CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

POSITION

Relating to: Patient Radiation Exposure Tracking

Radiation exposures from multiple medical imaging procedures are resulting in cumulative effective
dose estimates exceeding 50 to 100 mSv. Accounting for these exposures is important for many
reasons, particularly patient safety and welfare.

Recently, a joint position statement was published relating to the International Atomic Energy
Agency’s (IAEA) Patient Radiation Exposure Tracking System. The joint position statement was
adopted by the following organizations:

- European Society of Radiology (ESR);
- U.S. Food and Drug Administration (FDA);
- International Atomic Energy Agency (IAEA);
- International Society of Radiographers and Radiological Technologists (ISSRT);
- International Organization for Medical Physics (IOMP);
- World Health Organization (WHO); and
- CRCPD Board of Directors

CRCPD POSITION

The CRCPD hereby endorses the attached Joint Position Statement on Patient Radiation Exposure
Tracking.

Approved by the CRCPD Membership May 10, 2012

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CRCPD Chairperson

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Joint Position Statement on the IAEA Patient Radiation Exposure Tracking

By ESR, FDA, IAEA, IOMP, ISRRT, WHO and CRCPD*

Medical imaging is a well-accepted, valuable clinical tool when appropriately utilized. In recent years, individual patient exposure from radiological procedures using ionizing radiation has been increasing, including procedures in children, in part due to multiple procedures resulting in cumulative effective dose estimations exceeding 50-100 mSv in some cases. This creates increased responsibility of authorities, manufacturers and health professionals to develop and implement suitable solutions. One such solution is the IAEA Smart Card/SmartRadTrack project, the major purpose of which is tracking of patient exposure history [1-3]. In view of the interest of a number of organizations in patient protection, the IAEA decided to develop a joint position statement in cooperation with organizations and experts in imaging and clinical patient care. There are also new requirements in International and European Basic Safety Standards that indicate consideration of previous imaging procedures to fulfill justification.

The scope of patient radiation exposure tracking is to cover all imaging modalities which use ionizing radiation for interventional procedures and radiographic, fluoroscopic, computed tomography (CT), and nuclear diagnostic examinations. The scope also includes radiation dose recording, reporting and tracking. This statement is not intended to include tracking in radiation therapy.

The major goals of tracking include (1) supporting accountability for patient safety, (2) strengthening of the process of justification (e.g. information available at the point-of-care for the referring practitioner), (3) supporting optimization (e.g. use of diagnostic reference levels (DRLs)), (4) providing information for assessment of radiation risks, and (5) establishing a tool for use in research and epidemiology.

It is jointly agreed upon that:

1. Tracking of radiological procedures is useful (Annex).
2. Tracking is of particular interest for CT, interventional procedures and some nuclear medicine examinations that involve relatively higher doses.
3. Countries should consider including necessary provisions in their national requirements for patient radiation exposure tracking. Implementation must comply with relevant national privacy and confidentiality regulations.
4. The advances in picture archiving and communication systems (PACS) and other information technology, availability of radiation dose data in many imaging and image guided procedures in standardized radiation units and internationally harmonized formats, and increased utilization of electronic health records (EHR) provide evolving opportunities to successfully achieve increased coverage of both local and global patient radiation exposure tracking.
5. The IAEA has developed templates applicable for tracking at different levels such as hospitals, groups of hospitals, national and international health schemes/systems[4]. The tracking programme:

* European Society of Radiology (ESR), U.S. Food and Drug Administration (FDA), International Atomic Energy Agency (IAEA), International Organization for Medical Physics (IOMP), International Society of Radiographers & Radiological Technologists (ISRRT), World Health Organization (WHO), Conference of Radiation Control Program Directors, USA (CRCPD).
i. Should define specific aims;
ii. Needs to define the outreach scale. While global application is an ultimate goal, national or local integration systems may be the best initial target. However, there are potential trans-national geographic opportunities (e.g. EU initiatives). All of these will need to have standardized data and operations;
iii. Must be meaningful, considering consensus of stakeholders involved in radiation protection of patients;
iv. Should define methods of monitoring, evaluation and process improvement as part of impact assessment;
v. Must be harmonious with existing, as well as adaptable to, evolving technical, regulatory and practice standards. In particular, programmes must have a formally defined data model fully describing the data elements and meta-data that need to be communicated, and these data elements must be mapped to existing standards and terminologies for the purpose of interoperability. Any kind of indicator or data aggregation must have fully specified algorithms and functions;
vi. Must include public awareness and education of relevant professional groups about the tracking programme.

6. Challenges in implementation of a patient exposure tracking programme include the need for refinements based on:
   a. Health systems structure and health services organization;
   b. Available resources (e.g. personnel, economic and political considerations, and evolution in technology and clinical healthcare);
   c. Relevant population, e.g. children;
   d. Clinical setting;
   e. Dose and risk assessment;
   f. Ownership and purpose of dose interpretation such as: audit, quality assurance, diagnostic reference levels, point-of-care patient management, communication of information including patient privacy.

Summary
Radiation protection of patients includes accountability for radiation exposure from multiple medical imaging procedures. While there are challenges, it has become increasingly necessary for the organizations and professional communities to embrace a patient radiation exposure tracking programme for many reasons, in particular patient safety and welfare.

Annex: Potential Benefits from Patient Radiation Exposure Tracking

I. Benefits to patients
   a. Receive only the necessary radiation exposure for optimal care
   b. Knowledge that there is accountability/responsibility in the delivery of medical radiation
   c. Facilitate dialog with healthcare providers regarding radiation exposure
   d. Improve patient confidence in healthcare providers’ care

II. Benefits to healthcare providers referring patients for imaging/intervention
   a. Improved justification including decision support
   b. Control resources/costs from unneeded duplicate tests
   c. Minimize unnecessary radiation to patient by tracking cumulative exposure
   d. Assist in choosing among imaging/intervention providers and facilities
   e. Assist in choosing between modalities and techniques
   f. Facilitate dialogue with patients regarding radiation exposure
   g. Improve patient confidence in healthcare providers’ care

III. Benefits to healthcare providers involved in performance of imaging/intervention
   a. Improved justification including decision support
   b. Control resources/costs from unneeded duplicate tests
   c. Minimize unnecessary radiation to patient by tracking cumulative exposure
   d. Assist in protocol optimization
   e. Establishment and continuous review of diagnostic reference levels
   f. Provide dosimetry feedback mechanism for healthcare provider quality improvement
   g. Facilitate dialogue with patients regarding radiation exposure
   h. Improve patient confidence in healthcare providers’ care

IV. Benefits to policymakers
   a. Improved quantitative tools to protect public health and safety
   b. Improved quantitative approaches to radiation safety policymaking
   c. Control resources/costs from unneeded duplicate tests

V. Benefits to regulators
   a. Establishment and continuous review of diagnostic reference levels
   b. Provide data-rich regulatory environment enabling assessment of practice patterns beyond a single diagnostic reference level
   c. Ability to quantitatively audit individual providers, practices and facilities

VI. Benefits to researchers
   a. Provide extensive and robust radiation safety data sets to address research questions
   b. Incorporate patient-specific radiation metrics into research studies, including observational, epidemiological, comparative effectiveness, outcomes, and randomized control
   c. Provide quantitative basis for development of best practices
   d. Incorporate radiation metrics into appropriateness criteria

VII. Benefits to industry
   a. Facilitate partnership with other stakeholders in establishing patient radiation exposure tracking programmes