

Volume 44 No. 1 2015

ISSN 0146-6453
ISBN 9781473944398

ICRP

Annals of the ICRP

ICRP Publication 129

Radiological Protection in Cone Beam Computed
Tomography (CBCT)



Documents

Document Sharing Hub

Annals of the ICRP

Published on behalf of the International Commission
on Radiological Protection

Aims and Scope

The International Commission on Radiological Protection (ICRP) is the primary body in protection against ionising radiation. ICRP is a registered charity and is thus an independent non-governmental organization created at the 1928 International Congress of Radiology to advance for the public benefit the science of radiological protection. ICRP provides recommendations and guidance on protection against the risks associated with ionising radiation from artificial sources such as those widely used in medicine, general industry, and nuclear enterprises, and from naturally occurring sources. These reports and recommendations are published approximately four times each year on behalf of ICRP as the journal *Annals of the ICRP*. Each issue provides in-depth coverage of a specific subject area.

Subscribers to the journal receive each new report as soon as it appears so that they are kept up to date on the latest developments in this important field. While many subscribers prefer to acquire a complete set of ICRP reports and recommendations, single issues of the journal are also available separately for those individuals and organizations needing a single report covering their own field of interest. Please order through your bookseller, subscription agent, or direct from the publisher.

ICRP is composed of a Main Commission, a Scientific Secretariat, and five standing Committees on: radiation effects, doses from radiation exposure, protection in medicine, the application of ICRP recommendations, and protection of the environment. The Main Commission consists of a Chair and twelve other members. Committees typically comprise 10–15 members each.

ICRP uses Task Groups to prepare its reports. A Task Group is usually chaired by an ICRP Committee member and usually contains a number of specialists from outside ICRP. Thus, ICRP is an independent international network of specialists in various fields of radiological protection, and, at any one time, about two hundred eminent scientists and policy makers are actively involved in the work of ICRP. The Task Groups are assigned the responsibility for drafting documents on various subjects, which are reviewed and finally approved by the Main Commission. These documents are then published as the *Annals of the ICRP*.

International Commission on Radiological Protection

at the time of approval of this publication

Chair: C. Cousins, *UK*

Vice-Chair: J. Lochard, *France*

Scientific Secretary: C.H. Clement, *Canada*; sci.sec@icrp.org

J.D. Boice Jr., *USA*

D.A. Cool, *USA*

J.D. Harrison, *UK*

C.-M. Larrson, *Australia*

J. Lee, *Korea*

H. Liu, *China*

H.-G. Menzel, *Switzerland*

W.F. Morgan, *USA*

O. Niwa, *Japan*

Z. Pan, *China*

S. Romanov, *Russia*

E. Vaño, *Spain*

Emeritus Members

R.H. Clarke, *UK*

B. Lindell, *Sweden*

C.B. Meinhold, *USA*

F.A. Mettler Jr., *USA*

R.J. Pentreath, *UK*

C. Streffer, *Germany*

For full information on ICRP please visit www.icrp.org

Annals of the ICRP

ICRP PUBLICATION 129

Radiological Protection in Cone Beam Computed Tomography (CBCT)

Editor-in-Chief
C.H. CLEMENT

Associate Editor
N. HAMADA

Authors on behalf of ICRP
M.M. Rehani, R. Gupta, S. Bartling, G.C. Sharp, R. Pauwels,
T. Berris, J.M. Boone

PUBLISHED FOR

The International Commission on Radiological Protection

by



Please cite this issue as 'ICRP, 2015. Radiological Protection in
Cone Beam Computed Tomography (CBCT). ICRP Publication 129.
Ann. ICRP 44(1).'

CONTENTS

GUEST EDITORIAL	7
ABSTRACT	9
PREFACE	11
MAIN POINTS	13
GLOSSARY.....	15
1. INTRODUCTION.....	21
1.1. History of development.....	24
1.2. Current standards in radiological protection in CBCT.....	24
1.3. Responsibilities of different stakeholders	25
1.4. Why is it important to know CBCT doses?	26
1.5. Safety in perspective.....	26
1.6. Scope of this publication	27
2. CBCT TECHNOLOGY.....	29
2.1. Introduction.....	29
2.2. Technological issues	29
2.3. Clinical scenarios where CBCT is used.....	34
3. BIOLOGICAL EFFECTS OF RADIATION.....	37
3.1. Introduction.....	37
3.2. Tissue reactions	37
3.3. Stochastic effects	39
4. PRINCIPLES OF RADIOLOGICAL PROTECTION FOR PATIENTS AND WORKERS	41
4.1. Justification	41
4.2. Optimisation	42
4.3. Requirements for imaging facilities	42
5. ASSESSING PATIENT DOSES IN CBCT.....	45
5.1. Dosimetry in CBCT	45
5.2. Point-of-care scanning and clinic-based CBCT systems.....	45

5.3. C-arm CBCT systems	46
5.4. A unified approach to CT dosimetry.....	46
5.5. Tracking and reporting of radiation dose	47
5.6. Epilogue	47
6. OPTIMISATION OF PROTECTION OF PATIENTS AND WORKERS IN CBCT	49
6.1. Introduction.....	49
6.2. Factors influencing dose to the patient.....	50
6.3. Limitations of CBCT.....	68
6.4. Future developments	69
7. RADIATION DOSE MANAGEMENT IN SPECIFIC APPLICATIONS OF CBCT.....	73
7.1. Introduction.....	73
7.2. CBCT in radiotherapy.....	74
7.3. Neurointerventions	78
7.4. Vascular interventions	80
7.5. Non-vascular interventions	83
7.6. Orthopaedics/surgery	84
7.7. Urology.....	86
7.8. Ear/nose/throat and head diagnostics or surgery	87
7.9. Dental and maxillofacial.....	87
7.10. Breast.....	91
8. TRAINING CONSIDERATIONS FOR CBCT	93
8.1. Introduction.....	93
8.2. Curriculum.....	94
8.3. Who should be the trainer?.....	94
8.4. Training of service engineers.....	95
9. QUALITY ASSURANCE PROGRAMMES	97
9.1. Introduction.....	97
9.2. Quality control of CBCT equipment	97
9.3. Patient dose reporting	99
9.4. Diagnostic reference levels	99
9.5. Audit	100
10. RECOMMENDATIONS	101

REFERENCES.....	103
ANNEX A. ASSESSING PATIENT DOSES IN CBCT.....	117
A.1. Dosimetry in CBCT	117
A.2. Point-of-care scanning and clinic-based CBCT systems	118
A.3. C-arm CBCT systems.....	120
A.4. A unified approach to CT dosimetry	120
A.5. Tracking and reporting of radiation dose.....	126
A.6. Epilogue.....	127
CORRIGENDA.....	128

Guest Editorial

CBCT: WIDE RANGE OF CLINICAL APPLICATIONS AND WIDE RANGE OF DOSES

This publication on radiological protection in cone beam computed tomography (CBCT) is both timely and practical. Previous ICRP publications have addressed managing the dose in patients undergoing computed tomography (*Publication 87*), and managing patient dose in multi-detector computed tomography (MDCT) (*Publication 102*) (ICRP, 2000a, 2007a). While some of the same principles apply to CBCT, new challenges exist. CBCT is a technology that is becoming more prevalent in clinical practice. These scanners extend the use of computed tomography (CT) into new clinical environments and by new practitioners, not all of whom have had the radiation safety training that radiological technologists, medical physicists, radiologists, and radiation oncologists have traditionally received. In addition, this technology is in evolution, and opportunities exist for device manufacturers to standardise dose displays. Thus, there is a need for education, guidelines, and standardisation in the industry.

Over the past decades, conventional CT has been ‘game-changing’ technology in patient care. Abdominal CT scans have replaced more invasive surgical procedures. Head CT scans and CT angiography have replaced many catheter-based angiograms. In a survey of 235 internists, CT and magnetic resonance imaging ranked highest on the list of innovations whose loss would have the greatest adverse effect on patients (Fuchs and Sox, 2001). CT ranked ahead of several mainstream medical technologies such as gastrointestinal endoscopy, balloon angioplasty, and coronary artery bypass grafts. However, use of CT imaging comes with responsibility. Knowledge and tools are needed to balance the benefits and the harms. Now, as CBCT is used in other clinical areas by other providers, the need for education, standardisation, and guidelines presents an opportunity that must be met.

The use of CBCT spans a wide range of clinical specialties and procedures: radiotherapy; orthopaedics; urology; dental/maxillofacial; neurointerventions; and vascular and non-vascular interventions. Patient dose also demonstrates a large range, from <1 mGy for organ absorbed dose to >400 mGy for skin dose. This range could be even wider depending on the number of CBCT scans performed and the complexity of intervention. This publication provides practical guidance for dose management in general and in specific clinical settings.

Dose reduction comes with trade-offs. This will require standard measurements of both dose and image quality across all manufacturers. For equipment used for

fluoroscopy and CBCT, the aggregate dose to the patient for the entire procedure should be available. These data should be displayed on the operator console, and should be available for incorporation into the electronic health record. There are many ways to reduce dose. These include the design of CBCT equipment and how the equipment is used in specific clinical settings. This publication appropriately reinforces fundamental concepts such as ‘as low as reasonably achievable’. However, this publication also addresses another critical source of dose reduction. One of the best ways to reduce dose is to ensure that the imaging is appropriate or clinically indicated. Conventional CT examinations may be performed that do not represent the most appropriate imaging test for the clinical question being asked. Multiple strategies have been developed to address unnecessary use of imaging overall (Bernardy et al., 2009). Guidelines on appropriate use of CBCT need to be widely adopted.

In an era of population health, further development and use of CBCT should be driven by appropriate clinical need, balanced with risk to patients and workers. This publication provides a helpful direction for policy makers, imaging professionals, medical physicists, and manufacturers to optimise protection of both patients and workers, while preserving the expectation of high diagnostic yields from imaging and excellent clinical outcomes.

JAMES V. RAWSON

REFERENCES

- ICRP, 2000. Managing Patient Dose in Computed Tomography. ICRP Publication 87. Ann. ICRP 30(4).
- ICRP, 2007a. Managing patient dose in multi-detector computed tomography (MDCT). ICRP Publication 102. Ann. ICRP 37 (1).
- Fuchs, V.R., Sox, H.C. Jr., 2001. Physician s views of the relative importance of thirty medical innovations. Health Aff. 20, 30–42.
- Bernardy, M., Ullrich, C.G., Rawson, J.V., et al., 2009. Strategies for managing imaging utilization. J. Am. Coll. Radiol. 6, 844–850.

Radiological Protection in Cone Beam Computed Tomography (CBCT)

ICRP PUBLICATION 129

Approved by the Commission in January 2015

Abstract—The objective of this publication is to provide guidance on radiological protection in the new technology of cone beam computed tomography (CBCT). *Publications 87 and 102* dealt with patient dose management in computed tomography (CT) and multi-detector CT. The new applications of CBCT and the associated radiological protection issues are substantially different from those of conventional CT. The perception that CBCT involves lower doses was only true in initial applications. CBCT is now used widely by specialists who have little or no training in radiological protection. This publication provides recommendations on radiation dose management directed at different stakeholders, and covers principles of radiological protection, training, and quality assurance aspects. Advice on appropriate use of CBCT needs to be made widely available. Advice on optimisation of protection when using CBCT equipment needs to be strengthened, particularly with respect to the use of newer features of the equipment. Manufacturers should standardise radiation dose displays on CBCT equipment to assist users in optimisation of protection and comparisons of performance. Additional challenges to radiological protection are introduced when CBCT-capable equipment is used for both fluoroscopy and tomography during the same procedure. Standardised methods need to be established for tracking and reporting of patient radiation doses from these procedures. The recommendations provided in this publication may evolve in the future as CBCT equipment and applications evolve. As with previous ICRP publications, the Commission hopes that imaging professionals, medical physicists, and manufacturers will use the guidelines and recommendations provided in this publication for implementation of the Commission's principle of optimisation of protection of patients and medical workers, with the objective of keeping exposures as low as reasonably achievable, taking into account economic and societal factors, and consistent with achieving the necessary medical outcomes.

© 2015 ICRP. Published by SAGE.

Keywords: Cone beam CT; C-arm CBCT; ICRP recommendations; Dose management CBCT; Interventional CBCT; CT fluoroscopy

AUTHORS ON BEHALF OF ICRP
M.M. REHANI, R. GUPTA, S. BARTLING, G.C. SHARP,
R. PAUWELS, T. BERRIS, J.M. BOONE

PREFACE

The International Commission on Radiological Protection (ICRP) provides recommendations and guidance on application of its principles of radiological protection. This has been done through specific publications on the use of ionising radiation in medicine in various imaging and therapeutic modalities. This is in addition to the reports published by ICRP providing general advice on radiological protection and safety in medicine through *Publication 105* (ICRP, 2007c). Analysis of current technology from the point of view of radiological protection has resulted in recommendations directed at manufacturers that have potential for technological developments for safer technology. In this manner, ICRP has acted as an important resource presaging safety issues based on current and future use of technology, and identifying needs where technology can contribute. Of course, there are vast areas of optimisation where users can play a large role in minimising radiation doses to patients without compromising diagnostic or clinical purpose. In recent years, there have been evaluations of practices which have indicated that a large number of imaging procedures have not met the appropriateness guidelines. While ICRP has provided three levels of justification, there is increasing need to scrutinise justification at Level 3, and provide guidance on justification of an examination. The current climate of interest in radiological protection has enhanced the audience of ICRP publications to cover policy makers, health authorities, public health organisations, patient groups, organisations developing criteria on the appropriateness of different techniques and their use, and a variety of medical specialists who have now started using imaging technology that was not available to them a decade or so ago. This publication addresses the challenges faced with the new technology of cone beam computed tomography (CBCT) that is being used increasingly in day-to-day practice in hospitals by increasing numbers of medical specialists. The advice from ICRP is timely. Issues of patient and worker protection are also addressed in this publication.

The Commission launched a Task Group on Radiological Protection in CBCT in 2013.

The membership of the Task Group was as follows:

M.M. Rehani (Chairman)

S. Bartling

R. Gupta

The corresponding members were:

T. Berris (to October 2013)

J.M. Boone

G.C. Sharp

R. Pauwels (from December 2013)

Committee 3 critical reviewers were:

C. Martin

R. Loose

Main Commission critical reviewers were:

C. Cousins

H-G. Menzel

The membership of Committee 3 during the period of preparation of this report was:

(2009–2013)

E. Vañó (Chair)

J-M. Cosset (Vice-Chair)

M.M. Rehani (Secretary)

M.R. Baeza

L.T. Dauer

I. Gusev

J.W. Hopewell

P-L. Khong

S. Mattson

D.L. Miller

P. Ortiz López

K.Å. Riklund

H. Ringertz

M. Rosenstein

Y. Yonekura

B. Yue

(2013–2017)

E. Vañó (Chair)

D.L. Miller (Vice-Chair)

M.M. Rehani (Secretary)

K. Applegate

M. Bourguignon

L.T. Dauer

S. Demeter

K. Kang

P-L. Khong

R. Loose

C. Martin

P. Ortiz López

K.Å. Riklund

P. Scalliet

Y. Yonekura

B. Yue

MAIN POINTS

- The guidelines and recommendations on radiological protection in cone beam computed tomography (CBCT) are important because CBCT extends the use of computed tomography (CT) to areas that were not typically associated with CT imaging in the past, e.g. surgery, dental and otolaryngology [ear/nose/throat (ENT)] clinics, angiography suites, radiotherapy treatment vaults, and orthopaedic polyclinics.
- The manufacturers of CBCT scanners have invested considerable effort into meeting the electrical and mechanical safety requirements of the users. Similar diligence is needed for issues related to radiation dose and radiological protection.
- This publication provides a basis to develop informed decisions and to direct the use of CBCT for optimising the trade-off between clinical benefit and radiation risk.
- The International Commission on Radiological Protection (ICRP) emphasises that protection should be optimised not only for whole-body exposures, but also for exposures to specific tissues, especially those of the lens of the eye, the heart, and the cerebrovascular system.
- Equipment used for both fluoroscopy and CBCT should provide aggregate dose indices for individual patients throughout the procedure through electronic display on the operator console and a radiation dose structured report.
- Optimisation of both patient and worker doses, particularly when workers have to be near the machine, is important when monitoring of doses becomes an essential tool. Recording, reporting, and tracking of radiation dose for a single patient should be made possible in a consistent manner across vendors.
- Low-dose protocols may be sufficient to answer diagnostic questions focused on high-contrast structures, such as lung, bones, dental and maxillofacial scans, ENT scans (paranasal sinuses, skull, temporal bone), interventional material, and contrast-enhanced vessels (angiographic interventions).
- Higher-dose protocols should only be selected if visualisation of soft tissue structures, such as intracranial haemorrhage, soft tissue tumours, or abscesses, is the primary focus.
- Most interventional and intraprocedural C-arm CBCT systems can scan an angular range spanning 180–240° plus the cone angle of the x-ray beam. Localised critical organs, such as the thyroid, eyes, female breasts, and gonads, should be on the ‘detector side’ of the arc whenever possible.
- Clinical need permitting, every effort should be made by users to ensure that the volume of interest is fully incorporated in the field of view (FOV) provided by the CBCT scanners, while radiosensitive organs should be placed outside the FOV.
- The aim of CBCT should be to answer a specific diagnostic or intra-operative question vis-à-vis other imaging modalities, and not to obtain image quality that rivals multi-detector CT (MDCT). The decision by the referring practitioner to use CBCT should be made in consultation with an imaging professional.
- There is a need to provide checks and balances, such as dose check alerts implemented in CT in recent years, to avoid high patient doses compared with locally defined reference values.

- Methods that provide reliable estimates of dose to the eye under practical situations should be established and used.
- The user of CBCT in interventions can influence the radiation dose imparted to the patient significantly by judicious use of a 'low-image-quality or low-dose' scan instead of a 'high-image-quality or high-dose' scan.
- In radiotherapy, justified use of CBCT has potential at different stages of therapy such as: pretreatment verification of patient position and target volume localisation; evaluation of non-rigid misalignments, such as flexion of the spine or anatomical changes in soft tissue; and during or after treatment to verify that the patient position has remained stable throughout the procedure. Low-dose CBCT protocols should be used for pretreatment alignment of bony structures.
- Many machines were only capable of fluoroscopy initially, but can now also perform CBCT. Due to the improved clinical information in CBCT and its ability to remove overlying structures, the user may be tempted to over-use the CBCT mode. The CBCT mode should be used judiciously.
- In orthopaedics, justified use of CBCT can help in assessing the position of fractures and implants with respect to the bony anatomy, especially in situations where fluoroscopy alone is insufficient, and thus can help in patient dose management.
- In urology, low-dose CBCT protocols should be used when imaging high-contrast structures, such as calcified kidney stones.
- Dental and maxillofacial CBCT scans should be justified, considering alternative imaging modalities. Once justified, they should be optimised to obtain images with minimal radiation dose without compromising the diagnostic information.
- The level of training in radiological protection should be commensurate with the level of expected radiation exposure.
- All workers intending to use CBCT for diagnostic purposes should be trained in the same manner as for diagnostic CT, and those intending to perform interventional CBCT should be trained in the same manner as for interventional CT.

GLOSSARY

Absorbed dose, D

The absorbed dose, D , is the quotient of $d\bar{\varepsilon}$ by dm , where $d\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to matter of mass dm , thus:

$$D = \frac{d\bar{\varepsilon}}{dm}$$

The unit of absorbed dose is J kg^{-1} . The special name for the unit of absorbed dose is gray (Gy); $1 \text{ Gy} = 1 \text{ J kg}^{-1}$.

Automatic exposure control (AEC)

A device that automatically determines and provides the exposure needed to produce a preselected image quality by sampling the x-ray intensity at the image receptor.

Collimation

Geometrical limitation of the extent of the radiation beam.

Cone-beam computed tomography (CBCT)

In this publication, the term 'CBCT' is used to designate a subset of computed tomography (CT) scanners that share certain key design features, image quality characteristics, and application domains that distinguish this set of scanners from multi-detector CT (MDCT) scanners. The most characteristic design feature that distinguishes CBCT scanners from MDCT scanners is the use of a two-dimensional digital flat-panel detector to yield a three-dimensional volumetric image in one rotation. Flat-panel detectors in CBCT allow wide cone angle, large z-coverage, and high spatial resolution at the expense of low-contrast resolution.

Dental and maxillofacial imaging

In this publication, dental and maxillofacial imaging refers to imaging of high-contrast structures related to the teeth and jaw bones. Visualisation of other structures (e.g. maxillary sinus, temporomandibular joint, facial skeleton) can be considered as dental and maxillofacial imaging if the primary indication for imaging relates to dentistry. Ear/nose/throat imaging is considered as a separate application in this publication, although it often involves similar radiographic equipment.

Detector quantum efficiency (DQE)

A widely used metric that describes the quality of an x-ray detector. It measures the efficiency (i.e. signal-to-noise performance) of the detector to produce an image from a given incident fluence. Intuitively, it captures how well a detector translates the fluence incident on it into an image, relative to an ideal detector.

Deterministic effect

Injury in populations of cells, characterised by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Also termed ‘tissue reaction’. In some cases, deterministic effects are modifiable by post-irradiation procedures including biological response modifiers.

Diagnostic reference level (DRL)

Dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

Dose limit

The value of the effective dose or the equivalent dose to an organ received by an individual within a specified period from planned exposure situations that shall not be exceeded. Dose limitation is one of three fundamental principles of radiological protection originally defined by ICRP.

Effective dose, E

The tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body, given by the expression:

$$E = \sum_T w_T H_T$$

where H_T is the equivalent dose in a tissue or organ, T , and w_T is the tissue-weighting factor. The SI unit for effective dose is sievert (Sv), equal to J kg^{-1} .

Equivalent dose, H_T

The dose in a tissue or organ T given by:

$$H_T = \sum_R w_R D_{T,R}$$

where $D_{T,R}$ is the mean absorbed dose from radiation R in a tissue or organ T , and w_R is the radiation weighting factor. The unit for equivalent dose is the same as for effective dose (sievert, Sv), equal to J kg^{-1} .

Hounsfield unit (HU)

Number used to represent the mean x-ray attenuation associated with each elemental area of the CT image. Measured values of attenuation are transformed into HU (also known as CT numbers) using the Hounsfield scale:

$$\text{HU} = \frac{\mu_{\text{material}} - \mu_{\text{water}}}{\mu_{\text{water}}} \cdot 1000$$

where μ is the effective linear attenuation coefficient of the measured material relative to water for the x-ray beam used. The scale is defined so that water has a value of 0 HU and air has a value of -1000 HU.

Justification

One of three fundamental principles of radiological protection originally defined by ICRP. The justification principle requires that the net benefit of radiation exposure should be positive.

Multi-detector computed tomography (MDCT)

According to *Publication 102* (ICRP, 2007a), ‘MDCT systems are CT scanners with a detector array consisting of more than a single row of detectors. The ‘multi-detector-row’ configuration of MDCT scanners refers to the use of multiple detector arrays (rows) in the longitudinal direction (i.e. along the length of the patient). MDCT scanners use third-generation CT geometry in which the arc of detectors and the x-ray tube rotate together. All MDCT scanners use a slip-ring gantry, allowing helical acquisition.’ An arc of detector rows used in MDCT should be distinguished from a digital flat-panel detector typically employed by CBCT scanners, as these two different detector technologies

have a very distinct acquisition time, latency, dynamic range, and spatial resolution.

Noise

A fundamental statistical phenomenon that is present in all images. Noise tends to reduce the visibility of structures and objects, especially those that have relatively low contrast. In medical imaging, the objective is not to eliminate the noise, but to reduce it to a clinically acceptable level. Noise is the point-to-point variation in image brightness that does not contain useful information. The magnitude of noise is indicated by the standard deviation of the grey values within a region of interest in the image.

Occupational exposure

All exposure incurred by workers in the course of their work, with the exception of: (1) excluded exposures and exposures from exempt activities involving radiation or exempt sources; (2) any medical exposure; and (3) the normal local natural background radiation.

Optimisation of protection

The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors. In medical imaging, optimisation of protection implies lowest dose for the clinical purpose.

Phantom

A device that absorbs or scatters radiation in an equivalent manner to a patient, used to estimate radiation doses and test imaging systems without actually exposing a patient. A phantom may be an anthropomorphic or a physical test object.

Population dose

An expression for the aggregate radiation dose incurred by a population, defined as the product of the number of individuals exposed to a source and their average radiation dose. The collective dose is expressed in man-sieverts (man-Sv), and is intended solely as an instrument in the optimisation of radiological protection.

Scatter

Deviation of x rays from their original trajectory due to interaction with matter.

Shielding

The placement of a high-absorption material (e.g. lead) between the source and its environment for the purpose of reducing radiation dose to workers, patients, or the public.

Slice

A tomographic section (defined by the position and thickness) of a test phantom or patient under investigation during a single CT or CBCT exposure.

Stochastic effects

Malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold.

Worker

Any person who is employed, whether full-time, part-time, or temporarily, by an employer, and who has recognised rights and duties in relation to occupational radiological protection.

1. INTRODUCTION

- The guidelines and recommendations on radiological protection in cone beam computed tomography (CBCT) are important because CBCT extends the use of computed tomography (CT) to areas that were not typically associated with CT imaging in the past, e.g. surgery, dental and otolaryngology [ear/nose/throat (ENT)] clinics, angiography suites, radiotherapy treatment vaults, and orthopaedic polyclinics.
- The manufacturers of CBCT scanners have invested considerable effort into meeting the electrical and mechanical safety requirements of the users. Similar diligence is needed for issues related to radiation dose and radiological protection.
- This publication provides a basis to develop informed decisions and to direct the use of CBCT for optimising the trade-off between clinical benefit and radiation risk.

(1) The guidelines and recommendations on radiological protection in CBCT are important because CBCT extends the use of CT to areas that were not typically associated with CT imaging in the past, e.g. surgery, dental and otolaryngology (ENT) clinics, angiography suites, radiotherapy treatment vaults, and orthopaedic polyclinics.

(2) The International Commission on Radiological Protection's (ICRP) radiological protection principles and recommendations provided in earlier publications, particularly *Publications 87* and *102* (ICRP, 2000a, 2007a), apply to these newer applications and should be adhered to.

(3) The cone beam nature of the radiation field presents new challenges in dose management to ensure patient safety. The manufacturers of CBCT scanners have invested considerable effort into meeting the electrical and mechanical safety requirements of the users. Similar diligence is needed for issues related to radiation dose and radiological protection.

(4) This publication provides a basis to develop informed decisions and direct the use of CBCT for optimising the trade-off between clinical benefit and radiation risk.

(5) Appropriate use of CBCT, including radiological protection, is a joint responsibility of the referring practitioner and the imaging professionals. Imaging professionals also have responsibility towards optimisation of protection. When referring a patient for a diagnostic CBCT examination, the referring practitioner should be aware of the strengths and weaknesses for CBCT vis-à-vis multi-detector CT (MDCT), magnetic resonance imaging, and other competing imaging modalities. The decision to use CBCT should be made in consultation with an imaging professional.

(6) In this publication, the term 'CBCT' is used to designate a subset of CT scanners that share certain key design features, image quality characteristics, and application domains that distinguish this set of scanners from MDCT scanners. The most characteristic design feature that distinguishes CBCT scanners from MDCT scanners is the use of a two-dimensional (2D) digital flat-panel detector (FPD) to yield a three-dimensional (3D) volumetric image in one rotation. FPDs in CBCT allow a wide cone angle, large z-coverage, and high spatial resolution at the expense of low-contrast resolution. Some cone beam scanners still use an image-intensifier

tube. These scanners have a lot in common with flat-panel-based CT scanners and should be considered as CBCT devices. All CBCT scanners have a wide cone angle and large z -coverage. The use of a flat panel or image intensifier as a detector means that CBCT scanners have a lower dynamic range and lower soft tissue contrast than MDCT scanners, making them suitable for high-contrast structures such as bones and contrast-enhanced vasculature. Generally, CBCT scanners require longer scan times.

(7) It should be noted that a wide cone angle or large z -coverage is not, in itself, sufficient to define a CBCT scanner for the purposes of this publication. Many traditional MDCT scanners, built using individual rows of detectors made of scintillating ceramics, have a wide cone angle and large z -axis coverage. For example, the Aquilion One™ (Toshiba Medical Systems) is a 320-row scanner with 16 cm of z -coverage. This scanner, and others in its class, should be designated as wide-area MDCT scanners rather than CBCT scanners.

(8) CBCT represents an emerging technology that enables high-resolution volumetric scanning of the anatomy under investigation. Just as in MDCT, use of CBCT is increasing steadily in clinical practice. Although it is a relatively new modality, CBCT is already being used for a variety of clinical applications, such as dental imaging, head and neck imaging (including sinus CT), paediatric imaging, high-resolution bone imaging, and intra-operative and interventional imaging.

(9) CBCT imaging is also used in radiotherapy for pretreatment verification of patient position and target volume localisation. In this case, the CBCT system is usually mounted on the gantry of a linear accelerator at 90° to the therapeutic beam. For radiotherapy, CBCT imaging is often used for daily repositioning. Under classical fractionation schedules, high cumulative imaging dose to tissues outside the exposure field can accrue.

(10) Although the concept of CBCT has existed for over 25 years, it has only recently become possible to develop clinical CBCT systems that are both sufficiently inexpensive and sufficiently small to be used in operating rooms, outpatient clinics, emergency rooms, and intensive care units. Technological and application-specific factors that have converged to make clinical CBCT possible are:

1. compact, high-quality FPD arrays;
2. computer power sufficient for timely cone beam image reconstruction;
and
3. x-ray tubes designed for cone beam scanning.

(11) Most modern CBCT systems use a digital FPD instead of an image intensifier for image capture. By virtue of these specialised detectors, which are different from the detectors used in conventional MDCT, CBCT is capable of ultra-high spatial resolution and large-volume coverage in a single (or partial) rotation of the C-arm. Digital FPDs used in CBCT scanners also enable fluoroscopy, radiography, volumetric CT, and dynamic imaging using a single or partial rotation. These capabilities are extremely useful for intra-operative and vascular applications.

(12) The manufacturers of CBCT scanners have invested considerable effort into meeting the electrical and mechanical safety requirements of the users, which are mandated by national regulatory bodies. Similar diligence is needed for issues related to radiation dose. In this respect, the cone beam nature of the radiation field presents new challenges in dose management to ensure patient safety; guidelines are needed for various stakeholders in this new modality. This publication briefly describes the current state-of-the-art CBCT technology, reviews current dose measurement and management approaches, provides recommendations for safe use of CBCT scanners, and identifies gaps that relate to radiological protection where further research is needed.

(13) CBCT systems differ from MDCT systems in several ways that affect image quality and radiological protection. Some key differences are listed below.

(14) Due to the cone beam nature of the irradiated field and the associated non-uniformities in the primary and scatter radiation imparted to the scan volume, the standard dose metrics popularised by MDCT cannot be applied to CBCT, or even to wide-area MDCT scanners.

(15) CBCT systems usually have superior spatial resolution for high-contrast objects (e.g. bone, lung), but inferior contrast resolution for low-contrast objects (e.g. soft tissue). A trained and skilled user of CBCT can influence the radiation dose imparted to the patient significantly by judicious use of 'high-dose' and 'low-dose' scans. A high-dose scan is generally required if soft tissue structures are the main diagnostic focus, while a low-dose scan may be sufficient for angiographic scans with arterial or venous contrast media, or for defining the position of interventional catheters.

(16) Due to the higher spatial resolution of an FPD, CBCT slices are intrinsically thinner and have lower signal-to-noise ratios (SNRs) for the same dose than MDCT slices. Any attempt to match the SNR in a thin CBCT slice with a thick MDCT slice will result in a proportionate increase in dose. Instead, increasing the slice thickness, or other similar image processing methods, should be applied to improve the SNR in CBCT.

(17) In many CBCT scanners, the angular span over which the projection data are acquired can be customised. This feature may also be available in some MDCT scanners (e.g. some systems allow tube current to be reduced when the beam is covering radiation-sensitive organs such as the breast, thyroid, or lens of the eye). It should be used in both types of scanner systems to minimise the dose to selected organs.

(18) The purpose of this publication is to identify radiological protection issues for patients and workers and, in line with other ICRP publications, recommendations are set out for all stakeholders ranging from day-to-day clinical users, auxiliary support workers, buyers, manufacturers, and policy directing committees.

(19) The primary target audience of this publication, as for most other publications produced by the Commission related to protection in medicine, is health professionals working with CBCT, other workers tasked with radiological protection

and image quality optimisation in CBCT, manufacturers of imaging equipment, regulators, and policy makers in charge of radiological protection.

1.1. History of development

(20) The first CBCT scanner was built for angiography at the Mayo Clinic, Rochester, NY, USA in 1982 (Robb, 1982). Multiple teams in the early 1990s pursued the idea of multi-angle projections from a wide-area detector for medical imaging. For example, Saint-Félix et al. (1994) tested a system called the ‘Morphometer’ consisting of two imaging chains, each with an x-ray tube and an image intensifier. This CBCT system was designed for 3D angiography using the gantry of a conventional CT scanner. It reconstructed vascular images from a set of digitally subtracted angiography images. This gantry platform, which was never released clinically, was abandoned in favour of a C-arm supporting a single imaging chain.

(21) Fahrig et al. (1997, 1998) also developed a CBCT system based on an image intensifier and C-arm for use in angiography. Wiesent et al. (2000) developed a similar system comprising a C-arm plus an image intensifier for interventional angiography. Ning et al. (2000a,b) and Wang (1997) developed a CBCT angiography imager based on a GE 8800 CT scanner with an image intensifier–charge-coupled device chain and later with an FPD. Schueler et al. (1997) and Kawata et al. (1996) developed a CBCT angiography scanner based on a biplanar C-arm system.

(22) Siewerdsen and Jaffray developed a CBCT system for radiotherapy guidance based on an amorphous silicon FPD (Siewerdsen and Jaffray, 1999, 2001; Jaffray and Siewerdsen, 2000). Efforts are also underway to build a dedicated CBCT-based imaging system for mammography (O’Connell et al., 2010; Kalender et al., 2012; Packard et al., 2012).

(23) CBCT devices were introduced in dental and maxillofacial radiology in the late 1990s (Mozzo et al., 1998; Arai et al., 1999).

1.2. Current standards in radiological protection in CBCT

(24) The guidelines and recommendations on radiological protection in CBCT are particularly important as CBCT extends the use of CT to areas that were not typically associated with CT imaging in the past, e.g. surgery, dental and otolaryngology (ENT) clinics, angiography suites, and orthopaedic polyclinics. Fundamentally, CBCT is a form of CT; as such, most facility design and quality assurance (QA) requirements that apply to MDCT should also be applied to CBCT. This, however, can lead to an erroneous impression that CBCT is identical to MDCT, making it difficult to manage CBCT from operational and radiation safety points of view. Further complications arise when a user is tempted to regard CBCT as a ‘light’ or ‘low-dose’ CT; a view that is maintained because CBCT functionality is often an adjunct to existing capabilities, such as fluoroscopy and angiography in a C-arm or other clinic-based system. Embedded in these user biases is the risk for potential

overuse of CBCT resulting in unnecessary radiation dose to the patients and/or workers.

(25) Traditionally, the use of CBCT in dentistry has entailed a relatively low radiation dose. However, this is not always the case, and many recent applications of CBCT, especially in ENT and interventional procedures, can impart much higher radiation doses that equal or exceed those from MDCT (Kyriakou et al., 2008a; Dijkstra et al., 2011; Schulz et al., 2012). There are also situations in which multiple CBCT procedures have to be performed on one patient (such as CBCT-guided interventions), enhancing the need to keep the inflicted radiation dose to a minimum. Therefore, dose implications of CBCT pose a risk from the perspective of an individual patient, as well as for the risk from radiation exposure of the population as a whole.

(26) Imaging professionals and medical physicists are well aware of the radiation dose issues in CT. This knowledge, however, does not directly translate to CBCT, for which the trade-off between image quality and radiation dose can be quite complex. At the same time, clinical users, as well as those undertaking QA and members of radiation safety committees, need clear guidelines on operating and regulating these systems. This publication, which is thought to be the first on radiological protection in CBCT from an international source, provides a basis for developing informed clinical decisions on the use of CBCT and guidance for optimising the trade-off between clinical benefit and radiation risk.

1.3. Responsibilities of different stakeholders

(27) Approximately 80 million CT scans are performed every year in the USA, and this number is increasing on a yearly basis (Sierzenski et al., 2014). Multiple recent papers have drawn attention to the population dose from these scans (Brenner, 2010). There is also increasing realisation that a large fraction of this radiation dose to the population is avoidable as it comes from unjustified or inappropriate examinations. Currently, data on inappropriate use are mostly available for CT rather than CBCT. Appropriate use of CT scanning is a joint responsibility of the referring practitioner and the imaging professional, and most national regulations assign this responsibility either jointly or to the imaging professional. As a referring practitioner best understands the clinical need for the examination, he/she must interact with an imaging professional to decide upon the radiological examination or procedure that is in the best interests of the patient. Electronic referrals with decision support have the potential to simplify and streamline this interaction while making this process more evidence based (Sistrom et al., 2009). Such systems can go a long way towards facilitating the desired radiological examination performed with the lowest radiation dose, while maintaining the image quality needed for the clinical purpose. Practitioners, technologists, and medical physicists must understand their roles and responsibilities in this endeavour. To this end, there is a need to further develop methods that facilitate the interaction between referring

practitioner and imaging professional to translate their joint responsibility for radiological safety into practice.

(28) Over the years, manufacturers have played a vital role in technological developments to reduce patient doses from particular CT examinations. The Commission, while acknowledging this role, hopes that manufacturers will remain at the forefront of developing new technologies for radiological protection of patients and workers.

1.4. Why is it important to know CBCT doses?

(29) It is easy for a practitioner, not versed in the details of dose management, to dismiss CBCT as upgraded fluoroscopy coupled with 3D reconstruction. For the most part, the dose from CBCT is indeed lower than that from MDCT, which may reinforce this belief. However, uncritical application of CBCT under the assumption that it is a modality with minimal dose consequences could result in significant doses in some circumstances, and is not appropriate for protection of the patient.

(30) CBCT is a relatively new development in clinical practice. Data on radiation doses and possible effects of CBCT are still being gathered and analysed. Even at this early stage, however, studies indicate that there is room for optimisation to keep the radiation dose as low as reasonably achievable. This publication systematically summarises the available dose data related to use of CBCT, and discusses radiological protection issues for patients and workers. Given the potential of CBCT to become a significant source of radiation dose to patients in the future, it is appropriate to be mindful of the radiation exposure while using the full diagnostic potential of this exciting modality. In 1999–2000, while preparing *Publication 87* (ICRP, 2000a; Rehani and Berry, 2000), the Commission had similarly presaged the need to watch for increasing radiation doses from MDCT. Although this concern was not well appreciated at that time, it has become a major issue in subsequent years with multiple high-profile reports in the media. This publication provides a similar review of the current CBCT literature, and presents the data regarding radiation doses to patients and workers associated with the use of CBCT.

1.5. Safety in perspective

(31) Safety is achieved most readily when it is built into the system, rather than a matter of choice for users. A good example is a collision avoidance system; an innovation that started in the automobile industry but has been implemented in multiple types of imaging gantries to avoid accidents. With such a system in place, if the gantry of the imaging device comes into contact with a person or object, it simply stops moving. In the absence of such a system, when collision avoidance has to be accomplished primarily via user education, training, and instructions, the risk of injury from collisions will be higher. There are instances when both detection of an anomalous condition and its automatic avoidance cannot be implemented simultaneously. In such cases, detection and warning may accomplish a similar end result.

For example, radars for detection of speed limits have been shown to decrease the incidence of speeding violations.

(32) For radiation safety in MDCT, a display of radiation exposure information on the operator console has been present for a number of years. After a series of accidental exposures was reported in the USA in 2007–2008, MDCT systems can now automatically detect settings to prevent accidental exposure (NEMA, 2010). Such systems provide an additional layer of non-intrusive checks and balances in the conduct of a scan. Display of such information on CBCT consoles needs to be standardised. The Commission recommends development and implementation of safety systems that require the least amount of interaction from the operator and workers while providing:

- regular and continuous monitoring of radiation output throughout the examination;
- automatic comparison with reference or desired dose levels that need to be established;
- timely feedback to the system operator;
- wide availability of automatic adjustment of the dose to a prescribed level in a manner that is somewhat similar to automatic exposure control (AEC); and
- alerts when dose is higher than specified. Currently, dose checks do not apply to CBCT systems (NEMA, 2010).

(33) Other technologies that many CBCT vendors need to implement uniformly include automatic collimation control so that the x-ray beam always falls on the detector, guidance for instruments during image-guided interventions, and minimisation of scatter dose resulting from mechanical components.

1.6. Scope of this publication

(34) As a substantial amount of information is currently available on dental and maxillofacial CBCT, including a publication issued by the European Commission (EC) project SEDENTEXCT (Safety and Efficacy of a New and Emerging Dental X-ray Modality) (<http://www.sedentext.eu/>) (EC, 2012a), the decision was made to cover dental and maxillofacial CBCT briefly in this publication

(35) It should be emphasised that the main focus of this report is on doses to patients and workers from CBCT acquisitions. CBCT acquisition can be part of fluoroscopically guided procedures. In such cases, it is necessary to account for the dose from fluoroscopy and relevant implications. *Publication 117* included information pertinent to radiological protection of patients and workers in fluoroscopic procedures performed outside the imaging departments (ICRP, 2010), and *Publication 120* covered radiological protection of patients and workers during interventional fluoroscopy (ICRP, 2013). The term ‘patient dose’ has been used in this publication in a qualitative and relative sense, and wherever quantitative figures are provided, the appropriate dose quantity [i.e. skin dose, organ dose, kerma-area product (KAP), effective dose, etc.] has been mentioned.

2. CBCT TECHNOLOGY

2.1. Introduction

(36) In the past decade, development of digital FPDs for conventional x-ray radiography, fluoroscopy, and mammography has propelled the use of CBCT into the mainstream of medical imaging. Most CBCT systems in current use leverage the power of dynamic FPDs (i.e. able to acquire several frames s^{-1} compared with static FPDs) to provide volumetric 3D datasets.

(37) A C-arm gantry consisting of a digital FPD and a large cone-angle x-ray tube is the most commonly used platform for CBCT. There are a number of other implementations of CBCT that differ in the mechanical gantry used for scanning, the detector subsystem, the type of x-ray tube and filtration, the cone angle employed for imaging, and the algorithm used for reconstructions. The following section describes and introduces different types of CBCT scanners.

2.2. Technological issues

(38) As far as tomographic capabilities of a CBCT scanner are concerned, in simple terms, one can think of them as a conventional MDCT in which the rows of detector elements (typically 16–64 rows) have been replaced by an area detector (Ross et al., 2004; Grasruck et al., 2005; Popescu et al., 2005). In general, a CBCT scanner consists of an x-ray source, a detector, and a gantry to move this imaging chain around the patient. The most commonly used subsystems are described briefly below.

2.2.1. X-ray source

(39) The x-ray source used in a CBCT scanner must provide a broad, cone-shaped beam of radiation. Consequently, CBCT scanners use a much larger anode angle than a tube used in an MDCT scanner. Typical operating conditions are an x-ray tube voltage of 50–140 kVp, a tube current of 10–800 mA, and a total power of 10–80 kW. In order to take advantage of the small detector pixel size, the focal spot size ranges from 0.2 mm to 0.8 mm. The typical field of view (FOV) covered in one rotation, using a single FPD, can be as much as 25 cm in the angular direction, and 20 cm in the z -direction. Larger sizes are possible when multiple panels or dual scans are used, such that the principal axis of the x-ray illumination is offset from the centre of the panel to allow beam correction.

2.2.2. Detector

(40) While some older systems still use an image intensifier, most modern CBCT scanners use a digital FPD. FPDs provide higher dose efficiency and dynamic range

than other detector technologies they replaced (x-ray film, film/screen combinations, and image intensifiers); however, their dynamic range is lower than that of standard MDCT detectors (Miracle and Mukherji, 2009a). FPDs also generally provide higher spatial resolution than image intensifiers and conventional detector arrays used in MDCT. Direct digital readout up to 30 frames s^{-1} ensures that the data are available in a directly usable form for both projection and 3D reconstruction.

(41) The native resolution of a flat panel is typically at or below 200 μm , although higher resolution detector panels are available. After accounting for magnification and x-ray focal spot size, this yields an isotropic voxel resolution of approximately 150 μm . Generally, in 3D acquisition mode, FPDs are operated in a 2×2 binning mode (summing signals from two rows and two columns to increase the SNR and the readout speed, and reduce the matrix size), and the isotropic resolution is of the order of 200 μm . Therefore, compared with conventional MDCT scanners, a flat-panel-based CBCT system improves the spatial resolution by a factor of almost 12 on a voxel-by-voxel basis. Its high spatial resolution is capable of visualising complex human anatomy, including fine structures of the maxillofacial region and skull base.

(42) Typically, FPDs used in CBCT are composed of a matrix of detector elements that can span anywhere from $5 \times 5 \text{ cm}^2$ to $40 \times 40 \text{ cm}^2$. Such scanners, therefore, are capable of producing a large number of slices spanning anywhere from 5 to 20 cm in one rotation. The z -coverage afforded by these scanners can be large enough to image an entire organ such as the brain, heart, liver, or kidneys in one axial scan.

2.2.3. Gantry

(43) Depending on the mechanical system of the gantry, CBCT scanners can allow conventional fluoroscopy, angiography, and radiography in the same setup as well as providing high spatial resolution and large-volume coverage. These facilities make such machines especially attractive for intra-operative and vascular applications. The various gantry platforms in common use are described below.

C-arm-based CBCT

(44) All major imaging equipment vendors now provide C-arm scanners that employ digital FPDs integrated with a C-arm gantry (Fig. 2.1). The C-arm platform offers open architecture and ready patient access. There are two major C-arm-based setups that need to be distinguished: C-arm-based interventional CBCT systems and dedicated C-arm-based CBCT systems.

(45) *C-arm-based interventional CBCT systems.* One can use the C-arm for fluoroscopy and projective angiography (including digitally subtracted angiography). However, by putting the C-arm in a fast-spin mode while acquiring images, one can obtain projection data that can be converted into relatively high-quality, high-contrast CT images. Interventional procedures are usually performed using

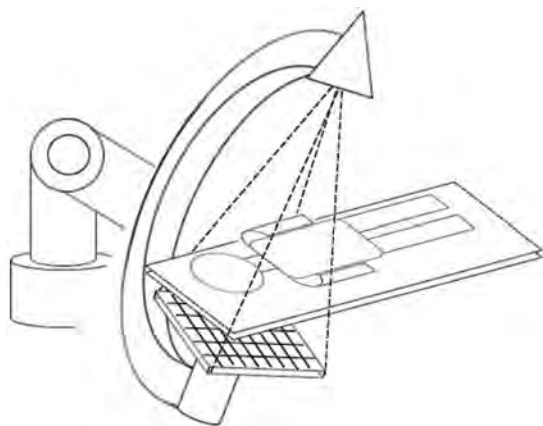


Fig. 2.1. C-arm-based cone beam computed tomography. A C-arm is used to mount the imaging chain, and this provides the necessary amount of freedom required to revolve around the patient. C-arm systems are used in surgical, orthopaedic, urologic, or interventional environments (image provided by Rolf Kueres).

fluoroscopy. The operator can use the CBCT mode intermittently for clarification and 3D localisation (Orth et al., 2008; Schafer et al., 2011). These machines, therefore, enable a seamless integration of these previously separate modalities. They are used in angiographic, surgical, orthopaedic, urologic, and other interventional settings.

(46) *Dedicated C-arm-based CBCT systems.* A number of systems dedicated for dental, ENT, head and neck, extremity imaging, and mammography are available. One popular variation of C-arm-based CBCT systems is the so-called ‘seat scanner’, in which a small C-arm, with a horizontal imaging chain consisting of an FPD and an x-ray tube, revolves around the head of the patient while they sit on a chair (Fig. 2.2). Alternatively, for certain models, the patient is in a supine or standing position. These scanners are dedicated to dental, maxillofacial, and temporal bone applications because of their relatively small scan FOV. Besides weight and mechanical considerations, there is no fundamental reason why their FOV cannot be increased. They are currently limited to these niche applications.

CT-gantry-based CBCT

(47) A flat-panel volume CT scanner combines a continuously rotating CT gantry with digital FPD technology (Fig. 2.3). It is, in fact, a CT machine in which the detector rows have been replaced by an FPD. From an operational point of view, the main difference between a CT-gantry-based and a C-arm-based cone beam system lies in basic engineering: the gantry-based systems are more stable and have fewer

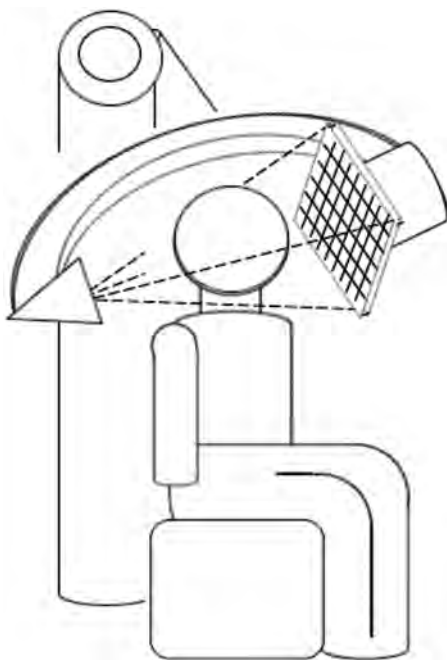


Fig. 2.2. Clinic-based cone beam computed tomography. The imaging chain is mounted on a horizontal rotating C-arm. These systems are usually used in head and neck applications (image provided by Rolf Kueres).

geometric inaccuracies compared with the C-arm-based systems. In addition, the isocentre of any CT gantry, by virtue of its mechanical design, is defined much more precisely than the best C-arm gantries. As a result, gantry-based designs may, in most cases, offer better spatial resolution.

(48) In a C-arm system, the detector and the x-ray tube are connected to the control hardware by an umbilical cord of cables that prevents them from spinning continuously around the patient. This is not the case for a CT-gantry-based system, in which a slip ring is used to take data from a rotating component. Elaborate collision avoidance schemes have been implemented to ensure operator safety. No such concerns exist for CT-gantry-based systems.

(49) By virtue of an FPD, CT-gantry-based CBCT systems are capable of ultra-high spatial resolution, direct volumetric imaging, and continuous rotation around a patient. Continuous rotation enables dynamic CT scanning; the ability to observe a process evolving with time [e.g. perfusion of an entire organ such as the brain, liver, or kidney (e.g. after transplant or an ischaemic event)].

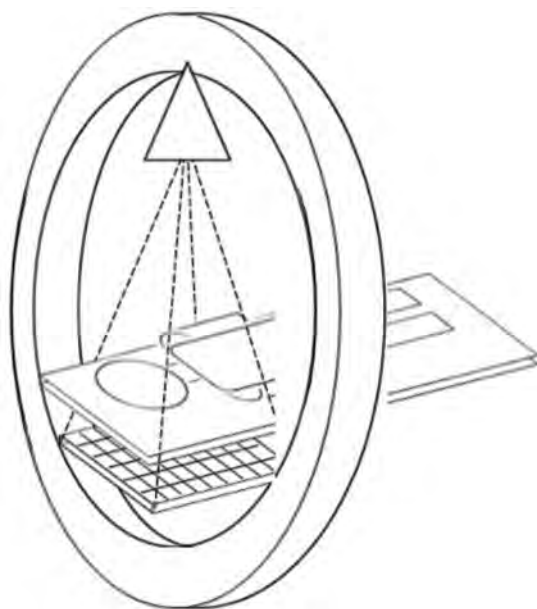


Fig. 2.3. Gantry-based cone beam computed tomography. The patient lies on a patient bed, and the imaging chain revolves around the patient as in multi-detector computed tomography (image provided by Rolf Kueres).

CBCT in radiotherapy

(50) In radiotherapy, CBCT is used for precise alignment of the target volume with a therapeutic, hard x-ray beam from a linear accelerator. Two separate arrangements (kV CBCT and MV CBCT) are popular. In kV CBCT, a separate imaging chain consisting of an x-ray tube operated in the kV range is used as the x-ray source, and an FPD is used for imaging. The entire imaging chain is mounted on the linac gantry, in an orientation that is orthogonal to the therapeutic beam. Similar to C-arm systems, a linac gantry only rotates up to 360° , after which the gantry must be rotated back. Some systems enable a larger FOV to be imaged by scanning target volumes asymmetrically using two 180° rotations, and shifting the FPD laterally for the second. Such systems use separate half-bowtie filters for the two parts of the scan. A routine CBCT scan is conducted prior to therapy for precise alignment.

(51) MV CBCT uses the high-energy x rays from the linac itself for imaging. An FPD that can operate at very high x-ray photon energies is used to acquire the projection data, and a separate imaging chain is not required. Given the high photon energy and associated decrease in photoelectric absorption, the soft tissue contrast of MV CBCT is markedly worse than that of kV CBCT. However, it is

sufficient to visualise bony anatomy, which may be acceptable for alignment purposes.

Co-integrated systems

(52) Co-integrated systems exist mainly in nuclear medicine (e.g. single photon emission tomography) (Sowards-Emmerd et al., 2009). Here, a flat-panel CBCT system is mounted on the same gantry as the nuclear imaging chain. The CBCT data are used for attenuation correction and anatomical localisation.

2.3. Clinical scenarios where CBCT is used

(53) In current clinical practice, CBCT scanners are used for a variety of imaging applications ranging from preclinical to clinical imaging (Table 2.1). Their use is primarily motivated by taking advantage of the following characteristics: (1) combining dynamic fluoroscopy/angiography and tomographic imaging; (2) large z-coverage; and (3) high-resolution imaging of high-contrast structures.

Table 2.1. Cone beam computed tomography (CBCT) in a variety of medical applications ranging from research to clinical imaging.

Application	Setup	Synonyms	Main reason why CBCT is used*	Use cases	Common use examples of CBCT
Non-vascular interventional procedures	C-arm system	3D C-arm, CBCT	1, 2	Liver intervention, abscess drainage, skeletal interventions	Spatial position of intervention instruments and material
Vascular head/body interventions	C-arm system	Angiographic CT, rotational angiography CT	1	Tumour embolisation, bleeding, revascularisation in peripheral occlusive disease	Spatial position of intervention instruments, rule out bleeding, embolisation therapy control
Vascular cardiac interventions	C-arm system	Rotational angiography CT	1	Electrophysiological catheter ablation	Spatial position of intervention instruments
Orthopaedic interventions	Mobile C-arm/O-arm systems		1, 2	Osteosynthesis	Spatial position of implants, complex fractures
Radiation therapy planning/guidance	Gantry or C-arm (with treatment system)		2	Tumour therapy	Patient registration, physiological motion control
Dental and maxillo-facial, ENT	Over-the-head C-arm 'seat-scanner'/gantry based	DVT	3	Dental workup, paranasal sinus, temporal bone	Diagnostic imaging, datasets for navigation (e.g. implant placement)
Breast [†]	Horizontal gantry based		2, 3	Rule out carcinoma, biopsy	

(continued on next page)

Table 2.1. (continued)

Application	Setup	Synonyms	Main reason why CBCT is used*	Use cases	Common use examples of CBCT
Urology	C-arm		2, 3	Lithotripsy, diagnostic workup	Diagnostic imaging, stone detection
Nuclear medicine hybrid imaging (SPECT/CT)	Transmission and emission systems mounted on rotating gantry		2	Attenuation correction, anatomical localisation (fused physiological and anatomical data sets)	Myocardial perfusion imaging, skeletal imaging, oncology imaging
Peripheral bone imaging	C-arm/gantry based		3	Osteoporosis	Bone microstructures, bone density
Animal imaging/specimen imaging	Bench-top, gantry based		2, 3	Research and veterinary	Experimental imaging

3D, three dimensional; CT, computed tomography; ENT, ear/nose/throat; DVT, digital volume tomography; SPECT, single photon emission computed tomography.

*1, combining dynamic fluoroscopy/angiography and tomographic imaging; 2, large z-coverage; and 3, high-resolution imaging of high-contrast structures.

†Digital breast tomosynthesis may also be regarded as a form of limited-angle CBCT with a specialised reconstruction algorithm.

3. BIOLOGICAL EFFECTS OF RADIATION

- **ICRP emphasises that protection should be optimised not only for whole-body exposures, but also for exposures to specific tissues, especially those of the lens of the eye, the heart, and the cerebrovascular system.**

3.1. Introduction

(54) The health effects of ionising radiation are classified into two main categories: tissue reactions (deterministic effects) and stochastic effects. Tissue reactions include skin erythema, hair loss, cataracts, infertility, vascular disease, and haematopoietic and gastroenterological effects. Stochastic effects, on the other hand, are cancer and heritable (genetic) effects.

(55) Tissue reactions appear when the radiation dose exceeds a specific threshold. The severity of the reaction depends on the total radiation dose received by the organ or part of the organ. Stochastic effects are governed more by the inherent randomness in microscopic interactions between radiation and biological matter. In most cancer models, the probability of cancer induction due to exposure to radiation is considered to be proportional to the radiation dose. Moreover, for the purpose of radiological protection, no matter how low the radiation dose, theoretically there is always a small probability that it will induce cancer or heritable effects.

3.2. Tissue reactions

(56) For tissue reactions, the damage to cells is related directly to radiation dose, and a dose threshold exists. *Publication 103* (ICRP, 2007b) states that, ‘The reason for the presence of this threshold dose is that radiation damage (serious malfunction or death) of a critical population of cells in a given tissue needs to be sustained before injury is expressed in a clinically relevant form. Above the threshold dose, the severity of the injury, including impairment of the capacity for tissue recovery, increases with dose.’ Tissue reactions have thresholds that are typically of the order of a few hundred mGy. Skin effects may occur at absorbed doses of 3 Gy; threshold doses for other organs are provided in Table 3.1.

(57) As a classical example, erythematous effects commonly occurred on workers’ hands during the early days of radiology, about a century ago. Such symptoms have occurred rarely in workers using medical x rays in the last 50 years. However, skin injuries have been observed among patients due to fluoroscopic procedures in interventional radiology and cardiology (ICRP, 2000b, 2013; Balter et al., 2010; Rehani and Srimahachota, 2011). Also, in interventional procedures, problems including hair loss and chronic occupational dermatitis have been reported for radiologists and cardiologists on body parts unprotected by the lead apron or lead table shield (Wiper et al., 2005; Rehani and Ortiz López, 2006). To the best of the authors’ knowledge, there have been no reports, to date, of skin injuries in patients undergoing CBCT. Regarding MDCT, skin injuries have been observed in the past few years

Table 3.1. Estimates of threshold organ doses for tissue effects in adult human testes, ovaries, lens of the eye, and bone marrow.

Tissue and effect	Threshold for total dose in a single exposure (Gy)	Threshold for annual dose in the case of fractionated exposure (Gy year ⁻¹)
Testes		
Temporary sterility	0.15	0.4
Permanent sterility	6.0	2.0
Sterility	3.0	>0.2
Lens of the eye		
Cataract (visual impairment)	0.5	
Bone marrow		
Depression of haematopoiesis	0.5	>0.4
Heart or brain		
Circulatory disease	0.5	

Reproduced from ICRP (2007b; Table A.3.1) with updated information regarding the lens of the eye and heart from ICRP (2012b).

in patients undergoing MDCT scans, mainly as a result of inappropriate use of scanners (ICRP, 2007a). Hair loss has been reported among patients undergoing brain perfusion CT (Bogdanich, 2009, 2010; Wintermark and Lev, 2010). Although skin injuries related to CBCT have not been reported among patients or workers, the technique is relatively new; as use of CBCT increases, there may be potential for such injuries, particularly in cases of poor radiological protection practice.

(58) Besides skin injuries, there have been recent reports of radiation effects on the lens of the eye, which is one of the most radiosensitive tissues in the body (Rehani et al., 2011; ICRP, 2012). Radiation-induced cataracts have been demonstrated among workers involved in interventional procedures using x rays (Vaño et al., 1998; ICRP, 2000b), but not with CT or CBCT. However, an earlier study by Klein et al. (1993) and a more recent study by Yuan et al. (2013) indicated that there may be elevated risk for damage to the lens of the eye in patients undergoing CT scans. Similar risks can be anticipated in patients undergoing CBCT (e.g. in neuroradiological interventions when the eye is exposed to the primary beam). Currently, there is a paucity of data and it is difficult to judge the risk for patients. Caution is recommended where the primary beam irradiates the eye, and thus careful attention to optimisation is necessary.

(59) In addition to patients, there are populations exposed to low doses. For some such groups, lens opacities have been documented, including workers in interventional suites (Ciraj-Bjelac et al., 2010, 2012; Vaño et al., 2010, 2013; Rehani et al., 2011), astronauts (Cucinotta et al., 2001; Rastegar et al., 2002), radiological technologists/radiographers (Chodick et al., 2008), atomic bomb survivors (Nakashima

et al., 2006; Neriishi et al., 2007), and people affected by the Chernobyl accident (Day et al., 1995).

(60) Recent epidemiological data suggest that tissue reactions can occur at threshold doses that are lower than considered previously (ICRP, 2010, 2012). These reactions usually take a long time to manifest. For lens opacities, the threshold for damage is now considered to be as low as an absorbed dose of 0.5 Gy, whereas it was previously set at 2 Gy (depending upon exposure scenario). The absorbed dose threshold for circulatory disease has been chosen as 0.5 Gy to the heart or brain, as a precautionary value. ICRP policy has been not to set any dose limits for patients. However, the current recommendation of ICRP for occupational exposure in planned exposure situations is an equivalent dose limit for the lens of the eye of 20 mSv year^{-1} , averaged over a defined 5-year period, with no single year exceeding 50 mSv (ICRP, 2012). Occupational doses to the lens of the eye of a few μGy in CBCT have been reported in the literature. Doses to the lens of the eye for patients are a few mGy for dental and head and neck CBCT with direct exposure, but doses are much higher for interventional CBCT. Details regarding doses to the lens of the eye in CBCT for patients and workers are available in Sections 6 and 7.

3.3. Stochastic effects

(61) Cancer and heritable effects come into the category of stochastic effects. The probability of carcinogenic effects is much higher than that of heritable effects. This follows from *Publication 103* (ICRP, 2007b) which states that the detriment-adjusted nominal risk coefficient or stochastic effects for the whole population after exposure to low doses of radiation is $5.5\% \text{ Sv}^{-1}$ for cancer and $0.2\% \text{ Sv}^{-1}$ for heritable effects. The latter is a theoretical risk for humans, as all documented cases of radiation-induced heritable effects come from observations in non-human species. Cases in humans have not been observed, even for atomic bomb survivors. Therefore, after careful review of many decades of literature, ICRP has reduced the tissue-weighting factor for the gonads relating to the risk of heritable effects to less than half the previous value, from 0.2 to 0.08 (ICRP, 2007b).