



Dose Management Software

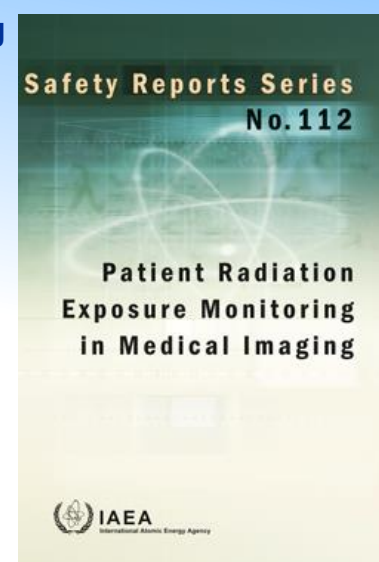
V.Tsapaki

Medical Physicist (Diagnostic Radiology)
Dosimetry and Medical Radiation Physics Section
Division of Human Health, IAEA

Safety Report “Patient Radiation Exposure Monitoring in Medical Imaging”, in collaboration with ICRP, WHO, UNSCEAR, IOMP, DICOM WG28 (Physics)

slide courtesy of Jenia Vassileva, ex NSRW, IAEA

NEW!



Patient exposure monitoring: A process including the mechanism and the operational elements related to collecting, interpreting, and acting upon quantities associated with clinical imaging operation



Tracking patient exposure data: An analysis process of ascertaining and monitoring *temporal trends* in individual or collective stored data

Managing patient exposure data: A process of *oversight* through exposure data recording, tracking, and analysis towards improvement of radiation protection and patient care

To understand what DMS offer, we have to go back in time, and remember what the situation in the past.

- *Most of the radiological units were non-digital (X-ray units were using screen/film cassettes and fluoroscopy units image intensifiers) and no record of the exposure factors used during examination was kept.*
- *Most of the units did not even have a kerma-area product (KAP) meter (referred in the past as dose-area product, DAP).*

What was the solution:

manual selection of patient dose related metrics in a limited number of exams (10-30 patients)

For fluoroscopy, an external KAP meter was used, and a medical physicist had to record (manually and in real-time) the KAP and fluoroscopy time (FT) readings, and also, indicative values of the exposure factors during the exam.

For DRL purposes, cumulative FT and KAP values were adequate.

Sample of relevant publications (courtesy of Ioannis Tsalafoutas)



The British Journal of Radiology, 72 (1999), 173–178 © 1999 The British Institute of Radiology

Patient doses from barium meal and barium enema examinations and potential for reduction through proper set-up of equipment

¹E YAKOUMAKIS, PhD, ²I A TSALAFOUTAS, MSc, ³P SANDILOS, PhD,
²H KOULENTIANOS, MD, ³A KASFIKI, PhD, ³L VLAHOS, MD and ¹Ch PROUKAKIS, MD

The British Journal of Radiology, 74 (2001), 727–734 © 2001 The British Institute of Radiology

Differences in effective dose estimation from dose–area product and entrance surface dose measurements in intravenous urography

¹E YAKOUMAKIS, PhD, ²I A TSALAFOUTAS, MSc, ²D NIKOLAOU, MD, ²I NAZOS, RT,
²E KOULENTIANOS, MD, PhD and ¹Ch PROUKAKIS, MD, PhD

Pediatr Radiol (2003) 33: 236–240
DOI 10.1007/s00247-002-0861-x

ORIGINAL ARTICLE

Konstantinos A. Gogos
Emmanuel N. Yakoumakis
Ioannis A. Tsalafoutas
Triantafillia K. Makri

Radiation dose considerations in common paediatric X-ray examinations

Patient Doses from Noncardiac Diagnostic and Therapeutic Interventional Procedures

Ioannis A. Tsalafoutas, PhD, Helen Goni, PhD, Petros N. Maniatis, MD, Paris Pappas, MD, Nick Bouzas, MD, and George Tzortzis, MD

J Vasc Interv Radiol 2006; 17:1489–1498

The British Journal of Radiology, 80 (2007), 107–112

Radiation doses to patients undergoing standard radiographic examinations: a comparison between two methods

¹V TSAPAKI, MSc, PhD, ¹I A TSALAFOUTAS, MSc, PhD, ²I CHINOFOTI, Tec, ²A KARAGEORGI, Tec,
³E CARINOU, MSc, PhD, ³V KAMENOPOULOU, MSc, PhD, ⁴E N YAKOUMAKIS, MSc, PhD and
²E D KOULENTIANOS, MD

Ioannis A. Tsalafoutas¹
Virginia Tsapaki²
Charikleia Triantopoulou³
Christina Pouli³
Virginia Kouridou¹
Ioanna Fagadaki³
John Papailiou³

AJR:191, November 2008

Comparison of Measured and Calculated Skin Doses in CT-Guided Interventional Procedures

PACE, Vol. 28

September 2005

Radiation Doses to Patients and Cardiologists from Permanent Cardiac Pacemaker Implantation Procedures

IOANNIS A. TSALAFOUTAS,* STAVROS G. SPANODIMOS,+ PETROS N. MANIATIS,+
GEORGE M. FOURNARAKIS,+ ELIAS D. KOULENTIANOS,§ and DIMITRIOS L. TSIGAS†

Radiation dose in repeated CT guided radiofrequency ablations

V. Tsapaki^a, I.A. Tsalafoutas^{b,*}, Ch. Triantopoulou^c, E. Kolliakou^c, P. Maniatis^c, J. Papailiou^c

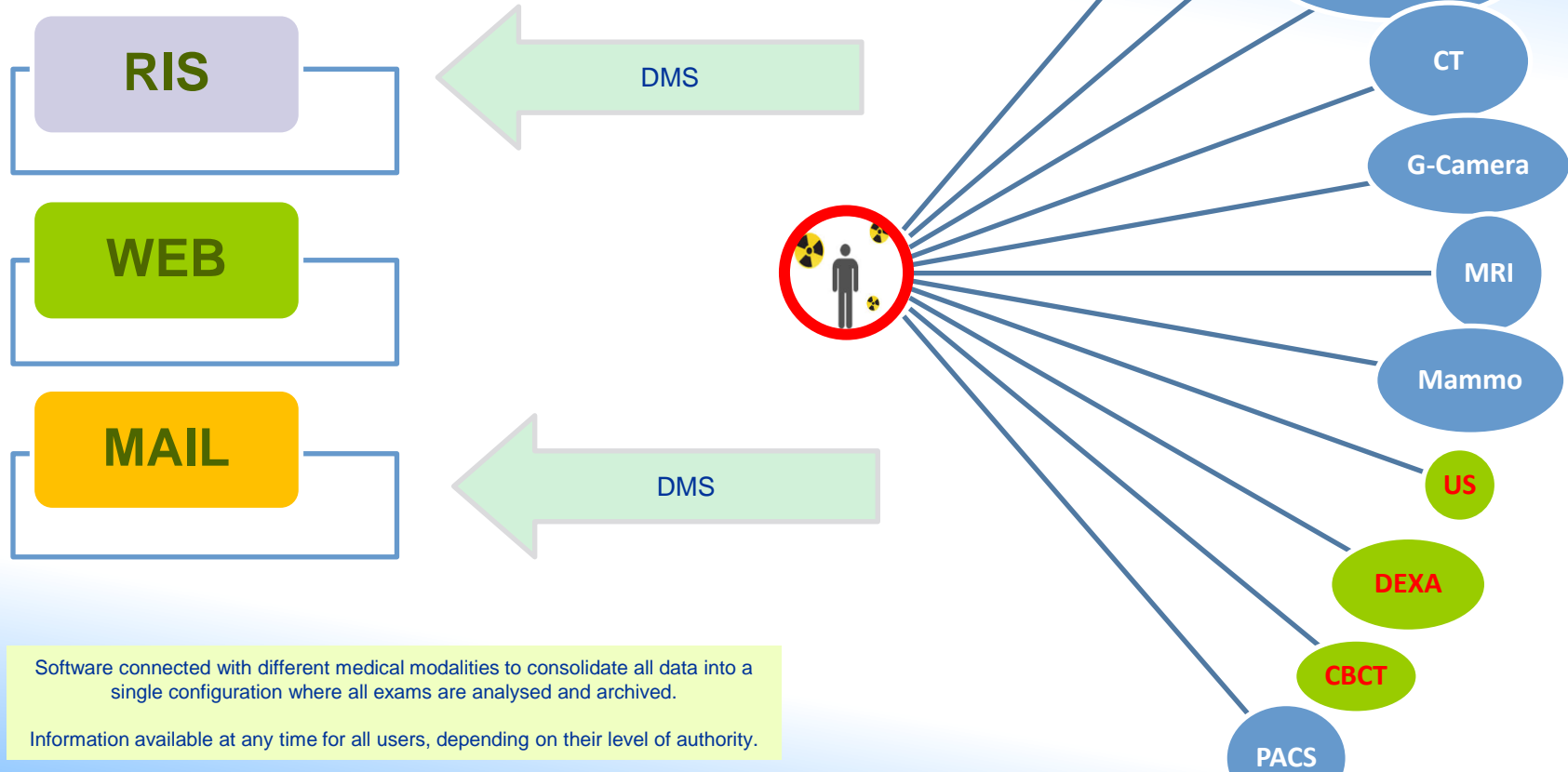
Physica Medica 30 (2014) 128–131



FROM MANUAL TO AUTOMATIC COLLECTION

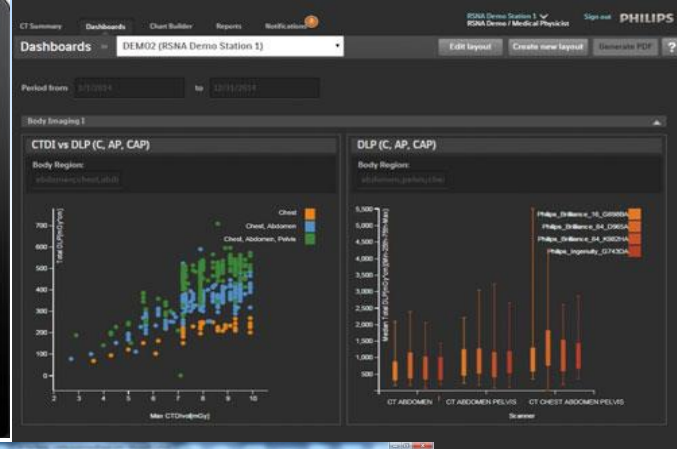
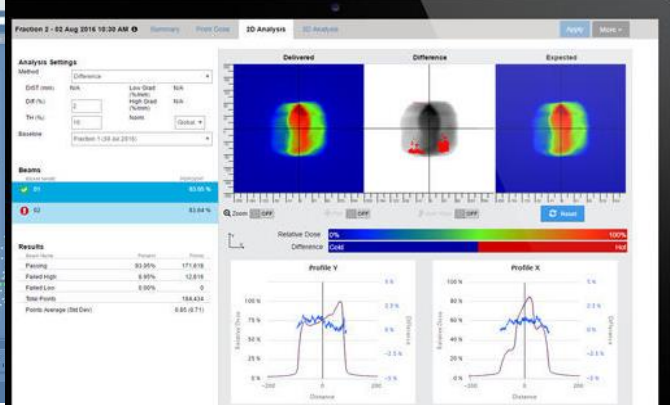
- Tracking of dose data is proven invaluable (numerous publications)
- Manual method is not practical since monitoring all the examinations can be difficult due to their large number.
- Data acquisition process can lead to mistakes, usually by mistyping the information.
- Besides the above flaws, it can be very time consuming
- Due to above dedicated personnel just for the data acquisition and categorisation will be needed.
- For efficient dose optimisation process a lot of data should be collected.
- These difficulties can be overcome with the use of tracking software.

Every imaging equipment can be connected to the Dose Monitoring/Management systems/software (DMS)

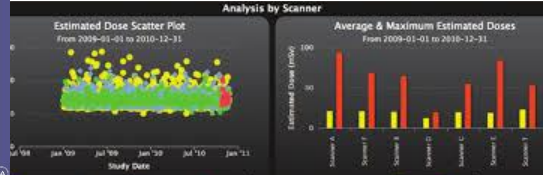
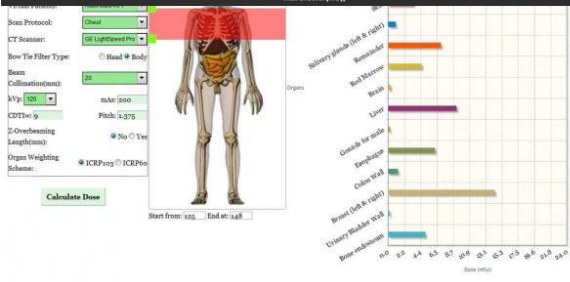
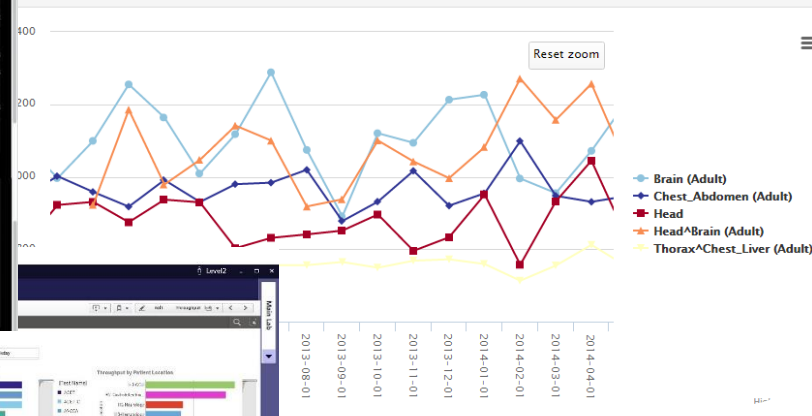


Software connected with different medical modalities to consolidate all data into a single configuration where all exams are analysed and archived.

Information available at any time for all users, depending on their level of authority.



Plot showing mean DLP of each study type over time (months).





ALARA PRINCIPLES CAN BE ADDRESSED TODAY WHEN USING RDMS

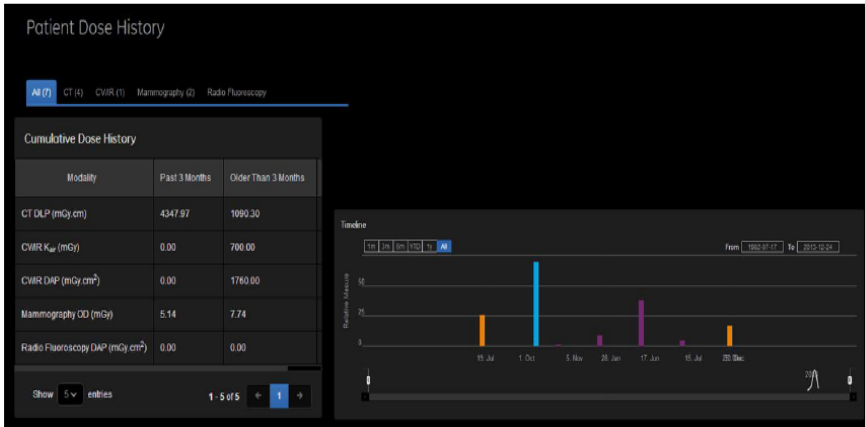
• JUSTIFICATION

- Exam history
- Exam analysis in terms of time and type
- analysis in terms of type
- Dose simulation before exam
- Unexpected variations from routine procedures

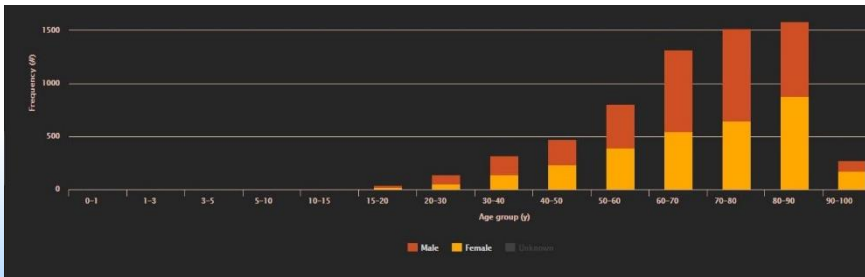
• OPTIMIZATION

- Patient dose estimation and comparison
- Benchmarking
- DRLs
- Dose alerts
- Incident and accidental exposure easily identified

DMS can provide dose trends, utilization, high dose examinations



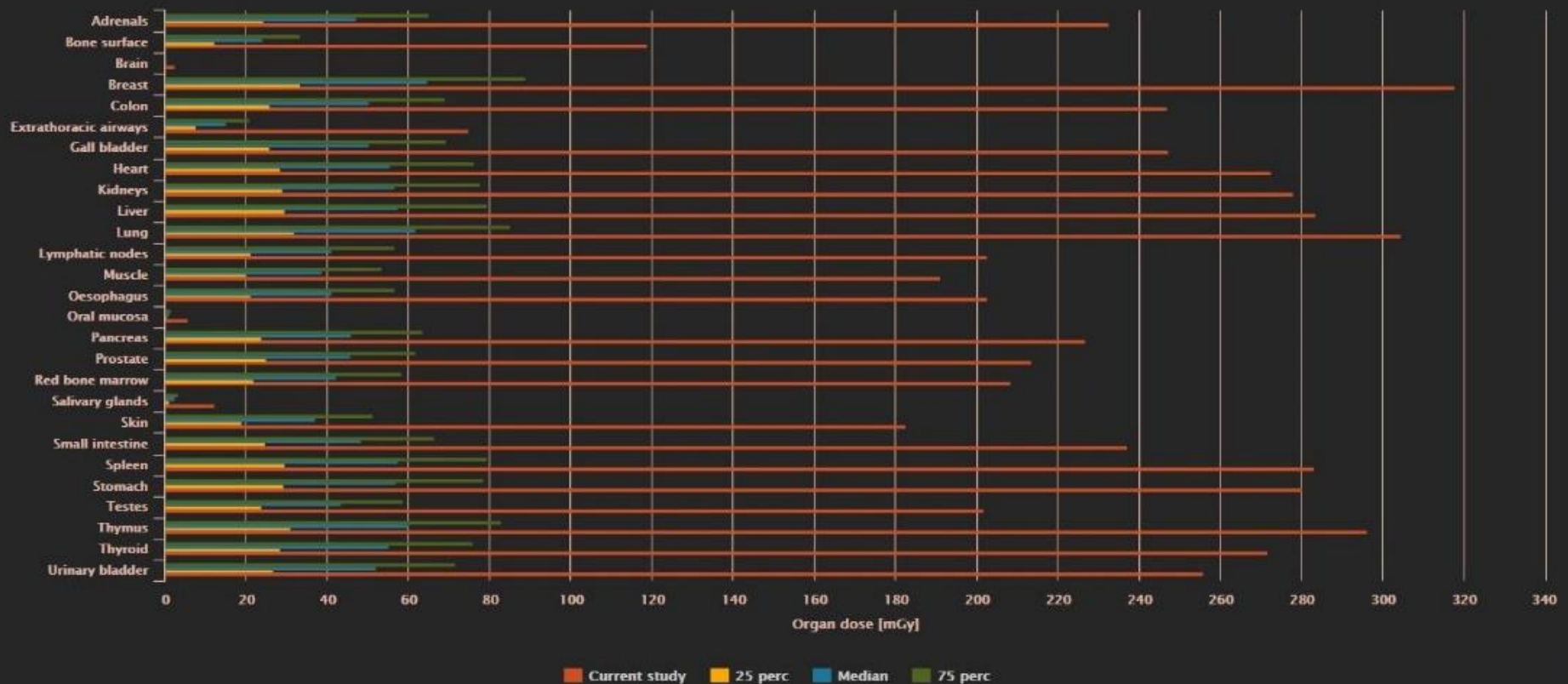
- Provide a “history” of examinations
- Analysis in terms of time, exam type, etc that would help in overall assessment of the exam type.
- Can give dose trends, device utilization, high dose studies and detailed X-ray exam information.
- The dose management software simulates patient dose before the X-ray exam is performed.



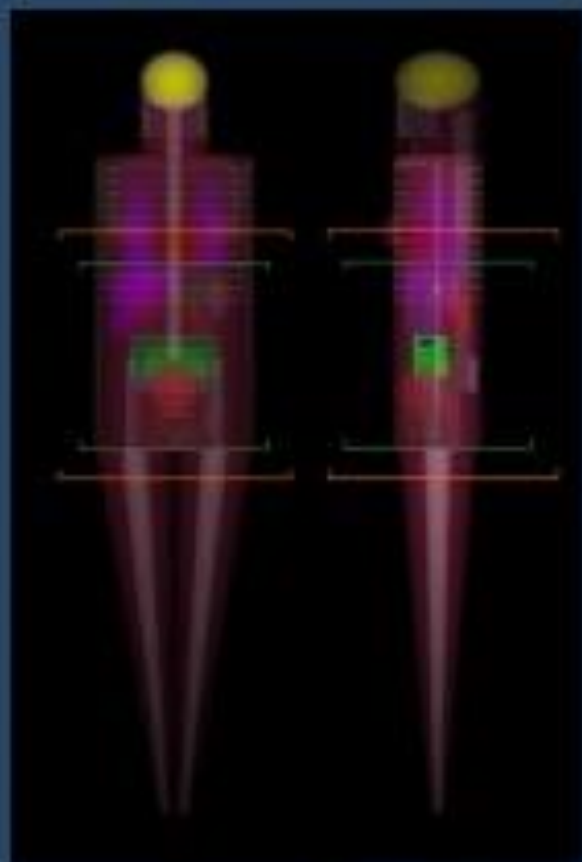
Some DMS use dose data to calculate organ doses



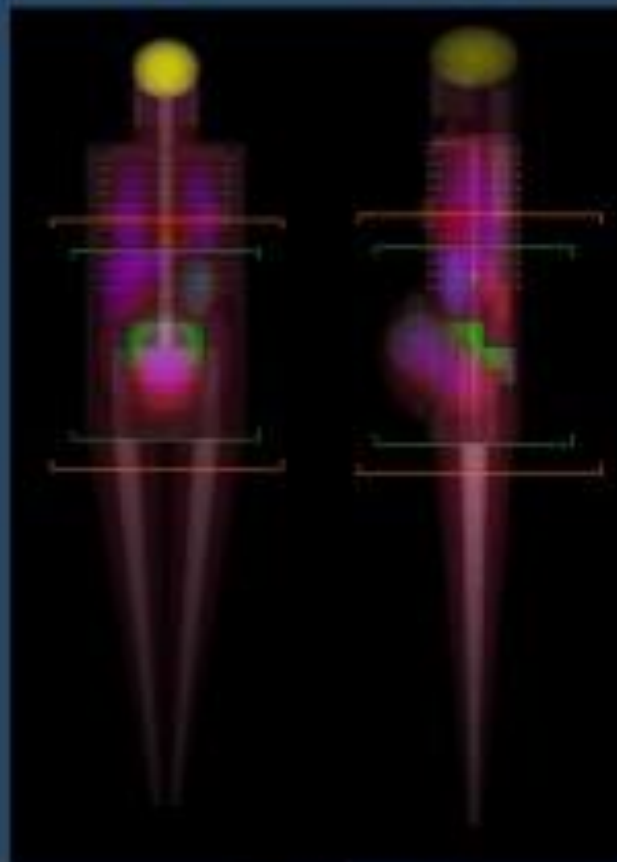
Organ dose comparison



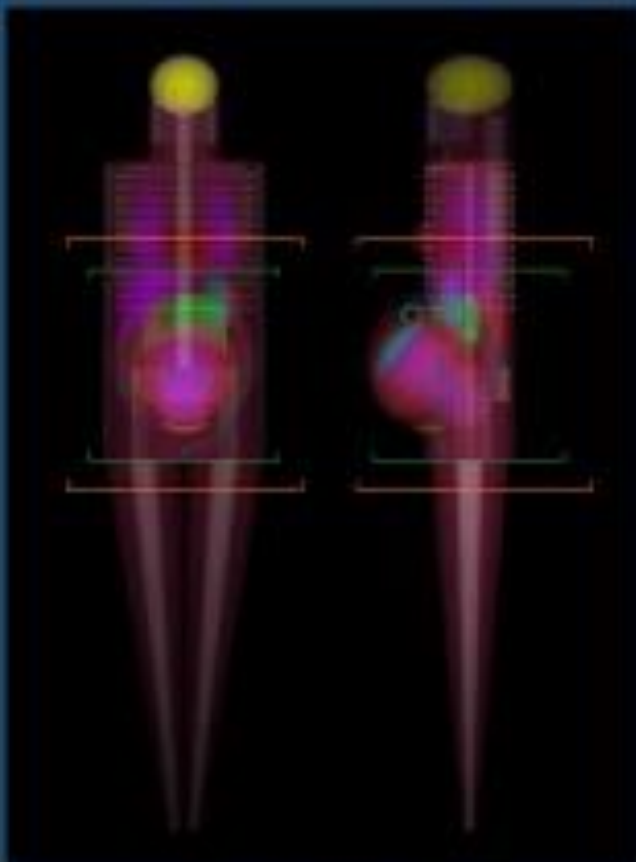
21 Pregnant Anthropomorphic Models: 3 Regular – 18 Bariatric



I TRIMESTER



II TRIMESTER



III TRIMESTER

CT Contrast information

Score card displays patient radiation dose, CT and MR contrast dose

<p>00192402X BARROTT, Jaquelyn X F DOB: 03/29/1952 Age: 63y Weight: 57kg Height: 188cm</p>	<p>A x6 CRP 183 35,5 mSv Fluoro S. - CAP - Gy-cm2 Ref. Point - mGy Contra... 262 mL Contra... 7,5 mL Contra... 7,5 mmol</p>	<p>CT x5 CRP 183 35,5 mSv DLP Ha... 156 mGy-cm DLP Bo... 1620 mGy-cm Contra... 262 mL MR x1 Contra... 7,5 mL Contra... 7,5 mmol</p>
<p>00265705X CRAFT, Dann X F DOB: 06/15/1955 Age: 60y Weight: 58kg Height: 167cm</p>	<p>A x2 CRP 183 - mSv Fluoro S. 5 CAP - Gy-cm2 Ref. Point - mGy Contra... 10 mL Contra... 2,5 mmol</p>	<p>MG x1 Right Br... 7,2 mSv Left Br... 6,2 mGy-cm MR x1 Contra... 10 mL Contra... 2,5 mmol</p>
<p>00249121X KERSS, Rebecca X F DOB: 11/13/1984 Age: 31y Weight: 56kg Height: 165cm</p>	<p>A x2 CRP 183 8,1 mSv Fluoro S. 5 CAP - Gy-cm2 Ref. Point - mGy Contra... 82 mL Contra... - mL Contra... - mmol</p>	<p>CT x1 CRP 183 8,1 mSv DLP Ha... - mGy-cm DLP Bo... 282 mGy-cm Contra... 82 mL MR x1 Contra... - mL Contra... - mmol</p>
<p>00252092 OPET, Colin X M DOB: 08/02/1946 Age: 69y Weight: 93kg Height: 188cm</p>	<p>A x2 CRP 183 24 mSv Fluoro S. 5 CAP - Gy-cm2 Ref. Point - mGy Contra... 100 mL Contra... 9 mL Contra... 9 mmol</p>	<p>CT x1 CRP 183 24 mSv DLP Ha... - mGy-cm DLP Bo... 1207 mGy-cm Contra... 100 mL MR x1 Contra... 9 mL Contra... 9 mmol</p>

Patients total contrast volume for this procedure (352 mL)

00028667X CT Thorax 01_CHEST_ROUTINE (Adult)
01_CHEST_ROUTINE
Performed: 10/09/2014 3:32 PM
SOMATOM Definition HNCT2

00141225X SCHUERING, Molly X
F DOB: 04/16/1965 Age at Exam: 29y

Contrast Vol: 352 mL
Peak Flow No: 2,1 mL/s
Number of Ij: 2

Summary

Name CT CHEST
Anatomical Region Chest
Has Test Injection Yes
Total Contrast Volume (Soline) (mL) 157
Total Soline Volume (mL) 24,9
Peak Pressure (psi) 23,061
Peak Flow Rate (mL/s) 2,1
Peak Pressure A (psi) 23,061
Peak Pressure B (psi) 0
Peak Flow Rate A (mL/s) 2,09
Peak Flow Rate B (mL/s) 2,1

Personalization Algorithms
None

Contrast Data

Catheter None
Injection Site Unknown
Contrast Dose 54,95 (g)

Contrast (A) Contrast A, 350 mg/mL

Events

Start Time 2014-10-09 15:57:18
End Time 2014-10-09 15:58:59
Termination Reason Normal
Transient Events
Template Deviations 1

Associated Orders

Description CT CHEST
Accession No. 00028667X

Equipment and Staff

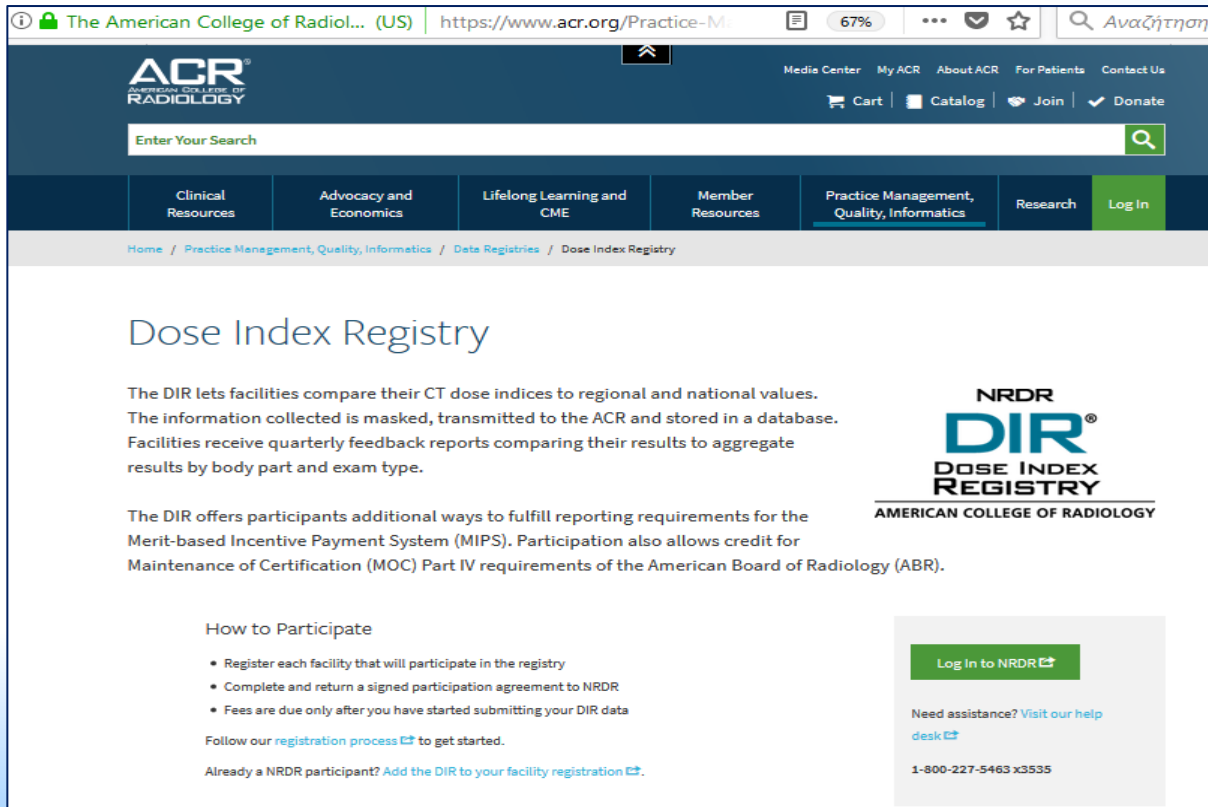
Operator Unknown
Injector StoBant 7

Notes

Injections

Index	Dose	Contrast Volume (mL)	Template	Started	Ended	Abnormal Events	Deviations
1	54,95 g	157	CT CHEST	15:57:18	15:58:59	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2	68,25 g	195	CT CHEST	16:41:35	16:43:21	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Estimates of population doses; Example of a dose registry



The screenshot shows the ACR website's navigation bar with the logo and menu items: Media Center, My ACR, About ACR, For Patients, Contact Us, Cart, Catalog, Join, and Donate. A search bar is present with the text "Enter Your Search". Below the navigation bar, there are tabs for Clinical Resources, Advocacy and Economics, Lifelong Learning and CME, Member Resources, Practice Management, Quality, Informatics, Research, and Log In. The main content area is titled "Dose Index Registry" and includes the following text:

The DIR lets facilities compare their CT dose indices to regional and national values. The information collected is masked, transmitted to the ACR and stored in a database. Facilities receive quarterly feedback reports comparing their results to aggregate results by body part and exam type.

The DIR offers participants additional ways to fulfill reporting requirements for the Merit-based Incentive Payment System (MIPS). Participation also allows credit for Maintenance of Certification (MOC) Part IV requirements of the American Board of Radiology (ABR).

**NRDR
DIR[®]
DOSE INDEX
REGISTRY
AMERICAN COLLEGE OF RADIOLOGY**

How to Participate

- Register each facility that will participate in the registry
- Complete and return a signed participation agreement to NRDR
- Fees are due only after you have started submitting your DIR data

Follow our [registration process](#) to get started.

Already a NRDR participant? [Add the DIR to your facility registration](#).

[Log In to NRDR](#)

Need assistance? [Visit our help desk](#)

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Enterprise Platform

INFINITT North America PRIMORDIAL SECTRA

September 2017
48 million exams
from more than
2100 facilities

- After data are collected they must be validated
- Parameters are occasionally mentioned in the wrong DICOM field
- Parameters may be mentioned in vendor specific fields



VALIDATION

the quality of output
depends on the quality of
input

Validation of data and specially
dosimetric data is done by the medical
physicist

Challenge 1 Enormous variety in machines (possible connectivity issues)

- So many different modalities (CT, mammography, radiography, fluoroscopy, interventional, nuclear medicine, MRI, etc)
- So many vendors in each modality.
- So many models per vendor
- All of them will have different way of implementation
- Older machines may not provide dose reports
- Older machines do not even report dose

Institution must be certain that the X-ray machines CAN be connected to the software.



Challenge 2: Enormous amount of data



Every time you change something in the protocol or you change the protocol name there will be a permanent trace in the history of the record. This is another important reason why we have so many data

- In one hospital it can be thousands of exams
- In many hospitals it can be millions of exams
- Hundreds of protocols for example for CT
- Mixture of old and new exams (data)



Challenge 3: Enormous variety in clinical protocol nomenclature

Different CT scanners have different protocol names.

- Before actual use of DMS, protocols should be standardized in terms of nomenclature.
- If not, then protocol mismatches and overlapping errors will happen between different CT scanners. For example, errors such as using same name for a single-phase contrast-enhanced protocol on one scanner and a triple-phase contrast-enhanced protocol on another scanner would lead to miscalculation of the average radiation dose of certain protocols.
- One can use the RadLex Playbook:
<http://playbook.radlex.org/playbook/SearchRadlexAction>

This is the biggest challenge after procurement and better be done at a imaging device level.

Challenge 4: Various dosimetric quantities for all modalities

$CTDI_w$

SSDE

MGD

CTDI

AGD

$CTDI_{vol}$

DLP

MSD

$CTDI_{air}$

KAP

DAP

K_{ar}

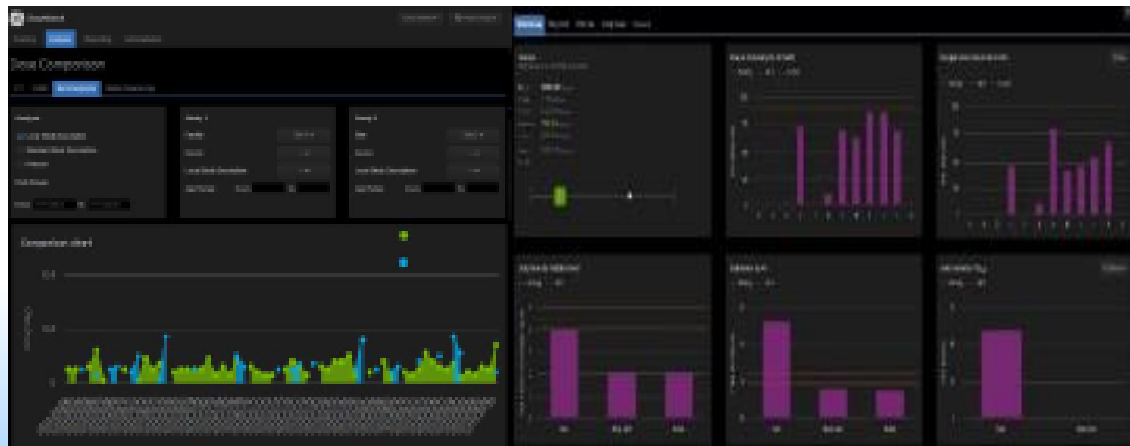
P_{KA}

ESAK

Challenge 5: Enormous amount of information

- The clinicians are bombarded with tons of graphs, figures, statistics and other info ..
- This tons of data do not necessarily lead to knowledge, innovation, insights

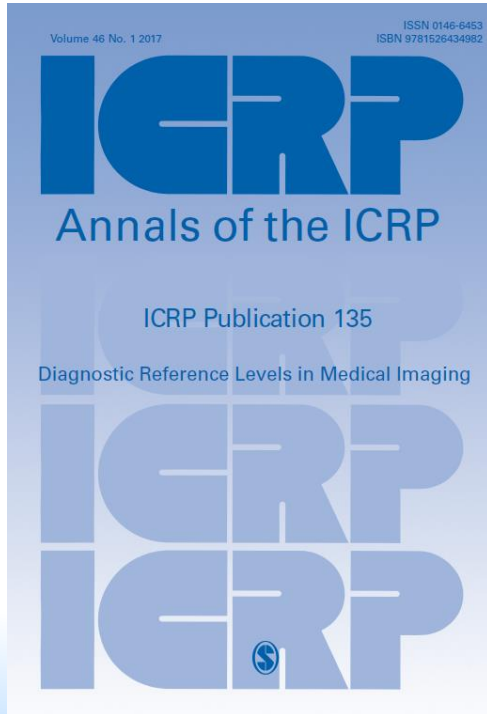
One has to scrutinize this data and be able to dig out meaningful information for the user



Challenge 6: Notification values are fixed and independent of patient size.

- Appropriate doses for bariatric patients may inappropriately trigger notification events
- This can lead today to unnecessary incident reviews required by authorities.
- Even worse, when the alert value is exceeded, the workflow may stop on the scanner until a user with the proper credentials authorizes scan continuation.

International Commission on Radiological Protection (ICRP), 2017. Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann. ICRP 46(1). IAEA



Patient dose management systems are helpful in fulfilling legal requirements or to identify unintended overexposures.

...the validity of the dosimetric indicators must be verified by medical physics experts, and corrected, if necessary, prior to their incorporation into patient dose management systems.

Radiation dose management systems; requirements and recommendations for users from the ESR EuroSafe Imaging initiative.

- Basic requirements
- Standard requirements
- High-level solutions

- DMS which can be tailored to the size and workload of a clinic/institution.
- If calculated organ or effective doses are provided, the uncertainties should always be considered.

During installation and subsequent operation of a DMS, the inclusion of an MPE is strongly recommended, especially in larger institutions or complex installations.



Radiation dose management systems—requirements and recommendations for users from the ESR EuroSafe Imaging initiative

Reinhard W. Loose^{1,2} · Eliseo Vano³ · Peter Mildenerberger⁴ · Virginia Tsapaki⁵ · Davide Caramella⁶ · Johan Sjöberg⁷ · Graciano Paulo⁸ · Alberto Torresin⁹ · Sebastian Schindera¹⁰ · Guy Frijia¹¹ · John Damlakis¹² · on behalf of the European Society of Radiology (ESR)¹³

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Abstract

The European Directive 2013/59/Euratom requires member states of the European Union to ensure justification and optimisation of radiological procedures and store information on patient exposure for analysis and quality assurance. The EuroSafe Imaging campaign of the European Society of Radiology created a working group (WG) on “Dose Management” with the aim to provide European recommendations on the implementation of dose management systems (DMS) in clinical practice. The WG follows Action 4: “Promote dose management systems to establish local, national, and European diagnostic reference levels (DRL)” of the EuroSafe Imaging Call for Action 2018. DMS are designed for medical practitioners, radiographers, medical physics experts (MPE) and other health professionals involved in imaging to support their tasks and duties of radiation protection in accordance with local and national requirements. The WG analysed requirements and critical points when installing a DMS and classified the individual functions at different performance levels.

Key Points

- DMS are very helpful software tools for monitoring patient exposure, optimisation, compliance with DRLs and quality assurance.
- DMS can help to fulfil dosimetric aspects of the European Directive 2013/59/Euratom.
- The EuroSafe WG analyses DMS requirements and gives recommendations for users.

Keywords Dose management systems · Radiation protection · Optimisation · Quality assurance

Abbreviations

ADT Admission, discharge and transfer
ALARA As low as reasonably achievable

CR Computed radiography
CT Computed tomography
DICOM Digital Imaging and Communication in Medicine

✉ Reinhard W. Loose
Loose@klinikum-nuernberg.de

¹ Institute of Medical Physics, Hospital Nuremberg, Prof.-Emst-Nathan-Str. 1, 90419 Nuremberg, Germany

² Institute of Radiology, University Hospital, Erlangen, Germany

³ Radiology (Medical Physics), San Carlos University Hospital, Madrid, Spain

⁴ Department of Radiology, University Medical Center Mainz, Mainz, Germany

⁵ Medical Physics, Konstantopoulo General Hospital, Naxos, Greece

⁶ Department of Radiology, University of Pisa, Pisa, Italy

⁷ Medical Radiation Physics and Nuclear Imaging, Karolinska Institutet, Stockholm, Sweden

⁸ IPC - Escola Superior de Tecnologia da Saúde de Coimbra, Coimbra, Portugal

⁹ Medical Physics Department, Ospedale Niguarda, Milan, Italy

¹⁰ Institute of Radiology, Cantonal Hospital, Aarau, Switzerland

¹¹ Descartes University Paris, Paris, France

¹² University of Crete Heraklion, Heraklion, Greece

¹³ European Society of Radiology, Vienna, Austria

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AAPM REPORTS & DOCUMENTS

WILEY

AAPM medical physics practice guideline 6.a.: Performance characteristics of radiation dose index monitoring systems

Dustin A. Gress¹ | Renee L. Dickinson² | William D. Erwin¹ | David W. Jordan³ |
Robert J. Kobistek⁴ | Donna M. Stevens⁵ | Mark P. Supanich⁶ | Jia Wang⁷ |
Lynne A. Fairbent⁸

¹Department of Imaging Physics, University of Texas MD Anderson Cancer Center, Houston, TX, USA

²Colorado Association in Medical Physics, Colorado Springs, CO, USA

³Department of Radiology, University Hospitals Cleveland Medical Center, Case Western Reserve University, Cleveland, OH, USA

⁴National Physics Consultants, Ltd., Mentor, OH, USA

⁵Northwest Permanente, PC, Kaiser Permanente Medical Center, Clackamas, OR, USA

⁶Department of Diagnostic Radiology and Nuclear Medicine, Rush University Medical Center, Chicago, IL, USA

⁷Environmental Health and Safety, Stanford University, Stanford, CA, USA

⁸American Association of Physicists in Medicine, Alexandria, VA, USA

Author to whom correspondence should be addressed, Dustin A. Gress

E-mail: DGress@mdanderson.org

Telephone: 281 298-1300

The American Association of Physicists in Medicine (AAPM) is a nonprofit professional society whose primary purposes are to advance the science, education and professional practice of medical physics. The AAPM has more than 8,000 members and is the principal organization of medical physicists in the United States.

The AAPM will periodically define new practice guidelines for medical physics practice to help advance the science of medical physics and to improve the quality of service to patients throughout the United States. Existing medical physics practice guidelines will be reviewed for the purpose of revision or renewal, as appropriate, on their fifth anniversary or sooner.

Each medical physics practice guideline represents a policy statement by the AAPM, has undergone a thorough consensus process in which it has been subjected to extensive review, and requires the approval of the Professional Council. The medical physics practice guidelines recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guidelines and technical standards by those entities not providing these services is not authorized.

The following terms are used in the AAPM practice guidelines:

- **Must and Must Not:** Used to indicate that adherence to the recommendation is considered necessary to conform to this practice guideline.
- **Should and Should Not:** Used to indicate a prudent practice to which exceptions may occasionally be made in appropriate circumstances.

1 | INTRODUCTION

Radiation dose index monitoring (RDIM) systems may generally be identified as software that retrospectively collects radiation dose indices (RDI) and other acquisition parameters from imaging studies that use ionizing radiation, and stores those indices in a relational database along with patient demographics. The software typically includes a graphical user interface, which allows the end user to

visualize RDI by study type, patient or other category for quality assurance or patient- or study-specific investigations. When collating data from these RDIM systems, it is important to understand the applications and limitations of the recorded dose indices.¹ At this time, none of the RDI represent location-specific absorbed dose in an individual patient. Most are related to X-ray beam output or X-ray absorption at the image receptor. Software indications of organ absorbed doses and effective dose are based on standardized

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12 | wileyonlinelibrary.com/journal/ajmp | *J Appl Clin Med Phys* 2017; 18(4):12–22

These systems have potential to revolutionize quality assurance in imaging and present unique research opportunities.

The data from DMS may be useful in assisting the medical physicist in such tasks as ongoing Quality assurance, Practice Quality Improvement and patient or fetal dose estimation.

estimated organ and effective dose values must only be used with the direction and involvement of a Qualified Medical Physicist, and with careful consideration and understanding of limitations of the quantities

Dose Management Systems (publication)



UPCOMING

There is little guidance on how to set up and assess the accuracy of a DMS, including a lack of standardization of procedures related to acceptance testing and periodic quality control tests.

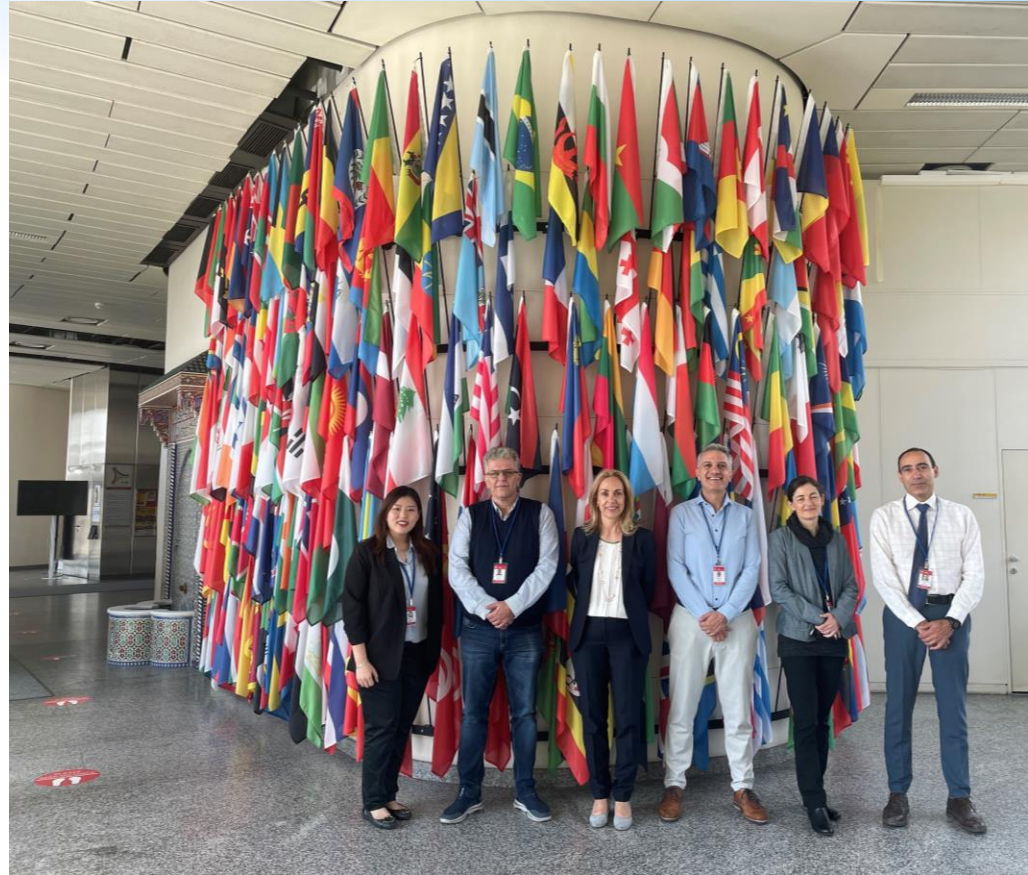


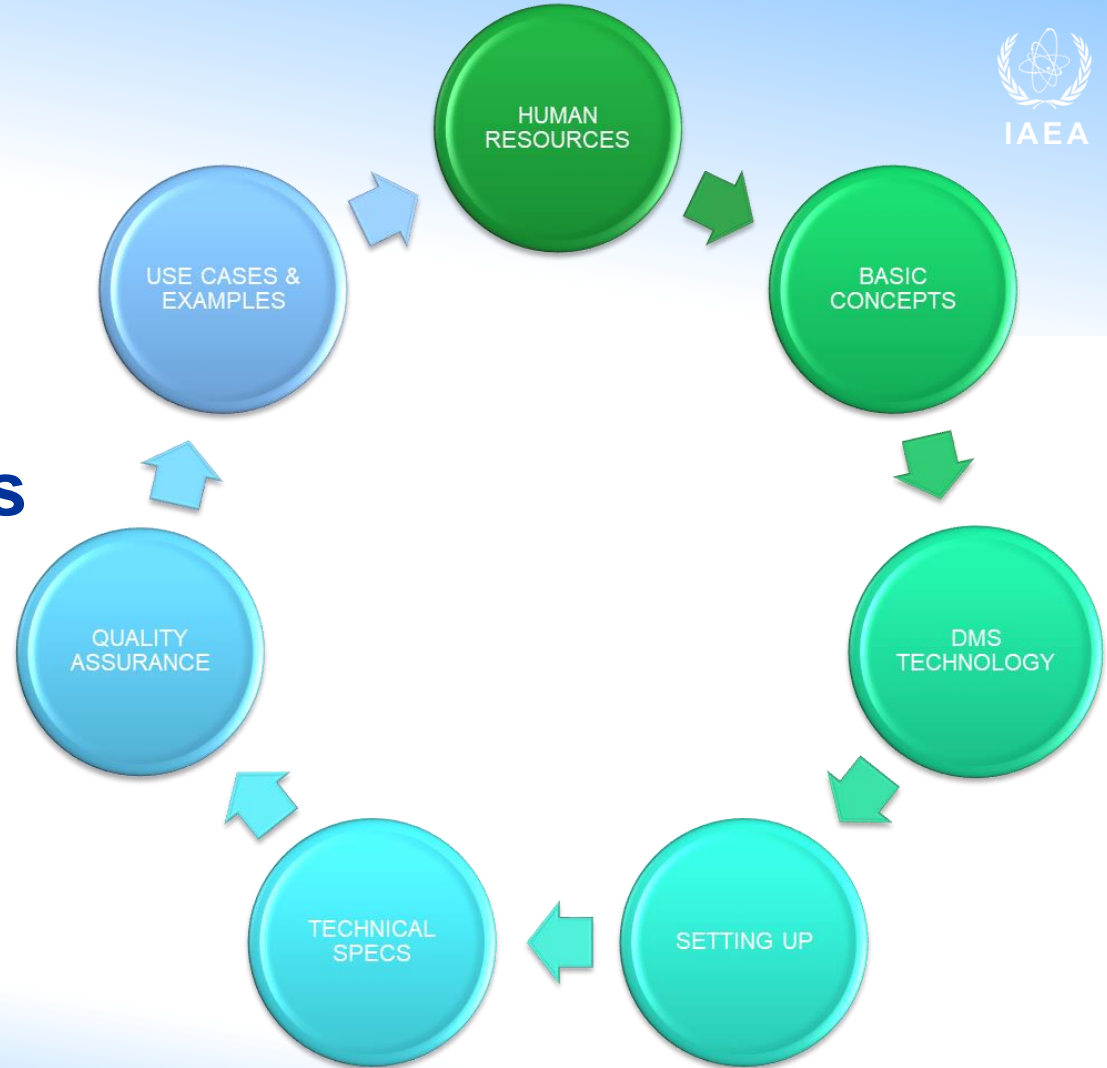
IAEA Expert meeting

Date: 30 May-3 June 2022

The purpose of the meeting was to discuss the current status on dose management systems use, identify gaps and challenges and finally define the contents of guidelines for medical physicists on the content, analysis, and evaluation of these systems to help Member States understand, set up and use them appropriately.

Ricardo RUGGERI	Argentina
Ioannis TSALAFOUTAS	Qatar
Laurentcia ARLANY	Singapore
to Mariano SÁNCHEZ CASANI	Spain
Ingrid REISER	USA





Draft table of contents

Information Collected

1. Certifications

FDA, CE, Joint Commission
other Certification



2. Data Transfer Methods, Patient/Facility Information

Data connection & Collection
Examination/Patient/Facility Records
Unit Conversion & Calibration Factors



3. Modalities, Metrics & Methods Supported

Acquisition & Reconstruction
Parameters Collected
Dose Metrics & Parameters Calculated
Image Quality Evaluation Tools
Occupational Dose Tracking



4. Statistical Analysis Capabilities

Information Dashboard
Export Capabilities
Analysis of data collected &
calculated



5. Customization

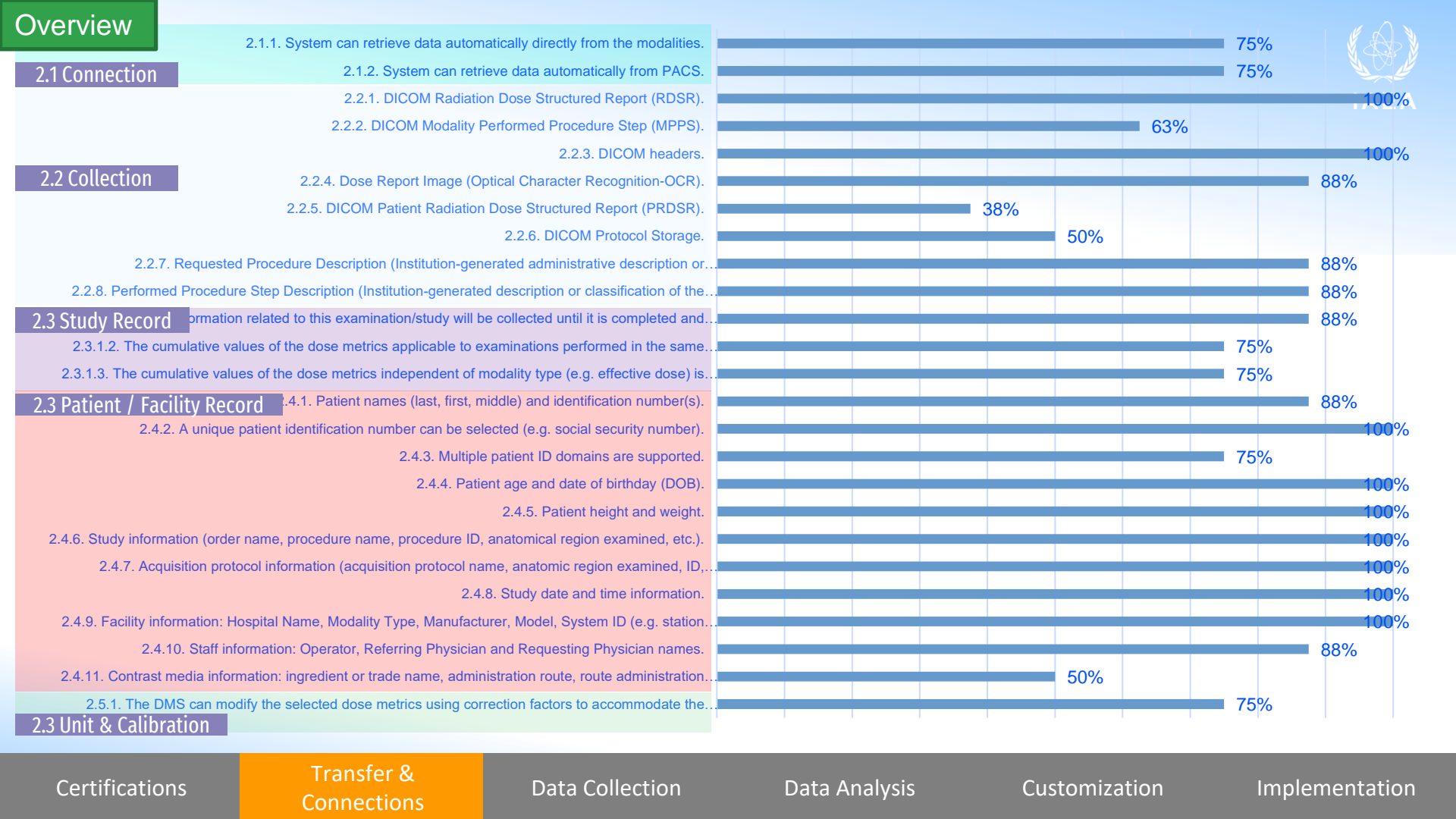
Setting Alerts
Master Protocols
DRL Libraries
User Rights



6. Implementation Process

IT installation requirements
Support & Functionalities
Implementations





Overview

2.1 Connection

2.2 Collection

2.3 Study Record

2.3 Patient / Facility Record

2.3 Unit & Calibration

Certifications

Transfer & Connections

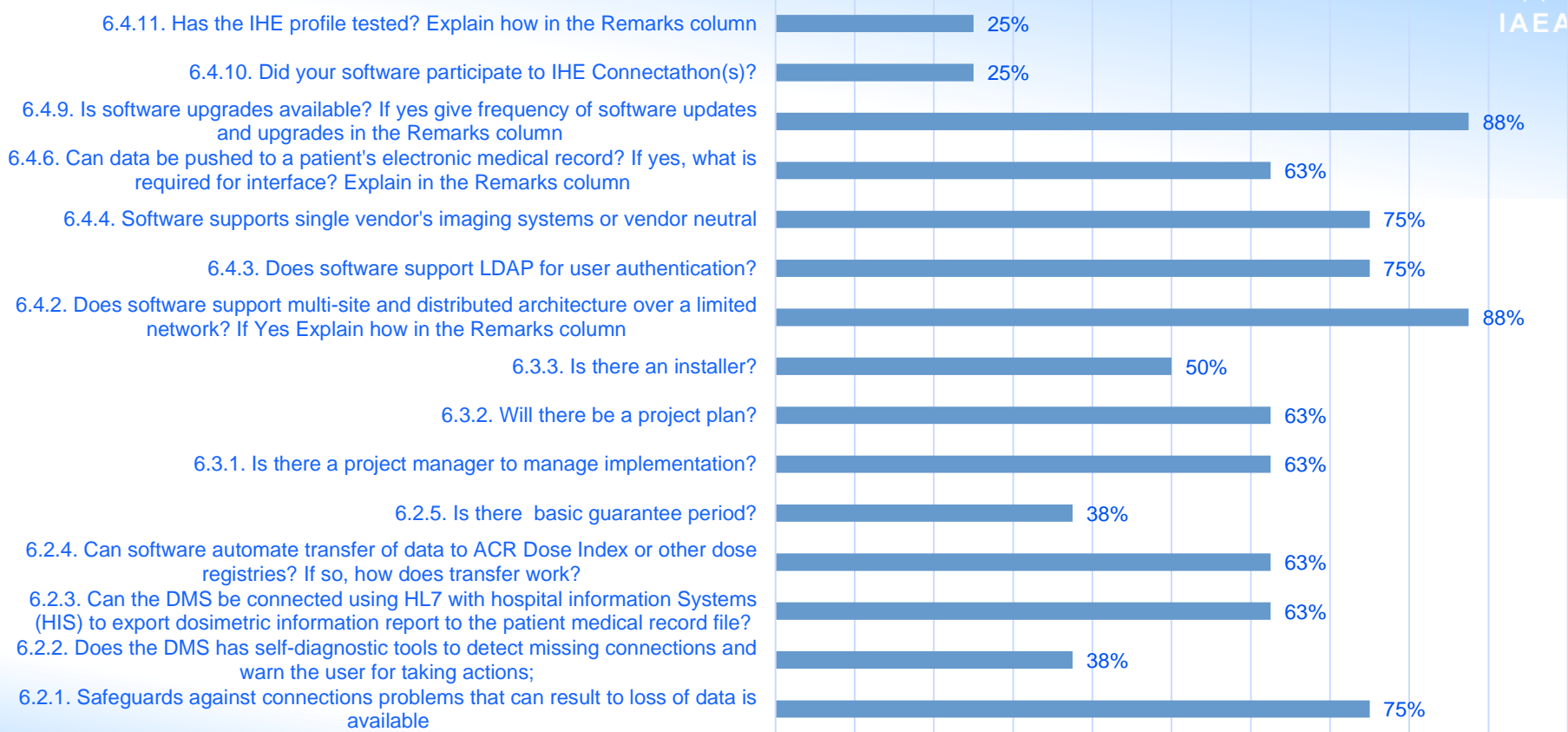
Data Collection

Data Analysis

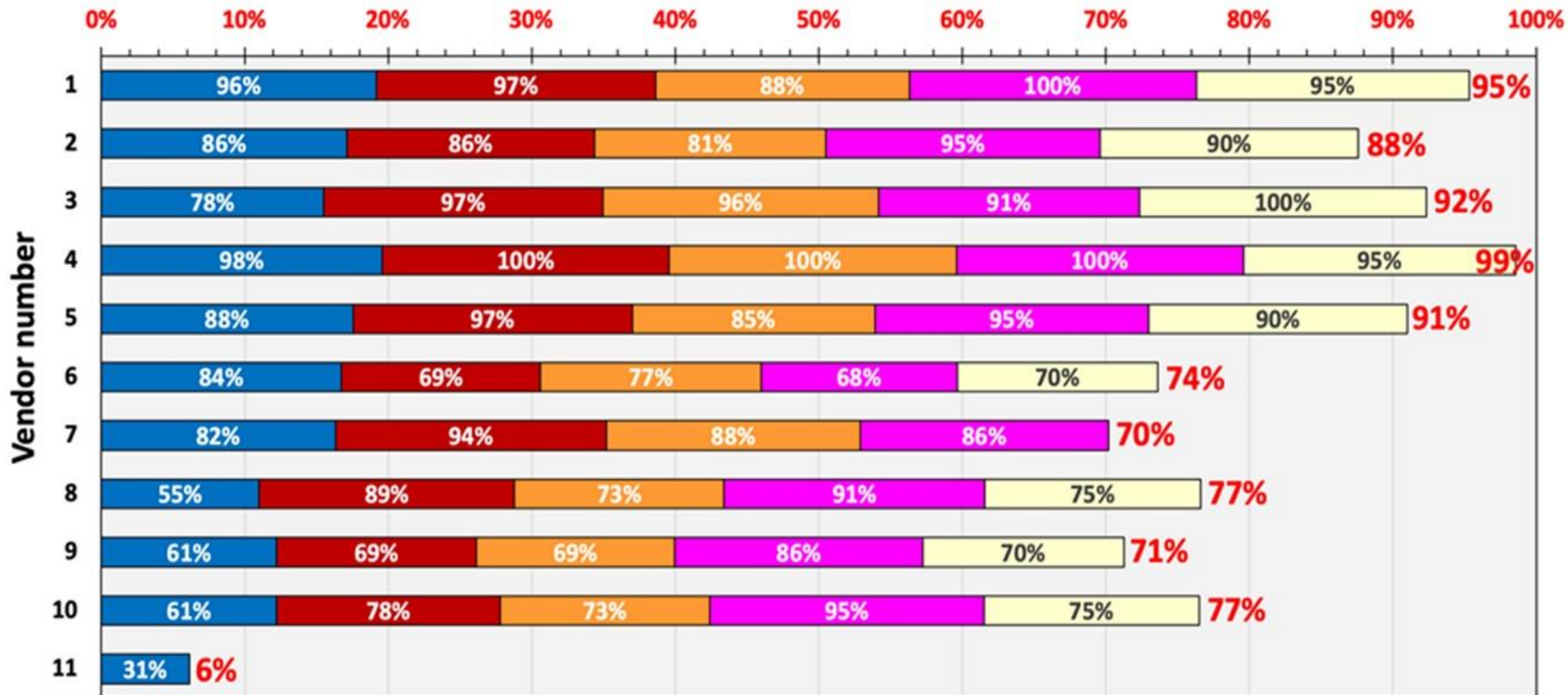
Customization

Implementation

Section 6. Implementation Process



DATA COLLECTION (5 SUB-SECTIONS): INDIVIDUAL MODALITY AND AVERAGE PERCENTAGES OF POSITIVE ANSWERS



DATA COLLECTION ■ CT ■ Interventional/Fluoroscopy ■ Radiography ■ Mamography ■ Dental Radiography (CBCT, Pan, Ceph)

Conclusions from the study

- Healthcare institutions contemplating the acquisition of a DMS solution should comprehensively explore the available DMS solutions, regarding the features and functionalities that they offer, to make sure that they align with their specific needs.
- Subsequently interested institutions must identify which of those advanced features, which may be optional and come at an extra cost, are either essential or desirable for their specific organization, considering the available budget.
- Finally, it should be confirmed whether the existing infrastructure and information technology personnel available are compatible with the proposed DMS installation, operation, and service support requirements. This approach could potentially optimize expenditure, ensuring a balance between operational efficiency and budgetary constraints.

Conclusions

- DMS are considered important tools for supporting the process of justification and optimisation at a health institutional level and for compliance with the regulation on radiation protection.
- More efforts are needed to eliminate the connectivity issues related to modality, varying clinical protocol nomenclature, identifying notification values for various patient sizes, etc.
- Advanced DMS must be used under the supervision of a qualified medical physicist.

For the future

Image quality assessment in relation to radiation dose for effective optimization tailored to each individual patient's needs