A New System for Recording the Radiological Effective Doses from Imaging Investigations

Lidia Dobrescu

A New System for Recording the Radiological Effective Doses from Imaging Investigations

Lidia Dobrescu
Romania, Bucharest, 27 Dr. N. Tomescu, 050595
lidia.dobrescu@electronica.pub.ro

Keywords: radiation safety, radiological smart card, radiological reports.

Abstract. The Romanian project of an integrated system for radiation safety of the patients investigated by radiological imaging methods is presented in this paper. The new system is based on smart cards and Public Key Infrastructure. The new system allows radiation effective dose data storage and a more accurate reporting system.

I. Introduction

In accordance with European Directive 97/43 EURATOM implemented in national regulations, all the ionizing radiation exposures during medical investigations must be carefully recorded and reported.

The International Commission on Radiological Protection (ICRP) recommends that the public limit of artificial irradiation should not exceed an average of 1 mSv effective dose per year, not including medical and occupational exposures. ICRP limits for occupational workers are 20 mSv per year, averaged over defined periods of five years, with the further provision that the dose should not exceed 50 mSv in any single year [1].

In order to record different types of investigations and their individual radiation absorbed dose, worldwide current medical practice uses paper forms, files and folders. The patients often sign a formal agreement. Modern radiological apparatus for computerized topographies or scintigraphies can provide the radiation doses during a particular investigation, but the recorded doses' types and the radiation measurement units in different types of investigations are not the same.

The reporting system is not accurate because the individual doses recorded by patients are not cumulated. Modern equipment of radiological investigations is continuously reducing the total dose of radiation due to improved film screen systems or improved technologies and so there is a substantially decrease in per caput dose, but the increasing number of investigations has determined a net increase of the annual collective dose.

A secure integrated system is designed in this new project. The new system is designed on smart cards technology. Integration of PKI infrastructures supplies a high level of security for the whole system including access to databases through various applications and it also ensures the confidentiality of citizens' personal data stored on cards and in a central data base.

II. Radiation Doses

The radiographies, CT-s and generally Xrays investigations can save lifes but their high level radiation doses can affect people health. More and more patients are investigated by radiographies and CTs and these kind of investigations using radiological methods strongly increases the cumulative radiation dose received by patients.Chest/Torax, Cervical, Thoracic and Lumbar Spine Radiographies and CT for head, neck, chest, spine and abdomen are common investigations performed in many countries

The Sievert (Sv) is the International System of Units (SI) derived unit of radiation dose. Confusion can be caused as there is commonly used one more radiation unit, the Gray. This last one is used for describing the absorbed dose in any material, while the Sievert is used with effective absorbed dose in biological tissue. In order to convert the equivalent dose provided by the radiation source from the medical investigation apparatus, the absorbed dose measured in mGy must be multiplied by a tissue factor which is usually below unit, shown in table I [2]. It can be easily noticed that for a head investigations, the bone tissue factor is ten times lower than for an abdomen investigation, so, even the radiation dose is higher; usually the biological effect is reduced.

TABLE 1. Tissue Weightning Factors [2]

Organ	Tissue weighting factor
Gonads	0.20
Colon, Bone marrow (red), Lung, Stomach	0.12
Bladder. Chest, Liver, Thyroid gland. Oesophagus	0.05
Skin, Bone surface	0.01
Adrenals, brain, small intestine, kidney, muscle, pancreas, spleen, thymus, uterus	0.05

A particular situation was determined by CT-s recorded radiation doses. The radiation dose provided by modern electronic equipments is expressed in two related measurement systems: CTDI (CT dose index) and in DLP (dose length product). The CTDI represents the radiation dose of a single CT slice and is determined using acrylic phantoms. The dose length product (DLP) is the CTDIvol multiplied by the scan length (slice thickness × number of slices) in centimeters.

DLP was chosen as the major input data for the system in CTs investigations but the reported data must reach the biological effective dose. Conversion factors can be used. However, these conversion factors are problematic in that they are only estimators of doses and do not represent the full range of pediatric sizes [3]. The conversion factors can slightly vary from different manufacturers [4]. Common CT doses are shown in Table II [5], [6].

TABLE II Radiation Doses received from CT Investigations

CT examinations	Effective dose (mSv)	Equivalent number of PA chest radiographies
Head	2	100
Neck	3	150
Calcium scoring	3	150
Pulmonary angiography	5.2	260
Spine	6	300
Chest	8	400
Coronary angiography	8.7	435
Abdomen	10	500
Pelvis	10	500
Virtual colonoscopy	10	500
Chest(pulmonary embolism)	15	750

For classic radiological investigation, an important topic for data management is the measurement and the calculation of radiation dose expressed in DAP. Dose area product (DAP) is used to measure the radiation risk from diagnostic x-ray examinations). It is defined as the absorbed dose multiplied by the area irradiated. It is expressed in (Gy*cm^2). DAP reflects not only the dose within the radiation field but also the area of tissue irradiated. It also has the advantage of being easily measured, with a DAP meter on the X-ray set. A DAP calculus example is shown in figure 1.

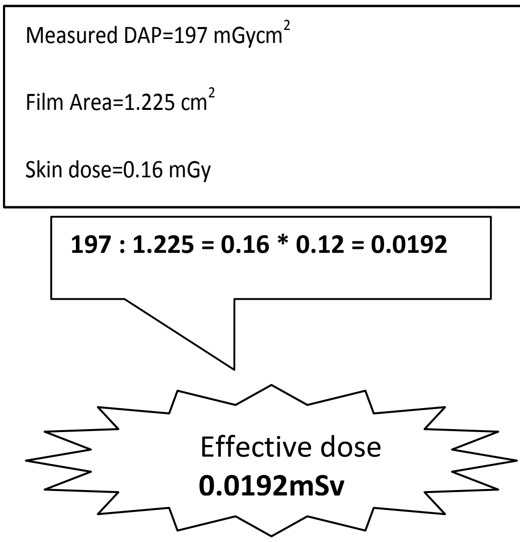

Fig.1 Effective dose calculus

Generally speaking ionizing radiation can be harmful and even lethal for humans. In Table III typically effects are shown [7]. Exposure to ionizing radiation increases the future incidence of cancer, but quantitative models predicting the level of risk are still not worldwide accepted. Induced cancer can be analyzed as a stochastic effect because its probability of occurrence increases with the dose, while the severity is independent of dose, but a threshold dose can be established as in deterministic effects.

TABLE III Threshold Radiation Doses

Indicative dose range (mSV)	Effects on human body
Up to 10	No direct evidence on human health effects
10-1000	No early effects; increased incidence of certain cancers in exposed populations at higher doses
1000-10,000	Radiation sickness (risk of death); increased incidence of certain cancers in exposed populations
Above 10,000	Always fatal

III. Current Medical Practice

During a study in the Central Military Emergency Universitary Hospital Dr. Carol Davila from Bucharest, Romania the patients were monitored for three months. A central data base from this hospital stored patients individual records.

Although the hospital's new modern equipment of radiological investigations can provide track information, it is impossible to cumulate all the doses received by a patient

One reason is that many hospitals do not have computerized radiological apparatus. Another reason is that the patients do not have a unique paper form to record all their investigations when they enter in a hospital. Finally, it is not such a difficult practice to repeat a certain investigation in another hospital. The pilot study from Bucharest has revealed many cases of over passing the maximum cumulative dose only during one single hospitalization. The conclusions are shown in figure 2

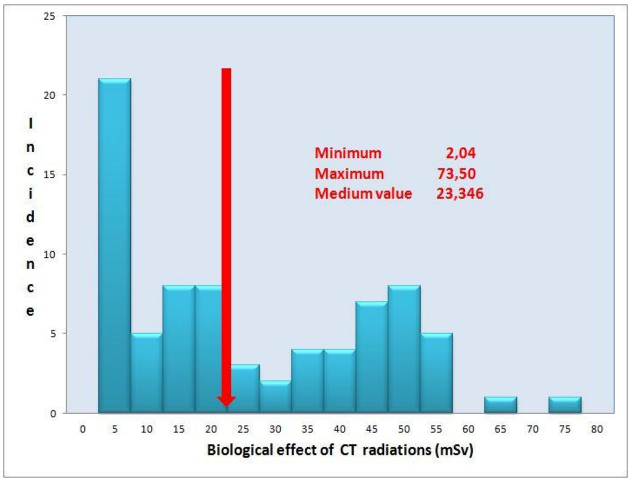

Fig. 2 Cumulative radiation dose in CT

IV. Integrated System Requirements and Implementation

The system provides the replication of the information stored in central databases, local databases and patient cards to cover all the following possible situations:

- The patient goes to the doctor without the patient card. In this case, the system provides the data corresponding to the patient based on the local database, if the patient has been investigated in that hospital unit; if the patient is new, the system will provide the data from the central database to the local database, so as to take the optimal decision in recommending the type of investigation. After the investigation, the system will store the new local database accumulated radiation dose to the patient, the information arriving in the central database. Later, when the patient goes to the doctor for further investigations with the card, the system will ensure synchronization between the information stored on the card and information stored in the local and central database.
- The patient goes to the doctor with no card and the hospital unit's information system does not have access to the central database (ex: for mobile laboratories). If the local database contains the information corresponding to the patient, the doctor will be able to use them for recommending a particular type of investigation. After the investigation, the system will store in the local database the new radiation doses accumulated by the patient. Later, when the local system can access the central system, the information corresponding to the patient will be synchronized between the two databases.
- The patient presents the card to the doctor but the doctor does not have access to any database (local or central). In this case the doctor, using a computer with a card reader can access the history of investigations and the doses received by the patient, as the current cumulative dose calculated and can recommend the most appropriate investigation. After investigation, the appropriate dose will be recorded on the patient's card and next time when the patient goes to the doctor with the card, this information will be stored in both in the local and the central database.

In addition, the system provides applications for:

- Viewing in real time the history of investigations, of the doses delivered to the patient and of the current cumulative calculated dose expressed in mSv.

▪ Aiding the medical staff in taking the adequate decisions regarding the indication of investigations according to the current calculated cumulative doses and the maximum doses allowed for the risk and age groups.

▪ Performing of various periodic reports in order to take different types of decisions related with the existing radioprotection regulations.

The proposed system includes the following modules:

a) Applications running on smart cards, called on card applications.

b) Off-card applications that are running on medical stations. They include smart card readers and writers in order to record and retrieve the information about the type of investigations and the specific emitted doses

c) A data base records all the necessary information in order to replicate a lost or destroyed card but also this database will provide the possibility of collecting data about the patients on several criteria, it will provide the possibility of standard or customized reports' creation.

d) The security solutions such as public key infrastructure PKI in order to achieve a high level of security of recording and retrieving data. A public-key infrastructure (PKI) is a set of hardware, software, people, policies, and procedures needed to create, manage, distribute, use, store, and revoke digital certificates. A PKI establishes and maintains a trustworthy networking environment by providing key and certificate management services that enable encryption and digital signature capabilities across applications — all in a manner that is transparent and easy to use. Digital certificates are electronic credentials that are used to assert the online identities of individuals, computers and other entities on a network. They are issued by certification authorities (CAs) that must validate the identity of the certificate-holder both before the certificate is issued and when the certificate is used.

The entire system is designed around the two types of cards: the patients' cards and the medical cards and it ensure many requirements:

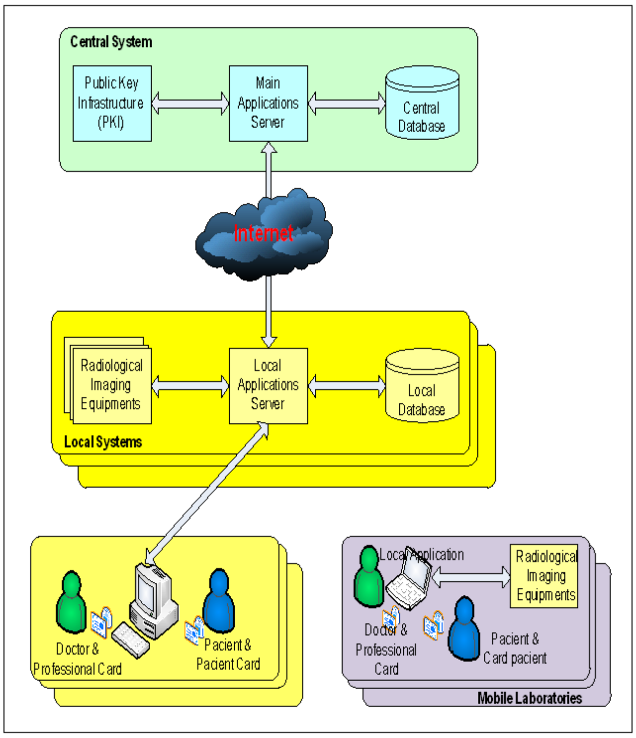

Fig. 3 The architecture of the integrated system

- The application ensures a secured authentication of doctors and patients using digital certificates and cryptographic hardware.

- The whole logic application is stored in the central server. The clients use the minimum functional software.
- The applications users have access through a web browser.
- The system uses cryptographic libraries FIPS 140-2 sau CC EAL4.(RYCOMBE, 2013).
- The keys are RSA 1024 bits minimum length.
- The cryptographic hardware must support PKCS#11, PKCS#15 and Microsoft Crypto API.(CRYPTSOFT, 2013).
- The cryptographic hardware must ensure the recovery of the cryptographic context.
- The certification system ensures roll –over facilities.
- The PKI system has an own relational database storing all the emitted certificates.

Two different data flows will be implemented:

- Electronic cards flow management that includes: smart cards issuance, their renewal in case of loss, damage or theft.
- Operational cards flow management including: patients and doctors authentication using unique PINs.

The system's general architecture is described in figure 3.

The project consortium has developed a system that integrates all activities with risks of radiations in case of radiological imaging methods. The smart cards allow authentication, digital signature and secure data storage.

The whole system is designed on two types of radiation safety cards:

- Citizen Radiation Safety Card – CRSC
- Professional Radiation Safety Card – PRSC – for medical and investigation laboratories personnel.

Acknowledgement

The results were obtained from the SRSPIRIM project in Romanian Partnerships Program, Collaborative Applied Research Projects Subprogram. University "Politehnica" of Bucharest, the Central Military Emergency Universitary Hospital "Dr. Carol Davila" of Bucharest and CERTSIGN S.A., UTI Group member, are developing this project. Special thanks to all the persons involved in this project for their support, work and ideas.

References

[1] ICRP, "2007.Radiological Protection in Medicine", ICRP Publication 105 Ann.ICRP37 (6).

[2] http:// www.euronuclear.org /info/ encyclopedia /t / tissue-weight-factor.htm.

[3] http://www.medscape.com/viewarticle/572551_2

[4] http://sascrad.de/data/ documents/ Chapter_3 from Tack and Genevois. pdf

[5] Wall, B.F., Hart, D., "Revised radiation doses for typical x-ray examinations", Br. J Radiol. 70 833 (1997) pp. 437 - 439.

[6] Einstein, A.J., Sanz, J., Dellegrottaglie, Milite, M., Sirol, M., Henzlova, M., Rajagopalan, S., "Radiation dose and cancer risk estimates in 16-slice computed tomography coronary angiography", J. Nucl. Cardiol. 15 2 (2008), pp. 232-240.

[7] http://www.unscear.org/unscear/en/faq.html?print