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IAEA HUMAN HEALTH SERIES No. 49

Dose Management Systems

From Setting up to Quality Assurance

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DOSE MANAGEMENT SYSTEMS
FROM SETTING UP TO QUALITY ASSURANCE

ENDORSED BY
THE AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE,
THE ASIA–OCEANIA FEDERATION OF ORGANIZATIONS FOR MEDICAL PHYSICS,
THE EUROPEAN FEDERATION OF ORGANISATIONS FOR MEDICAL PHYSICS,
THE FEDERATION OF AFRICAN MEDICAL PHYSICS ORGANISATIONS,
THE INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS,
THE INTERNATIONAL SOCIETY OF RADIOGRAPHERS AND RADIOLOGICAL TECHNOLOGISTS,
THE LATIN AMERICAN MEDICAL PHYSICS ASSOCIATION
AND THE SOUTH EAST ASIAN FEDERATION OF ORGANIZATIONS FOR MEDICAL PHYSICS

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2025

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Publishing Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
tel.: +43 1 2600 22529 or 22530
email: sales.publications@iaea.org
www.iaea.org/publications

Printed by the IAEA in Austria
September 2025
STI/PUB/2112
https://doi.org/10.61092/iaea.6h45-1o3c

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.
Title: Dose management systems: From setting up to quality assurance / International Atomic Energy Agency.
Description: Vienna: International Atomic Energy Agency, 2025. | Series: IAEA human health series, ISSN 2075-3772 ; no. 49 | Includes bibliographical references.
Identifiers: IAEAL 25-01776 | ISBN 978-92-0-108725-6 (paperback : alk. paper) | ISBN 978-92-0-108825-3 (pdf) | ISBN 978-92-0-108925-0 (epub)
Subjects: LCSH: Radiation dosimetry — Quality control. | Radiation dosimetry — Management. | Radiation — Health aspects. | Diagnostic imaging.
Classification: UDC 614.876 | STI/PUB/2112

FOREWORD

Dose management systems have been introduced into medical imaging to facilitate quality management, quality assurance, patient dose management and optimization of clinical practice. They can be used to collect, monitor and evaluate patient demographics and technical information, including dose metrics from various imaging modalities (both ionizing and non-ionizing), and to ensure regulatory compliance. Apart from collecting information on quantities relevant to patient dose, some types of dose management system can also extract other data to further enhance patient care and assist with quality improvement. Various dose management systems are available, both commercial products and open source solutions, with different features and capabilities determining their application. Some of these systems automate the collection, archival, analysis and reporting of technical data, while others use manual or semiautomated data collection approaches.

Although dose management systems are very useful, their installation and use involve challenges. There is little guidance on setting up a dose management system and assessing its accuracy, as well as a lack of standardization of procedures related to acceptance testing, quality assurance and periodic quality control tests. The IAEA has issued guidance on quality assurance, quality control and dosimetry for various modalities, although not specifically for dose management systems or other types of software product.

The present publication was developed to provide guidance on the content, data analysis and evaluation of these systems to help Member States to understand, set up and use them appropriately, a need identified by the Scientific Committee of the IAEA/World Health Organization Network of Secondary Standards Dosimetry Laboratories. The publication aims to provide up to date information on the setting up, quality assurance, quality control and optimization of use of this software.

This publication is endorsed by the American Association of Physicists in Medicine, the Asia–Oceania Federation of Organizations for Medical Physics, the European Federation of Organisations for Medical Physics, the Federation of African Medical Physics Organisations, the International Organization for Medical Physics, the International Society of Radiographers and Radiological Technologists, the Latin American Medical Physics Association and the South East Asian Federation of Organizations for Medical Physics.

The IAEA gratefully acknowledges all the experts who contributed to the drafting and review of this publication — in particular L. Arlany (Singapore), I.S. Reiser (United States of America), R. Ruggeri (Argentina), R. Sanchez (Spain) and I.A. Tsalafoutas (Qatar) — as well as the developers of commercial and open source software who provided valuable information. The IAEA officer responsible for this publication was V. Tsapaki of the Division of Human Health.

EDITORIAL NOTE

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

Dose Management Systems (DMSs) have emerged in the past years as pivotal tools in medical imaging, enhancing the framework of quality assurance (QA) and patient dose management [1]. A DMS is defined as a software tool used to collect, monitor and assess patient demographic data and technical information, including dose metrics, from a range of imaging modalities encompassing both ionizing and non-ionizing imaging systems. These sophisticated systems are instrumental in aggregating, monitoring and appraising a plethora of patient specific data, including demographic characteristics and intricate technical specifications, alongside dose metrics sourced from a diverse array of modalities. They are increasingly recognized as integral to enhancing QA programmes and to ensuring adherence to stringent regulatory compliance standards and incident reporting. Recent studies also highlight their crucial role in optimization efforts and their importance in maintaining best practices by ensuring that the necessary image quality is achieved with the appropriate level of radiation dose [2]. The spectrum of functionalities of DMSs extends beyond mere data accumulation pertaining to patient dose relevant parameters. These systems are adept at receiving and analysing a large amount of additional information, thereby significantly amplifying the scope of patient care and strengthening quality enhancement initiatives. The utility and application of these systems are dictated by their distinct features and capabilities, ranging from sophisticated commercial solutions to versatile open source platforms. An essential characteristic of DMSs is their ability to automate the collection, archival, analysis and dissemination of technical data, thereby surpassing traditional methodologies that often rely on manual or semiautomated data collection approaches. This automation not only streamlines workflow but also enhances the accuracy and reliability of data management in medical imaging practices.

At the same time, the intricacy of DMSs stems from their multifaceted nature. Unlike standalone devices, these systems integrate a complex network of hardware and software components, interfacing with a diverse array of medical devices, such as computed tomography (CT), angiography, mammography and magnetic resonance imaging (MRI) systems, or hybrid imaging devices used in nuclear medicine, such as positron emission tomography (PET) systems. At present, most DMSs are primarily designed for radiology departments. However, more DMSs are starting to incorporate nuclear medicine functionalities. This complexity is well documented in recent literature, where the integration challenges of such systems are frequently discussed. According to recent

studies, these systems are very diverse, often facing interoperability issues when connecting medical equipment from multiple manufacturers [1–3]. Recently, a white paper from the European Society of Radiology outlined the sophisticated architecture of DMSs, illustrating the myriad of components that need to seamlessly work together [4]. Finally, the quality of data entering a DMS is crucial for reliable analysis and effective dose management. Accurate data provided by medical imaging equipment are essential, as usually DMSs do not infer or make any corrections. Standardization and consistency, especially from medical imaging manufacturers, are vital to ensuring that the input data are clean and reliable. All this complexity significantly impacts the drafting of technical specifications and performance assessments of DMSs. Setting benchmarks and evaluating the efficacy of such systems is not straightforward. The performance metrics relate not only to the software's functionality but also to its ability to accurately communicate and process data from various sources while maintaining compliance with health informatics standards.

In summary, the challenge with DMSs lies in their composite structure, requiring meticulous consideration of both software and hardware components and their interactions. This complexity is well acknowledged in the field, making the task of developing technical specifications and performance evaluations demanding. Furthermore, there are gaps, particularly in the domain of operational standardization and accuracy assessment, with a scarce number of definitive guidelines on the establishment, calibration and evaluation of DMSs, including a noticeable gap in standardized protocols for acceptance testing, commissioning and in setting up, QA and regular quality control (QC). While the IAEA has promulgated comprehensive guidelines encompassing QC, QA and dosimetry across various medical imaging modalities, there remains a notable absence of specific guidance tailored to DMSs. Addressing these gaps and developing a standardized approach in the assessment and implementation of DMSs is imperative for advancing patient safety, optimizing radiation dose utilization and clinical practice, and ensuring consistent quality in health care.

1.2. OBJECTIVE

The objective of this guidance is to present and elucidate the technology and application of DMSs, define existing gaps and obstacles in their QA and dosimetric accuracy, and formulate comprehensive guidelines to assist in the effective and appropriate drafting of technical specifications, as well as in the QA and implementation of these systems. This publication examines the features of DMS technology, addressing both its potential and limitations, and proposes

strategies to overcome challenges in its procurement process and ensuring quality and accuracy in the use of this tool.

Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

This publication is intended to assist various health professionals working in medical imaging departments in decisions related to DMS procurement, installation, setting up, implementation and use. The focus is to inform and facilitate decisions and planning on the selection and QA of these systems for optimal, safe and accurate use using available resources.

1.4. STRUCTURE

The publication is divided into ten sections. Section 2 outlines the roles of various professionals in DMS management. It discusses the responsibilities of clinical staff within the medical imaging department and describes the roles of information technology staff, service engineers and administrative staff.

Section 3 presents dosimetric quantities, dose metrics used in DMSs and diagnostic reference levels (DRLs) and shows the importance of information systems in DMSs, including aspects of Digital Imaging and Communications in Medicine (DICOM) and interoperability, as well as the role of clinical workflow in DMS operations.

Section 4 focuses on the technical aspects and covers system components, including software and hardware architecture, and functionalities such as dose information extraction and data categorization. Advanced features such as organ dose calculation and image quality assessment are also discussed, along with additional tools such as software for statistical analysis.

Section 5 addresses the setup process and includes matching clinical indications with body regions and imaging protocols, establishing a committee for reviewing the protocols, setting DRLs, and establishing as well as implementing correction measures.

Section 6 outlines the suggested technical specifications for DMSs, focusing on the key requirements necessary for their efficient operation and integration into clinical workflows.

Section 7 outlines QA processes, including acceptance, commissioning and setting up, and routine QC tests of the DMS functionality and performances. It

discusses verifying DICOM tags, dose information transfer and dose calculations, and addresses the challenges of software upgrades and of adding new medical imaging modalities.

Section 8 provides some case examples of the use of DMSs in everyday clinical practice.

Section 9 explores the future potential of DMSs and emphasizes the importance of high quality data for leveraging advancements in technology such as big data analytics, machine learning and artificial intelligence. It highlights strategies for improving DMS functionality, addressing current challenges and unlocking new opportunities for enhanced workflow efficiency, patient outcomes and regulatory compliance.

Section 10 underlines the critical importance of data quality and rigorous QA in the effective functioning of DMSs, while emphasizing the need for continuous improvement and innovation to maximize the role of DMSs in optimizing clinical practices and dose management.

Appendix I provides the questions that were included in a questionnaire that was sent to various DMS developers to allow a deeper understanding of what these systems can currently offer in terms of technical, functional and other characteristics.

Appendix II provides the list of both open source and commercial DMS developers who participated in the technical survey presented in Appendix I.

2. ROLES AND RESPONSIBILITIES

This section outlines the structure of the DMS committee and defines the roles and responsibilities of its members, which are critical for the successful implementation and ongoing supervision of a quality management programme centred on the DMS. It is important to note that the specific roles and organizational structures proposed in this section might vary among institutions, depending on their departmental arrangements, established policies and available resources.

2.1. INTRODUCTION

The DMS is a valuable tool for managing procedures and protocols in medical imaging departments. To ensure its effective implementation, it is essential

FIG. 1. Schematic diagram of integration and nesting of QC, QA and quality management programmes.

for these departments to have a comprehensive quality management programme that integrates both QA and QC components specifically tailored for the DMS, as depicted in Fig. 1. A successful DMS needs to operate within the framework of this quality management programme, which is designed to oversee and enhance the entire process and workflow of the medical imaging department [1]. The quality management programme should provide specialized software tools and skilled personnel to support and maintain the various procedures needed for optimal DMS performance and overall departmental efficiency.

The successful and effective use of a DMS requires not only significant technical and administrative support but also the active involvement of multiple user groups, depending on the scope of the DMS (i.e. departments with medical imaging systems that provide data to the DMS). Given the complexity and interdisciplinary nature of DMS operations, establishing a dedicated DMS committee is strongly encouraged. This committee can play a pivotal role in overseeing the system's functioning, coordinating activities across departments, ensuring adherence to protocols and addressing any technical or procedural issues that may arise. By bringing together key stakeholders, the DMS committee helps to streamline decision making, foster collaboration and maintain the system's overall efficiency and effectiveness, ultimately enhancing patient safety and optimizing the use of department resources.

Generally, the members of the DMS committee can be divided into two broad categories: (a) members that are responsible for providing administrative and technical support and (b) user groups that consist of the end users who utilize the data generated by the DMS, including also those end users that do not directly interact with the DMS (e.g. a radiologist who receives reports using data from

the DMS). The responsibilities of these groups differ depending on the stage of DMS implementation, such as procurement, installation and regular maintenance activities, including system upgrades. Additionally, the roles and tasks of the committee members are influenced by the scope of the DMS, which includes the range of departments and imaging equipment that report data into the system and rely on these data to monitor and optimize their operational processes. A well structured DMS committee is essential to ensure seamless coordination across these activities, enabling the DMS to function effectively and contribute to enhanced patient care and safety.

The list of DMS committee members described below is not exhaustive and can be tailored to meet the specific needs and circumstances of each institution. The composition of the committee may vary depending on factors such as the size of the healthcare facility, the range of imaging modalities in use, the complexity of the DMS, and the regulatory and operational requirements of the institution. Local needs will dictate the inclusion of additional members or the adjustment of roles within the committee to ensure that all aspects of DMS implementation and maintenance are effectively covered. However, the individual most intimately familiar with all aspects of the DMS is the clinically qualified medical physicist (CQMP), who plays a pivotal role in its successful setting up, implementation, ongoing operation and overall optimization.

2.2. ADMINISTRATIVE AND TECHNICAL SUPPORT

Administrative and technical support are both crucial components in the effective implementation and operation of a DMS. Administrative support provides the necessary organizational backbone, ensuring that the DMS is integrated smoothly into the existing infrastructure and that its functions align with institutional goals and regulatory and data privacy requirements. Technical support is essential for maintaining the system's functionality, managing software and hardware configurations, troubleshooting issues and ensuring seamless integration with other systems, such as the picture archiving and communication system (PACS), the radiology information system (RIS) and the hospital information system (HIS). Together, administrative and technical support play key roles in facilitating communication among stakeholders, ensuring the system's reliability and providing the documentation and record keeping necessary for audits and continuous improvement. The following subsections describe in more detail the roles and responsibilities of the key members involved in providing both administrative and technical support. In smaller health institutions, it may be feasible for only one or two members to manage these responsibilities.

2.2.1. The licensee or registrant

Different countries may have different or even no regulations and certifications governing the use of DMSs in the clinical environment. Before choosing a DMS, it is necessary to verify that it complies with national import and administration certifications. It is also important to comply with the national regulations and with the scope of national norms/standards, requirements and laws that involve its use in the clinical environment. Each country has different mechanisms and scopes in the implementation of regulations and/or approvals on the use of DMS software, and some of them are carried out through the ministries of health, state organizations or nuclear regulatory authorities, medical device agencies/authorities and others.

The holder of the licence or registration is the legal representative (usually a medical or general director) of the health institution, who is accountable to the country's regulations. This individual is also responsible for appointing the personnel in charge of the quality management programme and holds ultimate accountability for ensuring that the DMS complies with applicable regulations [5, 6].

2.2.2. DMS manager

The DMS manager plays a pivotal role within the DMS committee and is crucial to the effective operation and utilization of the system. This individual ensures timely communication among all committee members and has a comprehensive understanding of the scope of the DMS, including all departments and medical imaging equipment reporting to the system. Trained in the full functionality of the DMS software, the DMS manager works closely with the DMS administrator and support team through all stages of implementation and ongoing use. Additionally, the DMS manager coordinates training for various user groups and collaborates with them to provide data, to set up the DMS and to manage dose alerts, dashboards and reports. This responsibility is often held by a CQMP, given the technical expertise needed for the role.

2.2.3. Clinical administrator

The clinical administrator is responsible for accurately managing patient demographic information, including the assignment of medical record numbers and other vital details. During patient data management procedures, such as reception, invoicing and appointment scheduling, administrative errors can occur, potentially leading to misinformation within the DMS. It is crucial for the

clinical administrator to understand the impact of these errors on the accuracy and functionality of the DMS, in order to be able to quickly identify and correct any issues. Therefore, it is essential for the clinical administrator to be well versed in the various pathways and workflows through which patient information travels — across the HIS, PACS, RIS, medical equipment and other systems — before it is integrated into the DMS. This knowledge ensures that data integrity is maintained throughout the process, supporting the effective operation of the DMS.

2.2.4. DMS administrator

The primary responsibility of the DMS administrator is to manage the administrative configuration of the DMS software. This includes overseeing user accounts, setting permissions and action levels, and ensuring that the DMS software accurately records information. Key tasks also involve maintaining detailed documentation of the system's configuration, user accounts, permissions and any changes made to the system. The DMS administrator is also responsible for handling alerts regarding potential issues, such as high radiation doses or equipment malfunctions, and notifying the appropriate personnel to address these concerns. Additionally, the DMS administrator ensures the ongoing proper functioning of the DMS by performing regular software updates and audits. If any issues arise, the administrator is responsible for coordinating with the relevant department to resolve the problem and escalating it to the DMS committee if necessary. This role is typically filled by a member of the medical imaging department who has information technology experience or qualification and understands radiation safety and workflow, such as the PACS administrator. It can be also assigned to a qualified member of the DMS committee, such as a CQMP, a medical radiation technologist (MRT) or others with relevant expertise.

2.2.5. Information technology staff

The information technology staff are essential to the correct functioning of the DMS. The staff manage and support the software developer in the installation of the system and perform regular updates and maintenance of the system. The staff can also ensure proper connectivity between the systems of the clinics. Tasks of the staff can also include implementing security measures to protect sensitive patient information, regular data backup and defining a recovery plan in case of data loss or corruption.

The information technology work group may have different formats, depending mainly on the size of the institution. It can be composed of a single staff member who oversees everything or it can be divided into groups with different responsibilities such as the following:

(a) Infrastructure (hardware and software maintenance).
(b) Connectivity (connectivity between systems such as the PACS, RIS, HIS, electronic medical records and others, as well as upgrades of these systems).
(c) Health informatics (applicability in the clinical environment and connectivity with computer systems and medical imaging equipment).
(d) Security, which is a critical consideration in the implementation and operation of a DMS, particularly given the rising threats of cyberterrorism and cyberattacks targeting healthcare systems. Modern healthcare infrastructure is increasingly adopting more sophisticated firewalls and network segmentation to protect sensitive patient data and ensure regulatory compliance. However, these security measures can inadvertently disrupt the transmission of DICOM or other data formats to the DMS if not properly configured.

2.2.6. Medical equipment service engineer

IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [6], states:

> "[M]aintenance and servicing of medical radiological equipment is usually performed by an engineer or technician employed either by a company offering such services (who may also be the manufacturer and/or the vendor) or by the medical facility itself (e.g. as part of an engineering, biomedical or clinical engineering, or service department)."

This includes ensuring that the equipment operates within the QC programme requirements established by CQMPs. The role of medical equipment service engineers is crucial during the installation of a DMS, as the service engineer, certified by the equipment vendor, is needed to configure the communication settings, DICOM parameters and data sharing protocols to ensure seamless integration with the PACS and/or the DMS. Their expertise ensures that the medical imaging equipment interfaces correctly with the DMS, facilitating accurate data flow and system performance.

2.2.7. DMS developer support

The software developer or vendor is responsible for providing specifications and requirements for software installation or upgrades, including details on data storage, operating systems, networking and connectivity. These requirements may vary depending on the volume of examinations reported to the DMS. The DMS developer collaborates closely with the hospital information

technology staff to establish connectivity, manage data flows and ensure that data are accurately received from all equipment reporting to the DMS. Additionally, the vendor works with the CQMP to verify that dose reporting is precise. Other important responsibilities include providing staff training both before the initial deployment and on a regular basis thereafter, offering remote or on-site support to troubleshoot issues, and ensuring the security and privacy of patient data throughout the system's operation, including promptly addressing and fixing any software bugs as they are identified.

2.3. USER GROUPS

A user group is a subset of individuals who are utilizing the DMS to accomplish a specific task. Typically, tasks may include: (a) optimization of imaging protocols; (b) radiation safety tasks, such as monitoring peak skin dose (PSD) levels in fluoroscopy; (c) regulatory compliance tasks, such as reporting of local DRLs; (d) radiation incident follow-up; (e) occupational risk assessment; (f) tasks related to pregnant patients; (g) tasks related to clinical audits; and (h) administrative control and supervision, depending on the technical features of the DMS. The tasks will depend on the regulatory requirements of the country, as well as policy requirements of the institution itself.

Each user group may oversee different modalities and should be familiar with the related imaging devices. Each user group is encouraged to have representation in the DMS committee. To ensure effective use and management of the DMS, user groups should have one of more of the health professionals outlined in Sections 2.3.1–2.3.3. This minimum representation helps to cover the diverse range of tasks and responsibilities associated with the system. However, this should not be seen as a limitation, as additional members can join to further enhance the group's expertise and coverage, depending on the specific needs and requirements of the institution.

2.3.1. Radiological medical practitioner

One of the main benefits of implementing a DMS is that it provides useful information for optimizing acquisition protocols and, depending on the technical features of the DMS, assuring clinical image quality using the appropriate radiation dose. It is important that each department or service has a radiological medical practitioner (RMP), who, together with the CQMP and the MRT, is responsible for the use and optimization of clinical protocols. This professional plays a critical role in ensuring that the clinical indications for medical imaging examinations are both appropriate and aligned with the

specific protocols established for optimal patient care. Their responsibilities include assessing the necessity of the requested imaging study, verifying that the chosen examination protocol is suitable for the clinical question at hand and providing accurate and detailed reports on the findings. To perform these duties effectively, this individual needs to be specialized in the appropriate area, such as radiology or nuclear medicine, and be able to play a pivotal role in refining the imaging process by identifying opportunities for improvement, whether in the clinical imaging protocol or in the overall workflow. This includes raising concerns about suboptimal image quality or technical issues that might impede accurate diagnosis and suggesting alternative imaging approaches when necessary.

2.3.2. Medical radiation technologist

The MRT, also called radiological technologist or radiographer, plays a crucial role in the medical imaging process [6]. This professional is tasked with performing the medical imaging examination and ensuring the optimal image quality necessary for correct diagnosis. The MRT who represents the MRT team should be in a senior position, bringing comprehensive knowledge and expertise in medical imaging to the role. The MRT's direct interaction with the patient makes this role particularly significant. This professional is responsible for positioning the patient correctly, optimizing the technical settings and ensuring that the resulting images meet the standards needed for precise medical evaluation. Serving as the final checkpoint before performing the imaging procedure, the MRT also verifies the patient's personal information, playing a crucial role in maintaining patient data accuracy. Effective communication with the clinical administrator is essential, especially when changes in the procedure are necessary or discrepancies are identified, to prevent errors from being entered into the DMS.

2.3.3. Clinically qualified medical physicist

The CQMP plays a critical role in the quality management programme, in the QA and QC programmes, as well as in the radiological protection of patients and others inside the medical facility, among other tasks [6, 7]. The CQMP's expertise extends to the optimization of clinical acquisition protocols, as the CQMP possesses the skills necessary to evaluate the doses used in medical imaging procedures and perform both qualitative and quantitative analysis of image quality. This technical evaluation complements the qualitative assessments made by medical staff, together forming the basis for optimizing acquisition protocols for various medical imaging studies.

Moreover, the CQMP is instrumental in establishing local DRLs and contributing to establishing and implementing national DRLs. All medical imaging departments should have a CQMP or should ensure the involvement of a CQMP in everyday clinical practice [5, 6]. The presence of CQMPs in departments is of paramount importance, as they play an integral role across all imaging modalities [6, 7]. Their involvement is direct and hierarchical in nature, overseeing equipment QC, ensuring the traceability of equipment operation under the QA programme and participating in initiatives focused on process and procedure optimization, among other responsibilities.

Given that the DMS is an essential tool for managing and optimizing processes, procedures and protocols, the responsibility for comprehensive monitoring of its correct operation and application lies with the CQMP. The CQMP is uniquely qualified to select and use meaningful and comprehensive data from the DMS, which can then be shared with the clinical team for further review and analysis in the process of optimization of acquisition protocols.

2.4. DMS COMMITTEE

The DMS committee is responsible for the procurement, installation, implementation and maintenance of the system. An example of the structure of this committee is given in Fig. 2. It is suggested that the DMS committee includes, at a minimum, a CQMP specialized in radiology and/or nuclear medicine, a radiologist or nuclear medicine physician, and a senior MRT. Additionally, the committee should include other relevant professionals as needed to address the specific requirements and challenges of the institution. As an example, it should include a hospital information technology liaison and a high level administrator or director with authority over all departments that have medical imaging equipment (such as a technical, medical, operations or administrative director, as determined by the institution's management hierarchy), because the decisions made from the data obtained from the DMS will have a great clinical and administrative–economic impact. In smaller health institutions, forming a large committee may not be feasible, and typically only one or two members are able to manage these responsibilities effectively.

For the efficiency of the committee, it is very important to define the missions, functions and skills expected of each of its members, and to allocate them the time and financial resources, necessary protected time and fair compensation so that they can fulfil their duties during their work hours. It is important for the highest management level of the healthcare organization to understand that the function of each DMS committee member should be valued as an essential part of the overall healthcare quality management. The structure

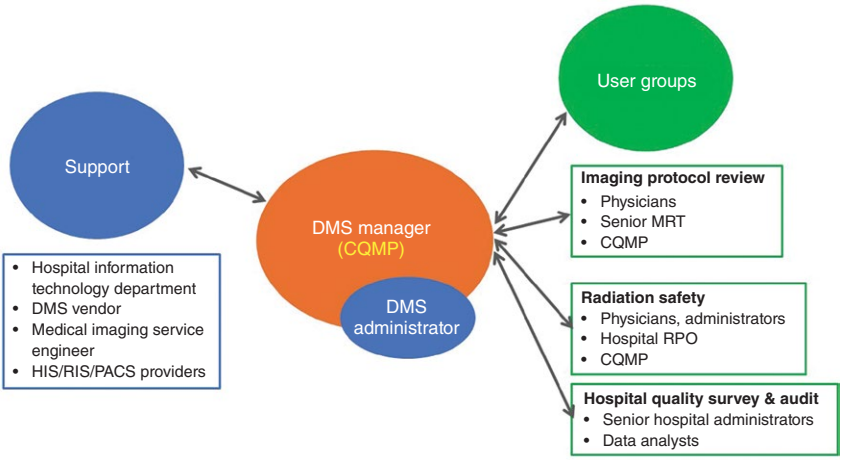

FIG. 2. Example structure of a DMS committee that includes various health professionals, such as a CQMP, an MRT and a radiation protection officer (RPO) in the user groups.

of the DMS committee shown in Fig. 2 is organized into three main components: support, user groups and DMS manager. The DMS manager is typically a CQMP, who oversees the system's operation, works closely with the DMS administrator and is responsible for ensuring effective communication and coordination between the support group and the user groups. The arrows in Fig. 2 depict the flow of information and collaboration between the DMS manager, support and user groups, highlighting the interconnected nature of these roles in managing and optimizing the DMS.

During the initial installation of the DMS, the committee is responsible for leading and coordinating the DMS implementation and is responsible for ensuring that project timelines, budgets and objectives are met. The DMS committee understands the system and networking requirements of the DMS, the data connections, firewalls, cybersecurity and such, and can ensure that radiation dose data from all equipment are received by the DMS. The DMS committee works with the users to ensure that indicated and estimated radiation dose values are correct and should be able to analyse collected data and suggest corrective actions on the basis of the findings.

The DMS committee should collaborate closely with the respective imaging modality protocol committees to optimize and harmonize acquisition protocols. It is also essential to include managers or designated medical representatives from each department that utilizes radiation generating imaging equipment (e.g. cardiology, neurosurgery, vascular surgery), along with the radiation protection officer, if the institution has one. Furthermore, if the institution has a quality management committee and/or a radiation protection committee, it is

advisable for the DMS committee to provide regular reports to these committees. This ensures that safety and quality initiatives are consistently aligned and integrated across the institution.

The data generated by the DMS can serve as a critical foundation for various quality initiatives aimed at enhancing patient care and operational efficiency. Specifically, these data can be leveraged to do the following:

(a) Optimize acquisition protocols. By analysing the detailed data provided by the DMS, clinical teams can finetune imaging protocols to achieve the best balance between image quality and radiation dose, ensuring that each procedure is both safe and effective.
(b) Establish and monitor local DRLs. DMS data are invaluable in establishing local DRLs and benchmarking them against national or international standards. Continuous monitoring of DRLs helps to ensure that radiation doses are as low as reasonably achievable while still providing diagnostic quality images.
(c) Support audits. The comprehensive data collected by the DMS can be used to support internal and external audits, providing evidence of compliance with regulatory requirements and institutional policies. These data also assist in identifying areas for improvement and verifying the effectiveness of corrective actions.
(d) Participate in national or international data registries. Contributing DMS data to national or international registries allows institutions to benchmark their performance against that of other facilities. This participation not only promotes collaboration and knowledge sharing but also contributes to the broader understanding and advancement of radiation safety and imaging practices globally.
(e) Enhance radiation protection programmes. DMS data can be used to closely monitor and analyse radiation exposure across different modalities and patient groups, helping to identify trends or outliers.
(f) Support education and training. The DMS can provide valuable data for educating and training medical staff on best practices in radiation use. By analysing case studies, dose distributions, trends and errors, the institution can tailor training programmes to address specific challenges and improve the competency of radiology personnel.
(g) Enable predictive analytics and risk management. By utilizing the data collected by the DMS, healthcare facilities can implement predictive analytics to anticipate potential issues, such as equipment malfunctions or patient populations at higher risk for radiation related complications. This proactive approach allows for timely interventions and better risk management.

(h) Assist in resource allocation and workflow optimization. Analysing DMS data can reveal patterns in resource usage, such as the frequency and duration of imaging procedures, which can be used to optimize workflows and allocate resources more efficiently. This could help to ensure that medical imaging departments operate smoothly, reducing patient waiting times and improving overall productivity.

3. BASIC CONCEPTS

This section introduces some of the fundamental concepts that are essential to understand before setting up and using a DMS, such as dosimetric and other related quantities that are thoroughly described in previous IAEA publications [8, 9]. The purpose of Ref. [9] was to provide consolidated information on monitoring patient radiation exposure in medical imaging, including recording, collecting and analysing relevant patient exposure data by manual or automatic means and to lay the groundwork for the development and implementation of systems for automatic data collection. Additionally, the role of information systems is emphasized in this section, as these systems are vital for integrating and managing the extensive data generated during imaging procedures, ensuring that patient and equipment related information is accurate and accessible. Lastly, maintaining efficient clinical workflows is key to optimizing patient care and resource utilization, from scheduling and image acquisition to analysis and reporting.

3.1. DOSIMETRIC QUANTITIES

The concept of patient dosimetry in medical imaging is a complex subject that for many years has been handled by a small group of healthcare professionals, such as CQMPs, MRTs and RMPs. The knowledge of the subject by other medical specialities, but also of the general public, has been greatly increased by the scientific literature [2].

The effects of radiation on tissues are classified into two categories: stochastic and deterministic [9]. Stochastic effects are those whose probability of occurrence increases with radiation dose. There are no specific dose thresholds for the occurrence of stochastic effects. The higher the radiation dose, the higher the probability is that a radiation effect, such as cancer or genetic mutations in offspring, can occur. Deterministic effects (such as tissue reactions; also called

tissue effects) occur when the dose exceeds a threshold level, but their occurrence also depends on individual patient radiosensitivity [10].

Detailed descriptions of all dosimetric quantities and units commonly used in medical imaging are provided in Refs [8, 9, 11]. The following subsections briefly revisit some basic concepts that are critical to understand for the effective application and interpretation of DMS data.

3.1.1. Incident air kerma

The incident air kerma (K_i) refers to the kerma deposited in air by an incoming X ray beam, measured along the central beam axis at the surface of the patient or phantom. This value accounts solely for the radiation reaching the patient or phantom, excluding any backscattered radiation. In the SI, the unit of kerma is the gray (Gy), and 1 Gy is equal to 1 J/kg.

3.1.2. Entrance surface air kerma

The entrance surface air kerma ($K_{a,e}$) refers to the kerma in air measured along the central beam axis at the surface of the patient or phantom. It accounts for both the radiation incident on the patient or phantom as well as the backscattered radiation. The unit is the gray.

3.1.3. Air kerma–area product

The air kerma–area product, P_{KA}, commonly referred to as kerma area product (KAP) or dose–area product (DAP), represents the integral of air kerma across the area covered by the X ray beam in a plane perpendicular to the beam axis. Its unit is Gy · m². Given that most manufacturers use the term KAP, this term will be used throughout this publication.

3.1.4. Computed tomography air kerma index

The computed tomography (CT) air kerma index is the quotient of the integral of the air kerma along a line parallel to the axis of rotation of the scanner over a length of 100 mm and the nominal slice thickness. It is also called CT dose index (CTDI) and it can be either weighted ($CTDI_w$) or volumetric ($CTDI_{vol}$). Given that most manufacturers use the term CTDI, this terminology will be consistently applied throughout this guidance publication. It is typically expressed in mGy.

3.1.5. Air kerma length product

The air kerma length product, also called dose length product (DLP), is the product of $CTDI_w$ or $CTDI_{vol}$ with the length of a CT scan. The air kerma length product does not take the size of the patient into account and is not a measure of absorbed dose. Given that most manufacturers use the term DLP, this terminology will be consistently applied throughout this guidance publication. It is typically expressed in mGy · cm.

3.1.6. Absorbed dose

The absorbed dose is a physical quantity that expresses the amount of energy absorbed per unit mass of a material and it is applicable to any type of radiation or material. The unit of absorbed dose is the gray. In the case of a specific organ or tissue, it is called organ dose.

3.1.7. Average glandular dose

The average glandular dose (AGD), also called mean glandular dose, is the estimate of the average absorbed dose to the glandular tissue of the breast. It is typically expressed in mGy.

3.1.8. Equivalent dose

The equivalent dose is a quantity used to describe the radiological effect that an absorbed dose of a certain type of radiation can produce, and its SI unit is the sievert (Sv). For photons (X ray and γ rays) and electrons of any energy, the equivalent dose is numerically equal to the absorbed dose. The equivalent dose is the most appropriate quantity for estimating the damage produced by radiation in an organ that has been irradiated by a specific type of radiation.

3.1.9. Effective dose

The effective dose (E) is a quantity that was devised to provide risk estimates in the case of partial exposure and to facilitate the comparison of patient doses from different diagnostic modalities that use different types of radiation. The effective dose is the sum of the equivalent doses of all irradiated radiosensitive organs multiplied by a weighting factor specific to each organ and tissue, as described in International Commission on Radiological Protection (ICRP) publications [12, 13]. The effective dose is not representative of the dose received by a particular patient, because

the abovementioned coefficients are generic and extracted from numerous radiobiology studies, while the weighting factors may change as new scientific evidence becomes available [12–14].

3.2. DOSE METRICS IN A DMS

DMSs receive dosimetric information from various medical imaging modalities, and the quantities reported by each modality vary. The DMS may also calculate additional quantities on the basis of these dosimetric inputs, such as the equivalent dose or the effective dose. Different medical imaging modalities use different dosimetric quantities and units to record radiation dose. These dosimetric quantities are not measured directly on patients but are instead derived from measurements performed using phantoms, which simulate human tissue. Furthermore, different equipment manufacturers of the same imaging modalities may also record different quantities and units. Therefore, it is crucial to understand and standardize these dose metrics and their units across the different imaging equipment manufacturers so that the accuracy and consistency of dose data collected by the DMS can be ensured. For the purpose of this guidance publication, only the dosimetric quantities that are usually reported by the DMS are analytically described.

Radiography, fluoroscopy or angiography systems commonly use KAP or DAP, measured in cGy · cm^2, μGy · m^2 or Gy · cm^2, depending on the type of machine. Another commonly used dosimetric quantity is the incident air kerma K_i defined at a specific reference point, which is measured usually in mGy and called air kerma at the patient entrance reference point ($K_{a,r}$). For each X ray equipment that reports K_i to the DMS, the CQMP can identify and verify the location of the reference point at which K_i is measured or calculated.

Mammography uses AGD. However, $K_{a,e}$ is also commonly calculated by some medical imaging manufacturers and archived as entrance surface air kerma or K_i.

CT systems currently calculate $CTDI_{vol}$, expressed in mGy, and the DLP, expressed in mGy · cm. The DLP is obtained by multiplying $CTDI_{vol}$ with the actual scan length (including overranging) and hence resulting in the unit mGy · cm. The size specific dose estimate (SSDE) is another parameter used by some CT manufacturers. The SSDE corrects the $CTDI_{vol}$ value measured in the phantom for the different patient dimensions and therefore is a more reliable estimate of the dose to the patient.

Dental systems (panoramic, cephalometric and cone beam CT (CBCT)) also use KAP, usually in mGy · cm^2 units, although some CBCT systems also provide the CTDI value (head) in mGy [8, 9]. It should be noted that although

CBCT is also widely used in radiation therapy, its applications in that field are beyond the scope of this publication.

In nuclear medicine, the radioactivity or administered activity, expressed in MBq, indicates the amount of radiopharmaceutical administered to the patient. This administered activity correlates with the radiation dose that the patient receives. This dose depends on factors such as the radiopharmaceutical's physical and biological properties, the organ or tissue that it targets and patient's metabolism, among others.

All these parameters need to be checked against those measured or/and calculated using external dosimeters during the commissioning of the equipment to ensure its accuracy. The accuracy of the dose metrics needs to be checked because the dose metrics will be used to make comparison with DRLs for each medical imaging modality. This verification needs to be performed periodically and at least once per year, especially when there are hardware replacements or software upgrades.

These common dose metrics, along with other exposure and geometric parameters related to each exposure (referred to as irradiation event), are usually included in the set of radiation dose structured report (RDSR) data objects [15]. It should be noted, however, that dose metrics may be stored in the RDSR report or in the DICOM headers with different units from those displayed on the medical imaging control console screen.

3.3. DIAGNOSTIC REFERENCE LEVELS

The DRL is a term initially introduced by the ICRP in 1996 [16], and a comprehensive description of DRLs, including their application, suggested values and methodologies for setting and updating them, is provided in Ref. [17].

The ICRP defines the DRL process as follows: "the cyclical process of establishing DRL values, using them as a tool for optimisation, and then determining updated DRL values as tools for further optimization" [17]. The DRL value is "an arbitrary notional value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of the DRL quantity obtained from surveys or other means" [17] observed at (a) a few healthcare facilities (termed "local DRL value") or (b) multiple facilities throughout a country (termed "national DRL value"). DRL values can be developed at a national level (national DRL) or at a local level (local DRL) when no national DRL value is available [17–19].

DRL values are defined for specific diagnostic medical imaging examinations. Initially, DRLs were defined for the 'standard sized adult patient' (a 70 kg adult). In the United States of America of America (USA), national DRL values in adult and paediatric CT were published in 2017 and 2022, respectively [20, 21]. Depending

on the imaging technology used to acquire the medical images, the DRL values may change; hence, regular updating of DRL values is an important tool in the dose optimization process. For example, for CT scanners equipped with new image reconstruction methods, images of equivalent quality at lower radiation doses may be produced, which would potentially result in reduced DRL values.

Reference [17] suggested DRL quantities that are suitable for particular imaging modalities, as shown in Table 1. These values are commonly available and easily obtained from various medical imaging manufacturer models. Setting medical imaging equipment to send these quantities and units to a DMS can make the data collection, monitoring and analysis much more efficient, consistent and easy to process.

A DMS can perform various types of data statistics by type of examination and/or applied acquisition protocols for each equipment of the health institution, together with information accompanying medical images. It can be therefore possible to use the DMS information with different indicators of the quality of the images (quantitative and/or qualitative) [17]. The DMS does not monitor DRL values but may check dose metrics against DRLs or be used to define DRLs, ideally alongside image quality evaluation.

For nuclear medicine, weight based administered activities ($MBq \cdot kg^{-1}$) are appropriate for all types of patients including children, adolescents and low weight patients.

TABLE 1. QUANTITIES AND UNITS SUITABLE FOR DRL VALUES [17]

Modality	Commonly reported DRL quantity	Unit
Radiography	P_{KA}, $K_{a,e}$	mGy, $mGy \cdot cm^2$
Mammography	$K_{a,e}$, AGD	mGy
Fluoroscopy[a]	P_{KA} (KAP, DAP), $K_{a,r}$	$mGy \cdot cm^2$ mGy
Computed tomography	$CTDI_{vol}$ DLP	mGy $mGy \cdot cm$
Nuclear medicine	Administered activity or activity per body weight	MBq $MBq \cdot kg^{-1}$

[a] For angiography systems, specific suggestions exist regarding the use of KAP, measured in $Gy \cdot cm^2$.

Patient dose history may sometimes be needed, as in the case of multiple fluoroscopically guided interventional procedures (FGIPs) over a short period of time or foetal doses. Patients undergoing multiple imaging modality examinations and procedures should have their dose recorded separately and according to each examination or procedure.

Initially, DRL values were set on the basis of manual data collection, using dose data from approximately 10–30 patients per type of examination at each participating institution, using standard sized patients only, and excluding small or obese patients. The use of DMS enables collection of radiation dose data from all examinations performed. Reference [17] proposed that DRLs are set according to a specific clinical indication, medical imaging examination and procedure. For proper use of a DMS and data management, local or national guidance on patient registration and on which patient related data should be provided would also be helpful. As an example, to establish adult DRLs for a healthcare facility without a DMS, the institution needs to collect dose data from at least 20 (preferably 30) standard sized adult patients and from 50 standard sized adult patients for mammography. With the DMS in place, patient dose data collection of any number can be retrieved and analysed more easily than with manual data collection. The automated process of dose collection by the DMS also eliminates errors that could be introduced by manual data collection and hence improves its accuracy. Patient weight data are an important consideration when establishing DRLs but are often difficult to obtain. However, with the DMS collecting large samples of dose parameters for DRL analysis, weight is no longer an issue (all patients can be considered, irrespectively of their weight) and can be excluded from the analysis [17]. Nevertheless, errors can always occur, making the process of data QA crucial to ensuring the accuracy of the data being analysed and interpreted.

Besides establishing and regularly updating a healthcare facility's local DRL, these values need to be compared with national or regional DRL values. This will allow the facility to review their local DRLs and examine if their values consistently exceed or are lower than other established DRLs. For example, when the facility's DRL values consistently exceed or are much lower than the national DRL values, an investigation should be performed to identify the cause of this deviation and corrective actions to be taken. Nevertheless, adequate image quality should always be made a priority, especially when aiming at lowering patient dose.

It is important to clarify that DRL values do not apply to individual patients and are not dose constraints that medical facilities must follow. Instead, they act as guidance levels for institutions to optimize their imaging protocols and practices by lowering patient dose to levels as low as reasonably achievable while ensuring diagnostic quality images.

DRL values are not static, and optimization of diagnostic examinations is a continuous process. As the technology advances, the software and hardware of imaging equipment are continuously improved and higher quality images can be obtained at lower exposure. Therefore, DRL values need to be updated as part of the optimization process. The proposed frequency of the update and review of DRL values is about every three to five years.

The DMS is useful in the dose reviewing process, as it can automatically collect and analyse patient dose data as per user requirements. The facility's DRL values can be updated more frequently and with ease. In addition, DRL values can be established for many more types of examination and procedure than with manual data collection, which would require more time and resources. Stratified DRL values depending on clinical indications may also be established with the DMS [19]. This allows the facility to evaluate many more different types of examination and patient groups, which then leads to improvement in their imaging practices in order to achieve greater optimizations for all patients. In healthcare services that involve medical imaging procedures, familiarity with the DRL process is essential for the optimization of clinical practice.

3.4. INFORMATION SYSTEMS

Information systems play a crucial role in streamlining the workflow and enhancing the quality of patient care in medical imaging [22]. These systems — including the HIS, RIS and PACS — are designed to be user friendly, allowing healthcare professionals to efficiently prepare and manage medical reports, patient images and demographic data, among other tasks. Most of these systems offer the functionality to utilize template-predefined generic reports that can be easily filled in by the reporting physician. This feature not only saves time but also ensures consistency and accuracy in documentation.

The HIS serves as the central information technology system of a healthcare facility, integrating all the critical patient information, including medical history, reports and administrative data. The HIS ensures that patient records are up to date and accessible, facilitating communication between various departments and improving the overall efficiency of patient management.

The RIS is a specialized database used to manage imaging orders and associated data within the medical imaging department. The RIS handles everything from patient medical imaging scheduling and tracking medical imaging procedures to storing detailed reports. It serves as the backbone for managing workflows, enabling practitioners or MRTs to access patient data, schedule appointments and maintain a comprehensive record of imaging studies.

The PACS is another critical component that facilitates the storage, retrieval, distribution and presentation of medical images. The PACS eliminates the need for physical film storage by digitizing images, making them easily accessible for review by various healthcare providers. The PACS also allows the automatic integration of images with the patient's electronic health record, ensuring that all relevant information is available in one place. Moreover, the PACS supports the storage of dose reports alongside images, enabling thorough documentation of patient exposure to radiation. The RIS is often integrated with the PACS to allow seamless management of images and reports.

For optimal efficiency, it is essential that these systems, particularly the PACS, have the appropriate permissions and programming to automatically store and manage images along with their respective dose reports. Ideally, once an imaging procedure is completed, the images and associated dose information are automatically transferred to the PACS, where they can be securely stored and accessed by authorized personnel. This automation can enhance workflow efficiency, reduce the risk of errors and ensure that all relevant data are accurately documented and readily available for clinical use.

3.5. CLINICAL WORKFLOW

Recognizing that clinical workflows can differ significantly among institutions and modalities, it is essential to outline a standard process for a medical imaging department to ensure efficient clinical outcomes and effective use of human resources. A well designed clinical workflow plays a critical role in the functionality of a DMS by integrating the clinical workflow into the DMS seamlessly in existing operations to streamline processes, improve data accuracy and enhance patient safety. By aligning with clinical workflows, a DMS ensures that dose data are collected and recorded efficiently at every step of the imaging process, from scheduling to reporting, without adding unnecessary complexity to the routine tasks of healthcare providers.

Typically, this process involves certain steps to ensure competent and successful patient care. These steps can include patient scheduling and preparation, imaging procedure execution, image processing and analysis, and review and reporting of results. Each of these steps requires meticulous coordination and adherence to quality and safety protocols to optimize patient outcomes and operational efficiency. An illustrative example relevant to a typical radiology department is provided in the following, although the principles are adaptable and can be applied to a diverse range of settings and circumstances.

(a) Appointment request:
    (i) The process begins when a clinician, often referred to as the referring physician, submits a request for a patient to undergo an imaging procedure. This request is typically based on clinical indications that suggest the need for diagnostic evaluation through medical imaging.
    (ii) The RMP then reviews the request to ensure that it is properly justified, considering both the patient's medical history and the clinical question at hand. If the RMP identifies any concerns or believes that an alternative imaging procedure would be more appropriate, the RMP might suggest an alternative examination. In such cases, it is crucial to have an open dialogue with the patient, explaining the rationale for the suggested change and discussing the potential benefits and risks associated with any unjustified or inappropriate imaging procedures.
(b) Medical imaging registration:
    (i) Once the request is deemed to be justified, the imaging procedure is scheduled at the radiology department. The scheduling process is designed to optimize the department's workflow while accommodating the patient's needs.
    (ii) The patient is provided with detailed information about the nature of the radiology study, including any necessary preparations that need to be completed prior to the procedure. For example, the patient may be instructed to fast for a certain period or to avoid certain medications. Additionally, any potential contraindications need to be assessed to ensure that the patient is fit to undergo the procedure.
    (iii) Patients are also advised to bring any relevant previous imaging studies (if available in soft or hard copy), which can be important for comparative analysis and for assessing changes over time.
    (iv) During registration, the patient's identification (e.g. medical record number) and study details (e.g. study description, accession number) are created and/or verified to ensure accuracy and prevent any potential mix-ups.
(c) Protocolling of study in the medical imaging department:
    (i) The next step involves the protocolling of the study, where the patient's medical history and clinical indications are verified to select the most appropriate imaging protocol. This step is crucial for ensuring that the imaging procedure is tailored to the specific diagnostic needs of the patient.
    (ii) The responsibility for protocolling may vary depending on the institution's policy, and in some cases, other qualified personnel, such as a senior RMP or MRT, may be involved in this task.

(d) Performing the study:
   (i) Before initiating the imaging procedure, the MRT confirms the patient's identity to ensure that the correct patient is being imaged, which is critical for overall patient safety.
   (ii) The MRT then verifies the clinical indication for the procedure, ensuring that it aligns with the requested imaging study.
   (iii) For female patients of childbearing age, the MRT follows the institution's protocols to confirm the patient's pregnancy status. This step is vital for minimizing potential risks to both the patient and the foetus, especially when ionizing radiation is involved.
   (iv) The MRT proceeds to perform the study using the appropriate acquisition protocol, ensuring that the images produced are of high quality and suitable for diagnostic interpretation.
   (v) Upon completion of the examination, the imaging device automatically generates images and dose reports. These reports, which document the radiation exposure during the procedure, may be automatically sent to a designated destination such as the DMS or the PACS. In some cases, the MRT may need to manually transmit these reports to the appropriate system.

(e) Medical report:
   (i) After the imaging study is completed, the RMP interprets the diagnostic images. This involves a detailed analysis to identify any abnormalities, patterns or findings that could explain the patient's symptoms or aid in their diagnosis.
   (ii) The RMP then completes the medical report, documenting the findings, conclusions and any suggestions for further action or follow-up studies. The report is a critical communication tool that guides the referring physician in managing the patient's care.

(f) Delivery of study results:
   (i) The final step in the process is the delivery of the study results. The completed medical report, along with the relevant imaging studies, is shared with the referring physician. This ensures that the referring physician has all the necessary information to make informed decisions about the patient's treatment plan. Depending on the institution's setup, the report may be delivered electronically through an integrated information system or, in some cases, a hard copy might be provided. In many European countries, it is advised — and in some cases, required by national legislation — to report the radiation exposure that a patient has received. The DMS can automate this process by seamlessly communicating with the software that generates the report, using established communication standards to ensure the accurate transfer of exposure data.

4. DMS TECHNOLOGY

The DMS is a sophisticated technology system. This section explores its key components, highlighting how each element contributes to the effective management of patient data. Understanding these components is essential for leveraging the full potential of a DMS in ensuring overall patient safety and regulatory compliance.

4.1. COMPONENTS OF A DMS

The basic architecture of a DMS (outlined in Fig. 3) has at least the following software architecture elements:

(a) A system capable of receiving information related to an X ray examination (e.g. patient demographics, examination protocol parameters, exposure parameters, geometric parameters), usually by means of the DICOM standard. The medical imaging systems can send this information directly or indirectly to the DMS workstation via the PACS, the RIS or the HIS.
(b) A system that reads and extracts the information to be stored in a database in a structured way. The structured database can be local or cloud based.
(c) A system can also add more information, which it calculates from the information obtained using internal algorithms.
(d) A system that gives access to this information through a user friendly interface; for example, by means of a web service.

The DMS can obtain dose metrics and other types of patient information from the PACS and the modalities and share them with the RIS and the HIS.

In the case of a local system in a small facility, with few X ray systems and users, the DMS can be basic and can be hosted in a personal computer. However, the DMS architecture can become complex when it needs to handle many hospitals at regional or national level with several hundreds of X ray units and the DMS has the capability to interact with the patients' health records, requiring several advanced hardware units and storing millions of records with complex data access policies.

The DMS can be physically installed in the institution or may be cloud based and maintained by the DMS vendor. Regardless of the deployment method, ensuring the integrity, confidentiality and security of stored data needs to be a top priority. This includes implementing robust access controls, data encryption, regular security audits and incident response protocols. Additionally, the system

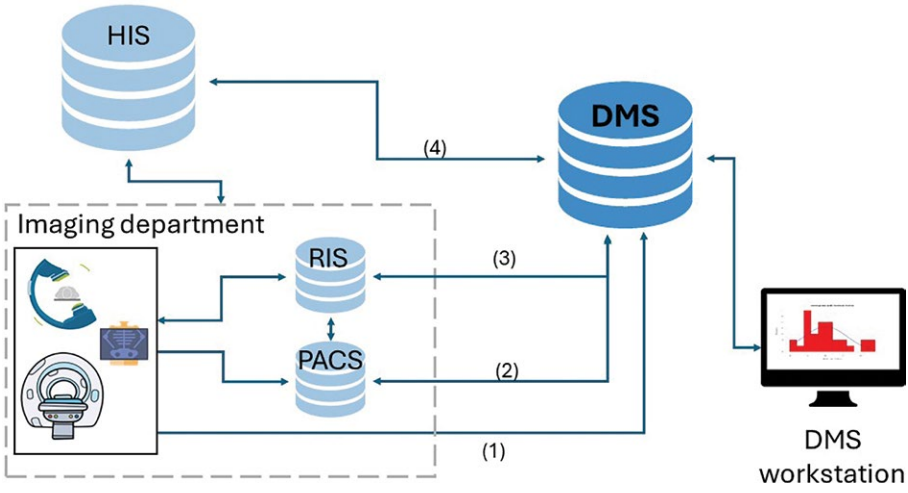

FIG. 3. Layout of the DMS communication architecture. Data can be supplied to the DMS via multiple paths: (1) direct input from the modality; (2) input from the PACS; (3) input from the RIS; (4) input from the HIS. Double-headed arrows indicate two-way communication.

needs to comply with national and international regulations concerning personal data protection. Maintaining compliance involves continuous monitoring, adherence to best practices and timely updates to address emerging security threats. Ultimately, safeguarding patient data is essential to maintaining trust, legal compliance and the overall functionality of the DMS. When the DMS stores or estimates parameters related to patient safety (such as the number of examinations performed within a specific period of time) that can affect patient care management, the system could be considered a medical device by some local regulations; in such cases, its design needs to comply with medical device requirements.

4.2. BASIC FUNCTIONALITIES

The following subsections provide a detailed description of the basic functionalities of the DMS.

4.2.1. Extraction of exposure information

The most appropriate way to extract the exposure information from the imaging studies is from the DICOM RDSR. The RDSR consolidates all irradiation events into a single, comprehensive record, detailing exposure

information for each event and eliminating the need to infer details from the DICOM headers of images stored in the PACS. Additionally, the RDSR captures and provides critical information on irradiation events that may not have produced any images sent to the PACS, ensuring that every aspect of the procedure is documented and accessible. Modern X ray systems can send the RDSR directly to the DMS or can store it in the PACS to be sent afterwards (sometimes the RDSR is queried and retrieved by the DMS). The main advantage of the RDSR is that it can include most of the information about the patient examination parameters (e.g. performed procedure, tube potential, tube current, time, filtration) in a small size file.

The DICOM standard has defined a set of RDSR data objects for recording and storing dose details in a DICOM study, including a generic template for any modality and more specific templates for CT, radiography, fluoroscopy, mammography and radiopharmaceuticals [15], where all the detailed information describing the patient exposure can be included, regardless of whether there is a single exposure from plain radiography or a complex FGIP with hundreds of different exposures.

It is also possible to retrieve patient exposure information from the DICOM metadata of the images stored in the PACS. In some DMSs, this requires retrieving the full imaging study from the archive, not just the RDSR; this has the drawback that the information traffic may increase significantly, in particular for CT, CBCT, breast tomosynthesis, PET-CT or other medical imaging studies that include a large number of images. This limitation may not be as important in small facilities with few X ray systems, but it is an important issue for DMSs with a regional or national scope, which might receive data from hundreds of facilities and systems. Another reason for a DMS to pull images from the patient study is to calculate certain metrics such as the water equivalent diameter (WED) and/or patient positioning metrics (e.g. to check how well a patient is centred in the CT scanner). For this reason, the RDSR is the preferred method for recording and storing dose details in a DICOM study [15].

In order to receive dose information such as fluoroscopy time, KAP (or DAP) and $K_{a,r}$ from angiography systems and other modalities, some DMSs take advantage of the dosimetric module of the Modality Performed Procedure Step (MPPS) DICOM class. In this DICOM service object pair class, in which X ray systems can send messages with information that describes the activities, conditions and results of an imaging procedure performed on a modality, information about the patient's exposure might also be included. By this means, it is possible to obtain data about the total cumulative dose indicators in a radiological procedure, but not about the single exposures. However, since 2017, the DICOM standard advice is not to include patient exposure information in MPPS messages but to use the RDSR instead, as this is the only DICOM object

Series	Type	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm
1	Scout	-	-	-	-
200	Axial	I10.580-I10.580	2.96	1.48	Body 32
201	Axial	I62.340-I62.340	26.64	13.32	Body 32
2	Helical	S70.500-I399.500	16.52	855.40	Body 32
3	Helical	S70.500-I399.500	16.53	855.80	Body 32
			Total Exam DLP:	1726.00	

FIG. 4. Snapshot of a dose report stored as a DICOM image by a CT system (courtesy of Hospital Clínico San Carlos, Madrid).

considered by the Integrating the Healthcare Enterprise Radiation Exposure Monitoring (IHE REM) profile [23].

When a medical imaging system produces dose reports as a secondary capture object, such as the report shown in Fig. 4, it is possible, at least for some DMSs, to extract the exposure information using an optical character recognition software. When the RDSR is not available, the dose report image can be used to extract some important exposure parameters. However, considering that many other parameters are missing, it is preferable to use the RDSR if available.

All the information obtained should be structured and stored in a database that will permit access to and analysis of the data, including the estimation of other variables related to patient exposure. In some cases, it could be necessary to correct or modify some recorded values (see Section 5.6). In that case, it is desirable that the DMS keeps the original parameter provided by the X ray system and adds the corrected value as a new corrected parameter. For example, in the case of a correctly calibrated KAP meter, this correction factor will be 1, but if the KAP meter is known to overestimate readings by 30%, then the correction factor will be 0.77. This new parameter can be then used instead of the original, and both should be kept on record. This correction factor can be also needed when the units in which a parameter is reported are different from the standard unit, in order to convert the parameter to the correct units. A person responsible for saving these correction factors needs to be designated and to have specific access rights to carry out this task. It is important to note that the detailed dose distribution along the *z* axis[1] during CT scans varies significantly

[1] The *z* axis in a CT system refers to the longitudinal movement of the scanning table during image acquisition.

with the variation of radiation dose across different slices. Traditional methods that utilize the average $CTDI_{vol}$ multiplied by the scan length may not provide a true reflection of the variation of organ doses within a single series. A more refined approach that considers the individual $CTDI_{vol}$ for each slice would be more beneficial. For example, in areas such as the lungs, where *z* axis modulation causes the radiation dose to fluctuate by a factor of 3–4, calculating the dose per slice could provide a more accurate estimate of the radiation received by the lung and breast tissues.

It is important to note that some dosimetric parameters of interest for dose management, such as dose metrics or protocol names, are optional data elements of type 3 or 'user option' in the DICOM standard [24, 25]. This means that manufacturers are not required to include these parameters in the DICOM information of the studies or in the RDSR, allowing them the discretion to omit such data while still remaining DICOM compliant. Consequently, the performance of any DMS is inherently dependent on the amount of information provided by the medical imaging system. Moreover, even for data elements that DMS vendors do choose to include, the interpretation of the DICOM standard can vary significantly across medical imaging manufacturers. Unfortunately, there are instances where this interpretation is not only inconsistent but also demonstrably incorrect. The minimum needed information related to X ray exposure that should be stored by a DMS has been outlined in documents from various scientific societies [4, 26]. Furthermore, the DICOM standard, while comprehensive, includes many non-mandatory fields and optional data elements that manufacturers are not required to implement. This variability can result in inconsistent data being provided by different imaging systems, potentially affecting the accuracy and completeness of the information transmitted to a DMS. The DMS developer needs to be able to accurately interpret the DICOM conformance statement provided by the medical imaging equipment manufacturers. It is essential that the CQMP ensure that this document is correctly identified and thoroughly understood to guarantee proper integration and functionality between the DMS and medical imaging systems.

4.2.2. DMS dashboards

The usefulness of a DMS is inevitably correlated with how user friendly the access to the information is. The dashboard in a DMS should display the key pieces of information that need to be accessed easily and quickly; for example, activity descriptors such as number of procedures performed in different rooms, the median values of dose indicators, temporal trends or specific notifications alerting about anomalies. Some DMSs provide several dashboards dedicated to specific X ray modalities or tasks, with graph, table, calendar or other views.

A desirable characteristic of a dashboard is customizability, enabling users to adapt one or several dashboards to their specific needs. The system should also allow the user to query specific pieces of information by using a flexible set of filters (e.g. by modality, date, type of procedure, patient age, X ray system, department, various DICOM tags) to search the information at patient single exposure level, or to download the information in table format for further analysis with other external software or another programming language (e.g. Excel, R, python).

4.2.3. Patient dose audits

Among the basic functionalities of a DMS, the ability of performing patient dose audits (i.e. to check, for example, the median values of dose metrics of a sample of patients versus national DRLs) can be considered as the most important functionality, as it helps to achieve compliance with some regulatory requirements. It is important to note that using a DMS for patient dose data collection eliminates the need to include only standard sized patients, because the system can collect and analyse all patient data. If it is possible to include a DRL library for the clinical examinations desired, it would be possible to automate this operation.

DRLs can be established at local, national or regional level, and it is the responsibility of the user — typically, the CQMP — to create and maintain the DRL library. The CQMP should have the appropriate access permissions within the system to manage and update the DRL library as needed. It is important to note that, as proposed by the ICRP [17], the median (not the average) of the patient dose indicators is to be compared with the respective DRLs values; therefore, the DMS should allow the estimation of the median and other percentiles.

Reference [17] also clarifies that DRLs are not meant to audit individual patient doses but rather to assess a sample of patients undergoing the same type of procedure. The median values from such a sample are intended to represent the expected values of the dose metrics for a typical patient with average body size and standard procedure complexity. It is understandable that individual dose metrics values of obese patients or of high complexity procedures are expected to be larger than the dose in a typical patient and may exceed the DRL.

4.2.4. Notifications and alerts

The ability to perform automated analysis of various aspects of patient dose audits and to generate notifications when specific criteria are met is an exceptionally valuable feature for a DMS. For instance, a monthly automatic comparison of the median KAP value for a specific X ray room and procedure

against the local or national DRL value, with a notification generated if the DRL is exceeded, would be immensely useful. Obviously, manually conducting this comparison for all procedures and facilities would require significant effort and time, making this automated functionality essential for establishing regular and efficient monitoring programmes for patient doses.

Furthermore, notifications can be triggered when a predefined threshold is exceeded, prompting investigations into individual cases [9]. This is particularly beneficial in a patient follow-up programme for potential skin injuries in FGIPs. For example, consider a scenario where the same patient undergoes multiple FGIPs over a few weeks, with each procedure reaching $K_{a,r} \approx 2$ Gy, and the cumulative dose from all procedures exceeds 5 Gy. DMSs can be invaluable in ensuring that such patients receive appropriate instructions and follow-up care when they have potentially received a high cumulative skin dose from multiple procedures, instead of just one. This capability is vital for safeguarding patient health and optimizing clinical outcomes.

An alert system can also inform about outliers detected (i.e. individual diagnostic studies with extreme doses — low or high), a compromising image quality or the delivery of an excessive and unnecessary amount of radiation dose, in order to investigate the root causes (e.g. a malfunction of the system, incorrect use of the X ray system, selection of the wrong acquisition protocol, repetition of a procedure that increases the risk of erythema or other deterministic effect) and find a solution.

Alerts can be in the form of emails, colour coded data shown in the dashboard, or any other means available in the DMS. A DMS might have options for users to subscribe to different types of alert.

Any generated notification should be investigated and may require reports and/or actions from the relevant members of the DMS committee.

Integration in the DMS of a functionality that gives a response (by means of a comment or a report written by a qualified expert) to any notification or alert generated would greatly facilitate the management of such alerts. If the number of notifications received exceeds the capacity of the DMS team, this functionality could become unusable. That is why the design of notifications and alerts should be carefully managed by the DMS team through the designation of a specific user profile to create and maintain a reasonable number of notifications.

4.2.5. Categorization of radiological procedures

One of the most critical parameters related to the dose management process is the correct identification of the type of medical imaging procedure, with a particular emphasis in radiological procedures, which requires a specific functionality to be correctly addressed by a DMS. This identification reflects the

examined body region but also the intent (i.e. clinical indication) and therefore shapes the requirements on image quality, which inevitably affects the radiation dose and the exposure parameters selection in the X ray unit. For example, in the abdominal region, a CT study intended to detect liver lesions has different requirements on radiation dose and image noise than a CT study for the detection of kidney stones.

To analyse efficiently patient dose related information, it is necessary to categorize or classify in the same group all the examinations that are similar in terms of anatomical area examined, clinical indication and/or radiation dose requirements. This should be done irrespectively of whether these examinations have been labelled with the same or different names during the procedure workflow. To mitigate the risk of undetected errors during the imaging process, it is important to recognize that despite significant advancements in DMS functionalities, these systems are not yet equipped to identify every type of procedural error. For example, if a CT scan of the knee was requested but a CT of the hip was mistakenly selected on the CT scanner, most DMSs would not automatically flag this discrepancy. Although DMSs can provide quality checks on data, this function is not routinely implemented.

The type of radiological procedure can be introduced by the referral in the HIS when the procedure is requested; it can be added by the medical imaging administrative staff in the RIS; it can be edited by the RMP or MRTs; and it should be linked to a specific acquisition protocol in the X ray unit, which, in many cases, has a name or label that might have been set by the X ray unit manufacturer.

There are specific DICOM tags used to include this process in the patient radiological information (e.g. requested procedure description (0032,1060); performed procedure step description (0040,0254); protocol name (0018,1030)) that should be included in the DMS, and the naming of the type of procedure in these information sources should be harmonized to avoid the misclassification of the radiological procedure in terms of clinical intent and/or radiation dose. However, achieving this harmonization can be very challenging, especially when multiple medical imaging systems are used for the same examination, each potentially employing different nomenclature. Moreover, some manufacturers do not accurately report certain DICOM tags, further complicating this process. For example, there are instances where a CT manufacturer fails to provide correct protocol names for scans conducted in combination studies, leading to significant discrepancies in data reporting and interpretation. The problem of harmonization is further complicated when considering the interconnection of different information systems such as the HIS, RIS, PACS and medical imaging systems, which should all use the same naming for each specific examination to ensure correct examination grouping; this is not often true in daily practice.

Another challenge is that the nomenclature used at the HIS/RIS level is designed for billing purposes and often differs from the terminology used to describe procedures — especially in interventional settings. To address this problem, some scientific societies and organizations have proposed a standard system for naming radiological procedures [27–29].

A DMS could help to improve the identification of the type of procedure by incorporating any of these standard naming systems, including customized libraries to classify radiological tasks according to the type of procedure, acquisition protocol and DRL. It could be helpful to utilize 'master protocols', which can be defined as a set of labels created by the DMS administrator to categorize the acquisition protocols recorded in the system. These master protocols can be mapped to clinical tasks and DRL values to ensure consistent and accurate data classification. It is important to clarify that these master protocols may need to be applied at different levels, depending on the specific needs and capabilities of the DMS. For instance, they could be applied at the study level, the level of individual irradiation events or at the acquisition protocol level (e.g. where scans within a study share the same protocol name DICOM tag). The flexibility to implement master protocols at any of these levels is crucial. However, it is worth noting that some vendors allow standardization of the naming only at the study level, which may limit the granularity and precision of the protocol categorization. Therefore, understanding the limitations and capabilities of the specific DMS in use is essential for effective implementation of master protocols.

Using the master protocol methodology, it is possible to group all procedures with the same clinical intent, or perhaps different radiological procedures that are well known to have the same radiation dose requirements, and coming from different medical imaging rooms in the same master protocol, irrespective of their protocol naming. In this way, the DMS can treat all data related to differently named studies as being the same study type in terms of radiation dose needed.

The classification of clinical procedures is explained in more detail in Section 5.2.4.

4.3. ADVANCED FUNCTIONALITIES

The following subsections offer a comprehensive overview of the advanced functionalities provided by the DMS, highlighting features that support enhanced dose management, image quality assessment and protocol management, among others.

4.3.1. Skin dose map and peak skin dose

In FGIPs, dose monitoring is of particular importance, as it is possible to deliver high radiation doses to patients, with a non-negligible risk of skin injuries. The PSD is the radiation quantity used to trigger investigation of potential skin injuries [30, 31]; however, at the time of writing, it is a quantity that most angiography X ray units do not provide. It is important to note that some regulatory bodies may have specific requirements for monitoring and reporting PSD in FGIPs.

To estimate the PSD, detailed technical data from each X ray projection during the FGIP are needed. Some DMSs can store and manage this critical information for accurate dose calculation, while others cannot. For a truly accurate estimation of the PSD, it is also essential to have precise data on the patient's position and size — information that is often lacking. Additionally, it is necessary to obtain information about the transmission factor of the patient table and pad, as well as a possible correction factor for the displayed K_i. Both pieces of information should be supplied by the user. However, it is important to note that if user specific measurements are not provided, some vendors may apply default values instead. For these reasons, a wide range of solutions with varying levels of accuracy exists, depending on the availability and quality of information used for PSD estimation [32].

Some DMSs provide the projection of all X ray beams on one specific plane, others on a cylindrical phantom and, the most sophisticated DMSs, on an anthropomorphic phantom (Fig. 5). A DMS capable of storing exposure information at the radiation event level can incorporate methods to estimate the PSD, aiding in patient follow-up programmes for potential skin injuries. However, this is effective only if the methodology used is clearly described, along with its limitations. All estimation results, based on the available patient exposure data and the applied algorithm, should be thoroughly evaluated and approved by a CQMP to ensure accuracy and reliability.

4.3.2. Patient size estimation

Patient radiation dose is strongly influenced by the patient's size, making it essential to include this parameter in dose monitoring. This ensures that the radiation administered is appropriately adjusted to the patient's size. Analysing the behaviour of automatic exposure control in clinical practice is crucial, as it provides real world insights that complement the evaluations performed by a CQMP using phantoms. In most cases, obtaining patient weight and height is challenging, as this information usually has to be manually entered by personnel not directly involved in radiation dose monitoring or retrieved from other

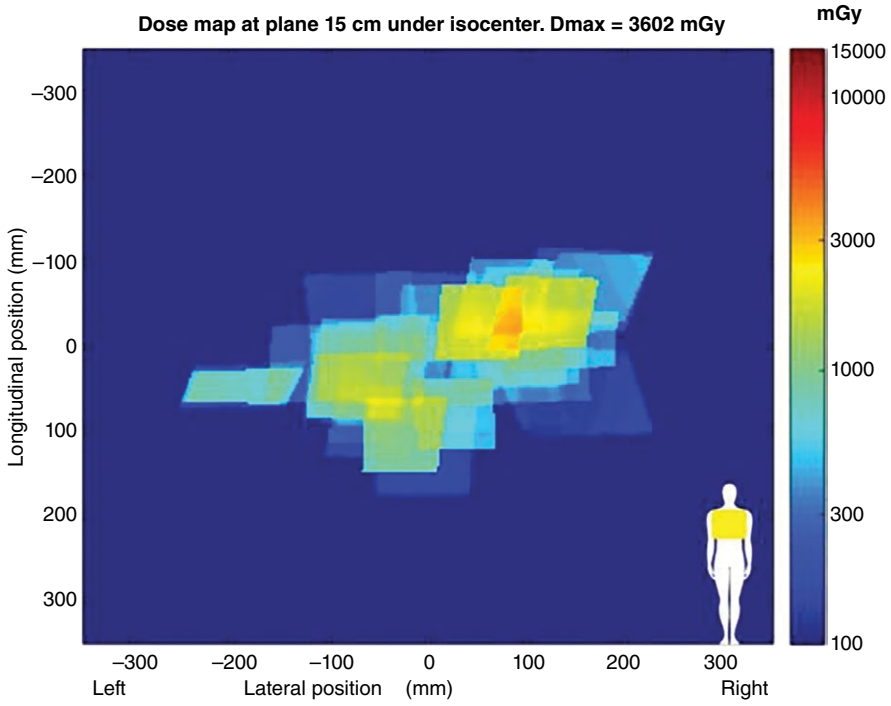

*FIG. 5. Example of skin dose mapping and PSD. The maximum skin dose (Dmax) is 3602 mGy. The axes represent the lateral (*x *axis) and longitudinal (*z *axis) positions on the skin surface. (Image courtesy of Hospital Clínico San Carlos, Madrid.)*

databases with complex access policies. This often leads to incomplete records, with patient size data frequently left blank. An exception exists in mammography, where the unit can provide the compressed breast thickness (CBT). However, this capability is generally absent in other imaging modalities. Nevertheless, in general, medical images inherently capture the shape of the patient's body, making it possible to extract patient size information from CT scans [33] or plain radiographs [34, 35].

In the case of CT, the effective diameter and WED are the preferred quantities to account for patient size when estimating radiation dose and optimizing image quality [36–38]. The SSDE, which combines patient size information with scanner output, is suggested by the American Association of Physicists in Medicine as a basic dose indicator to be included in DMSs for CT optimization [26]. These quantities have been standardized for worldwide use through an International Electrotechnical Commission norm [39]. It is worth noting that many modern CT scanners can estimate patient size from the localizer acquisition and use this information to apply automatic current modulation during

axial or helical scans. However, at the time of writing, some CT manufacturers do not include key patient size metrics — such as effective diameter, WED or SSDE — in the RDSR. This omission presents a significant challenge for accurate dose monitoring and optimization in CT imaging.

In cases where the X ray equipment does not provide patient size information, the DMS can utilize specialized algorithms to estimate patient thickness from X ray images. This capability aids in analysing the performance of automatic exposure control systems, contributing to the optimization of medical imaging practices and enhancing overall dose management. When this functionality is available, the CQMP overseeing the process needs to verify the accuracy and assess any uncertainties in the patient size estimation. Additionally, DMS vendors should be proactive in addressing any issues identified by CQMPs, promptly providing patches and updates to ensure that their system consistently performs the calculations accurately and as intended.

4.3.3. Image quality

Optimizing image quality is the most important part in the optimization process in medical imaging, and it would be desirable for DMSs to provide tools for its proper management. As the DMS deals with dose and other information from clinical studies, the correct way is to include an assessment of the image quality in clinical studies and not in phantom studies. The difficulty of dealing with the image quality assessment of clinical studies has had as consequence that some DMSs did not include this functionality as basic or essential [4, 26]. The European Society of Radiology recommends [4]:

> "For each dose entry, a link to the corresponding image or series of an individual examination should be provided so that the images can be accessed quickly in order to visually assess the patient's dimensions and the image quality."

Some DMS providers have proposed to estimate automatically a 'noise index' from clinical images using published methodologies [40, 41] in order to include some image quality indicator in the analysis for some specific CT studies. There are also proposals to use artificial intelligence to estimate image quality, although currently such tools are not yet commercially available [42]. Once implemented, these technologies could help to establish relationships between dose indices, patient size, image quality and noise levels, further enhancing optimization efforts. This should be managed and analysed by a CQMP, as the noise index estimation is not as standardized as that of, for example, $CTDI_{vol}$ or of the SSDE. It would also be beneficial to include additional image quality

indicators, such as spatial resolution and low contrast detectability, detectability index or preferably a parameter that describes image quality on the basis of clinical criteria. This would provide a more comprehensive assessment of image quality in relation to patient care.

4.3.4. Protocol management

One of the challenges in the optimization of medical imaging clinical practice is protocol management. This is especially critical in CT imaging, where the number of acquisition protocols can extend into the hundreds, and variants of these protocols can number in the thousands. Unintended changes or errors in acquisition protocol settings could significantly impact the outcome of the CT examination, potentially affecting image quality, patient dose or both. This is particularly important in the case of multiphase patient studies. For this reason, the American College of Radiology has advocated for appropriate acquisition protocol management, which includes periodic reviews to identify and correct any unintended changes or errors that may arise [43]. It has been demonstrated that unintended changes in CT acquisition protocols can be detected within relatively short periods of time, especially when compared to the overall life cycle of a CT scanner [44, 45].

A DMS can incorporate functionalities to retrieve acquisition protocols stored in CT units and compare each technical parameter with the corresponding master protocol (as agreed upon by the medical imaging department) stored in a master protocol library. There is a DICOM object for protocol storage management that includes the description of a defined protocol for comparison with the acquisition protocol. This allows continuous verification of the correctness and consistency of the acquisition protocol. When paired with suitable reporting and notification functions, this feature can significantly streamline acquisition protocol management, a critical task in any medical imaging department.

4.3.5. Reject/repeat rate analysis

A basic task in the QA programme of a medical imaging department is to check if there is an irregular repetition rate of medical images in any room or facility [46]. In the screen film era, this was a labour intensive process, as rejected X ray films from a specific period had to be manually counted and compared with the total number of radiographs performed to calculate the reject/repeat rate. The assumption was that every rejected film resulted in a repeat radiograph, making the reject and repeat rates equal.

For a proper reject analysis, the rejected film had to be reviewed (most often retrospectively) to determine the rejection reason. In modern digital X ray

systems, the images that are not acceptable or are of low diagnostic quality can be rejected. When an image is rejected, the operator can select the rejection reason from a list (e.g. wrong positioning, patient motion, too noisy). The rejected image will not be sent to the PACS, but the total number of images and rejection reasons can be recorded and analysed. Identifying the most common rejection reasons in the different rooms may be useful for selecting the appropriate course of action. For example, many noisy images may be due to the wrong automatic exposure control system adjustment or the use of manual instead of automatic techniques in a certain X ray system. Nevertheless, images rejected because of improper patient positioning (which leads to anatomical cut off) or collimation can be frequently attributed to the MRT's error, although lack of patient cooperation and patient movement may also be the cause. In addition, reject/repeat analysis is not just about improving efficiency but also about reducing unnecessary patient radiation exposure. Each rejected image represents an additional radiation dose to the patient, so reducing reject rates can have a significant impact on patient safety.

Further analysis can help to identify whether the majority of rejected images are linked to a particular facility (e.g. the emergency department), specific shift (e.g. night shift) or even a specific operator who may require additional training. If this information is stored in a DMS, the reject analysis could be easily performed. This can be applied in all modalities, including CT, mammography and fluoroscopy.

4.3.6. Organ dose and effective dose calculation

Radiological risk, particularly the risk of stochastic effects such as cancer, depends on several factors, including the absorbed dose, but also on the type of radiation and the radiosensitivity of the exposed tissues or organs. As mentioned in Section 3, the effective dose E is often used in radiological protection to represent the overall risk to the body by taking into account the different sensitivities of organs to radiation. The effective dose can be useful for comparing the dose delivered by different imaging modalities when planning a patient exposure, and it is periodically requested in national surveys by the authorities for collective dose evaluations.

Occasionally, both physicians and patients request dose estimations for specific medical imaging examinations, such as when a pregnant woman undergoes X ray or nuclear medicine procedures, to assess the potential risk. To address this need, some DMSs currently offer advanced functionalities that include the calculation of patient organ doses and/or E. These functionalities can help healthcare professionals to provide more precise dose estimates in sensitive cases or situations where detailed dose information is critical. It is essential to keep in mind that E is not the preferred quantity for patients' dose tracking [16], and

measured or estimated quantities such as KAP or $CTDI_{vol}$ are more suitable for this purpose. It is also important to note that risk estimation based on organ doses is subject to high uncertainties, and health specialists should be cautious in their use, in particular when dealing with the risk assessment for individual patients.

The Biological Effects of Ionizing Radiation committee has stated that "Because of the various sources of uncertainty it is important to regard specific estimates of LAR[2] with a healthy skepticism, placing more faith in a range of possible values" [47]. The ICRP has recently stated that "Although doses incurred at low levels of exposure may be measured or assessed with reasonable accuracy, the associated risks are increasingly uncertain at lower doses" [16]. The American Association of Physicists in Medicine "recommends against using dose values, including effective dose, from a patient's prior imaging exams for the purposes of medical decision making" [48]. Finally, the IAEA states [9]:

> "As a first-order approximation, radiation risk as the probability of fatal cancer can be estimated from effective dose using the approximated overall fatal risk coefficient of 5% per sievert...However, the method has limited applicability to individual patients, as it ignores differences in age, sex and health status between the population undergoing medical imaging procedure and the population for which the nominal coefficients were derived."

Accurate organ dose calculation necessitates detailed information about the radiological procedure, which can be easily stored in a DMS. With the appropriate tools and algorithms, these systems can automate the process, streamlining dose calculations and reducing the burden on healthcare professionals while improving accuracy and consistency. For organ dose estimation, the necessary information extends beyond the exposure and geometric factors; it is also crucial to know the specific anatomical area that was exposed during the procedure. This can be difficult if a certain acquisition protocol has not been assigned to a respective anatomic area and irradiation geometry. Currently, DMS vendors apply the following approaches to estimate *E* with different levels of accuracy:

(a) Using published multiplying conversion factors, that relate a type of radiological procedure and respective dose quantity (e.g. KAP, DLP) with *E*. It should be noted that published conversion factors are not intended for the estimation of *E* for individual patients, as they are typically generalized for broader population studies and may not account for patient specific characteristics [49]. These factors were originally developed for collective dose estimation based on specific patient sizes and exposure conditions,

[2] LAR: lifetime attributable risk.

which may differ significantly from those of the individual patient being assessed. As a result, using these factors for individual *E* estimations can lead to significant uncertainties and inaccuracies. No organ dose information can be provided with this methodology.

(b) In the case of CT, if SSDE values are available, organ dose and *E* can be roughly calculated using published data [50]. In this case, the patient size is considered, but the actual irradiated body region is approximated. This method has also limitations.

(c) Utilizing specialized software to estimate individual organ doses and *E*. This method can provide more accurate results by incorporating a precise model of the patient's anatomy and the specific body region exposed. Enhanced accuracy can also be achieved by factoring in detailed information about X ray beam quality and the distance between the patient and the radiation source. This method, often employing Monte Carlo simulations, offers the highest level of precision but may require user interaction to ensure that the results are reliable and acceptable.

Whether automatically calculated by the DMS or manually tailored for a specific patient (such as a pregnant woman), any organ dose or *E* estimation method needs to be reviewed and validated by a CQMP. Additionally, any limitations of the method should be clearly communicated to ensure proper understanding and interpretation of the results. DMS vendors bear significant responsibility in this process. They should be fully transparent about the methodologies that they are utilizing and should ensure that these methodologies are implemented accurately and consistently. Moreover, vendors should be held accountable for the correct application of these methods, as any discrepancies can impact the overall reliability and effectiveness of the DMS in clinical practice.

4.3.7. Occupational dosimetry in fluoroscopically guided interventional procedures

Professionals involved in FGIPs can be exposed to high levels of scatter radiation, sometimes exceeding annual dose limits, making their radiological protection an ongoing challenge. The ICRP has suggested managing occupational dosimetry in FGIPs in conjunction with patient dose monitoring to enhance safety for healthcare workers [51, 52]. For this purpose, it is necessary to store the occupational dose information associated with the patient dose information for FGIPs.

This can be achieved using the occupational dose recorded by a compatible electronic occupational dosimetry system (Fig. 6). As shown in the figure, patient dose information provided by the X ray unit and the occupational

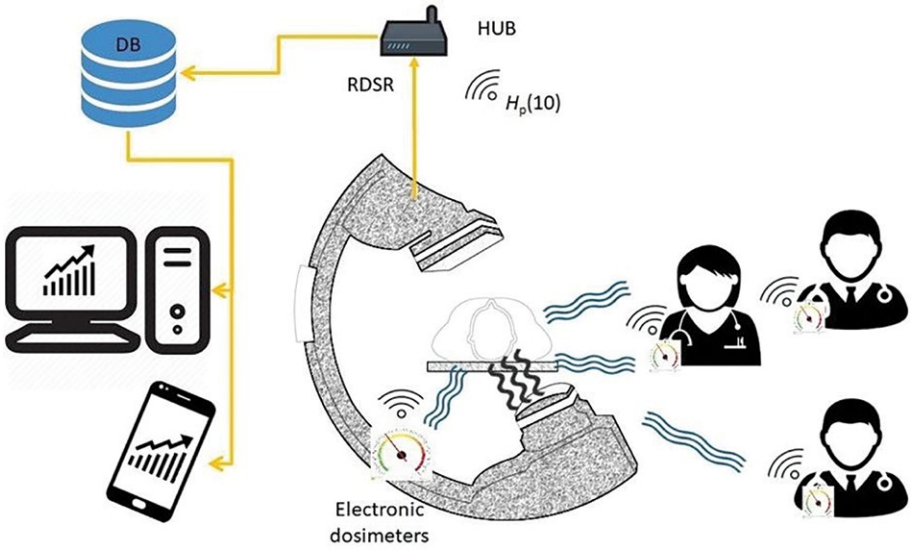

FIG. 6. Schematic representation of a patient and occupational DMS for FGIPs (courtesy of Hospital Clínico San Carlos, Madrid).

records provided by compatible electronic personal dosimeters are received by a central unit called HUB, which creates an occupational dose report structured at procedure and radiation event level. This report can be archived in the DMS and can be used for the joint optimization of both patient and occupational dosimetry in FGIPs. Therefore, in the information recorded for any irradiation event, the occupational dose and dose rate measured by the dosimeters present in the room during these irradiation events can also be obtained (Fig. 7).

The electronic dosimeter system (labelled HUB in Fig. 6) needs to be able to receive the patient dose information and the professional occupational dose and to arrange them in a report structured at irradiation event or procedure level. Then, a DMS could present the occupational dose in a more detailed format to help in the optimization process. Finally, the occupational dose for a specific procedure and interventionalist can be analysed as shown in Fig. 7. In this figure, each bar represents the occupational dose Hp(10) measured at the chest over the apron at each irradiation event. The interventionalist received cumulative doses smaller than 5 μSv at the beginning of the procedure, and higher occupational doses of up to 50 μSv per event afterwards. The total cumulative dose received in this procedure by the interventionalist at chest height over the apron was 973 μSv, causing an alert in the system.

This functionality also allows the classification of occupational doses received by a professional according to the type of procedure performed,

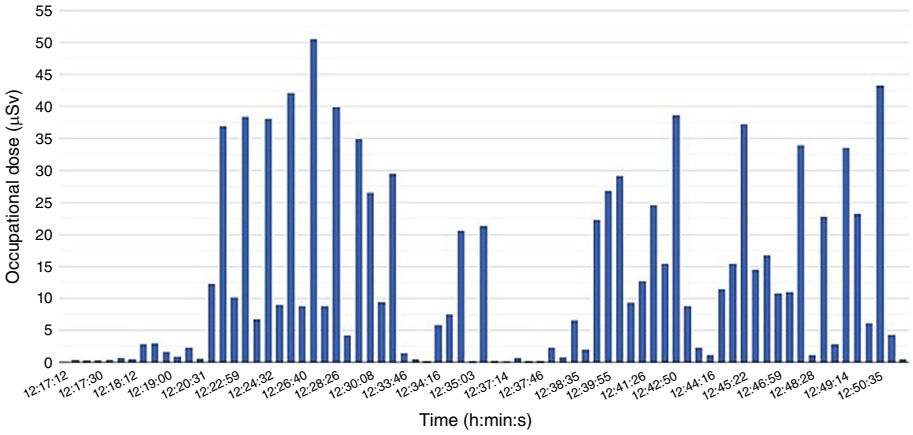

FIG. 7. Graph presenting the cumulative occupational dose for one professional recorded during an FGIP (biliary drainage) by a DMS (courtesy of Hospital Clínico San Carlos, Madrid).

enabling tailored advice to improve their radiological protection. For instance, Fig. 8 illustrates the cumulative dose received by an interventionalist over a six month period. This graph was created with Microsoft Excel using the information provided by a DMS and shows the occupational dose received by an interventional radiologist, as monitored by an electronical dosimeter worn at chest height over the apron. The procedures classified as 'central venous catheter insertion' contributed the most to the total occupational dose. The information is specific and personal to the interventionalist wearing the electronic dosimeter and may or may not be applicable in general for all interventionalists. It was observed that the cumulative dose over the apron (20 mSv) was high enough to consider the professional at risk of exceeding the dose limit for the eye lens. With this information, tailored advice can be provided to the professional, highlighting which specific procedures contributed the most to their occupational dose. This insight helps to prioritize optimization measures to reduce radiation exposure.

This functionality permits radiation protection officers and CQMPs to explore the possibilities of FGIP optimization together with the interventionists. The example presented here concerns a prototype that is not commercially available. For a more widespread use of this functionality in DMSs, efforts by industry and stakeholders are still needed for the normalization of occupational information recorded by electronic dosimeters.

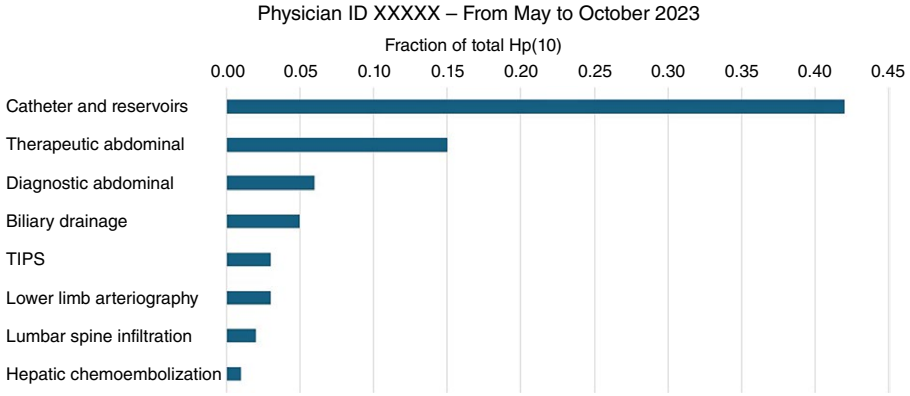

FIG. 8. Cumulative dose received by an interventionalist over a six month period. TIPS: transjugular intrahepatic portosystemic shunt. (Image courtesy of Hospital Clínico San Carlos, Madrid.)

4.3.8. Tracking patient exposure history

In 2012, the IAEA and several key stakeholders released a joint position statement on patient radiation exposure history [53]. It was agreed that tracking a patient's dose exposure history could assist referring physicians and RMPs in avoiding unnecessary repeat examinations. Additionally, this practice can offer significant advantages to policymakers, regulators and researchers by providing comprehensive, detailed quantitative data on patient exposure in radiology, supporting more informed decision making and policy development.

It is also important to note that some scientific societies have raised concerns about using a patient's cumulative dose as a basis for justifying new diagnostic procedures involving ionizing radiation [48]. More specifically, "the decision to perform a medical imaging exam should be based on clinical grounds, including the information available from prior imaging results, and not on the dose from prior imaging-related radiation exposures" [48]. In an effort to establish a unified approach to managing radiation exposure from recurrent imaging, the IAEA assembled a panel of experts to find common ground. This initiative resulted in clearer suggestions regarding radiation exposure in recurrent imaging practices [54], and it highlights the need for careful consideration of cumulative exposure in clinical decision making, ensuring that each procedure is appropriately justified on its own merits.

The DMS, which records patient exposure information, can assist in this effort. However, it is important to emphasize that cumulative dose data should not be used as the sole factor in justifying new diagnostic procedures. Furthermore,

this challenge cannot be fully addressed at the hospital level alone; it requires action at the national or regional level by assigning a unique identifier to patients, regardless of the hospital or country where the ionizing radiation exposure occurs. Implementing such a system remains a challenge for many countries and regions.

5. SETTING UP A DMS

The implementation of a DMS in a healthcare institution is a process that involves multiple groups of people and departments at its different stages. Owing to the complexity of the system configuration, setup and maintenance, a DMS committee should be established as described in detail in Section 2.

Each user group should establish the purpose and goals to be achieved by using the DMS. While the primary purpose is often to ensure that the institution achieves compliance with regulatory and accreditation requirements, which may vary between countries, goals can be tailored on the basis of local needs and priorities and can include, but are not limited to, the following (not presented in hierarchical order):

— Quality improvement, which includes identifying areas for development in medical imaging acquisition protocols, equipment performance and staff training;
— Trend analysis;
— Outlier analysis;
— Establishing local DRLs;
— Comparison of local DRLs against national DRLs (if available);
— Comparison of patient doses and DRLs against the literature;
— Inter- and intra-institution dose level analysis.

5.1. INITIAL INSTALLATION

The installation of a DMS requires substantial support from the hospital's information technology staff, who need to fully understand the scope of the project and allocate adequate time and personnel to its implementation. Information technology support should coordinate with various departments, including PACS administrators, imaging system service engineers and hospital networking teams, to ensure seamless integration. Additionally, information technology staff need to ensure that the necessary infrastructure for the DMS

is established, whether through standalone servers within the hospital, through a virtual machine within the hospital's information technology environment or through a cloud based service. This coordinated effort is critical for the smooth and effective installation of the DMS.

If the DMS is purchased from a vendor, the vendor's engineers should handle the software installation and ensure that basic setup is properly completed. In contrast, if the DMS is open source software, additional information technology staff may be needed, as the developers often do not provide installation or maintenance support. Section 7 offers a detailed overview of the QA programme, including key components such as acceptance testing, commissioning and routine QC. However, owing to the importance of these steps during the setup process, a summary of the essential procedures is provided below to emphasize their significance and ensure a clear understanding from the start.

After the software has been installed and all systems are connected and reporting data, the CQMP needs to perform acceptance and commissioning testing. This is essential to verify that received data are accurately stored, including key parameters such as dose metrics and values, units, date and time formats, and other relevant information. These tests ensure that the DMS is functioning correctly and that all data are reliably captured and reported (Sections 7.1, 7.2).

After completing the installation of the DMS, it is important to perform regular QC (Section 7.3). The data flow should be monitored to ensure that the expected number of examinations is received, as per the hospital electronic medical record. For example, changes in the facility's information technology network, or equipment software updates, can cause disruptions and loss of data. The user groups work with the DMS administrator to manage the addition of newly installed equipment, or equipment that is taken out of service. The user group also works with the DMS administrator to manage user permissions. It is important to note that the DMS vendor plays a crucial role in facilitating these processes. For example, routine monitoring of data flow can be an automated feature of the DMS. For instance, if an X ray system suddenly stops reporting studies for a day or more, the DMS can be configured to automatically alert one of the users. Users do not need to create their own manual processes for checking whether medical imaging equipment is still reporting to the DMS; this essential function can be integrated and supported by the DMS to ensure continuous monitoring and prompt response to any disruptions.

5.2. DATA CATEGORIZATION

Healthcare facilities produce large amounts of radiation dose data and other data. In order to aggregate these data into meaningful and actionable

summary statistics and reports, each incoming radiation dose report needs to be categorized. To accomplish this, DMSs have multiple predefined organizational structures, which are typically based on the location of equipment, the type of equipment, as well as the clinical examination type and imaging protocol. These hierarchies may be independent and can include the following:

— Institution.
— Equipment type.
— Equipment model.
— Medical procedure or clinical task that can be described by order code or study description.
— Imaging protocols:
  - Acquisition protocols;
  - Master protocols.
— Other (e.g. vendor, dual-energy capability).

The DMS user groups are responsible for defining and setting up these organizational structures according to the structure and needs of their institution. Each user group is responsible for analysing and reviewing data, setting up dashboards and generating radiation dose reports for radiation safety committees, protocol review committees and other facility-wide hospital quality review committees. Depending on national regulations, there may be mandatory or voluntary dose reporting requirements. For example, in the United States of America (USA), while there are no mandatory dose reporting requirements, many facilities voluntarily report paediatric radiation doses to Leapfrog, which is a non-profit organization that collects and analyses data to inform value-based purchasing and improve decision making actions[3]. Many health care facilities may participate in the Dose Index Registry of the American College of Radiology[4]. There are also a number of US Joint Commission accreditation requirements that DMSs can help the user to satisfy. The European Commission states [55]:

> "Member States shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration where appropriate the distribution by age and gender of the exposed."

[3] https://www.leapfroggroup.org/

[4] https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry

5.2.1. Categorization by location and equipment type

The purpose of data categorization is to help the user to access information quickly and create meaningful reports. DMSs generally provide categorization schemes, but these can vary significantly and may not always be user customizable. Therefore, it is crucial that the user group thoroughly understands how their system categorizes data and sets up the scheme carefully.

An important type of categorization is by location and equipment type, which allows users to group data on the basis of the specific facilities and imaging equipment used. This can help to differentiate between imaging departments, such as radiology or cardiology, as well as distinguish between different modalities such as CT, mammography or X ray units. Categorization by equipment type can also be helpful in comparing performance or dose metrics values across various machines, making it easier to pinpoint areas for optimization. The categorization structure will be tailored to meet the specific needs of the institution, region or country, depending on the scope and requirements of the DMS. This careful setup ensures that reports generated are relevant and meaningful for improving workflow, safety and patient care.

5.2.2. Institution level categorization

An example of an organizational structure for a multicentre healthcare enterprise is shown in Fig. 9. In this example, the healthcare enterprise consists of two institutions. One institution (A) is a hospital with medical imaging services in the department of medical imaging and in the department of radiation oncology. There may be additional departments that utilize radiation based imaging, such

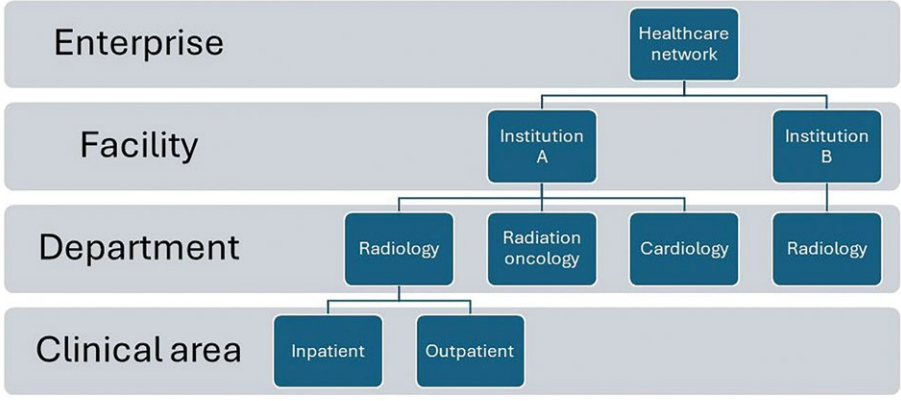

FIG. 9. Example of an institution level categorization.

as cardiology, perioperative procedures and urology, which often utilize C-arm X ray systems for fluoroscopic image guidance during procedures. Within a larger institution, imaging may be performed at multiple separate locations, such as in an emergency department, an outpatient centre and an inpatient centre, which might all be associated with the department of radiology.

The second institution (B) in this healthcare network is an outpatient clinic with ambulatory (i.e. outpatient) services only, namely a single clinical area in the facility where imaging is performed.

5.2.3. Equipment level categorization

Another basic organizational structure is by type of equipment and its clinical use. An example for CT is given in Fig. 10. In addition to one broad equipment category (i.e. CT), it can be useful to define subcategories indicating

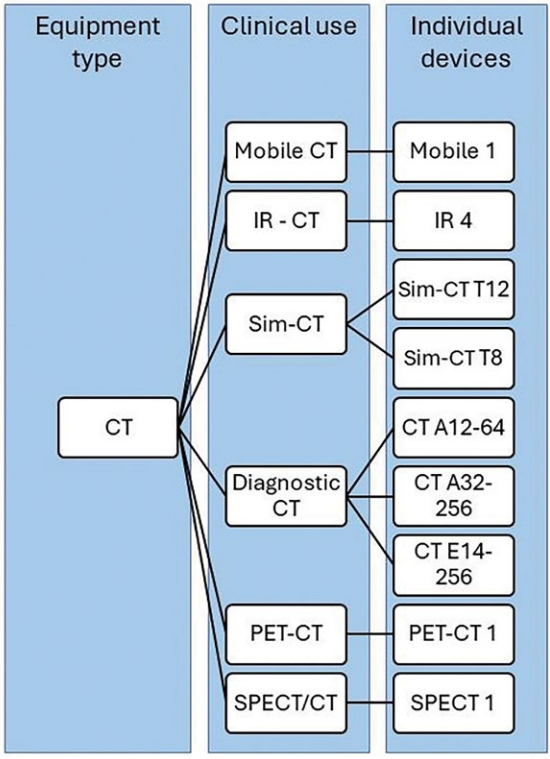

FIG. 10. Example of categorization by equipment type. Categories should be set up to group together individual devices serving the same clinical purpose.

the clinical use of the equipment, if those result in different dose levels for the same type of equipment. For example, the radiation dose levels produced by a CT scanner in the interventional suite during FGIPs can potentially be much higher (specially in non-optimized use) than that of a CT scanner used for general diagnostic procedures, while a PET-CT scanner whose images are solely used for attenuation correction will produce CT images at very low radiation dose levels. These differences in radiation dose levels are expected, and therefore it is helpful to subcategorize CT equipment accordingly.

For some DMSs, equipment and institution level categorization schemes may not be independent, with equipment type replacing the lowest available hierarchy (e.g. the clinical area in the example shown in Fig. 9).

5.2.4. Categorization of clinical indications

The assessment of patients' radiation doses should be done considering the clinical indication of the diagnostic studies, because scans of the same anatomic region may require different doses, such as a CT of the chest for lung cancer screening or a CT of the chest for pulmonary embolism [17, 19].

The setup of this categorization scheme should be coordinated by a senior MRT, who is familiar with the clinical indications and acquisition protocols and can generate a meaningful grouping and sorting scheme, with the support of a CQMP, who is familiar with the expected radiation doses, under the supervision of an RMP.

Categorization of radiation dose data by clinical indication can be quite complicated, as the identification of the study depends on several pieces of information generated during the workflow of diagnostic activities. As described in Section 4.2.5, patient radiation dose data contains various DICOM labels in the examination metadata. Of these DICOM labels, the 'study description' label (DICOM tag 0008,1030) and the 'protocol name' label (DICOM tag 0018, 1030) may be used for categorization by clinical indication. The clinical workflow is described in detail in Section 3.5. Figure 11 shows the steps of the clinical workflow in a particular medical imaging department, during which these labels are assigned for most examinations. However, under special circumstances, the study description may be changed after an examination (for example, if contrast could not be administered but contrast imaging had already been performed). The 'protocol name' label generally corresponds to the first acquisition protocol that the patient is scanned with. However, if other acquisition sequences are added after the first acquisition is completed, that change is not registered.

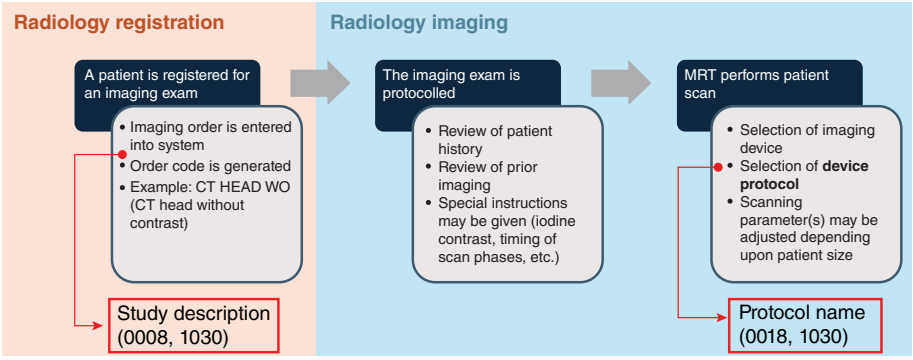

FIG. 11. Assignment of the 'study description' and 'protocol name' DICOM tags in a typical medical imaging clinical workflow.

5.2.5. Categorization by study description

The clinical indication of an examination is codified in the study description, which is a high level code that is defined by the institution to describe the performed examination. An example of a study description could be 'CT Head WO', indicating a CT scan of the head and brain without contrast. This classification scheme is useful because it distinguishes between different examination types that require different radiation doses, and makes comparison to published DRLs generally more straightforward.

Further, there is generally one unique study description per examination type at an institution. In addition, the named study description is an optional DICOM tag (0008,1030), and, if enabled, it is present in the examination DICOM metadata and the RDSR.

While institutions generally create their own order codes, the Radiological Society of North America has developed a radiology lexicon (RadLex) to standardize code names for radiological procedures for use in radiology reporting, decision support, data mining, data registries, education and research [27]. Use of standard codes is beneficial when comparing multi-institution data. Initially, the RSNA RadLex playbook served as a standalone resource [27]. However, recognizing the potential for greater impact through collaboration, joint efforts have been made with Logical Observation Identifier Names and Codes (LOINC)[5] [29] to create a unified model. This collaboration has resulted in the LOINC RSNA Radiology Playbook, which offers a comprehensive terminology system that represents radiology orderables, results and their attributes [56].

[5] https://loinc.org/

One caveat in categorizing radiation dose data by study description concerns cases in which a single CT acquisition is used for multiple clinical indications. For example, if the ordering physician requests both a 'CT chest W' (CT chest with contrast) and a 'CT abdomen/pelvis W' (CT abdomen/pelvis with contrast), a multi-protocol such as a prebuilt protocol is used to scan the patient from the top of the lungs to below the pelvis, and separate sets of CT image reformats are generated: one covering the chest and another covering the abdomen and pelvis (i.e. the acquisition is 'split' into two CT orders). These are then read by different subspeciality radiologists (i.e. chest or abdomen), following reformatting of the images by each subspeciality.

The use of multi-protocols is common practice in CT, as it reduces radiation dose in the overlapped scanned region. The primary reason for this is to prevent an increase in radiation dose, which would occur if the two scans are conducted as two separate procedures. This increase would arise because certain anatomical regions would be scanned twice, along with additional unnecessary radiation from the overranging (overscan) at the end of the first scan and the beginning of the second scan. The dose metrics associated with a given study description will be different depending on whether a multi-scan protocol is used. The impact of a multi-scan protocol (i.e. a split protocol) in chest examinations is demonstrated in Fig. 12, which shows a significantly increased DLP associated with the use of a multi-scan protocol, as the DLP of the whole multi-scan (chest/abdomen/pelvis) is assigned to all separate parts of the examination (chest, abdomen and pelvis). Median DLPs for two CT chest examination types, with and without intravenous contrast ('CT Chest W' and 'CT Chest WO', respectively) are shown. When a routine chest protocol is used to scan the patient's thorax only, the median DLP

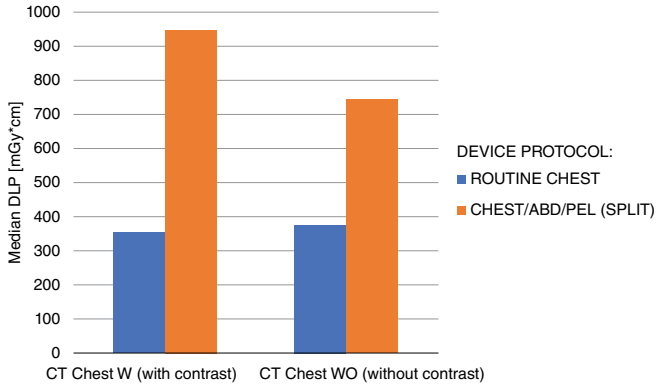

FIG. 12. Median DLP for two CT chest examination types, with intravenous contrast (CT chest W) and without intravenous contrast (CT chest WO) (courtesy of I.S. Reiser, University of Chicago).

is significantly lower than when a multi-protocol is used, such as a scan of the chest, abdomen and pelvis regions of the patient. It is important to take this into consideration when analysing and comparing radiation dose levels.

To understand which acquisition protocols contribute to a given study description, it is helpful to visualize the relationship between study descriptions and acquisition protocols by using a flow chart. Such a diagram, generated from institutional data, is shown in Fig. 13. This chart is called a Sankey plot. The left column shows a selection of acquisition protocols, where numbers represent the number of scans performed using this protocol. This Sankey plot reveals that three different acquisition protocols are used to perform scans when a 'CT upper abdomen and pelvis W' examination is requested. The most frequent is a routine abdomen/pelvis protocol, followed by a chest/abdomen/pelvis split protocol. In addition, the images for this examination might be generated during a pulmonary embolism chest scan, followed by a scan through the abdomen (called 'PE BT abdomen/pelvis'). These are all appropriate acquisition protocols but may

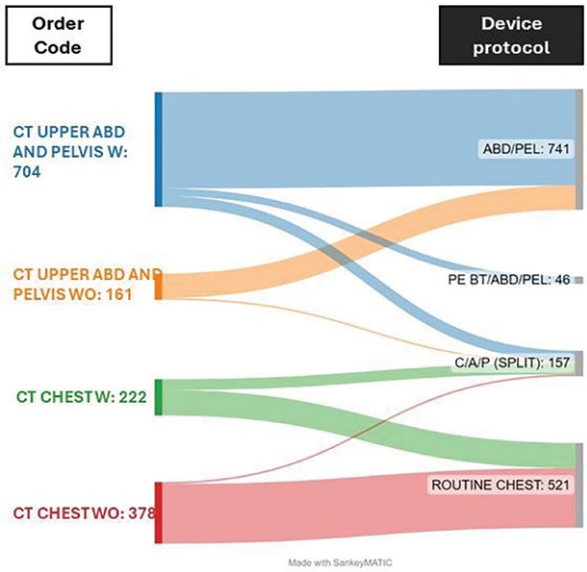

FIG. 13. Sankey plot showing the relationship between study description and acquisition protocol as a flow chart. The numbers indicate the number of CT examination records that were assigned a study description and acquisition protocol. This graph reveals that there is no one to one relationship between study description and acquisition protocol. ABD/PEL: abdomen/pelvis protocol; PE BT/ABD/PEL protocol: pulmonary embolism chest scan, followed by an abdomen pelvis protocol; C/A/P (SPLIT): chest/abdomen/pelvis split protocol. (Image courtesy of I.S. Reiser, University of Chicago.)

produce different radiation dose levels. Another feature can be learned from the Sankey plot. At this institution, the same acquisition protocol is used to scan with intravenous contrast and without; the latter is done by simply turning off the contrast use in the protocol on the CT operator console. Therefore, examinations performed with the acquisition protocol routine abdomen/pelvis are assigned to the study description 'CT upper abdomen and pelvis W' or 'CT upper abdomen and pelvis WO'.

5.2.6. Categorization by acquisition protocols

To minimize variations in radiation dose resulting from multi-scan protocols (e.g. split protocols), categorizing X ray examinations by acquisition protocol generally ensures the most consistent grouping of examinations in terms of radiation dose. This approach helps to standardize dose management across similar procedures. However, this is also the most difficult categorization because of the variability of acquisition protocol names, which are often not standardized among CT scanners in a single institution and because of the large number of device protocols that are typically found on a CT scanner — upwards of 50 to more than 100 protocols on a single scanner. The exact number is different at each institution and depends on the granularity of patient size specific protocols, paediatric protocols and/or trauma protocols.

5.2.7. Categorization by master protocols

A few DMS vendors support the use of master protocols (see Section 4.2.5 for a description of this functionality). Master protocols can be defined by the user, and individual acquisition protocols can be linked to one master protocol. The use of master protocols solves the problem of having multiple patient size specific acquisition protocols or having many different acquisition protocol names. While in principle an institution could, and should, standardize protocol names across imaging devices, having identical acquisition protocol names on multiple devices is not always feasible, because some vendors include a protocol numbering scheme in their acquisition protocol names, while other vendors include the anatomy category name with the acquisition protocol. Differences in CT scanner technology further complicate this issue. For CT scanners that lack reliable, or any, automatic tube voltage selection functionality, it may be necessary to implement size based acquisition protocols for procedures such as routine abdomen/pelvis scans. In contrast, CT scanners equipped with advanced automatic tube voltage selection may allow a single, standardized protocol for the same routine abdomen/pelvis examinations, although the tube voltage may vary from examination to examination depending on patient size.

Further, it may be desirable to group together patient size specific protocols for the same clinical indication. For example, multiple paediatric acquisition protocols for one clinical indication are usually created for different patient age or weight groups.

For certain CT scanners, once a master protocol is created, acquisition protocols can be mapped to that master protocol. If the acquisition protocol name on the imaging device changes, the mapping may break. For some CT systems, this occurs if the ordering of acquisition protocols is changed. Therefore, if master protocols are used in a DMS, the mapping needs to be verified regularly.

Master protocols can be set up in two ways:

(a) One master protocol for each imaging device protocol. This setup has the benefit of a one to one mapping of the imaging device protocol. The drawback is the large number of master protocols that need to be created and maintained.
(b) One master protocol for each imaging device protocol that should result in a comparable radiation dose. This setup reduces the number of master protocols within the DMS. This approach groups together protocols that are similar in terms of radiation dose but differ in anatomic coverage, scan phase delay or contrast administration. The approach was used to categorize CT examinations into 19 broad categories according to body region and clinical indication, with each group of indications requiring similar image quality [57]. Clinical indications for the same anatomy region and for a similar dose level may be grouped into the same category. For example, tumour/lymphoma staging, abdominal/pelvic metastasis on follow-up, and non-specific abdominal pain can be grouped in the same master protocol category [57].

The DMS master protocol may include the functionality of setting DRLs and/or alert thresholds or assign more detailed acquisition protocol descriptions.

5.3. REVIEW OF PROTOCOLS

Some DMSs include an acquisition protocol management functionality, which allows storing of clinical/acquisition protocols as well as providing a mechanism for tracking regular clinical protocol reviews.

Clinical protocols consist of a complete set of instructions for MRTs to perform an imaging examination. A clinical protocol is specific to an imaging examination and should specify the clinical indication, applicable patient group (e.g. adult or paediatric, grouped according to patient size and/or age),

specification of the region to be imaged, contrast agent administration and scan timing, specific views (such as in radiography) or contrast scan phases (such as in CT) to be acquired. A clinical protocol may include specific breathing instructions and may include notes on patient positioning. A clinical protocol also includes acquisition parameters and should include expected radiation dose ranges. In the case of CT, parameters for requested reformats should be provided. A clinical protocol is therefore more extensive than an acquisition protocol, which includes only imaging parameters (i.e. acquisition parameters, reformat and/or image processing parameters). The clinical protocol may also list any specific automatic sending of images as well as associated ordering and billing codes and may include directions for examination ordering in the PACS (i.e. hanging protocols) or other RMP-directed instructions for the MRT. Clinical protocols for some standard clinical CT examinations can be found on the website of the American Association of Physicists in Medicine[6].

In essence, the clinical protocol provides all information that is needed by an MRT to perform an imaging examination. There are multiple people contributing information to a clinical protocol: foremost an RMP, a senior MRT and a CQMP. Clinical protocols provide a platform for communication between RMPs and MRTs to ensure imaging examinations are performed as expected by RMPs. CQMPs review the acquisition parameters and help to ensure that radiation dose levels are appropriate, and they are responsible for ensuring adequate image quality (i.e. the noise level in the images should be neither too high, which would prevent a confident diagnosis, nor too low, which would probably indicate elevated radiation dose levels).

Clinical protocol review is a critical component of the optimization and quality improvement process, necessitating thorough and meticulous work. This process involves evaluating and refining imaging protocols to ensure that they are up to date with current best practices, enhance diagnostic accuracy, minimize patient exposure to radiation and optimize the use of available resources. Rigorous clinical protocol review helps to maintain high standards of care and supports continuous improvement in medical imaging departments. RMP-specific duplicate protocols should be avoided; instead, all RMPs in a given clinical department should come to a consensus on commonly agreed protocols. This will help MRTs to know the requirements when performing imaging examinations and minimize the number of acquisition protocols that need to be reviewed and maintained on a scanner.

The institution can determine time frames for protocol review and maintain a record of when protocols are reviewed or when new protocols are created. These time frames may also be defined by regulatory requirements, to which

[6] https://www.aapm.org/pubs/CTProtocols/?od1n

institutions need to adhere to ensure compliance with standards and guidelines. While not always necessary, communicating any changes to protocols to all relevant stakeholders is advised to ensure consistency and awareness. A DMS should support the protocol review. Many DMSs provide protocol modules that may allow management of clinical protocols. They may be able to ingest protocol files exported from X ray units such as CT scanners. However, there is no standard protocol export format, so the DMS protocol module may not recognize protocols from different vendors or even from different models. In the case of CT, there is a DICOM standard protocol object, which is not widely adopted but could potentially be an option specifically for CT.

5.4. SETTING DIAGNOSTIC REFERENCE LEVEL VALUES IN THE DMS

The DMS allows the setting of DRL values in a DRL library. DRL values are defined for specific clinical tasks or indications; therefore, their definition in the DRL library needs to be done in agreement with the master protocols library according to the clinical indication, study description or protocol name categorization (see Section 5.2). DLRs should not be used to compare dose indicators from individual patients, as DRLs are not limiting values.

Generally, national DRLs should be established by national authorities on the basis of scientific knowledge. Examples of national or regional DRLs can be found in the scientific and official government literature [58–62]. They can be obtained from national, regional or international surveys. Incorporating a DRL library in the DMS facilitates the patient dose audit at hospital, department, room and clinical indication level, provided that a suitable categorization has been set up.

It is important to note that DRLs are a different concept from trigger levels. Trigger levels can be defined in a DMS as a level of investigation to be used with individual patients; for example, if an FGIP has resulted in high doses that can produce skin injuries. Sometimes, trigger levels can be defined using DRL values. For example, it may be helpful to establish alerts for certain CT indications when the DLP exceeds two or three times the corresponding DRL, prompting a review of the imaging protocols or patient specific factors. Filters and threshold criteria on patient descriptors can be set as well, such as patient age, gender and patient size, where patient size might be the WED or patient diameter. It is essential to remember that establishment of DRLs needs to always incorporate a thorough assessment of image quality. This ensures that efforts to reduce radiation exposure do not result in compromised image quality, which could negatively impact patient care and clinical outcomes.

5.5. SETTING ALERTS AND TRIGGER LEVELS

Setting up different types of alert to highlight events that require immediate action is one of the most valuable functionalities of DMSs and needs to be done carefully. The alerts engine can highlight data in graphs or tables and can even send an email to the person responsible for taking action. Alerts may be set up by defining trigger levels. An example of a trigger level could be the KAP, $K_{a,r}$ or fluoroscopy time in FGIPs, which could be used to recommend follow-up of potential skin injuries, as jointly suggested by the Cardiovascular and Interventional Radiology Society of Europe and the Society of Interventional Radiology of the USA [31, 63]. The definition of alerts and trigger levels is also useful for outlier detection, as proposed by The Joint Commission[7]. It is possible to define a trigger level as two or three times the DRL for a specific study to determine the percentage of patients that exceed this trigger level.

To set an alert for a specific type of DMS record, the DMS needs to check if every single record meets the alert specifications; therefore, a high number of alerts for a frequent type of record (e.g. for all CT studies) may demand considerable computing resources.

As mentioned in Section 4.2.4, alerts are designed to initiate investigations and actions that will lead to improved patient care. Notifications generated by the alert system need to be thoroughly investigated and may require follow-up reports or actions from the DMS team. For each alert, the system should allow the inclusion of comments or documentation detailing the investigation process and its results, ensuring that every alert is properly addressed and recorded for future reference. Alerts that do not prompt actionable responses from the DMS team are ineffective and should be addressed. This issue is further complicated by the inconsistent implementation of the DICOM standard by medical imaging manufacturers, which can lead to inaccuracies in the alerts generated, making it even more critical to refine and organize these alerts.

5.6. SETTING UP DOSIMETRIC CORRECTION FACTORS

The DMS should allow users to define correction factors for dosimetric quantities reported by imaging equipment. In some instances, different X ray systems may present the same dose indicator quantities in different units, necessitating the use of correction factors to harmonize the recorded information. In other cases, while the dose indicators may be provided in the correct units,

[7] https://www.jointcommission.org/

the reported values might still differ from the actual measurements. This discrepancy should occur only if RDSRs are not used, as RDSRs standardize the dose indicator units for all values. Even when dealing with DICOM metadata, the units are usually standardized, although exceptions may exist, especially in older medical imaging systems. The only situation where unit inconsistencies might arise is when optical character recognition methods are used to extract dose data. This point is worth clarifying to reassure users that such unit discrepancies are not an issue when RDSR data are used. For some dose quantities such as KAP, international standards state that "The overall uncertainty of the displayed values of the cumulative kerma area product above 2,50 Gy.cm^2 shall not exceed 35%" [64], and this applies to values displayed in real time and to values transmitted to the DMS. A CQMP can reduce this uncertainty by performing cross-calibrations using reference dosimeters properly calibrated by an authorized metrology laboratory, thus obtaining correction factors for the dose indicator provided by the X ray unit. Reference dosimetry probes duly calibrated can provide dosimetric quantities with uncertainties much lower than those of X ray units; however, the final uncertainty of cross-calibration correction factors obtained by a CQMP will depend on different parameters, such as the method used for KAP estimation by the X ray system and the beam quality [65].

Dose indicators provided by the X ray systems need to be checked by a CQMP [7–9, 65], and if deviations over tolerance levels are found, dose indicators need to be corrected at the origin (i.e. in the X ray unit). This methodology is preferable, as it can significantly reduce the uncertainty of dose indicators from the X ray systems, leading to more accurate and reliable measurements. In any case, the DMS should have the functionality of setting correction factors for each individual equipment that reports into the DMS. It is also particularly important to store the original (uncorrected) and corrected dose values in the DMS. This allows traceability and auditing of the correction process. In addition, it is essential to make sure that corrected values are clearly labelled as such in the DMS to avoid confusion with the original values.

6. DMS TECHNICAL SPECIFICATIONS

This section aims to assist health institutions that wish to obtain a DMS in drafting tender specifications during the procurement process. The technical specifications suggested are drafted on the basis of the results of a technical survey performed for the purposes of this publication. Data were collected using

the IAEA's International Research Integration System[8], which was designed to streamline the data collection process. The platform supports the collection of numerical and textual data, various types of image, as well as DICOM images with subsequent tag extraction, and it is hosted on the secure IAEA cloud infrastructure. The IAEA made efforts to reach all DMS developers, and the overall responses, along with all the survey questions, are provided in Appendix I.

These technical specifications can serve as a comprehensive guide for evaluating and selecting an up to date DMS during the procurement process. Ensuring that a DMS meets both essential and desirable technical requirements is crucial for optimizing performance, enhancing data accuracy and maintaining compatibility with evolving medical imaging technologies. By using these specifications as a guide, healthcare institutions can ensure that their DMS not only meets current clinical needs but also has the flexibility to adapt to future advancements, ultimately contributing to improved patient care and radiation dose management

6.1. GENERAL REQUIREMENTS

The following list describes general technical requirements, both essential and desired/optional, that a DMS should have to be up to date with the latest state of the art. In the following paragraphs, the word 'should' denotes essential requirements, while the term 'can' refers to desirable functions and features:

(a) The DMS should be able to automatically collect data (directly or indirectly) from the medical imaging modalities of interest related to each individual patient examination, including modality and facility information, patient demographics, examination parameters and patient dose related metrics, as well as other information that may be desirable and could be used for optimization purposes of different aspects of medical imaging examinations. Thus, the DMS should collect information at facility level, at modality level, at room level, at patient level and others.
(b) The DMS should be able to perform the basic statistical analysis of the data collected, especially regarding those data related to patient dose related metrics.
(c) The DMS should be able to export data to allow advanced statistical analysis using various spreadsheets.

[8] https://iris.iaea.org/#pages/welcome.html

(d) The DMS should be able to produce alerts when patient dose related metrics are above or below specific preset reference values or outside specific preset reference ranges.
(e) The DMS operation should comply with any national and/or regional patient data protection policies and regulations in place.
(f) The DMS should comply with any national and/or regional policies regarding certifications that may be needed.

6.2. DATA CONNECTION AND TRANSFER REQUIREMENTS

The following list outlines the data connection and transfer requirements for the effective collection, integration and processing of information from various imaging modalities by the DMS:

(a) The DMS should work as a separate DICOM hospital network node and communicate with other DICOM compliant devices in one or more of the following ways: DICOM storage, service class provider and DICOM MPPS or any other method. The specifics should be in the vendor's DICOM conformance statements.
(b) The DMS should be able to automatically collect data from the radiological, nuclear medicine and other imaging modalities of interest, using any type of connection that allows this, via direct connection to each individual modality, via connection to the PACS, using a combination of the previous methods or/and any alternative method applicable that complies with patient data protection policies and regulations.
(c) The DMS should automatically create a record for each and every individual examination performed in any of the radiological, nuclear medicine and other imaging modalities of interest connected to the DMS and populate the record data fields with the respective data using the DICOM RDSR, DICOM metadata or any other appropriate means (e.g. MPPS, optical character recognition software).
(d) The DMS should be able to associate examinations performed to the same patient (using unique identifiers such as social security number or universal medical record number) so that the total number of examinations performed in the same patient and the cumulative dose metrics, where applicable, could be calculated.
(e) The DMS should record each individual acquisition (irradiation event) performed separately (as well as the cumulative values where applicable (e.g. DLP, KAP)) for CT, radiographic, mammographic, dental examinations and others. Saving all exposure information is important, especially in

FGIPs. Detailed analysis of FGIPs and advanced features such as PSD calculations require recording of each individual radiation event separately.

(f) Regarding patient, modality and examination data, the DMS should be able to record all of the following parameters: patient name (last, first, middle) and identification number(s); patient sex, age and/or date of birth; patient height and weight; study information (e.g. procedure name, anatomical region examined); acquisition protocol information (e.g. acquisition protocol name, anatomic region examined, acquisition number or/and radiation event number); study date and time information; facility information (hospital name, modality type, manufacturer, model, system identity document and image receptor identity document); and staff information (operator, referring physician and/or requesting physician). A list of the parameters that can be recorded in the examination record needs to be provided.

(g) The DMS can record contrast media information using Health Level Seven[9] or other means (e.g. ingredient or trade name, administration route, route administration time start–stop, total quantity administered, flow rate, volume, concentration) where applicable.

(h) The DMS should be able to account for calibration regarding patient dose related metrics.

(i) The DMS can have provision to account for unit conversion issues regarding patient dose related metrics.

(j) The DMS should allow manual data entry for examination parameters that cannot be automatically collected by modalities or the PACS and allow manual corrections of possible errors in any of the parameters collected, but only by users with proper user rights and audit trail.

6.3. PATIENT DATA

The following list presents the requirements for managing and handling patient data within the DMS.

(a) Regarding patient related metrics, the DMS should be able to record at least the following metrics provided by each of the supported medical imaging modalities:

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[9] Health Level Seven is a set of international standards for the exchange, integration, sharing and retrieval of electronic health information. It provides a framework for how healthcare information is packaged and communicated between different systems. See https://www.hl7.org/

(i) CT scanners: $CTDI_{vol}$ per series, DLP per series, total DLP for the complete study (in case of multiple scans), as well as SSDE and WED when they are provided by the CT system. If the CT scanner provides SSDE and modality generated WED metrics, the DMS should record these metrics as well. For $CTDI_{vol}$ values, it should be indicated whether these refer to the head (diameter of 16 cm) or body (diameter of 32 cm) CTDI phantom. This should also apply to the DLP for individual irradiation events.

(ii) Fluoroscopic and angiography systems: KAP or DAP values, fluoroscopic time, number of frames, as well as total $K_{a,r}$ and $K_{a,r}$ per radiation event. The DMS should also report total KAP or DAP separately for fluoroscopy and for cine or single shot acquisitions, number of cine acquisitions, and according to each plane for biplane systems.

(iii) Radiographic systems: KAP or DAP per radiograph and cumulative for the whole examination, as well as the total number of radiographs.

(iv) Mammographic systems: AGD per projection. K_i or/and $K_{a,e}$ per projection is also desirable, as well as the number of projections per examination.

(v) Dental panoramic, cephalometric and CBCT systems: KAP or DAP per acquisition for panoramic and cephalometric examinations, and KAP or DAP or/and CTDI per CBCT examination (depending on whether the CBCT system calculates one or both dose metrics).

(vi) Nuclear medicine equipment such as PET-CT or SPECT (single photon emission computed tomography): Administered activity and radiopharmaceutical.

(vii) MRI: Specific absorption rate, operating level and others.

(b) Regarding the additional parameters of each acquisition, the DMS should record as many of the following suggested parameters when these are provided by each of the supported modalities. The DMS vendor should provide a list of those parameters that can be recorded:

(i) CT scanners: Scan length per acquisition series, acquisition parameters (tube potential, scan time per rotation, mAs or/and μAs), acquisition parameters (scan type (axial/helical), scan field of view (FOV), pitch, collimation used (e.g. 64 rows × 0.5 mm), X ray total beam width, gantry tilt), reconstruction parameters (e.g. display FOV, reconstruction slice thickness, reconstruction kernel), study and acquisition protocol information (e.g. protocol name, anatomical region examined, clinical indication, iterative reconstruction and artificial intelligence reprocessing levels), automatic tube current modulation (ATCM) related parameters (noise index or reference mAs or other dose/

image quality setting indicator, minimum and maximum mA limits), if applicable, and patient positioning information. It is noted that each scan can be reconstructed using more than one reconstruction parameter set. For example, while the routinely used slice thickness can be 5 mm, additional reconstructions with a slice thickness of 1 mm or others can be also added to the main reconstruction set.

(ii) Fluoroscopic and angiography X ray systems (when all radiation events are recorded separately): Event number, exposure parameters per fluoroscopic or radiographic acquisition (e.g. tube potential, mA, fluoroscopy time, pulse width, mAs or/and μAs, pulse frequency, added filtration), geometric parameters (FOV, gantry/tube angle(s), table position *X*, *Y*, *Z* coordinates, source to image receptor distance (SID), C-arm position, focus isocentre distance, focus reference point distance), acquisition protocol name and examined anatomic region.

(iii) Radiographic systems: Exposure parameters (tube potential, mA, exposure time, mAs or/and μAs, added filtration), geometric parameters (FOV/field size, SID, grid information), acquisition protocol name and examined anatomic region, automatic exposure control parameters, exposure index, target exposure index, and deviation index.

(iv) Mammographic systems: Exposure parameters (anode/filter combination, tube potential, mA, mAs or/and μAs, exposure time), acquisition parameters (FOV/field size, half-value layer), geometric parameters (SID, CBT, compression force, grid used (yes/no), magnification) and protocol parameters (left or right breast, projection type and angle, automatic exposure control mode).

(v) Dental panoramic, cephalometric and CBCT systems: Exposure parameters (tube potential, mA, exposure time, mAs or/and μAs), geometric parameters (FOV/field size or volume size, SID), acquisition protocol name and examined anatomic region.

(c) Regarding the parameters that can be calculated by the DMS, a list of those parameters that can be calculated and reported using data collected from the modalities can be provided together with information on the methods used for their calculation, together with additional costs involved when these are offered as optional. If the DMS calculates and reports any parameters, the following information on the methods used for their calculation should be provided:

(i) CT scanners: SSDE per scan series, $CTDI_{vol}$ w/acq[10], DLP w/acq and SSDE w/acq, body mass index when the weight and height of the patient are recorded; patient anteroposterior, lateral, anteroposterior and lateral or effective diameter and/or WED, patient positioning

[10] w/acq: weighted by acquisition.

calculation and the type of ATCM (i.e. mA modulation graph on anteroposterior or/and lateral scan projection radiograph). Also, effective dose *E* using preset conversion coefficients or other more elaborate Monte Carlo methods which may also provide organ dose calculations and foetus dose calculation in case of pregnant women, taking into account the patient size/age only, and scan length, and actual scanned region and ATCM pattern used should be provided. If such elaborate *E* and organ dose calculation methods are available, the DMS vendor should give information on the library of the different anthropomorphic phantoms. Finally, any image quality evaluation metrics that can be calculated and stored in the examination record, whether these are based on automatic methods used by the DMS or on manual evaluations (e.g. scored by the radiologist when reviewing the CT images in the PACS monitors), should be also reported.

(ii) Fluoroscopic and angiography systems (when all radiation events are recorded separately): Incidence air kerma map (skin dose mapping) and/or PSD calculated automatically or semiautomatically (some user input may be needed), using data collected from the angiography system. Any image quality evaluation metrics that can be calculated and stored in the examination record, whether these are based on automatic methods used by the DMS or on manual evaluations (e.g. scored by the radiologist when reviewing the fluoroscopic and digital acquisition images in the PACS monitors), should be also reported.

(iii) Radiographic systems: *E*, organ and foetus dose and image quality metrics, as for fluoroscopic systems.

(iv) Mammographic systems: Image quality evaluation metrics that may be calculated and stored in the examination record, whether these are based on automatic methods used by the DMS or on manual evaluations (e.g. scored by the radiologist when reviewing the mammographic images in the PACS monitors), should be also reported.

(v) Dental panoramic, cephalometric and CBCT systems: effective dose *E* and image quality metrics, as specified in (c-i)–(c-iv).

6.4 STATISTICAL ANALYSIS AND EXPORT CAPABILITIES

The following list outlines the technical requirements for the statistical analysis and export capabilities of the DMS, which enable comprehensive data analysis and reporting, among others:

(a) The DMS should have a main graphical user interface (GUI)/dashboard for statistical analysis of all or part of the data stored in the DMS.
(b) The DMS can have one or more preset dashboard(s) for statistical analysis of all or part of the data stored in the DMS.
(c) The DMS should allow creation of customizable dashboard(s) for statistical analysis of all or part of the data stored in the DMS.
(d) The DMS should allow a visual presentation of the data, facilitating comparison of the median values of a DRL quantity for a specific examination/study with the applicable DRL values. This presentation should allow stratification by user specified groups of equipment.
(e) In the visual presentation described in Section 6.4.4, the 75th percentile and the median value of the selected metric can be calculated and indicated, to allow setting local DRLs.
(f) In the visual presentation described in Section 6.4.4, filters can allow selection of patients in a specific age or/and size group. If DRLs stratified depending on age or/and patient size are available, the DRL value that is applicable to the selected group of patients should be automatically shown in the graph or tables.
(g) The presentation of a correspondence table showing the patient sample size, the minimum, maximum, mean and standard deviation values of the sample size for each facility shown in a bar graph is also desirable, with an indication (colour or icon) of whether it is above or below the respective DRL.
(h) The DMS can also allow the presentation of data stored in other graph types, such as *X*–*Y* scatter plots, histograms, box and whisker plots and pie charts. Data points shown in the graphs should be interactive and when selected should display more information about the selected data point and the respective examination record and provide a link that allows to open the respective examination and review the images. Where applicable, the *X* and *Y* axis minimum, maximum and step values of these diagrams can be automatically adjusted. Manual adjustment is also desirable.
(i) The DMS can allow the selection of DRL values from different databases (e.g. using drop-down lists or check boxes) for checking conformance with DRLs of other countries, local DLRs, institutional DRLs, or DLRs other than those from the standard DRL library. Information about the selected DRL database should be clearly indicated on the GUI.
(j) The DMS should allow the application of queries using multiple criteria to filter the data and present them in graphs or tables. Examples of such queries can be the following:
    — Report the number and/or percentages of chest CTs with SSDE in the range 5–10 that were performed last year per facility.

— Report the number of radiographs performed last week per facility, where a tube potential value within the range 50–60 was used.

Both collected and calculated data can be selected as filters or as *X* and *Y* parameters.

(k) The DMS can allow the presentation of data and combined results of queries in preset or customizable tables.

(l) The data stored in DMS (collected and calculated), whether filtered or unfiltered, should be able to be exported in a format appropriate to be imported and statistically analysed using various statistical programs.

(m) The DMS can customize data columns (i.e. the parameters) to be exported (all or specific parameters), depending on the level of information detail needed by the analysis task.

(n) The DMS should support the creation of a customized export filter library, to allow consistent export of specific data regarding certain modalities or statistical analysis tasks on demand. An option to anonymize the data exported should be available.

(o) The DMS should allow exporting of graphs or results of combined queries as screenshots or figures, pdf files or spreadsheet format files (tables with numbers and/or graphs), or business intelligence software format files.

(p) The DMS should keep all data records in a database.

6.5. CUSTOMIZATION

The customization specifications of the DMS can help users to tailor the system to their specific needs, including configuring alert thresholds, defining user roles and permissions, and adapting data categorization on the basis of institutional protocols, as follows:

(a) The DMS should produce an alert in one or more of the following cases, when a parameter or dose metric value found in an examination or study record is:
   (i) Greater than a reference value/threshold (upper threshold);
   (ii) Smaller than a reference value/threshold (lower threshold);
   (iii) Not within a given reference range of values (reference range or lower and upper threshold).

(b) The DMS should produce a trend alert if a specific parameter shows a gradual increase or decrease over time, allowing subtle shifts or emerging trends to be highlighted for users.

(c) Alert levels (i.e. reference values that are used as thresholds to produce alerts in any of the cases described above) should be set on the DMS manually

or/and be linked to the respective DRL values of each master protocol. Different alert levels for different age categories or/and body size categories should be supported.

(d) The DMS should demonstrate the alerts using one or more of the following ways:
  (i) Distinct symbols or icons beside the respective values;
  (ii) A change in the colour of the respective parameter value;
  (iii) Any other way that makes the alert clear to the user.

(e) The DMS can allow setting alerts for collected and calculated dose metrics and parameters in the level of single acquisition/radiation event and in the level of study/full examination (e.g. cumulative dose metric values, number of examinations).

(f) The DMS can allow setting of alerts regarding the cumulative number of examinations performed or cumulative dose metric values measured within one or more customizable ranges of time.

(g) The DMS should keep the alerts produced active until they are resolved by an authorized user who will have to perform a specific action (e.g. adding a comment), and it is desirable that resolved alerts are denoted by a distinct colour or icon.

(h) The DMS should have a tab or dashboard to display all active alerts and optionally the alerts resolved. This tab should support multiple filters to select the type of alert (e.g. above threshold 1 or 2), the status of the alert (active or resolved), the date and time interval, the modality type(s), the specific facility (or facilities) and others.

(i) The DMS should support the grouping of similar examination and/or acquisition protocols in the same category as being the same examination/acquisition. This category, encompassing all the different names that are commonly used in different facilities to describe the same or similar examinations, will be referred to as master protocol, although various DMSs may use alternative naming or concept for this grouping.

(j) The master protocols, either for whole examinations or for single acquisitions, should be preset and/or customizable.

(k) Master protocols should be assigned with reference/threshold values for the applicable dose metrics (collected or calculated). Master protocols can also be assigned reference/threshold values for various exposures and other parameters.

(l) The reference/threshold values for dose metrics collected or calculated, other parameters and DRLs of a master protocol should support stratification depending on patient attributes (such as age or weight) or even other secondary conditions that may apply to an attribute of the examination or acquisition for specific values or ranges of values.

(m) The DMS can provide safeguards to detect, prevent or notify the user in case of contradicting conditions or restrictions and/or overlapping ranges of reference/threshold values.

(n) Each master protocol should be linked with the DRL value of the respective examination of the standard DRL library, so that the DRL values are shown in the master protocol information. Linking with other DRL libraries is desired for comparison of dose metrics data with DRL data from different libraries. These DRL values could be used to set the reference values for alerts (e.g. reference value level 1 (orange alert) is equal to the DRL, reference value level 2 (red alert) is equal to two times the DRL). Once assigned to any master protocol, examinations/studies with different names and descriptions and acquisition protocols should be automatically linked to all the master protocol's attributes regarding reference values/alert levels, DRLs and secondary conditions (e.g. age or size stratification of DRLs).

(o) The DMS can have safeguards to alert or notify the user in case the same examination or acquisition protocol has been assigned to more than one master protocols.

(p) The DMS can allow the creation of different master protocols for similar examinations in terms of scanned anatomy, number of acquisitions and others, but with different clinical indications. When a new unassigned examination/study or a new acquisition protocol is detected in the data collected, then the DMS should produce a distinct warning (using graphics, icons or colours) to inform the user that this new protocol needs to be managed. The warning symbol should remain on until the new protocol is assigned to a master protocol.

(q) If the DMS uses algorithms to allow the automatic assignment of a new unassigned study or acquisition protocol to a master protocol (e.g. on the basis of the name or description), a distinct warning (using graphics, icons or colours) should be produced, to inform the user that this assignment is tentative. The master protocol that is automatically chosen needs to be confirmed or changed by the system administrator; until then, the warning should remain on.

(r) The DMS should have at least one DRL library. It is desirable to have multiple preset and/or customizable DRL libraries with data applicable to different examinations/studies and with national DRLs from various countries or regions. A customizable DRL library with local DRL values should be also supported. The selected DRL library should be clearly indicated when reports are produced that compare the median metric values of the various examinations from the organization's systems with the DRL values of a library.

(s) The DMS can allow DRL libraries to contain standard and customizable notes and comments regarding the source of DRL values included or other relevant information.
(t) If the system has only one preset DRL library at installation, this can be updated automatically or/and manually by authorized personnel. If any value in the preset DRL libraries is manually updated/modified, users need to be notified by a warning sign (e.g. using a note or highlighting this value).
(u) The DMS can have safeguards to detect and notify the user for contradicting and/or overlapping ranges in DRL stratification settings.
(v) The DMS should support the classification of users in different categories with different access rights. Users with basic/standard access rights can only view data and perform statistical analysis and can have restrictions regarding the modalities or even the facilities whose data they can access.
(w) The DMS should allow the management of the master protocol and DRL library only by users with system administrator rights.
(x) Preset user rights groups can be modifiable; alternatively, the DMS should not allow modification of the preset groups but should offer the administrator the capability of creating additional user right groups with customizable access rights.
(y) The DMS should have safeguards to prevent the administrator from losing access to any of the menus relevant to access rights.

6.6. IMPLEMENTATION PROCESS

The implementation specifications of the DMS cover the essential steps for system setup, including installation, configuration and integration with existing medical imaging systems and HISs. Proper implementation ensures that the DMS operates smoothly in the clinical environment, facilitating reliable data capture, seamless connectivity and optimal performance from day one, as follows:

(a) The DMS developer should state where the software and database will be installed (physical or virtual server) and whether the DMS can upload existing data prior to DMS installation.
(b) The DMS developer should specify the safeguards in place to protect against partial or complete database damage, as well as access issues that could arise from hard disk or other storage media failures, or from cloud connection problems.
(c) The DMS should be medical equipment manufacturer neutral. If not, a detailed list of medical imaging equipment that present compatibility problems and how these problems can be circumvented needs to be provided.

(d) The DMS should include safeguards to prevent data loss due to connection issues, as well as self-diagnostic tools that detect connectivity problems and alert the user to take corrective action.
(e) The DMS can support integration with the HIS using Health Level Seven standards to export dosimetric information to the patient's medical record. This integration can be implemented without compromising the functionality, safety or performance of the connected systems, including the PACS.
(f) The DMS can allow automatic or semiautomatic transfer of data to dose registries.
(g) The DMS provider can enable the transfer of information from a previous DMS (in the event of a change of provider) to ensure that existing patient data records are preserved, allowing seamless continuity in data management.
(h) The DMS should have the necessary servers and/or storage area to maintain a continuous flow so that there is no loss of information over time.

7. QUALITY ASSURANCE

The DMS can help to improve patient care in imaging departments, and the quality of the information stored, processed and presented by these systems should be assured by the DMS administrator. As a medical device, the DMS needs to adhere to high standards of accuracy, reliability and safety. Ensuring that the DMS functions effectively requires a robust QA programme with regular quality checks to maintain patient data integrity and ensure compliance with regulatory standards.

7.1. INTRODUCTION

There are several situations that can lead to missing or incorrect information being stored in a DMS, potentially affecting the accuracy and reliability of patient data tracking. These include the following:

— Problems with network connection or information technology infrastructure may result in missing patient data until the connection problem is solved.
— A release upgrade in the software of an X ray or other medical imaging system can produce a change in the structure of the information sent to the DMS and a rejection or misinterpretation of the data.
— The information of interest could be included in different DICOM tags with different format and could accidentally be interchanged. For example,

the $K_{a,e}$ value can be included in different DICOM tags and units, such as DICOM tag 0040,0302 (in dGy) or in DICOM tag 0040,8302 (in mGy). Correction factors may be needed to make the units consistent.
— In some cases, reporting of dose information can be configured at the protocol level. This can lead to misconfiguration of some protocols, resulting in the failure to send the RDSR or dose information to the appropriate repository.
— Different manufacturers may interpret the cumulative dose information in different ways. For example, in an FGIP, the total KAP might not include the fluoroscopy component or the CBCT component, which are reported separately. Dashboard information might be incorrect or misinterpreted.
— Depending on the methodology used to calculate the effective diameter or WED in CT (slices or scan projection radiograph), the accuracy might be different for different manufacturers.
— The accuracy in the estimation of the PSD is strongly dependent on the methodology used for calculation and on the amount and quality of the information available from the FGIP, and it might be different for different manufacturers.
— Alert systems may fail to detect cases that require investigation and follow-up or may fail to send notifications.

Many of these issues could be checked and solved when the system is installed, but others may require regular checking. Therefore, it is encouraged to establish a QA programme with acceptance testing [66], commissioning and regular QC [67, 68]. Some other aspects need to be set up by the user. These tasks can be performed or supervised by the CQMP in collaboration with other members of the DMS committee, as appropriate.

There is limited literature available regarding the specific QC tests that should be conducted on a DMS, as well as the ideal frequency for these assessments. This scarcity of information highlights the need for standardized guidelines and protocols to ensure the consistent performance and reliability of DMSs. The American Association of Physicists in Medicine has emphasized that QC testing of a DMS after installation presents a significant challenge that needs to be carefully addressed [26]. The European Society of Radiology strongly encourages the inclusion of a medical physics expert in the installation process and subsequent operation of the DMS [4]. The Spanish Society of Radiological Protection and the Spanish Society of Medical Physics have jointly suggested [69] the importance of monitoring each stage of the DMS process, including the following:

(a) Production of dose indicators in the X ray unit;
(b) Dose indicator collection;

(c) Alert management;
(d) Information extraction.

A proposal published by Samara et al. [3] outlines several key aspects that should be regularly evaluated in a DMS, including suggested testing frequencies and acceptable tolerances. Additionally, the proposal provides a template for DMS QC to streamline the process and ensure consistency. Drawing on the insights from certain publications [3, 4, 26, 66, 67, 69] and incorporating the expert opinions of the contributors to this publication, the set of tests described in the following subsections is proposed to ensure the proper functioning and the reliability of a DMS.

7.2. ACCEPTANCE TESTING

Acceptance testing is a type of testing conducted collaboratively with the DMS vendor to determine whether the DMS meets the specified requirements and is ready for deployment in a real-world environment. The process involves verifying that the system performs as expected in various scenarios, including those that reflect the actual conditions under which it will operate. Acceptance testing ensures that all functionalities work correctly, that the system integrates seamlessly with other systems (e.g. PACS, HIS, RIS) and that it adheres to user requirements. This phase often includes testing critical elements such as data accuracy, report generation, system alerts and data transfer capabilities.

The outcome of acceptance testing is a formal confirmation that the DMS is functioning correctly and is ready for use in a clinical setting. If the system passes all tests, it is accepted for deployment, which means that it can be officially integrated into the healthcare facility's operations. If any issues or discrepancies are identified during testing, they should be resolved before the system can be approved. The ultimate goal of acceptance testing is to ensure that the DMS will perform reliably and effectively, thereby supporting operational efficiency from the moment that it is implemented. For instance, if any of the DMS functionalities are found to be inaccurate or malfunctioning, it is the responsibility of the DMS vendor to promptly address and correct these issues. Vendors are expected to provide timely support to resolve any discrepancies, and they should work closely with the institution to ensure that the system meets their standards before use. Additionally, the vendor needs to be transparent about the methodologies used in the DMS and to take accountability for ensuring that these methodologies are implemented correctly.

During acceptance testing, particular attention should be given to the following aspects:

(a) It is important to confirm that all medical imaging systems, the PACS and other systems are correctly connected to the DMS and to provide the necessary information with 100% accuracy. Conducting connectivity tests using communication commands such as a DICOM echo (also known as DICOM ping) can be beneficial, but it is also advisable to verify that 100% of the diagnostic studies performed on an X ray unit over a given period are successfully captured in the DMS. This comprehensive check ensures that no information is lost and that the system is fully reliable.

(b) Upon the installation of a new system — whether it involves new medical imaging equipment or an upgrade to the DMS — it is essential to confirm the device configuration and ensure the consistency of the information received and presented.

(c) When the DMS transmits information to other systems, such as sending radiation dose reports to patients' medical records, it is crucial to verify the accuracy of these data during the installation process.

(d) It is important to ensure that the DMS accurately generates and displays key statistics. A simple example is the calculation on the DMS dashboard of the median value of a dose indicator over a selected time period. To verify the accuracy of the DMS, the user can manually calculate the median from a subset of cases and compare it with the median provided by the DMS. Comparing this manually calculated median with the DMS-generated median helps to confirm that the system is performing as expected and that the data being used for analysis and decision making are accurate and reliable.

(e) It is crucial to ensure the effectiveness of an alert system in identifying cases that require investigation or follow-up. This reliance means that the alert system needs to be highly functional in two key areas:

  (i) Accurately detecting cases that meet the criteria for concern or require further action;

  (ii) Promptly notifying the appropriate individual or team responsible for making informed decisions and managing the alert, ensuring that no critical issue goes unnoticed.

(f) All calculations performed by the DMS, including effective diameter, WED and PSD, should be thoroughly validated. Given that standardized methodologies for estimating many of these dosimetric quantities may not exist, verification can be challenging. In certain instances, it may suffice to confirm that the correct conversion factors are applied. However, in other cases, it may be necessary to conduct independent calculations or even take direct measurements using the X ray unit to ensure accuracy.

(g) When estimating the effective dose using conversion factors, it is essential to ensure that the correct body part and corresponding conversion factor are selected for the calculation. This verification should be performed for each

X ray system connected to the DMS and for the most commonly performed radiological procedures. The accuracy of these estimations will depend on both the specific clinical application and the local regulatory requirements.

(h) In the context of CT imaging, size estimation metrics such as effective diameter, WED and SSDE may vary depending on the machine. However, these calculations do have standardized methods for verification [39]. The SSDE may be either included in the DICOM data — calculated directly by the CT system — or computed by the DMS itself [33, 36, 37, 50, 70]. To ensure accuracy, it is advisable to conduct independent calculations and cross-check the results for a representative sample of 5–10 CT studies from each CT scanner connected to the DMS. This process helps to confirm the reliability of the size estimation and dose calculations across different systems.

(i) The PSD for FGIPs can vary significantly depending on the X ray system in use. It is therefore essential to carefully assess each system for its unique characteristics and ensure that PSD calculations are accurate and reliable. In some instances, the precision of these calculations may be compromised because of missing or incomplete information, which underscores the importance of thorough verification. Particular attention should be paid to the specific configuration and operational parameters of each system, as these factors can influence the accuracy of the PSD estimation. For instance, some manufacturers may include elements such as DICOM tags 113788 (‘collimated field height’) and 113789 (‘collimated field width’) in the RDSR. These elements provide comprehensive information about the rectangular shape of the X ray field for all irradiation events during the procedure. However, other manufacturers might include only element 113790 (‘collimated field area’), which assumes a square field shape. This difference can affect the accuracy of the data, depending on the system in use.

(j) To accurately estimate the PSD, it is crucial to first evaluate the quantity and quality of the information available. This assessment helps to identify any limitations that may impact the accuracy of the PSD calculation. It is essential to review the specific elements included in the RDSR for the X ray procedure [71]. Following this evaluation, it is typically necessary to perform measurements on the X ray units using calibrated dosimeters to ensure precise and reliable PSD estimations.

(k) The accuracy needed for PSD verification depends not only on the calculation methodology but also on the measurement techniques employed. Certain dosimeters, such as ionization chambers or solid state detectors, provide highly accurate point measurements but lack spatial information. In contrast, dosimeters such as radiochromic films offer high spatial resolution but can suffer from significant inaccuracies if not meticulously calibrated [72, 73]. The European Commission research project VERIDIC (Validation

and Estimation of Radiation Skin Dose in Interventional Cardiology), which focuses on patient specific dose calculation in interventional cardiology [32, 74], has proposed a methodology for verifying the accuracy of skin dose mapping software, addressing these challenges and enhancing the reliability of PSD measurements.

Only after all these functionalities have been thoroughly verified and confirmed during acceptance testing can the DMS be approved for use. This step is crucial to ensure that the system operates accurately and reliably, meeting all specified requirements. Following successful acceptance, the DMS should undergo a comprehensive commissioning process, which is essential for gathering the necessary information for clinical use.

7.3. COMMISSIONING AND USER SETUP

To ensure that a DMS operates at its highest potential, a thorough commissioning process is essential before the system is put into clinical use. This involves configuring the DMS to match the specific characteristics and workflows of the facility where it will be deployed. Key tasks during commissioning include entering facility specific details such as equipment information and workflow configurations, which help to tailor the DMS to accurately reflect the unique environment in which it will function. Additionally, setting up appropriate user roles and permissions is crucial for maintaining system integrity, as it ensures that only authorized personnel can configure, modify and manage critical settings. This meticulous setup process safeguards the accuracy and reliability of the DMS and prevents unauthorized changes, preserving the system's overall effectiveness in clinical practice.

Examples of important commissioning tasks and functionalities that need to be set up include the following:

(a) During the setup process, it is essential to configure a DRL library that includes DRL values from different countries or regions. The DRL library needs to be mapped with the protocol library to enable accurate comparison of clinical dose indications against the relevant DRLs for various diagnostic tasks. Some DMSs have defined such libraries for specific countries or regions.
(b) Setting up a comprehensive clinical protocol library is crucial for managing CT protocols in alignment with actual clinical tasks. This library should be regularly reviewed and updated to ensure that it remains accurate and relevant to current clinical practices.

(c) It is necessary to configure rejection rules during the setup phase to exclude specific medical imaging modalities or QC tests from the DMS. These rules are vital for ensuring that only patient relevant data are processed and analysed, thereby maintaining the system's integrity and efficiency.
(d) As part of the setup process, correction factors for dose metrics need to be configured for certain X ray modalities to ensure accurate dose management.
(e) To ensure precise calculations, the setup should also include the configuration of factors needed for the estimation of various quantities.
(f) To enhance the accuracy of PSD estimations in FGIPs, the setup process should involve the input of specific physical parameters related to the X ray unit geometry and the attenuation properties of the examination couch.
(g) Effective alert functionality depends on properly configuring warning and alert levels for each diagnostic task during the setup. This ensures that the system can promptly notify users when predefined thresholds are exceeded.
(h) During the setup phase, it is crucial to establish a dedicated QC patient profile. This profile can be specifically designed to rigorously test and validate the DMS functionalities by simulating various clinical scenarios, thereby ensuring the system's performance, accuracy and reliability before it is fully implemented in routine clinical practice.

7.4. ROUTINE QUALITY CONTROL

Many of the functionalities and characteristics of a DMS are designed to tolerate only minimal systematic errors, which can often be detected and corrected during the system's acceptance testing or commissioning phase. However, owing to the potential for 'random' errors and the critical nature of certain features — such as alert systems — routine QC is essential to ensure ongoing reliability and performance. Additionally, any upgrades to medical imaging units or the DMS itself necessitate retesting specific functionalities as part of routine QC to maintain system integrity. The checks below highlight the importance of routine QC in a DMS. It is essential for detecting and correcting errors, maintaining system reliability and ensuring that critical features, such as data integrity, connectivity and alert systems, function as intended. By consistently performing routine QC tests, the user can ensure that the DMS operates at peak performance.

— Data integrity checks: Routine QC includes regularly running automated data integrity checks to identify and address issues such as duplicate records, missing data or data format errors. This ongoing monitoring is crucial for ensuring the accuracy, consistency and reliability of the data in the DMS. By routinely verifying data integrity, minor issues can be detected and

corrected before they escalate, thereby maintaining the overall quality and dependability of the system.

— Connectivity verification: Routine QC is particularly important for verifying the connectivity between X ray systems and the DMS. Connectivity issues can lead to significant data loss, especially in systems that monitor doses from FGIPs, where continuous data flow is critical for patient follow-up. Regular connectivity checks, especially after system upgrades or changes, help to ensure that the DMS consistently captures all necessary data. Implementing an automated feature in the DMS that periodically checks connectivity and alerts users to any issues can further enhance the system's reliability and prevent data loss.
— Alert system testing: The alert system in a DMS is a vital function, particularly in FGIPs, where it detects high dose cases that might lead to skin injuries and require timely follow-up. Routine QC ensures that this system remains functional and responsive. By regularly simulating alert scenarios and testing the system's ability to generate and deliver alerts, routine QC helps to maintain the effectiveness of this critical feature, ensuring that potential patient safety issues are identified and addressed promptly.

7.4.1. Quality control patient profile

DMSs typically apply strict controls on patient identification to ensure that the recorded dose information accurately corresponds to actual patient procedures and is not skewed by QC tests or engineering adjustments. This is crucial because incorporating QC data into patient records can lead to inaccurate dose information, particularly since many QC procedures intentionally push the X ray system to its operational limits.

To prevent such data contamination, it is highly beneficial to establish a dedicated QC patient profile that is not associated with any real patient. This profile serves solely for the purpose of testing the functionality of the DMS. By using a QC patient, CQMPs can perform imaging studies or generate 'artificial' dose reports using templates, all aimed at verifying the performance of the DMS without risking the integrity of actual patient data. For example, utilizing a QC patient can significantly enhance the verification of dose map estimation functionality in FGIPs. A series of studies can be sent to the DMS, using specific X ray projections with well characterized beam parameters and known skin doses. This can be achieved by irradiating a phantom on an angiography unit under the identity of the QC patient or by generating artificial dose reports that are specifically modified by the CQMP. Additionally, the QC patient profile can be invaluable for testing the alert system; by creating an artificial dose report with intentionally high doses and sending it to the DMS, the alert functionality can be thoroughly evaluated.

The QC patient profile needs to be strictly reserved for QC purposes and needs to be segregated by the DMS from actual clinical data. This ensures that it does not skew dashboard information or affect any statistical estimations. For the QC patient to function effectively, the DMS needs to provide clear and detailed instructions to the administrator on how to create a simulated patient record, such as an RDSR.

7.4.2. Suggested quality control tests

Table 2 outlines the key QC tests that are essential for the optimal performance of a DMS, providing detailed information on the frequency of each test as well as the expected levels of accuracy to ensure the system's reliability and compliance with baseline values established during commissioning.

TABLE 2. DMS QUALITY CONTROL TESTS [3, 69]

Function	Frequency	Accuracy
Device connection	At least for every new medical equipment or upgrade	100%
Alert system		
Device configuration (DRL, protocols, libraries)	Automatic self-monitoring of connection with regular reports analysed on a weekly basis	
Input verification (data transfer, data verification, units)		
Connection with other software (correct URL for each patient)		
Data export		
Dashboard information		
Patient specific dose estimations: patient size, PSD and others		Depends on clinical use and local regulation

Note: DRL: diagnostic reference level; PSD: peak skin dose.

8. USE CASE SCENARIOS

The following examples illustrate the types of information that can be obtained from various DMSs, showcasing the significant potential of these systems. Most of the data presented are directly provided by the DMS,

demonstrating the system's ability to enhance efficiency and accuracy in clinical practice. Additionally, certain cases highlight instances where data extracted from the DMS are further analysed by a CQMP using alternative statistical software, underscoring the flexibility and depth of analysis that can be achieved when integrating DMS data with advanced processing tools. The case examples provided below are drawn from the extensive experience of the group of experts who contributed to this publication, offering real-world insights into the practical applications of a DMS.

8.1. CASE 1: AVERAGE GLANDULAR DOSE IN MAMMOGRAPHY

The distribution of AGD values with increasing CBT is shown in Fig. 14. The CBT values have been grouped in 5 mm CBT bins and the respective median values of the calculated AGD values in each bin have been calculated. These data refer to 25 380 two dimensional (2-D) mammograms acquired using a single mammography unit during a period of about 10 months (1 January 2023 to 10 November 2023). These values were compared with the respective acceptable and achievable EUREF (European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services) values [75].

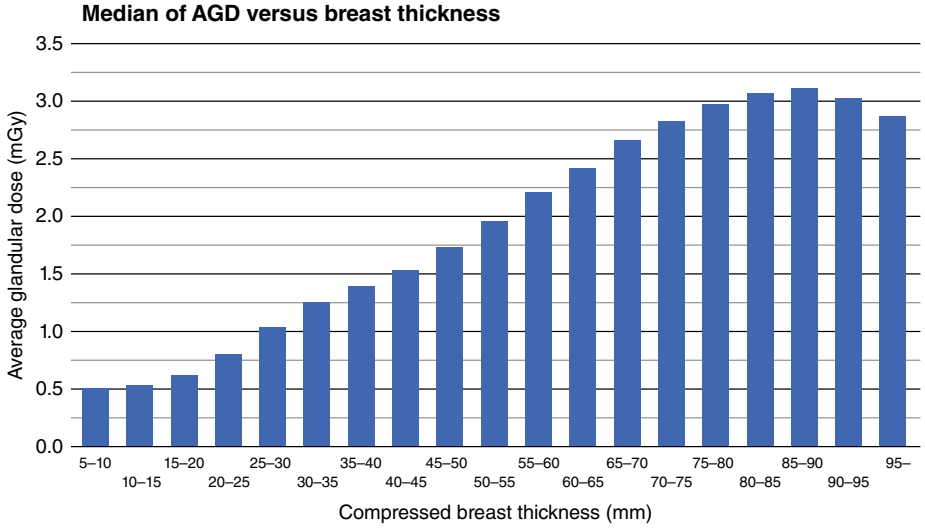

FIG. 14. Two dimensional mammography projections of AGD versus CBT in segments of 5 mm, measured by a specific mammography unit from 1 January to 10 November 2023 (courtesy of Hospital Clínico San Carlos, Madrid).

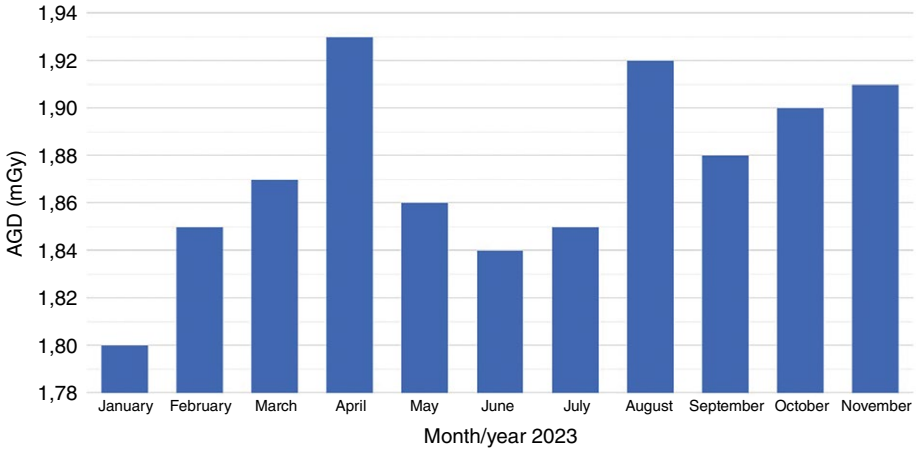

FIG. 15. Timeline representation of the monthly mean of the AGD during the year 2023 (courtesy of Hospital Clínico San Carlos, Madrid).

8.2. CASE 2: MONTHLY MEAN AVERAGE GLANDULAR DOSE DISTRIBUTION

A timeline representation of the monthly mean of AGD values is presented in Fig. 15. The figure shows the DMS dashboard for the year 2023. These data refer to 7893 2-D mammograms of breasts with CBT values in the range 4.5–5.5 cm acquired in a single mammography unit during 2023. Variations of ±0.07 mGy with respect to the average 1.87 mGy are observed, not detecting important changes in dose metric behaviour.

8.3. CASE 3: WEEKLY AVERAGE OF COMPRESSION FORCE

In this case, the DMS allows the data to be downloaded in csv format. The data were analysed by a CQMP using the Pandas and Matplotlib Python libraries. The weekly average of the compression force for CBT values in the range 4.5–5.5 mm is shown in Fig. 16. Error bars representing the standard deviation are included in the graph. A significant reduction in compression force was identified, with the average force dropping from 90 N to 60 N during July and August of 2020. This issue was promptly addressed during a meeting with the mammography department, leading to corrective actions. However, a similar drop in compression force was observed again from March to May 2021. This analysis underscored the importance of ongoing monitoring, through the weekly

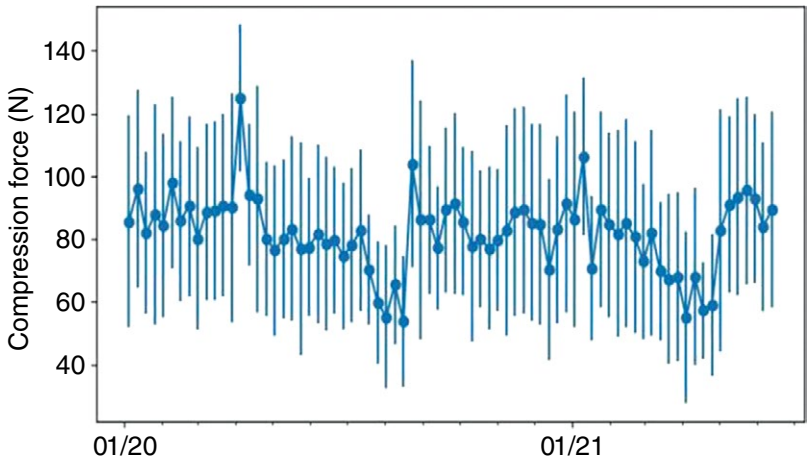

FIG.16. Average weekly breast compression force for compressed breast thickness in the range 4.5–5.5 mm (courtesy of Hospital Clínico San Carlos, Madrid).

tracking of compression force and other critical parameters, to ensure consistent quality in mammography.

8.4. CASE 4: MEDIAN DOSES IN INTERVENTIONAL CARDIOLOGY

Figure 17 shows a comparison of the median values of KAP and the respective DRL values in various interventional cardiology procedures. The data were filtered in the DMS for a specific angiography X ray system in 2023.

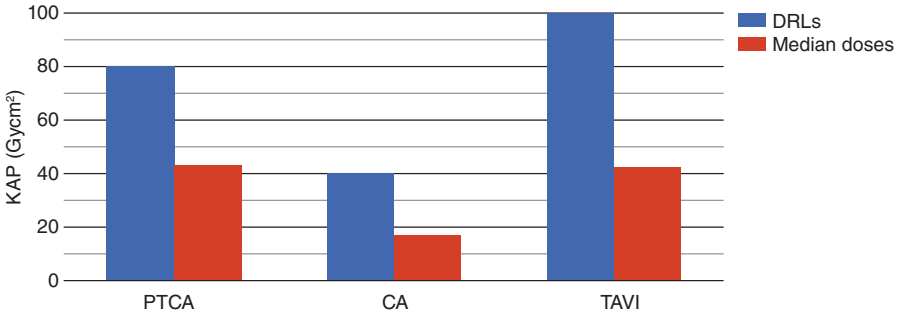

FIG. 17. Comparison of the median values of KAP with the DRLs in interventional cardiology practices for the year 2023. The types of procedure analysed were percutaneous coronary angioplasty (PTCA), coronary angiography (CA) and transcatheter aortic valve implantation (TAVI) (courtesy of Hospital Clínico San Carlos, Madrid).

The total number of procedures analysed was 490. The DRL values used for comparison were the national DRLs for percutaneous coronary angioplasty and coronary angiography [58] and the European DRL value for transcatheter aortic valve implantation [76].

8.5. CASE 5: RUN CHART FOR MONITORING $K_{a,r}$ IN FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

High radiation doses from FGIPs can potentially cause skin injury to the patient. While the PSD depends on many factors, a suitable proxy for radiation dose monitoring is $K_{a,r}$, which is transmitted to the DMS and can be monitored via a run chart. The chart in Fig. 18 shows $K_{a,r}$ values as a function of time. This DMS displays alert thresholds along with the chart. Alert thresholds are defined by the user. Furthermore, each data point is interactive in this DMS and can be selected to open a window that displays information of the corresponding patient examination. Figure 18 shows four devices with the highest number of examinations displayed in colour, while radiation doses from all other equipment are shown in grey.

Figure 19 shows a similar graph from a different DMS. This is the case with a $K_{a,r}$ value over 5 Gy, which is the trigger level to start patient follow-up for potential skin injuries.

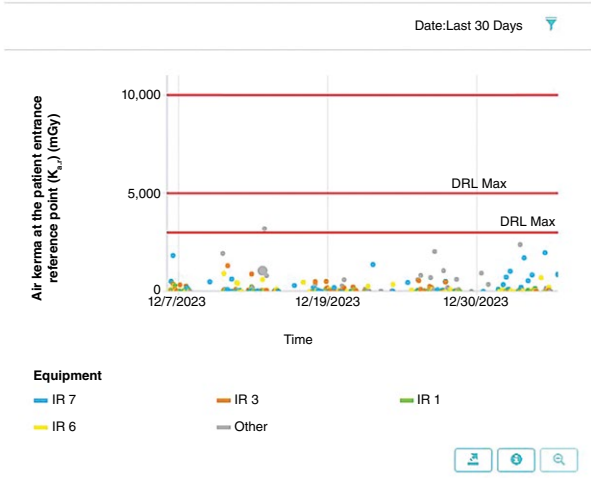

FIG. 18. $K_{a,r}$ *as a function of time for multiple fluoroscopy systems (IR1, IR3, IR6 and IR7), as given by the DMS. The red lines correspond to alert thresholds and the DMS automatically labels the lower two lines to show the different thresholds (courtesy of I.S. Reiser, University of Chicago).*

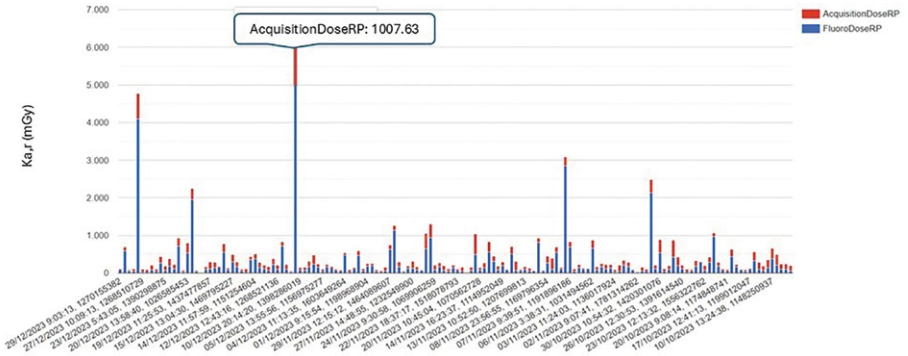

FIG. 19. $K_{a,r}$ *as a function of time from a different DMS provider (courtesy of Hospital Clínico San Carlos, Madrid).*

Some DMSs provide alerts by email to the person(s) responsible for the management of radiation doses, as shown in Fig. 20. This person can access more information about the case by looking at the records stored at patient level, as shown in the figure. The patient in the example underwent one procedure on 15 April and another procedure on 17 April. Therefore, both procedures should be considered in the investigation of possible skin injuries.

When analysing the procedure with the highest $K_{a,r}$ for this particular patient, a PSD of 5202 mGy was estimated by the DMS, as shown in Fig. 21. The other procedure had a $K_{a,r}$ of 143 mGy and the PSD was estimated as 67 mGy. Assuming the worst case scenario, in which both procedures delivered the maximum dose at the same point, the total PSD would be 5269 mGy. This value is above the PSD threshold of that particular institution (5 Gy) and thus the patient was referred for follow-up for potential skin injuries. At the time of writing, no serious injuries were detected.

Saturday 15th April	13:18	XA CLARITY HCSC-CA. KAP: 11.71 Gy.cm^2. $K_{a,r}$: 143.2 mGy. Approximately equivalent to environment radiation dose received during 0.9 years. Values are validated by the responsible medical physicist.
Monday 17th April	17:47	XA CLARITY HCSC-Other therapeutic procedure. KAP: 309.98 Gy.cm^2. $K_{a,r}$: 5669.73 mGy. Approximately equivalent to environment radiation dose received during 25.7 years. Values are validated by the responsible medical physicist.

FIG. 20. DMS alerts for high radiation doses (courtesy of Hospital Clínico San Carlos, Madrid).

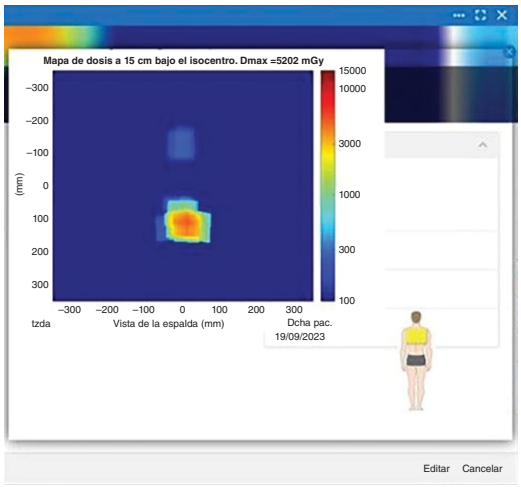

FIG. 21. DMS provided PSD map in an FGIP (courtesy of Hospital Clínico San Carlos, Madrid).

8.6. CASE 6: COMPUTED TOMOGRAPHY ACTIVITY DASHBOARDS

The pie chart in Fig. 22 illustrates the patient workload activity for a CT scanner over the course of one trimester, encompassing a total of 8008 studies. These studies are categorized by procedure performed and the image displays only the first page of a three-page list that includes 50 different types of procedure. Notably, half of the workload is concentrated in just four procedure types, while 75% of the activity is accounted for by 11 procedure types. The procedure descriptions correspond to the DICOM tag (0008, 1030) for 'study description' generated by the institution. This visual representation was instrumental for the CQMP overseeing CT dose management, enabling the identification of the most frequently performed procedures and initiating targeted optimization actions to enhance patient care and safety.

8.7. CASE 7: COMPUTED TOMOGRAPHY MEDIAN DOSE METRICS

Figure 23 presents a comparison of CT DLP values against national DRLs. The figure displays median DLP values for four types of CT procedure: pulmonary arteries; head without contrast; chest without contrast; and chest–abdomen–pelvis with contrast. The data, gathered from four CT scanners and encompassing a total of 21 159 studies, highlight how these procedures compare with the national

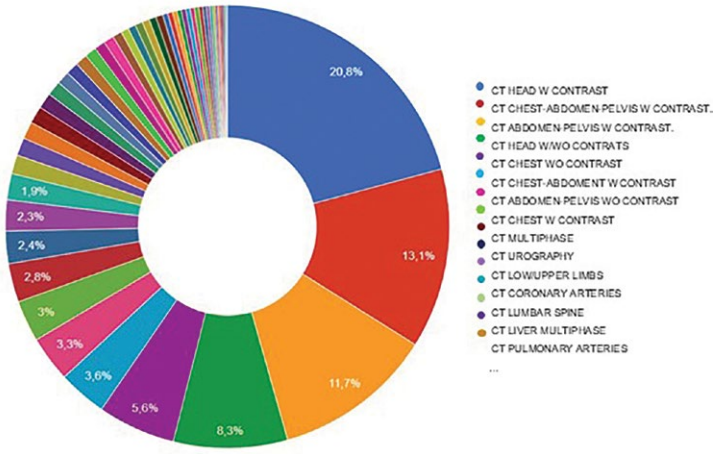

FIG. 22. Pie chart showing the patient workload activity for a CT scanner over the course of one trimester including 8008 studies. The chart highlights key procedures such as head CT with contrast (blue); head CT without contrast (green); chest–abdomen–pelvis with contrast (red); abdomen–pelvis with contrast (orange); chest CT with contrast (purple); chest CT without contrast (light green); liver multiphase; urography; and extremities (courtesy of Hospital Clínico San Carlos, Madrid).

DLP DRLs. To generate this analysis, CT records were categorized on the basis of the 'procedure performed' and 'protocol name' labels. Additionally, the DLP DRL library was configured to incorporate the relevant national DRLs, ensuring an accurate and meaningful comparison.

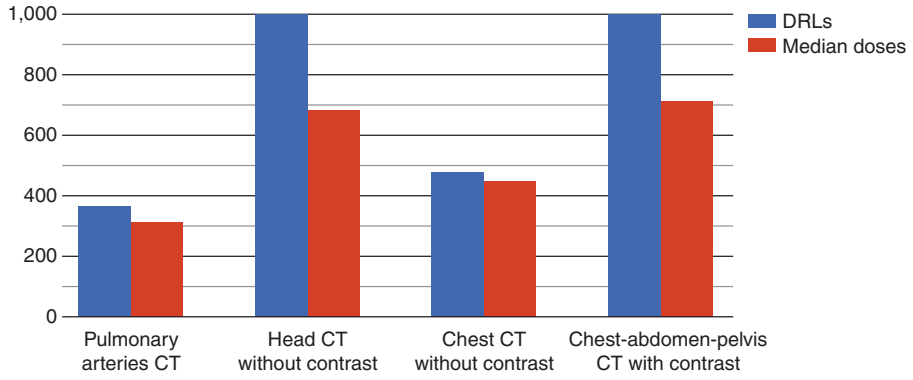

FIG. 23. Comparison of CT studies with national DRLs for pulmonary arteries CT, head CT without contrast, chest CT without contrast and chest–abdomen–pelvis CT with contrast (courtesy of Hospital Clínico San Carlos, Madrid).

8.8. CASE 8: SCATTER PLOTS FOR COMPUTED TOMOGRAPHY DOSE MONITORING

Scatter plots are an efficient way to study the variation of the collected data on CT dose metrics with respect to different patient sizes. Figure 24 shows a scatter plot displaying various CT dose metrics as a function of patient size. In these graphs, the WED was chosen to represent the patient size. Other size metrics may be available, such as patient diameter (e.g. effective, anteroposterior and lateral).

In Fig. 24 (a), $CTDI_{vol}$ is shown for low dose chest CT examinations performed on two different CT scanners, CT1 and CT2. It is immediately seen that the protocol(s) on CT1 utilize ATCM, resulting in an increase in $CTDI_{vol}$ as

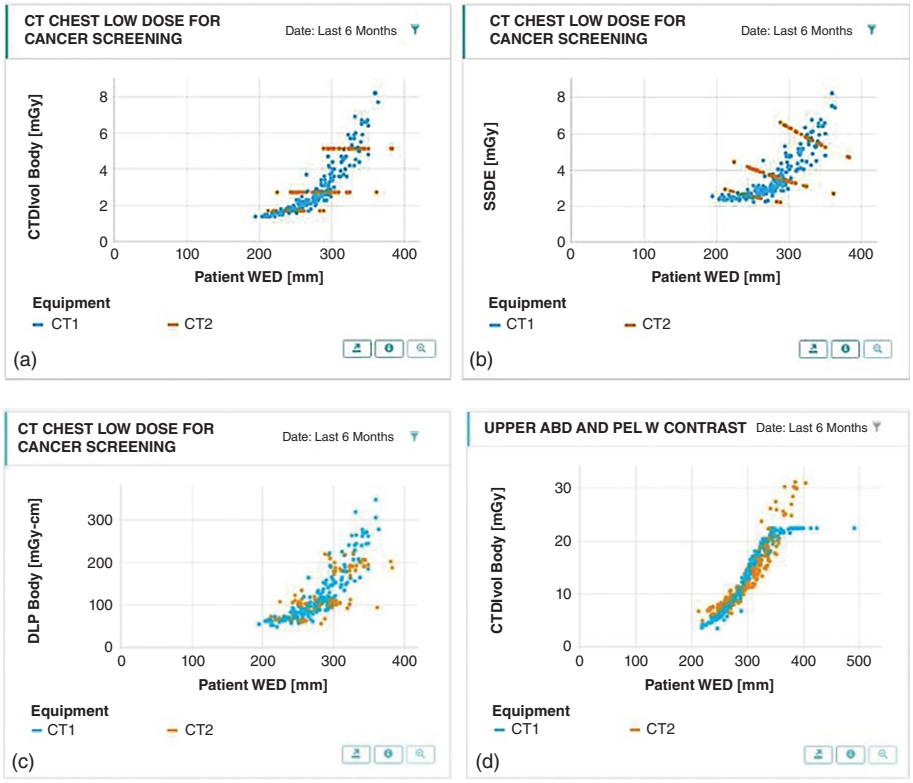

FIG. 24. (a)–(c) $CTDI_{vol}$, SSDE and DLP as function of patient WED from low dose chest CT examinations for lung cancer screening. (d) $CTDI_{vol}$ data from CT examinations of the upper abdomen and pelvis with iodine contrast. In this DMS, each data point is interactive and can be selected to open a window that displays information of the corresponding patient examination(s) (courtesy of I.S. Reiser, University of Chicago).

patient size increases. In CT2, $CTDI_{vol}$ does not change smoothly with patient WED; instead, it has three distinct values that extend over three ranges of WED values that overlap. This is indicative of the use of constant mAs protocols (no use of ATCM) for three patient sizes (small, medium, large). The overlap of the $CTDI_{vol}$ values over these three WED ranges clearly indicates that the CT operators' perceptions of patient size vary greatly. The scatter plot is an effective tool to identify protocols that may be inadvertently set to manual (no ATCM) technique. It should be noted that the American College of Radiology guidelines on the use of ATCM or constant mAs protocols for different patient sizes consider that both selections are valid.[11]

Figure 24 (b) shows the same data as a function of SSDE. The SSDE is an estimate of patient dose, and for a constant $CTDI_{vol}$, the SSDE decreases as patient size increases. For CT1, the SSDE is not constant as a function of patient size, because a higher dose is needed to achieve an image quality target in larger patients, in terms of both $CTDI_{vol}$ and SSDE.

Figure 24 (c) shows the DLP as a function of WED for the same data as Fig. 24 (a) and (b). There is more variation in the data because the DLP varies with scan length, which should be individually adjusted for each patient. However, the three groups of DLP values are still discernible for the CT2 scanner.

Figure 24 (d) displays $CTDI_{vol}$ from routine abdomen protocols. Both scanners use tube current modulation to adjust radiation dose, but the modulation methods differ. On CT1, the dose is adjusted on the basis of a constant noise target (General Electric noise index), while C2 adjusts the dose according to an image quality target (Philips DoseRight index). This leads to different dose dependencies according to patient size for each scanner. Additionally, on CT1, a maximum X ray tube current is set, causing $CTDI_{vol}$ to level off (plateau) for patient sizes of around 350 mm or larger.

Figure 25 shows a scatter plot where $CTDI_{vol}$ is presented versus the WED in a DMS produced by a different developer. The figure combines $CTDI_{vol}$, WED and the global noise level (as calculated for soft tissue) for 3 mm thick abdominal CT slices into a single graph. The plot illustrates that for a given WED, higher $CTDI_{vol}$ corresponds to lower global noise levels. It also illustrates how the automatic exposure settings of a CT scanner can be verified in one overview. The colour code represents the global noise level estimated by the DMS itself [40, 77]. When using the global noise level, it is possible to also take into account an image quality indicator together with a dose indicator and the patient size.

[11] https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards

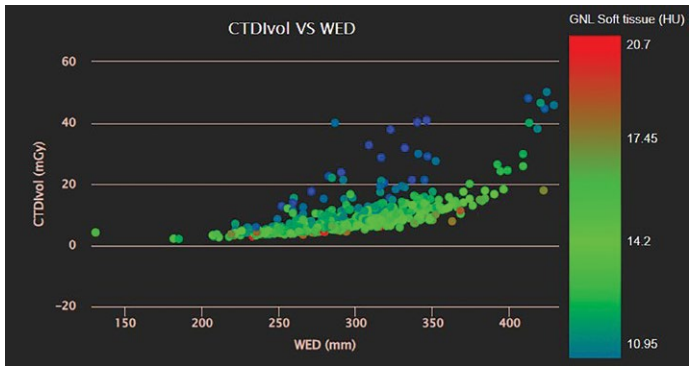

FIG. 25. Scatter plot of $CTDI_{vol}$ versus WED from a DMS produced by a different developer (courtesy of H. Bosmans, University Hospital Leuven).

8.9. CASE 9: COMPUTED TOMOGRAPHY PROTOCOL OPTIMIZATION

Figure 26 shows a clustered bar chart that can be used to monitor changes in $CTDI_{vol}$ values and to compare values with local DRLs. This example shows the radiation dose from a soft tissue neck protocol performed on two CT scanners of the same vendor and model. The $CTDI_{vol}$ values were inconsistent, and one scanner exceeded the user defined DRL. In collaboration with radiologists and MRTs, the acquisition parameters were adjusted on both scanners. The clustered bar chart shown in the figure allows visualization of changes over time, as well as comparison with user defined DRLs. In this example, inconsistencies in radiation dose were discovered by the DMS and changes to the soft tissue neck protocol on both scanners were made.

8.10. CASE 10: COMPUTED TOMOGRAPHY DOSE METRICS SUMMARY REPORTS

DMSs generally provide summary reports that include detailed statistics, such as minimum and maximum values, quartiles, and others. An example of such a summary table is shown in Fig. 27 for the DLP of CT abdomen examinations performed at two different locations in a large metropolitan area.

Figure 28 shows linked histograms of sizes of two different patient populations and CT systems. Clicking on an icon on the top right of each histogram provides further summary statistics for each histogram, such as the mean and median.

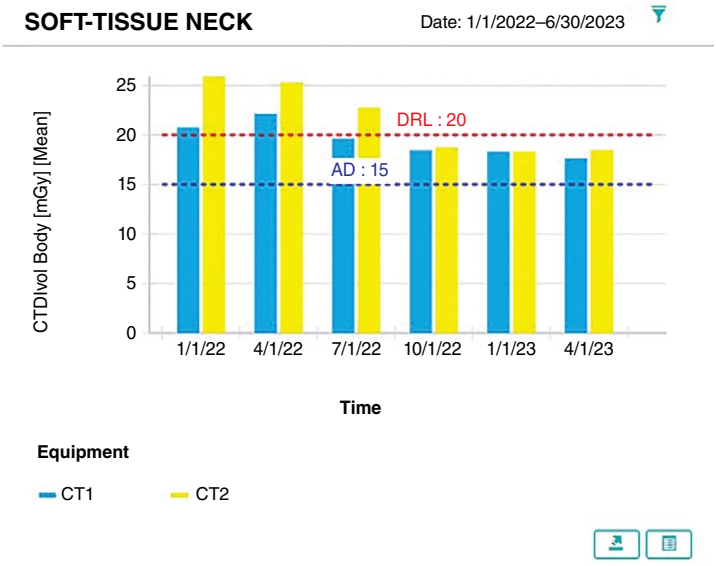

FIG. 26. Clustered bar chart visualizing changes in $CTDI_{vol}$ over time for two scanners, CT1 and CT2, as well as in comparison with user defined radiation dose thresholds (AD: achievable dose and DRL). In this example, changes to the soft tissue neck protocol on both scanners were made in August of that year (courtesy of I.S. Reiser, University of Chicago).

The median DLP is substantially higher for CT1 (Fig. 28 (b)) than for the other scanner (CT East Clinic, Fig. 28 (a)). The histograms created to compare the WED of the patients scanned on the two CT systems revealed substantial differences in the patient size distributions.

Box and whisker plots for $CTDI_{vol}$ were created to confirm the above findings, as shown in Fig. 29. Figure 29 (a) includes dose data from all patients,

DLP (body) – Upper ABD Date: Quarter 3

Equipment	Minimum [mGy-cm]	Maximum [mGy-cm]	Average [mGy-cm]	First Quartile (25%) [mGy-cm]	Median [mGy-cm]	Third Quartile (75%) [mGy-cm]	Number of Exams
CT 1	361	3578	876	550	784	1128	198
CT East Clinic	153	2155	610	429	510	697	90

FIG. 27. Example of a summary statistics table. In this example, the dose metric is the DLP, but this can be configured to use other metrics, such as $CTDI_{vol}$ (courtesy of I.S. Reiser, University of Chicago).

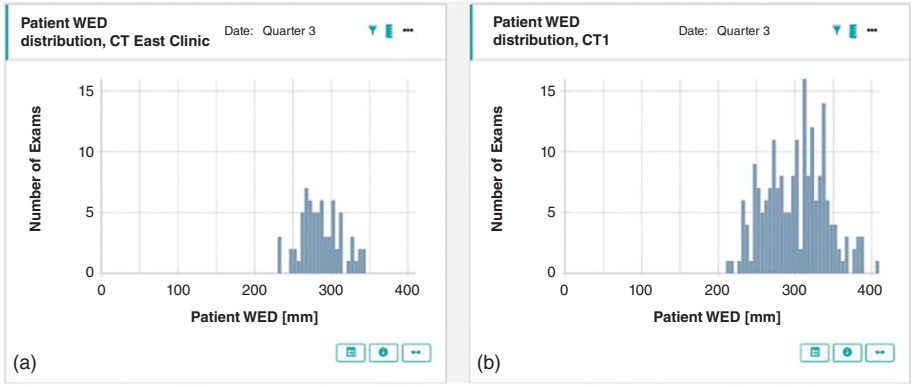

FIG. 28. Linked histograms of the sizes of two different patient populations for two different CT systems. (a) CT East Clinic system and (b) CT1 system (courtesy of I.S. Reiser, University of Chicago.)

while Fig. 29 (b) includes data only from patients within a specific WED range (240–270 mm). The $CTDI_{vol}$ distributions of the two scanners differ in Fig. 29 (a), as in Fig. 28, but when comparing patients of equal size, the radiation dose distributions of both scanners were more similar.

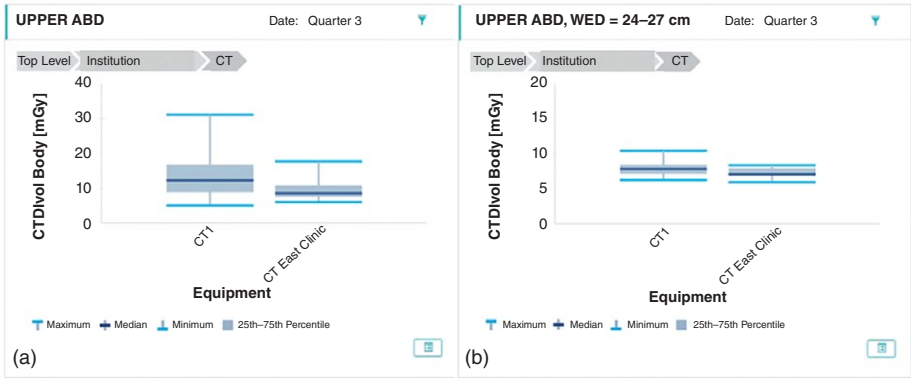

FIG. 29. Box and whisker plots can be useful to compare $CTDI_{vol}$ values for the same type of examination in two different CT scanners (courtesy of I.S. Reiser, University of Chicago).

8.11. CASE 11: EQUIPMENT UTILIZATION ANALYSIS

DMSs may also provide charts to visualize equipment utilization. The example in Fig. 30 shows two CT scanners, one of which is in the emergency department and the other one (CT1) is located in another clinical area that does not operate on weekends.

Another useful chart for visualizing equipment use is the pie chart (Fig. 31). Pie charts can be helpful to illustrate the workload distribution across a fleet of an

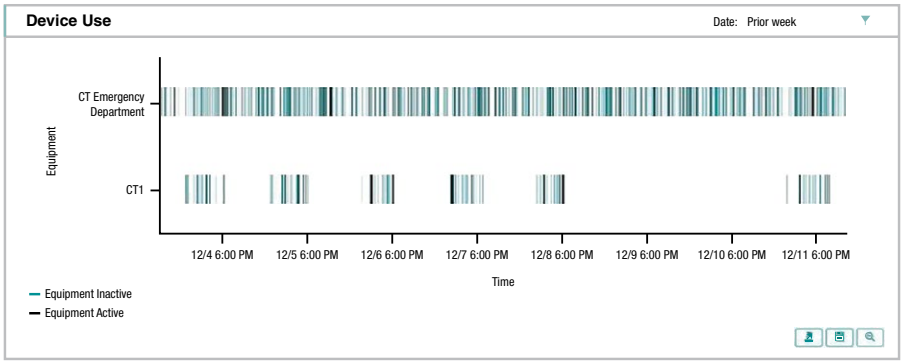

FIG. 30. Chart showing the utilization of equipment in two clinical areas, the emergency department (top) and a clinical area that does not operate on weekends (bottom). (Image courtesy of I.S. Reiser, University of Chicago.)

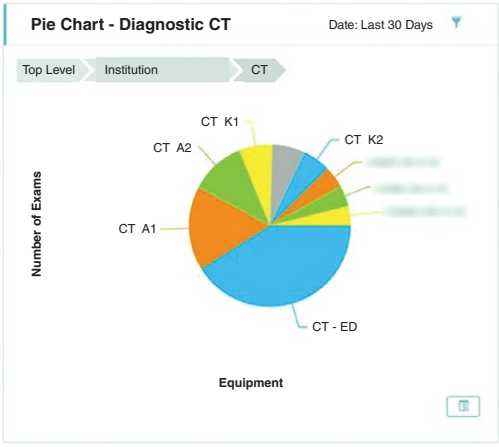

FIG. 31. Pie chart illustrating the workload distribution between different CT scanners. Clicking on the icon on the bottom right corner will present the same information in a table format (courtesy of I.S. Reiser, University of Chicago).

equipment type. These charts are also useful to show the types of scan performed in different clinical areas.

8.12. CASE 12: STUDY LEVEL METRICS AND MULTIPLE ORDERS IN COMPUTED TOMOGRAPHY

It is not uncommon for multiple orders to be filled during one patient visit to a CT scanner. In such cases, each individual irradiation event may be assigned to one or more orders. Simultaneous orders for non-contrast brain and cervical spine examinations are an example. In this setting, a DMS user is likely interested in descriptive statistics for either the cervical spine or the non-contrast brain acquisition, for instance, to compare the median cervical spine $CTDI_{vol}$ with a national DRL value. Even for this common and relatively simple use case, one can easily be led to inaccurate conclusions if a DMS reports descriptive statistics for study level metrics.

As an example, the DMS used by the institution of one of the contributors assigns to each study a study level $CTDI_{vol}$ and provides the user descriptive statistics calculated from this metric. In the case of examinations with multiple acquisitions, the DMS assigns to the study the maximum $CTDI_{vol}$ across all acquisitions performed during the examination, even when the CTDI phantom differs across acquisitions. For an examination including both brain and cervical spine acquisitions, this leads to the study almost always being assigned the $CTDI_{vol}$ of the brain acquisition, partly because the cervical spine $CTDI_{vol}$ is commonly reported using the large phantom, while the brain $CTDI_{vol}$ is reported using the small phantom. If the DMS is used to calculate the median $CTDI_{vol}$ for all 'cervical spine without contrast' orders using this study level metric, the result will therefore not be the median $CTDI_{vol}$ for the cervical spine acquisitions. On the emergency centre scanner at the same institution, the median $CTDI_{vol}$ obtained from the study level metric is more than double the true median $CTDI_{vol}$ for cervical spine acquisitions. The true value was calculated using a recently added feature in the DMS that provides series level analyses. The reason for the discrepancy is the prevalence of combination brain and cervical spine examinations performed on the scanner. A lack of familiarity with the pitfalls of study level metrics could easily have led a user to believe that there was an issue with the scanner's cervical spine protocol.

8.13. CASE 13: INTERPRETATION OF COMPUTED TOMOGRAPHY IRRADIATION EVENTS

The interpretation of the DICOM standard definition of CT irradiation event can vary across makes and models of clinical CT scanners. An important example

arises in the context of cerebral perfusion scanning. On modern CT scanners, it is common to have the ability to change the temporal sampling rate throughout a perfusion acquisition. Whether a change in temporal sampling rate constitutes a new irradiation event, however, is dependent on the scanner make and model. For instance, on one clinical scanner that employs wide axial collimation for cerebral perfusion scans, each time that the sampling rate is changed, the subsequent set of acquisitions is considered a new irradiation event. By contrast, on a scanner of a different make and model that employs shuttle mode scanning for perfusion acquisitions, the entire perfusion acquisition is always considered a single irradiation event, regardless of whether the sampling rate is varied. This difference in interpretation can lead to confusion in a DMS. An example is the task of comparing $CTDI_{vol}$ values from cerebral perfusion examinations across scanners. Scanners that treat a perfusion scan as multiple, separate irradiation events will report a separate $CTDI_{vol}$ for each event. Scanners that treat the entire perfusion scan as one irradiation event will report a single $CTDI_{vol}$. This latter value is most likely what a user wants to compare across scanners. At the time of writing, not all DMSs have the capability to automatically determine when $CTDI_{vol}$ values should be summed across the multiple irradiation events that may make up a single perfusion scan. Thus, users may have to export the data from the DMS and perform this comparison themselves.

8.14. CASE 14: MAGNETIC RESONANCE IMAGING PATIENT DATA ANALYSIS

The DMS is also capable of analysing patient acquisition data from MRI. Such assessments are crucial to ensure that the system's performance aligns with the manufacturer's specifications, particularly when a patient is wearing an active device during exposure. Figure 32 illustrates a dorsal MRI examination that evaluates the specific absorption rate in watts per kilogram and the rate of change of the magnetic field (dB/dt) in millitesla per second for various sequences and their corresponding operating modes. Beyond these evaluations, the DMS can analyse various parameters of each sequence to aid in audit processes and facilitate optimization.

8.15. CASE 15: SPECIFIC ABSORPTION RATE ANALYSIS

DMSs provide a robust platform for monitoring and analysing time trends of MRI examinations across all connected MRI scanners within a specified time frame. Each point illustrated in Fig. 33 represents an individual MRI examination,

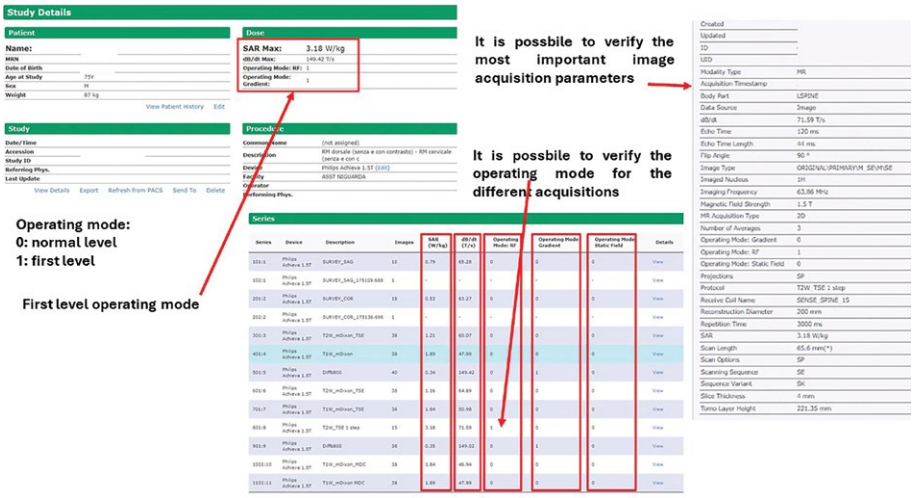

FIG. 32. DMSs enable monitoring of various operating conditions for each MRI scanner across different examination series (courtesy of Medical Physics Department, Azienda Socio Sanitaria Territoriale Grande Ospedale Metropolitano Milano).

pinpointing the estimated specific absorption rate. Selecting any of these points enables a deeper dive into comprehensive patient specific data, showcasing detailed exposure metrics and acquisition parameters, as depicted in the figure. This advanced functionality is instrumental in identifying examinations with elevated specific absorption rate levels, allowing healthcare professionals to conduct thorough audits and refine MRI protocols. By leveraging these insights, medical teams can enact targeted optimization strategies to enhance both the safety and the efficacy of patient care in MRI procedure optimization.

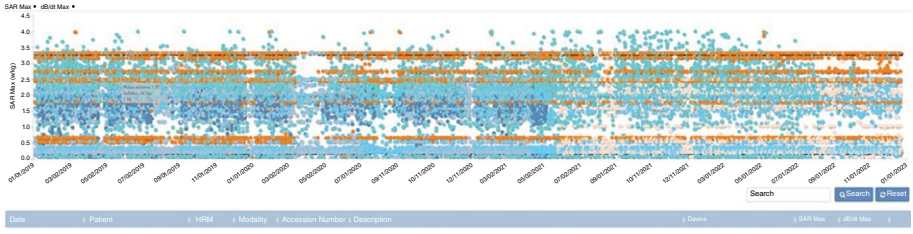

FIG. 33. For specific time periods, the trend of MRI scanner performance exceeding the 'normal level' of specific absorption rate can be assessed. The graph displays specific absorption rate measurements for all patients over time, with each dot representing an individual examination (courtesy of Medical Physics Department, Azienda Socio Sanitaria Territoriale Grande Ospedale Metropolitano Milano).

8.16. CASE 16: AUTOMATED MAMMOGRAPHY QUALITY CONTROL MONITORING

A mammography specific technical quality monitoring solution integrated in the DMS enables continuous oversight of daily QC testing. In this particular user case, a custom 40 mm polymethyl methacrylate phantom was exposed under normal clinical conditions, covering the entire active area of the detector, and the so called 'for processing' images were provided to the DMS from each mammography system. Following EUREF guidelines for long term reproducibility, the signal to noise ratio in the reference region of interest was tracked over time with a ±10% tolerance on the average value [75]. This tracking was visualized in a plot (Fig. 34), which helps to assess consistency over both the short and the long term. It also facilitates the identification of interventions such as recalibrations or part replacements and aids in diagnosing potential issues.

Thumbnail images are also available for review, displaying the mean pixel value, its deviation and the deviation in peak variance. Although artefacts still require review by staff on a diagnostic monitor, these thumbnails offer an additional opportunity to detect any artefacts or misalignments (Fig. 35).

8.17. CASE 17: ADAPTING DIAGNOSTIC REFERENCE LEVELS FOR DOSE OPTIMIZATION IN BREAST SCREENING

In accordance with Ireland's regulatory standards, a local DRL needs to be established for comparison with the national DRLs. However, using a single DRL

FIG. 34. Daily signal to noise ratio values plotted with a ±10% tolerance range (indicated in green). The trend plot visually represents the modality's acceptability over time (courtesy of E. Keavey, BreastCheck, Ireland).

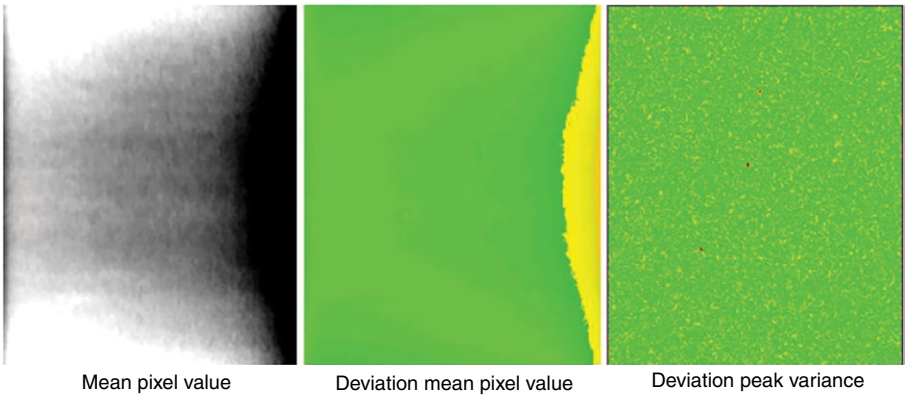

FIG. 35. Thumbnails displaying the mean pixel value, its deviation and the deviation in peak variance, with the later potentially indicating dirt on the phantom (courtesy of E. Keavey, BreastCheck, Ireland).

is applicable only to the average CBT, rendering this single value ineffective for other CBT ranges. Additionally, applying a single DRL across all system types poses challenges owing to variations in dose operating levels. The diverse range of CBTs and dose operating levels encountered in mammography limits the practicality of standard DRLs. Benchmarks are established at the 95th percentile on the basis of CBT bands and system type. The DMS enables straightforward visualization of these data (Figs 36 and 37), supporting ongoing dose audits. Specifically in Fig. 36, the data are presented for a single mammography system with the following column headings: (a) 'count' is the number of images in each CBT band for this system; (b) 'median' is the median AGD per CBT band for this mammography system; (c) 'comparison', when green, indicates that all

COMPLIANCE MONITORING - SERIES LEVEL (ORGAN DOSE)

Parameter type: Organ Dose I mGy | Dri Version: Version 2022

Study Group	Count (#)	Median	Comparison	Upper ACC
NDRL	5808	1.78	ALL 100	2.2
Mammo unit 1_Medium CBT	2761	1.7	ALL 100	2.55
Mammo unit 1_Large CBT	1891	1.93	ALL 100	2.88
Mammo unit 1_Small CBT	923	1.45	ALL 100	1.99
Mammo unit 1_Very Large Breast	233	2.33	ALL 100	3.13

FIG. 36. Data for a single mammography system (courtesy of E. Keavey, BreastCheck, Ireland).

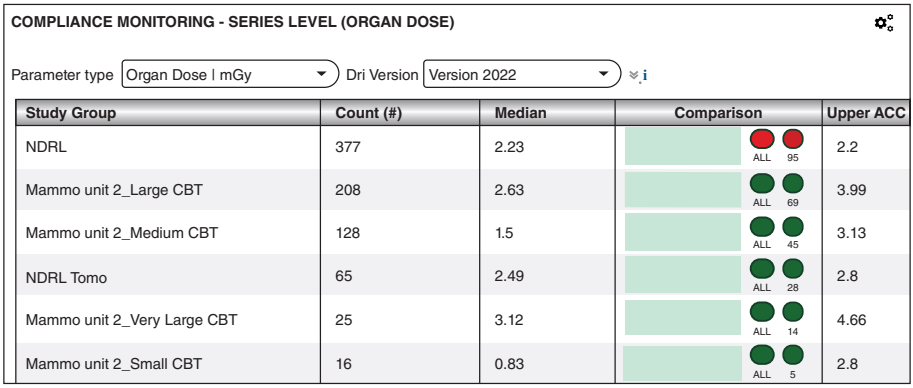

FIG. 37. Image highlighting non-conformance of this mammography system with the national DRLs, as shown by red markings (courtesy of E. Keavey, BreastCheck, Ireland).

ranges currently conform to the benchmarks; and (d) 'upper ACC' shows the value of the benchmark. The median value is continuously updated according to the selected date range, allowing real time comparison with the benchmarks. Comparing the median values for the relevant CBT on each mammography system with the established benchmarks addresses regulatory requirements in a more consequential and actionable manner. In Fig. 37, all CBT ranges comply with their respective benchmarks. In this case, the count clearly shows that a significant number of the CBTs in this period fall into the large CBT range, thus increasing the median value being compared with the national DRLs.

In conclusion, the case examples presented are not exhaustive but serve to illustrate the wide range of capabilities that can be achieved through various DMSs. These examples highlight the significant potential that DMSs hold for enhancing efficiency and illustrate their flexibility and capacity for more advanced analysis when integrated with other tools. While DMSs provide a powerful tool for data extraction and analysis, it is essential to recognize that mistakes can happen, whether in data collection, processing or interpretation. Therefore, proper validation, continuous monitoring and attention to detail are crucial for maintaining accuracy and reliability in the results obtained.

9. FUTURE PROSPECTS

Looking into the future, the evolution of DMSs promises to significantly enhance workflow efficiency, patient outcomes, safety and regulatory compliance

in medical imaging. Advances in technology, such as big data analytics, machine learning and artificial intelligence, are expected to further optimize DMS capabilities, enabling more precise patient data monitoring, predictive analytics and personalized care. However, the effectiveness of these advancements heavily relies on the quality of data imported into the DMS. Ensuring high data quality is crucial, as inaccuracies or inconsistencies can undermine the potential of DMSs. To fully realize the benefits of these evolving technologies, it is essential to focus on the continuous improvement of DMSs themselves. This includes enhancing data integrity, streamlining user interfaces and ensuring robust system functionality across diverse clinical environments. The following subsections explore key strategies for improving DMSs and future prospects, highlighting emerging trends, potential innovations and the evolving role of these systems in the ever changing landscape of medical imaging practices.

9.1. QUALITY OF DATA

Given the rapidly advancing capabilities of DMSs and their growing importance in enhancing workflow efficiency, patient safety and regulatory compliance, there is an urgent need to improve the quality of data imported from medical imaging systems. The effectiveness of a DMS is directly tied to the accuracy and completeness of the data that it receives from these systems. Unfortunately, data inconsistencies — such as incomplete or incorrectly formatted DICOM tags — are very common, often due to the non-uniform implementation of the DICOM standard across different manufacturers. Critical data elements such as dose indexes, protocol names and exposure settings are sometimes missing, inaccurately reported or inconsistently labelled by various medical imaging modalities. This lack of uniformity can lead to significant challenges in DMS functionality, from incorrect dose calculations to the misclassification of imaging procedures. As a simple example, the protocol names associated with CT scans can be incorrectly recorded, potentially leading to confusion and errors. Additionally, it is important to recognize that even when vendors include the necessary data elements, their interpretation of the DICOM standard can vary significantly across manufacturers. In some cases, these interpretations are demonstrably incorrect, further complicating data accuracy and consistency.

To address these issues, it is imperative that medical imaging equipment manufacturers standardize their data output, ensuring that all relevant DICOM fields are consistently and accurately populated. Furthermore, it is essential that any new imaging systems being developed strictly adhere to these standards, providing complete and accurate data to the DMS. Additionally, DMSs need to include robust data cleanup features to automatically identify and correct

inconsistencies in the input data, ensuring that the information being analysed is reliable and accurate.

A long term solution can be the close collaboration between medical imaging manufacturers, regulatory bodies, industry stakeholders and scientific societies or organizations to establish and enforce stricter adherence to DICOM standards. Medical imaging manufacturers need to ensure that all relevant data are accurately and consistently reported in both the RDSR and DICOM headers. It is crucial that all issues related to digital data integrity and accuracy be reported to the relevant national authorities, as digital data are now a critical component of patient safety. In addition, agreements with manufacturers of medical imaging equipment and DMSs can include clear clauses on data quality. These agreements should outline specific sanctions or economic consequences if the data provided by the systems do not meet the agreed upon specifications. This can help to ensure accountability and motivate manufacturers to deliver systems that meet the standards for patient safety and effective management.

Additionally, the development of industry-wide guidelines for protocol naming and reporting would help to alleviate the burden on DMS vendors and end users, reducing the need for continual software patches and workarounds. Improving the quality of data coming from the medical imaging systems is not merely a technical enhancement; it is a critical step towards ensuring that DMSs can operate at their full potential. This will lead to more accurate data monitoring, more reliable and meaningful analysis and, ultimately, better patient care.

9.2. PERSONALIZED ORGAN DOSE AND RISK ASSESSMENT

Patient organ dose calculation and risk assessment are features that gain interest and become important especially for certain DMS vendors; yet they are often affected by uncertainties and a lack of transparency from vendors in terms of the methods used. Some manufacturers offer the capability to calculate organ doses, but the information about the accuracy and reliability of these calculations is often not communicated effectively to the end users. It is crucial for DMS vendors to embrace greater openness about their systems, particularly regarding the methodologies and uncertainties involved in organ dose calculations. Looking into the future, the evolution of DMSs could significantly focus on personalized organ dose assessments. This advancement would align with the growing trend towards personalized medicine, where treatments and diagnostics are tailored to individual patient characteristics. By incorporating patient specific data, DMSs could provide more accurate and individualized assessments of organ doses, enhancing both the safety and efficacy of medical imaging.

Furthermore, there is an observable increase in patient awareness and demand for risk assessments related to medical exposures. This trend is driving an increasing interest in the development and validation of risk estimation tools that are more personalized. Patients are becoming more informed and involved in their healthcare decisions and are seeking detailed information about the potential risks associated with medical imaging procedures. This shift in patient expectations and the growing emphasis on personalized healthcare provide a fertile ground for DMS developers. They are encouraged to innovate and expand the capabilities of DMSs to include more sophisticated, accurate, personalized organ and/or risk assessment tools.

9.3. BIG DATA

It is a fact that currently DMSs are clinical repositories that contain large amounts of clinical, technical and administrative patient data. These repositories gather extensive data on large patient cohorts over time, enabling institutions not only to track and analyse trends in utilization but also to evaluate patient outcomes. This capability allows a deeper understanding of the effectiveness of medical interventions and patient care practices. Additionally, these repositories support the execution of advanced QA and medical management queries, providing insights that can lead to improved clinical practices and better patient outcomes, while remaining independent from the original data collection systems. Although a vast amount of information is stored, including long term outcomes and related patient data, the practice of extracting these data into larger regional or international repositories for exploring new and potentially valuable biomedical connections is a relatively recent development. Recent studies have also shown that applying large scale data mining tools to complex clinical datasets is feasible, offering a promising and potentially valuable alternative to traditional hypothesis-driven scientific research [78]. However, the analysis of big data to draw such conclusions and make informed decisions is not an easy process and requires advanced statistical analysis tools and specialized personnel or even artificial intelligence applications.

The use of DMSs in their present form is not sufficient on its own for advanced research purposes. Inexperienced or busy users may need extra time and effort, as the tools provided are often static and lack interactivity, which can reduce motivation to seek out answers on questions raised during clinical routine and workflow [79]. In some DMSs, the dashboards are complicated, difficult to use or they are not visually intuitive. In the future, dashboards can become easier to use and intuitive, since DMS users will often have only basic level of computer skills and limited time to learn or be trained. To maximize the

benefits that DMSs may offer, they should be able to provide users with summary information at a glance [80].

In this context, the DMS has the potential to function as a business intelligence tool, effectively organizing and managing data from various systems such as the PACS, HIS and/or RIS, through the creation of real time statistical dashboards. Alternatively, a dedicated business intelligence tool could further enhance data integration by seamlessly connecting all these systems including a DMS, enabling comprehensive analysis and decision making. Typically, business intelligence encompasses a range of technologies, processes and tools that allow the collection, processing and analysis of large amounts of data to generate useful information. The main function of a business intelligence tool is to link different databases and connect their contents through various indicators to then create statistical dashboards fed with real time data. For example, the HIS database contains patient demographic data; the PACS stores medical imaging studies, image quality indicators and other relevant information (such as the type and quantity of radiopharmaceutical injected in a nuclear medicine diagnostic study); while the DMS holds data on dose and other technical parameters (Fig. 38). However, although an indicator that links these three databases to each other — for instance, a medical record number — might not be available, other types of data might serve this purpose.

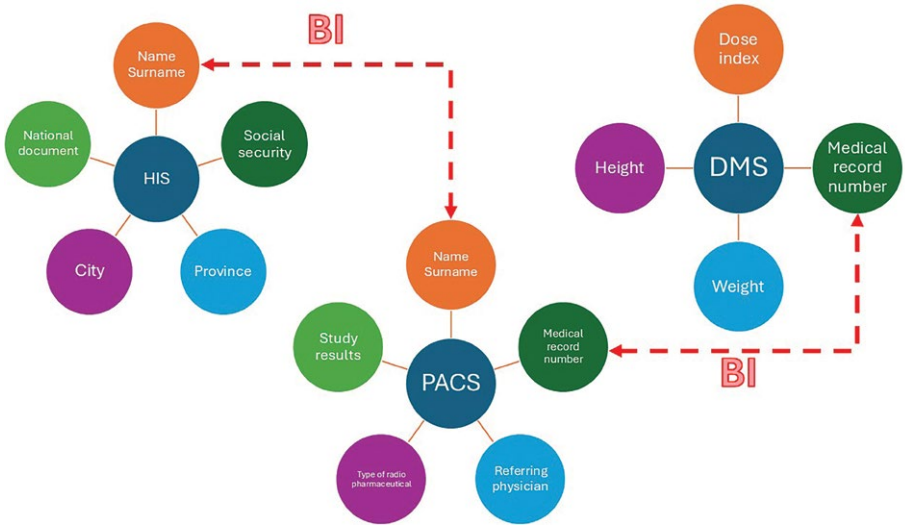

FIG. 38. Schematic showing the linking of certain databases (HIS, PACS, DMS) through a business intelligence tool (BI).

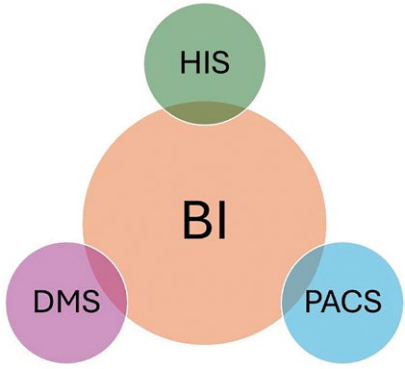

FIG. 39. Schematic of a business intelligence tool (BI) as a connector for various databases (HIS, PACS, DMS).

The final result can be interpreted as a business intelligence software acting as both a repository and a connector for various databases, much like a neural network system. In this analogy, the tool is responsible for creating networks or bridges between databases, allowing the retrieval of real time statistical data (Fig. 39).

It is important to highlight that this tool accesses different databases in real time, allowing the visualization of any trends in a medical institution through the management of statistical data. Therefore, one of the main uses of these tools can be to analyse how the health institution's ecosystem behaves when any of the parameters are modified. DMS users may benefit from creating a dashboard that indicates the number of patients from a particular city or region (obtained from the HIS) who have undergone an *x* type of study with *y* results (obtained from the PACS) and have presented *z* dose indicator values (obtained from the DMS) (Fig. 39). Such a dashboard would allow users to observe which types of pathology are more frequent in a certain region and the demographics of the population in order to optimize the institution's resources (such as the type and technology of the ideal medical imaging equipment).

9.4. QUALITY MANAGEMENT AND DMS

The importance of quality management in optimization of processes and resources (human, infrastructure, technology and others) has been discussed in Section 2. However, given that healthcare institutions are dynamic ecosystems that constantly evolve, the continuous monitoring of processes and their ongoing changes complicate the implementation of a quality management system in

medical imaging. It requires substantial effort and the involvement of many human resources.

To address these challenges, new work modalities and tools — such as process mining, patient relationship management and robot process automation — have been developed. Process mining, for example, is defined as an analytical discipline for discovering, monitoring and improving processes as they are. It allows institutions to monitor, analyse and improve their health processes with great precision. In processes or subprocesses of the clinic where interaction with the patient is necessary, patient relationship management tools play a crucial role by providing a teleconsultation environment and interaction tools (e.g. chat with document, forms, patient reported clinical outcome measures, patient experience questionnaires, chatbots, appointment and prescription services), from both the patient's and the health professional's perspectives. However, there are also repetitive processes that do not directly add value but are crucial for the institution's functioning. For these processes, tools such as robot process automation have emerged, allowing automation without human intervention or with minimal human involvement.

All of these tools within a quality management system rely on substantial connectivity, facilitated through an application programming interface, where the DMS can play a critical role in ensuring seamless integration and data flow across systems. The DMS could interact with other tools within the institution and its corresponding databases to facilitate or expedite the optimization processes of the quality management system, saving time and resources.

9.5. ARTIFICIAL INTELLIGENCE AND DMS

The practice of medical imaging is undergoing substantial transformations, largely influenced by the remarkable advancements in artificial intelligence. While medical imaging technologies continue to evolve, the integration of artificial intelligence into clinical settings has brought about innovative methods for optimizing and refining medical imaging processes. As medical imaging equipment becomes more sophisticated and its usage more widespread, MRTs, RMPs and referring physicians are experiencing heightened work demands. As reported in the literature, artificial intelligence is currently used for optimization in various radiological modalities, such as CT, through automation and optimization of data acquisition processes, including patient positioning, workflow or acquisition parameter settings [81]. However, there is limited literature on the ability of such artificial intelligence tools to accurately detect pathology [82]. All efforts are confined to the medical imaging modalities directly, with scarce information on artificial intelligence applications related to DMS technology or use.

At the same time, and to ensure that artificial intelligence systems do not optimize solely towards minimizing radiation dose at the expense of image quality, it is crucial to incorporate robust image quality indicators. A promising first step in this direction has been the use of global noise as an image quality metric, which has proved to be highly effective and is already widely utilized in some DMSs, sometimes more widely than traditional dose indicators [77]. Moving forward, the development and implementation of advanced image quality measures need to be prioritized to maintain a balance between dose reduction and diagnostic accuracy. While global noise is a good starting point, there is still a significant opportunity for the creation of more comprehensive and nuanced image quality metrics that can account for factors such as spatial resolution, contrast and detectability of clinical details. A strong focus on these developments will be essential for future artificial intelligence driven dose optimization efforts, ensuring that diagnostic integrity is preserved while patient safety is improved.

In addition to optimizing radiation dose and image quality, artificial intelligence based approaches to personalized dosimetry (e.g. in CT) are emerging as a powerful tool in medical imaging. Some DMSs are now capable of receiving images alongside exposure data, opening the door to advanced artificial intelligence techniques such as organ segmentation. By analysing patient specific anatomy directly from the images, artificial intelligence can deliver more personalized and accurate dosimetry calculations. This capability can allow precise organ dose estimations by taking into account individual patient characteristics, which goes beyond the more generalized dose indicators traditionally used.

Medical imaging creates a huge database of images and various related patient data that are archived at institutional level, regional or national dose or other patient data registries. In the future, use of artificial intelligence in these registries could transform the role of these archives. Currently, such repositories are used mainly for occasional data retrieval for the purpose of comparison of the performance of participating facilities with respect to the national DRL and to each other. However, their role could be transformed to become a key element in the process of improving the hospital's everyday clinical practice or even national health systems. In this new capacity, data could be regularly reprocessed and reanalysed, providing ongoing support for clinical decisions and identifying trends or outliers that need to be considered. This approach could enhance precision and personalized medicine by enabling comparisons across different population groups and different radiological facilities.

Another potential application of DMS related repositories, particularly when integrated with an artificial intelligence system trained for clinical decision support, could be the justification of radiological examinations on the basis

of clinical indications [83]. This could help to address issues such as possible overutilization of CT scans by ensuring that imaging procedures are more closely aligned with clinical needs and guidelines [84].

One of the biggest problems of DMSs currently is the vastly different terminology of the protocol names used across different facilities or medical imaging modalities. This causes errors when the DMS attempts to categorize and link each examination in the correct master protocol. This problem may be further accentuated by human errors in the selection of the correct examination protocol for the prescribed examination, the use of adult examination protocols for paediatric patients, the use of a paediatric protocol for a different age or size group, the lack of data on age, weight and height, among others. Therefore, one of the possible artificial intelligence applications that could be incorporated in future DMS is one that would check whether each examination is properly categorized. This could be achieved by an artificial intelligence application that is trained to detect anatomic landmarks that can be included or excluded in the images of certain examinations and check for scanned lengths and image sizes to identify wrongly classified examinations. Additionally, the relationship between dose metrics and patient data (including age, weight, height and size of the imaged anatomy) can help to identify instances of excessive scanning in CT, or excessively large radiation fields in radiographs that may be concealed by cropping. An artificial intelligence application capable of detecting these anomalies would be extremely beneficial, even if its use is limited to outlier cases owing to resource constraints on all examinations.

9.6. INDUSTRY 4.0 AND DMS

Industry 4.0, often referred to as the fourth industrial revolution, marks a pivotal advancement in the digitization of the manufacturing sector [85], including the health sector [86]. This era is characterized by the convergence of cutting edge technologies that are revolutionizing traditional production processes. Key drivers of Industry 4.0 include the exponential growth of data and the expanding reach of connectivity, enabling real time communication and decision making across global supply chains. Additionally, sophisticated analytics and artificial intelligence are empowering businesses to derive actionable insights from vast amounts of data, leading to smarter and more efficient operations. Enhanced human–machine interaction, through innovations such as augmented reality and advanced user interfaces, is transforming the way in which workers engage with technology on the factory floor. Furthermore, significant strides in robotics and automation are not only improving precision and productivity but also reshaping the workforce and the nature of industrial work. Together,

these disruptive trends are ushering in a new era of manufacturing that is more interconnected, intelligent and agile than ever before. In this regard, disciplines dealing with medical imaging and DMS are no exception, showcasing immense potential, particularly in enhancing the quality and efficiency of the services provided. Industry 4.0 represents a new paradigm in production, characterized by the adoption of Industry 4.0 technologies. These solutions are centred around interconnectivity, automation and the utilization of real time data, fundamentally reshaping how industries operate.

As health is rapidly moving to a patient oriented era, Industry 4.0 technologies integrated with DMSs can play a crucial role, mainly from the perspective of optimizing processes, productivity and radiological protection.

Several key Industry 4.0 technologies, many of which have been discussed in Sections 9.4 and 9.5, hold the potential to make a substantial impact in the short term. These include the following:

— Artificial intelligence algorithms: Algorithms that can be used to analyse vast datasets, enabling predictive analytics, enhancing decision making processes and optimizing workflows in real time.
— Robotic process automation: Automation of repetitive and time consuming tasks, streamlining operations, reducing human error and freeing up valuable resources for more complex activities.
— Process mining: Use of data to map, analyse and improve existing workflows, offering insights that drive efficiency and identify bottlenecks in organizational processes.
— Patient relationship management: Focus on enhancing the patient experience by personalizing interactions, improving communication and ensuring a more patient centred approach to care delivery.
— Business intelligence tools: Tools used to aggregate and analyse data from various sources, providing actionable insights that help organizations to make informed strategic decisions and improve overall performance.

As healthcare increasingly adopts a patient centred quality management approach, DMSs enhanced by Industry 4.0 solutions can play a crucial role in optimizing clinical processes and elevating patient care. Figure 40 illustrates how various advanced technologies can be integrated through an application programming interface. This interface can facilitate seamless connectivity between the DMS and the key Industry 4.0 technologies mentioned above. These technologies, when combined, can enable real time data analysis, workflow optimization, enhanced patient care and improved decision making processes within a healthcare setting. By combining the power of these interconnected systems, healthcare institutions can significantly improve

FIG. 40. Interaction between different databases and tools for the successful implementation of a quality management system.

efficiency, accuracy and overall performance in managing radiological procedures and patient outcomes.

An example from clinical practice is a lung screening CT programme, which usually spans multiple clinics with varied CT scanner technologies. In this case, the incorporation of Industry 4.0 technologies offers significant enhancements in patient management and diagnostic precision. Artificial intelligence can optimize the allocation of resources by analysing variables such as patient proximity to scanners, their anthropometric data, appointment availability and necessary diagnostic image quality. This information, sourced from the DMS, can be processed in real time by artificial intelligence algorithms and presented via business intelligence dashboards. Additionally, robotic process automation can automate routine tasks such as scheduling and sending reminders, while process mining provides continuous analysis of workflows to boost efficiency. Another example could be using artificial intelligence to automatically select the most suitable clinic for a patient's lung screening examination by evaluating factors such as scanner proximity, available appointment slots, patient size (to ensure compatibility with scanner capacity) and expected image quality according to predefined study protocols. Business intelligence tools can then provide real time insights into these factors, allowing instant adjustments to scheduling and scanner utilization to maximize both diagnostic accuracy and dose efficiency. Simultaneously, patient relationship management systems update patients about the nearest available appointments, enhancing both patient experience and care continuity. Artificial intelligence can also enhance decision making processes by

learning from ongoing human feedback and expert medical opinions, continually refining its algorithms to better meet healthcare needs. To further augment this setup, patient relationship management can be integrated to streamline communication and enhance the patient experience. When artificial intelligence determines the best clinic location and appointment time for a patient, the patient relationship management system can immediately inform the patient via their preferred communication method — for example, email, message or mobile app notifications. It can also provide rescheduling options, instructions for preparing for the scan and updates on scan results or subsequent appointments. Patient relationship management can also be utilized to improve post-procedure care by reminding patients of necessary periodic follow-ups, which are crucial in lung screening programmes. This ensures consistent patient engagement, fosters adherence to follow-up examinations and strengthens the overall patient centred approach to care.

Finally, business intelligence and artificial intelligence tools allow the retrospective analysis of data to predict behaviours, create health strategies and prospectively analyse their outcomes once implemented (Fig. 41). They could also enable the implementation of clinical research and technology development programmes on the basis of real time data and information management, requiring less time and resources, introducing new paradigms based on the knowledge economy. These critical applications underscore the pressing need for a significant investment in human resources, not only to ensure the effective use of DMSs but also to guide and manage the emerging technologies and applications of the future. Appropriate staffing and expertise will be essential to fully leverage the potential of DMS advancements and maintain a forward-looking approach.

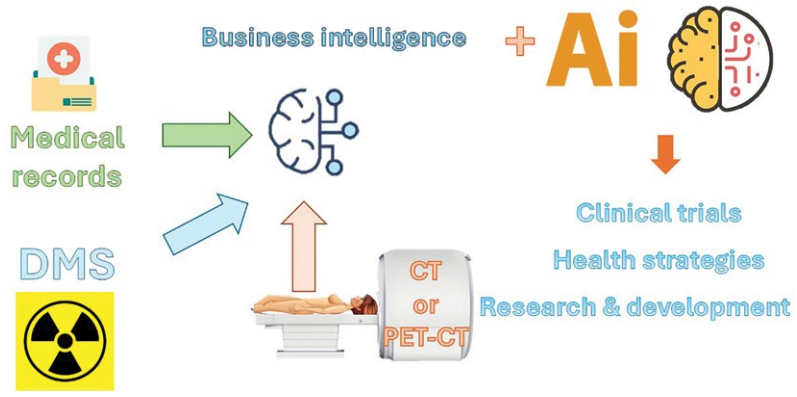

FIG. 41. Example of interaction of Industry 4.0 technologies with results obtained from artificial intelligence (Ai) and imaging studies such as PET-CT or CT.

10. CONCLUSIONS

This publication has explored the functionalities and the characteristics of the DMS, providing a comprehensive description of their critical role in the optimization of everyday clinical practice and the enhancement of workflow efficiency. Using the findings of a thorough survey conducted to evaluate the current capabilities of DMSs and analysis of the responses from participating DMS developers, the essential and advanced functionalities of DMSs — both those currently available and those anticipated in the future — were presented.

A key takeaway from this exploration is the paramount importance of the quality of data input to the DMS. The effectiveness of any DMS is fundamentally dependent on the accuracy and consistency of the data that it receives. Inaccuracies, incomplete data and inconsistencies can significantly undermine the system's ability to provide reliable analysis and support informed decision making. Therefore, improving the quality of data input to the DMS is not just desirable but essential for maximizing the system's potential.

Equally important is the role of QA in the effective functioning of a DMS. QA processes need to be meticulously designed to monitor and verify every aspect of the DMS, from data integrity checks to the accuracy of dose calculations and the proper configuration of system alerts. Regular QA activities should include verifying that all systems feeding data into the DMS are functioning correctly, ensuring that data are accurately captured and reported, and conducting periodic reviews of DMS performance. These QA processes are not seen as one-time activities but as ongoing efforts that adapt to new challenges and advancements in technology.

Looking forward, this publication encourages ongoing efforts to enhance data quality and urges further exploration into the potential of DMSs for dose data analysis. As the landscape of DMSs continues to evolve, the standards and practices that govern the quality of data input need to advance as well. Continuous improvement and innovation in this area are vital for ensuring that the DMS remains a pivotal component in the future of dose management in medical imaging.

Appendix I

SURVEY RESULTS

In preparation of this publication, a technical survey was conducted to collect as much information as possible on the current capabilities of DMSs. A survey comprising 302 questions was created, with 93% of questions/comments designed for simple 'yes'/'no' responses. Free-text fields, choices from a set list of options and comment sections were also provided to enable participants to share additional details or clarify their responses when needed. The questions were formulated according to current knowledge of the functionalities and capabilities of different DMSs, with the aim of evaluating their appropriateness and effectiveness for end users. This survey was organized into six distinct parts, each gathering specific types of information: (a) certifications; (b) methods of data transfer; (c) operational parameters and dose metrics for each supported medical imaging modality; (d) statistical and reporting functions; (e) customization options for examination identification, grouping and alerts; and (f) details on the implementation process and technical support. Table 3 contains the list of questions/comments together with the percentage of overall 'yes' responses to the questions. A 'yes' response indicates that the specific functionality or feature is available in the designated DMS. The objective was to ensure that the survey would yield meaningful insights into the alignment of each DMS with user requirements and industry standards.

The findings from this survey reveal significant disparities among the DMS options currently existing. Therefore, healthcare institutions considering the implementation of a DMS need to thoroughly examine the various options available, focusing on the features and functionalities that each DMS provides to ensure compatibility with their unique requirements. They should also determine which advanced features, potentially available at additional costs, are necessary or advantageous for their institution, considering their budget. Additionally, it is crucial to verify that the existing infrastructure and staff are suited to meet the requirements for installing, operating and maintaining the proposed DMS. By adopting this methodical approach, institutions can optimize their expenditures, achieving a balance between operational effectiveness and financial limitations.

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES

Section	Question/comment	Positive answers (%)
Certification	Food and drug administration certificate	38
	Conformite Europeenne (CE) mark	62
	The DMS helps health providers to comply with joint commission requirements	77
	Other certifications	38
Data transfer	The system can automatically retrieve data directly from the modalities	85
	The system can retrieve data automatically from the PACS	77
	Other connection method(s) available	54
Data collection	DICOM RDSR	100
	DICOM MPPS	62
	DICOM headers	100
	Dose report image (optical character recognition)	92
	DICOM patient RDSR	46
	DICOM protocol storage	54
	Requested procedure description (institution generated administrative description or classification of requested procedure)	85
	Performed procedure step description (institution generated administrative description or classification of performed procedure step)	85
	Other data collection method(s) available	77
Examination study/record	All information related to any examination/study can be collected until it is completed and, depending on the DMS specifications, it will calculate other parameters and dose metrics	92
	Total values of dose metrics applicable to all examinations of the same patient performed in the same modality type are calculated	85
	Total values of dose metrics independent of modality type for the same patient are calculated	77

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Examination study/record	Other information related to examination/study records created in DMS and cumulative dose metric calculations	46
Information collected (patient, examination, facility)	Patient names (last, first, middle) and identification number(s)	92
	A unique patient identification number can be selected (e.g. social security number)	100
	Multiple patient identification number domains are supported	85
	Patient age and date of birth	100
	Patient height and weight	100
	Study information (e.g. order name, procedure name, procedure identification number, anatomical region examined)	100
	Acquisition protocol information (e.g. acquisition protocol name, anatomic region examined, identification number, acquisition number or/and radiation event number)	100
	Study date and time information	100
	Facility information: hospital name, modality type, manufacturer, model, system identification number (e.g. station name) and image receptor name (e.g. in case of X ray systems with two or more receptors)	100
	Staff information: operator, referring physician and requesting physician names	92
	Contrast media information: ingredient or trade name, administration route, route administration time start–stop, total quantity administered, flow rate, volume, concentration and others	62

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Unit conversion and calibration factors	The DMS can modify the selected dose metrics using correction factors to accommodate the possible use of units other than the usual ones in certain systems (e.g. cGy instead mGy) or/and display dose metrics in the units preferred by the administrator or/and account for calibration problems (e.g. when the KAP meter of a system is known to produce overestimated readings by about 20% and cannot be adjusted better)	77
Unit conversion and calibration factors in CT	$CTDI_{vol}$ per acquisition with phantom identification (head 16 cm or body 32 cm)	100
	DLP per acquisition	100
	Scan length	100
	Total DLP (for the whole examination/study)	100
	Total DLP analysis	85
	Modality generated SSDE	85
CT acquisition and reconstruction parameters	Tube potential	100
	Scan time per rotation	100
	mAs or/and μAs	92
	Axial/helical	100
	Scan FOV	85
	Pitch	100
	Collimation used (e.g. 64 mm × 0.5 mm)	92
	X ray total beam width	92
	Gantry tilt	69
	Patient centring	62
	Reconstruction: display FOV	54
	Reconstruction slice thickness	62
	Reconstruction kernel	62
	Protocol parameters (study): procedure/protocol name	92

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
CT acquisition and reconstruction parameters	Protocol parameters (study): description and identification number	92
	Protocol parameters (study): anatomy/region	92
	Protocol parameters (acquisition): procedure/ protocol name	100
	Protocol parameters (acquisition): description and identification number	100
	Protocol parameters (acquisition): anatomy/ region	100
	ATCM applied	69
	Noise index or reference mAs or other dose/ image quality setting indicator	54
	Minimum and maximum mA limits when applicable (set by the automatic exposure control)	85
	Modality generated patient WED	54
	X ray total beam width	77
	Other parameters and remarks	77
CT calculated dose metrics and related parameters	SSDE	77
	$CTDI_{vol}$ (weighted by acquisition)	54
	DLP (weighted by acquisition)	46
	SSDE (weighted by acquisition)	31
	Body mass index when the weight and height of the patient exist; different body mass index categories can be assigned with different colours, so the patient body mass index will be denoted (e.g. with different font or background colour)	62
	E calculation per acquisition (and total): using preset DLP to *E* conversion coefficients per scanned anatomic region for standard sized adult patient	62

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
CT calculated dose metrics and related parameters	*E* calculation per acquisition (and total): using preset DLP to *E* conversion coefficients per scanned anatomic region for standard sized adult patient and paediatric patients in different age categories	62
	Organ dose and *E* calculation per acquisition (and total): using Monte Carlo derived conversion coefficients adapted for patient size/age only (library of different anthropomorphic phantom sizes exists)	69
	Organ dose and *E* calculation per acquisition (and total): using Monte Carlo derived conversion coefficients adapted for patient size/age, scan length and actual scanned region (library of different anthropomorphic phantom sizes exists)	69
	Organ dose, foetus dose and *E* calculation per acquisition (and total) for pregnant patients: using Monte Carlo derived conversion coefficients depending on patient size/age, scan length and actual scanned region (library of different anthropomorphic phantom sizes and pregnancy semester exists)	62
	Patient anteroposterior, lateral, anteroposterior and lateral, or effective diameter (cm)	69
	WED per acquisition	54
	Diameter calculation method(s): using localizer/scan projection radiograph, reconstructed axial images (CT images) or both	54
	Patient positioning centring calculation	62
	ATCM: mA modulation graph on anteroposterior or/and lateral scan projection radiograph	62
	The $CTDI_{vol}$ of spatially complex distributions (e.g. when ATCM is used) is considered for calculating total $CTDI_{vol}$ from different acquisitions	23

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
CT calculated dose metrics and related parameters	Geometric or anthropomorphic phantom library(ies) used to perform the Monte Carlo calculations (describe in brief)	54
CT image quality evaluation tools	Image quality evaluation tools (automatic or manual) available in the DMS for CT (describe in brief)	23
Fluoroscopy and angiography dose metrics collected	Total KAP	92
	Total fluoroscopy time	92
	Total $K_{a,r}$	92
	KAP per acquisition (fluoroscopy, cine or single shot)	92
	Exposure time per acquisition (fluoroscopy, cine or single shot)	92
	$K_{a,r}$ per acquisition (fluoroscopy, cine or single shot)	92
	Total incidence air kerma mapping (skin dose mapping)	69
	Incidence air kerma mapping per acquisition (skin dose mapping)	73
Fluoroscopy and angiography acquisition and reconstruction parameters	Tube potential	92
	Tube current (mA)	92
	Tube load (mAs or/and μAs)	92
	Pulse width (ms or s)	92
	Pulse frequency	92
	Added filtration	92
	Collimators	92
	Gantry/tube angle(s)	92
	Table position (X, Y, Z coordinates)	85
	SID	92
	C-arm position	85
	Focus isocentre distance	92

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Fluoroscopy and angiography acquisition and reconstruction parameters	Focus reference point distance	85
	Procedure protocol name	92
	Description (study)	92
	Anatomy/region (study)	85
Fluoroscopy and angiography calculated dose metrics and related parameters	*E* calculation per acquisition (and total): using preset KAP to *E* conversion coefficients per scanned anatomic region for standard sized adult patient	69
	E calculation per acquisition (and total): using preset KAP to *E* conversion coefficients per scanned anatomic region for standard sized adult patient and paediatric patients in different age categories	69
	Organ dose and *E* calculation per acquisition (and total): using Monte Carlo derived conversion coefficients adapted for patient size/age only (library of different anthropomorphic phantom sizes exists)	54
	Organ dose and *E* calculation per acquisition (and total): using Monte Carlo derived conversion coefficients adapted for patient size/age, irradiated region and irradiation geometry (library of different anthropomorphic phantom sizes exists)	54
	Organ dose, foetus dose and *E* calculation per acquisition (and total) for pregnant patients: using Monte Carlo derived conversion coefficients depending on patient size/age, irradiated region and irradiation geometry (library of different anthropomorphic phantom sizes and pregnancy semesters exists)	46
	Incidence air kerma mapping (skin dose mapping) when the fluoroscopic system supports this functionality	62
	Incidence air kerma mapping (skin dose mapping) when the fluoroscopic system does not support this functionality	54

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Fluoroscopic image quality evaluation tools	Image quality evaluation based on the interpretating radiologist, that is, manual evaluation using a scale (e.g. bad/not diagnostic, fair, medium, good, excellent)	38
	Image quality evaluation based on automatic methods	23
Radiography dose metrics collected	Total KAP	92
	Total $K_{a,r}$	92
	Total KAP per radiograph	92
	$K_{a,r}$	92
Radiography acquisition and reconstruction parameters	Tube potential	92
	mAs or/and μAs	92
	mA	92
	Exposure time per radiograph	92
	Acquisition parameters	92
	FOV	92
	Additional filter	92
	Geometric parameters	92
	SID	92
	Grid type used	85
	Protocol parameters (study)	92
	X ray projection protocol name	92
	Description and identification number	92
	Anatomy/region (study)	92
	Automatic exposure control chambers activated	54
	X ray projection protocol name	92
	Description and identification number	92
	Anatomy/region	92

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Radiography calculated dose metrics and related parameters	*E* calculation per acquisition (and total): using preset KAP to *E* conversion coefficients per scanned anatomic region for standard sized adult patient	62
	Effective dose *E* calculation per acquisition (and total): using preset KAP to *E* conversion coefficients per scanned anatomic region for standard sized adult patient and paediatric patients in different age categories (0–1, 1–5, 5–10, 10–15, 15–18 years)	62
	Organ dose and *E* calculation per acquisition (and total): using Monte Carlo derived conversion coefficients adapted for patient size/age only (library of different anthropomorphic phantom sizes exists)	31
	Organ dose and *E* calculation per acquisition (and total): using Monte Carlo derived conversion coefficients adapted for patient size/age, irradiated region and irradiation geometry (library of different anthropomorphic phantom sizes exists)	31
	Organ dose, foetus dose and *E* calculation per acquisition (and total) for pregnant women: using Monte Carlo derived conversion coefficients depending on patient size/age, irradiated region and irradiation geometry (library of different anthropomorphic phantom sizes and pregnancy semesters exists)	31
Radiography image quality evaluation tools	Image quality evaluation based on the interpretating radiologist, that is, manual evaluation using a scale (e.g. bad/not diagnostic, fair, medium, good, excellent)	38
	Image quality evaluation based on automatic methods	38
Mammography dose metrics collected	AGD	92
	Entrance surface air kerma	77
	AGD (per mammography image)	92
	Entrance surface air kerma (per mammography image)	85

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Mammography acquisition and reconstruction parameters	Anode/filter combination	92
	Tube potential	92
	mAs or/and μAs	92
	mA	92
	Exposure time per mammograph	85
	FOV	77
	Half value layer (when included in DICOM)	73
	SID	85
	CBT	92
	Grid used	92
	Compression paddle	77
	Magnification	62
	Projection protocol name	92
	Description and identification number	92
	Automatic exposure control mode used	54
	Left/right breast	92
Mammography image quality evaluation tools	Image quality evaluation based on the interpretating radiologist, that is, manual evaluation using a scale (e.g. bad/not diagnostic, fair, medium, good, excellent)	38
Dental dose metrics collected	Total KAP	69
	Total CTDI	77
	KAP per acquisition	69
	CTDI per acquisition	77
Dental acquisition and reconstruction parameters	Tube potential	77
	mAs or/and μAs	77
	mA	77
	Exposure time per acquisition	77

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Dental acquisition and reconstruction parameters	FOV	77
	Additional filter	77
	SID	69
	Magnification	69
	Acquisition protocol name	77
	Description and identification	77
	Automatic exposure control mode	62
Dental calculated dose metrics and related parameters	*E* calculation per acquisition (and total)	
	Using preset conversion coefficients per scanned anatomic region for standard sized adult patient	54
	Using preset conversion coefficients per scanned anatomic region for standard sized adult patient and paediatric patients in different age categories	54
Dental image quality evaluation tools	Image quality evaluation based interpretating radiologist, that is, manual evaluation using a scale (e.g. bad/not diagnostic, fair, medium, good, excellent)	31
Other supported modalities	DMS supports occupational dose tracking	23
	Other supported modalities or systems	54
Dashboards for statistical analysis of information and export capabilities	One main GUI/dashboard for statistical analysis of all or part of the data stored in the DMS	92
	Preset dashboard(s) for statistical analysis of all or part of the data stored in the DMS	92
	A bar graph diagram displaying the median values of an applicable dose metric (depending on the modality) for a specific examination/study (single or multiple acquisitions) for different facilities, in relation to the respective DRL for a selectable range of dates, patient age and others is supported	92

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Dashboards for statistical analysis of information and export capabilities	When the use of stratified DRLs based on patient age (e.g. paediatric DRLs) or/and other body size attributes (e.g. weight, effective diameter) is supported, the system allows selection of the relevant criteria. The age range or body attribute of the patients can be selected (e.g. from drop-down lists or check boxes). The applicable DRL will then be displayed in the graph. Only patients within the selected age range or body attribute category will be included in the results shown in the graph or tables	62
	An automatic comparison of the median values observed in different facilities for a specific examination/study selected with respect to all stratified DRL values applicable for the selected sample is supported. The results can be in the form of a table, where the different age categories or body size attributes are reported and the median (and probably the sample size) for each specific facility is displayed, with an indication (colour or icon) of whether it is above or below the respective DRL	77
	For the comparison of median values with DRLs, except from the standard ones (e.g. national), other DRL value sets stored in the DRL libraries can be selected (e.g. using drop-down lists or check boxes) for checking conformance with DRLs of other countries, or local or institutional DRLs regarding examinations/studies with multiple or single acquisitions	77
	Apart from the DRL values shown in the graph or/and the tables, information about for the selected DRL database is clearly indicated on the GUI	77
	Calculation of the 75% of the distribution of the bar graph diagram displaying the median values of an applicable dose metric for different facilities, for a selectable range of dates, patient age and others, is supported for setting the institutional DRL	69

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Dashboards for statistical analysis of information and export capabilities	Customizable dashboards, for statistical analysis of all or part of the data stored in the DMS, are supported	92
	Results of analysis are given in preset type graphs	92
	Results of analysis given in a graph type that is customizable or selectable from a list, such as bar, pie chart, *X*–*Y* plot graphs and others (e.g. frequency distribution bar graph)	77
	Data points of graphs are interactive, so that by selecting a data point in a graph, more information is displayed about this data point and the associated examination record	77
	Data points of graphs are interactive, so that by selecting a data point in a graph, a link to the examination enables review of the images associated with this point	77
	Results of analysis are given in preset type tables	92
	Graphs available on DMS GUI/dashboard	
	Tables are available on DMS GUI/dashboard	92
	Creation of customized GUI or dashboard library is supported	69
	Reject analysis capabilities (e.g. for X ray images deleted or not sent to the PACS), depending on the modality relevant features (e.g. some X ray systems require to record a reason for deleting or repeating a radiograph) are supported	54
	DMS has correlated equipment management module that analyses productivity, efficiency, direct profit margin and others	54
	Other methods of reporting statistical analysis results	73
	Facility information: hospital, modality and others (e.g. report the number of chest CT studies that were performed during last year per facility)	92

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Dashboards for statistical analysis of information and export capabilities	Patient information: name, identification number, age and others (e.g. display a frequency bar graph of the age of patients examined last month in mammography)	77
	Personnel information: operator, interpreting radiologist, referring physician and others (e.g. report the median DLP values of all CT abdomen examinations performed last month in a certain facility, for all different CT operators)	77
	Examination/study parameters: anatomic region, examination protocol, anatomic region, acquisition protocol and others (e.g. report the number of patients examined in the abdominal region in the last month per modality)	92
	Exposure parameters: tube potential, mAs, pitch factor and others, depending on the supported modalities	77
	Combined queries on selected dose metrics and other parameters: DLP, KAP, AGD, contrast media quantity and others, depending on the supported modalities	77
	Combined queries on selected calculated dose metrics and other parameters: SSDE, *E*, scan length, patient body mass index and others, depending on the supported modalities	69
	Filtering capabilities of DMS	92
	DMS analysis results step selection	85
Exporting data and statistical analysis results	Screenshots or figures	92
	Portable document format files	85
	Spreadsheet format (tables with numbers and/or graphs)	85
	Business intelligence software format	54
	Filtered data used to produce a statistical analysis report can be exported in spreadsheet format or a similar format for further analysis	92

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL ‘YES’ RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Exporting data and statistical analysis results	Data column to be exported is customizable (all columns or specific columns) depending on the level of information detail needed	77
	Creation of customized export filter library is supported	62
Alert setting	Alerts can be produced when a parameter or dose metric value found in an examination/study record is bigger than a reference value/threshold (upper threshold)	85
	Alerts can be produced when a parameter or dose metric value found in an examination/study record is smaller than a reference value/threshold (lower threshold)	54
	Alerts can be produced when a parameter or a dose metric value found in an examination/study record is or is not within a given reference range of values (reference range/lower–upper threshold)	54
	Alert level reference values can be set on DMS	77
	Alert levels can be linked to the respective DRL values of each master protocol	54
	Distinct symbols or icons beside the respective values	62
	A change in the colour of the respective parameter value	69
	Dose metrics and other parameters (e.g. number of acquisitions within an examination/study, tube potential value or planned scan length of a CT)	69
	Alerts in the single acquisition or radiation event level are supported	69
	Alerts in the examination/study level are supported (total acquisitions/irradiation events)	77
	Alerts regarding the total number of examinations performed or total dose metric values obtained within a single customizable range of time are supported	77

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Alert setting	Alerts regarding the total number of examinations performed or total dose metric values obtained within multiple customizable ranges of time are supported	54
	Alerts can be produced when some attributes of modalities have exceeded a preset time, (e.g. when the examination date in an X ray unit and the calibration date of an image receptor of this unit have a difference of more than one year) to alert the user to request a calibration of the image receptor in this X ray unit, according to the service schedule	31
Resolving alerts	Alerts will remain active until resolved	54
	Alerts are resolved when the authorized user performs a specific action (e.g. adding a comment)	62
	Resolved alerts are denoted by a distinct colour or icon	54
Alert tabs	Tab(s) to display the active alerts are supported	23
	Tab(s) to display the resolved alerts are supported	23
	The tab(s) displaying the active alerts support multiple filters to select the type of alert (e.g. above threshold 1 or 2), status of alert (active/resolved), date/time interval, modality type(s), specific facility(ies) and others	23
Master protocol alert	Master protocol's preset and/or customizable categories in the DMS exist	85
	Master protocols, either for whole examinations or single acquisitions, can be assigned with a number of reference/threshold values, for a number of exposure parameters, dose metrics collected or calculated, as well as DRLs	62
	Reference/threshold values for parameters, dose metrics collected or calculated, and DRLs of a master protocol may be stratified, depending on of patient attributes (e.g. age, weight) or even other secondary conditions that may apply to an attribute of the examination or acquisition for specific values or range of values	69

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL ‘YES’ RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Master protocol alert	Safeguards exist to detect, prevent or notify the user regarding contradicting conditions or restrictions and/or overlapping ranges	46
	Each master protocol can be linked to the DRL value of the respective examination in a DRL library to support the feature of comparison of DMS data with DRL data from different libraries	69
	Examinations/studies with different names, descriptions and others, and acquisition protocols, once assigned in the respective master protocol, are automatically linked to all its attributes regarding reference levels, alerts, DRLs and secondary conditions	77
	These examinations/studies can be included in a master protocol, certain expected range of values of exposure parameters (e.g. tube potential, ATCM noise index setting, scan length range length) so as to produce secondary alerts or warnings in the case that the parameters used for the acquisition differ from the standard/desired ones	54
	Safeguards exist to prevent or notify the user of assigning the same examination or acquisition protocol to more than one master protocols	38
	Creation of different master examination/study protocols and acquisition protocols for similar examinations in terms of scanned anatomy or number of acquisitions and others, but different clinical indications, is supported	38
	When a new unassigned examination/study or a new acquisition protocol is detected in the data collected, then a distinct warning (using graphics, icons or colours) is produced to inform the user that this new protocol needs to be managed. The warning symbol remains on until the new protocol is assigned to a master protocol	54

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Master protocol alert	When algorithms are used to allow the automatic assignment of new unassigned examination/study or acquisition protocol to a master protocol (e.g. based on the name or description), a distinct warning (using graphics, icons or colours) is produced to inform the user that this assignment is tentative. The master protocol automatically chosen has to be confirmed or changed by the system administrator; until then the warning remains on	23
	Master protocols are managed only by users with system administrator rights	69
	Master protocols can be fed/uploaded on the DMS computers	27
DRL libraries	The system has multiple preset and/or customizable DRL libraries, with data applicable to different examinations/studies, with national DRLs from various countries. A customizable DRL library with local or institutional DRL values is supported	69
	DRL libraries can contain standard and customizable notes and comments regarding the source of DRL values included or other relevant information	46
	Preset DRL libraries (of the DMS manufacturer) can be updated automatically	54
	Preset DRL libraries (by the DMS manufacturer) can be updated manually (by authorized personnel)	62
	If any value in the preset DRL libraries (by the DMS manufacturer) is manually updated/ modified (by authorized personnel), this will be denoted by a warning (e.g. using a note or highlighting this value)	38
	Safeguards exist to detect and notify the user about contradicting and/or overlapping ranges in DRL stratification settings	23
	DRL libraries are managed only by users with system administrator rights	69

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
User rights	DMS supports the classification of users in different categories with different access rights (e.g. master protocols and DRL libraries are commonly accessed only by users with administrator rights). Simple users can only view data and perform statistical analysis and can have restrictions regarding the modalities or even the specific facilities whose data they can access	85
	User rights in the preset categories are standard and cannot be modified, or they can be modified but safeguards exist to prevent the administrator from being locked out of user right menus	46
	DMS offers the capability of creating additional user categories with customizable user rights	69
Installation requirements	Installation location of DMS (software and database)	77
	Minimum server specification requirements	0
	Optimum server specification requirements	0
	Precautions for protection against loss of data, as in the case of a hard-disk crash	0
	The workstations of users with administrator rights and simple users have different specification requirements	15
	Specifications for the administrator workstation	8
	Specifications for the simple user workstation	8
	Days needed for hardware set-up and software installation, including the standard configuration of the DMS parameters	8
	Hours needed for connection of the DMS with the PACS	8
	Input needed from the facility's information technology and PACS vendor's technicians to complete the connection of the DMS with the PACS	0

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL 'YES' RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Installation requirements	Hours needed for connection of any new modality (connected to the PACS) with the DMS	8
	Hours and input needed from the facility's information technology and PACS vendor's technicians to complete the connection of the DMS with any new modality that is not connected to the PACS directly	0
	Minimum training needed for users with administrator rights (days)	8
	Minimum needed training for simple users (days)	8
	Dosimetric data from examinations performed before the connection of the DMS to the PACS can be uploaded to the DMS	8
Support and functionalities	Safeguards are available against connection problems that can result in loss of data	62
	The DMS has self-diagnostic tools to detect missing connections and warn the user to take action	54
	The DMS can be connected using Health Level Seven with the HIS to export a dosimetric information report to the patient's medical record file	69
	The DMS software can automate transfer of data to dose registries	69
	Basic guarantee period duration (years)	54
Implementation process	A project manager will manage implementation	69
	A project plan will be available	69
	An installer will be available	62
	What personnel are involved in implementation?	69
	What is the implementation process?	62
	What is the training process?	62
	What is the support process?	62

TABLE 3. SURVEY QUESTIONS WITH PERCENTAGE OF OVERALL ‘YES’ RESPONSES (cont.)

Section	Question/comment	Positive answers (%)
Information technology matters	Explain the interface process to PACS	
	The DMS software supports multi-site and distributed architecture over a limited network	85
	The DMS software supports LDAP for user authentication	77
	Regarding connection with PACSs: the DMS is medical imaging equipment neutral (i.e. it does not support only specific or single medical imaging equipment)	85
	Regarding connection directly with imaging modalities (e.g. CT scanners, mammography systems): the DMS is medical imaging equipment neutral (i.e. it does not support only specific or single vendors only)	92
	Data can be provided to a patient’s electronic medical record	69
	List connection methods/protocols to transfer data to other systems	77
	Where does dose information reside?	69
	Software upgrades are available	92
	The DMS was included in integrating the healthcare enterprise connection(s)	38
	The Integrating the Healthcare Enterprise (IHE) profile has been tested	38

Appendix II

LIST OF DMS DEVELOPERS

Table 4 presents the list of open source and commercial DMS developers that participated in the technical survey. Data were collected using the IAEA's International Research Integration System designed to streamline the data collection process. Efforts were made to reach all known DMS developers.

TABLE 4. OPEN SOURCE AND COMMERCIAL DMS DEVELOPERS PARTICIPATING IN THE IAEA'S TECHNICAL SURVEY

No.	Participating DMS developers
1	Bayer AG
2	Dubrava University Hospital
3	General Electric
4	Hospital Clínico San Carlos
5	INFINITT Europe
6	Medsquare
7	Openrem
8	Pacshealth
9	Pixelmed
10	Proaqct
11	Qaelum
12	Dicom Port
13	Siemens

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ABBREVIATIONS

AGD	average glandular dose
ATCM	automatic tube current modulation
CBCT	cone-beam computed tomography
CBT	compressed breast thickness
CQMP	clinically qualified medical physicist
CT	computed tomography
CTDI	CT dose index
DAP	dose–area product
DICOM	digital imaging and communications in medicine
DLP	dose length product
DMS	dose management systems
DRL	diagnostic reference level
FGIP	fluoroscopically guided interventional procedure
FOV	field of view
GUI	graphical user interface
HIS	hospital information system
ICRP	International Commission on Radiological Protection
KAP	kerma–area product
MPPS	modality performed procedure step
MRI	magnetic resonance imaging
MRT	medical radiation technologist
PACS	picture archiving and communication system
PET	positron emission tomography
PSD	peak skin dose
QA	quality assurance
QC	quality control
RDSR	radiation dose structured report
RIS	radiology information system
RMP	radiological medical practitioner
SID	source to image receptor distance
SSDE	size specific dose estimate
WED	water equivalent diameter

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