Dose Monitoring in Radiology Departments: Status Quo and Future Perspectives

Dosismonitoring in der Radiologie: Status quo und Zukunftsperspektiven

Authors

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Key words

- dose monitoring
- computed tomography
- radiation dose
- DICOM
- structured report

Abstract

The number of computed tomography examinations has continuously increased over the last decades and accounts for a major part of the collective radiation dose from medical investigations. For purposes of quality assurance in modern radiology a systematic monitoring and analysis of dose related data from radiological examinations is mandatory. Various ways of collecting dose data are available today, for example the Digital Imaging and Communication in Medicine – Structured Report (DICOM-SR), optical character recognition and DICOM-modality performed procedure steps (MPPS). The DICOM-SR is part of the DICOM-standard and provides the DICOM-Radiation Dose Structured Report, which is an easily applicable and comprehensive solution to collect radiation dose parameters. This standard simplifies the process of data collection and enables comprehensive dose monitoring. Various commercial dose monitoring software devices with varying characteristics are available today. In this article, we discuss legal obligations, various ways to monitor dose data, current dose monitoring software solutions and future perspectives in regard to the EU Council Directive 2013/59/EURATOM.

Key Points:

- ▶ Automated, systematic dose monitoring is an important element in quality assurance of radiology departments.
- ▶ DICOM-RDSR-capable CT scanners facilitate the monitoring of dose data.
- ▶ A variety of commercial and non-commercial dose monitoring software tools are available today.
- ▶ Successful dose monitoring requires comprehensive infrastructure for monitoring, analysing and optimizing radiation exposure.

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Zusammenfassung

Die Zahl der Computertomografieuntersuchungen nimmt in den letzten Dekaden kontinuierlich zu und ist verantwortlich für einen Großteil der medizinisch bedingten Exposition der Bevölkerung mit ionisierender Strahlung. Im Sinne der Qualitätssicherung ist eine kontinuierliche Auswertung der dosisrelevanten Daten von radiologischen Untersuchungen unabdingbar. Verschiedene Wege der Dosiserfassung stehen heute zur Verfügung, so z.B. der Digital Imaging and Communication in Medicine-Structured Report (DICOM-SR), die optische Bilderkennung oder DICOM – Modality performed procedure steps (MPPS). Der DICOM-SR ist Teil des DICOM-Standards und stellt mit dem DICOM-Radiation Dose Structured Report (DICOM-RDSR) eine einfache und zuverlässige Lösung zur Erfassung der dosisrelevanten Daten dar, so dass ein standardisiertes und umfassendes automatisches Dosismonitoring erleichtert wird. Eine Vielzahl an kommerziellen Softwarelösungen mit unterschiedlichem Funktionsumfang ist inzwischen verfügbar. Dieser Artikel gibt einen Überblick über die aktuellen gesetzlichen Voraussetzungen, die Möglichkeiten zur Erfassung der relevanten Dosisdaten in radiologischen Abteilungen, aktuell erhältliche Softwarelösungen und zukünftige Perspektiven im Hinblick auf die EU-Grundnorm 2013/59/EURATOM.

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Introduction

The last three decades have witnessed a significant increase in the number of radiological examinations worldwide [1]. Today, computed tomography (CT) is responsible for the largest portion of the collective medically indicated radiation dose. While CT accounts for only 8 % of all diagnostic examinations with ionizing radiation in Germany, it already accounts for approximately 60 % of the collective effective dose and continues to rise [2–4]. Any use of ionizing radiation on humans is governed by the ALARA principle ("as low as reasonably achievable") [5]. This principle has led to numerous technical innovations and new developments [6]. Examples include iterative image reconstruction technology [7], automatic tube current modulation [8, 9], automatic tube potential selection [10, 11], organ-specific dose reduction programs [2, 11] and low-dose examination protocols [12].

The German Office for Radiation Protection (BFS) publishes reference values for diagnostic and interventional radiological procedures with X-ray radiation including CT (Table 1) [13]. The reference values each apply per acquisition series and are categorized by bodily region. They are published for the volumetric computer tomography dose index (CTDI_{vol}) and the dose length product (DLP). In addition, there are specific reference values for pediatric patients, which are further categorized by bodily region into different age

groups or weight classes. Many other European countries have also published diagnostic reference levels, some of which differ considerably from the reference levels. An overview is presented in Table 2 [14].

The evaluation of dose-relevant CT-data on the basis of prescribed reference levels constitutes an important aspect of radiation hygiene and quality management of a modern radiology department in a hospital as well as in a medical office. A systematic and regular analysis of dose-relevant

Table 1 National diagnostic reference levels provided by the German Federal Office for Radiation Protection for CT studies in Patients older than 15 years [13].

CT examination region	CTDI _{vol} [mGy]	DLP [mGycm]
cranium	65	950
viscerocranium (tumor)	22	250
viscerocranium (sinusitis)	9	100
thorax	12	400
lumbar spine (intervertebral disc, axial)	42	250
lumbar spine (bones, spiral)	16	500
epigastrium	20	450
abdomen	20	900
pelvis	20	450

CTDI_{vol}: Volumetric computed tomography dose index; DLP: Dose length product; CT: Computed tomography.

country	protocol	CTDI _{vol} [mGy]	DLP [mGycm]	comparison to german reference values (↑: higher, ↓: lower, ↔: identical)
Belgium	cranium	x	1020	↑
	abdomen	x	830	↓
	thorax	x	400	↔
England	cranium	55/65 ¹	760	↓
	abdomen	13	460/510 ²	↓
	thorax	10	430	↑
Finland	cranium	65–90 ³	1000	↑
	abdomen	15	600	↓
	thorax	30	500	↑
France	cranium	65	1050	↑
	abdomen	x	x	x
	thorax	x	475	↑
Ireland	cranium	x	950	↑
	abdomen	x	640/850 ⁴	↓
	thorax	x	460	↑
Italy	cranium	60	1050	↑
	abdomen	35	800	↓
	thorax	30	650	↑
Austria	cranium	x	1300	↑
	abdomen	x	1200	↑
	thorax	x	550	↑
Switzerland	Cranium	65	1000	↑
	Abdomen	15	650	↓
	Thorax	10	400/450/600 ⁵	↔

CTDI_{vol}: Volumetric computed tomography dose index; DLP: Dose length product; CT: Computed tomography; X: No reference value published.

¹ Cerebrum/posterior cranial fossa.

² Abdomen + pelvis.

³ Cranium/cerebrum.

⁴ Abdomen + pelvis / thorax + abdomen + pelvis.

⁵ Thorax / Thorax-angiography / Thorax + epigastrium.

Table 2 Selection of national diagnostic reference levels from various European countries and comparison to the German national diagnostic reference levels [13, 14].

data is therefore essential. The automatic recording of all dose-relevant data in a central database enables systematic evaluation at any time and makes adequate quality management considerably easier.

Legal provisions

According to §28 of the German X-ray Ordinance (RöV) each application of X-ray radiation on a patient must be documented [15]. In addition to other information such as the justifying indication, for example, the documentation of the “patient’s radiation exposure, insofar as it has been recorded, or the data and information necessary for ascertaining the exposure” is required (► **Table 3**) [15]. The X-ray images as well as the records must be retained for at least 10 years following the last examination or, in the case of minors, until the patient’s 28th birthday. Electronic storage is permitted if it can be ensured that the records will be available and readable for the duration of the mandatory retention period. In addition, the original or the basic image, i. e. the initially acquired, unchanged image and every subsequent change must be visible.

The EU Council Directive 2013/59/EURATOM officially went into effect in January 2014 and must be adopted by the member states as national law by 2018 [16]. The Council Directive requires both the recording of dose data for each CT examination or interventional angiogram as well as the notation thereof in the report for each examination. The standard additionally calls for optimizing the applied radiation dose and consulting medical physicists [16, 17].

Recording and evaluating dose-relevant CT data

In addition to the DICOM-structured report (SR) [18–20], DICOM-modality performed procedure steps (MPPS) reports [21, 22], optical recognition of CT-dose reports [23] and the analysis of DICOM headers [24, 25] are the most commonly used methods of recording dose data. In the meantime, various software programs – some commercially distributed and each employing a different approach –

are available for the automatic recording and evaluation of dose-relevant data. The differences in the various types of data collection are described below.

Optical image recognition

Each CT machine generates a “patient record”, which consists of an image containing, among other information, CTDI_{vol} and DLP and is normally saved in the Picture Archiving and Communication System (PACS). The images must conform to the DIN standard 6878–1. Optical recording of data using corresponding software tools employing optical character recognition (OCR) is retrospectively possible. It is not necessary to make a change on the scanner, since the protocol is normally generated automatically. The OCR algorithm must be adapted one time to the respective scanner [26]. It has been shown that, while it is possible to reliably record data [26], converting data into image files and then converting them back into data is an overall unnecessary use of resources.

DICOM header and DICOM-MPPS

The DICOM header is part of each DICOM object and contains general parameters for the specific examination and, in theory, offers the possibility of gathering dose data from CT examinations [18]. However, this method is time-consuming, because the CTDI_{vol} must be computed from CTDI_w and the pitch factor, necessitating that the collimation and field of view be factored into the equation [25]. In addition, the values for overscanning in the process of a spiral CT must be estimated through an approximation [25]. An OCR algorithm is frequently combined with the readout of the DICOM header to obtain further examination data.

For each examination, a DICOM-MPPS report is sent to the PACS and/or to the radiology information system (RIS) [22]. The DICOM-MPPS report contains information on the particular examination and thus offers the possibility of gathering dose-relevant data. However, there is often considerable variability between different DICOM-MPPS, thus complicating a systematic evaluation of multiple devices or involving multiple different institutions [26].

DICOM- (Radiation Dose) Structured Report

Introduced in 1993, the DICOM standard is an international standard for storing and exchanging medical images and image-related information [27]. In the meantime, the DICOM standard has been implemented in nearly every medical imaging device employing ionizing radiation. The DICOM-structured report (DICOM-SR) is a hierarchically structured document containing text as well as links to other data such as images, for example [20]. In addition to the header, the DICOM-SR contains a portion with relevant “contents”. The content comprises information arranged in a branching manner on different hierarchical levels that are linked to one another (XML structure). In addition, there are various references to, for example, images outside the SR.

DICOM-SR was initially implemented with the goal of providing a fixed structure for radiological reports, which were traditionally recorded through dictation. The advantages and disadvantages of this reporting format continue to be actively debated [20, 28–30].

The DICOM-Radiation Dose Structured Report (RDSR) is an object in the DICOM-SR, which contains various dose-rele-

Table 3 Seven points regarding the recording obligations due to § 28 from the German x-ray regulations [15].

German X-ray Ordinance § 28, Documentation requirement:	
1	the results of the patient interview according to § 23 paragraph 2 sentence 2 and paragraph 3 sentence 1
2	the time and type of application
3	the bodily region examined
4	information on the justifying indication according to § 23 paragraph 1 sentence 1
5	in the case of an examination, the report generated
6	the patient’s radiation exposure, provided that it was recorded, or the data and information necessary for ascertaining this parameter
7	in the case of treatment, the radiation plan according to § 27 paragraph 1 sentence 1 and the radiation protocol according to § 27 paragraph 3

Point six includes the radiation exposure and the required information for its determination.

Table 4 Overview of available dose monitoring software devices (selection, alphabetical order).

name	manufacturer	data acquisition	site	user access	modalities
Agfa HealthCare Dose Monitoring, powered by tqmlDose™	Qaelum	RDSR, MPPS, OCR, header	local	web	CT, XA, DR, MG
Dose M™	Infinitt	RDSR, MPPS, OCR, header	local	web	CT, XA, DR, MG
Dose Monitor™	PACS Health	RDSR, MPPS, OCR	local	web	CT, XA, DR, MG
DoseIntelligence™	Pulmokard	RDSR, MPPS	cloud	web	CT, XA, DR, MG
DoseMetrix™	Primordial Design	RDSR, MPPS, OCR, header	local	web	CT, XA, DR, MG
DoseTrack™	Sectra	RDSR, MPPS, OCR	cloud	SA	CT, XA, DR, MG
DoseUtility™	Pixelmed Publishing Open source	RDSR, OCR	local	web	CT
DoseWatch™	GE Healthcare	RDSR, MPPS, header	local	web	CT, XA, DR, MG
DoseWatch explore™	GE Healthcare	eigener standard	cloud	web	CT ¹
DoseWise™	Philips	RDSR, MPPS, OCR, header	local	SA	CT, XA, DR, MG
Imalogix™	medInt Holdings LLC	RDSR, MPPS, OCR, header	cloud	web	CT, XA, DR, MG
Novadose™	Novarad	RDSR, MPPS, OCR	local	SA ²	CT, XA, DR, MG
openREM™	The Royal Marsden NHS Foundation Trust (RMH), open source	RDSR, OCR, header	local	web	CT, XA, DR, MG
Radiance™	open source	RDSR, OCR	local	export, dashboard	CT
Radimetrics™	Bayer	RDSR, MPPS, OCR	local	web	CT, XA, DR, MG
Scannerside™	Drs. Talati, Moore of Rightdose, Inc.	RDSR, OCR	cloud	web	CT, XA
Teamplay™	Siemens Healthcare	RDSR, OCR	cloud	web	CT, XA, DR, MG

CT: Computed tomography; XA: Angiography; DR: Digital radiography; MG: Mammography; SA: Standalone application, RDSR: DICOM Radiation Dose Structured Report; OCR: Optical Character Recognition; MPPS: Modality Performed Procedure Step; Header: DICOM-Header. This information was obtained from the manufacturers' websites or was furnished by the manufacturers themselves. The authors make no claims regarding the accuracy or completeness of the information. Other modalities such as nuclear medicine or digital volume tomography modalities as well as specific other data collection methods are not listed. The data for Siemens Teamplay are taken from the white paper [46].

¹ GE-CT only.

² License from DoseMonitor™, integrated into the PACS and RIS.

vant parameters such as, for example, DLP and CTDI_{vol} for the overall study as well as individual examination series [18]. Because the DICOM-SR is a supplement within the DICOM-standard, there is, in an ideal situation, no variability between different CT machines, different manufacturers and institutions. To our knowledge, however, this has not yet been examined in a systematic study. In addition to CT, dose-relevant data of other imaging methods with ionizing radiation such as radiography, angiography, fluoroscopy, mammography and the CT portion of PET-CT can be gathered, with DICOM-SR differing among the particular modalities. Dose-monitoring programs based on DICOM-RDSR have already been introduced for various modalities (☛ Table 4). While specifically older devices currently still do not support DICOM-SR, retrofitting is possible in some cases.

Mapping of CT protocols

In the process of systematic dose-monitoring, automatic benchmarking of the dose data collected is desirable, e.g., with the existing national diagnostic reference levels. To facilitate classification, the local CT protocols of a radiological device must be classified according to the bodily regions to which the reference values apply. In this regard, the handful of reference values does not always satisfy the numerous CT protocols of today's clinical practice. Many different CT protocols which are routinely used for a vast array of clinical requests must be assigned to the same examination region (e.g., abdominal CT for tumor staging and low-dose CT for detecting ureter stones). This poses a major challenge when

implementing automatic dose-monitoring, since there is huge number of different CT protocols and widely varying nomenclature. Concepts for the standardization of CT protocols are currently being developed [31]. Some of the available software solutions as well as the American Dose Register are additionally adopting the Radlex Playbook [32 – 34] to facilitate an automated and optimally accurate assignment. There is currently no data on the accuracy of the different assignment algorithms. Other manufacturers are putting their faith in manual assignment. While this allows, on hand, the most accurate assignment of all protocols, it is very time-consuming. On the whole, correct assignment of CT-protocols is crucial for comparison against reference values.

Current possibilities of automated dose-monitoring

The vast number of possibilities for dose-monitoring of radiological examinations has significantly risen in recent years. Initial efforts used Excel files to record dose data [25]. In the meantime, however, many major manufacturers have introduced dedicated tools for gathering and analyzing CT dose data (☛ Table 4) [35]. These solutions differ from one another in terms of method of dose detection, modalities supported and the scope of analytical options. Local applications can offer a dedicated evaluation for each individual patient and thereby, for example, plot a temporal course of radiation exposure. This is desirable specifically for patients undergoing multiple examinations (e.g., tumor patients receiving follow-up care) and is additionally part of the EU Council Directive 2013/59/EURATOM. Local applica-

tions offer ready access to patient images, thereby facilitating, for example, the computation of “Size-specific dose estimates” (SSDE) [36, 37]. SSDE constitute a correction of the $CTDI_{vol}$ value based on the patient’s constitution. For this purpose, the effective patient diameter is frequently used, which has to be ascertained with measurements in the scout images [36]. Use of water-equivalent diameter for computing SSDE is currently being developed [37]. Ascertaining SSDE still necessitates making measurements in the patient images following examination. While this is likewise possible, for example, through the “American College of Radiology, Dose Index Registry” (ACR-DIR), it requires sending the scout images to the register, which involves larger data volumes per examination [32].

Decentralized, cloud-based solutions constitute a second option for implementing dose-monitoring. In this scenario, dose data is sent encrypted and anonymized or pseudonymized to a cloud server, where it is then evaluated. The server is typically accessed via a web interface using an internet browser. The advantage of this method is that it involves less local IT effort and expense and can be implemented quickly and easily. In addition, a decentralized server with multiple users can presumably be operated more cost-effectively than multiple individual solutions. Another advantage of a cloud-based system is that it allows the possibility of benchmarking and comparing the dose data of different cloud users. In this way, subgroups can be formed, and comparison with similarly sized or equipped institutions is potentially possible. In the case of decentralized dose-monitoring solutions, the central storage of potentially sensitive data makes data security and anonymization/pseudonymization crucial. While comprehensive data evaluation in the form of an overview of protocols, scanners or modalities is still possible, there are data privacy hurdles, particularly when evaluating data related to individual patients. A solution is therefore necessary for these software products to comply with the EU Council Directive 2013/59/EURATOM in the future.

While some companies install free-standing user programs for data access, many manufacturers offer access via a web interface. There are also solutions that are (or can be) inte-

grated into the local PACS and RIS. Sample images for the user interfaces for Radimetrics™ (Bayer Healthcare, Leverkusen, Germany), Dosewatch™ (GE Healthcare, Solingen, Germany) and DoseIntelligence™ (Pulmokard, Herdecke, Germany) are presented in **Fig. 1–3**. Both the overall interest in automated dose-monitoring and the number of commercially available programs are growing. According to a 2014 survey held by KLAS Enterprise, LLC, 83 % of participating institutions had already acquired or were actively seeking dose-monitoring software [38].

Outlook

Because of legal provisions and the documentation requirement stipulated therein, the increasing migration to electronic archiving and growing expenses, there is increased focus on the technical evaluation and archiving of dose relevant data in radiology. The DICOM-SR currently represents the best and most comprehensive method of systematically gathering dose data [26]. However, as many CT scanner do not support the standard at this point, other methods for dose recording are frequently used at the present time. Nevertheless, DICOM-SR will presumably prevail in the long term. Incorporating further parameters into this standard would be desirable. It must be born in mind that the currently used dose parameters ($CTDI_{vol}$ and DLP) are values computed based on phantom measurements [39]. In its Report 220, the American Association of Physicists in Medicine (AAPM) therefore proposed implementing the SSDE in the DICOM standard [37]. In this way, dose-monitoring programs could automatically incorporate the patient’s constitution into the evaluation in the future without accessing the patient images of each examination and thereby bring about a more accurate estimate of patient dose.

There is growing interest in gathering and evaluating dose data in cloud systems and regional / national registers. The “Radiation Exposure Monitoring” (REM) profile of the initiative “Integrating the Healthcare Enterprise” (IHE) is a standard for gathering, organizing and distributing dose-

Fig. 1 Sample analysis regarding size-specific dose estimates (SSDE) with Radimetrics™. Image was provided by Bayer Healthcare, Leverkusen, Germany.

Fig. 2 Sample analysis regarding the dose length product (DLP) for various CT-protocols using DoseWatch™. Image was provided by GE Healthcare, Solingen, Germany.

Fig. 3 Sample analysis of various CT-protocols benchmarked to national diagnostic reference levels using DoseIntelligence™. Image was provided by Pulmo-kard, Herdecke, Germany).

relevant data [40]. In the United States, dose-relevant data is already being saved in a national register with the aid of the IHE-REM profile [32]. Cloud-systems and national/international dose registers enable participating institutions to comprehensively evaluate the radiation exposure of large demographic groups and offer major opportunities for further radiation dose reduction in the future. Dose deviations for certain examinations of the individual institution / individual medical office compared to other participating fac-

ilities can be documented and can prompt the institution to optimize its own protocols. As already mentioned, data privacy aspects are of critical importance in decentralized solutions. In Germany, comprehensive approaches for automatic dose-recording in central registers are being developed, e. g., in the case of the project “IT-supported method for recording examination parameters” [IT-gestütztes Verfahren zur Erfassung von Untersuchungsparametern] (IVEU, TÜV-Süd Life

Service GmbH) fostered by the German Office for Radiation Protection and the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety [41–43]. In North Rhine-Westphalia as well, subsidization has already been sought for a cross-site dose register. Currently, a unique software solution based on DICOM SR objects and optical image recognition has been developed as part of the IVEU project. Progress in the development has been reported, and the first version is already available for download [41, 42]. However, evaluation software furnished in a register is very unlikely to offer the flexibility of an individual software solution. Customization of commercially available software solutions for automatically generating reports using the structure prescribed by the specific register is already possible in some instances and is by all means desired.

Despite the EU Council Directive 2013/59/EURATOM, Germany currently requires no automated, comprehensive dose monitoring in addition to the provisions of the German X-ray Ordinance and the ALARA principle. In the United States, however, California and Texas have introduced an automated dose-monitoring requirement applicable for each hospital operating CT equipment. The first major analyses have already been published and can be used for implementing new diagnostic reference levels [44]. In the meantime, the Joint Commission, a non-profit organization certifying more than 20 500 health facilities in the United States, has prescribed automated dose-monitoring for radiology departments [45]. It is anticipated that Germany will implement the EU Council Directive 2013/59/EURATOM in the near future. In addition, given the growing public concern regarding radiation exposure from medical examinations, it can be assumed overall that regulations will continue to tighten in the near future.

Regardless of the advances in the area of dose data recording and processing presented in this article, the basis for any comprehensive dose-monitoring must always be a functioning infrastructure. This is true, on one hand, when it comes to initially adapting any software to local structures and protocols. In addition, regular analysis of gathered data and monitoring action following modifications/optimizations to CT protocols are imperative. Many of the programs introduced here provide a dose alarm that requires immediate reaction in the process of quality assurance. Immediate reaction to faulty dose application (through user error, equipment error or faulty examination protocols) is possible only through a local evaluation of dose data at the place of examination. For example, manually adapting dose parameters (and thus manually overriding dose adaptation automation) can be entirely sensible in individual cases, i.e. for pediatric or intensive-care patients. However, improper use can result in an increase in applied dose, which can easily be prevented though immediate intervention (in this case, training). In addition to automated data recording and processing, a well-trained and adequately staffed team as well as the implementation of efficient structures are therefore particularly critical for successful quality assurance in dose monitoring.

Summary

Automated, systematic dose monitoring is an important component of quality management in radiology departments. Because the EU Council Directive 2013/59/EURATOM must be implemented as national law by 2018, further tightening of national requirements can be assumed. The increasing prevalence of DICOM-RDSR-compatible CT machines greatly simplifies recording dose data. Standards such as DICOM-RDSR and IHE-REM additionally facilitate participation in central dose registers. In the meantime, there is a vast assortment of powerful software solutions, each with its unique scope of functions. Although growing technological possibilities simplify automated data acquisition in the process of dose monitoring, problems such as standardization and mapping of CT protocols still need to be solved. It must not be forgotten that successful dose monitoring as part of quality assurance additionally always requires comprehensive structures for evaluating, monitoring and optimizing dose exposure.

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