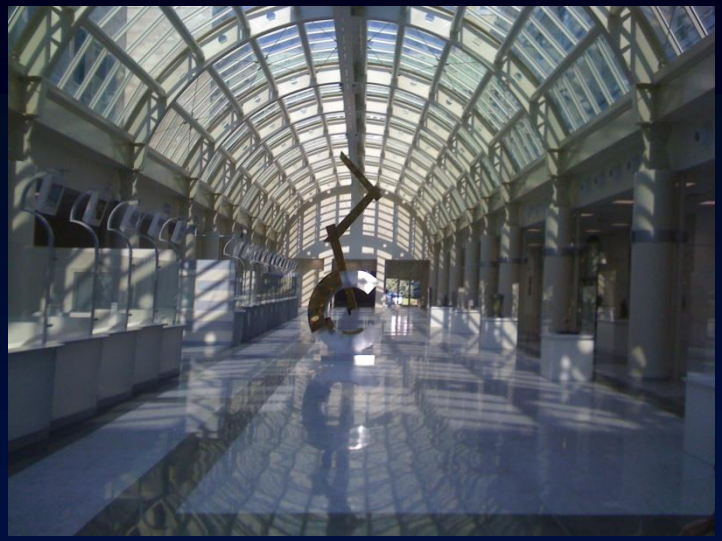

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Q5.1.1 Do stakeholders believe current regulatory requirements are sufficient to satisfy this requirement?

- **Yes with the following recommendations:**
  - **Use, if possible, the national existing methodology to trace accidental and unintended exposures**
  - **Prepare a guideline which describes the criteria to trace events**

Q5.1.2 Is sufficient attention given to diagnostic exposures as well as therapeutic exposures?

- Enought attention is not given to diagnostic exposures, particularly for CT and angio procedures
- Possibly a lot of accidental X-ray exposures of pregnant patients in Europe take plase every year.

- Unfortunately, there is no guidance/policy at European level on how to prevent these events (effective screening is needed, however guidelines do not exist) and how to manage pregnant patients exposed accidentally.

Q5.2.1 To what degree is the risk assessment already undertaken as part of good medical practice?
Q5.2.2 Would such a requirement cause difficulties for stakeholders (eg introduce delay in making new techniques available)?
Q5.2.3 In whose competence should be making of these studies of risks? (concerning Article 63(b)

- **The analysis of risk should take into account accidental or unintended exposure coming from Clinical and Technical problems; in most cases the possibility of accidents is linked to the incorrect handling of new and complex technologies**
- **Continuous education and training is not always planned; there is a big problem if the final user is not able to know the problems and the possible solutions**
- **Interdisciplinary approach to the studies risks is mandatory; clinical, physics, administrative skills must be integrated**

Q5.7.1 Are the professional bodies best placed to provide guidance on clinically significant events and are they willing to do so?
Q5.7.2 To what degree is such guidance already available – for diagnostic exposures, for interventional procedures, for radiotherapy?
Q5.7.3 Can this be provided at European level or should this be left to be solved out within each Member State (for example by professional bodies themselves or in cooperation with the competent authority)?
(concerning Article 63(d)

- **To define exposure levels for clinically significant events is very difficult**
- **More difficult in radiodiagnostic rather than in radiotherapy but we need to try to provide some preliminary guideline at European level where each Member State competence can be discussed.**
- **We have taken into account that some State do not have sufficient expertise to deal with the problem and find the right proposals**

Q5.8.1 Do stakeholders have experience of criteria which have been developed that have credibility within their communities that could be used as part of requirements for reporting of significant events?
Q5.8.2 What is the purpose of reporting significant events as soon as possible to the competent authority? What should the competent authority do with such immediate reports?
Q5.8.3 Should events, which the competent authority should know about but they don't need any quick intervention of the authority, be reported later? (i.e. they wouldn't be significant events for reporting as soon as possible and the duty to report them later would go beyond the requirements of BSSD)?
Q5.10 What are stakeholders' views on the value of reporting total numbers of events (with some description graded with the risks) within a specified period, which could later be used as part of inspection processes etc when considering local safety culture?
(concerning Article 63(e)(i)

- **Two additional very important points are:**
  - **who is in charge of detecting Accidental and Unintended exposures?**
  - **who has the responsibility to report Accidental and Unintended exposures?**

Q5.19.1 Is dissemination of information a responsibility of the competent authority, the health Ministry (or similar) or individual undertakings that have experienced significant events?
Q5.19.2 What experience do stakeholders have of the value of dissemination of this type of information?
Q5.19.3 How practical is it to produce valuable but anonymised information that meets the needs of the wider radiological community while respecting the wishes of individual patients involved in significant events?
(concerning Article 63(f)

- **Spreading information is a responsibility of the competent authority, but the consultation of professional association is mandatory: the theoretical approach must be adapted to the real problems and solutions through sustainable reporting.**
- **We are living with limited human and economical resources**

Medical Physics Expert and BSS

- **One of the main responsibilities of MPEs is the 'analysis of events involving or potentially accidental or unintended medical exposures'.**

Medical Physics Expert and BSS

- **Our role:**
  - **a) analysis of these events and**
  - **b) record keeping is very important (the skill and the competence MPEs for implementation of the relevant BSS articles is mandatory)**
  - **Staff education and training is needed on categorization of events**

Quality Assurance Program in ionizing radiation technique (QA)

- Quality assurance programmes have evolved from equipment verifications to include the entire process, from the prescription to delivery and post treatment follow-up
- Major accidental exposures take place in the absence of written procedures and checks
- Either because a QA did not exist or it was not fully implemented (checks omitted)
- A quality assurance program is the key element in prevention of accidental exposure
- QA, track and analysis of Accidental and unintended exposures require staff and time resources

Quality of dosimetric data collection

- Now the Radiation Dose Index Monitoring (RDIM) system is necessary
- We need the support of the Vendors (COCIR) for implementation of the new DICOM standards able to have the “better metrics” connected with
  - “modality output” RDSR
  - “patient dose” P-RDSR


THANK
YOU!

The Medical Physicist Expert
Connection between Physics and Medicine

Medical Physicist Expert

Physics **Medicine**

Radiation Oncologist
Radiologist
Nuclear Medicine Physician

(1) COLLECTION OF DATA

NOW the manual collection of data is not the right methodology

- **Incomplete**
- **Inaccurate**
- **Time consuming**

(1) AUTOMATIC COLLECTION OF DATA

Pemnet

NEXO™ [DOSE]
Multi-Modality Radiation Informatics

DoseWatch*
a dose management solution

radiance

QAELUM
TOTALQUALITYMONITORING

radimetrics
is now part of Bayer HealthCare

Sectra DoseTrack

OPENREM OpenREM

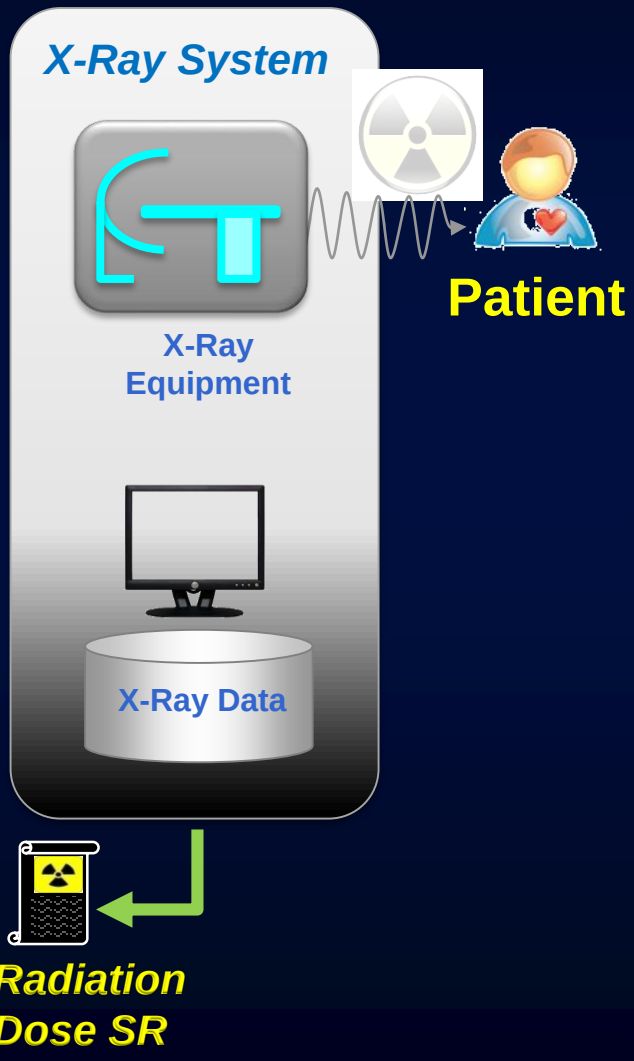
Radiation Dose Index Monitoring (RDIM) system

(2) DICOM

- **DICOM is an international cooperation between:**
  - **Industry**
  - **EFOMP**
  - **AAPM**

DICOM Working Group (WG28 –Physics)

- **We are working to define new profile of:**
  - **RDSR**



Patient Radiation Dose SR (P-RDSR)

Patient Dose Determination: Data Flow Requirements