Dose Management in Diagnostic Radiology - application of the DICOM imaging standard and a Monte Carlo dose engine for exposure surveillance

HANS-ERIK KÄLLMAN
Abstract


Ionizing radiation is used in diagnostic radiology with a large contribution to the health of the patients. The regulations to limit the detrimental effects, e.g. cancer induction, are based on recommendations from the International Commission on Radiological Protection (ICRP). Epidemiological evidence for radiation induced cancer is expressed as a function of absorbed dose in the irradiated organs. The committee for Biological Effects of Ionizing Radiation has favored the use of Lifetime Attributable Risk, a risk estimator applicable to individuals exposed in medical applications. The imaging in radiology complies with a technical standard that potentiates the retrieval of exposure information that can be used in optimization of patient exposure. The information can also be used as input in organ dose calculations.

The aims were to apply the benefits of the technical image standard to radiation safety management by automated collection and analysis of exposure data and to adapt a Therapy Planning System (TPS) for radiotherapy to calculate dose for a Computed Tomography (CT) machine.

An automated workflow for extraction, communication and analysis of exposure data from the image files in the central image archive was defined and implemented at the institution (papers I-II). A source model for Monte Carlo simulation of the CT was developed taking into consideration the energy spectrum of the photons, the spiral movement of the X-ray beam, the beam shaping filter and the tube current modulation (paper III). The source model was used exploring the possibilities to utilize the tissue characterization methods and segmentation tools available in the TPS to devise a strategy to automate organ dose calculations for patients undergoing thorax examinations in a CT (paper IV).

The exposure data workflow was finalized showing that the technical standard for images could supply a framework for automated assembly and analysis of the data, supporting the local implementation of optimization. The CT was modeled with regard to its irradiation characteristics with uncertainties in the dose calculations below 4%. Dose calculations with the tissue characterization methods available in the TPS deviated by less than 2% from measurements and a strategy for automation of organ dose calculations was devised that could facilitate individual risk estimates in CT.

**Keywords:** Radiology, metadata, DICOM, radiation safety, Monte Carlo, source model, patient model, optimization, justification

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Dedicated to my family and my parents
who made me a curious person
This thesis is based on the following papers, which are referred to in the text by their Roman numerals.


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### Abbreviations

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<th>Description</th>
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<tr>
<td>ALARA</td>
<td>As Low As Reasonably Achievable</td>
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<td>BEIR</td>
<td>Biological Effects of Ionizing Radiation</td>
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<td>BSS</td>
<td>Basic Safety Standards</td>
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<td>CT</td>
<td>Computed Tomography</td>
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<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
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<td>DRL</td>
<td>Diagnostic Reference Level</td>
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<tr>
<td>EC</td>
<td>European Community</td>
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<tr>
<td>ED</td>
<td>Effective Dose</td>
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<td>EI</td>
<td>Exposure Index</td>
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<tr>
<td>HL7</td>
<td>Health Level 7</td>
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<tr>
<td>HVL</td>
<td>Half-Value Layer</td>
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<tr>
<td>ICRP</td>
<td>International Commission on Radiological Protection</td>
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<tr>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
</tr>
<tr>
<td>Kerma</td>
<td>Kinetic energy released per mass</td>
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<tr>
<td>LAR</td>
<td>Lifetime Attributable risk</td>
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<tr>
<td>LNT</td>
<td>Linear Non Threshold</td>
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<tr>
<td>MC</td>
<td>Monte Carlo</td>
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<tr>
<td>PACS</td>
<td>Picture Archiving and Communication System</td>
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<tr>
<td>RDSR</td>
<td>Radiation Dose Structured Report</td>
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<tr>
<td>TPS</td>
<td>Therapy Planning System</td>
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1 Introduction

1.1 Radiation safety

Detrimental effects of ionizing radiation on humans and the environment are countered by a regulatory system for radiation safety. The International Commission on Radiological Protection (ICRP), a non-governmental organization for collaborative consensus guidance in radiation safety, has issued three central principles for protection of the public: justification and optimization of exposure and application of dose limitations.\textsuperscript{1} The recommendations are taken into account in an European Commission directive, the Basic Safety Standards (BSS),\textsuperscript{2} which is translated to national regulations in Europe.

The overall aim of this thesis is to improve on the clinical implementation for two of the principles: optimization of the radiation dose for the required diagnostic information and justification of the radiation risk as compared to the benefits for the patient. Dose limitations do not apply to patients, but to occupational exposure, and are not further addressed here.

1.2 Health effects of medical exposure

Diagnostic imaging with ionizing radiation is beneficial to global health. It provides alternatives\textsuperscript{3} to and helps in the planning of invasive surgical procedures,\textsuperscript{4} screening procedures saves lives through early disease detection\textsuperscript{5} and it contributes to an increasing understanding of the human body through the application of functional imaging.\textsuperscript{6} At the same time diagnostic radiology is by far the largest contributor to exposure of the public from artificial radiation sources\textsuperscript{1}. The recent trends are unequivocal, over the past decades there has been a steady increase in the number of Computed Tomography (CT) examinations, in the US by almost 8% annually between 1996 and 2010.\textsuperscript{7} Nearly all European Community (EC) member states for which data are available reported an increase between 2009 and 2014 in the number of CT scans relative to the size of their respective populations.\textsuperscript{8} Many factors points toward a future increase, an ageing population, health care consumerism and new imaging technologies. Deficiencies in social systems, general healthcare cost\textsuperscript{9} and the risks associated with the use of ionizing radiation are inhibiting factors that
must not dissuade necessary radiological procedures. The benefits of a medical exposure is often well known, but comparison to risk might be difficult due to ambiguous applications of current risk models.\textsuperscript{10}

Radiation detriments are often categorized as stochastic or deterministic, the former being radiation induced cancer and heritable diseases. There is no direct evidence for radiation induced heritable diseases in humans,\textsuperscript{1} but they have been demonstrated in animal and cell studies and remain a reason for precaution. Cancer risk estimates are based on epidemiological studies of atomic bomb survivors, medical exposures and environmental studies.\textsuperscript{1} As with other epidemiological investigations there is a threshold below which the relationship between dose and cancer is hard to confirm due to confounding factors, uncertainties and poor statistics of rare events. As a consequence, the incidence for radiation induced cancer at exposure levels used in medical exposure is associated with large uncertainties. Nevertheless, results from epidemiological studies in combination with laboratory studies on cell populations and animals and the mechanisms behind radiation induced cancer make it reasonable to assume a linear relationship between cancer incidence and radiation dose, referred to as the Linear Non Threshold (LNT) hypothesis.\textsuperscript{1} Supported by recommendations from radiation safety organizations, the LNT hypothesis has been implemented in the regulations on medical exposures in the EC.

Deterministic effects of radiation exposure, such as skin burn\textsuperscript{11} or hair loss,\textsuperscript{12} are not frequent and often occur under circumstances where the patient has a life threatening condition. Skin burns, for instance from coronary interventions, can be prevented, but not altogether avoided when lifesaving radiological procedure must be completed. The management of the risks for deterministic effects is not the main focus in this thesis, but the tools developed can provide information for prevention and evaluation of deterministic effects as well as cancer risks.

1.3 Risk models

The ICRP and the American national research council committee for Biological Effects of Ionizing Radiation (BEIR) continuously review studies on radiation induced cancer, as illustrated in Figure 1, as to update the recommendations used in radiation protection management.\textsuperscript{1,13} Both organizations use the same basic data for estimation of cancer incidence, but their risk estimators are adapted to their respective objectives; ICRP “helps to prevent cancer and other diseases and effects associated with exposure to ionizing radiation, and to protect the environment” while BEIR “strives to provide the best possible risk analysis for x-rays with organ doses between 0-100 mGy”, i.e. focusing on medical exposures.
1.3.1 ICRP and Effective Dose

Cancer risk is estimated by the ICRP using the Effective Dose (ED, unit Sievert, Sv) concept, a quantity based on the absorbed dose to risk organs (unit Gray, Gy) weighted by factors that depend on organ radiosensitivity, cancer type and radiation type. The quantity of ED should be perceived as a coarse predictor of radiation detriment, and is not intended for individual risk estimates. ED reflects the estimated detriment based on cancer incidence, mortality, loss of years alive and quality of life impact averaged in a mixed population.\(^1\) Thus, thyroid exposure and liver exposure with the same detriment will have different consequences as the two diseases are very different. Understanding the detriment is central for the interpretation of ED as the probability for cancer as well as the consequences of the cancer is mixed into the concept. The detriment can, according to the ICRP, be estimated to 5%/Sv. For a population exposed to 1 mSv each, one arrives at a cancer detriment of 5 individuals per 100,000, which might be hard to communicate to a patient. While not intended for individual risk estimates, ED is a convenient tool for benchmarking purposes or for occupational risk estimates where the measurement uncertainties are generally large enough to supersede the uncertainties in the risk model itself. ED can be used to classify radiological examinations into risk classes, relating the detriment for a mixed population between classes. In a classification published by the European Commission\(^{14}\), examinations above 5 mSv are classified as high dose examinations. Among these are CT examinations of the abdomen and thorax with an ED between 5-10 mSv for a complete examination.
1.3.2 BEIR and Lifetime Attributable Risk

The preferred risk estimator by the BEIR is the Lifetime Attributable Risk (LAR), which is the risk for cancer induction from an exposure during the remaining life for a person of a certain age and gender. The LAR risk factors are estimated in epidemiological studies from excess cancer in identified risk organs as a function of organ dose. The uncertainties are large, as indicated in Figure 2, on the other hand LAR reflects the risk for the actual patient and supplies an organ specific estimate for cancer induction, once the organ dose is known. The probability for cancer is intuitively understood by medical professionals in contrast to the concept of ED.

![Figure 2. Lifetime Attributable Risk (LAR) for lung exposures from chest CT and chest radiography as a function of age at the exposure and gender. Adapted from BEIR for lung organ dose of 0.5 mGy for the radiography and 5 mGy for the CT. To indicate the approximate order of uncertainty, the relative uncertainty for a population of mixed ages (95% confidence interval) has been applied for all ages for a female chest CT.](image)

The increasing use of CT implies an increased population risk\textsuperscript{15}. When applying the risk models from the ICRP and BEIR the interpretation of the results are discordant considering the definition of the quantities of ED and LAR. Moreover, as the ED is averaged over gender and age it will underestimate the risk for children and adolescents and overestimate the risk for an elderly population as compared to the LAR. Yet, as the level of risk and the risk quantities
are debated, there is no evidence that the precautionary principles established by international bodies, such as the ICRP or the BEIR, on the use of ionization radiation in diagnostic radiology will be abolished. Limitation of medical exposure will continue to be based on As Low exposure As Reasonably Achievable, also known as the ALARA principle.

1.4 Regulations and infrastructures in radiology and radiotherapy

Radiation safety is a concept with a larger scope as opposed to radiation protection, the latter often associated with radiation shielding. Radiation safety in radiology is founded on the application of reference dose levels for guidance in dose optimization and the principle of justification of medical exposures. Occupational exposure is also addressed by the ICRP through staff dose constraints and radiation shielding regulations. The scope of this dissertation is patient exposure and it covers large scale collection and analysis of exposure data extracted from the increasing quantity of examinations produced in radiology, and the specific task of calculating patient specific risk applied to CT.

In 2018, the BSS for protection against the dangers arising from exposure to ionizing radiation must be implemented as law in all member states in the EC, in Sweden by regulations from the Swedish Radiation Safety Authority. Complying with the legislation requires a detailed knowledge of the different exposure situations. Radiology is no longer centralized in the radiology department but most providers of healthcare have centralized medical image archives. With limited resources for radiation safety, the information in the archive should be effectively utilized for radiation safety management.

The referring practitioner initiates a patient exposure as an examination is ordered. This requires a need for knowledge of both the radiation risks and the possible gain of the procedure. Electronic patient records structured for efficient analysis and feedback through clinical decision support should be able to provide information on the benefits for the patient by summarizing previous results for the same type of procedure and patient characteristics. It is the responsibility of the health care organization to provide pre-examination risk estimates that can divert the referring practitioner from unjustified exposures. The risk information is currently available using the information in the imaging archive in combination with tools for radiation dose calculation in patients. Tools to communicate risk to referring practitioners are developing and it is the responsibility of the medical physics community to further detail the risk estimates and make them valid in the discussion between the practitioner and the patient.
Adhering to the definition of radiation safety, large scale automated collection of dose and image quality indicators, addressed in papers I and II, is crucial in the implementation of optimization. Accessing structured data from a database enables extraction of descriptive statistics that can identify normal conditions as well as outliers from distributions of exposure parameters instead of manually sampling the parameter distributions.

In radiation therapy, the procedure starts with CT imaging which also provides the basic data for dose calculation. The targeted tumor volumes and the surrounding tissues at risk are segmented in a Therapy Planning System (TPS) which also provides accurate (2-3%) dose calculation algorithms. The dose calculation capabilities together with the segmentation tools available in commercial TPS can potentially be used to estimate organ doses to cancer risk organs for diagnostic CT, a possibility explored in papers III and IV that deals with an adaption of a commercial TPS to diagnostic CT.

1.5 Imaging data in medical applications

To reduce population risks, regulations are imposed to ensure implementation of safety systems. For practical reasons the patient exposure is expressed in imaging device specific quantities. E.g. in projection radiography the product of the air kerma (kinetic energy released per mass) and the size of the radiation field are used, and in mammography, the estimated average glandular dose is used based on air kerma at the entrance side of the breast. These exposure indicators are examples of information that is available in parametric form as metadata in medical images. The collection and utilization of such information is addressed in paper I. A parameter that describes the dose to the imaging detector, thus relatable to image quality, is the Exposure Index (EI) which can indicate overexposure leading to unnecessary patient exposure, or underexposure leading to inferiorly noisy images. An example of automated constancy control of imaging settings through EI surveillance is covered in paper II.

Optimization of patient exposure is based on quality control of equipment and implementation of diagnostic reference levels i.e. guideline values issued by the authorities on patient exposure that should not be exceeded. In diagnostic radiology the large volume and variety of examinations is a particular challenge. Collection and analysis of patient exposure data from metadata in digital image archives presents a good opportunity to identify clinical applications with potential risk to individuals as well as to collectives.

Thanks to the consistency in data required by computer applications, the image data, as well as the exposure data, is standardized to a high degree by the DICOM (Digital Imaging and Communications in Medicine) standard.
1.5.1 The development and scope of the DICOM standard

To implement effective workflows, medical images need to be communicated and stored in a standardized way as to allow components from different vendors to be used. The DICOM standard deals with both the format of images produced by diagnostic equipment, and the communication and storage methods. The standard is regularly updated by the Association of Electrical Equipment and Medical Imaging Manufacturers and has been widely applied in diagnostic radiology and radiotherapy, with the first standard released in 1985. A vendor has the right to claim conformance and is then obliged to adhere to the specifications. Under the umbrella of Integrating the Healthcare Enterprise (IHE), the interconnectivity of devices from different vendors are validated in practical workshops to ensure correct interpretation of the standard. IHE is also promoting the coordination of the DICOM standard with the Health Level Seven (HL7) standard for exchange, integration, sharing, and retrieval of electronic health information. Concerning traditional patient records not including images, the HL7 and DICOM standards are developing in parallel. This means that the infrastructures supporting images or traditional patient records can interchange clinical information such as the purpose of a diagnostic procedure from connected placeholders within each standard. The DICOM standard is, in practice, self-sufficient for a vendor of Picture Archive and Communications System (PACS) that constitutes the electronic infrastructure for communication and storage for all images and clinical data in a radiology department. IHE is the safeguard for interconnectivity between PACS and the electronic patient record within a healthcare organization.

1.5.2 Image metadata for radiation safety management

A diagnostic examination complying with the DICOM standard is structured in a study, image series and separate images. The imaging device logs the settings of the imaging protocol and the exposure data. The standard requires that all images are associated with metadata, i.e. auxiliary information to describe their content and context. These data are embedded in each image file and each parameter is identified by an 8-digit code. The data includes exposure information, as well as the relation between the images belonging to the same study. Besides the acquisition information, the metadata ensures that the study can be identified by a receiving device with enough data to be put into context. The structure of the information is well defined which makes automated extraction of metadata robust provided the standard is consistently implemented. A structured collection of metadata is in this thesis referred to as a metadata repository. When viewing a study in a clinical workstation for reporting, selected parts of the metadata are shown but exposure details are normally not shown to avoid cluttering. The increasing availability of exposure information in the metadata was an incentive for papers I-II, which deals with metadata retrieval and analysis.
1.5.3 Structured reports of radiation safety information

Recognizing the usefulness of the metadata information, the Radiation Dose Structured Report (RDSR)\textsuperscript{20} has been introduced by the DICOM committee offering a structured summary of the patient exposure in an examination. The information flow in the infrastructure and the metadata and RDSR are described in Figure 3. A major advantage of the RDSR is that the exposure summaries contain exposures that are not stored in the image archive, such as fluoroscopy series in interventional radiology. This information cannot be recovered from the metadata as the images must be stored. The information in the RDSR is also available in the metadata but the RDSR offers a more comprehensive format for access by systems tailored for radiation safety management. Although some of the image specific metadata are excluded in the compilation of the report, the perspective of study specific information is enhanced, supplying a less cumbersome path for study exposure overviews. One of the most significant parameters for risk management is the organ dose following a patient exposure. This quantity can be interpreted in terms of cancer risk by means of risk factors. The estimation of organ doses in CT is covered by papers III-IV.

The combination of metadata and RDSR offers detailed technical information, easy accessed overviews and a structured base for the tasks of dose and image optimization and patient dose control. Today, all major vendors of radiological equipment offer RDSR which will likely become the dominating source of information for radiation safety management in the future. RDSR does not in itself supply the tools for further analysis and interpretation of the radiation risks, but rather potentiates the access of structured exposure information to both system vendors and the scientific community. This is a strategic choice to encourage the development of expert systems that can derive risk indicators to be applied in individualized risk estimates. The implication of Paper III-IV is that a TPS for radiotherapy could entail such an expert system applied on the calculation of organ doses in diagnostic CT examinations.
Figure 3. The information flow of exposure data in a DICOM study. A CT study contains over 50 separate images, all containing exposure data in the metadata and a separate Radiation Dose Structured Report (RDSR). The study is sent to the Picture Archive and Communication System (PACS) for storage and further distribution to users. The study is automatically forwarded to the metadata repository by the PACS, the pixel data is discarded and the metadata and RDSR are inserted in a database facilitating effective extraction of exposure data. The RDSR integration in the repository is a recent addition not described in the papers.
1.6 DICOM exposure data and optimization

The application of DRL for radiation safety in radiology motivates the use of a structured repository for patient exposure data. The radiation safety process is shown in Figure 4, and is further outlined by the author in this paragraph where the component and subsystem labels relating to the figure are written in italic. *Research & development* is driven by the vendors of the equipment as well as scientific institutions. New imaging devices with improved possibilities to decrease exposure without impairing image quality undergo *Vendor optimization* before delivery. The improvements on devices are often stepwise which poses a challenge to the application of DRL as the system is inert when decreased exposure levels are introduced. *Local DRL*, agreed on recommendations from the vendors, can be applied in transitional periods. *Local implementation of optimization through DRL* is initiated for example by observed problems in clinical audits or by changes in DRL. The purpose of the *Local optimization* at the healthcare provider is to ensure that the DRL is applied in an optimized production chain and that the DRL is valid with regard to the local clinical objectives. The DRL are optimized by the *Regulatory Authority* occasionally following *International recommendations* but generally through *Regulatory optimization* through national surveys where exposure data is collected and forwarded to the *Regulatory Authority* in regular intervals from all healthcare providers in a country or region. The local dose level is adapted to the DRL and the result is confirmed through exposure levels from the Metadata repository. To maintain optimization for future events such as software upgrades or changes in patient demography, the exposure level can be monitored automatically as described in paper II or by visually in graphs.
Diagnostic Reference Levels is an established concept for dose optimization. It is dependent on largescale collection of exposure data and should be supported by extraction of DICOM exposure data from medical images to reach its full potential as surrogate for risk data. The data derived through the standard provides structured exposure data that can be related to the patient without compromising patient integrity. As the number of examination protocols continue to grow, more and more procedures are available covering increasingly diversified clinical objectives. It is important that not only the technical descriptors of exposure continues to develop, but that the clinical use of radiation is further explained by the standard. This will ensure that future optimization efforts will have validity for the specific problem or issue.
1.7 Organ dose and justification

Organ dose estimates from patient exposures are essential in a clinical justification support system as they enable risk estimates using LAR. The American College of Radiology and the European Society of Radiology are both implementing the decision support system iGuide\textsuperscript{21} with the objective to provide a larger evidence base for patient referral to radiological procedures and to “ensure that recommendations concerning referral criteria for medical exposures, including radiation doses, are available to the prescriber of medical exposures”, according to their agenda and quoted from the BSS. The possibility to integrate a developing system for risk assessment based on organ dose calculations is outlined by the author in Figure 5, the utilization of organ dose calculations in clinical decision support with components and sub systems labels in italic in the text.

At the Examination and study evaluation, the health care professional is faced with one patient at a time and a large variety of solutions for diagnosis and treatment. The need of effective Clinical Decision Support is obvious. Electronic Patient Records should guide the professional in actions regarding the patient. Local records are updated and adapted to the actual clinical resources, providing Local Clinical Evidence for the probability of success for a treatment. Together with International Clinical Evidence, they should constitute the basis for the selection of diagnostic methods and therapy. However well adapted to the situation, clinical patient records primarily support the administration of the consultation where the professional meets the patient. Summaries of treatment results versus diagnostic workup strategies to guide in the planning are underdeveloped or too time consuming to access during a short patient visit. Predicting the outcome of a treatment is normally up to the practitioner and the personal experience of how well a practice is implemented.

The introduction of standards for coding of clinical and technical information should improve the possibility to predict the outcome for defined treatments and diagnostic procedures through an increased evidence base. The international classification of deceases ICD-10,\textsuperscript{22} published and maintained by the World Health Organization, must apply everywhere and may not comply with the fast developments in diagnosis and treatment. However challenging, the clinical code systems are being integrated in the technical development of electronic patient records which should potentiate technical breakthroughs implemented by the vendors.
In Imaging – post examination organ dose estimate the Organ Dose Calculation implemented in papers III-IV contributes with a post examination assessment of radiation risk. It could be integrated in the imaging device or as a stand-alone expert system with input from the 3D imaging and the image Metadata. The organ dose exported to the RDSR Organ Dose provides a standardized representation of the risk that can be further processed in the other sub-systems.

The potential for automation of organ dose calculations, as described in paper IV, creates a large knowledge-base for Pre examination organ dose estimates. Continuous update of organ dose results to an Organ Dose Repository, with suitable Patient Descriptors from the Electronic Patient Record, the Metadata and the RDSR constitutes a possibility to extract organ dose estimates for Risk Assessment before ordering a procedure. The selection process
could be based on machine learning as the number of examinations in the Organ Dose Repository would increase rapidly and be well adapted to the local facility. With an increasing interchange of organ dose results between similar facilities estimates could be obtained early in the implementation of a new procedure. This would require a detailed technical knowledge of the imaging devices, stressing the importance of the detailed Metadata in the DICOM images.

Presuming that the clinical record content can provide a Benefit Assessment in a standardized format that is valid versus the Risk Assessment in a Risk Benefit Analysis, the Justification can be performed in a separate expert system. This might allow the justification system to develop independently as an add-on to any clinical record. The requirement for this is an agreed method to compare patient benefit and radiation risk. Today, the risk is expressed in risk classes, ED or LAR each of which has no simple relationship to patient health. As human health is hard to represent by one single concept for all possible diseases, there is probably not one single solution and practitioners should get used to compare different treatment outcomes, decrease in quality of life, invalidity or mortality to radiation risk. For this to be possible the radiation Risk Assessment should: 1) be based on a general agreement on how to express risk providing a standardized input to a justification system; 2) be understandable, promoting LAR which is analogue to other treatment risks and valid for an individual; 3) be credible by accounting for uncertainties in the estimate; and 4) be valid for the clinical situation, using the same classification in the Risk Assessment as in the Electronic Patient Record, e.g. ICD-10.

For Scientific improvement of risk estimates (LAR) it is important that Epidemiological Studies on medical exposure utilize equivalent methods for Organ Dose Calculations and supply results that are standardized according to the RDSR organ dose DICOM format and the procedure classifications. The description of the exposure regarding the atomic bomb survivors is rudimentary as compared to the description that can be accomplished using the image sets of a patient in combination with an accurate source model as described in paper III-IV. This leads to questions such as if the organ dose should be defined as an average to the complete organ or to the part of the organ that is susceptible to cancer induction. If so, specific cancer incidence probabilities derived from medical exposure should be used.

1.8 Aims of the thesis
The general aim of the thesis is to investigate the benefits of applying the DICOM standard in radiation safety management.
Papers I-II aims to explore the possibility for automated collection and analysis of information available in the DICOM images as defined by the DICOM standard to support implementation of optimization, as indicated in section 1.6.

Papers III-IV aims to explore the adaptation of a Therapy Planning System for radiotherapy to calculate patient individualized CT dose to cancer risk organs. A strategy for automation of the calculations to facilitate implementation is explored in paper IV.
2 Methods

2.1 Papers I and II

2.1.1 Optimization of patient exposure and data in DICOM
The process for optimization of medical exposure is to be based on the ALARA principle mainly through application of DRL, as exemplified in section 1.6. Paper I describes the implementation of a programmed workflow that applies the DICOM standard by automatically sending all produced images from the PACS to a separate DICOM node where the metadata is extracted and inserted in a separate database where it can be easily accessed. 4-5 million images are processed annually in our institution and the number of data points for each image is about 100 depending on the imaging modality. The utilization of information can reveal systematic problems in selected parts of the production but also create overviews to guide in optimization efforts. The large amount of information retrieved in the workflow can be analyzed automatically which is covered in paper II.

One of the advantages of metadata is its flexibility. The vendors of diagnostic devices transfer information to the metadata on a mandatory basis for important information and on an optional basis for information that is image specific or to novel to fit into the standard. Contained in the DICOM standard, the definition, reporting and utilization of patient exposure data is steadily developing ensuring a reliable process to support rational radiation safety procedures in exposure optimization.

2.1.2 Image production, communication and storage
The architecture of the PACS sets, together with the DICOM standard, the technical basis for design of auxiliary systems for radiation safety purposes such as the metadata collection server. The fundamental parts of a PACS system is depicted in Figure 6. The imaging devices are connected to the PACS and the images are communicated to the image archive. Viewing of the patient studies are made on designated viewing workstations and the clinical tasks are optimized by a workflow manager supplying the image context to be used in different clinical settings.
2.1.3 Technical prerequisites

The technical framework in the clinical workflow where the studies were performed consisted of an AGFA PACS (AGFA Healthcare, Belgium) installed in a regional network of institutions linked to a centralized image archive. The radiology departments were distributed in four hospitals and seven primary health care facilities, supplying radiology services to the county Dalarna with approximately 280 000 inhabitants populating an area of almost 30 000 km².

The metadata are contained in the individual image files stored in the image archive and must to be made available for easy access. On viewing and reporting, the patient name, the examination performed etc. is favored in the clinical workstations by managing routines. In order to effectively access the information the PACS builds temporary cache tables to facilitate a fast workflow for the major task of the PACS, displaying images for one patient at a time.

Most of the metadata are by PACS vendors not judged to be of immediate clinical use, and therefore not included in the cache tables of the workflow manager. As the complete set of metadata must be collected from a large number of images it must be automated.
2.1.4 Approach

The PACS was configured to send all stored image files to the metadata collection server, which passively receives the information without further interaction with the PACS. On the collection server, the pixel data is discarded. Metadata deemed compulsory in the DICOM standard and any vendor specific data judged to be of relevance in the context is extracted. The wide selection of data assures that the context can be maintained in the analysis of the patient exposure. The metadata is anonymized in the process, thus no ethical considerations are needed.

In paper II, the open access statistical software R\(^23\) was used as analysis platform since it contains a general and well described level change detection package applicable to the EI values\(^24\). The study was limited to central body parts and focused on examinations using automatic exposure control, a device designed to keep the dose to the detector on a defined level. Projections on extremities, from below the hip and beyond the shoulder were excluded from the study due to the low patient risk.

2.2 Papers III and IV

2.2.1 Organ dose and the system for justification

Justification of medical exposures requires a knowledge of both benefits as well as potential harm for the patient. The intention of papers III-IV was to develop methods to support the system for justification as described in section 1.7.

The ICRP defines the need for justification of patient exposure in three levels:\(^1\) Use of ionizing radiation in medicine is *in general* beneficial for human health. This is treated as a matter of fact and is supported by numerous studies. The *use of a specific procedure* must be justified and the BSS requires that the member states of the EC enforce this process as may be fit for each member state. Healthcare planners are introducing well described referral pathways\(^25\) where the use of radiological procedures are ensured to be motivated in centralizing justification procedures. For a clinical case that does not fit in a national referral pathway the local radiological service must provide referral guidelines that support exposure justification. Post examination individualized organ dose calculations would provide the best possible risk estimate when justifying a procedure in centralized studies. All examinations must be justified *on an individual level*. The considerations to make as a practitioner is if the information that is needed is already available in the patient record, if there are alternative imaging methods available or if treatable health problems can be diagnosed by other methods. Exposure of asymptomatic patients is discouraged unless it is part of a voluntary health screening program with per-
missions from the authority. Post examination individualized organ dose calculations would enhance the practitioner’s knowledge on risks and could form a knowledge base for pre examination risk prediction.

2.2.2 Monte Carlo simulation of a CT
As the CT scan starts, the radiation source in the CT starts to emit photons all the while the patient is transported on the couch through the gantry of the CT. The transport can be done stepwise or continuously projecting a spiral movement on the patient. The intensity of the beam is adapted to the examination, and to the actual patient by modulating the tube current during rotation of the X-ray tube. A radiation filters shapes the lateral intensity profile of the x-ray beam and the useful x-ray beam is collimated to the width of the detectors in the axial direction.

In paper III-IV a TPS is used for dose calculations utilizing a Monte Carlo (MC) calculation dose engine. In general, MC simulation is the application of random numbers to simulate a process with known probabilities. Simulating the radiation process includes randomization of the photon energy, the distances a photon can travel in the particular tissue before it interacts, the type of photon interaction process and results in the absorption of energy that can be scored in a voxelized geometry. The x-ray source of the CT must be described as to enable sampling of the energy and direction of the photons. This was worked out in paper III.

As photon interaction cross-sections depend on tissue compositions, these must be estimated. The patient images are the best available description of the patient anatomy and the CT numbers, derived from the attenuation of the photons, can be used for this purpose. The applied methods are addressed in paper IV.

2.2.3 Paper III
A TPS (RayStation™, RaySearch Laboratories, Stockholm, Sweden) was configured to calculate dose from a CT (GE Healthcare, Wauwatosa, WI, USA). After characterizing the x-ray beam with the tube in stationary position by the Half-Value Layer (HVL) in aluminum and air kerma along the principal axes of the isocenter plane perpendicular to the beam, four different variations on the beam-shaping bow-tie filter were evaluated. The four models accounted for different degrees of HVL information but all reconstructed the measured air kerma distribution after the bow-tie filter by adjusting the photon sampling function. The dose calculations were verified by comparison with measurements in solid water as well as in an anthropomorphic phantom.
2.2.4 Paper IV

In the TPS the elemental composition of the voxel can be defined by replacement materials or by mapping the CT number to an elemental composition. The latter was calibrated using a phantom with inserts containing known materials. After scanning the phantom, the relationship between CT number and elemental composition was established using fitting of a parametric function. The acquired relationship was then applied to the reference materials in the TPS.

Using the MC source model developed in paper III, dose calculations based on the CT number mapping was validated by comparison with dose measured by TLD and also compared to dose calculated with specific material compositions entered into the TPS as “replacement” materials for the default lookup from CT numbers.

The images from a CT thorax examination of a female patient were used to compare dose calculations with CT number mapping and replacement materials. The organs of the patient were segmented in accordance with the guidelines in ICRP report 110\textsuperscript{26} and dose calculations were made using both material representations.

In an effort to automate the organ segmentation using the tools in the TPS, a strategy for organ approximation was selected based on the organ contrast and location. The cancer risk organs included in the thorax scan was divided in two groups; high contrast organs that could be automatically segmented and low contrast soft organs that could be replaced by larger water volumes or replaced by organ models. The organ dose to the approximated risk organs was compared to the calculations in the anatomically correct ICRP 110 model with and without replacement materials. Finally the LAR for cancer incidence was calculated using the LAR factors from BEIR\textsuperscript{13} and the uncertainty contributions from the cancer risk estimates were compared to the uncertainty in the different patient models used in the calculations.

2.2.5 Ethical considerations

The studies required no approval by the ethical committee as no sensitive patient information was used.
3 Results and discussions

3.1 Paper I

The hypothesis of the study was that the DICOM structures could be used as template for a database intended for radiation safety purposes. It may seem simple at a glance, but implementation and utilization of complex standards in multivendor environments can fail in many aspects. All vendors need to comply with the standard, and the PACS environment must communicate the information in a reliable and complete way.

The implemented technical solution proved that the DICOM standard was sufficiently implemented to facilitate large scale collection of metadata. Moreover, the creation and communication of metadata were found to be reliable, thus creating a valid support for radiation safety measures. The collection of metadata did not impact negatively on any part of the clinical workflow.

The structure of the DICOM standard proved to be a comprehensive platform for storage, analysis and display of the data. As exemplified by Figure 7 below, different events in the radiation safety work could be monitored and malfunctions could be detected.

![Figure 7](image)

*Figure 7: Monthly average EI values for thorax anterior projections captured for different examination rooms. The EI is inversely proportional to the air kerma on the detector surface. The trend at a is the result of changes in EI due to dose adjustments, at b an X-ray generator malfunction resulting in tube output decrease, at c a detector calibration error (from paper I).*
New inventions in imaging, or image processing, may create new needs for monitoring of patient exposure. The benefit of the solution described in this work is that novel information often can be found in the metadata on implementation of new techniques in the imaging devices, as the metadata serves as a structured general storage of technical information on the production of the image. The DICOM definition of the metadata fields provide the vendors with a consensus based structure for established parameters, but it also leaves room for new information dependent on specific imaging device technique. Metadata in general need summarizing to yield relevant information such as e.g. the accumulated dose from different modalities to a specific patient.

3.2 Paper II

In digital projection radiography, there is an individual exposure setting for each particular projection, on each imaging device. Presuming that the settings are optimized, a method for constancy control should be applied.

The EI₈, related to the average incident kerma on the entrance plane of the detector, is sensitive to exposure changes as well as changes in the methodology applied by the radiology nurses. The EI value can be monitored in graphs but the large number of exposure settings makes it laborious which would make automation beneficial.

The hypothesis of the study was that an automated routine for detection of changes of level in the EI value could be implemented to have the same detection performance as a human observer indicating level changes in a graph, depicting EI values as a function of time.

It was found that changes in EI values could be detected with a sensitivity of 0.700 and a specificity of 0.995 using the median test for level change detection with manual evaluation of EI value timelines as the golden standard. The sensitivity improved to 0.730 and the specificity to 0.997 when adding the Wilcoxon rank sum test to the routine.

The routine could be automated, extracting the metadata from the previously designed metadata repository, calculating the analysis results in R with a subsequent export of the analysis back to the metadata repository.

The manual evaluations used as reference were based on visual observation of graphs, showing the EI value as a function of time. Changes in the beginning or end of the EI value sets, as well as gradual level changes were reported hard to detect by the observers. When excluding these types of level changes from the sensitivity/specificity analysis the sensitivity was increased to 0.870.

Optimization of the analysis parameters was performed on a collection of projections with large variation in distribution types, from normal distributed, e.g. chest frontal, to heavily skewed normal for more peripheral projections of
the patient. It was not concluded how the distribution type influenced the possibility of the observers to detect a level change as compared to the automated routine.

The strength of the study, apart from the actual results, is that it demonstrates that a general solution for automated analysis could be implemented with an open access tool, and that automation of the analysis could be performed with relatively simple methods. Furthermore, as the optimization was performed on data sets with a range of distribution types it is reasonable to assume that the surveillance workflow can be optimized also for scenarios different from the investigated.

3.3 Paper III

The hypothesis of the study was that a model of the CT could be implemented in the TPS including the CT specific spectrum, the shape and thickness of the bow-tie filter and the tube current modulation of the automatic exposure control with an input from the CT, DICOM data and measured parameters.

With the x-ray tube in stationary mode, the calculated depth dose was in agreement with the measured dose. Validation of the calculations in a spiral scan by comparison with TLD measurements in an anthropomorphic phantom showed differences in the same order as the measurement uncertainties, 4%. The four evaluated bow-tie filter models showed no significant difference, indicating that a reconstruction of the measured kerma distribution is an efficient way to simulate a bow-tie model independently of the acquired information on HVL profile in the beam. Thus, the CT source could be modeled by the TPS including the tube current modulation in the spiral scan.

The absolute dose calibration using the CT dose index phantom proved to be simple, using a phantom that is readily available in most medical physics institutions. When deciding on how to spend the measurement efforts in characterizing a CT, the comparison between the bow-tie models showed that a careful characterization of the kerma distribution should be of the utmost importance while the HVL characterization is less critical. Using the HVL specified by the vendor for the central part of the bow-tie filter should suffice as long as the kerma distribution after the bow-tie is restored in the simulation. This is reasonable as the intensity profile is attained using graphite which has small influence on the HVL and does not affect the CT number calculation.

As the focus of the study was to model the CT in a thorax examination, further work is necessary to validate the results for other beam energies and bow-tie combinations.
3.4 Paper IV

Using the source model developed in paper III, the possibility to automate organ dose calculations was explored. The hypothesis was that material characterization through CT number mapping in the TPS could be used for the CT beam energy, furthermore that the tools for organ segmentation could be used to facilitate extraction of organ doses over volumes representing cancer risk organs. The dose calculations in the patient with organs segmented according to ICRP 110 recommendations showed small deviations from dose measured by TLD, 1.1% when applying CT number mapping and 1.5% when using replacement materials. Comparing calculated organ doses in the patient, the relative difference between the anatomically correct ICRP model with replacement materials and the selected strategy for automation using CT number mapping was between 0% and 19% depending on the organ. The largest differences were noted for the lung and the red marrow, 16% and 19% respectively, which might be accounted for by the difference in defining organs as homogenous ICRP organs or by selecting specific parts of the organ using gray scale thresholds and CT number mapping but this aspect was not analyzed. In the larger perspective, the relative difference is small compared to the uncertainties in the LAR factors.

The calibration of the CT number mapping was successful indicating that the reference materials in the TPS, intended for high energy photon dose calculations, also can be used in calculations with low energy photons from a CT. The calibration procedure is dependent on measured CT numbers and care must be taken to assure that the results are valid for the calculations at hand as the CT number might show variations with beam energy, bow-tie filter or other technical parameters.

The organ segmentation tools of the TPS could not identify low contrast organs such as breast and abdominal organs, which was circumvented through use of dummy organs at relevant positions filled with water. For the thyroid and the esophagus no other possibility was apparent than to replace the organs with models. The esophagus is recognized by the ICRP as a separate cancer risk organ, but there is no LAR factor supplied by the BEIR for this organ.

Mapping CT number to elemental composition offers a possibility not only to simplify the organ segmentation for dose averaging, but also to represent the patient organs to the limit of the resolution of the CT, including the structural and chemical inhomogeneity of the organs. Together with the segmentation tools, the TPS offers the possibility to automate organ dose calculations which could support individualized dosimetry for all patients undergoing CT examinations, facilitating large scale validation of current risk estimates.
4 Conclusions

From the findings we conclude that

Paper I-II
- The DICOM standard is well implemented in the imaging workflow, from the imaging devices to PACS storage
- The standard provides a robust template for automated collection, storage and distribution of metadata from digital images, produced in a geographically distributed radiology service
- The patient exposure can be summarized and explained by the collected data, thus contributing to radiation safety management
- Changes in the EI value for projections in radiography can be automatically detected in the metadata using the open access statistical tool R

Paper III
- The CT machine can be implemented in the TPS replicating the beam movement and intensity modulation of a spiral scan with dose modulation, on the basis of the specifications available in the metadata of the digital images, the log file of the CT and the technical specifications of the CT
- The bow-tie filter is possible to model based on the measured kerma distribution after the bow-tie filter and the HVL as specified by the vendor

Paper IV
- The difference between calculations with CT number mapping and replacement materials is 1.1% and 1.5% respectively compared to TLD measurements in an anthropomorphic phantom
- Estimation of organ dose for the risk organs of a female thorax patient is feasible for automation using the segmentation tools in combination with the tissue characterization models available in the TPS
5 Future perspectives

5.1.1 Controlled patient exposure and DICOM

The workflow described in paper I was accomplished in November 2004, including automated collection, storage and visualization of patient exposure from DICOM metadata. Quality control of equipment has been based on periodic measurements of basic equipment performance, in Sweden a regulated activity since 1984. The regulation provides a basic system for quality control, but the performance of modern diagnostic devices is stable once installed and optimized for the intended clinical use. The possibility for clinical operation errors presents a problem not covered by the regulation. Two examples are using adult exposure settings for infants, or misinterpretation of the proper use of automatic exposure control. A possibility for detection of such errors is to monitor level changes in exposure as described in paper II. This could be a favored feature as it can handle many separate examination protocols and thus reveal problems that are unique to a specific clinical workflow that has been compromised by operational misconceptions or errors in optimization efforts. Automation of exposure change detection can also be an option in validation of software upgrades.

Workflow integration of exposure limits can be implemented in PACS solutions. The general principle is to compile local reference values for exposure that can be used as a mean to supply a reasonable maximum exposure for which the system is programmed to yield a warning.

The introduction of RDSR supplies a wider variety of adapted and standardized dose quantities that can be applied in different situations such as skin dose in interventional radiology and it seems reasonable to assume that RDSR will become the main source of information for radiation safety purposes in the future. The technical metadata in the images is still a source of information on the image acquisition and could continue to coexist with RDSR data, but as vendors of systems for exposure data rely more heavily on RDSR for simplicity, this should be the future direction. However, the metadata used as input in paper III to specify the source model for the CT was not available in the RDSR, which could indicate that technical information for more specialized applications still needs to rely on metadata for complete description of the patient exposure.
Future research in this field should be focused on automated statistical methods to detect problems in patient exposure. Furthermore, the information needs to be distributed to the staff in the clinical workflow. The information of a deviation should be displayed on a workstation at the examination room where the deviation occurred.

5.1.2 Justification and tools for risk assessment

The DICOM standard has been a prerequisite for the development of an effective infrastructure for communication and storage of digital images. Written patient records in scrolling text, not possible to utilize in data processing, are still dominating and contra-productive to the development of evidence-based radiology. These records satisfy the immediate and understandable need of the practitioner to document a patient consultation but is unpractical for automated analysis.

The trend to use large data sources for clinical decision support, including risk assessment and optimization objectives, is enforced by staff rotation practitioners reliant on previous documentations. The possibility to consult a practitioner by an application on a smartphone sets new requirements for distribution of standardized patient information as well as the practitioner’s knowledge of the locally available options for treatment and diagnosis. Patient involvement requires explanations to the patient to motivate cooperation despite conflicting information available at online sources. In the absence of a concrete risk benefit analysis of a procedure, the practitioner might be overrun by the patient and unable to implement the best possible treatment plan for the patient.

An increasing patient demand for risk assessment could create an increasing interest for validation of risk estimators and personalized risk assessment in medical exposure. Automation of organ dose calculations on a platform such as the TPS used in paper III-IV will facilitate such an objective. In principle a TPS could be repacked into a product for integration in the radiology workflow. This requires additional development for which a demand needs to be demonstrated to the suppliers and the healthcare providers. A low cost specialized subset package of the functionality of a TPS could be of commercial value to a vendor of CT machines, taking advantage of the competence in radiotherapy dose planning to emphasize the radiation safety commitment of the vendor. The calculation resources needed is moderate as the calculations can be completed in minutes or in shorter times with faster algorithms already developed in the radiotherapy community. Another alternative is to integrate the organ dose calculation capacity of a TPS in the PACS. This could provide a more general solution but would require an extensive knowledge of the CT machines normally not present in the development environment of a PACS vendor. As outlined in section 1.7 it is reasonable to believe that a future integration of organ dose calculations should reside within the imaging device,
while the risk assessment could be resident in the PACS. Hopefully the inter-
play between patient empowerment, clinical decision support and the need of
vendors of CT machines and PACS solutions to provide radiation safety solu-
tions can create a situation where it will be commercially sustainable to pro-
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Antalet undersökningar är stort, miljontals bilder produceras varje år inom ett normalstort landsting, och verksamheten är spridd på många kliniker. Exponeringsnivåer inom sjukvården ska jämföras med nationella riktlinjer, åtgärder ska vidtas om avvikelse upptäcks och uppföljning av åtgärder ska utföras. Undersökningarna ska dessutom optimeras utifrån det lokala perspektivet för att försäkra att bestrålningen är så låg den kan vara utan att äventyra den diagnostiska säkerheten.

Denna avhandling behandlar centrala krav inom strålsäkerhetslagstiftningen och syftar till att 1) bereda ett lokalt underlag för optimering av strål- doser genom att tillgängliggöra exponeringsinformation som finns i medicinska bilder och 2) tillämpa metodik inom strålbehandling vid beräkning av organdoser för patientindividuell riskbedömning.

I den första delstudien utvärderades ett tekniskt arbetsflöde för insamling och övervakning av exponeringsdata från diagnostiska bilder. Metodiken bygger på en tillämpning av den tekniska standarden för medicinska bilder som grund för kommunikation av bilder från den centrala lagringsplatsen i det be- fintliga bildlagringsystemet, extraktion av metadata som importeras i en dat- tabasstruktur som följer samma tekniska standard samt en modell för presen-
tation av utvald data som stöd för monitorering och optimering av patientdoser. Studien visade att den tekniska standarden möjliggör en rationell hantering av data och att den kan distribueras på ett effektivt sätt i verksamheten.

Delstudie två utvärderade möjligheten att detektera förändringar i expoefringsnivån för kliniska undersökningar genom att tillämpa en automatiserad statistisk metod. Resultatet visade att automatiserad detektion av förändringar i optimerade undersökningar är möjlig med rimlig specificitet och sensitivitet.

I delstudie tre undersökt möjligheten att tillämpa metodik från strålbehandling för beräkning av dosen från en datortomograf för diagnostiskt bruk. Strålkällan i datortomografen beskrivs med avseende på rörström, strålvalité, och intensitetsfördelning av strålfältet för att kunna beräkna stråldosen med Monte Carlo-metoden för stråltransport. Arbetet visade att ett kommerziellt dosplaneringssystem kunde replikera uppmätta dosfördelningar från datortomografen utifrån ett underlag baserat på information från datortomografen och mätningar.

I den fjärde delstudien undersökt möjligheten att använda attenueringsvärdet, CT-talet, i bilder från en datortomograf som underlag för att beskriva den atomära sammansättningen i patientens vävnader vid Monte Carlo simulering av organdoser i cancerriskorgan. Metoden, som används normalt i dosplaneringssystem, jämfördes med den gängse metoden inom dosberäkning inom diagnostik, att introducera eräsättningsmaterial med känt atomär sam- mansättning som underlag för fotonväxelverkan. Vidare utvärderades möjlig- heten att med hjälp av tillgängliga metoder för materialspecifikation och organsegmentering i dosplaneringssystemet automatisera organdosberäkningar i riskorgan och beräkna cancerrisken med hjälp av cancerriskfaktorer från literaturen. Resultatet visade att metoderna för beskrivning av vävnadernas atomära sammansättning var ekvivalenta, efter kalibrering av metoden baserad på CT-tal. Tillämpat på bilderna från en patient som genomgått en thoraxundersökning visade resultatet en potential för automatisering av organdosberäkningar med hjälp av dosplaneringssystemet med osäkerheter i organdosbestämning- ningen väl understigande osäkerheten i cancerriskfaktorerna.

Övergripande kan konkluderas att den tekniska standarden för medicinska bilder utgör ett omfattande och effektivt underlag för automatiserad insamling och statistisk bearbetning av exponeringsdata från bilder i det digitala arkivet som ger stöd för arbetet med optimering av stråldoser och bildkvalité. Vidare att ett dosplaneringssystem för radioterapi erbjuder en effektiv möjlighet att automatisera beräkning av organdoser vid datortomografiundersökningar som stöd för berättigandebedömning vid bestrålning av patienter i medicinskt syfte.
8 References


17. DICOM NEMA http://medical.nema.org/.


A doctoral dissertation from the Faculty of Medicine, Uppsala University, is usually a summary of a number of papers. A few copies of the complete dissertation are kept at major Swedish research libraries, while the summary alone is distributed internationally through the series Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine. (Prior to January, 2005, the series was published under the title “Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine”.)