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

Lidia Dobrescu
“Politehnica” University of Bucharest, Romania
lidia.dobrescu@electronica.pub.ro

IEEE/ICAIT 2014

7th IEEE/International Conference on Advanced Infocomm Technology
November 14-16, 2014
Fujian Normal University, China

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Abstract

The Romanian project of an integrated system for radiation safety of the patients investigated by radiological imaging methods is presented here. 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.

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Outline

1. Introduction
2. Radiation Background Study
3. Radiological Investigations
4. Integrated System Requirements, Solution and Implementation
5. Application
6. Conclusions

Introduction

- The continuously increasing number of medical investigations using radiological methods imposes the necessity of recording the radiation effective doses for the patients.
- The patients travel from one hospital to another, all over the country or all over the world.
- The total volume of prescribed medical investigations, starting from minor dental radiographies and ending at major CT scans prove a serious lack in monitoring and tracking of the cumulative radiation doses in many health services all over the country and their received radiation doses are quit impossible to be cumulated.

European and National Radiation Protection Legislation

- 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 50mSv in any single year.
- All the measures adopted in the European and national directives are concerned not only with avoiding unnecessary or excessive exposure to radiation but also with improving the quality and effectiveness of medical uses of radiation.
- All exposures to X-rays are considered risky, so the prescription of a radioactive medical investigation implies an important responsibility to ensure appropriate protection.

Radiation Doses Measurement Units

There are many different units for radiation, used on a large scale:

- Becquerel (Bq) and Curie (Ci) used for radioactivity released by a material source.
- Coulomb/Kilogram (C/Kg) and Roentgen (R) used for monitoring the total amount of radiation traveling generally through the air.
- The Gray (Gy) as the most important and the Rad (rad) - used with quantities of absorbed dose.
- Roentgen equivalent man (Rem) and Sievert (Sv) used for the biological effects of the absorbed radiation .
- The Sievert (Sv) as derived unit of radiation dose in the International System of Units (SI), was chosen as the central unit in the project.

Background Radiation

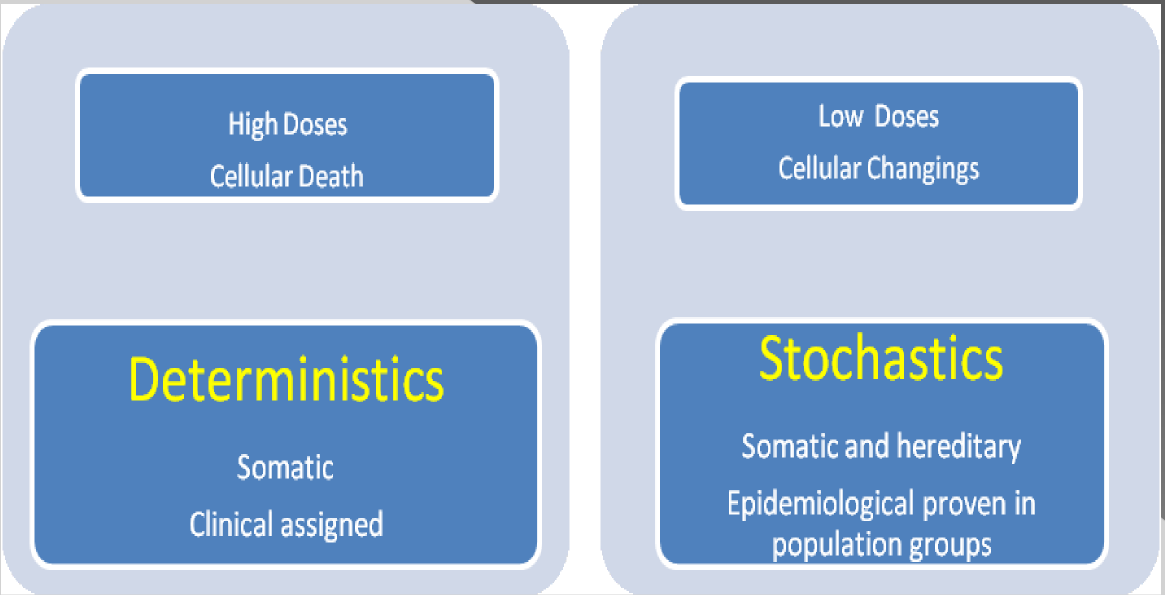
Radiation is a natural phenomenon in the human environment but it remains invisible for us. Natural radioactive substances in the air, water, earth, food are called background radiation.

Source of radiation	Radiation dose (mSV)
10 hours airplane flight	0.03
Chest X-ray	0.05
CT scan	10
Annual natural background	2.4

Threshold Radiation Doses

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.



Threshold Radiation Doses

A threshold dose can be established as in deterministic effects.

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

Models for Risk versus Dose

- The most popular linear no-threshold LNT model assumes proportionality between dose and cancer risk with a linear dependence from 1 mGy to 100 Gy . This model can be suitable for small-dose exposures and it is still divisive. The threshold model assumes that very small exposures are harmless.
- Another radiation model, Hormesis explains that very small doses of radiation can be beneficial. The adaptive responses of the human cells were observed at low doses and disappear with higher doses .
- A protective mechanism at the cell and tissue levels has been described in many experiments. It operates against cancer developing mechanisms. A dose of 10 mGy reduces the rate of spontaneous transformation in culture cells below the background level. Epidemiologic studies suggest that Hormesis also exists in human cells.

Risk Factor versus Age

More refinements can be used in order to consider attributable lifetime risk. The multiplicative risk projection model can be different for males and females, always relatively higher for females.

Age Group (years)	*Multiplication factor for risk*
<10	x 3
10-20	x 2
20-30	x 1.5
30-50	x 0.5
50-80	x 0.3
80+	Negligible risk

Human Cells Sensitivity to Radiation

Radio sensitive	*Radio resistant*
Breast tissue	Heart tissue
Bone marrow cells	Large arteries
Mucosa lining of small intestines	Large veins
Sebaceous (fat) glands of skin	Mature blood cells
Immune response cells	Neurons
All stem cell populations	Muscle cells
Lymphocytes	

Radiological Investigations

The measurement and the calculation of radiation dose uses Dose area product (DAP) and tissue factors.

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

Radiological Investigations

The radiation dose is expressed in DAP: dose area product is used to measure the radiation risk from diagnostic x-ray examinations.

DAP, usually expressed in $mGy \cdot cm^2$ can be measured with DAP meters.

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Effective Dose Calculus

Measured DAP=197 $mGycm^2$

Film Area=1.225 cm^2

Skin dose=0.16 mGy

197 : 1.225 = 0.16 * 0.12 = 0.0192

Effective dose

0.0192mSv

Computed Tomography 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).

DLP, measured in mGy*cm, was chosen as the major input data for the system.

ED/DLP coefficients have been used for converting DLP values in effective doses in mSv.

They are currently provided by the manufacturer of the CT scanner.

Computed Tomography DLP

On the CT scanner console CTDIvol is mandatory displayed.
The total amount of radiation delivered to the patient at a given examination, however, is dependent on the CT scan length. The product of CTDIvol and scan length form the DLP, which can be used to quantify the total amount of radiation dose that patients receive during a given scan.
The DLP is measured in mGy*cm.

A calculus example is:
For an abdomen CT investigation where the cross-section is above 21.56 cm, the CTDIvol =30 mGy and the DLP =646.8 mGy*cm.

Computed Tomography ED/DLP Coefficients

Siemens Conversion Factors

Conversion factor from DLP to Effective Dose in [mSv/(mGy·cm)]					
Region of the Body	0-year-old	1-year-old	5-year-old	10-year-old	Adult
Head and neck	0.013	0.0085	0.0057	0.0042	0.0031
Head	0.011	0.0067	0.0040	0.0032	0.0021
Neck	0.017	0.012	0.011	0.0079	0.0059
Chest	0.039	0.026	0.018	0.013	0.014
Abdomen and pelvis	0.049	0.030	0.020	0.015	0.015
Trunk	0.044	0.028	0.019	0.014	0.015

Typical CT Radiation Doses

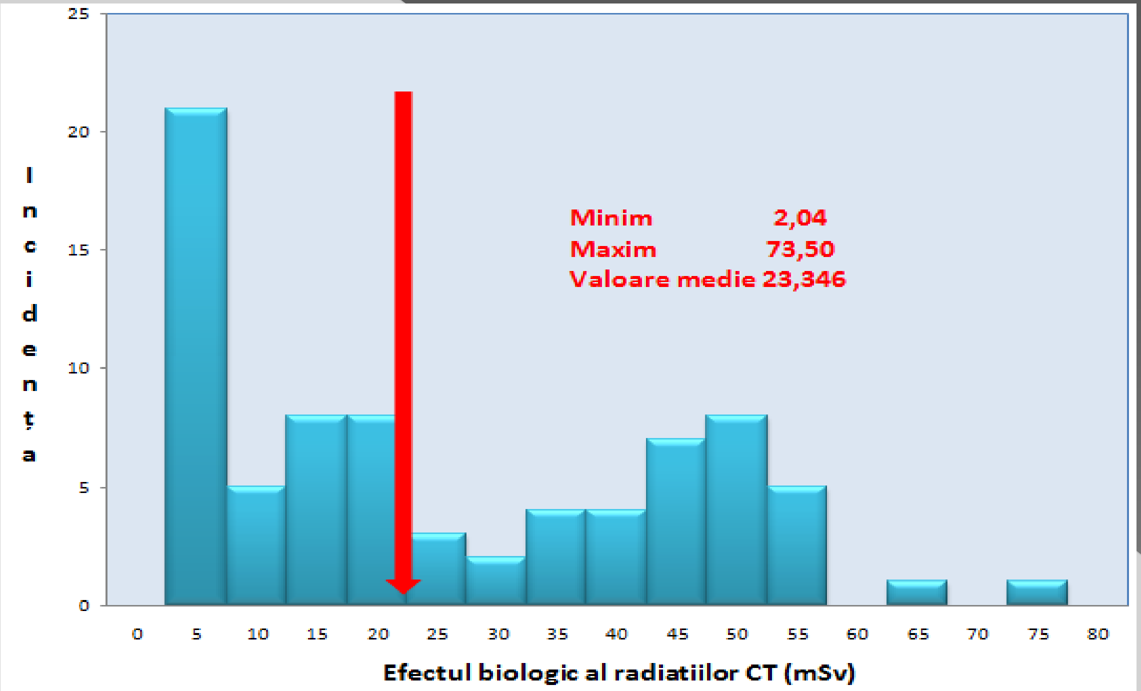
Based on the assumption of an average "effective dose" from chest x ray, the normal effective doses from CT investigation are shown in the table:

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

Current Medical Practice

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.

The pilot study from Bucharest has revealed many cases of over passing the maximum cumulative dose only during one single hospitalization.



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Integrated System Requirements

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

1. The patient goes to the doctor without the patient card.
2. 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).
3. The patient presents the card to the doctor but the doctor does not have access to any database (local or central).

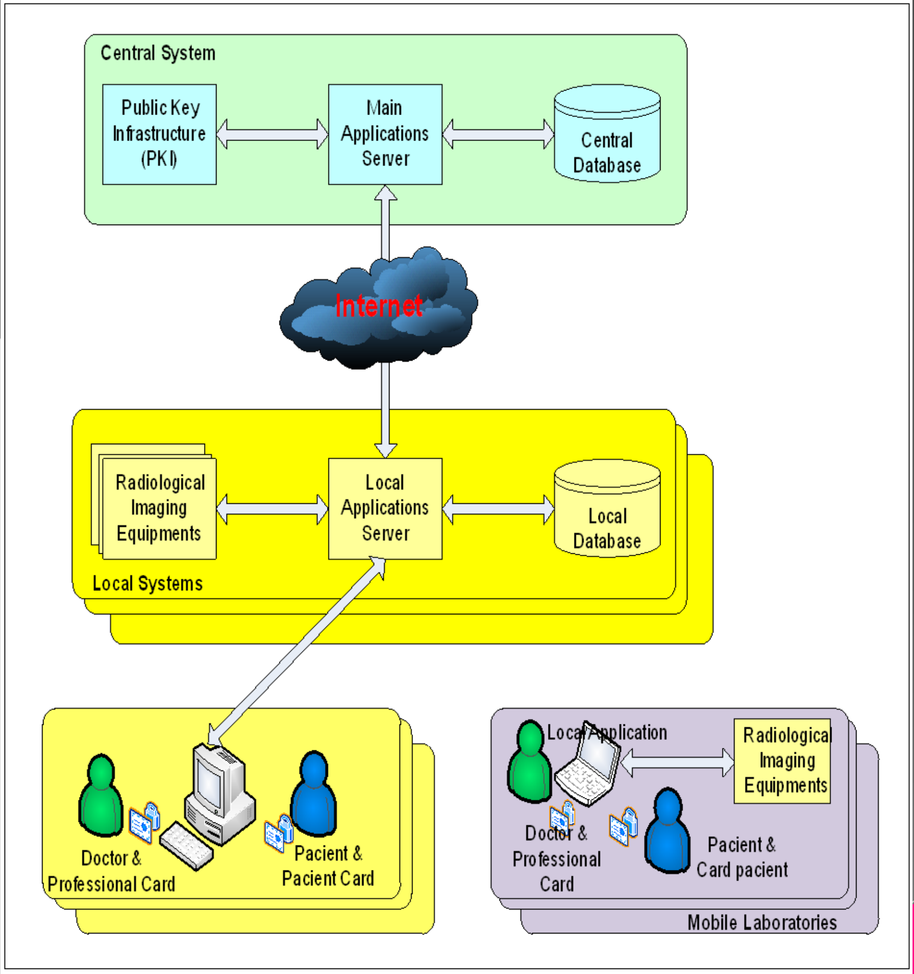
In addition, the system provides applications for:

1. Viewing in real time the history of investigations,
2. Aiding in taking the adequate decisions regarding the indication of investigations according to the current calculated cumulative doses and the maximum doses
3. Performing of various periodic

Integrated System Solution

The proposed system includes the following modules:

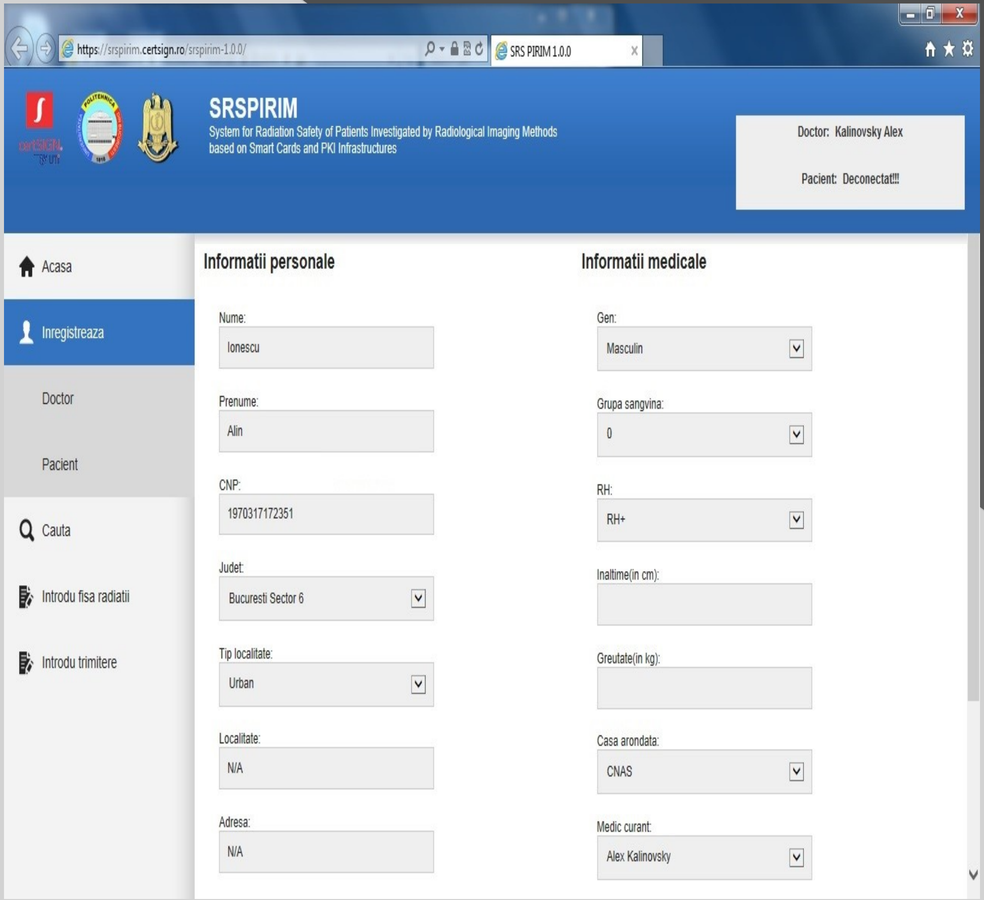
- ➢ Applications running on smart cards, called on card applications.
- ➢ Off-card applications that are running on medical stations.
- ➢ A data base that records all the necessary information.
- ➢ The security solutions such as public key infrastructure PKI in order to achieve a high level of security of recording and retrieving data



Integrated System Implementation

1. 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.
2. The applications users have access through a web browser. The system uses cryptographic libraries FIPS 140-2 sau CC EAL4.(RYCOMBE, 2013).
3. The keys are RSA 1024 bits minimum length.
4. The cryptographic hardware must support PKCS#11, PKCS#15 and Microsoft Crypto API.(CRYPTSOFT, 2013).
5. The cryptographic hardware must ensure the recovery of the cryptographic context.The certification system ensures roll –over facilities.
6. The PKI system has an own relational database storing all the emitted certificates.
7. 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.

Application



Conclusions 1

- Radiation effects can be deterministic or stochastic, prompt or delayed, somatic or genetic.
- Exposure to ionizing radiation increases the future incidence of cancer.
- The current medical practice uses paper forms for recording the type of investigations and the radiation absorbed dose.
- Modern equipment of radiological investigations is continuously reducing the total dose of radiation due to improved technologies, but the increasing number of investigations has determined a net increased annual collective dose.
- Despite the high volume of imaging investigations with radiation risk, a major lack in monitoring and track the cumulative radiation doses of the patients has become a serious problem that can be solved by a new electronic integrated system.

Conclusions 2

- The new system, designed on smart cards technology and PKI infrastructure, covers a major need of the health–care system.
- The pilot study from Bucharest has revealed many cases of over passing the maximum cumulative dose only during one single hospitalization.
- The Sievert (Sv) is the central unit of radiation dose implemented in the project.
- Compared to classical radiography, CT is a high-dose imaging method. Cumulating the total effective dose for each patient provides a more accurate method to generate reports.

ACKNOWLEDGMENT

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

Thank you for your attention !

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