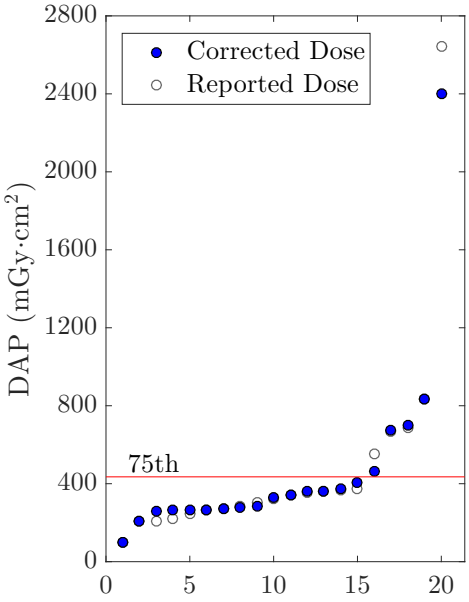


(d) Jaw cysts and tumours

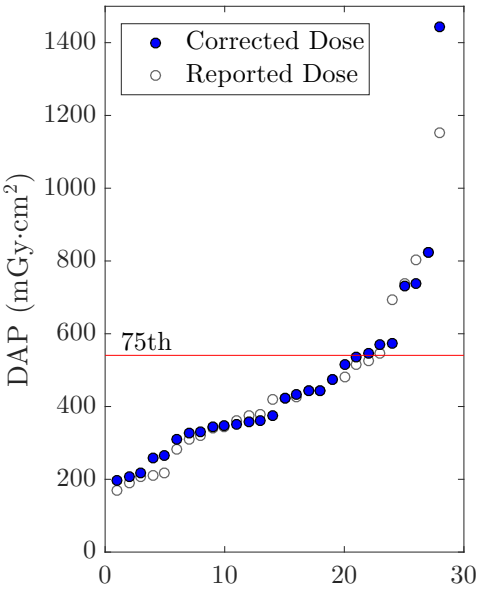
Figure 5.2 *Indication-specific dose data, part 1. Corrected dose refers to the data corrected for display error. Reported dose denotes the dose values given by the respondents. Both data types are sorted in ascending order. The red horizontal line indicates the level of the 75 the percentile of the corrected data.*



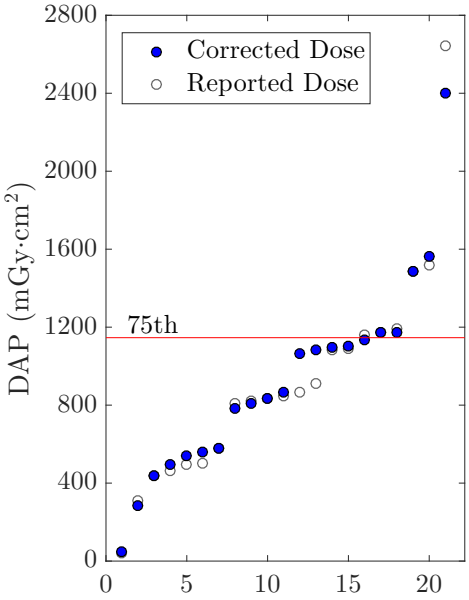
(a) Localisation of unerupted and supernumerary teeth (excluding wisdom teeth)



(b) Obscure pain conditions



(c) Assessment of the periapical region and the root canal morphology of the tooth



(d) Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus

Figure 5.3 *Indication-specific dose data, part 2. Corrected dose refers to the data corrected for display error. Reported dose denotes the dose values given by the respondents. Both data types are sorted in ascending order. The red horizontal line indicates the level of the 75 the percentile of the corrected data.*

Table 5.2 *Descriptive statistics of the dose data corrected for display error. Min and Max refer to the minimum and maximum values of the data. All values have been rounded to the nearest integer.*

Indication	**Min** ($mGy \cdot cm^2$)	**Max** ($mGy \cdot cm^2$)	**Mean** ($mGy \cdot cm^2$)	**Median** ($mGy \cdot cm^2$)	**75th Percentile** ($mGy \cdot cm^2$)
1. Presurgical imaging of implant treatments					
a) imaging of areas with a single missing tooth	27	730	286	262	353
b) imaging of the maxilla or mandible	72	1443	504	442	606
2. Assessment of the relationship between a wisdom tooth and the mandibular canal	100	1443	394	284	376
3. Jaw cysts and tumours	128	1340	450	357	491
4. Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)	27	390	207	214	286
5. Obscure pain conditions	98	2401	472	338	435
6. Assessment of the periapical region and the root canal morphology of the tooth	197	1443	462	399	541
7. Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus	48	2401	929	866	1146

5.2.2 Proposals for Diagnostic Reference Levels

Based on indication-specific number of data points, examination frequencies as well as visual inspection of graphs akin to those presented in Figures 5.2 and 5.3 of the previous subsection, seven indications with one indication comprising two subindications were deemed suitable for the establishment of proposals for indication-based

DRLs. The DRL proposals are provided in Table 5.3. All of the proposed values for DRLs are derived from the 75th percentile of the patient dose data that was corrected for display error of the CBCT units.

Table 5.3 *Proposals for indication-based diagnostic reference levels.*

Indication	**DRL Proposal** ($mGy \cdot cm^2$)
1. Presurgical imaging of implant treatments	
a) imaging of areas with a single missing tooth	360
b) imaging of the maxilla or mandible	610
2. Assessment of the relationship between a wisdom tooth and the mandibular canal	380
3. Jaw cysts and tumours	500
4. Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)	290
5. Obscure pain conditions	440
6. Assessment of the periapical region and the root canal morphology of the tooth	550
7. Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus	1150

The quality of the acquired dose data and the proposed DRLs can be regarded as complying well with the guidance on DRLs given by the ICRP and the EC. As recommended by the ICRP [44, p. 51], the proposed DRLs are based on national data and they are based on a percentile point of the dose distributions. Furthermore, the data was obtained from both hospitals and dental clinics of different types and sizes, which was one of the requirements imposed by the EC [24, p. 11].

Regarding the DRLs, the EC guidance states that different procedures should receive their own DRLs [24, p. 8]. The proposed DRLs conform with the foregoing criterion by being indication-based. Concerning the values for DRLs, the EC advises that the values should be higher than the median or mean of the dose distributions and suggests the use of the 75th percentile of the dose distributions [24, p. 11]. In the case of five out of the seven indications, all of the foregoing characteristics are met. For the indications ”Assessment of the relationship between a wisdom tooth and the mandibular canal” and ”Obscure pain conditions”, the proposed DRL value is lower than the mean but is nevertheless higher than the median. Figures 5.2(c) and 5.3(b) of the previous subsection show that in the case of both of the aforementioned indications, the dose data includes high-value outliers that pull the mean

value upwards. Therefore, the median can be seen as a more appropriate point of reference and thus, also the data of the afore-mentioned indications can be seen as having suitable characteristics for the establishment of DRLs.

The suggestion of using the 75th percentile is based on the assumption that the patient dose distributions are skewed with a tail to the right, i.e. towards high dose values [24, p. 11]. When examining the dose distributions presented in Figures 5.2 and 5.3 in histogram form (not shown), a tail to the right is seen for all of the seven indications (including the subindications), except for the indication "Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)". The missing tail in the case of the foregoing indication could already be anticipated based on the descriptive statistics provided in Table 5.2, which show that the mean and median of the dose distribution are nearly the same for the indication in question. Thus, the use of the 75th percentile is not optimal in this case. However, it would be important to establish a DRL or some other benchmark for the indication "Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)" because the indication concerns children and children are especially radiosensitive [24, p. 8]. Moreover, the foregoing indication was found to be among the most common indications in Finland in terms of examination frequency. Therefore, a DRL proposal was given for the afore-mentioned indication despite the shape of the dose distribution.

As discussed previously, information and data on DRLs for CBCT examinations is scarce but the SEDENTEXCT consortium has issued an AD of 250 mGy·cm^2 for the placement of a single-tooth implant in adults [102, p. 93]. In the study at hand, a DRL of 360 mGy·cm^2 is proposed for the indication "Presurgical imaging of implant treatments: a) imaging of areas with a single missing tooth". The proposed DRL is thus approximately 1.4 times the AD. The AD was determined employing the 75th percentile but it was derived from data normalised to a small FOV size [35, p. 10], whereas no normalisation was conducted in this study. Therefore, it was expected that the DRL for single-tooth implant treatments would exceed the AD. The AD was stated to correspond to the 33rd percentile of the non-normalised data [35, p. 11]. Calculated from the data used for this study, the 33rd percentile of the dose distribution for the indication "Presurgical imaging of implant treatments: a) imaging of areas with a single missing tooth" is 210 mGy·cm^2, i.e. lower than the AD.

In addition to the indication "Presurgical imaging of implant treatments: a) imaging of areas with a single missing tooth", the indications "Assessment of the relationship between a wisdom tooth and the mandibular canal" as well as "Assessment of the periapical region and the root canal morphology of the tooth" essentially pertain to imaging of a single tooth. Thus, the FOV sizes used in the examinations should be approximately the same for all the foregoing indications. However, it is seen in Table 5.3 that the DRL proposal for the indication concerning the periapical region and root canal is significantly higher than those for the other of the afore-mentioned indications. This finding highlights the importance of determining DRLs based on the indication and not on the FOV size, for example. The requirements on image quality and resolution for the imaging of the periapical region and the root canal are different from those regarding examinations for the other two indications, which results in the observed considerable difference in dose.

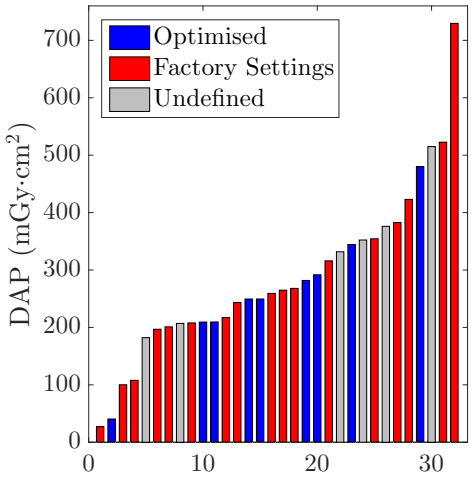
5.3 Further Analyses on Dose

The patient dose data was further analysed to see the effect of optimisation on dose. Moreover, it was studied, whether CBCT units of a particular manufacturer or model produce doses differing significantly from those produced by devices of other manufacturers or models. The following two subsections present the results of the foregoing analyses.

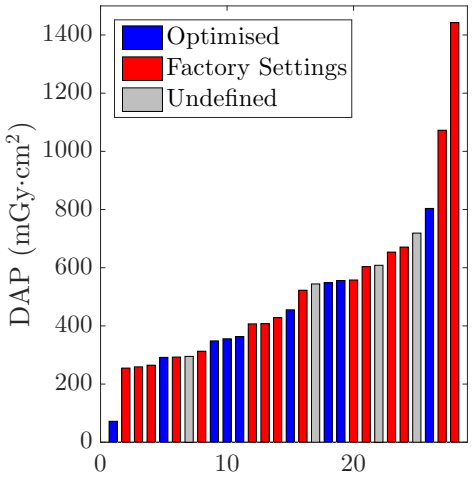
5.3.1 Effect of Optimisation on Dose

The respondents were enquired, whether they had used optimised imaging parameters and settings or employed the factory default settings of their device. As discussed in 4.2.5, the answers regarding optimisation were divided into three categories: 1) optimisation was conducted, 2) factory settings were used or 3) the type of the employed settings was undefinable based on the answers. Figures 5.4 and 5.5 show the effect of the foregoing categories on dose. The analysis of the effect of optimisation was conducted for the same data presented in the previous section. In the bar charts of Figures 5.4 and 5.5, each bar corresponds to a single corrected dose value and the bars are arranged in ascending order. The colours of the bars represent the afore-described categories concerning optimisation.

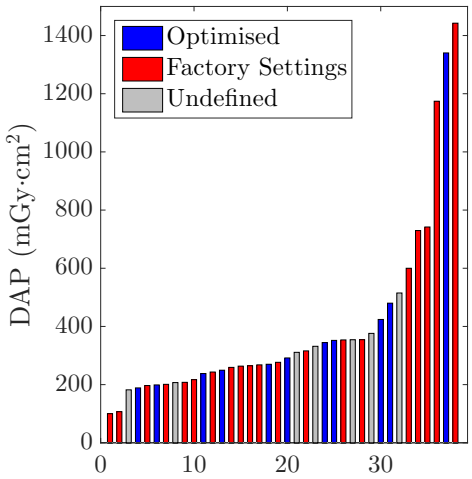
Figures 5.4 and 5.5 show that the dose values of the respondents who reported having conducted optimisation are found at both ends as well as in the middle



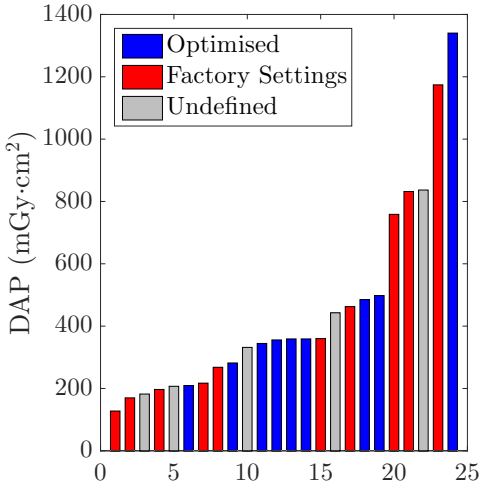
(a) Presurgical imaging of implant treatments: imaging of areas with a single missing tooth



(b) Presurgical imaging of implant treatments: imaging of the maxilla or mandible

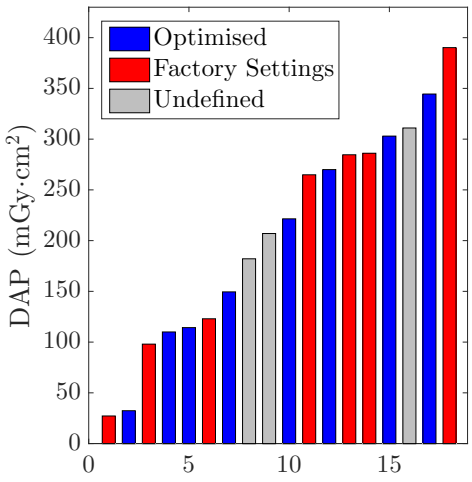


(c) Assessment of the relationship between a wisdom tooth and the mandibular canal

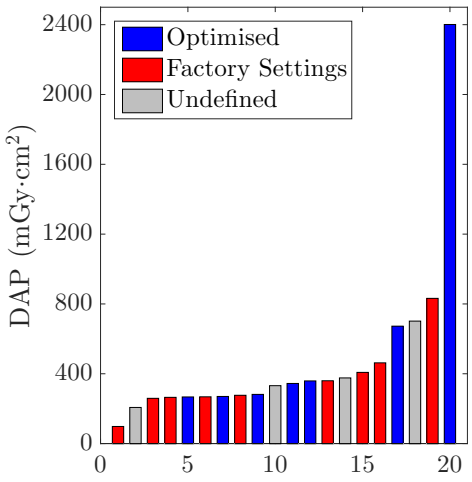


(d) Jaw cysts and tumours

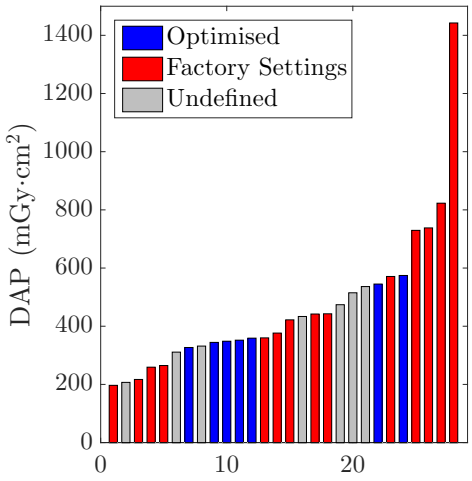
Figure 5.4 *Effect of optimisation on dose, part 1. Each bar represents a single corrected dose value. The colour of the bar denotes different categories regarding the optimisation of the imaging parameters and settings. On the horizontal axis, the bars are arranged in ascending order according to the dose value.*



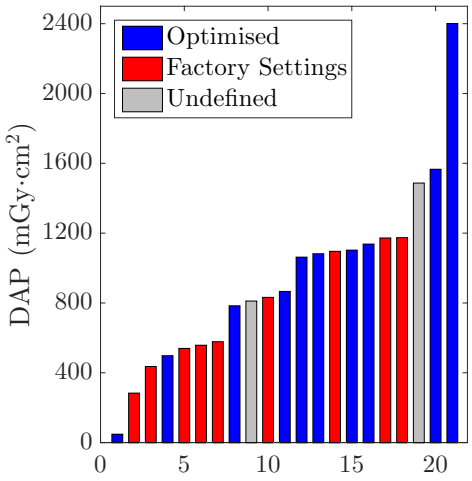
(a) Localisation of unerupted and supernumerary teeth (excluding wisdom teeth)



(b) Obscure pain conditions



(c) Assessment of the periapical region and the root canal morphology of the tooth



(d) Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus

Figure 5.5 *Effect of optimisation on dose, part 2. Each bar represents a single corrected dose value. The colour of the bar denotes different categories regarding the optimisation of the imaging parameters and settings. On the horizontal axis, the bars are arranged in ascending order according to the dose value.*

parts of the distributions formed by the ordered dose values. However, there are also indications where none of the very lowest doses resulted from optimisation and the highest dose was obtained with parameters and settings reported as being optimised. This is the case for the indications "jaw cysts and tumours" and "obscure pain conditions". It is also seen in Figures 5.4 and 5.5 that many of the respondent facilities did not perform optimisation but relied on factory default settings.

Based on Figures 5.4 and 5.5, it can be concluded that the use of optimised imaging parameters and settings does not seem to have resulted in a generalised dose reduction compared to the use of factory default settings. However, at the level of individual places of use, the effect of optimisation on dose cannot be deduced from the results since it is not known what the doses would have been without optimisation. The finding that optimisation did not appear to have lead to a generalised dose reduction can be seen as illustrating the fact that optimisation is a weighing process between numerous factors and dose is only one of the factors [43, p. 14], as discussed previously in conjunction with the principle of optimisation (in Subsection 3.1.2 General Principles). On the other hand, the principle of optimisation also includes the requirement to comply with the ALARA principle [45, p. 33]. Thus, despite optimisation being a weighing process between several aspects, the ALARA principle imposes restrictions on the outcome of the process with respect to dose. Therefore, it is highly questionable, whether optimisation has been conducted adequately in those cases where the dose is very high and the place of use claims that optimised settings were employed.

Overall, when examining all completed questionnaires and all of the indications included in the survey, 51% of the respondent facilities had used optimised settings in association with at least one indication or reported that optimisation was conducted sometimes. The foregoing percentage also includes places of use, where optimised settings were only used in conjunction with a minority of the indications pertaining to the place of use in question. The afore-mentioned percentage of facilities that have conducted optimisation to some extent is modest, considering that the principle of optimisation is laid down in legislation [19, 78] and that the ICRP has specifically emphasised the role of optimisation in radiological protection [43, p. 13; 46, pp. 14, 44].

As demonstrated by Figures 5.4 and 5.5 and as can be inferred from the aforementioned relatively low percentage of the respondent facilities that had conducted

optimisation, the use of the pre-defined settings and programmes of the CBCT devices is prevalent. When discussing the afore-mentioned settings and programmes with representatives of some manufacturers, the resulting image quality arose as the major determinant underlying the choice of parameters of the pre-set programmes. Image quality serving as the principal determinant could lead to the resulting images being 'too good' in the sense that poorer image quality would suffice for diagnosis. 'Too good' images are problematic because the parameters that affect image quality, such as tube current, also influence the dose [67] and consequently, the patient may be exposed to unnecessarily high doses. The foregoing assumption of 'too good' image quality is also supported by studies, which have found that, for example, the tube currents of pre-set protocols can be lowered significantly without rendering the resulting image non-diagnostic [18,68]. Against this background, the factory default settings performed surprisingly well with respect to dose in the indications explored above. In effect, in the case of six out of the eight indications and subindications explored, the lowest dose was attained by using factory default settings.

Even though many of the respondents have employed factory default settings directly, that is not the way the settings are intended to be used based on the user manuals of some manufacturers. The user manuals include remarks, such as that the lowest dose that produces sufficient diagnostic image quality should always be used [39, p. 4; 103, p. 4; 104, p. 2] or that the pre-defined protocols are provided for guidance purposes only and the users should form their own imaging protocols [74, p. 1; 75, p. 1; 76, p. 1].

5.3.2 Effect of Manufacturer and Model on Dose

In addition to the effect of optimisation on dose, it was studied whether CBCT devices of a particular manufacturer or a model produce higher or lower doses than others. The analysis was conducted in an indication-specific manner for the same seven indications studied in the previous sections of the chapter. The results for all of the indications were similar and thus, data is only shown for one of the indications. Figure 5.6 presents the results pertaining to the indication "Presurgical imaging of implant treatments: a) imaging of areas with a single missing tooth". Similar to the previous section, each bar in the graph corresponds to a single corrected dose value. On the horizontal axis, the columns or doses are grouped according to the manufacturer. Each group, i.e. each manufacturer, is displayed in a different colour.

Within each group, the columns, i.e. the dose values, are arranged in ascending order. The vertical texts above the bars denote the different models of the devices.

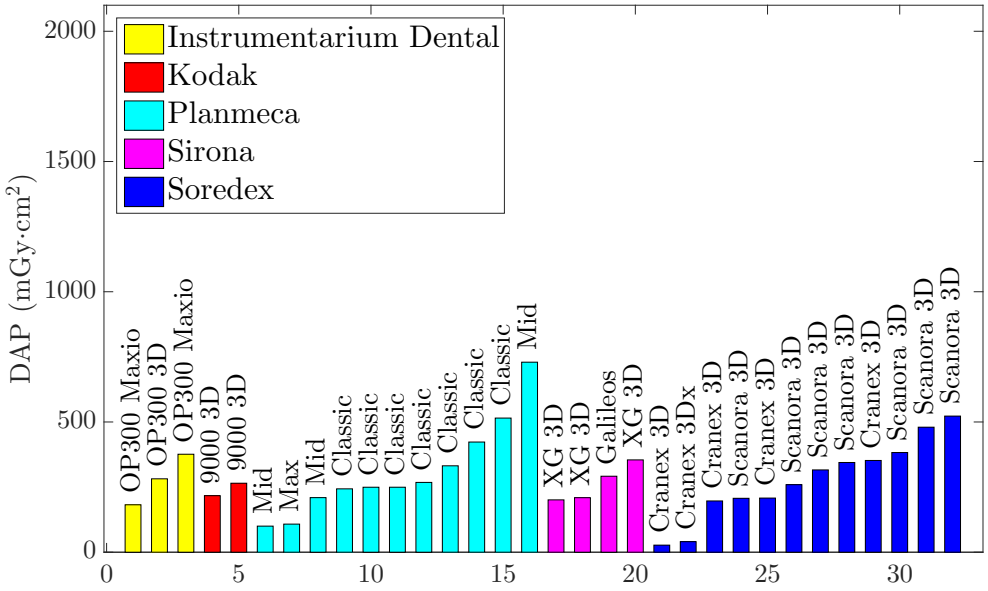


Figure 5.6 *Effect of manufacturer and model on dose. The data presented is for the indication "Presurgical imaging of implant treatments: a) imaging of areas with a single missing tooth" Each bar represents a single corrected dose value. On the horizontal axis, the dose values are grouped according to the manufacturers of the CBCT devices. Each manufacturer is indicated by a different colour of the bar. Within each group, the bars are arranged in ascending order according to the dose value. The vertical texts above the bars refer to the different scanner models of the manufacturers. Some of the model names are not given in full: the models of Planmeca refer to those of the ProMax series and the models of Sirona to those of the Orthophos series.*

Figure 5.6 shows that the doses produced by the CBCT units of the most popular manufacturers, Planmeca and Soredex, cover a wide range. For both manufacturers, there are doses among the lowest observed but also the highest doses are produced by the devices of the foregoing manufacturers. The same applies to the most popular scanner models of the afore-mentioned manufacturers. For example, for the indication depicted in Figure 5.6, the highest dose among those for Planmeca was obtained using the model ProMax Mid. However, also the lowest dose for Planmeca was generated by the same model. Similarly, in the case of Soredex, the doses for Scanora 3D comprise the highest dose among those of Soredex but also the fourth lowest dose as well as doses between the afore-mentioned extremes. Due to the small

number of doses for the remaining three manufacturers, it is hard to appropriately assess the effect of manufacturer or model on dose for Instrumentarium Dental, Kodak or Sirona. However, it can be concluded that none of the scanners of the afore-mentioned manufacturers stood out as producing doses that would have been out of line compared to the other manufacturers in any of the seven indications studied.

The above-discussed result that devices of the same manufacturer and even the same scanner models were found to produce a wide range of doses, suggests that the observed variation in dose values results mainly from the actions of the users, i.e. how the device is used, rather than from the device itself. The foregoing conclusion is reinforced when comparing the imaging parameters and settings employed by the users who had obtained the highest and lowest doses with the same scanner model. For example, in the case of the users of the model ProMax Mid for the indication presented in Figure 5.6, the user with the highest dose had used high-definition (HD) resolution, whereas the one with the lowest dose had used normal resolution combined with a ultra-low-dose imaging protocol. The foregoing thus again accentuates the importance of the optimisation of protocols employed.

It has to be noted, though, that analysing the effect of the scanner model is not as straightforward as presented here since scanners of different production years can incorporate different versions of software, for example, and also afterwards the software can be updated and other modifications, such as fitting of new sensors, can be made. Therefore, the devices being of the same model does not necessarily mean that the devices are similar in all respects. Thus, to conduct a more comprehensive analysis on the effect of scanner models on dose, the software versions and other characteristics specific to individual devices as well as all the modifications made afterwards should be taken into account.

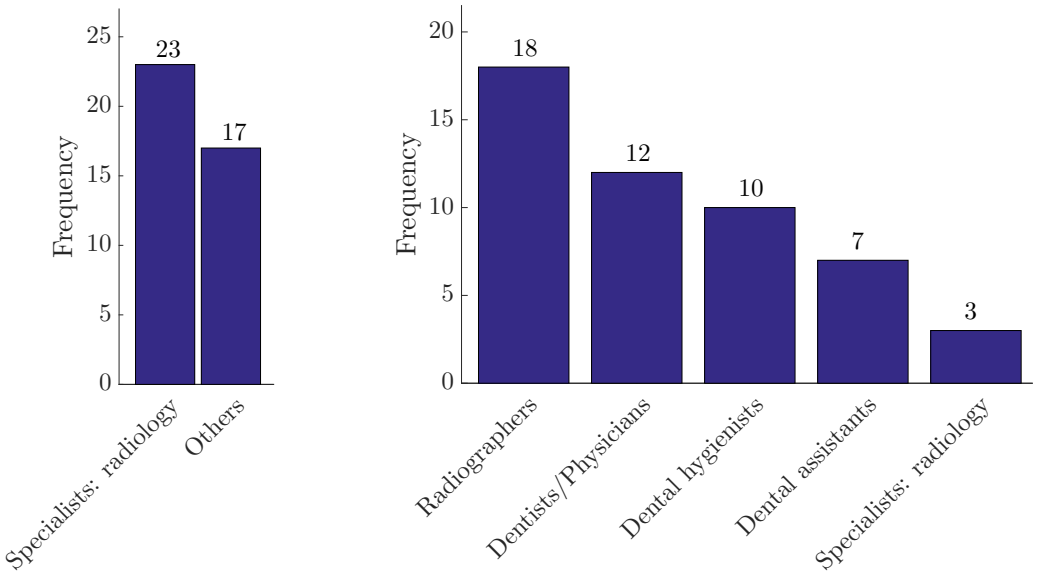
5.4 Qualifications

As described previously, STUK has imposed special requirements on the qualifications of the people responsible for CBCT examinations as well as of the personnel conducting the examinations [93]. For analysis, the qualifications of the people-in-charge and the personnel performing the examinations were arranged in categories based on the assumed radiological knowledge and the frequency of the categories

was studied, as explained in 4.2.7 Qualifications. The frequency refers to the number of times the category was mentioned in the completed questionnaires. For each place of use, each category was counted only once, regardless of the actual number of people representing the category. The frequencies of the categories are illustrated in Figure 5.7 regarding both the people responsible for the examinations and the personnel performing the imaging.

Figure 5.7 shows that the frequencies of the two categories concerning the qualifications of the people-in-charge are close to each other with the category comprising specialists in radiology or oral radiology being slightly more common. Regarding the qualifications of the personnel performing examinations, it is observed that all of the eligible categories are represented. The category formed by radiographers is the most common, whereas the category consisting of specialists in radiology or oral radiology is infrequent.

Regarding five of the respondent facilities, the qualifications of the people responsible for the examinations were not provided in the survey responses or were reported unclearly. In the case of two places of use, the dentist-in-charge lacked the required supplementary training in CBCT imaging. The information pertaining to the qualifications of the personnel performing the examinations was incomplete in the responses from two places of use. At five places of use, CBCT imaging was conducted without the requested supplementary training concerning CBCT imaging. At four of the afore-mentioned five facilities, all members of the personnel conducting CBCT examinations lacked the supplementary training. However, based on the information received from the respondents, most of those who did not have the requested qualifications were on the supplementary training course at the time the survey was conducted or were planning to complete the supplementary training when next possible. At the remaining place of use, one member of the personnel had not completed the supplementary training, whereas the rest of the personnel had the required qualifications. An important finding of the study is thus that some dentists-in-charge as well as some members of the personnel performing CBCT examinations lack the required supplementary training even though the transition period given for completing the afore-mentioned training ended already over three years ago [93].



(a) Qualifications of the people responsible for CBCT examinations

(b) Qualifications of the personnel performing CBCT examinations

Figure 5.7 *Qualifications of the people-in-charge for CBCT examinations and of those performing the examinations. The foregoing qualifications are arranged in categories, the frequencies of which are shown in the bar graphs. The categories are presented in abbreviated form. The abbreviated forms refer to the following categories: in a) specialists: radiology = specialists in radiology or oral radiology; others = dentists (licentiates of dentistry), physicians (licentiates of medicine), medical and dental specialists with a speciality other than radiology or oral radiology and in b) dentists/physicians = physicians (licentiates of medicine), medical and dental specialists with a speciality other than radiology or oral radiology; specialists: radiology = specialists in radiology or oral radiology.*

6. CONCLUSIONS

The main objective of the study was to collect national patient dose data for the establishment of indication-based DRLs for CBCT examinations of the head and neck region in Finland and based on the data, to form proposals for the prospective DRLs. Concomitant with the primary objective, the study was to determine the indications for which CBCT examinations are conducted in Finland and indication-specific examination frequencies. Furthermore, the study aimed to investigate the qualifications of the people in charge of the CBCT examinations as well as those of the personnel performing the examinations, and whether the qualifications complied with the requirements imposed by STUK. Additionally, the study explored the use of optimised imaging parameters and the effect thereof on dose. Dose was also analysed with respect to the manufacturer and model of the CBCT device used.

The study was conducted as a survey among Finnish facilities performing CBCT examinations of the head and neck. The survey employed a self-designed questionnaire with a pre-defined list of indications for CBCT examinations. The respondents were asked to report dose readings in an indication-based manner assuming the patient was an average-sized male and for the indications pertaining to children, assuming the patient was typical of the indication. Additionally, information on the CBCT unit, imaging parameters and settings, the use of optimised settings as well as estimated examination frequencies were requested. Completed questionnaires were received from 43 places of use and for 47 CBCT devices, the response rate being 57%, in terms of listed places of use and 56%, in terms of registered devices. The reported dose readings were corrected for dose display error and the corrected data was used in the analyses. The proposals for the DRLs were derived from the 75th percentile values of the indication-specific patient dose distributions. The 75th percentiles were determined using a built-in function of MATLAB R2015b that employs linear interpolation in computing the percentiles.

The results of the study show that CBCT imaging is applied to a wide variety of

indications in Finland. Despite a wide spectrum, only nine of the indications covered 93% of all CBCT examinations of the head and neck. The nine most common indications included one indication concerning only children. In terms of examination frequency, the most important indications for CBCT examinations in Finland fell into the following categories (starting from the most common): 1) presurgical imaging of implant treatments, 2) the assessment of the relationship between a wisdom tooth and the mandibular canal, 3) inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus and 4) assessment of the periapical region and the root canal morphology of the tooth. The afore-mentioned most important indications are in accordance with those found in the recommendations on the clinical use of CBCT [20,26]. Thus, indication-wise, CBCT appears to be applied appropriately in Finland. The results are also concordant with literature reporting that the imaging of sinuses has emerged as a common indication alongside the more traditional dental indications [15, 30, 106].

The sum of the estimated monthly examination frequencies reported by the respondents translated into a total number of approximately 20 000 CBCT examinations per year. The afore-mentioned annual total is, however, significantly higher than suggested by the preliminary results of another survey conducted by STUK [82] that pertained to the same target group and year as the study at hand. The substantial difference in the results of the two studies may indicate that the examination frequencies provided by the respondents of this study are overestimated. Based on the results of the two studies, it can, however, be concluded that the total annual number of CBCT examinations of the head and neck is over 10 000 in Finland. The number of examinations is of such magnitude that CBCT can be regarded as a common examination type and hence, there are grounds for the establishment of DRLs.

The number of data points was sufficient for a closer analysis of the dose distributions in the case of seven indications, one of which consisted of two subindications. One of the afore-mentioned indications pertained to children, whereas all the others were indications for adult examinations. In all of the analysed cases, the indication-specific patient dose range was extensive, with minimum-to-maximum dose ratios ranging from 7 to 50. With few exceptions, the data for each indication consisted of one dose value or data point per place of use. Thus, the foregoing results also indicate that the differences in patient dose are substantial between the places of use across Finland. In terms of patient safety, such differences in dose should not

exist. The existence of such large differences shows that there is a serious need for DRLs for CBCT examinations in Finland.

DRL proposals were made for all of the afore-mentioned seven indications, including individual proposals for the subindications. All of the DRL proposals for adult examinations can be considered compliant with the guidelines of the EC and ICRP on DRLs with respect to the quality of the dose data and the statistical characteristics of the dose distributions. The shape of the distribution of the indication pertaining to children was not optimal for the use of the 75th percentile approach. A DRL proposal was, nevertheless, formed for the afore-mentioned indication since children are especially sensitive to radiation [24, p. 8] and thus, it is important to provide at least some kind of a benchmark for the indication in question.

The most important finding regarding the qualifications was that there were several places of use, where CBCT imaging was conducted with qualifications not meeting the requirements issued by STUK. Furthermore, in the case of two places of use, the dentist-in-charge lacked the supplementary training on CBCT that is required for the dentists responsible for CBCT examinations.

The exploration of the use of optimised imaging parameters and settings revealed that only 51% of the respondents had used optimised settings or at least conducted optimisation sometimes, if not in conjunction with all indications or examinations. For some of the respondents, the type of the employed settings could not be defined based on the answers. The rest had used the default factory settings of their CBCT units. The portion of the respondents who had used optimised settings is strikingly low, considering that the principle of optimisation is laid down in the ST Guides of STUK, in the Finnish and European legislation as well as in the international recommendations of the ICRP [19, 46, 78, 94, 111]. Moreover, despite providing default programmes and settings, also manufacturers state in the user's manuals that the purpose of the default settings is only advisory and that the lowest dose producing sufficient image quality should be strived for [39, 74–76, 103, 104]. The use of optimised settings did not, however, appear to result in a generalised dose reduction, and many of the lowest values were actually obtained by using factory default settings. The foregoing can be seen as demonstrating that dose is not the only component in the process of optimisation, but potentially also as an indicator of inadequate optimisation. When examining dose as a function of the device used, the observed large variations in dose could not be attributed to any single manufacturer or de-

vice model. Rather, even the same models of the same manufacturer were found to produce a wide range of doses within the same indications, suggesting that the dose variations mainly result from the actions of the user.

The study and its results are an important contributor to radiation safety in Finland. First and foremost, the study provides STUK with patient dose data and proposals for indication-based DRLs, which enable the establishment of the Finnish DRLs for CBCT examinations. The DRLs for CBCT examinations are already being prepared by STUK based on the study and will be issued in the near future. The establishment and the application of the DRLs is expected to modify the Finnish patient dose distributions by removing the highest dose values observed in this study. DRLs are revised at intervals of some years. In conjunction with the revision of the prospective DRLs, the realised effect of the DRLs can be assessed by using the results of the study at hand as a reference. Moreover, the questionnaire developed for the study and the methods used in analysing the data can be utilised in future dose studies concerning CBCT examinations.

In addition to providing data and proposals for the establishment of DRLs, the study gives essential information on the radiation practices regarding CBCT examinations in Finland. The results of the study showed that a significant portion of the respondents had not optimised the imaging parameters but had directly used the factory default settings of the devices, which is against the principle of optimisation. Furthermore, the study revealed infringements of the requirements of STUK for the qualifications of the people in charge of and performing CBCT examinations. The afore-mentioned results are a signal that the matters of optimisation and required qualifications should be looked into more closely in the future. A possibility for addressing the former issue would be to enquire about the optimisation of the imaging settings as a part of the inspections conducted by STUK at the places of use. The current inspection practices already include checking the qualifications, which raises the question how it is possible that several instances of lacking qualifications were found. However, it is likely that the places of use in question had not been inspected after the introduction of the current qualification requirements. Moreover, the personnel performing the examinations may change between the inspections. Therefore, the introduction of a system for checking the qualifications regularly between the inspections should be considered by STUK.

The study can also be considered pioneering in an international perspective in the

sense that Finland is one of the first, if not the first, country to issue DRLs for CBCT examinations. The ICRP stated in its publication devoted to CBCT in 2015 that little progress has been made towards the establishment of DRLs for CBCT and that the literature on DRLs for CBCT is scarce [98, p. 100]. The study is thus of significant importance in providing new information to the field.

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APPENDIX A. QUESTIONNAIRE

CBCT Examinations of the Head and Neck Region

Safety licence number:
Place of use:
Device (manufacturer and model):
Filtration of the device (Al/Cu and thickness):
Qualifications of the dentist/physician responsible for the examinations:
Qualifications of the personnel performing the examinations:

		Imaging Parameters					**Imaging Settings**			**Dose**	
Indications	Estimated number of examinations per month	Tube voltage (kV)	Tube current (mA)	Voxel size (mm) or resolution setting	Field of view (FOV) size (Ø x H), cm	Scanning/ exposure time (s)	Patient size setting	Name of the imaging programme of the device	Were factory default settings or optimised imaging settings used? (F = factory settings/ O = optimised)	Dose display DAP (mGy cm^2)	Error of the dose display (%, direction +/-)
Presurgical imaging of implant treatments a) imaging of areas with a single missing tooth b) imaging of the maxilla or mandible											
Assessment of the relationship between a wisdom tooth and the mandibular canal											
Jaw cysts and tumours											
Tooth fractures											
Alveolar fractures											
Jaw or condylar fractures											
Dysfunction of the masticatory system (TMJ area)											
Orthognathic surgery											
Localisation of unerupted and supernumerary teeth (excluding wisdom teeth) (children)											
Cleft palate (children)											
3-dimensional cephalometry											
3-dimensional cephalometry (children)											
Airway assessment											
Obscure pain conditions											
Assessment of the periapical region and the root canal morphology of the tooth											
Periodontal diseases											
Inflammatory changes, polyps and tumours of the paranasal sinuses and the nasal meatus											
Trauma of the paranasal sinuses (including orbital floor)											
Fractures of the cervical spine											
Spondyloarthropathy of the cervical spine											
Anomalies and changes of the outer auditory canal as well as of the inner and middle ear											
Otomastoiditis											
Assessment of inner or middle ear implant positioning											
3D modelling											
Computer-aided surgical planning											
Manufacturing of customised implants											

APPENDIX B. COVER LETTER

STUK **COVER LETTER** 1(3)

6th May 2015

Translation of the original cover letter (in Finnish) with contact details omitted.

Dose survey: diagnostic reference levels in cone-beam computed tomography examinations of the head and neck region

The Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000; 2 §, 16 § and 17 §) obliges the parties running a radiation practice to apply diagnostic reference levels (DRLs) to X-ray examinations. The decree also stipulates that the DRLs for the most common examinations are established by the Radiation and Nuclear Safety Authority (STUK).

STUK is establishing DRLs for cone-beam computed tomography (CBCT) examinations of the head and neck region. The aim of the present dose survey is to determine indication-based DRLs. In addition, indication-specific examination frequencies, the use of default imaging settings of the devices as well as the qualifications of the dentists/physicians responsible for the CBCT examinations and those of the personnel conducting the examinations are studied.

For the establishment of the DRLs, we ask you to complete the attached Excel table in a device-specific manner according to the instructions given below.

General

The Excel table consists of a single sheet (Head and Neck CBCT), in which information pertaining to a single device and to the examinations conducted using the device in question shall be filled in. The information shall be entered in an indication-specific manner using the pre-defined list of indications provided in the table. The information shall be given assuming the patient was an average-sized male with the exception of the indications followed by the text ”children” in red and in parentheses. For the latter indications, please enter the information assuming the patient being examined represents a patient typical of the indication in question. We also ask you to mark the age of the typical patient after the text “children” in the column Indications.

In the box at the top of the sheet, please fill in the safety licence number and the place of use of the device as well as the following information regarding the device: manufacturer, model and filtration (if known). Regarding the filtration, the material and the thickness of the filter shall be given. Additionally, qualifications of the dentists/physicians responsible for the examinations and those of the personnel performing the examinations shall be entered. The qualifications refer to the qualification requirements laid down in ST-Guide 3.1 (13.6.2014; item 3.2).

STUK • SÄTEILYTURVAKESKUS
STRÅLSÄKERHETSCENTRALEN
RADIATION AND NUCLEAR SAFETY AUTHORITY

Osoite • Laippatie 4, 00880 Helsinki
Postiosoite • PL 14, FIN-00881 Helsinki
Puh. (09) 759 881 • Telekopio (09) 759 88 248 • www.stuk.fi

Please submit the completed form by e-mail to ****.****@****.fi by **22th May 2015** at the latest.

Questions concerning the survey can be addressed to Sonja Turnbull-Smith, ****-******, ****.****@****.fi and Atte Lajunen, **-********, ****.****@****.fi

Additional instructions on completing the form are given below.

Indications

The column Indications contains a pre-filled list of indications for the CBCT examinations of the head and neck region. Each indication has its own row. The indications are divided into five groups: 1) dentition and jaw area 2) paranasal sinuses 3) cervical spine area 4) temporal bone and 5) others. The grouping is indicated by colour coding in the table. We ask you to complete the information with respect to the indications concerning your place of use. The rows concerning other indications shall be left blank.

Estimated Number of Examinations

In the column Estimated number of examinations per month, we ask you to estimate the number of examinations conducted per month for each indication.

Imaging Parameters

In the section Imaging Parameters, the tube voltage and current, the size of the field of view (FOV) as well as the scanning or exposure time employed in the examination shall be completed in the unit given in parentheses. The FOV size shall be given in the form of diameter x FOV height. Additionally, the voxel size in millimetres or the resolution setting of the device used in the examination shall be given.

Imaging Settings

In the section Imaging Settings, the selected patient size and the name of the imaging programme used shall be given. The imaging programme of the device refers to pre-set imaging programmes or imaging protocols that are found in some CBCT devices and that provide pre-defined imaging parameters (e.g. tube current and voltage). In addition, information is requested on, whether the factory default settings of the afore-mentioned imaging programmes/protocols were used directly or whether the imaging parameters were optimised. If factory default settings were used directly, please enter the letter 'F' in the column "Were factory default settings or optimised imaging settings used?". If optimised parameters were used, shall the letter 'O' be entered in the afore-mentioned column. The information obtained through the question is used to study the prevalence of the use of optimised settings.

Dose

In the column Dose display DAP, the DAP dose reading given by the dose display of the device shall be filled in. In the column Error of the dose display, please enter the percent error of the dose display according to maintenance documentation or

measurements by STUK. In conjunction with the percent error, the direction of the error shall also be given (e.g. +10 %). A positive sign implies that the reading of the dose display is higher than the true dose. A negative sign shall be used if the reading of the dose display is lower than the true dose. The error of the dose display should be determined using the same tube voltage and FOV size as used in the examination, for which the DAP dose reading of the dose display has been given.

Thank you very much for your co-operation already in advance!