Supporting X-ray safety compliance with effective dose management documentation

Complete documentation of radiation doses
Interview with

ERIK VAN RIJN  Business Manager Dose Monitoring at Agfa HealthCare
JURGEN JACOBS  Managing Director and co-founder of Qaelum (cover image)

The rise in the number of X-ray examinations, CT scans, nuclear medicine scans, and other examinations based on ionizing radiation has had a positive impact on patient health, but does result in higher radiation exposure. In recent decades, the radiation dose exposure of the population in industrialized countries has increased sixfold. Dose management is therefore an important aspect of radiological routine — with the support of the right hardware and software.
This issue has now also been addressed by the European Union. By spring 2018, the Euratom Directive 2013/59 (the EU directive on radiation protection) must be implemented in the national law of member states. The most important requirement of the new legislation is the complete documentation of patient doses. In addition, the input of an expert in medical physics is required to a certain degree for each modality. We spoke to Erik van Rijn, Business Manager Dose Monitoring at Agfa HealthCare, and Jurgen Jacobs, Managing Director and co-founder of Qaelum, about the content and impacts of the new legislation.

What requirements will be introduced by the new Euratom Directive 2013/59?

Erik van Rijn: There are basically three points, which will ultimately make dose management systems standard in all radiological clinics or practices. Firstly, the Directive requires the reporting of accident-related exposures and unintentional exposures with a much higher radiation dose. This is only possible if, in addition to recording all exposures, clinical staff also monitor unintended overexposures. Secondly, a quality assurance program must be implemented to ensure that the quality of radiological services and radiation exposure satisfy the relevant requirements. And thirdly, an appropriate statistical evaluation of all exposures must be carried out for all relevant types of examination in CT and interventional radiology.

How does dose documentation work at the moment?

Jurgen Jacobs: X-ray safety regulations require patient radiation exposures – or the data required to estimate it – to be recorded. This is typically done in the radiology information system (RIS), and in the case of all digital detectors except imaging plates, also in the image management system (PACS). In some CT machines, dose documentation is carried out by means of a picture containing the dose information. This satisfies the documentation requirement.

IT systems do not currently offer regular computer-aided evaluation. How do dose management systems work?

E. van Rijn: The dose data is extracted from the PACS and prepared accordingly. Relevant data is read from sources such as MPPS messages, DICOM header information or Radiation Dose Structured Reports. In the case of imaging plate systems, for example, where automated documentation is very difficult or impossible, the dose values are entered manually in the RIS and extracted from there. This process is susceptible to potential errors.
Can you then achieve dose management just by using the right software?

**J. Jacobs:** No. The goal of optimized dose application for radiological examinations and interventions can only be achieved through the joint efforts of everyone involved, such as radiology assistants, physicians, nursing staff, medical physicists, and IT administrators. Calculating or estimating the dose parameters before the examination is also a very important aspect of dose management. This starts when the procedure is being explained to the patient and ends with the optimization of radiological procedures.

What are the implications of the implementation of the Euratom Directive 2013/59 for hospitals?

**E. van Rijn:** It means the introduction of dose management systems in radiology. In turn, these systems are an important step toward improved quality management and the optimization of radiation exposure. However, it does involve costs for the acquisition or upgrading of existing dose documentation systems. There will be considerably more efforts at all levels to achieve the goal of optimum dose application. In this context, “optimum” means the lowest possible dose for the patient to produce a radiological image suitable for reliable diagnosis.

What kind of evaluations must a dose management system provide for the user?

**J. Jacobs:** There are several. In addition to basic information such as average dose values, standard deviations, and the upper and lower dose reference values for specific types of examinations, it is also necessary to carry out machine-related evaluations that allow comparisons to be made between individual machines. It is also crucial to be able to view the dose over time for a particular type of examination. Additionally, the system must trigger an alarm when the average dose values exceed the diagnostic reference values or when they require mandatory reporting.

The software tqm|DOSE is a dose management system. What are its characteristics?

**E. van Rijn:** tqm|DOSE is a solution from Qaelum that can be fully integrated in different Agfa HealthCare solutions like XERO Viewer and Enterprise Imaging. It offers high-performance functions for documenting and statistically preparing the administered radiation dose. One key feature of tqm|DOSE is that, in terms of sources, it is not restricted to specific vendors or protocols, so it can be used in combination with all modalities and information sources. The solution is also based on the very highest standards. It was developed by an ISO 13485-certified company and is a CE Class IIb-labeled product.
What specific features does the solution offer?

**J. Jacobs:** tqmDOSE allows radiologists to monitor all the relevant parameters in real time in the medical imaging environment. Before starting the examination, they benefit from proactive notifications and safety checklists. Immediately after the examination, a dose analysis is available at patient, user, machine, and modality level with special consideration of outlier results. These evaluations can also be viewed on mobile devices. This makes it possible to prepare a detailed workflow analysis and continually improve clinical processes.

How does tqmDOSE assist the user with data analysis?

**J. Jacobs:** The user can create personalized dashboards that display evaluations appropriate to the specific user and role. It is also possible to show special MR features such as the specific absorption rate (SAR), patient weight, nuclear-medical details or the ultrasound workflow. To give radiologists and radiology assistants direct feedback, there is a real-time display that brings together all the important information in words and graphics. For each study, the corresponding data and the dose histogram can be consulted at a glance. Activity reports also list the most recent events.

“One key feature of tqmDOSE is that, in terms of sources, it is not restricted to specific vendors or protocols, so it can be used in combination with all modalities and information sources. The solution is also based on the very highest standards.”

— Erik van Rijn, Business Manager Dose Monitoring at Agfa HealthCare
Is tqm|DOSE an administration system, then?

E. van Rijn: No – it also offers an array of quality assurance features, for example. This includes detailed workflow analyses, not just for radiation dose but also for MR and ultrasound. The Size Specific Dose Estimate (SSDE) allows the positioning of the patient to be analyzed and simulated. Machine-specific dimensions are used and patient localization is defined on the basis of the segment result. The system then suggests precise positions.

Another function is the evaluation of scan overlaps, which can be analyzed in order to minimize overlaps between two consecutive series.

Last but not least, tqm|DOSE can generate reports. This applies not only to legally required documents but also to specific, dynamic, and static reports. Dynamic reports can be created with a simple drag and drop, personalized, and stored as a webpage. Static reports include export to popular file formats such as PDF.
Details as of PDF Creation Date

<table>
<thead>
<tr>
<th>Document Metadata</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
</tr>
<tr>
<td>Livelink ID:</td>
</tr>
<tr>
<td>Version#:</td>
</tr>
<tr>
<td>Version Date:</td>
</tr>
<tr>
<td>Status:</td>
</tr>
<tr>
<td>Owner:</td>
</tr>
<tr>
<td>Created By:</td>
</tr>
<tr>
<td>Created Date:</td>
</tr>
<tr>
<td>PDF Creation Date:</td>
</tr>
</tbody>
</table>

This document was approved by:

Signatures:

1. Benton Bailey (mitkq) on 2016-09-13 04:29 PM CET
2. Debbie Huff (moqyl) on 2016-09-08 09:46 PM CET

Detailed Approver History:

- Approval Workflow started on 2016-09-08 02:53 PM CET
  - Approval task originally assigned to ShaeAnn Cavanagh (aximv)
    - Approval task completed by Debbie Huff (moqyl) on 2016-09-08 09:46 PM CET (workflow proxy)
  - Approval task originally assigned to and completed by Benton Bailey (mitkq) on 2016-09-13 04:29 PM CET

Version & Status History

<table>
<thead>
<tr>
<th>Version#</th>
<th>Date Created</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2016-09-08 02:51 PM CET</td>
<td>Approved - 2016-09-13</td>
</tr>
<tr>
<td>1</td>
<td>2016-06-30 02:34 PM CET</td>
<td>Reviewed - 2016-07-12</td>
</tr>
</tbody>
</table>