WG 1: Optimisation of Patient Exposure in CT Procedures

- Synthesis Document –

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Introduction

Working Group 1 focussed on the "*Optimisation of Patient Exposure in CT Procedures*". Originally, the mandate included occupational exposures, too. But it was decided by the *Steering Committee* not to work on this issue, since CT fluoroscopy – the only application of CT relevant to occupational exposures – will be dealt within the framework of *Working Group 2*.

The working group includes representatives of the relevant scientific bodies, i.e. EURADOS, EFOMP, EFRS and ESR, as well as well-known experts in the field of CT technology, risk assessment and medical exposures. The details are summarized in the table below:

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As a first step, the working group developed a matrix structure with seven pillars and eight cross-cutting issues relevant to the optimisation of patient exposure in CT procedures:

Pillars	Cross-cutting Issues
CT medical exposures	CT paedriatics
CT risk / benefit estimation	CT oncology
CT dose reduction techniques: equipment	CT cardiology
CT dose reduction techniques: protocols	CT function: contrast enhanced dynamic investigation
CT dose efficiency parameters	CT colonography
CT dose reporting	CT screening
CT diagnostic reference levels	Networking
	training and education

Based on this matrix structure, the working group defined the following working packages (WP) and the corresponding responsibilities:

#	Working Package (WP)	Responsible
1	CT medical exposures	J. Griebel (Lead), E. Nekolla
2	CT risk / benefit estimation	J. Griebel (Lead), E. Nekolla
3	CT dose reduction techniques: equipment	M. Prokop
4	CT dose reduction techniques: protocols	M. Prokop
5	CT dose efficiency parameters	H. D. Nagel
6	CT dose reporting	M. Ginjaume
7	CT diagnostic reference levels	V. Tsapaki
8	Training & education	D. Pekarovic (Lead), D. Pronk-Larive, V. Tsapaki

WP 1 was included to underline the pivot impact of CT on medical exposures and the resulting need for reduction of CT patient doses. As a direct consequence of the findings in WP 1, a review on CT risk / benefit – as provided in WP 2 for both healthcare and individual health assessment (opportunistic screening) - is imperative, since an appropriate risk / benefit assessment is a prerequisite for any justification of CT procedures. Concerning healthcare, it is concluded that a reliable benefit-risk analysis of radiological imaging procedures has to be broken down to diagnosis-related groups of patients, and it is recommended to launch research projects addressing these important issues. Concerning individual health assessment, it is underlined that - when some CT procedures, such as CT colonography, are considered as an acceptable option for cancer screening - these CT procedures have to be embedded in a well-established screening algorithm and have to be properly quality assured along the whole screening chain, and that respective actions have to be initiated on a national and / or international level. In addition, in WP 2, the strong interrelation between justification and optimisation for the reduction of CT patient doses is addressed. Unfortunately, the review indicate that actions initiated by international radiation protection organizations and national regulators often show the tendency to suggest separate approaches to develop and consolidate both fundamental principles of medical radiation protection.

WPs 3 to 7 directly address the issue of optimisation of CT patient exposure. This is in particular valid for WPs 3 and 4, highlighting the impact of equipment and protocols on CT dose reduction.

WP 5 addresses a promising approach that may have a significant impact on CT patient dose reduction and, as a consequence, on upcoming regulations on CT. The introduction of a dose efficiency parameter, that characterises CT scanners with respect to image quality in relevant clinical scenarios, would facilitate decision making when purchasing a new scanner, allow for a fair competition between manufacturers, and enable to set the appropriate dose level in protocol optimization.

In WP 6 on CT dose reporting, it is noted that the *European Guidelines on Quality Criteria for Computed Tomography* were published in 2000. Later, the EC funded, as part of its 6th Framework Programme, the project *CT Safety & Efficacy. A Broad Perspective*, which provided in 2004 useful recommendations and guidelines for optimization in emerging techniques such as multi-slice CT. However, since then, the EC has not published any other official document for quality criteria in CT. This highlights the need of harmonisation and of new guidelines.

In WP 7 on CT diagnostic reference levels, it is finally concluded that the European DRLs should be revised to include MSCT and the new dose quantity $CTDI_{vol}$, and that it seems to be necessary to established DRLs by more European countries. In addition, it is outlined that DRLs published so far show large variations which – concerning CTDI - may be mainly due to variations in the technical protocols used and differences in the CT scanner, while variations in DLPs are mainly due to variations in the clinical set up. These large variations, especially for DLPs, show that appropriate optimisation offers great potential to reduce patient CT dose.

WP 8 on training & education is considered as an important cross-cutting issue which in particular reflects the points of view of radiographers, medical physicists and radiologists, and thus, of EFRS, EFOMP and ESR.

WP 1: CT Medical Exposures

Authors: J. Griebel, E. Nekolla

I. Introduction

In Article 12 of the Medical Exposure Directive of 1997 [EC, 1997], entitled "*Estimates of Population Doses*", the European Commission requires Member States to ensure that the distribution of individual dose estimates from medical exposure is determined for the population and for relevant reference groups of the population, as may be deemed necessary by the Member State. As a consequence, in various countries in Europe, respective surveys were launched focussing on both the total collective effective dose and the collective effective dose of various types of X-ray exams. The results available raised awareness that medical exposures are by far the largest source of man-made population exposures to ionizing radiation and that CT is the major contributor followed by angiographic and interventional procedures. Similar concerns were shared in other parts of the world. So, in the *American College of Radiology White Paper on Radiation Dose in Medicine* [ACR 2007], it is stated that *"the current annual collective dose estimate from medical exposure in the United States has been calculated as roughly equivalent to the total worldwide collective dose generated by the nuclear catastrophe at Chernobyl. Therefore, one can assume … that this dose may likely result in an increase in the incidence of imaging-related cancer in the US population in the not-too-distant future."*

II. Synopsis of Relevant Literature

II.1 International Reviews

II.1.1 UNSCEAR

Since 1955 the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has regularly monitored the medical uses of radiation as part

of its systematic worldwide review of sources of exposure to ionising radiation [UNSCEAR 2000]. The Committee concluded that medical exposure remains by far the largest man-made source of radiation exposure for the world's population, and continues to grow at a substantial rate – although there is an uneven distribution of medical radiation services in different countries with different levels of health care [UNSCEAR 2010].

In the UNSCEAR 2000 Report it was noted that about 14% of the total collective effective dose due to medical exposures aroused from CT examinations in 1985 – 1990, and about one third in 1991 – 1996. According to the new UNSCEAR report [2010], CT accounts for 42% of the total collective effective dose due to medical diagnostic radiology in 1997 – 2007. The contribution of CT examinations to the overall frequency of radiological procedures has continued to increase rapidly ever since the practice was introduced in the 1970s. Because of the relatively high doses per CT examination this has great impact on the overall population dose due to medical exposures [UNSCEAR 2010]. The assessment of medical exposures due to CT scanning is therefore particularly important.

The rapid growth in the number of CT procedures has resulted in the situation that population and per caput doses from medical exposure and those from the previously largest source, i.e. from natural background, are within the same order of magnitude in some countries. In Germany, e.g., the per caput effective dose from medical exposure was about 1.8 mSv in 2009 while that from natural environmental radiation was 2.1 mSv.

II.1.2 DOSE DATAMED

At the end of 2004, the European Commission, on advice from the Article 31 Group Working Party on Medical Exposures, initiated a study to review the current situation in Member States regarding the implementation of Article 12 of the Medical Exposure Directive of 1997 "*Estimates of Population Doses*" and to develop appropriate guidance, specifically, to harmonized methods for future surveys of population exposure from medical X-rays. The EU-funded project was

called DOSE DATAMED (2004 - 2007), and the project group was recruited from radiation control authorities or expertise institutes in ten European countries (United Kingdom, Switzerland, Germany, Sweden, Norway, Netherlands, France, Luxemburg, Belgium, and Denmark). The guidance was published in 2008 by the European Commission as report No 154 in the Radiation Protection Series [DOSE DATAMED 2008]. The data from national surveys in the ten DOSE DATAMED countries have confirmed – as a general pattern – the increasing importance of CT as a source of exposure to populations.

Fig. 1 gives the results of the DOSE DATAMED comparison of frequencies and doses for CT examinations of the head, chest, abdomen, and for all CT examinations. The values of the mean effective dose (E) per exam for all CT examinations are of the same order of magnitude in each country, except for France where it is about half the average value for all the other countries. The differences in “collective E per year per 1000 population” between countries is consequently mainly due to the different CT examination frequencies. The ratio between the highest and the lowest national value for all CT is about 6 for the frequency of CT exams, about 2 for the effective dose per CT exam, and about 7 for the “collective E per year per 1000 population”. Roughly the same is true for CT examinations of the head and chest. There are, however, larger deviations for CTs of the abdomen. Because of the general trend of increasing frequency of CT examinations over the years, it is important to take into account the calendar year in which the surveys were performed, especially for Denmark and Sweden.

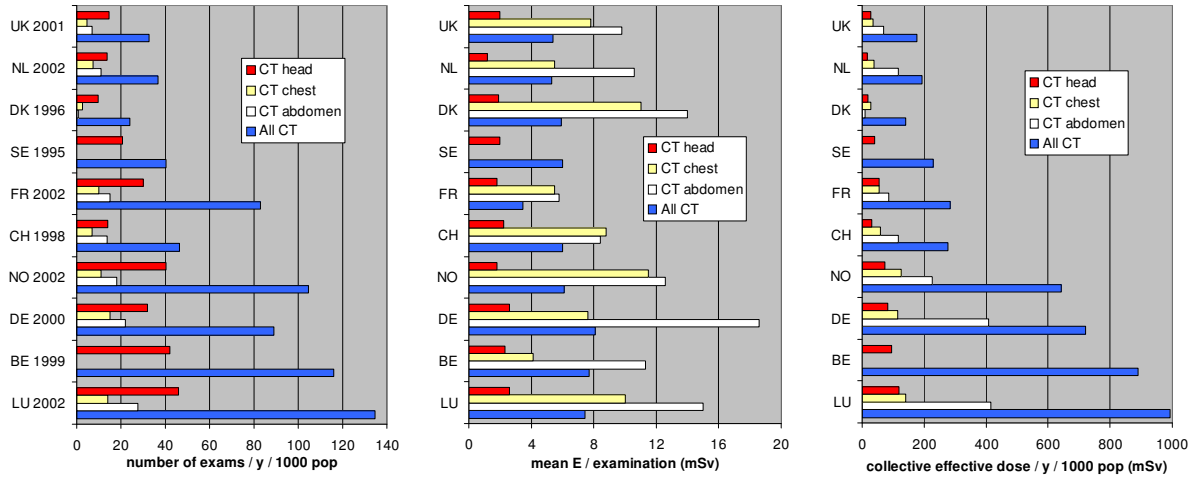

FIGURE 1: Frequency and dose data for three CT examinations and all CT in the ten DOSE DATAMED countries [DOSE DATAMED 2008]

The network of Heads of European Radiation Control Authorities (HERCA) has appointed a working group (WG6) to test the feasibility of the EC guidance by DOSE DATAMED on estimating population doses from medical x-ray procedures [DOSE DATAMED 2008]. Fourteen European countries (Belgium, Denmark, Estonia, Finland, France, Germany, Iceland, Lithuania, Netherland, Norway, Sweden, Switzerland, UK) have collected the most recent frequency and/or dose information for at least the "TOP 20" examinations that were identified by DOSE DATAMED as contributing the most to the total collective effective dose [Aroua 2010]. The results from these latest national surveys confirmed the trend that the contribution from conventional radiography examinations to the "TOP20" has decreased, while the contribution from CT has increased and is now in the range 46 – 81%.

II.2 Recent Results from Selected Countries

II.2.1 Germany

In Germany, the frequency of CT examinations increased by about 100% [Nekolla 2009] in the decade between 1996 and 2005. In 1996 the number of CT examinations accounted for about 3% of the total X-ray frequency, in 2005 for

about 7%. CT contributes about half of the total cumulative effective dose in 2005.

The Federal Office for Radiation Protection (BfS) was assigned the official task to regularly assess medical radiation exposures of the general population. A standardised method has been developed to perform this assessment annually. The results can be found in annual reports on "*Environmental Radioactivity and Radiation Exposure*" prepared by the BfS to support the *Federal Ministry for the Environment, Nature Conservation and Nuclear Safety* (BMU) in its national and international obligations of reporting [BMU 1], and in annual reports to the Federal Parliament (Bundestag) [BMU 2].

The annual evaluation of medical exposure in Germany permits a trend analysis. In *Fig. 2* the frequency of X-ray examinations, and in *Fig. 3* the mean effective dose (mSv) per caput and year due to X-ray diagnostics is given for the years 1996 to 2009 [BMU 1, BMU 2].

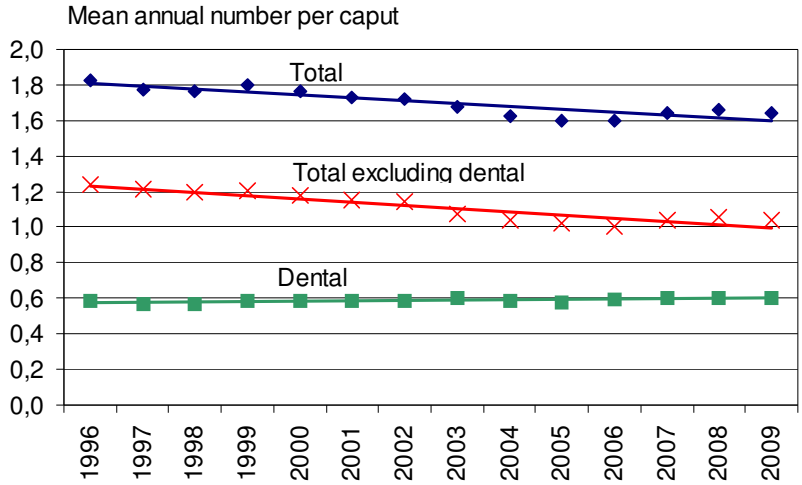

FIGURE 2: Frequency of X-ray examinations in Germany

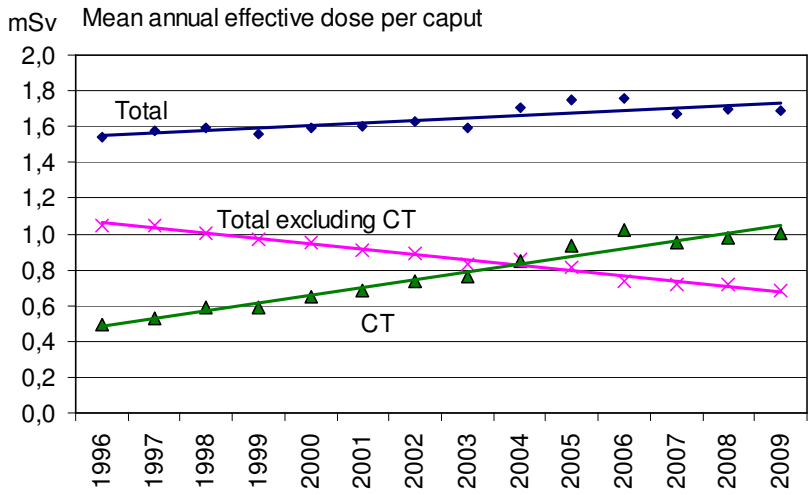

FIGURE 3: Mean effective dose (mSv) per inhabitant and year due to X-ray diagnostics in Germany

From the data in *Figs. 2* and *3* it can be concluded that the steady increase in medical exposures between 1996 and 2009 are mainly caused by CT. In addition, the evaluation in 2009 reveals that CT alone contributes about 60% to the collective effective dose, while it only contributes about 8% to the total frequency (see *Fig. 4*).

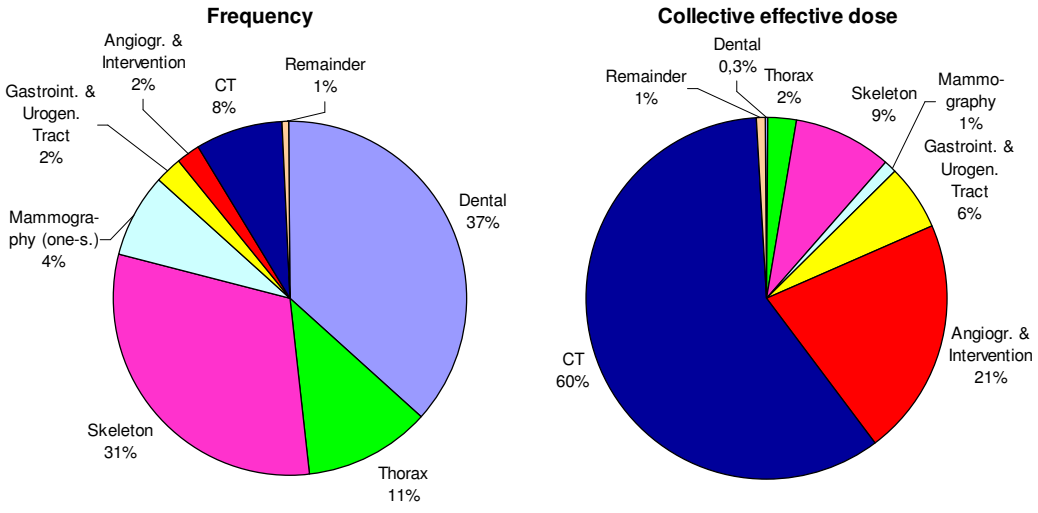

FIGURE 4: Contribution of various examination types to total frequency (left) and to total collective effective dose (right) in 2009

II.2.2 Norway

Similar to Germany, in Norway, the CT examination frequency increased by about 100% during the decade from 1993 to 2002. The CT contribution to the total collective effective dose was estimated to account for 59% of the total in 2002 as opposed to 30% in 1993 [Børretzen 2007]. In 1993, the four biggest contributors to the total collective effective dose were barium enema, CT abdomen, X-ray lumbar spine and CT head/brain, in total accounting for 36% of total dose. In 2002, the four CT examinations of abdomen, thorax, pelvis and lumbar spine contributed most to the collective effective dose, accounting for 44% of total dose.

II.2.3 Switzerland

In 2007, a nationwide investigation was conducted in Switzerland for the year 2003 to establish the exposure of the population by medical x rays and update the results of the 1998 survey [Aroua 2007]. Compared to 1998, an increase of CT frequency of 66% was observed. This increase was associated with a decrease of IVUs, barium enemas, and angiographies which was explained by the fact that these procedures are growingly replaced by CT. The dose per CT exam increased on average by 20%, and the collective effective dose for all CT by about 100% between 1998 and 2003. In 2012, the results of a new survey, covering the years until 2008 was published [Samara 2012]. This survey demonstrated that in 2008 the contribution of CT was only 6% in terms of examination frequency (0.1 exam per caput) but 68% in terms of effective dose (mean effective dose per caput: 0.8 mSv).

II.2.4 Luxembourg

In Luxembourg, a national evaluation on radiation doses from diagnostic procedures was conducted for the period 1994-2002 [Shannoun 2006]. The impact of CT to total collective effective dose from medical radiation has considerably increased in this time period. The per caput effective dose due to CT has risen from 0.48 mSv in 1994 to 0.99 mSv in 2002. CT contributed 50% to the total collective effective dose (including nuclear medicine) in 2002. Excluding nuclear medicine procedures, the contribution of CT was 54% in 2002. Luxembourg has one of the highest CT examination rates compared to other countries with high health care level.

II.2.5 United Kingdom

In the United Kingdom, the annual per caput effective dose in 2001/2002 of 0.38 mSv from all X-ray exams is low in comparison with other countries with a high health care level. This is due to both a lower frequency of X-ray examinations and generally lower doses in the UK than in other developed countries. CT examinations had increased in frequency by 39% from 1997/98 to 2001/02. Over the last 10 years back from 2001/2002 CT has more than doubled its contribution and was responsible for 47% of the collective effective dose from medical X-rays in 2001/2002 [DOSE DATAMED 2008].

II.2.6 France

In France, CT examinations accounted for 8% of the total number of radiodiagnostic procedures (including nuclear medicine), but for 39% of the total collective effective dose in the year 2002 [Scanff 2008]. In 2012, an update of the 2002 data was published [Etard 2012]. The mean effective dose per inhabitant from all radiodiagnostics (incl. nuclear medicine) was 1.3 mSv in 2007. CT represented 10% of the examinations and 58% of the effective dose, respectively. The annual number of examinations per inhabitant was constant between 2002 and

2007 (about 1.2 exams). However, the corresponding average effective dose per inhabitant increased by 57% from 0.83 to 1.3 mSv per year. This increased dose was due mostly to a growing number of CT and nuclear medicine examinations.

II.2.7 USA

In the USA, where the highest per caput effective dose from all radio-diagnostics (including nuclear medicine) was reported (3 mSv in 2006), 16% of frequency and 49% of total collective dose is associated with CT [NCRP 2009]. Excluding nuclear medicine procedures, CT contributed about 17% to frequency and 66% to total collective effective dose. On average, the number of CT procedures increased more than 10% per year from 1993 to 2006 in the USA. Most of the CT procedures were examinations of the abdomen/pelvis/spine (38%) contributing about 58% to total collective dose from all CT.

II.3 Frequency of CT Devices

There is a considerable increase in the number of CT devices particularly for countries with a high level of health care [UNSCEAR 2010]. In addition, the Organisation for Economic Co-operation and Development (OECD) has reported wide variations in the number of CT scanners per million of the population. Japan has the largest number of CT scanners per head of the population, which is, for example, approximately 60 times more than in Mexico [UNSCEAR 2010]. The median number of CT scanners in the countries studied by the OECD survey was 14 per million of the population.

According to the DOSE DATAMED project (see *Fig. 5*), there is a general trend towards an increase in the CT examination frequency as the number of CT systems per head of population increases. Countries with high CT exam frequencies (Germany, Belgium and Luxemburg) have nearly 5 times the number of CT scanners per million population than the UK (which has the lowest CT exam frequency). However, Switzerland and Norway also have a high number of CT scanners per million population, but this does not apparently result in a high fre-

quency of examinations. The widely scattered population in Norway with many parts of the country being relatively inaccessible could account for the high numbers of Norwegian CT scanners serving a small population.

For Germany, the temporal changes in the number of CT scanners is given in *Fig. 6*. For comparison, the time trend for the number of CT examinations is given in the same figure.

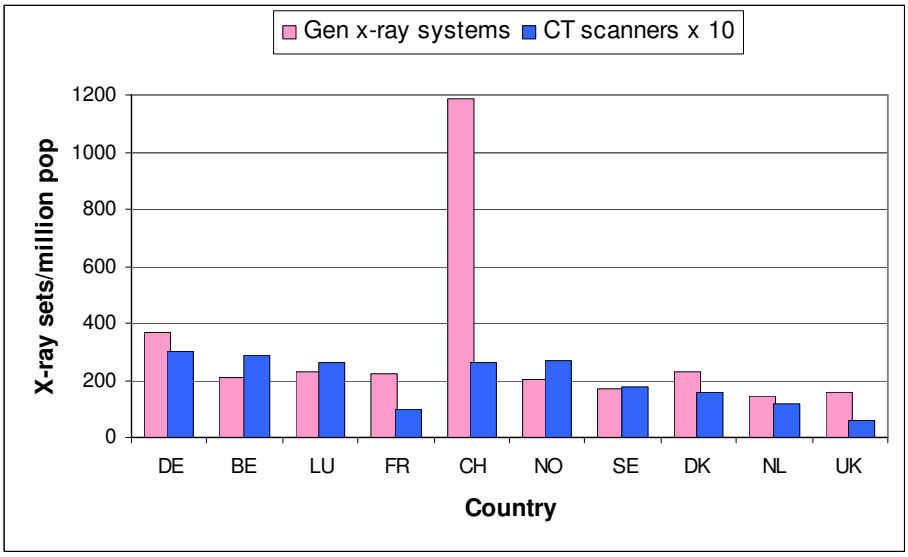

FIGURE 5: Frequency of general X-ray systems and CT devices (x 10) in the ten DOSE DATAMED countries [DOSE DATAMED 2008]

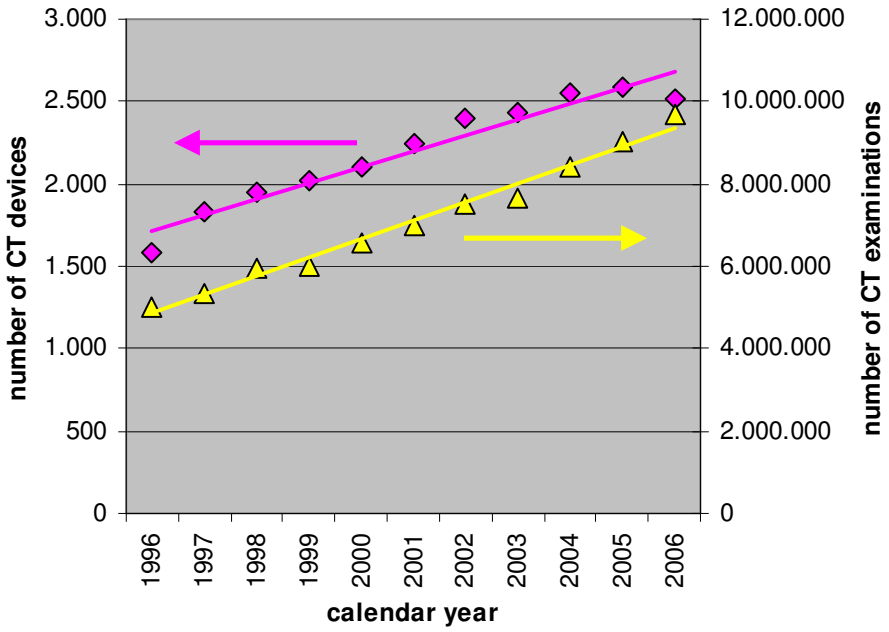

FIGURE 6: Frequency of CT devices (left ordinate) and of CT examinations (right ordinate) in Germany from 1996 to 2006.

III. Final Analysis

Both the international reviews (see *Chapter II.1*) and the recent results from selected countries (see *Chapter II.2*) reveal the steadily increasing impact of CT on medical exposures over the last decade, resulting in steadily increasing total effective doses due to diagnostic imaging. It is interesting to note that this trend is attended by a decrease in the frequency of conventional X-ray exams – apart from angiography and interventional procedures. Although this decrease is – at least in part – caused by the increasing use of alternative diagnostic imaging techniques such as sonography or magnetic resonance imaging, it may be speculated that CT is the driving force of these inverse trends. Thus, in summary, it may be concluded that low dose imaging techniques such as conventional X-ray exams are steadily being replaced by high dose CT exams, resulting in the observed increase of medical exposures.

In line with this kind of reasoning, it has to be considered that the clinical impact of CT in many cases outweighs the diagnostic value of conventional X-ray exams. Unfortunately, the available data are insufficient to investigate this issue. In particular, a thorough analysis weighing the clinical benefit from the increasing use of CT against the resulting radiation risks would require detailed information of both age of the patients and clinical indication of the performed CT exams. Apart from few exceptions, such as Denmark with its centralised health care system, such data are not available at present. Nevertheless, this kind of studies would be important in order to adequately evaluate the increasing impact of CT on medical exposures and respective research programmes launched, for example by the EU, would have to be highly appreciated.

In addition, there is a strong correlation between the number of CT devices and the CT examination frequency (see *Chapter II.3*). As outlined above, this correlation reflects the pivotal importance of CT in diagnostic imaging and the resulting response of the health care systems all over the world to this challenge. However, it may also be speculated that the reimbursement system – in particular in countries such as Germany or the USA with a high percentage of private practices ("pay per exam") – has a certain impact also on this development.

Finally, it has to be mentioned that the available surveys mainly focus on resource rich countries, while data on resource poor and emerging countries are still insufficient. Nevertheless, it may be speculated that a similar trend has also to be assumed in these countries. To verify this speculation, adequate surveys in resource poor and emerging countries are necessary. In this context, the HERCA initiative (see *Chapter II.1.2*) is of special importance since it addresses this issue, and in particular it strives for the goal to provide technical support to resource poor countries in Europe in designing and conducting this kind of surveys. It is highly appreciated that the EC is supporting this approach by launching the two-years project "*Study On European Population Doses From Medical Exposure (Dose Datamed 2*)" in 2010. The project started in the beginning of 2011, http://www.ddmed.eu. The *Dose Datamed 2* project will – for the first time – estimate the population dose from diagnostic procedures for all Europe based on the

TOP 20 X-ray procedures (including seven CT categories), identified by the initial DOSE DATAMED project (2007), and the Top 5 nuclear medicine examinations.

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WP 2: CT Risk / Benefit Estimation

Authors: J. Griebel, E. Nekolla

I. Introduction

Radiological imaging always poses some risk of adverse health effects to the person examined – in particular radiation-induced cancer. Although individual risk estimates for single examinations are small, the concern over radiation risks is related to the currently increasing use of X-ray diagnostics - to be precise: small individual risks applied to an increasingly large population may result in a potential public health issue some years in the future. As outlined in *Working Package #1* as well as in various references [e.g.: Hall 2008], this is in particular true for the increasing use of CT.

In the past, health strategies focused on a patient with recognized symptoms presenting to a medical doctor in a hospital or private practice. If the medical doctor needs further diagnostic information, he refers the patient to a radiologist performing the adequate X-ray exam. This scenario is usually denoted as **health-care**.

With the evolving new technology of multi-slice spiral CT, a new emerging scenario has to be considered, that is **individual health assessment** – also denoted as **opportunistic screening**. At present, predominantly the following CT procedures are discussed:

- lung CT for early detection of lung cancer, in particular in smokers and asbestos workers;
- virtual CT colonoscopy – also denoted as CT colonography - for early detection of intestinal polyps (which might be pre-cancerous lesions) and colorectal cancer;
- CT quantification of coronary artery calcification (which is considered as sensitive marker of arteriosclerosis);
- whole-body CT, particularly for early detection of cancer.

A prominent example is whole-body CT screening, which is increasingly promoted – especially in the USA, but also in other countries such as UK and Germany – by private providers in the last few years [Fenton 2003, Illes 2003, COMARE 2007].

Screening is a significant departure from the conventional clinical model of care, because apparently healthy individuals are offered a test. An effective screening detects either risk factors for developing a disease or the disease itself at an early stage where treatment can improve clinical outcome. The aim is to identify those individuals who are more likely to be helped than harmed by further diagnostic tests or treatment [British Medical Association 2005].

It is important to distinguish opportunistic screening from organized screening programmes. Organized screening programmes systematically invite all members of a certain population to take a screening test. For example, several breast screening programmes in Europe were established where all women in a given population for instance between 50 and 69 years of age routinely receive invitations to have an X-ray mammography examination. These programmes are evidence based and meet stringent quality requirements [IARC 2002, EUROSCREEN 2012]. At present, no CT based organized screening programmes have been launched.

Up to now, CT based individual health assessment may not play a dominant role in medical exposures in Europe. However, this could change dramatically within the next few years, if opportunistic CT screening is extensively advertised by providers and – as a consequence – is widely accepted by the public. This kind of advertisement must be critically questioned as long as there is lack of evidence in supporting the screening procedures on offer, since asymptomatic individuals are potentially put at risk while the benefit is vague. This is especially the case as the service is unlikely to be properly quality assured or coordinated. Furthermore, in an opportunistic screening individuals are unlikely to receive sufficient information to enable them to make an informed decision as to whether or not to undertake the screening test.

In summary, in both scenarios – healthcare and individual health assessment – it is pivotal to weigh the total potential diagnostic or therapeutic benefits of CT against the individual detriment, providing the base for the appropriate justification of CT scanning. Hereby, it is worth noting that the application of ionising radiation in both healthcare and individual health assessment requires an individual justification, while officially approved screening programmes are justified generically.

II. Synopsis of Relevant Literature

II.1 National and International Recommendations and Guidelines

II.1.1 Process of Justification

Radiation protection in medicine is based on the concepts of justification and optimisation. Over the last decades much successful work has been devoted to developing and consolidating approaches to optimisation. In contrast, less effort has been applied with respect to justification and the efforts applied have not yet been as successful [Report of a Consultation on Justification 2009]. Nevertheless, authoritative sources suggest that a substantial fraction of radiological examinations may be unnecessary [Report of a Consultation on Justification 2009], indicating the great impact of justification on radiation protection in medicine. Even an optimised application of X-rays fails to comply with the principles of radiation protection in medicine, if it is not justified.

Justification of medical exposures has widely been addressed by international organisations. As stated for example in the Revised Basic Safety Standards [IAEA Draft 4.0], the concept of justification claims that medical exposures shall be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause. In addition, the benefits and risks of available alternative techniques that do not involve exposure from ionizing radiation have to be taken into account. Also, the justification of medical exposure for an individual patient shall be carried out taking – amongst others – the

appropriateness of the request and the urgency for the procedure into account. This is particularly important for paediatric patients whose radiation risk is higher compared to adult patients. In summary, exposures to ionizing radiation shall only be justified if they show a sufficient net benefit.

II.1.2 Healthcare

Concerning national or international recommendations and guidelines, benefit versus risk considerations in the healthcare setting are mainly addressed in the context of referral criteria, also denoted as appropriateness criteria. Various countries all over the world have produced such kind of criteria. On the international level, the European Commission [EC 2001] published guidelines on this issue. In all of these national and international publications, CT plays a major role. In addition, WHO held a consultancy meeting on "*Referral Guidelines for Appropriate Use of Radiation Imaging*" in March 2010. 36 experts, representing 23 agencies and professional societies from across WHO's six regions, agreed upon a roadmap to develop an international set of evidence-based referral guidelines and facilitate their implementation [WHO 2010]. However, as outlined in the meeting, it has to be taken into account that – according to the conceptual framework of medical radiation protection – the benefit versus risk considerations provided by referral criteria are intended to support the general medical doctor in his/her referral of the patient to the radiologist. They do not primarily refer to the radiologist and cannot replace the justification of an X-ray application in an individual patient. However, referral criteria may serve as a tool facilitating communication between medical and radiological practitioner in order to improve the quality of prescription and, in the long term, patient management.

II.1.3 Individual Health Assessment

At present, only a few national guidelines address the analysis of risk versus benefit in CT based individual health assessment. In a *Joint Guideline from the*

American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology on *Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps* [Joint Guideline 2008], the pros and cons of CT colonography (CTC) are outlined and its potential role in colorectal screening is addressed. The recommendations can be summarized as follows:

- CTC surveillance could be offered to those patients who would benefit from colorectal screening (i.e. both men and women, beginning at age 50) but either decline colonoscopy or who are not good candidates for colonoscopy for one or more reasons.
- The interval for repeat exams after a negative CTC has not been studied, and is uncertain. However, if current studies confirm the previously reported high sensitivity for detection of cancer and of polyps ≥ 6 mm, it would be reasonable to repeat exams every 5 years if the initial CTC is negative for significant polyps until further studies are completed and are able to provide additional guidance.
- Until there is more research on the safety of observation, colonoscopy should be offered to patients whose largest polyp is 6 mm or greater.

The *Committee on Medical Aspects of Radiation in the Environment*, in its 12th report, provides guidance on *The Impact of Personally Initiated X-Ray Computed Tomography Scanning for the Health Assessment of Asymptomatic Individuals* [COMARE 2007]. Current evidence based on a thorough benefit versus risk analysis suggests that:

- there is little evidence that demonstrates, for **whole-body** CT scanning, that the benefit outweighs the detriment; it is recommended therefore that services offering whole-body CT scanning of asymptomatic individuals should stop doing so immediately;
- there is no benefit to be derived from CT scanning of the **lung** in asymptomatic individuals;

- CT scanning to determine **coronary artery** calcification should only be undertaken on individuals with intermediate risk identified by a comprehensive cardiovascular Framingham risk score assessment; it should not be performed in subjects deemed to be at high or low risk of cardiovascular disease;
- there may be a place for CT colonography as an investigation for **colorectal** cancer; however, outside of the *NHS (National Health Service)* screening programmes, screening for colorectal cancer should only be undertaken in individuals in the appropriate age group, and not, therefore, under the age of 50 years.

The *German Radiation Protection Committee (SSK)* addressed the issue of individual health assessment. In its recommendation in 2006 [SSK 2006], the expert panel focussed on the minimum prerequisites to be fulfilled for the application of ionising radiation being considered justified for individual health assessment. The experts claim that:

- S3-level guidelines[1] of relevant scientific bodies have to be available for the respective screening procedure;
- adequate information about both potential benefit and potential risk and harm has to be provided to the individual undergoing the screening procedure;
- the screening procedure has to be embedded in a well-established screening algorithm and
- the screening procedure has to be properly quality assured along the whole screening chain, including:
  - the clear definition of risk profiles,
  - the development of optimised and standardised CT protocols

[1] A S3-level guideline is based on a systematic, evidence-based and interdisciplinary consensus between relevant scientific bodies.

- the development of optimised and standardised algorithms for reading and diagnostic workup of suspicious findings, and
- the implementation of measures to ensure adequate training and education as well as documentation and evaluation.

II.2 Recent Scientific Literature

II.2.1 Healthcare

In regular reports of international bodies, e.g. *UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation)* or the *BEIR (Biological Effects of Ionizing Radiation) Committee*, the latest radio-biological and radio-epidemiological data and findings are compiled and evaluated, and appropriate radiation risk models are developed [UNSCEAR 2000b, BEIR 2006]. Thereby, estimates on risk per unit of dose are derived using the so-called linear, non-threshold (LNT) hypothesis, which is based on the assumptions that

- any radiation dose – no matter how small – may cause a small increase in risk and
- the probability of this increase is proportional to the dose absorbed in the tissue.

Although the risks evaluated at low dose levels are hypothetical, a majority of scientists recognises the assumption of linearity as a pragmatic guideline adopted in the absence of scientific certainty. It is for this reason that current radiation protection standards as well as risk assessments are generally based on the LNT hypothesis.

In 2007, a review on risk due to CT examinations was published by Brenner and Hall [Brenner 2007]. In a similar paper in 2008, Hall and Brenner provided relevant CT organ doses and risk estimates for head and abdomen CT using risk estimates published by the BEIR VII committee in 2006 for a U.S. population [Hall 2008]. Based on these findings they conclude that:

- the relevant organ doses are in the range for which there is now direct credible epidemiological evidence of an excess risk of cancer, without the need to extrapolate risks from higher doses;
- even for high-dose radiological procedures, the risk to the individual patient is small, so that – for the healthcare scenario – the diagnostic benefit to the patient would outweigh the radiation risk;
- concerns arise when CT examinations are used without a proven clinical rationale, when alternative modalities could be used with equal efficacy, or when CT scans are repeated unnecessarily; it has been estimated, at least in the US, that these scenarios account for up to one-third of all CT scans.

In a study published in 2004, Berrington de González and Darby combined data on the frequency of diagnostic X-ray use (see *working package #1*), estimated radiation doses from X-rays to individual body organs, and risk models with population-based cancer incidence rates and mortality rates for all causes of death to estimate the risk of cancer from diagnostic X-rays [Gonzalez 2004]. Assuming a mean effective dose of 1.5 mSv per inhabitant in Germany (previous data from [UNSCEAR 2000b]) the authors estimated that about 2000 cancer cases per year diagnosed in persons aged up to 75 years could be attributable to X-ray diagnostics in Germany.

A critical problem of the assessment mentioned above is that it is based on collective dose estimates or mean per caput doses. That means, they do not take into account that medical exposures are not equally distributed among the population but rather cumulate to a considerable amount in certain groups of severely-ill patients, e.g.: cancer patients. Therefore, a reliable benefit-risk analysis of radiological imaging procedures has to be broken down to diagnosis-related groups of patients, in particular to those highly exposed. To address this issue for the example of cancer patients, Brix et al. [Brix 2009] performed an analysis based

on examination-specific RIS/KIS[2] data. From this data, the cumulative 5-year effective dose was estimated for each patient as well as the mean annual effective dose per patient and the mean patient observation time for each of the ten most common cancer sites. The following results of the study are of particular relevance:

- CT contributed more than 80% to the cumulative effective dose from all medical X-ray procedures in these patients
- the cumulative 5-year dose to patients with favourable survival rates (more than 70%, for example in breast and prostate cancer) is much lower than that of very unfavourable survival rates (for example in pancreas and lung cancer),
- about half of cancer patients pass away within a period of time that is shorter than the mean latency period for the development of radiation-induced cancer, which means that a large fraction of the medical exposure is not relevant with respect to radiation detriment.

There are, however, methodological limitations of the study because X-rays that may be carried out in the same patients in other imaging facilities (e.g. for therapy follow-up) were not considered. Thus, the dose estimates reported systematically underestimate the real situation and have to be interpreted as minimum exposure levels.

II.2.2 Individual Health Assessment

II.2.2.1 Benefit

- **Lung cancer screening:**

Lung cancer has one of the lowest survival outcomes of any cancer because the majority of cases is only diagnosed when symptoms develop which often means that the tumour is then at a late stage. Because treatment at a less advanced

[2] RIS: Radiology Information System, KIS: Hospital Information System (=HIS)

stage by surgical resection has been shown to substantially reduce mortality, early detection of lung cancer is considered to be very important.

Lung cancer is the only site where prospective randomized clinical trials (RCT) are performed to find out whether a benefit of CT screening exists. There are six RCTs in Europe (NELSON from Netherlands/Belgium [van Iersel 2007], DLCST from Denmark, ITALUNG, DANTE and MILD from Italy, and LUSI from Germany [Pastorino 2010]) in which more than 32,000 persons have been enrolled. One RCT from the UK is in preparation (UKLS). The largest RCT is the *National Lung Screening Trial (NLST)* sponsored by the National Cancer Institute (NCI) of the United States [Church 2003]. The NLST is comparing low-dose spiral CT and standard chest X-ray for detecting lung cancer. The study opened for enrolment in September 2002 and closed in February 2004. By February 2004, nearly 50,000 current or former smokers had joined NLST at more than 30 study sites across the USA. In November 2010, the NCI released initial results from the NLST stating that 20% fewer lung cancer deaths were observed among trial participants screened with CT compared to participants screened with chest radiography. A full analysis with more detailed results was published in the New England Journal of Medicine in June 2011 [NLST 2011]. The largest European trial is the NELSON trial. It started in August 2003 and intends to show whether screening for lung cancer by multi-slice low-dose CT in current or former smokers (about 15 000 participants) will lead to a 25% decrease in lung cancer mortality. Results are expected not before 2015. In light of the NLST results, the European randomized CT screening (EUCT) investigators held a workshop, and came to the conclusion that there are many questions to be answered and that all European RCTs should be continued and evaluated before lung cancer CT screening can be recommended [EUCT investigators 2011].

Besides these RCTs, there are several feasibility studies (mainly on risk patients like smokers/ex-smokers) from USA, Japan, and Europe on lung cancer CT screening (including altogether more than 50 000 patients). Most of them reported on shifts towards less advanced stages, better resectability of lung cancer,

better median and 5 year survival, and acceptable rates of invasive interventions due to benign lesions.

A report of the International Early Lung Cancer Action Program [I-ELCAP 2006] contributes substantial data concerning the clinical effectiveness of CT lung cancer screening. In total, the I-ELCAP involved about 31 600 asymptomatic persons who were at increased risk for lung cancer (mostly current or former smokers). All participants underwent baseline screenings using spiral CT between 1993 and 2005. Based on specific protocols dictated by the baseline screening results, about 87% of patients underwent additional annual spiral CT screenings. It was concluded by the authors that annual spiral CT screening has the potential to detect lung cancer that is curable. The Department of Medical Imaging at the University Toronto became the first Canadian site of I-ELCAP in 2003, and reported in 2007 the results from the first 1000 baseline studies. It confirmed that low-dose CT identifies small, early-stage, resectable lung cancer in a high-risk population [Roberts 2007].

Among the participants in the I-ELCAP study who received a diagnosis of lung cancer based on spiral CT screening and a resulting biopsy, 85 percent had stage I lung cancer. The statistically estimated 10-year survival among these patients was 88 %. Among stage I patients who underwent surgery within 1 month of diagnosis, the estimated 10-year survival rate was 92 %. However, it must be taken into account, that very few patients in the I-ELCAP study have been followed for 10 years. In fact, the study provides only an estimate of survival based on a median of 3.3 years of follow-up. Using survival as an endpoint to infer a screening benefit can be misleading because by diagnosing disease in advance of symptoms, survival will increase even if there is no delay in death. These results can, therefore, not be taken as proof that CT screening for lung cancer decreases mortality.

Other reports demonstrate limitations of lung cancer screening by CT [Bach 2007, Diederich 2004]. An analysis of CT screening studies at the Mayo Clinic, the H. Lee Moffitt Cancer Center, and the Instituto Tumori in Italy included more

than 3,200 asymptomatic individuals who had smoked for an average of 39 years [Bach 2007]. Because the studies lack control groups, statistical modelling was used to create artificial control groups. The results from screening were then compared with what might have been expected in the absence of screening: Screening led to a three-fold increase in the number of lung cancers diagnosed (i.e. over-diagnosis), and a 10-fold increase in lung cancer surgeries (i.e. over-treatment), compared with what was expected without screening. Bach et al. [2007] concluded that screening may led to additional testing and treatments for tumours that may never have caused harm, but may not significantly reduce lung cancer mortality.

To examine the current evidence on the clinical effectiveness of screening for lung cancer using CT, a systematic literature review was carried out by Black in 2006. A total of 12 studies of CT screening for lung cancer were identified (two RCTs and ten studies of screening without comparison groups). The proportion of people with abnormal CT findings varied widely between studies (5-51%). The prevalence of lung cancer detected was between 0.4% and 3.2% (the number needed to be screened in order to detect one lung cancer is between 31 and 249). Incidence rates of lung cancer were lower (0.1-1%). Among the detected tumours, a high proportion were stage I or resectable tumours, 100% in some studies. However, the authors concluded that currently there is insufficient evidence that CT screening is clinically effective in reducing mortality from lung cancer [Black 2006, 2007].

- **Colorectal cancer screening:**

In the case of colorectal cancer, the rationale of early detection is that the disease itself can be prevented by the detection and removal of benign, neoplastic adenomatous polyps (adenomas), from which more than 95% of cancers arise [Bond 2000]. Thus, it may be concluded that colorectal cancer screening offers the potential to increase survival rates considerably.

However, up to now, it has only been demonstrated in a RCT on faecal occult blood (FOB) that colorectal screening can significantly reduce mortality and mor-

bidity from colorectal cancer [Scholefield 2002] – although FOB testing often fails due to false negative or false positive results. Another tool for colorectal cancer screening is double contrast barium enema. Alternatively, examinations with use of optical colonoscopy is highly recommended by many organizations. Yet, there is low public acceptability of screening for colorectal cancer by colonoscopy. A higher rate of patient compliance can be expected with CT colonoscopy [Gluecker 2003] although the patient must undergo a colonic preparation, as with double-contrast barium enema or colonoscopy. Besides, if polyps or tumours are diagnosed by CT, conventional colonoscopy is required to verify the diagnosis, to obtain a biopsy sample, and to remove them.

At present, there is no published evidence from RCTs examining the effectiveness of CT colonoscopy. Yet, CT colonoscopy has been evaluated by several comparisons with conventional colonoscopy and compares favourably in terms of detecting clinically relevant lesions, i.e. polyps at least 8 mm in diameter [Pickhardt 2003].

The estimates of the sensitivity of CT colonoscopy by Pickhardt for detecting lesions found on colonoscopy are higher than estimates in some other studies [e.g. Cotton 2004]. A meta-analysis also found that the reported sensitivities for CT colonoscopy vary widely, even for larger polyps, and concluded that before any screening method can be recommended for general use, it must be demonstrated to be highly and consistently sensitive in a variety of settings [Mulhall 2005].

The detection of polyps of less than 5 mm in diameter on virtual colonoscopy and subsequent matching on optical colonoscopy are both unreliable. However, there appears to be a majority opinion that colonic polyps of less than 5 mm in diameter should be regarded as clinically insignificant [Pickhardt 2003]. Pickart et al. [2003] evaluated that in the case of virtual colonoscopy 8 mm might be a reasonable threshold for an intervention by optical colonoscopy. Patients with lesions of about 5 to 7 mm could receive short-term follow-up by virtual colonoscopy (in

intervals of 2 to 3 years). All other patients could undergo routine follow-up (in intervals of 5 to 10 years).

A systematic review from 2010 (data from four studies with 20,562 screening subjects) confirmed that a 6-mm polyp size threshold for polypectomy referral would identify over 95% of subjects with advanced adenomas, whereas a 10-mm threshold would identify 88% of cases [Hassan 2010].

Pickhardt et al. also investigated the clinical importance and height definition of flat (nonpolypoid) colorectal lesions detected on screening CTC in a US screening population [2010]. They concluded that flat colorectal lesions detected on CTC demonstrated less aggressive histologic features compared to polypoid lesions, and that – excluding carpet lesions – a maximal height of 3 mm appears to be a reasonable definition.

A lot of studies have been exclusively based on patients with symptoms suggestive of cancer or individuals at increased risk of colorectal cancer. However, there are also studies on average risk patients. E.g. in a US study of asymptomatic average risk adults, CT colonoscopy screening identified 90% of subjects with adenomas or cancers measuring 10 mm or more in diameter that were detected by optical colonoscopy [Johnson 2008]. Secondary analyses showed that CT colonoscopy had a lower sensitivity for smaller colorectal lesions (6 to 9 mm).

In a consensus statement of the European Society of Gastrointestinal and Abdominal Radiology (ESGAR), technical quality standards for CT colonography were updated based on examination of the existing literature [Neri 2012]. The recommendations are “aimed to provide CT-colonography guidelines for practising radiologists”, and “should help radiologists who are starting/updating their CTC services” [Neris 2012].

- **Calcium scoring:**

Quantification of coronary artery calcification (CAC) can identify patients with an increased risk of coronary artery disease [Greenland 2004]. In symptomatic patients, calcium scoring can be used to confirm a suspected diagnosis in order to

decide on the appropriate treatment and on secondary prevention. On the contrary, in asymptomatic persons, the long-term risk of coronary artery disease should be assessed. This might be helpful especially for those persons being at intermediate risk where clinical decision making is most uncertain [Greenland 2004].

A systematic review was carried out by Waugh et al. [2006]. Seven studies were identified that assessed the association between CAC scores on CT and cardiac outcomes in asymptomatic people and included 30,599 people. Six used electron-beam CT. There are no randomised controlled trials to evaluate screening for coronary artery disease using CT. The relative risk of a cardiac event was 4.4 if CAC was present, compared to there being no CAC. As CAC score increased, so did the risk of cardiac events. The correlation between CAC and cardiac risk was consistent across studies. There was evidence that CAC scores varied among people with the same Framingham risk factor scores, and that within the same Framingham bands, people with higher CAC scores had significantly higher cardiac event rates. However, it remains unclear whether CT screening for CAC would provide sufficient extra information over risk factor scoring (e.g., via Framingham risk scores) for it to be worthwhile. CT screening would miss many of the most dangerous patches of arterial disease, because they are not yet calcified, and so there would be false-negative results: normal CT followed by a heart attack. There would also be false-positive results in that many calcified arteries will have normal blood flow and will not be affected by clinically apparent thrombosis: abnormal CT not followed by a heart attack [Waugh 2006].

- **Whole-body screening :**

To date, there is no scientific evidence demonstrating that whole-body CT of asymptomatic persons provides more benefit than harm. Whole-body CT screening is controversially discussed [Beinfeld 2005]. There are few firm data on which to base the potential benefit of whole-body CT. A retrospective study evaluated the frequency and spectrum of findings reported with whole-body CT [Furtado 2005]. On average, 2.8 suspect findings per patient were detected, most of them being

benign, and in 37% of cases additional tests were necessary for further clarification.

As outlined in *Chapter II.1.3*, the *Committee on Medical Aspects of Radiation in the Environment (COMARE)* [COMARE 2007] concluded in its report on the impact of CT scanning for the health assessment of asymptomatic individuals that there is little evidence of benefit from whole-body CT scanning either in its ability to identify disease at a more treatable stage or in its ability to reassure. There is a general consensus from the international radiology community that whole-body CT scanning is not to be recommended [COMARE 2007] (e.g. the *American Medical Association* (2005), the *American College of Radiology* (2002), the *US Health Physics Society* (2003)).

II.2.2.2 Radiation Risk and Benefit-Risk Considerations

An assessment of radiation risks induced by X-ray screening procedures, e.g. CT, has to take into account that these procedures typically are aimed at members of a certain population, such as – for example in breast cancer screening – women between 50 and 69 years of age. Furthermore, similar to healthcare procedures, screening procedures using ionizing radiation typically expose only parts – and thus only specific organs – of the body. As a consequence, for a reliable risk assessment, organ related absorbed doses as well as age, gender and organ specific risk estimates are necessary [Nekolla 2008].

Risk analyses for CT screening have been presented by Brenner and colleagues for lung cancer CT, virtual colonoscopy, and whole-body CT screening [Brenner 2004a, Brenner 2005, Brenner 2004b, Brenner 2007]. A summary of results – together with other findings mentioned below - is provided in *Tab. 1*. For lung CT and virtual CT colonoscopy, they are based on risk estimates derived from cancer incidence data of the Japanese atomic bomb survivors with follow-up period 1958 to 1987, for whole-body CT screening they are based on risk estimates for cancer mortality given by the Biological Effects of Ionizing Radiation (BEIR) V committee in 1990. Brenner et al. used representative scanning protocols to es-

timate organ doses, and gave radiation risk estimates for a U.S. population. In 2008, Hall and Brenner published estimates of CT radiation risks for diagnostic radiology in both healthcare (see *Chapter II.2.1*) and screening settings. For virtual colonoscopy, they concluded that it seems to be clear that, in terms of the radiation exposure, the benefit/risk ratio is potentially large. For lung cancer screening, they refer to [Brenner 2004] concluding that a reduction in mortality from annual CT screening of more than 3% would be necessary to outweigh the potential radiation risks. For calcium scoring, Hall and Brenner give radiation risk estimates merely for lung cancer mortality, arguing that for higher ages it would be expected that the lung cancer risks would considerably outweigh any risks to the breast. For whole-body screening, Hall and Brenner conclude that radiation exposure to an individual from a single whole-body CT scan is relatively high. Together with the high rate of false positive findings leading to further investigation and the implication that whole-body CT scans should be repeated at frequent intervals, they further conclude that the cumulative radiation exposure at individual and population level, and hence the potential radiation risk is considerable. In line with the COMARE report [COMARE 2007], it may be stated that there is little evidence that demonstrates, for whole-body CT scanning, that the benefit outweighs the detriment.

	Lifetime excess cancer risk		
	Female	**Male**	**averaged over both sexes**
Lung CT [Brenner 2004]: Lifetime excess lung cancer risk for smokers undergoing *annual* screening from age 50 to 75	0.85%	0.23%	–
Lung CT [Nekolla 2008]: Lifetime excess total cancer risk for smokers undergoing *annual* screening from age 50 to 69	0.59%	0.23%	–
Virtual colonoscopy [Brenner & Georgsson 2005]: Lifetime excess total cancer risk from *single* paired CT at age 50	0.13%	0.15%	–
Virtual colonoscopy [Hall & Brenner 2008]: Lifetime excess total cancer risk from *single* paired CT at age 50	–	–	0.14%
Virtual colonoscopy [Nekolla 2008]: Lifetime excess total cancer risk from three paired CT exams at age 50, 60, 70	0.12%	0.12%	–

Calcium scoring [Hall & Brenner 2008]: Lifetime excess lung cancer *mortality* risk from single exam (men aged 45–75 years and women aged 55–75 years)	0.016%	0.009%	0.013%
Calcium scoring [Nekolla 2008]: Lifetime excess total cancer risk from five exams from age 50 to 66	0.18%	0.07%	–
Whole-body CT [Brenner & Elliston 2004: Lifetime excess total cancer *mortality* risk from *annual* screening from age 50 to 74	–	–	1.5%
Whole-body CT [Nekolla 2008]: Lifetime excess total cancer risk from *biannual* screening from age 50 to 68	1.08%	0.8%	–

TABLE 1: Lifetime excess lung cancer risk for various CT screening settings

For a German population, lifetime attributable risks for four specified CT screening scenarios (calcium scoring, virtual colonoscopy, lung cancer, and whole-body screening) were calculated based on radiation risk models published by the BEIR VII committee in 2006 for a German population, being representative for a population in Central Europe [Nekolla 2008]. The authors concluded that the radiation risks associated with CT screening should not be neglected from a radiation protection perspective, and that, on the other hand, there are, to date, no valid data from randomized controlled trials demonstrating a benefit, i.e. a significant reduction in cancer mortality due to CT screening. Thus, scientific evidence is, at present, insufficient to recommend organized CT screening programmes.

III. Final Analysis

Tremendous developments in CT technology have taken place over the last decade. The growing use of radiation related to this technology is of great benefit to individual patients and to society as a whole. However, it has also led to a large increase in medical radiation exposure, which raises radiation protection concerns. Thus, some CT exams such as whole-body CT deliver in one single examination the dose to a patient that may exceed the dose limit of 20 mSv per year for an occupationally exposed worker. In addition, attention needs to be paid to control exposures delivered by CT, since organ doses – in particular in re-

peated CT scanning – may reach values beyond 50-100 mGy. Concerning dynamic contrast-enhanced CT exams, even higher organ doses may occur [Brix, 2010]. Scientific evidence is sufficient to conclude a statistically significant increase of cancer rates attributable to radiation exposures in this dose range.

To justify these high-dose applications of X-rays it is pivotal to critically weigh the benefits of CT against the individual detriment. It is important to note that the principle of justification is at least as important as the principle of optimization in order to ensure radiation protection in medicine. Unfortunately, the actions initiated by international radiation protection organizations and national regulators often show the tendency to suggest separate approaches to develop and consolidate both fundamental principles in medicine – with emphasis on medical and radiological practitioners concerning justification and with emphasis on technical staff and medical physicists concerning optimization. However, in clinical practice, a close interaction of both principles is strongly needed. Even an optimised application of X-rays fails to comply with the principles of radiation protection in medicine, if it is not justified. As a consequence, it should be considered to extend the ALARA approach by launching concerted actions taking both principles into account.

Concerning healthcare, evolving new X-ray technologies such as multi-slice spiral CT have a rapidly growing impact on the treatment of patients. Hereby, it has to be considered that only a small fraction of the population receives medical exposures in any year, in particular elderly and severely-ill persons, who may hopefully benefit from these new X-ray technologies. With respect to risk, it is important to note that life-expectancy may be shorter than latency period for radiation-induced cancer for a significant fraction of patients undergoing CT, and that radiation-induced cancer risk may by outweighed by benefit for those surviving the latency period – provided an adequate justification has been carried out. Nevertheless, in order to obtain sufficient scientific evidence, a reliable benefit-risk analysis of radiological imaging procedures has to be broken down to diagnosis-related groups of patients, in particular to those being highly exposed as well as those being in particular radio-sensitive, e.g. pregnant women and children and

young adults. It has to be highly recommended to launch research projects addressing these important issues.

The rapid development in multi-slice spiral CT does not only have a great impact on healthcare but also on individual health assessment, since it offers the potential to scan large parts of the body within only a few seconds. However, due to the typically low prevalence of serious diseases in an asymptomatic population, the vast majority of individuals undergoing screening is not affected by the disease. These individuals do not derive a direct health effect, but can only be harmed either by radiation induced cancer or by adverse health effects such as false-positive results and overdiagnosis. With respect to benefit, it has to be kept in mind that – in contrast to X-ray mammography – no valid data from prospective, randomized clinical studies are yet available, indicating a significant reduction in cancer mortality due to CT screening. Nevertheless, national guidelines of scientific bodies in particular in UK und USA conclude that there are sufficient data to include some CT procedures, such as CT colonography, as an acceptable option for cancer screening. When considering scientific evidence being sufficient for this option it is pivotal to claim that the respective individual health assessment by CT is embedded in a well-established screening algorithm and is properly quality assured along the whole screening chain. Unfortunately, no standardised and optimised protocols and algorithms are yet available concerning the definition of risk profiles, technical performance of CT, reading and diagnostic workup of suspicious findings, training and education as well as documentation and evaluation. It has to be highly recommended to initiate actions on national and international level addressing these important issues. From the radiation protection perspective, these issues were treated in some more detail in a HERCA “Position Paper on Screening” in the framework of the exposure of asymptomatic individuals in healthcare [HERCA 2012]. The position paper proposes a clear distinction between screening and radiological procedures as part of an individual health assessment and highlights special requirements for the latter.

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WP 3: CT Dose Reduction Techniques: Equipment

Author: M. Prokop

I. Introduction

CT dose reduction has been an issue in Europe already since the 1990s. In the US, dose issues emerged around paediatric CT protocols and have resulted in the Image Gently Initiative.

Dose reduction in CT is usually achieved by reducing the tube load and thus the radiation exposure to the patient. If all other parameters are kept constant, this reduction in radiation exposure will result in less x-ray quanta that hit the detector and consequently will result in a reduced image quality with higher image noise. CT dose reduction techniques rely on achieving a diagnostic image quality even if the detector dose is reduced. Those reduction techniques involve either an optimization of the scanner hardware, adaptation of the tube output to the absorption in the examined body part, or image filtering and image processing techniques. The latter will improve image quality and will allow for using less radiation dose under the condition of still achieving a diagnostic quality image.

The following techniques allow for dose reduction without or with a minimum loss of image quality:

- Improved detector technology (receptor material, detector electronics, scatter reduction)
- Adaptive collimation to reduce over-ranging
- Dose modulation and automated exposure control
- Adaptive filtering of raw data
- Iterative reconstruction of raw data

The following techniques allow for dose reduction with a trade-off in image quality:

- Scan thin –read thick (reduction of through-plane resolution)
- Smoothing filter kernels (reduction of in-plane resolution)
- Low kVp techniques (increase in contrast from materials with high atomic number like contrast material but also increase image noise)
- Optimization of contrast material injection (increase of contrast from contrast material).

These techniques will make dose reduction possible but will also compromise on some aspects of image quality, such as through-plane resolution, in-plane resolution or contrast resolution for (non-contrast-enhanced) tissue. To which extent they can be applied depends very much on the clinical task.

Cardiac dose reduction techniques are focused on the specific requirements of cardiac imaging and the synchronization of the scan with the ECG signal. Which of the techniques are used will depend strongly on the clinical indication and the available scanner configuration. There are some additional hardware techniques that reduce dose to tissues outside the heart:

- ECG dose modulation for retrospective gating
- ECG pulsing for prospective triggering
- ECG triggered spiral scanning
- Reduced scan field of view

Most dose reduction techniques will be switched on as a standard in all CT applications on a specific scanner. Others would have to be tailored to the clinical question at the therefore required image quality.

II. Review of Relevant Literature

II.1 Dose Reduction by Optimizing Scanner Hardware

II.1.1 Improved Detector Material and Electronics

The move from gas detectors (Xenon) to solid-state detectors in the 1990s has improved the dose efficiency of detectors by roughly 30%. Solid-state detectors are nowadays standard in all CT systems. The detector material, however, varies widely. While the detection efficiency of the receptor materials are already very high (usually > 90%), after glow effects and detector electronics become focus of attention. Detector noise has been neglected in single slice CT units but becomes the limiting factor in multidetector CT.

New types of detector electronics have therefore been developed with more transistors, less wiring and direct connection to the detector material. Such detector elements nowadays consist of the receptor material combined with a chip that contains most processing steps from amplification to preprocessing. As a result, the radiation dose required to obtain a defined image quality has reduced as newer and newer scanner generations are being introduced.

II.1.2 Improved Afterglow

Afterglow refers to the effect that signal transformation from x-rays to light photons within the detector material is not instantaneous but is spread out over time. There is a decay of light emission over time that influences the detector signal as the tube rotates around the patient: signal from previous rotation angles superimposes over the current signal. This afterglow effect has to be tackled mathematically but increases electronic noise. Newer detector materials with less afterglow therefore decrease noise and allow for dose reduction.

II.1.3 Improved Scatter Reduction

As the detector systems of multidetector CT scanners become wider, the amount of scattered radiation increases. This problem gets even more pronounced with dual source scanners. Various techniques for scatter reduction have been implemented, most of which rely on modeling the scattered fraction. One manufacturer, however, has introduced a novel two-dimensional anti-scatter grid that substantially reduces scattered radiation even for a wide detector system. Again, this technique leads to a better signal-to-noise ratio and allows for either improving image quality or reducing the radiation dose.

II.1.4 Adaptive Collimation

With increasing widths of the detector system, the relative amount of the penumbra decreases. At the same time, however, the effect of over-ranging increases. This effect can become the dominant contributor to radiation dose to the patient. For this reason, and an adaptive collimation technique has been developed that gradually opens the detector along the z-axis as the scan commences and closes the detector towards the end of the scan range. This technique can reduce the effect of overranging a factor of two. Overranging as such, however, will still be present.

II.2 Dose Modulation Techniques

Dose modulation techniques vary the mAs values as the scan progresses and adapt the mAs values to the individual absorption within the patient or organ region. Dose modulation was primarily performed in the scan plane (XY plane), later this was to modulation along the patient longitudinal axis (Z-axis). Recent developments suggest modulating the dose in such a way that especially radiation sensitive organs such as the eye lenses or the breasts are less exposed.

II.2.1 Dose Modulation in XY Plane

Dose modulation in the XY plane increases the mAs during projections with high absorption (e.g. lateral projection through the shoulder regions) and reduces the mAs during projections with less absorption (e.g. AP chest). This can be performed based on an estimation of the AP and lateral absorption from one or two localizer scans, or it can be done adaptively, based on the absorption measured on the previous half rotation. The technique works well if there are no substantial variations along the patient axis. However, it fails and is even counterproductive if areas with strong absorption differences such as neck/shoulder regions are examined. In this case, either the neck is overexposed or the shoulders are underexposed. The technique should therefore always be combined with z-axis modulation.

II.2.2 Dose Modulation along Z Axis

Dose modulation along the z-axis adapts the mAs values to the variations in absorption along the patient axis. This variation can again be determined from localizer scans or from the previous half rotation. As detectors become wider, the latter on-line adaptive technique (that uses information from the previous half rotation) is working less well. Even if dose modulation is based on PA and lateral localizer scans, wider detectors will inevitably include more heterogeneously absorbing body regions, thus either overexposing low absorption regions or underexposing highly absorbing regions.

II.2.3 Dose Modulation in XYZ

Dose modulation should always combine modulation in the scan plane and along the patient axis. This type of modulation adapts the radiation exposure to the absorption within the examined region. The same limitations hold as described above for z-axis modulation. With increasing width of the detector and the correspondingly increased anatomic coverage at every point of the scan, xyz modula-

tion is less effective because it has to provide enough dose for the most absorbing areas, thus relatively overexposing the less absorbing areas. In scanners with wise detectors, xyz modulation has to be combined by adaptive filtering or iterative reconstruction to be most efficient.

II.2.4 Automatic Exposure Control

Automatic exposure control combines dose modulation with a prediction of the dose required to obtain a predefined signal-to-noise. Usually the required mAs values are estimated from localizer scans. A number of techniques are presently in use: one technique is based on a reference mAs value that represents the mAs value used for an average sized patient. This technique is intuitive for technologists but may cause problems in achieving the predefined quality goals. The second technique is based on a noise index, which describes the image noise that would be obtained in the center of a human sized water phantom. This technique provides better control over the image quality but still is not able to completely predict the result. The final technique uses machine learning and the input of technologists to estimate the mAs settings for an unknown patient from the chosen settings in devious patients. The system models the choice of the technologists for adapting mAs to patient size.

While automated exposure control is a big step towards individual optimization of exposure and stabilization of image quality, a few issues remain:

No single noise index is optimum for all size patients. In fact, less noise is acceptable in slim patients and children while more noise can be accommodated in large patients with larger amounts of fat, which serves as a natural contrast agent that helps in distinguishing various organs.

In systems that use a reference mAs, this size-dependence of required image quality is built into the system. Yet the curve that defines this size-dependence is not transparent for the user despite the fact that it can be altered and adapted to a specific imaging task.

Self-learning exposure control systems assume that the radiographer knows how to choose the correct exposure setting during the training period. The radiographer thus becomes the “gold standard”, which makes these exposure control systems rely heavily on the skill of radiographers. In fact, learning becomes impossible if the adaptation of mAs settings to patient size chosen by the radiographers is not consistent, e.g. in a situation where multiple radiographers work on the same scanner.

II.2.5 Anatomic Dose Modulation

Anatomic dose modulation is a developing technique in which the mAs are reduced when radiation sensitive organs are directly exposed, such as in the AP direction for the breasts or the eye lenses. Conversely, the dose is increased in the reverse direction.

II.3 Reconstruction and Filtering Techniques

II.3.1 Noise-reducing Post-processing

Noise-reduction techniques based on image data are not widely used although most manufacturers provide some options for doing so.

The simplest one, image smoothing reduces spatial resolution. One manufacturer, however, is experimenting with an adaptive filter that combines windowing with various amounts of smoothing, thereby imitating the current practice that a high-resolution filter kernel is used in regions that can be viewed with a wide window setting (such as lungs or bone) and a more smoothing filter kernel is used for soft tissues that are viewed with a narrower window setting.

Contour-preserving smoothing allows for preserving spatial resolution while reducing image noise. These options have not been widely used but have a certain overlap with iterative processing techniques that are expected to become the new future standard in CT. Depending on the implementation, artifacts may occur

that may let an image look “unnatural” or even may induce artifactual structures that actually represent processed noise.

Some manufacturers include noise-reduction in their 3D rendering technique to provide better image quality at a relatively low dose.

II.3.2 Adaptive Filtering of Raw Data

Adaptive filtering of raw data is based on local averaging of projection data so that the signal is increased and the local SNR is improved. This is only done for projections with low signal and high noise levels. As this filtered raw data is used for image reconstruction, noise and image artifacts are substantially reduced while spatial resolution is only mildly effected. A good implementation is required to profit most from this technique without inducing overly smooth images.

II.3.3 Iterative Reconstruction of Raw Data

Iterative reconstruction of raw data is only possible with the recent increase in computation power. It requires up to 10 times longer for image reconstruction than conventional filtered back projection. The most sophisticated techniques that model the physical properties of the scanner take much longer and require hours on specific high-end hardware to calculate one dataset. The fact that such (expensive) systems are being developed and sold, suggests a dramatically increased radiation awareness, especially in the United States.

Iterative reconstruction can substantially increase image quality, especially for low dose data acquisition. Various flavors are available, ranging from iterative reconstruction in image space, to reconstructions in image and raw data space and, most efficiently, iterative reconstructions in raw data space. The more information about the scanner system is used for iterative reconstruction, the better is the image quality and the larger is the magnitude of dose reduction achievable, but also, the more processing power is required.

The amount of dose reduction that can be achieved is bigger than with most other techniques. For this reason, this technology deserves and gets a lot of attention.

Iterative reconstruction techniques are still not mature. Artifacts are frequently present: an artificial look may reduce the amount of filtering and thus, dose reduction, that is deemed acceptable by radiologists. In addition is the terminology not yet standardized and vastly different algorithms are sold under the same header.

II.4 Dose Reduction by Reducing Resolution

Reducing the spatial resolution will decrease image noise. This technique can be used to regain image quality as radiation dose is reduced. Whether such a technique is possible depends strongly on the clinical application.

II.4.1 Scan Thin – Read Thick (Reduction of Through-plane Resolution)

The “scan thin-read thick” approach to multidetector CT has become the clinical standard in most circumstances. It is based on the acquisition of a near isotropic data set, from which images in arbitrary planes can be reconstructed. Radiation dose is chosen in such a way that the image quality of thick sections (usually 3 to 5 mm thickness) is diagnostic but that image noise on the original thin section data is too high. Compared to a 1 mm section, 5 mm section with the same image noise requires less than a fifth of the radiation exposure. The technique is very powerful and therefore the basis for all image interpretation and dose containment.

The increased partial volume effects are often compensated by the fact that not only axial but also images in coronal, sagittal or problem-adapted planes can be reconstructed.

II.4.2 Smoothing Filter Kernels (Reduction of In-plane Resolution)

Smoothing filter kernels will lead to reduction of in plane resolution, which is only acceptable if the structures of interest are large enough. Frequently, however, users choose for more sharpness than actually necessary in a CT image, which comes with an unnecessary increase in radiation exposure to achieve a similar SNR.

II.5 Dose Reduction by Maximizing Contrast

II.5.1 Low kVp Techniques

Low kVp techniques increase the contrast from materials with high atomic number like contrast material or bone but also increase the general absorption from radiation. In regions with comparatively little absorption to the increase in contrast outweighs the increase in absorption. Low kVp techniques are very powerful tools for CT angiography or other CT techniques in which contrast enhancement needs to be maximized. They need to be combined with wide window settings and allow for keeping the SNR constant while reducing radiation dose. They have become standard for contrast enhanced examinations in children, for the chest and the heart.

However, if low kVp settings are erroneously used for large patients or regions with substantial absorption, such as the abdomen in obese adults, image quality may be severely compromised by excessive noise or, in case automated exposure control techniques were used, the radiation exposure to maintain diagnostic image quality will be excessive.

II.5.2 Optimization of Contrast Material Injection

Optimization of contrast material injection increases contrast from contrast material in the body and could in theory be used to improve SNR, which again might

make dose reduction possible. In clinical practice, however, these techniques are not used for dose reduction but for improvement of image quality.

II.6 Cardiac Dose Reduction Techniques

Cardiac imaging with CT used to be a technique with a high radiation exposure (up to 30 mSv effective dose, and up to 100 mSv organ dose). New scanning techniques have reduced the dose requirements dramatically.

II.6.1 ECG Dose Modulation for Retrospective Gating

For retrospective ECG gating the radiation dose is switched on during the whole cardiac cycle. However, usually only a small portion of this data is used for image evaluation. This is the data in which the cardiac motion is minimal so that the motion artifacts within the coronaries are as small as possible. ECG dose modulation reduces the mA during those phases of the cardiac cycle in which data will most likely not be necessary for reconstruction of the coronaries.

The technique works best if the heart frequency is constant and low (< 60 bpm): under these circumstances only during a short period in mid diastole the mA values are maximized and outside this predefined range the mA values are sent to a minimum value which depends on the manufacturer (4% or 20% of the maximum value). As the heart rate goes up, the optimum phase switches to systole, which makes it difficult for patients with a heart rate in the transition zone between 60 and 80 bpm. For these patients, the period in which the mA values have to be kept at 100% has to include both mid diastole and end systole. This makes ECG dose modulation relatively inefficient and strongly heart-rate-dependent. Depending on the scanner, the heart frequency and the minimum value, the temporal dose efficiency (i.e. the ratio between the dose used for image reconstruction and the dose given to the patient) varies between 5% and the and 50%.

II.6.2 ECG Pulsing for Prospective Triggering

Prospective triggering is a technique for cardiac CT, in which the optimum heart phase is determined prospectively. The appropriate interval from the preceding R-wave is determined so that the scan can be performed during a motionless period (usually mid diastole).

The technique is more vulnerable to changes in heart frequency than retrospective gating. It works best for very fast acquisitions (dual source CT) or very large detectors (320-slice scanners). Variations in heart frequency can be compensated by giving extra dose at the beginning and end of the planned acquisition interval ("padding") so that the reconstruction interval can be shifted somewhat to accommodate the variations in heart frequency. The more padding is used, the less dose-efficient the technique becomes. Depending on the padding, the temporal dose efficiency varies between 50 and 100%.

II.6.3 ECG Triggered Spiral Scanning

ECG triggered spiral scanning is the newest addition to the cardiac scanning techniques. Here a spiral scan is timed so that the scan range covers the heart during diastole. Prerequisite is very fast data acquisition, which is possible with the newest scanner generation that accommodates table speeds of more than 40 cm/s. With these scanners, the heart can be acquired in less than 0.3 s. The temporal dose efficiency of this technique is 100%.

Low enough heart frequency and proper timing are, however, crucial for the success of the scan. Otherwise substantial motion artifacts can occur.

II.7 Dose Reduction Technique in Children

For paediatric applications, justification and indication for the examination are of paramount importance.

All techniques described above can be used for minimizing radiation exposure to children. Most important is child-sizing of exposure settings. Automated exposure control techniques, however, may not optimally compensate for the smaller body size of children. In fact, techniques that aim at obtaining a constant noise level will actually *under*-expose children because in small bodies less noise can be accepted or slightly higher resolution reconstruction filters will have to be used to optimize image quality. Manufacturers have started providing size-dependent protocols for children that address these issues while still using dose modulation techniques to further optimize exposure settings.

Practical approaches to paediatric CT will be discussed in the next chapter.

III. Final Analysis

In the past decade, development of detector and scanner hardware was driven by optimization of image quality, first for body imaging, and recently for cardiac and perfusion imaging. With each new scanner generation, the options for radiation dose reduction were increased as well, mainly owing to improvements in detector technology and scanner design. With increasingly wider detectors, however, dose optimization becomes more of a challenge due to inhomogeneity of attenuation within the anatomic regions covered by the detector and because of more problems with overranging.

Dose modulation techniques adapt the dose to the individual size of patients, to the absorption within the body and try to spare radiation-sensitive organs. These techniques, however, face challenges with new wide-detector scanners. In addition, the variability in technical solutions makes it difficult to compare settings. Here the manufacturers have to work on standardization of terminology. Despite this adaptive dose modulation, settings may have to be adapted patients outside a specific standard range.

For further optimization kV settings and contrast injection parameters have to be individualized as well. Future automation of this process is to be welcomed.

An indicator on the CT scanner console that relates the prescribed dose to the corresponding DRL should be considered. For quality control purposes, manufacturers should consider establishing a technique that generates a database on each individual scanner that records the exposure summary including patient demographics (weight, height, gender).

Iterative image reconstruction and various filtering techniques promise to vastly improve image quality for low-dose acquisitions and are the most promising new development in the field. Standardization of terminology should be attempted.

ECG synchronization has been the reason for very high radiation exposure for cardiac CT, but current techniques based on prospective triggering promise to bring down the dose to levels of standard CT techniques.

Paediatric patients pose no exception to the rules defined above for dose optimization. However, special care has to be taken to ensure sufficient image quality while child-sizing CT protocols. Here, manufacturers should work together on more unified and simplified approaches to achieve this.

WP 4: CT Dose Reduction Techniques: Protocols

Author: M. Prokop

I. Introduction

The ever increasing diagnostic options and clinical benefits of multislice computed tomography (MSCT) have lead to a dramatic increase in CT utilization. As a result, radiation exposure of the population due to CT has increased substantially over the past decade. Dose reduction efforts in CT have to rely on good justification of the indication for the exam and in an individual optimization of the CT protocols.

Justification is a task that is carried out in consultation between the referring physician and the radiologist. Due to limited knowledge of referring physicians about imaging techniques and their capabilities, however, the radiologist plays a crucial role for checking this justification and suggesting potential alternatives. While new scanner generations have increased the technical possibilities for dose containment, expanding CT applications have counteracted a possible reduction of population exposure. Special attention has to be given to new functional imaging applications of CT where multiple acquisitions are performed and dose containment techniques are only in their infancy.

Optimization of the CT scan protocols involves setting up standardized protocols that use individual adaptation of the scan parameters and exposure settings to compensate for individual variations in body size. Such adaptations are especially important in children where unadjusted protocols may lead to an unnecessarily radiation exposure with a substantial and unnecessary increase in radiation-induced cancer risk. Adaptations are also necessary for obese patients in order to maintain sufficient image quality. A specific CT protocol has to be chosen so that it is able to provide the clinically required image quality while aiming at a dose as low as reasonably possible. The set up of a “core team” consisting of a specialized CT radiologist, a CT radiographer and a qualified medical physi-

cist is recommended to ensure the best compromise between image quality and dose containment.

II. Synopsis of Relevant Literature

II.1 International Reviews

II.1.1 Justification

Justification of the CT is an essential prerequisite for reducing radiation exposure to the patient population. The “Radiation protection 118”, referral guidelines for imaging updated 2008 for the European Commission, provide a good overview over current indications for, among others, CT imaging (1). The European Guidelines for Multislice Computed Tomography (2) describe that, as the indications of CT are ever expanding, it is essential that the referring physician provides adequate clinical information so that the radiologist can judge whether the exam is justified (2). Unnecessary repeat exams should be avoided. Information from previous exams may be used to limit the exposed range. Other imaging modalities using no ionizing radiation should be considered if they are expected to provide adequate answers to the clinical request.

II.1.2 Protocol Optimization

The need for protocol optimization has been seen in Europe already in the 1990s and has lead to the EU Quality Criteria for Computed Tomography (3). An update of these efforts has lead to European Guidelines for Multislice Computed Tomography that have been developed by a consortium funded by the European Commission. These comprehensive guidelines describe a long list of factors that need to be optimized for ensuring a good image quality while remaining dose-conscious (2):

- Justification
- Supervision by qualified personnel (radiographer and radiologist)

- Proper patient preparation
  - Ensuring patient cooperation
  - Consider protective shielding
  - Remove dense items from clothing
  - Enquire about recent contrast media studies
  - Consider fasting
  - Provide oral contrast media if required
  - Ensure proper patient position
- Optimize scan projection radiograph
- Chose acquisition time
  - Target volume
  - Table speed
  - Rotation time
  - Pitch
  - Beam collimation
- Optimize exposure factors
  - Tube voltage
  - Tube current X time (mAs) and pitch
- Optimize image reconstruction
  - Section thickness
  - Reconstruction increment (overlap)
  - Filed of view (FOV)
  - Reconstruction matrix
  - Reconstruction algorithm (filter, kernel)

- Optimize intravascular contrast application
  - Dose and concentration of contrast media
  - Flow rate
  - Timing (delay) for proper phase of perfusion
- Reformats
  - Multiplanar reformats (adjust plane orientation, thickness)
  - 3D reconstructions (VR, SSD, MIP, MinIP, virtual endoscopy)

The same consortium has also worked on recommendations for paediatric CT. These focus on appropriate selection of paediatric patients for MSCT (justification), optimizing patient preparation (oral contrast, artifact reduction), increasing scan speed to reduce motion effects, optimize breath hold and contrast material injection and choosing the correct exposure parameters that are adapted to the reduced patient size.

Efforts in the United States focused mainly on protocol adaptations for children and have lead to the “Image Gently” campaign (4). The following 10 optimization steps for paediatric CT are suggested:

1. “Increase awareness and understanding of CT radiation dose issues among radiographers,
2. Enlist the services of a qualified medical physicist,
3. Obtain accreditation from the American College of Radiology for your CT program,
4. When appropriate, use an alternative imaging strategy that does not use ionizing radiation,
5. Determine if the ordered CT is justified by the clinical indication,
6. Establish baseline radiation dose for adult-sized patients,
7. Establish radiation doses for paediatric patients by "child-sizing" CT scanning parameters,

8. Optimize paediatric examination parameters
    a. center the patient in the gantry,
    b. reduce doses during projection scout (topogram) views,
    c. axial versus helical mode,
    d. reduce detector size in z direction during acquisition,
    e. adjust the product of tube current and exposure time,
    f. when to adjust the kilovoltage,
    g. increase pitch,
    h. manual or automatic exposure control,
9. Scan only the indicated area: scan once,
10. Prepare a child-friendly and expeditious CT environment. “

The National Cancer Institute of the US suggests the following steps to reduce radiation exposure to paediatric patients (5):

- Justification: *“Perform only necessary CT examinations.* Communication between paediatric health care providers and radiologists can determine the need for CT and the technique to be used. There are standard indications for CT in children, and radiologists should review reasons prior to every paediatric scan and be available for consultation when indications are uncertain. When appropriate, consider other modalities such as ultrasound or magnetic resonance imaging, which do not use ionizing radiation.”
- Optimize scan parameters: *“Adjust exposure parameters for paediatric CT based on:*
    - Child size: guidelines based on individual size / weight parameters should be used.
    - Region scanned: the region of the body scanned should be limited to the smallest necessary area.

  - Organ systems scanned: lower mA and/or kVp settings should be considered for skeletal, lung imaging, and some CT angiographic and follow up examinations."

- Adjust scan protocol: *"Scan resolution*: the highest quality images (i.e., those that require the most radiation) are not always required to make diagnoses. In many cases, lower-resolution scans are diagnostic. Be familiar with the dose descriptors available on CT scanners. Minimize the CT examinations that use multiple scans obtained during different phases of contrast enhancement (multiphase examinations). These multiphase examinations are rarely necessary, especially in body (chest and abdomen) imaging, and result in a considerable increase in dose."

In their Public Health Notification on "Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients" the FDA suggests the following measures:

- "Optimize CT Settings based on patient weight or diameter and anatomic region of interest …
- Reduce tube current …
- Develop and use a chart or table of tube-current settings based on patient weight or diameter and anatomical region of interest.
- Increase table increment (axial scanning) or pitch (helical scanning). Note that some newer CT scanners may automatically suggest or implement an increase in mA if pitch is increased. For these models, increasing the pitch may not result in a lower radiation dose. Contact the CT scanner's manufacturer for recommendations on your model's automatic current adjustment features.
- Reduce the number of multiple scans with contrast material…
- Eliminate inappropriate referrals for CT…"

Recent problems with deterministic effects of radiation exposure during CT brain perfusion have lead to efforts to optimize protocols for neuroimaging. The ACR

and American Society of Neuroradiology suggest the following actions to minimize patient dose: (7)

- "Together, the lead radiologist, lead CT technologist [radiographer], and qualified medical physicist should design and review all new or modified protocol settings, to insure that both image quality and radiation dose aspects are appropriate.
- Develop internal radiation dose thresholds during any new CT protocol design.
- If an estimated dose value is above the applicable threshold for any routine clinical CT exam, implement steps to insure patient safety and reduce future risk.
- Institute a regular review process of all protocols to be sure that no unintended changes have been applied that may degrade image quality or unreasonably increase dose.
- Do not disable the CT dose estimate interface option; be sure that the dose information is displayed during the exam prescription phase.
- CT staff should maintain CT-specific continuing education that focuses on patient safety.
- Obtain ACR CT Accreditation for an independent check of a facility's personnel, imaging techniques, image quality and dose. "

II. 2 Scientific Literature

The following considerations highlight some of the issues mentioned above that are currently discussed in the scientific literature.

II.2.1 Patient Preparation

- ***Radiation Shields***

An ongoing practical issue relates to the use of shields to reduce radiation dose to radiosensitive organs, such as breast, thyroid, lens of the eye, or gonads. These shields have to be placed after the localizer radiographs have been taken.

The proper protocol depends on the design of the AEC features of the scanner; one approach is not appropriate for all CT scanner manufacturers. If not used properly, the presence of shielding may lead to increased radiation dose to the patient (8).

- ***Patient Positioning***

Placing the patient in center of gantry avoids unnecessary high skin exposure.

Choice of scan protocol

- ***Scan Projection Radiographs***

PA localizer radiographs, for some indications also lateral localizer radiographs are performed to establish the scan range and in some scanners, to guide the automated exposure control programs. By choosing 80 kV and minimum mAs the dose can be reduced to a minimum without affecting scan range selection.

- ***Number of Phases***

Each additional phase of a multiphase CT exam increases dose. Reduction to a minimum is therefore important but depends on clinical indication. A potential solution is the split bolus technique that splits the contrast bolus into two sequentially injected aliquots and combines contrast enhancement characteristics of two separate phase, eg. arterial and portal phase for trauma cases, and arterial, nephrographic and excretory phase for CT urography. This technique, however, is reserved for special indications in which such an approach is adequate and does not lead to missing important findings.

- ***Scan Range***

The scan range should be kept as short as possible (e.g. lung embolism studies). Do not include liver routinely in chest scans. Automated techniques that detect anatomic features and suggest an optimized scan range should be activated if available.

- ***Spiral or Sequential Scan Mode***

A spiral mode is usually more dose-efficient than a sequential scan mode. The only exception is HRCT of the chest in which a discontinuous sequential scanning protocol may be used. Typically 1mm-sections are acquired every 10mm. This dramatically reduces exposure but needs to be weighed against the discontinuous data acquisition that is only able to assess diffuse lung disease and may miss focal lesions.

II.2.2 Choice of Scan Parameters

- ***Adaptation of Tube Voltage***

Low kV techniques have become increasingly important for contrast-enhanced exams. The technique strongly increases contrast but also increases noise. The noise increase depends on the absorption in the body. An improvement in contrast-to-noise-ratio (CNR) can be reached in regions of low to modest absorption. Alternatively, the exposure can be reduced without adversely affecting CNR. To accommodate the higher intravascular contrast, the window setting has to be widened accordingly. Lowering the kV is a powerful dose-reduction technique for CT angiography in the head, neck, chest, heart and in the abdomen of slim patients or children.

- ***Individual Adaption of mAs settings***

Individual adaptation of mAs settings to the patient size ensures more constant image quality for large patients and less radiation exposure for small patients and children. The mAs setting also has to be adjusted to the organ site (less for

chest, more for abdomen). The results can be presented in a weight-based exposure table. Alternatively, simple formulas can be used to estimate how to adjust exposure parameters based on a reference weight. The formula suggested by Rogalla provides stable results and calculates the percentage of the reference mAs based on the patient weight:

Percentage = (weight+5kg)/ reference weight

The reference mAs should be chosen so that image quality is adequate in patients with the reference weight (e.g. 80 kg). It is important to note, however, that this adequate quality only needs to be reached for thicker sections (usually 5mm for body imaging) but not for the thin sections that can also be reconstructed from the raw data.

- ***Automated Exposure Control / XYZ Dose Modulation***

Automated dose modulation along the z-axis is generally recommended for reducing dose while maintaining adequate image quality.

Pure XY modulation techniques are discouraged under most conditions: for the example of chest imaging, the asymmetry in the shoulder region (AP versus lateral diameter) is marked and leads to substantial down-regulation of exposure in AP/PA directions as opposed to the lateral directions. For the central chest, however, the difference between AP and lateral exposure is less, which means that the exposure in both directions is similar to the exposure for the shoulder. The result is a substantial overexposure for the (less-absorbing) central chest or a substantial underexposure of the shoulder region.

XYZ dose modulation is to be preferred over XY dose modulation because it compensates for variation in x-ray attenuation along the z-axis. Some scanners require choice between z-axis modulation and XY modulation. For regions with strong variations in attenuation along the z-axis (neck-chest or chest-abdomen), z-axis modulation is more efficient while for regions with relatively modest variations along the z-axis (abdomen), XY modulation may be more advantageous. Adaptive dose modulation techniques are now a standard technique for CT.

There is still substantial variation between manufacturers as how these concepts are implemented. Increasingly recommendations about dose indices and target mAs are being published. However, the lack of a uniform terminology makes it difficult to compare results across various vendors.

- ***Detector Width***

Wide detector width (beam collimation) reduces penumbra effects but increases over-ranging with spiral scanning. For this reason, adaptive collimation techniques have been developed that open the collimation at the beginning of the scan and close it at its end. The most dose-efficient technique varies with detector width, scanner manufacturer and scan range. For children and short scan ranges it is usually not advisable to use the maximum detector width during spiral scanning. An intelligent algorithm that suggests the lowest overall exposure for a given scan range should become implemented on the scanner interface.

- ***Pitch***

For single slice CT a high pitch is advantageous for providing the best compromise between slice thickness and radiation dose.

For multislice CT, the effect of pitch is strongly dependent on the scanner manufacturer and the actual scanner model used. If the mAs are adjusted with varying pitch so that the “effective mAs” = mAs/Pitch are constant, then the radiation exposure should remain constant as well. High pitch has the advantage of a shorter scan time and potentially less motion artifacts but provides more over-ranging and is more prone to image reconstruction artifacts.

II.2.3 Choice of Reconstruction Parameters

- ***Scan Thin – Read Thick***

The “scan thin – read thick” principle is based on multiplanar reformations form a noisy near-isotropic data set. It has found widespread application in CT protocols since it retains spatial resolution within the imaging plane while reducing noise by

increasing the thickness of the reconstructed image. The “scan thin – read thick” principle avoids having to increase dose because of thinner sections.

The thickness of the original thin sections has to be adapted to the required spatial resolution in z-direction. In general, higher resolution (i.e. a minimum section collimation) is used for skeletal structures or the chest, while a slightly lower resolution (2x minimum collimation) is acceptable for the abdomen. This is important because dose efficiency of many scanners (<64-slice) is higher for the slightly wider collimation.

- ***Thickness for Image Review***

The section thickness for image review is not well examined. In general, 5mm sections are used for review but for dedicated applications thinner sections are required (e.g. 3mm for renal stones).

The thickness of the diagnostic images determines the dose required for image acquisition. By increasing this thickness from 3mm to 5mm, the dose requirements are reduced by a factor of $(5/3)^2 = 2.8$ (!) if image noise is kept identical. Usually, dose is not reduced that much but the reduced noise is used to improve low-contrast resolution. By also reconstructing an orthogonal plane (usually coronal), “partial volume effects” can be overcome for image interpretation.

- ***Filter Kernels***

More smoothing filter kernels lead to a stronger reduction in noise (or dose requirement for similar noise) than they lead to a reduction in spatial resolution. Also for this topic almost no clinical studies have evaluated as to how smooth a kernel can still be used.

- ***Adaptive Filtering***

Adaptive filtering leads to a substantial reduction in noise by filtering only those projections from the raw data that are subject to a lot of noise (e.g. lateral projections in the shoulder region). The result is only a minimum loss of spatial resolution but a substantial reduction of artifacts and noise. All studies so far have shown the beneficial nature of this technique.

- ***Iterative Reconstruction***

Iterative reconstruction is the most modern noise reduction technique discussed. It combines an iteratively reconstructed image with an image obtained form back projection to reduce the artificial look of such images. Various flavors are available depending on the manufacturer and on the reconstruction speed. Iterative reconstructions can be based mainly on image data with minimum input from raw data, or can be completely raw-data-based. The more information about the scanner is used during the iterative reconstruction process, the longer requires the reconstruction but the better are the resulting images.

Iterative reconstruction has only recently been introduced but clinical studies promise a substantial improvement in image quality or a corresponding reduction in required exposure dose. Again it is a technique that should always be used but precise filter strengths are still being discussed.

III. Final Analysis

Proper justification is the most important tool for reducing radiation exposure to the population. Guidelines on how to best make use of imaging have been pioneered in Britain but are now being translated and implemented in many European countries. These guidelines need continuous updating and adaptation to new indications for CT imaging. The European Society of radiology (ESR) is taking a leading role in this. However, the operator dependence of ultrasound and the higher cost of MRI make it difficult to choose for these alternatives in daily practice.

A multitude of CT parameters has to be optimized to provide the best compromise between dose and image quality. Protocols therefore need to be standardized by a qualified team of experts that should include a radiologist, a radiographer and ideally also a medical physicist. We suggest that every institution establishes such a “CT core team”. This core team should not only be responsible for protocol optimization but also for adequate training of those professionals who

prescribe appropriate CT protocols according to indication (radiologists or specially trained radiographers). The core team should also be responsible for training and supervising the CT radiographers that perform the actual scans so that these are able to adapt the standard protocols to individual patient size and special conditions that require protocol adaptations.

Adequate training of CT personnel (minimum requirement: training of core team) with regard to dose optimization should be mandatory for new scanners. It has to be considered how to ensure that the training was successful and the knowledge of CT personnel is adequate.

Since standard settings of manufacturers are the basis of most protocols in clinical practice these protocols have to become dose-optimized. Consider making it mandatory for vendors to provide a set of protocols that provide a certain predefined dose level. To encourage continuous dose optimization for new scanners, the dose levels for these protocols should be chosen such that they are well below (e.g., 50%) of the average DRL across EU countries (or comparable EU-wide reference levels).

In order for CT radiographers to understand the amount of dose they are applying, an indicator that relates the given dose to the corresponding DRL may be helpful. For quality control purposes, manufacturers should consider establishing a technique that generates a database on each individual scanner that records the exposure summary including patient demographics (weight, height, gender).

Individual adaptation of protocols to patient size and organ systems must be made as simple as possible: scanner-based systems such as adaptive dose modulation have to be implemented wherever possible. They are of paramount importance, especially for children. However, the variability in technical solutions makes it difficult to compare settings. Here, the manufacturers have to work on standardization of terminology. Despite this adaptive dose modulation, settings may have to be adapted to patients outside a specific standard range. For further optimization, however, kV setting and contrast injection parameters have to be individualized as well. In clinical practice, this individualization is mainly based on

spreadsheets or protocol tables. Future automation of this process is to be welcomed.

Adaptive filtering and iterative reconstruction are recent techniques for optimizing image quality. They can be used to reduce exposure without loosing diagnostic confidence. Adaptive filtering has become standard, while iterative reconstruction is still under development and has not yet been standardized.

The basis for any choice of protocol is the “scan thin – read thick” principle. It defines that the dose should be adjusted in such a way that image quality of sections of diagnostic quality are optimized and not of thin sections. Manufacturers should have to provide an explicit warning on their scanner console if dose modulation is optimized for thin sections and a certain dose ($CTDI_{vol}$) threshold is exceeded for a standard size patient. Such a dose threshold should be related to the average DRL across EU countries (or comparable EU-wide reference levels).

The core team responsible for CT protocols should make sure that the number of scan phases is minimized and the use of multiphase protocols is monitored.

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WP 5: CT Dose Efficiency Parameters

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I. Introduction

In many areas of daily life, benchmarking of products in terms of energy/fuel consumption or CO_2 emission has become standard for obvious reasons. With respect to the ongoing debate on the increased radiation exposure resulting from CT examinations, it would be highly desirable to know the dose efficiency of a CT scanner. This would facilitate the decision making when purchasing a new scanner, allow for a fair competition between manufacturers, and enable to set the appropriate dose level in protocol optimization

Low contrast detectability (LCD), which is dose dependent, is often regarded as a suitable metric for dose efficiency. However, due to the subjective assessment by visual inspection, it is difficult and time-consuming to obtain reliable results. Although LCD specifications are regularly provided by the scanner manufacturers, these are lacking due to two major issues (see tab. 1):

a) results often differ in more than one relevant parameter, thus making a direct comparison impossible;

b) specifications published by the manufacturers are generally too optimistic.

	Manufacturers' Specifications					ImPACT's Test Results			
Manufacturer	**A**	**B**	**C**	**D**		**A**	**B**	**C**	**D**
Scanner	**A 16**	**B 16**	**C16**	**D 16**		**A 16**	**B 16**	**C16**	**D 16**
Contrast C (%)	0.3	0.3	0.3	0.3		0.3	0.3	0.3	0.3
Detail size d (mm)	4	5	5	5		5	6	6	6
U (kV)	120	120	120	120		120	120	120	120
Q (mAs)	248	150	100	190		173	241	200	130
$CTDI_{w,H}$ (mGy)	31.5	17.7	18.2	41.8		22.0	31.6	36.4	28.6
h_{rec} (mm)	10	10	10	8		12	10	10	12
Phantom D_{eq} (cm)	18.0	18.0	18.0	18.0		18.0	18.0	18.0	18.0
CTDEV	**33**	**38**	**37**	**20**		**26**	**16**	**13**	**14**

Table 1: Comparison of the low contrast detectability of 16-slice scanners of the four major CT manufacturers, taken from the ImPACT test reports of each type of scanner (ImPACT 2004/1, ImPACT 2004/2, ImPACT 2004/3, ImPACT 2004/4), are based on the specifications given by the manufacturers and ImPACT's own test results. Use of a figure of merit (CTDEV, see section II.2) allows for comparison of results that differ in more than one relevant parameter.

In this context it is important to note that LCD assessment is not subject to any standard, as it is principally not possible to standardize a method based on visual perceptibility. This and other observations indicate that LCD specifications have become questionable and cannot serve for benchmarking purposes. The same applies to a dose efficiency index (DEI) originally proposed by Muramatsu (Okumura 2002), as this is also based on subjective assessment of LCD. Instead, objective methods that can easily be carried out and verified, and appropriate indices are required.

II. Synopsis of Relevant Literature

Except for one publication dealing with the assessment of noise power spectrum (NPS), no peer-reviewed literature on this topic exists up to now. Nevertheless, there are currently three approaches that might serve for the intended purpose:

a) ImPACT's Q_2 value (IPEM 2003),

b) the CT dose efficience value (CTDEV, Nagel 2010) based on the statistical method of Chao et al. (Chao 2000),

c) the noise equivalent quanta (NEQ) derived from NPS measurements as discussed in the publication of Boedeker et al. (2007)

The essentials of these approaches shall be outlined in brief.

II.1 ImPACT's Q_2 Value

The Q_2 value defined by ImPACT (Image Performance Assessment in CT, the CT evaluation facility of the Medicines and Healthcare Products Regulatory Agency in London) is an attempt to assess the dose efficiency of a scanner without making use of low contrast detectability. It incorporates objectively measured standard imaging performance parameters (dose, noise, spatial resolution and slice width) into one number, using a formula derived by ImPACT from fundamental relationships between image quality and dose, and is calculated as follows:

$$Q_2 = \sqrt{\frac{f_{av}^{\ 3}}{\sigma^2 \cdot h_{rec} \cdot CTDI_{vol}}} \qquad (1)$$

where

- f_{av} = spatial resolution (in lp/cm), given as (MTF50%+MTF10%)/2 (see fig. 1)
- σ = image noise (in %) for a 5 cm^2 region of interest at the centre of the field of view in the standard ImPACT water phantoms;
- h_{rec} = the full width at half maximum (FWHM) of the imaged slice profile (z-sensitivity) (in cm!);
- $CTDI_{vol}$ = volume CT dose index (in mGy) for the head or body phantom, depending on the size of the standard ImPACT water phantom used.

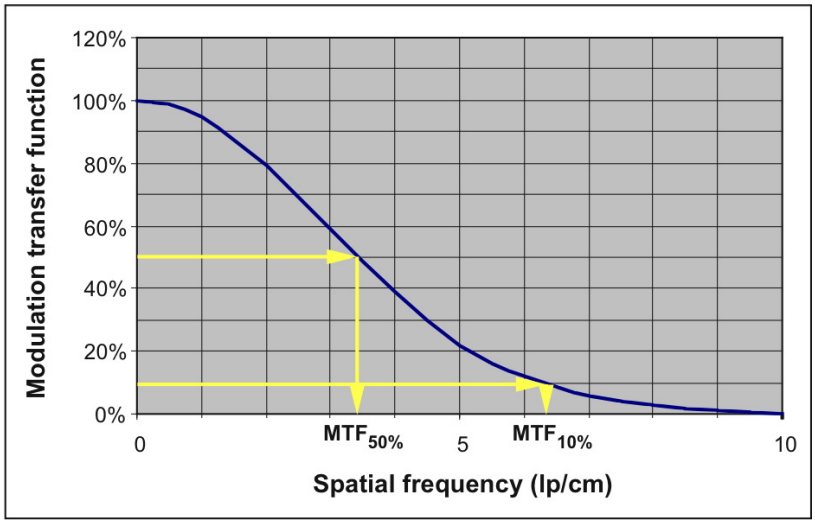

Figure 1: Determination of f_{av} = spatial resolution (in lp/cm), given as (MTF50%+ MTF10%)/2, where MTF50% and MTF10% are the spatial frequencies corresponding to the 50% and 10% value of the modulation transfer function.

Except for the determination of MTF, no dedicated software is required for the assessment of Q_2. In order to minimize the dependency of Q_2 upon reconstruction algorithms, filter kernels with standard spatial resolution values (i.e. with MTF50% and MTF10% values as close as possible to 3.4 lp/cm and 6.0 lp/cm) are required. Typical values of Q_2 are in the order of 5 to 7 for head scans and 1.5 to 2 for body scans.

In its essence, the Q_2 value is inversely proportional to the image noise in a small central area of the image under specified conditions (dose, slice thickness, phantom type and diameter) for a spatial frequency of approximately 5 lp/cm. The resulting figures are relative numbers on a non-linear scale, with higher figures expressing a corresponding increase in dose efficiency.

II.2 CTDEV Based on the Statistical Method of Chao et al.

The 'CT dose efficiency value (CTDEV)' (Nagel 2010) is a figure of merit that

puts all parameters that are relevant for the specification of LCD into a single number that is based on the fundamental theory of Rose (1973):

$$CTDEV = 10^5 \cdot \frac{e^{0.207 \cdot (D_{eq} - 16)}}{d^2 \cdot C^2 \cdot h_{rec} \cdot CTDI_{w,H}} \quad (2)$$

where

- d = size (diameter) of the low contrast detail (in mm);
- C = detail contrast (in %, with 1% = 10 HU);
- D_{eq} = PMMA-equivalent phantom diameter (in cm);
- h_{rec} = slice thickness (in mm), and
- $CTDI_{vol,H}$ = applied dose (in mGy) in terms of the volume CTDI for the 16 cm head phantom

Hence CTDEV serves to put LCD specifications on a comparable basis. This figure of merit can already be used for LCD values obtained from subjective assessment (see tab. 1). The resulting figures are relative numbers on a linear scale, with higher figures expressing a corresponding increase in dose efficiency. Typical values of CTDEV for state-of-the art scanners are in the order of 20 to 40.

Alternatively, the same findings can also be expressed in terms of a standard dose $CTDI_{std}$ defined as

$$CTDI_{std} = CTDI_{vol,H} \cdot \frac{(C/0.3)^2 \cdot (d/4)^2 \cdot (h_{rec}/5)}{\exp^{0.207 \cdot (D_{eq} - 16)}} \quad (3)$$

that refers to typical situation encountered in brain imaging with 0.3% (3 HU) difference in contrast C, 4 mm detail size d and 5 mm slice thickness h_{rec}. Hence $CTDI_{std}$ can directly be associated with the dose required in a CT protocol for a specific scanner. The lower the value, the more dose efficient is the scanner.

In order to overcome the problems with visual assessment of LCD, Chao et al. proposed a statistical method that is based on an analysis of the noise related to

enlarged pixels (Chao 2000). For this purpose, a uniform phantom (e.g. the 486 image uniformity module of the Catphan phantom) is scanned with specified dose settings, with subsequent reconstruction of 10 mm thick slices and 22.7 cm display field-of view (DFOV). An 18x18 square array of ROI's ('enlarged pixels') are defined on the resulting image (fig. 2). Each ROI is 10 pixels by 10 pixels, which has an area equivalent to a circular object of approximately 5 mm in diameter for the DFOV used and 512 x 512 image pixels.

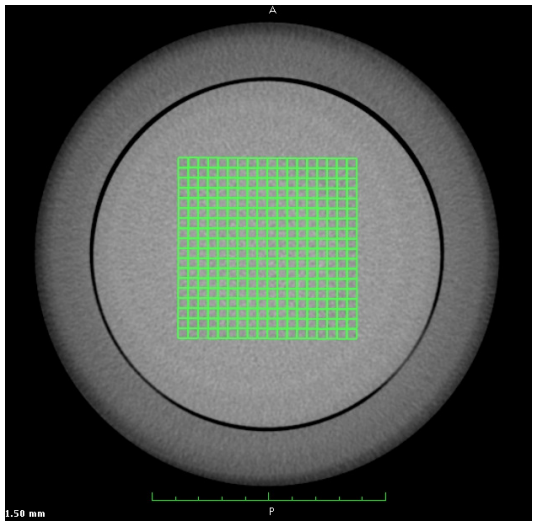

Figure 2: 18x18 square array of ROIs for assessment of LCD from the standard deviation σ_μ of the mean CT numbers in each ROI

The mean CT number of each ROI is calculated and the distribution of the 324 separate results is used to estimate the standard error of the mean, σ_μ. σ_μ is relevant in determining the low contrast detectability since the ROI limits noise to the spatial frequencies of the detail (i.e.: at about 1 line pair per cm in this case). By measuring the distribution of mean CT numbers of many ROI's, and assuming a normal distribution, a prediction can be made for the necessary CT number of a low contrast detail having the same size as the ROI's in order to detect it at a 95% confidence level. This threshold contrast is 3.29 times the standard deviation of the mean CT numbers, σ_μ (Fig. 3).

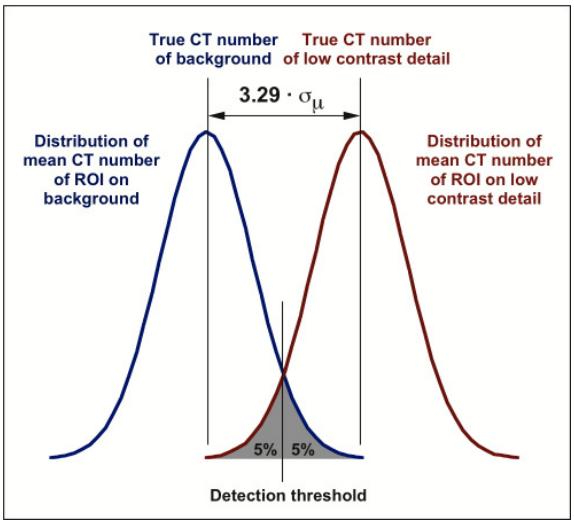

Figure 3: Threshold contrast, defined as 3.29 times the standard error σ_μ, to detect a low contrast detail at 95% confidence level.

Dedicated software is required to perform the noise measurements described above. For this purpose, ImageJ (an open-source software developed and distributed by the NIH) in combination with a plug-in ('LowContrastDetectability') written by A. Jahnen (CRP Henri Tudor, Luxemburg) can be used.

The statistical method as described above has been applied by one manufacturer (General Electric) since 1999 for the assessment of its low contrast specifications (Chao 2000). Since 2008, the same method is used by another manufacturer (Philips) in the built-in quality control procedure for testing the constancy of low contrast detectability.

In its essence, CTDEV is inversely proportional to the square of image noise in a large central area of the image under specified conditions (dose, slice thickness and diameter) for a spatial frequency of 1 lp/cm, related to a phantom made of PMMA with 16 cm diameter. The resulting figures are relative numbers on a linear scale, with higher figures expressing a corresponding increase in dose efficiency.

II.3 NEQ based on measurement of the noise power spectrum

To characterize the noise content of an image, pixel standard deviation (S.D.), is a commonly used metric. However, S.D. only reflects noise magnitude and ignores the spatial correlations introduced into the noise by the reconstruction algorithm. Contrary to the S.D., both the variance and spatial frequency content of the noise associated with a particular imaging protocol can be described by the noise power spectrum (NPS). While work on NPS in radiographic applications is widespread, in addition to some cone-beam therapy oriented applications, noise power spectrum (NPS) and noise equivalent quanta (NEQ) have been largely absent from the diagnostic CT scene. In a recent publication (Boedeker 2007), however, the implementation of the concept of NPS and NEQ on modern, multislice diagnostic CT scanners was investigated in detail.

Although not explicitly addressing the issue of dose efficiency, noise equivalent quanta NEQ. i.e. the effective number of photons in an image, can also serve as a suitable metric of dose efficiency. NEQ is actually the zero frequency of NEQ(*f*), the effective number of photons at each spatial frequency f (fig. 4). The assessment of NEQ(*f*) requires the measurement of the modulation transfer function (MTF) and the noise power spectrum (NPS) in a homogeneous phantom under defined conditions (dose, slice thickness, phantom material and diameter) and is given as

$$NEQ(f) = f \cdot \frac{MTF(f)^2}{NPS(f)} \qquad (4)$$

In practice, NEQ (0) is obtained in the low frequency range at about 1.5 lp/cm, as frequencies below 0.3 cm^{-1} do not behave as expected due to extrapolation (fig. 4). Except for certain non-traditional, over-enhancing filter kernels, NEQ (0) is almost independent from the reconstruction algorithm and can thus be used as a relative metric for the dose efficiency of a scanner under defined conditions.

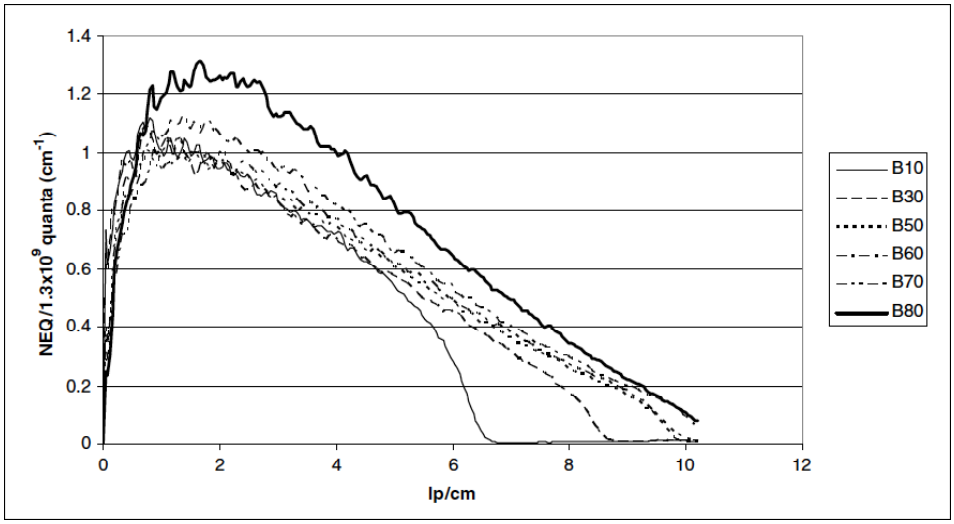

Figure 4: NEQ(f) for a variety of filters, normalized to 1.3 * 10^9 quanta, with dose efficiency defined by NEQ (0); in practice, NEQ is taken from the low frequency range at 1.5 lp/cm (from Boedeker 2007).

In order to obtain MTF and NPS, dedicated software is required. Up to now, neither commercial nor open-source software exists that allows to easily measure the NPS.

In its essence, NEQ is inversely proportional to the square of image noise in a large central area of the image under specified conditions (dose, slice thickness, phantom diameter and material) for a spatial frequency of 1.5 lp/cm. The resulting figures are relative numbers on a linear scale, with higher figures expressing a corresponding increase in dose efficiency.

III. Final Analysis

With Q_2, CTDEV and NEQ, three indices and the underlying methodologies already exist that could serve for the purpose of specifying the dose efficiency of CT scanners. The main differences between them are the degree of complexity to obtain the desired quantity (CTDEV: most easy, NEQ: most complex), the spatial frequencies to which the indices refer to (CTDEV and NEQ: low frequency

range (ca. 1 lp/cm), Q_2: mid frequency range (ca. 5 lp/cm), with the low frequency range being most relevant for low contrast detectability), and the dependence on image noise (Q_2: inversely proportional to image noise, CTDEV, and NEQ: inversely proportional to the square of the low frequency image noise). With respect to both ease of use and relevance, CTDEV based on the statistical method of Chao et al. looks most promising.

While Q_2 has regularly been used by ImPACT for performance testing of a larger number of scanners, the applicability of CTDEV and NEQ has been verified up to now on a limited scale only (Nagel 2010, Boedeker 2007). Hence comprehensive tests on a representative selection of scanners are required. In addition, standardization of the test procedure is mandatory in order to ensure the comparability of the results.

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WP 6: CT Dose Reporting

Authors: M. Ginjaume

I. Introduction

Since its introduction in the seventies, the number of CT scanners and CT examinations has constantly grown. In addition, CT examinations represent relatively high patient radiation exposures to an increasing number of patients. Thus, as discussed in chapter 2, the assessment of medical exposures due to CT scanning is particularly important [UNSCEAR 2010]. This chapter presents an overview of literature and main open questions related to CT dose quantities and CT dosimetric protocols.

Risk evaluations, comparison and optimization of techniques are based on the measurement of the patient “dose” due to the CT exposure. It is thus of special importance to agree on the concepts, definitions and procedures to assess the radiation exposure due to CT examinations. Because of the inherent complexity of the CT technique, specific dosimetric quantities had to be defined in the early eighties.

II. Synopsis of Relevant Literature

Four main topics related to dose reporting in CT are considered in this literature synopsis. First, the definitions of CT dosimetric quantities relevant for CT beam description and for the establishment and use of diagnostic reference levels are summarised. Then, the definitions of risk-related quantities and the list of available conversion coefficients relating these quantities to the readily measurable ones are presented. Finally different procedures to measure, in the clinics, the CT dosimetric quantities are discussed.

II.1 CT Dosimetric Quantities

The current procedure for reporting radiation dose in computed tomography is based on the use of "*the computed tomography dose index (CTDI),* which was introduced in the early eighties [Shope, 1981], together with the use of *dose-length product (DLP)* [EC, 2000; ICRP 2007].

II.1.1 Computerized Tomography Dose Index

CTDI integrates the radiation dose imparted within and beyond a single slice and it is defined by the following equation:

$$CTDI = \frac{1}{T}\int_{-\infty}^{+\infty} D(z)dz \qquad (1)$$

Where, T is the nominal slice thickness and D(z) is the dose profile along a line parallel to the z-axis (tube rotation axis).

The CTDI can be measured in air or in a phantom and this is usually indicated with a subscript, i.e. $CTDI_{air}$. The CTDI value provides information about the characteristics of the radiation beam, filtration, collimation,etc.

In practice, dose profiles are measured in a defined length. In Europe, the EC Guidelines [EC, 2000] propose an integration range over a length of 100 mm positioned symmetrically about the scanned volume. $CTDI_{100}$ notation is used in this case. The adaptation of CTDI 100 was eventually standardized by the International Electrotechnical Commission [IEC, 2002] and has been adopted by CT manufacturers and regulatory authorities internationally.

It must be kept in mind, that some manufacturers specify the CTDI of their scanners using the definition of the Food and Drug Administration (FDA), $CTDI_{FDA}$. In this case the integration interval is 14 times the nominal length of the slice, and the dose is given in terms of absorbed dose in PMMA [FDA, 1984]. Conversion factors between $CTDI_{100}$ and $CTDI_{FDA}$ can be found in [EC, 2000]. In 2006, to harmonise criteria, the FDA proposed to use $CTDI_{100}$ instead of $CTDI_{FDA}$ [FDA, 2006].

For CTDI measurement, two polymethylmethacrylate (PMMA) cylinders of 14 cm length are used. For head examinations, a phantom diameter of 16 cm is used and for body, a phantom diameter of 32 cm is applied. The phantoms are called, respectively, *head and body CTDI phantoms* (Figure 1). CTDI is usually measured using a specially designed "pencil" ionization chamber with an active length of 100 mm both in free air at the centre of rotation ($CTDI_{air}$) and within the holes of the 2 phantoms. $CTDI_c$ and $CTDI_p$ are defined respectively as the CTDI values measured with a pencil chamber dosemeter positioned in the centre and in the periphery of the PMMA head or body phantom.

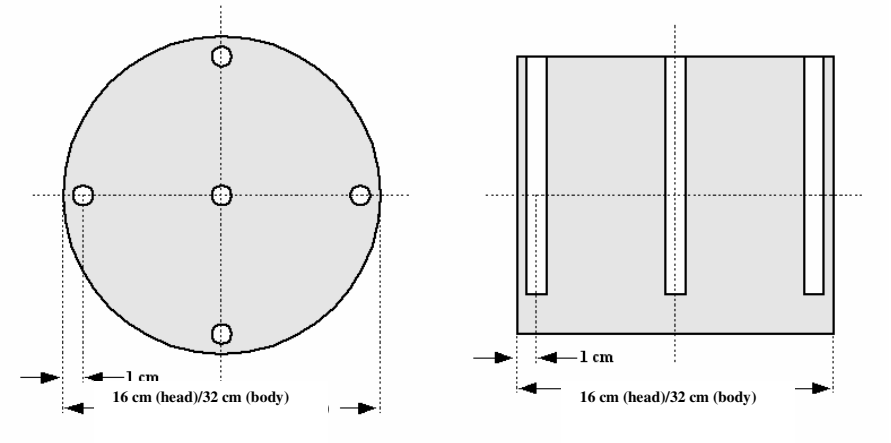

Figure 1: CT PMMA phantoms

$CTDI_w$ is used for approximating the average dose over a single slice in order to account for variations in dose values between the center and the periphery of the slice. It is defined by the following equation:

$$CTDI_w = \frac{1}{3} CTDI_c + \frac{2}{3} CTDI_p \qquad (2)$$

$CTDI_p$ is the average of the four $CTDI_p$ values measured in the periphery of the phantom (12, 3, 6 and 9 o' clock).

$CTDI_{vol}$ [IEC, 2003], initially also called $CTDI_{w,eff}$, represents the radiation dose in one tube rotation in multiple detector CT (MDCT) and allows for variations in exposure in the z direction when the pitch (p) is not equal to 1.

The pitch for a scan sequence is the ratio of the table feed in one rotation (I) to the product of the nominal section thickness (T) and the number (N) slice of simultaneous tomographic sections from a single rotation. The product (NT) corresponds to the slice collimation.

$$CTDI_{vol} = \frac{NT}{I} CTDI_{w} \quad (3)$$

$$CTDI_{vol} = \frac{CTDI_{w}}{p} \quad (4)$$

Equation (4) applies when p is not equal to 1.

$CTDI_w$ or $CTDI_{vol}$, are measured in mGy. $CTDI_{vol}$ display on the CT console is required for all new scanners [IEC, 2002; EC, 1997].

The subscrip, *n,* $_n$CTDI, is sometimes used to denote when measurements of CTDI have been normalized to unit radiographic exposure (mAs), it is expressed in terms on mGy/mAs.

The interpretation of dose values displayed on the scanner's console needs special attention in some situations, such as when the pitch is not 1. Many dose recommendations are expressed in $CTDI_w$, whereas the CT console displays $CTDI_{vol}$. In order to allow comparisons, the pitch correction involved in $CTDI_{vol}$ should be reverted by multiplying $CTDI_{vol}$ by the pitch factor.

It should be noted that CTDI has a number of limitations, especially in the case of multi-slice scanners, which have been reported by several authors and will be discussed in paragraph II.4.3.

II.1.2 Dose Length Product

DLP is used to calculate the dose for a series of slices or a complete examination and is defined by the following equation:

$$DLP = \sum_{i}^{N} CTDI_{w} TN \quad (5)$$

Where i represents each one of the individual N scans of the examination that covers a length T of patient anatomy.

DLP is measured in terms of mGy.cm. It is an indicator of the total radiation dose given to the patient during a specific examination or series of slices, whereas, CTDI is by definition an indicator of the level of local "dose" in the irradiated slice. This practically means that for a given technical protocol with certain $CTDI_{vol}$, the DLP of 2 scanning regions with different lengths will be different. Many new scanners show DLP values on the CT console.

As outlined in WP 7 "CT diagnostic reference levels", some dose reference levels are expressed in terms of DLP. However, since in some examinations, more than one series of scans are made, it is very important to clearly indicate if DLP values are referred per series or per examination.

II.1.3 CT air-kerma index, CT air kerma–length product

The International Commission on Radiation Units and Measurements (ICRU) is the International Organisation in charge to define a coherent system of radiological quantities and units in all fields where ionizing radiation is used, and to develop recommendations on how to measure radiation-related quantities in order to ensure a reliable exchange of results. However, ICRU had not published any report dealing with patient dosimetry for x rays used in diagnostic medical imaging, until 2005. Its first report on this issue was ICRU Report 74 [ICRU, 2005]. ICRU Report 74 dedicates a paragraph to CT dose quantities, following a similar approach as the one described in the two previous paragraphs but it recommends the use of the quantity CT air kerma index ($\mathbf{C_{KL}}$) instead of CT dose index (CTDI), and air kerma-length product ($\mathbf{P_{KL}}$) instead of dose-length product (DRL). ICRU considers the use of the term *air kerma* to be more appropriate than *absorbed dose or dose*, because this quantity is in fact the quantity measured in practice, and, in addition, it is more consistent to other applications of radiation. For diagnostic x-ray energies, the absorbed dose and the kerma in the same ma-

terial are numerically equivalent, thus, the new recommendations of ICRU would practically not imply any changes in measurements.

Likewise we had the quantities defined in equations (1), (2) and (5), ICRU Report 74 defines CT air-kerma index free in air, weighted CT air-kerma index and CT air kerma–length product. For simplicity and to limit the extension of this report, the ICRU definitions are not given here but can be found in [ICRU, 2005].

The International Atomic Energy Agency (IAEA) in the Technical Reports Series No. 457 "*Dosimetry in diagnostic radiology: an International Code of Practice*" [IAEA, 2007] follows the recommendations and notations given in ICRU 74 for CT dosimetry quantities.

Since CT scanner consoles and most international recommendations, in particular EC guidelines [EC, 2000] and IEC standards [IEC, 2003; IEC 2009], use the terms CTDI and DLP, in the next paragraphs of this report, the quantities defined in II.1.1 and II.1.2 will be used instead of the equivalent ICRU Report 74 proposal. The terms, CTDI and DRL, are now commonly used and understood by technicians, radiographers and radiologists. The introduction of the new terms described in II.1.3, will surely not be easily understood. New EC Guidelines on the recommended CT dosimetric quantities would be desirable to ensure harmonisation within EC.

II.2 CT Risk-related Quantities

Health effects of radiation exposure are generally grouped in two categories: deterministic effects due in large part to the killing or malfunction of cells following high doses; and stochastic effects, i.e.: cancer and heritable effects, involving mutation of somatic cells or heritable disease.

CT procedures, except CT fluoroscopy which is not included in the scope of this report, are considered to deliver low dose levels, thus stochastic effects are the main risks. The energy deposited in organs and tissues of the human body is proposed as indicators of the probability of stochastic risks.

II.2.1 Mean Absorbed Dose in a Specified Tissue or Organ

D_T is the mean absorbed dose in a specified tissue or organ and it is equal to the ratio of the energy imparted T, to the tissue or organ to the mass, m_T, of the tissue or organ, [ICRU 51].

$$D_T = \frac{\bar{\varepsilon}_T}{m_T} \qquad (6)$$

The mean absorbed dose in a specified tissue or organ is sometimes simply referred to as the organ dose. The unit of absorbed dose is the Gray (Gy).

However, the probability of stochastic events is found to depend not only on the absorbed dose but also on the type and energy of the radiation depositing the dose (ICRP, 1991). In order to relate the radiation dose to radiation risk (detriment), it is necessary to take into account variations in the biological effectiveness of radiations of different quality as well as the varying sensitivity of organs and tissues to ionising radiation.

II.2.2 Equivalent Dose in a Specified Tissue or Organ

The equivalent dose, $\boldsymbol{H_T}$, to an organ or tissue, *T*, is defined in ICRP 60 [ICRP, 1991], ICRP 103 [ICRP, 2007b] and ICRU 51 [ICRU, 1993]. For a single type of radiation, *R*, it is the product of a radiation weighting factor, w_R, for radiation *R* and the organ dose, D_T:

$$H_T = w_R D_T \qquad (7)$$

The radiation weighting factor, w_R, allows for differences in the relative biological effectiveness of the incident radiation in producing stochastic effects at low doses in tissue or organ, *T*. For X ray energies used in CT, w_R is taken to be unity.

The unit of equivalent dose is the sievert (Sv).

II.2.3 Effective dose

The effective dose, ***E***, is defined in ICRP 60 [ICRP, 1991], ICRP 103 [ICRP, 2007b] and ICRU 51 [ICRU, 1993]. It is the sum over all the organs and tissues of the body of the product of the equivalent dose, H_T, to the organ or tissue and a tissue weighting factor, w_T, for that organ or tissue.

$$E = \sum_T w_T H_T \tag{8}$$

The tissue weighting factor, w_T, for organ or tissue T represents the relative contribution of that organ or tissue to the total detriment arising from stochastic effects for uniform irradiation of the whole body. The unit of effective dose is the sievert (Sv). The sum over all the organs and tissues of the body of the tissue weighting factors, w_T, is unity.

The European Directive 96/29 EURATOM [EC, 1999] and the corresponding transcription in European National legislation are based on ICRP 60 [ICPR, 1991] set of w_T factors. However the new ICRP 103 recommendations [ICPR, 2007] have introduced a new set of w_T values on the basis of epidemiological studies on cancer induction in exposed populations and risk assessments for heritable effects. *Tables 1* and *2* show the two sets of weighting factors. The main changes correspond to the reduction of the value of the weighting factor for the gonads, because of the important reduction in the nominal risk coefficient for heritable effects. There are also some changes in the list of the remainder tissues and in the formula to account for the contribution of the remainder organs to the effective dose. w_T represent mean values for humans averaged over both sexes and all ages and thus do not relate to the characteristics of particular individuals.

Tissue	w_T	Σw_T
Gonads	0.20	0.20
Bone-marrow (red), Colon, Lung, Stomach,	0.12	0.48
Bladder, Breast, Oesophagus, Liver, Thyroid, Remainder tissue*	0.05	0.30
Bone surface, Skin	0.01	0.02
	Total	1.00

Table 1: ICRP Publication 60 recommended weighting factors

* *Remainder tissues: Adrenals, Brain, Large intestine, Kidneys, Muscle, Pancreas, Spleen, Thymus, Uterus/cervix*

Tissue	w_T	Σw_T
Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissue*	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

Table 2: ICRP Publication 103 recommended weighting factors

* *Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (male), Small intestine, Spleen, Thymus, Uterus/cervix (female)*

II.2.4 Relevant Risk-related Quantity for Medical Exposure of Patients

The effective dose has long being used as a useful quantity to assess the potential radiological risk of a patient [Fujii, 2009; Gregory, 2008; Cohnen, 2003], and several programmes are available for its calculation [ImPact, 2009, Stamm and Nagel, 2002]. However, the new ICRP recommendations do not recommend its use for this application [ICRP, 2007b].

According to ICRP Publication 103, paragraphs 151 and 152 "*The relevant quantity for planning the exposure of patients and risk-benefit assessments is the*

equivalent dose or the absorbed dose to irradiated tissues. The use of effective dose for assessing the exposure of patients has severe limitations that must be considered when quantifying medical exposure. Effective dose can be of value for comparing doses from different diagnostic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as the use of different technologies for the same medical examination. However, for planning the exposure of patients and risk-benefit assessments, the equivalent dose or the absorbed dose to irradiated tissues is the relevant quantity."

"The assessment and interpretation of effective dose from medical exposure of patients is very problematic when organs and tissues receive only partial exposure or a very heterogeneous exposure which is the case of CT".

This point of view is also shared by the International Commission on Radiological Protection in its Publication 102 [ICRP, 2007a] and by Brenner [Brenner, 2007] among others. But, these statements are in contradiction with previous considerations about the effective dose as an indicator of overall patient dose risk [ICRP, 1991, EC, 2000].

II.3 Dose-Conversion coefficients for assessment of organ and tissue doses

Since, the risk-related quantities are not measurable, a 'conversion coefficient', c, relating them to some dosimetric quantities readily measurable are needed to assess them. In general they can be expressed as equation (9) [ICRU, 2005].

$$c = \frac{specified\ \ dosimetric\ quantity}{normalization\ quantity} \qquad (9)$$

For CT, when stochastic effects are of interest, the specified dosimetric quantities are the organ dose, D_T, or the effective dose, E, and the CT dose index, CTDI, or CT dose length product, DLP, are used as normalization quantities.

The EC guidelines [EC, 2000], provided a series of normalised values of effective dose per dose-length product over various body regions for a broad estimate of effective dose. Monte Carlo calculations for CT have been carried out to supplement the relative lack of normalised organ dose data available for paediatric patients. Shrimpton [Shrimpton, 2004] in report NRPB-PE/1/2004 presented a new series of coefficients for newborn, 1 year old, 5 year old, 10 year old, 15 year old and adult. Shrimpton's coefficients were also published as appendix C of the 2004 *European Guidelines for Multislice Computed Tomography* [Bongartz, 2004]. These results confirm the trends for an enhancement of the doses to small children relative to those to adults under similar conditions of CT exposure. More recently, the AAPM report nº96 [AAPM, 2008], also adopted the same values of normalised effective dose per dose-length for various ages. *Table 3* reproduces the NRPB-PE/1/2004 set of coefficient values.

Region of body	Effective dose per DLP (mSv (mGy cm)$^{-1}$) by age				
	0[a]	1y[a]	5y[a]	10y[a]	Adult[b]
Head & neck	0.013	0.0085	0.0057	0.0042	0.0031
Head	0.011	0.0067	0.0040	0.0032	0.0021
Neck	0.017	0.012	0.011	0.0079	0.0059
Chest	0.039	0.026	0.018	0.013	0.014
Abdomen & pelvis	0.049	0.030	0.020	0.015	0.015
Trunk	0.044	0.028	0.019	0.014	0.015

[a]All data normalised to $CTDI_w$ in the standard head CT dosimetry phantom.

[b]Data for the head & neck regions normalised to $CTDI_w$ in the standard head CT dosimetry phantom; data for other regions normalised to $CTDI_w$ in the standard body CT dosimetry phantom.

Table 3: Normalised values of effective dose per dose-length product (DLP) over various body regions and patient age (obtained from [Shrimpton, 2004])

Another aspect to be considered when using conversion coefficients for children is that one must be aware that these coefficients have been obtained for a 16 cm CT dose phantom, whereas the CT console indicator will provide DLP or CTDI assuming the use of the 32-cm diameter body phantom. In paediatric examinations, the figures displayed in the CT console should be multiplied by a factor of 2

for children and of 3 for infants in order to give a realistic estimate of the patient's dose.

It would be useful to have EC recommended conversion coefficients or normalised values of effective dose, with clear indications of their correct interpretation and practical use.

If the conversion coefficients for children are finally accepted there is still lack of conversion coefficients to estimate the effective dose in the case of breast CT scan, where the scanned tissue is significantly different from the phantom material.

A more precise procedure to estimate the organ absorbed dose and the effective dose, is by using several available software, such as CT-Expo [Stamm and Nagel, 2002] and the ImPACT CT Patient Dosimetry Calculator [ImPact, 2009]. The users start by selecting a specific type of scanner, then they indicate the limits of the scan range and the protocol settings. The software then calculates organ doses and the effective dose, in general the effective dose is obtained for ICRP 60 tissue weighting factors, but the 2009 version of the ImPact Programme as well as the 2011 version of CT-Expo (v2.0) also gives the option to use ICRP 103 factors. These methods, although they are more precise than the use of conversion coefficients, they only provide an estimate of doses for standard phantoms. Thus, their results should not be applied to examinations of individual patients. Nevertheless, methods of computational dosimetry continue to advance with the development of more realistic (voxel) mathematical phantoms based on digital images of humans [Petoussi-Henss, 2002], which now allow the estimation of patient-specific doses.

II.4 CT Dosimetric Protocols

II.4.1 CT ionization chamber calibrations

The IAEA code of practice for dosimetry in diagnostic radiology [IAEA, 2005] describes the equipment necessary to perform calibrations of diagnostic dosimeters

and the recommended procedures. In particular, for the calibration of CT “pencil” ionization chambers they recommend a special procedure, which requires the use of a lead rectangular aperture to irradiate a specific part of the chamber between 20 and 50 mm. The width of the aperture should be known to within 0.01 mm. The recommended X ray qualities for the calibration are the IEC RQT radiation qualities [IEC, 2005].

In a preliminary survey, within EURADOS (The European Radiation Dosimetry Group), it was noted that there are small differences in the calibration methods for CT pencil chambers within Europe. In addition it was observed, that although the basic calibration facilities were available, only few countries had established specific procedures for CT ionization chamber calibration.

II.4.1 CT dose measurements in hospital

In most countries, CT dose console indications ($CTDI_{vol}$ and DLP) are verified periodically using a CT “pencil” ionization chamber, TLDs or non-invasive x-ray quality control devices, which usually have several silicon-diodes for the measurement of air-kerma. In this case, the width of the beam at the measuring point is obtained using a radiographic film. The standard CT PMMA phantoms shown in figure 1 are used for the measurements.

However, from the above mentioned EURADOS survey, it seems that only some of the devices used in the quality control in hospitals, are properly calibrated in a reference calibration laboratory.

Results from the EC working group on European Guidelines for Multislice Computed Tomography showed a good correspondence between measured $CTDI_{vol}$ and the displayed values on the CT consoles for major manufacturers on the European market.

II.4.3 CTDI limitations

Since the introduction of *CTDI* there have been important advances and changes in CT technology, as well as an increase of operation modes and applications of CTs [Wang, 2008]. CTDI was initially defined for axial scanning. Its application for helical and cone-beam CT systems has some limitations [Brenner, 2005; Dixon, 2006; Boone, 2007]. Several groups are working on proposing alternative quantities [Dixon, 2003; Mori, 2005; Merimaa, 2010].

$CTDI_{100}$ measurement requires integration of the radiation dose profile from a single axial scan over ±50 mm, usually performed with a 100 mm-long, 3 cm^3 active volume "pencil" ionisation chamber. For narrow scan slices, up to 40 mm, it is a good estimate of the average absorbed dose, along the z-axis, from a series of contiguous irradiations. However, for slice collimations greater than 100 mm, such as those of 256 or 320 CT scanners, $CTDI_{100}$ underestimates the absorbed dose.

To overcome this problem, Mori [Mori, 2006] proposes to use a longer phantom and a longer probe, at least 300 mm long each. However, this approach can imply an overestimation of organ doses when compared to CT-Expo or ImPACT-PDC calculations [Nagel, 2010].

The American Association of Physicists in Medicine proposes in Report nº111, *Comprehensive methodology for the evaluation of radiation dose in X-ray computed tomography* [AAPM, 2010]*,* a new measurement paradigm based on a unified theory for axial, helical, fan-beam and cone-beam scanning with or without longitudinal translation of the patient table [Dixon, 2003].

The report is very recent and so far published results on its application have not yet been identified. They propose to measure the dose in a "point" instead of a dose profile integral, and to use a small 0.6 cm^3 "Farmer-type" ionisation chamber (typical reference ionisation chamber for radiotherapy). Some practical questions, such as the type of phantom, are not clearly stated in the report. According to the IEC CT working group preliminary results, the AAPM new methodology improves dose estimates for total body scans and small organ scans (i.e. uterus)

but it significantly over-estimates doses for typical scan ranges and for extended organs.

An internationally agreed proposal in this field would be desirable. Depending on the chosen alternative, it can involve major changes in the selection of instruments, phantoms or procedures.

III. Final Analysis

The Directive 97/43/EURATOM formalises from the legal point of view the need for practical CT dosimetry in Europe [EC, 1997]. It demands that CT scanners provide an indication of patient dose and that users implement quality assurance programmes, which must include patient dose assessment. The European guidelines on quality criteria for computed tomography [EC, 2000] were published in 2000, but emerging techniques such as multi-slice CT and fluoro CT were not specifically addressed. In the preamble a regular up-dating was foreseen. Later, the EC funded, as part of its 6th Framework Programme, the project *CT Safety & Efficacy. A Broad Perspective*, which provided in 2004 useful recommendations and guidelines for optimization in multi-slice CT, the *European Guidelines for Multislice Computed Tomography* [Bongartz, 2004]. However, since then, the EC has not published any other official document for quality criteria in CT.

The synthesis paragraphs of this chapter highlight the need of harmonisation and of new guidelines as regards:

- CT dosimetric quantities (CTDI and DLP or C_{KL} and P_{KL}).
- CT phantoms for in situ patient dose assessment.
- Calculation of effective dose or proposal of a better indicator for risk assessment (conversion coefficients to effective dose (*E/PKL*) for different size of paediatric patients; for breast scans; to study the meaningfulness of effective dose for risk estimations).

- Recommendation for in situ calibration of CT consoles (AAPM or IEC methodologies) and for promoting the calibration of instruments to ensure traceability in quality assurance programmes.
- Recommendation for calibration laboratories to establish CT reference qualities.

Finally, it is worth mentioning the IAEA *Smart Card/SmartRadTrack* project launched in 2006 [IAEA, 2006], which is an interesting approach to ensure the correct track of radiation exposure of patients. It can provide a complete and systematic overview of CT doses and uses in the world. On the one hand it can help to have a better follow-up of individual patients and on the other it can provide realistic data on the collective risk associated with radiation medical practices.

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WP 7: CT Diagnostic Reference Levels

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I. Introduction

Computerized Tomography Dose Index (CTDI) and/or Dose Length Product (DLP) are the quantities proposed as diagnostic reference levels (DRL) for CT [BSS 1996 and draft revised BSS 2010, EC 1999, EC MSCT 2004, BfS 2003 and 2010, NRPB 2005, ICRP 2001 and 2007, Brix 2003, Wall 2003]. It should be noted that the International Commission on Radiation Units and Measurements (ICRU) has recently recommended the use of the quantity CT air kerma index for CT [ICRU 2006]. However, since all manufacturers use the term CTDI it seems appropriate to use the term CTDI for simplicity till the newer term becomes familiar.

The main objectives of DRLs are to improve a regional, national or local dose distribution by identifying and reducing the number of unjustified high or low values in the distribution, to promote good practice and an optimum range of values for a specified medical imaging protocol. In this context, CTDI and DLP measurements should be part of the dose optimization program in a CT department. Determination of local DRLs should be done using a sample of 10 standard sized patients, for example the common CT scan of the abdominal region, and mean values of the results should be compared to the abdomen DRL set by professional bodies. In the case of local values being higher than nationally or internationally set DRL, appropriate corrective actions should be applied, so as to reduce the dose to the abdomen.

II. Review of Relevant Literature

II.1. Publications of National or International Bodies

Numerous international organizations have produced guidelines to facilitate the process of CT radiation dose optimization. Some examples of which are presented in this section:

- **IAEA BSS 1996 / Draft of Revised BSS 2010:**

According to the BSS 1996 of the IAEA, the term guidance level is introduced which is a level of a specified quantity above which appropriate actions should be considered. In some circumstances, actions may also need to be considered when the specified quantity is substantially below the guidance level. Specifically for medical exposure, it is a value of dose, dose rate or activity selected by professional bodies in consultation with the Regulatory Authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, taking into account the particular circumstances and applying sound clinical judgement. In CT the BSS recommends multiple scan average dose measured in mGy, which is derived from measurements on the axis of rotation in water equivalent phantoms, 15 cm in length and 16 cm (head) and 30 cm (lumbar spine and abdomen) in diameter.

BSS 1996 was revised during the last years, the draft of which was sent to the Member States and international organizations for comments. A new version was prepared taking into account all these comments during July and August 2010. Draft 4.0 will be submitted to the IAEA Safety Standards Committees for review and approval at their meetings to be held in late November/early December 2010. In this draft document, it is mentioned also that a review of DRLs should be conducted at certain time intervals so as to determine whether the optimization of protection of patients is adequate or whether corrective action is required if the typical doses or activities for a given radiological procedure:

(i) Exceed the relevant diagnostic reference level

(ii) Fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

- **ICRP Publication 73 (ICRP, 1996):**

The ICRP in its report 73 in 1996 introduced the term “diagnostic reference level”, the purpose being advisory. It is considered as a form of investigation level to identify unusually high levels, which calls for local review if consistently exceeded. In principle, there could be a lower level also (below which there is insufficient radiation dose to achieve a suitable medical image). Diagnostic reference levels are not for regulatory or commercial purposes, not a dose constraint, and not linked to limits or constraints. The selection should be done by professional medical bodies, using a percentile point on the observed distribution for patients, and specific to a country or region. Diagnostic reference levels should be used by authorized bodies to help manage the radiation dose to patients so that the dose is commensurate with the clinical purpose. The concept of a diagnostic reference level permits flexibility in the choice of quantities, numerical values, and technical or clinical specifications, in order to allow authorized bodies to meet the objectives relevant to their circumstances. The guiding principles for setting a diagnostic reference level (DRL) are:

(a) The regional, national or local objective is clearly defined, including the degree of specification of clinical and technical conditions for the medical imaging task;

(b) The selected value of the DRL is based on relevant regional, national or local data;

(c) The quantity used for the DRL can be obtained in a practical way;

(d) The quantity used for the DRL is a suitable measure of the relative change in patient tissue doses and, therefore, of the relative change in patient risk for the given medical imaging task; and

(e) The manner in which the DRL is to be applied in practice is clearly illustrated.

The ICRP Committee 3 encourages authorized bodies to set diagnostic reference levels that best meet their specific needs and that are consistent for the regional, national or local area to which they apply.

- **ICRP Publication 102:**

This document does not set specific DRLs but presents values given in the literature as shown in the tables below for adults and children separately. As quoted in the text, data in *Tables 2.1* and *2.2* pertain mostly to 2, 4, 8, or 16-MDCT systems. There is a paucity of data on 16 or 64-slice scanners for MDCT systems.

Table 2.1. Diagnostic reference levels in DLP (mGy cm) for adults from different studies. Data given as third quartile (75%) values

Examination	IAEA study (Tsapaki et al., 2006)[a]	UK DRL-SDCT (Shrimpton et al., 2005)	UK DRL-MDCT (Shrimpton et al., 2005)	European DRL-SDCT (EC, 2000a)	European DRL-MDCT (Bongartz et al., 2004)
Head	527	760	930	1050	337
Chest	447	760	940	650	267
Abdomen	696	510	560	780	724

[a] Data from ten representative centres in six countries, including both SDCT and MDCT scanners.

Table 2.2. Diagnostic reference levels for paediatric patients (Shrimpton at al., 2005). Data given as third quartile (75%) values

Examination	$CTDI_w$ (mGy)[a]	$CTDI_{vol}$ (mGy)[a]	DLP (mGy · cm)
Chest: 0–1 yr old	23	12	204
Chest: 5 yr old	20	13	228
Chest: 10 yr old	26	17	368
Head: 0–1 yr old	28	28	270
Head: 5 yr old	43	43	465
Head: 10 yr old	52	51	619

[a] Calculated values of $CTDI_w$ and $CTDI_{vol}$ relate to the 16 cm diameter dosimetry phantom.

- **UNSCEAR 2008 Report:**

The latest report of UNSCEAR in 2008 gives the following comment regarding DRL: “due to the fact that it is very difficult to make measurements in groups of patients that differ a lot in size and built from the norm, one can do measurements on all patients undergoing the specific procedure for a measuring period

and then take the average of these measurements. This can be the outcome of a standard size patient. An alternative approach would be to apply a weight and height conversion factor to allow for deviation in size from the reference man".

- **EU Criteria Report 16262 (EU 1999):**

As quoted in the European Criteria Report 16262, the purpose of a reference dose quantity for a diagnostic medical exposure is to provide quantification of performance and allow comparison of examination techniques at different hospitals. Diagnostic reference dose values should not be applied locally on an individual patient basis, but rather to the mean doses observed for representative groups of patients. Reference dose values are intended to act as thresholds to trigger internal investigations by departments where typical practice is likely to be well away from the optimum and where improvements in dose-reduction are probably most urgently required. Typical levels of dose in excess of a reference dose value should either be thoroughly justified or reduced. In the absence of a well-defined scanning protocol, typical dosimetric practice should be determined on the basis of the mean results derived for a sample of at least 10 patients for each procedure. The document contains CTDI and DLP reference values for routine CT protocols as shown in tables 1 and 2 in section 3.

- **Federal Office for Radiation Protection (BfS, 2010):**

In a several nationwide surveys, the DRLs for adults and paediatric patients have been evaluated by the *Federal Office for Radiation Protection* (BfS), the latest version of which being published in 2010 [BfS 2010]. The two following tables have been extracted from the original document, the first of which presenting $CTDI_{vol}$ and DLP for the most common CT examinations in Germany [Hirnschädel: neurocranium / Gesichtsschädel: facial bones / Lendenwirbelsäule (Bandscheibe axial, Knochenspirale): lumbar spine (disc axial, bones) / Oberbauch: upper abdomen / Becken: pelvis / Gesamt-Abdomen: total abdomen / Alter- bzw. Gewichtsklasse: age or weight category / Neugeborene: newborns]:

CT-Untersuchungsart	$CTDI_{Vol}$ * [mGy] zur Orientierung	*DLP* ** [mGy x cm] pro Scanserie
Hirnschädel	65	950
Gesichtsschädel (Tumordiagnostik)	22	250
Gesichtsschädel (Sinusitis)	9	100
Thorax	12	400
Lendenwirbelsäule (Bandscheibe axial)	42	250
Lendenwirbelsäule (Knochen-Spirale)	16	500
Oberbauch	20	450
Abdomen	20	900
Becken	20	450

The second table provides DRLs for paediatric patients in 6 different age categories:

Untersuchungsart	Alters- bzw. Gewichtsklasse	$CTDI_{Vol}$-16 [mGy] #	$CTDI_{Vol}$-32 [mGy] #	*DLP*-16 * [mGy x cm]	*DLP*-32 * [mGy x cm]
Hirnschädel	Neugeborene	27	-	300	-
	≤ 1 Jahr	33	-	400	-
	2 - 5 Jahre	40	-	500	-
	6 - 10 Jahre	50	-	650	-
	11 - 15 Jahre	60	-	850	-
	> 15 Jahre	65	-	950	-
Gesichtsschädel (Tumordiagnostik)	Neugeborene	9	-	70	-
	≤ 1 Jahr	11	-	95	-
	2 - 5 Jahre	13	-	125	-
	6 - 10 Jahre	17	-	180	-
	11 - 15 Jahre	20	-	230	-
	> 15 Jahre	22	-	250	-
Thorax	≤ 5 kg (Neugeborene)	3	1,5	40	20
	6 - 10 kg (≤ 1 Jahr)	4	2	60	30
	11 - 20 kg (2 - 5 Jahre)	7	3,5	130	65
	21 - 30 kg (6 - 10 Jahre)	10	5	230	115
	31 - 50 kg (11 - 15 Jahre)	-	8	-	230
	51 - 80 kg (> 15 Jahre)	-	12	-	400
Gesamt-Abdomen	≤ 5 kg (Neugeborene)	5	2,5	90	45
	6 - 10 kg (≤ 1 Jahr)	7	3,5	170	85
	11 - 20 kg (2 - 5 Jahre)	12	6	330	165
	21 - 30 kg (6 - 10 Jahre)	16	8	500	250
	31 - 50 kg (11 - 15 Jahre)	-	13	-	500
	51 - 80 kg (> 15 Jahre)	-	20	-	900

- **American College of Radiology (ACR, 2009)**

In 2009, the *American College of Radiology* (ACR) recommended $CTDI_{vol}$ as the reference quantity providing 2 adult and 1 paediatric values for specific examinations:

Examination	Reference Levels ($CTDI_{vol}$)
CT head	75 mGy
CT adult abdomen	25 mGy
CT pediatric abdomen (5 years old)	20 mGy

- **National Radiation Protection Board (NRPB Report 67, 2005):**

This is the largest CT study, carried out in 2003, providing data for 850 protocols in 2000 individual patients and for 12 common CT adult and paediatric protocols from 162 CT scanners representing more than a quarter of all UK scanners. The report was published in 2005. CTDI and DLP were chosen as the reference dose quantities and some of the DRL values are shown in the *Tables 1* and *2* in *Section 3*. For paediatric studies, the NRPB provides DRLs for brain and chest.

II.2. Scientific Literature

- **Brix 2003 (German study):**

This was a nationwide survey the aim of which was to characterise MSCT practice in Germany. The survey was conducted in 2002 in a concerted action by the *German Roentgen Society* (DRG), the *Federal Office for Radiation Protection* (BfS) and the *Association of Manufacturers of Electromedical Equipment* (ZVEI). During the study, all hospitals (n=146) and private practices (n=61) running an MSCT scanner at the beginning of 2002 were requested by letter to provide dose relevant data on 14 standard CT examinations in a questionnaire. The study includes data on 113 responders out of 207 owners that received the questionnaire, the results of which can be found in *Tables 1* and *3* in *Section 3*.

- **Galanski M, Nagel HD and Stamm G (2006):**

This is the only nationwide study on paediatric CT with DRLs for 6 age groups and 5 types of CT examinations. Some of the DRLs are given in *Table 3* in *Section 3*.

III. Final Analysis

Tables 1 and *2* provide DRLs in terms of CTDI and DLP from various national or international studies, respectively [EC 1999, EC 2004, BfS 2010, NRPB 2005, ACR 2009, Brix 2003, Kharuzhyk 2010, JongHak 2010, Nowotny R 2000]. It must be noted that surveys with small sample size, showing only a snapshot of the current situation using scanners of only one or two vendors, can be found more frequently in medical journals. These small surveys will always contain biased data because they are not representative of all scanners and sites. The larger surveys are all carried out on behalf of national authorities such as *National Radiological Protection Board* (NRPB) in UK, *Bundesamt für Strahlenschutz* (BfS) in Germany and *Bundesministerium für soziale Sicherheit und Gesundheit* (BMSG) in Austria with a typical time frame of 5–15 years between updates. Large-scale surveys are necessary to take into account the considerable variations in patient size and differences in scan parameters and settings even within the various sites. It must be noted that most of the DRLs found in the literature are from European countries. The current status of the DRLs in France, Germany, Greece, Italy, the Netherlands, Sweden, Switzerland and the UK is as followed: CT DRLs are set for 4 types of CT exams in France, Italy and Sweden, for 7 in Germany, for 8 in Switzerland and 12 for UK. In Greece, DRL values for 7 types of CT exams are in the process of approval, whereas in the Netherlands, DRLs are not established yet. Finally, recent studies indicate that current DRLs can be further reduced and that DRLs specific to the requirements of clinical indications for particular CT procedures are also desirable [ICRP 2007]. For paediatric patients very limited data are found. *Table 3* shows UK DRLs on brain and chest.

The following comments can be made through this literature research:

- The European DRLs should be revised to include MSCT and the new dose quantity $CTDI_{vol}$.
- DRLs must be established by more European countries. Current values appear to be limited.

- The DRLs that appear in *Tables 1* and *2* show large variations. Variations in CTDI are mainly due to variation in the technical protocol used and differences in the CT scanner. Therefore, more standardized protocols could harmonize CTDI DRL values. Variations in DLP are mainly due to variations in the set up. For example in some countries abdomen means the whole abdomen whereas in others it means only the upper abdomen. Also the number of series as well as the definition of series varies. For the abdomen examination the number of series can be from 1 to 4 series between countries.
- DRLs established by other international bodies could be useful for dose optimization process, especially for other regions of the world with different normal sized patients (Asian average weight is lower than the European average weight [Tsapaki 2006].
- The large variations found, especially for DLP, show that substantial optimization can be achieved. It is possible that different definitions cause this and mutually agreed terms could partly overcome this problem.
- It should be underlined that although European DRLs are set for common radiographic examinations, no European DRLs currently exist on paediatric CT examinations.
- Extensive studies should be carried out to establish paediatric CT DRL.

Exam	UK	Germany	Austria	Belarus	Sweden	Sweden*	Swiss	EUR	EUR	ACR	Korea
Author	*NRPB 67*	*BfS, 2010*		*Kharuzhyk*	SSI FS			16262	MSCT		*Jong Hak C*
Year	*2005*	*2010*	*2000*	*2010*	*2002*	*2008*	*2010*	*1999*	*2004*	*2009*	*2010*
Brain	65/55	65	68.9	60	75	65	65	60	60	75	69
Chest	13/14	12	18.9	20	20	12	15	30	10		19
Abdomen	14	20	19.8	25	25	13	15	35	25	25	19
Pelvis	14	20	23.5	25			15	35			

Table 1: Comparison of Diagnostic Reference Levels (DRL) in terms of $CTDI_{vol}$ [mGy] as reported by various countries and organizations.

** private communication*

Exam	UK	Germany	Austria	Belarus	Sweden	Sweden*	Swiss	EUR16262	Eur MSCT	ACR	Korea
Author	*NRPB 67*	*BfS, 2010*		*Kharuz-*	SSI FS *02:2*						*JongHak C*
Year	*2005*	*2002*	*2000*	*2010*	*2002*	*2008*	*2010*	*1999*	*2004*	*2009*	*2010*
Brain	930	950	1275	730	1200	1082	1000	1050	337	-	1056
Chest	580	400	484	500	600	428	450	650	267	-	1234
Abdomen	470	900	1109	600		778	650	780	724	-	1844
Pelvis	-	450	589	490			650	570		-	

Table 2: Comparison of Diagnostic Reference Levels (DRL) in terms of DLP [mGy x cm] as reported by various countries and organizations.

	ACR, 2009	NRPB, 2005	BfS, 2010	NRPB, 2005	BfS, 2010
	$CTDI_{vol}$ [mGy]			DLP [mGy x cm]	
Brain 0-1 y	-	35	33	270	400
Brain 5 y	-	50	40	470	500
Brain 10 y	-	65	50	620	650
Chest 0-1 y	-	12	4	200	60
Chest 5 y	-	13	7	230	130
Chest 10 y	-	20	10	370	230
Abdomen 0-1 y	-	-	7	-	170*
Abdomen 5 y	20	-	12	-	330*
Abdomen 10 y	-	-	16	-	500*

Table 3.: Paediatric DRLs for brain, chest and abdomen

* the abdomen includes the pelvic area

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WP 8: Training & Education

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I. Introduction

Computed Tomography (CT) is one of the most important technological developments of the 20th century, starting with a single 10 mm slice machine in the early seventies and evolving to multi-detector CT (MDCT) with capabilities of acquiring from a single to 320 simultaneous slices. The number of CT procedures is continuously increasing all over the world. This phenomenon is mainly due to the availability of more equipment and the incredible increase of acquisition speed, giving the possibility to perform many more examinations and therefore to study more patients. Due to the shorter scanning times, increasingly patients receive repeated CT examinations especially in the oncology and emergency departments of hospitals and shoulder to pelvic scans are becoming more common. Therefore, justification is continuously questioned.

It is important to assure that radiological health professionals (radiologists, radiographers and medical physicists) are keeping up with this evolution, in order to guarantee “doing more” simultaneously with “doing better”. Therefore, the appropriate and continuous training of personnel performing CT procedures and reporting the scans needs to be emphasized.

CT is a strictly defined imaging technique. Based on the clinical request, a certain CT protocol is chosen. The protocol is selected from a menu list on the scanner, a few individual adaptations are made, the contrast material – if any - is injected, and the scans are performed. This process results in four distinct groups of professionals whose training has to be adapted to their specific needs:

1. The medical practitioners requesting a CT examination. This group requires knowledge about indications for CT, its alternatives and the associated risks and benefits.
2. The core CT team that defines and optimizes the set of standard scan protocols on a specific scanner (radiographer, medical physicist and radiologist). This team will usually start with a standard set of protocols provided by the manufacturer and adapt it to the local needs. This team requires in-depth knowledge of scan parameters and how to optimize them.

3. The professionals (radiologists, radiographers) define the CT protocols. This group has to have knowledge when not to use CT, but another image technique, according to patient clinical indication. They are ultimately responsible for the individual choice of the correct protocol associated with each of the set of available standard protocols at a specific scanner / institution.
4. The radiographers that actually perform the examination. This group requires knowledge about individual routine adaptations required for each patient, such as centring of patients, adapting scan range, adapting protocol to patient size, optimizing modality performance in order to obtain the best diagnostic image at the lowest possible dose.

Training and education therefore should meet the different needs of these four groups of professionals. Groups 1 and 3 are mainly busy with justification. Groups 2 and 4 have the task of optimization. Of all groups, group 2 is essential for the process within a department of radiology: it is the task of this core team to instruct and train group 3 to be able to correctly prescribe protocols and to train and supervise group 4 to correctly perform the CT scans. It is mainly to group 2 that most of the training efforts presented below are directed.

II. Synopsis of Relevant Literature

II.1 Training and Education of Radiologists (ESR's Point of View)

II.1.1 ESR White Paper on Radiation Protection

The contribution of the ESR to urgent needs in medical radiation protection is stated in the "ESR White Paper on Radiation Protection" as follows

- The ESR strongly supports education and training in radiation protection of all medical staff involved with justification and optimisation of imaging examinations.
- Dissemination of information regarding radiation protection to all European countries (professionals, general population) is one of the primary tasks of the ESR.
- Justification: the ESR takes initiatives and is a strong partner in the cooperation to establishing European referral guidelines for imaging.

- Optimisation: the ESR supports all efforts to optimise imaging for the individual patient. Standards and DRLs for specific examinations are important tools in optimisation.
- The ESR actively cooperates with international organizations, such as the ICRP, IAEA, EC, IRQN, WHO, EMAN.

II.1.2 Referral Guidelines for Imaging

As assistance to the referring physicians or the radiologists in training, the *American College of Radiology Appropriateness Criteria* [ACR 2008] and the *Referral Guidelines for Imaging* by the *Royal College of Radiologists* in UK [RCR 2007] provide valuable information on the clinical indications for CT. These have been accepted or adapted by other organizations [EC 1999, EC 2004]. Relative radiation level (RRL) designations are found in the *Appropriateness Criteria* that indicate which imaging procedures expose patients to radiation and the relative magnitude of that exposure, based on the dose that would be received by an average-sized adult. A similar approach was used also by the *Royal College of Radiologists* in its imaging guidelines publication.

The radiologist should have appropriate training in CT as well as alternative imaging methods such as sonography (US) or magnetic resonance imaging (MRI). In the study of Jacob, 2004, who investigated the knowledge of terrestrial and medical exposure among doctors of various grades and specialties with an 11-question multiple choice questionnaire, it was found that only 27% of all doctors and 57% of practitioners, who had the responsibility of justifying procedures, passed the test. Even in well developed countries the need for constant training is essential. Soye, 2008 proved that clinician awareness of radiation dose and risk is poor and that training can increase the awareness for ionizing radiation. Constant training through journal publications and conferences within and outside radiology specialties are required so as to optimize exposure settings and assess the need for CT in an individual patient [Tsapaki 2010]. Relevant information should be distributed through scientific associations, national or international organizations, or societies involved in health care (especially for children) and the World Wide Web [Tsapaki 2010].

II.1.3 Protocol Optimization

The ESR and associated specialist European radiological societies such as ESTI, ESGAR, ESSR, ESCR, CIRSE, encourage and regularly include information about technical optimization of CT protocols and the optimum choice of protocol in the refresher courses of their meetings. Many of these presentations are accessible electronically via the ESR website and the EPOS system. In addition, the European School of Radiology (ESOR) provides in depths training on imaging technologies and also includes appropriate information on these issues in their courses.

For imaging of children, the ESR embraces the principles described in the “Image Gently” campaign (see also WP 4) that encourages specific child-sized imaging protocols.

II.2 Training and Education of Medical Physicists (EFOMP’s Point of View)

II.2.1 IAEA – Training Material

The *International Atomic Energy Agency* has a number of activities in order to promote radiation protection in CT and disseminate knowledge regarding this subject [Rehani 2008]. These activities are divided into the following categories: (1) coordinated research projects, (2) development of guidance, (3) technical cooperation (TC) activities aimed at building competence in member states, (4) information exchange through training activities and through the dedicated web site of IAEA on radiological protection of patients (http://rpop.iaea.org), and (5) mechanisms to report incidents. IAEA training activities are grouped into the following: 1) development of a standardised syllabus, 2) development of training CDs containing power point slides of lectures, including practical exercises, classroom exercises, questions, support material in terms of publications and, in some cases, manuals to assist in adapting the material to different audience groups, 3) organisation of regional training courses, 4) support countries in organising national training courses through training material and provision of experts. Other international organizations should follow this attempt so that other associated professions are also informed.

II.2.2 ICRP Publication 102: Managing Patient Dose in Multi-Detector Computed Tomography

As the ICRP 2007 states, there is a substantial lack of comprehension of CT radiation dose among requesting physicians and there are considerable variations in the scanning protocols and radiation doses between different CT centres. The Commission recommends that radiologists and operators are trained to adapt CT scanning techniques based on clinical indications (e.g., standard dose indications for liver metastases studies; low dose indications for screening, paediatric, and kidney-stone studies) and to assess associated radiation doses with different scanning parameters.

II.2.3 Core Curriculum for Medical Physicist in Radiology

EFOMP has drafted competences for a core curriculum for medical physicists in radiology:

- ***Computed Tomography Competences***

  Hardware:

  - To demonstrate awareness of different designs of computed tomography systems, like multislice CT, dual source CT, and volumetric CT scanners; CT scanners for diagnostic imaging and for radiotherapy planning;
  - To demonstrate awareness of different modes of operation of CT scanners;
  - To be able to advice on the purchase and use of the most appropriate computed tomography system for a specific clinical application.

  Acquisition:

  - To understand common acquisition parameters for CT imaging;
  - To understand static 2D and 3D acquisitions in CT;
  - To understand dynamic 2D and 3D acquisitions in CT;
  - To demonstrate familiarity with special requirements for paediatric CT imaging;
  - To demonstrate familiarity with special requirements for quantitative imaging in CT;
  - To become acquainted with contrast enhanced studies in CT;

- To be aware of special requirements with regard to radiation protection in CT, particularly in CT guided interventions;
- To demonstrate awareness of the application of Radiostereometric Analysis imaging
- Dual energy imaging, including dual energy X-ray absorptiometry (DXA)
- Dental applications of radiography.

Core curriculum items:

- Basic principles of computed tomography (filtered back projection, Hounsfield unit, multi detector row CT, multisource CT, cone beam CT, axial and helical acquisition and reconstruction, dynamic acquisition and reconstruction (CT fluoroscopy), CT radiograph, bolus tracking, prospective triggering (ECG), retrospective gating (ECG, respiratory), CT perfusion);
- Acquisition parameters (tube voltage, bow tie filter, tube current, rotation time, tube current modulation, collimation (scanned field of view, slice thickness, beam collimation, over beaming, over scanning);
- Contrast enhancement in computed tomography;
- Image reconstruction (reconstruction kernel, slice width, reconstructed field of view);
- Image quality (spatial resolution and low contrast resolution, contrast to noise ratio, point spread function, modulation transfer function, noise power spectrum, contrast detail curves);
- Dose (computed tomography dose index, dose length product);
- Acceptance and constancy tests of computed tomography systems:
- Introduction to clinical applications of computed tomography;

II.3 Training and Education of Radiographers (EFRS' Point of View)

At the European level several EU documents (two of which are now under revision) are important for education and training in radiation protection of all health professionals using ionising radiation.

II.3.1 Council Directive 97/43/Euratom

Council Directive 97/43/Euratom (1997) addresses health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, known as the *Medical Exposure Directive* (MED). The MED had to be transposed into national law no later than 13 May 2000.

According to Article 7 of the *Medical Exposure Directive*, Member States shall ensure that the practitioner and those individuals that are mentioned in Article 5(3) and 6(3)

- have adequate theoretical and practical training for the purposes of radiological practices,
- as well as relevant competence in radiation protection.

Individuals undergoing relevant training programmes may participate in practical aspects for the procedures mentioned in Article 5(3).

Member States shall ensure that continuing education and training after qualification is provided and shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools. Article 9 requires Member States to ensure that practitioners conducting special practices (like for example CT) receive appropriate training.

- **Implementation of the MED Directive**

Several surveys show that the directive has been implemented into national legislations of EU member states in distinctly different ways. This makes the roles and responsibilities of health care workers concerning radiation protection, markedly different between these countries. Unfortunately, there is no European consensus about what the indicated "*adequate*" theoretical and practical training and competence should be.

On the other hand, it's important to be aware that in the great majority of European countries, radiographer's education is integrated at the higher education level, having in their programs specific syllabus regarding radiation protection. However it's fundamental to develop a program to harmonize the theoretical and practical training between different countries and even universities.

II.3.2 EU Radiation Protection 116 (2000): Guidelines on Education and Training in Radiation Protection for Medical Exposures

These guidelines contain some specific recommendations for the application of the MED Directive and were developed with the assistance of the group of health experts established under Article 31 of the EURATOM Treaty. The guidelines are not binding on Member States, and form part of a number of technical guides drawn up to facilitate implementation of the MED. Staff with responsibility for medical exposures that will need training in radiation protection were identified.

In the general recommendations for training programmes in radiation protection a list of topics can be found which should be incorporated in training programmes with additional comments from WHO (Interventional Radiology), ESTRO (Radiotherapy), EANM (Nuclear Medicine)) and ISRRT (European Committee). RP 116 (2000) recommends that specific cases could require revision, for example radiographers. In this case, the differences in content and in hours of training between Member States are significant and some complementary efforts to harmonise this specific training will be needed.

II.3.3 EUR 1626 and 1999

Radiographers use different guidelines for optimization of CT procedures. Firstly, radiographers should know or be informed when CT is justified (RP 118). Secondly, image quality is a task that should be decided in cooperation with radiologists and medical physicists, before a CT protocol is approved for use (EUR 1626, 1999). Proper use of all parameters which affect image quality and dose are important for radiographers and should be provided by all vendors.

II.3.4 Image Gently

Optimization of paediatric protocols became a major topic in the last few years. Changing small things (like topogram/scanogram from AP to PA direction) can be a first and very easy step on how to start the examination. Patient size is a first step in the decision making by the radiographer on which protocol should be used. The basic models for further preparation with reference to paediatric CT optimization are described in the Image Gently campaign (2009), see WP 4 for more details.

It is important to note that an ongoing practical issue relates to the use of shields to reduce radiation dose to radiosensitive organs, such as breast, thyroid, lens of the eye, or gonads. The proper protocol depends on the design of the AEC features of the scanner; one approach is not appropriate for all CT scanner manufacturers. If not used properly, the presence of shielding may lead to increased radiation dose to the patient [AJR 2010; 194: 868-873].

Effect of scan parameters on dose especially such as tube current, tube voltage (kV), beam (slice) width (mm), helical pitch, number of slices/tube rotations (scan length) are issues whose proper use radiographer should understand (ImPACT). With the evolution of new detector sizes, the optimization of the effect of z overscanning on patient effective dose should lead to new principles as useful tool for overview in all CT protocols (Tzedakis, 2007).

II.3.5 IAEA TECDOC -1621 (2009)

In 2001, IAEA (IAEA-TECDOC-1621, 2009) decide to evaluate the following questions:

1. Identify a pragmatic approach to noise measurement, and define target values for image noise;
2. Study the differences in image quality perceived by radiologists in different countries due to different noise levels or patient body weights;
3. Determine patient doses in the various countries and compare them with published diagnostic reference levels;
4. Determine the influence of patient weight and technical factors on image noise, image Quality;
5. Identify patient size parameters that may be used to help optimize exposure factors Derive a methodology and exposure tables for individualizing patient exposure without reducing diagnostic confidence.

In practice, the dose reduction achieved was effected without loss of an acceptable level of image quality. According to this study we can make conclusions for further principles to improve our daily practice.

Finally, quality control (QC) is a very important step in CT modality. On a routine basis, radiographers should perform: calibration of CT numbers, uniformity of CT num-

bers, high contrast resolution, noise, low contrast detectability and slice thickness (IAEA-TECDOC-1423, 2004). If the radiographer is trained he can perform the monthly QC and send the results to the medical physicists for further evaluation. For completion of this task all vendors should supply customers with test phantoms to fulfil the mentioned requirements. During specific training modules (ImPACT) it was clarified that measurements can be divided in the following groups: Electrical safety, Mechanical safety, Laser safety, Radiation safety, Mechanical accuracy, Dosimetry and Imagining performance. Within the mechanical accuracy, radiographers can be trained to perform: Alignment of indicating lights with scan, coronal and sagittal planes; Agreement between internal and external scan plane lights*; Co-incidence of internal scan plane lights and scan plane; Coronal and Saggital plane lights*; Accuracy of distance indicator on gantry; Couch travel accuracy for helical scans; Gantry Tilt. Concerning imagining performance, radiographers can be trained to perform measurements on noise, CT number uniformity, CT number linearity, low contrast resolution, and spatial resolution (CT Scanner Acceptance Testing, ImPact 2001). All these measurements can improve the radiographer's skills in understanding how a modality works. Furthermore, the question of when the CT image is good enough for diagnostic purposes remains open.

II.3.6 EFRS comments

An important step is to promote to radiographers schools and societies the importance of teaching the fundamental aspects of CT optimization, and all the technical possibilities for dose reduction, and also the fact that, because each vendor has its own technology and strategies, radiographers need to understand and maximise the equipment possibilities.

The first cycle of education should teach radiographers to learn and to understand that continuous professional education is fundamental.

The second step is to request from vendor application specialists to focus more in dose reduction strategies protocols than achieving high quality images. Radiographers should be able to understand and control all software packages offered by the equipment to achieve better optimisation after the installation of the equipment. Obviously for this goal it is important also to collaborate with the radiologists and to develop together protocols that maximise diagnosis and minimise patient dose.

EMAN WP1 could develop a guidance booklet as a tool to promote CT optimization. To start this process a WP1 internet blog will be a powerful tool, in order to get experts together to share experiences.

With regard to the European Commission Guidelines on clinical audit for medical radiological practices it is necessary to promote the radiological team concept all through Europe, i.e.: A team of a radiologist, a radiographer and a medical physicist is necessary to promote a safety culture and health care best practice.

III. Final Analysis

Training of a “core team” that is responsible for optimisation of CT protocols at a specific institution is of paramount importance for ensuring good quality while keeping radiation dose as low as reasonably possible. Such teams have to be established to ensure deep enough knowledge about CT parameters and how they influence radiation dose and image quality. It should be the task of this team not only to optimize CT protocols but also to ensure local training of radiologists or specially trained radiographers with respect to optimum utilization of scanning protocols (indication) and training of radiographers with respect to adapting protocols to individual patients.

The prerequisites in knowledge for this team are well described in the Core Curriculum for Medical Physicist in Radiology developed by EFOMP.

While there is ample educational material available for radiologists with respect to protocol optimization for specific clinical tasks (via the congresses of ESR and its subspecialist societies), there is a lack of dedicated courses that focus on optimizing CT protocols in general and are geared towards the whole core team consisting of the radiologist, a radiographer and a medical physicist.

For imaging of children, the ESR embraces the “Image Gently” campaign described in WP 4 that encourages specific child-sized imaging protocols. However, there is not yet a formal accreditation procedure for CT programs established by ESR.

Being the individuals that are responsible for the performance of the CT examination, radiographers are the last link in the radiation protection chain. Because of the big differences in the role and education of radiographers, it is important to improve radiographer’s competencies in a number of countries, through the implementation of education and training recommendations.

A first step is now undertaken by the EFRS by formulating a minimum standard in radiation protection education to be included in the initial education curriculum. Once this document is approved by the membership of the federation, other stakeholders will be involved in a process of recognition at the European level. In future the same should be done for Continuous Professional Development in specialised areas, like CT.

It is not yet investigated, but from the European radiographer network point of view, there is evidence that training courses after the acquisition of new equipment are very often insufficient. This endangers not only the patients and staff, but can also bring about a sub optimal result compared to the possibilities of the equipment.

The role of a radiographer and his knowledge and skills have never been evaluated or reported. Future studies based on the role of radiographers in optimising dose in CT examination should be explored and factors that encourage radiographers for wider roles should be identified. There is no European policy formulated yet for a minimum level of education and training for the various professionals working with CT equipment. The European organisations for radiographers (EFRS) and medical physicists (EFOMP) are now undertaking the first steps in this direction.

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Summary

WP 1: CT Medical Exposures

(1) To adequately validate the results of studies on CT medical exposures, a thorough analysis weighing the clinical benefit from the increasing use of CT against the resulting radiation risks are needed, but require detailed information of both age of the patients and clinical indication of the performed CT exams. Apart from few exceptions, such as Denmark with its centralised health care system, such data are not available at present. Respective research programmes should be launched, for example by the EU.

WP 2: CT Risk / Benefit Estimation

(1) The ALARA approach has to be extended by concerted action taking into account both the principle of justification and the principle of optimization since even an optimised application of X-rays fails to comply with the principles of radiation protection in medicine, if it is not justified.

(2) The harmonization of referral guidelines on a European level and their EU-wide implementation are pivotal. Within this long-term initiative, the interaction between referral and justification and the roles of the responsible professionals need to be clarified. To ensure this clarification, the responsibility of the radiological practitioner in the justification process as well as the responsibility of the medical practitioner in the referral process should be clearly stated by the relevant authorities. This should establish the basis for an optimized interaction and communication between these two important stakeholders in medical radiation protection.

(3) Concerning the use of CT in **healthcare**, there is a lack of sufficient scientific evidence demonstrating that the benefit outweighs the risk. To do so, the benefit-risk analysis of CT imaging procedures has to be broken down to diagnosis-related groups of patients, in particular to those being highly exposed as well as those being in particular radio-sensitive, e.g. pregnant women and children and young adults. It is highly recommended to launch research projects addressing these important issues, in particular to assess benefit-risk ratios on relevant diagnosis-related groups of patients.

(4) Concerning the use of CT in **individual health assessment**, no standardised and optimised protocols and algorithms are yet available concerning the definition of risk profiles, technical performance of CT, reading and diagnostic workup of suspicious findings, training and education as well as documentation and evaluation. It is highly recommended to initiate actions on a national and international level addressing these important issues.

WP 3: CT Dose Reduction Techniques: Equipment

(1) Manufacturers should consider to provide a dose indicator on the scanner console that relates the prescribed dose to a reference level (e.g., average DRL across EU countries). A warning should be given if reference levels are exceeded.

(2) Adequate documentation of patient-specific parameters (weight and height) as well as exposure is necessary for monitoring exposure practices. Manufacturers should consider providing an automatic mode for generating a database for each individual scanner that records relevant patient and exposure parameters.

(3) Further automation to individually adapt kV settings and contrast material dose should be encouraged.

WP 4: CT Dose Reduction Techniques: Scan Protocols

(1) Each CT facility should identify a “core team” including a radiographer, a radiologist and a medical physicist♦ and being responsible for optimisation of CT protocols. This “core team” is also responsible for ensuring training of CT radiographers and supervision of utilization of scanning protocols. Although - in some European countries - there is a shortage of medical physicists trained and educated in radiological imaging, WG 1 wants to underline that medical physicists have to play a pivotal role in this process.

(2) Adequate training of the radiological “core team” for appropriate protocol setup and adjustment is mandatory. Manufacturers as well as professional societies need to be involved.

(3) Manufacturers should be required to provide at least one standard set of protocols for new scanners, which is optimized towards dose-efficiency. The dose for these protocols should be below predefined levels that, for example, could be connected to the average DRLs across EU countries.

(4) Techniques for adapting standard protocols to individual patient size should be simplified. Regulatory boards and manufacturers should provide a common nomenclature for adaptive dose modulation techniques in order to be able to more easily compare settings. Further automation to individually adapt kV settings and contrast material dose should be encouraged.

WP 5: CT Dose Efficiency Parameters

(1) The implementation of a standardized benchmarking of CT systems characterizing the dose efficiency related to image quality of CT systems (dose efficiency parameter), and the declaration of this standardized dose efficiency parameter in the technical data-sheet for each CT system on the market needs to be established.

(2) This requires the involvement of various stakeholders: (1) CT manufacturers and medical physicists (to develop and verify the test methods), (2) standard committees (to set up a standard), (3) regulatory bodies (to set up requirements) and (4) radiation protection authorities (to provide funds for the required activities).

♦ the order of the professions does not reflect any difference in their importance

WP 6: CT Dose Reporting

(1) Harmonisation of the nomenclature is necessary between various fields in which ionising radiation is used, but care has to be taken to avoid doing more harm than good when substituting C_{KL} and P_{KL} for CTDI and DLP. A greater role of radiologists and other practically involved heath care professionals is warranted.

(2) The concept of equivalent dose or absorbed dose instead of effective dose should be introduced more into clinical practice. However, it is too early to come with concrete suggestions.

(3) The same holds true for the introduction of new measurement techniques for measuring dose in CT systems with a wide x-ray beam and detector. An international consensus should be reached before introducing such new techniques into EU recommendations.

(4) There is a need for introducing a program within the EU for calibration of instruments to ensure traceability in quality assurance programmes for CT.

WP 7: CT Diagnostic Reference Levels

(1) The European DRLs should be revised to include MSCT and the new dose quantity $CTDI_{vol}$. This should be a dedicated European project related to dosimetry.

(2) DRLs must be established by more European countries. Current values appear to be limited. National regulatory authorities could be informed on this subject.

(3) The DRL show large variations. Variations in CTDI are mainly due to variation in the technical protocol used and differences in the CT scanner. Therefore, more standardized protocols could harmonize CTDI-DRL values. Variations in DLP are mainly due to variations in the set up. For example in some countries abdomen means the whole abdomen whereas in others it means only the upper abdomen. Also the number of series as well as the definition of series varies. For the abdomen examination the number of series can be from 1 to 4 series between countries. The harmonization could be done by the ESR.

(4) The large variations found, especially for DLP, show that substantial optimization can be achieved. It is possible that different definitions cause this and mutually agreed terms could partly overcome this problem. This could be addressed to the ESR, EFOMP and the EFSR for joint attempts for optimization.

(5) Extensive studies should be carried out to establish paediatric CT-DRL. This subject could be directed to the European Commission, the national regulatory authorities or international bodies such as the IAEA or WHO.

(6) DRL should be set up not only for routine CT examinations but also for others such as cardiac or perfusion CT. This could be addressed to the ESR, EFOMP and the EFSR for joint attempts as well as the European Commission, the national regulatory authorities or international bodies such as the IAEA or WHO.

WP 8: Training & Education

(1) Each CT facility should identify a “core team” (see *Chapter 2.4*) responsible for optimisation of CT protocols. This “core team” is also responsible for ensuring training of radiographers and supervision of utilization of scanning protocols.

(2) Training of at least one member of the “core team” should be based on the Core Curriculum for Medical Physicist in Radiology developed by EFOMP.

(3) There is need for dedicated courses that focus on optimizing CT protocols in general and are geared towards the whole “core team”. ESR, EFRS and subspecialty societies can play a major role in establishing these training programs.

(4) There is a need for a formal accreditation procedure of CT training and education programs established by ESR.

(5) Education and training recommendations for radiographers have to be established by EFRS and adopt suggestions from other professional bodies and organizations such as ESR and EFOMP.

(6) Training courses after the acquisition of new equipment is needed, taking into particular account the specific features of the new equipment.