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Radiation Safety Integrated System for Patients Investigated by Radiological Imaging Methods

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Abstract- **In this paper we present the project of an integrated system for radiation safety and security of the patients investigated by radiological imaging methods such as radiographies, computed tomographies or scintigraphies. The system is based on smart cards and Public Key Infrastructure. The implementation of system's architecture has three distinct levels of storage: a central database, many local databases and Citizen Radiation Safety Cards. The smart cards allow authentication, digital signature and secure data storage.**

Keywords: **radiation safety, smart card, integrated system.**

I. INTRODUCTION

The current practice for recording the radiation doses for patients investigated by radiological imaging methods does not allow, or complicates, the aggregation of data in order to determine if the maximum allowed cumulative dose has been reached. So, a secure integrated system is needed. The new system, designed on smart cards technology covers one major need of the health-care system. Such a radiation safety system can provide a couple of secure services like electronic record of patient's radiological investigations, assistance in prescription of future radiological investigations based on patient's history and different reports and statistics. The smart cards allow authentication, digital signature and secure data storage.

The system implements the following application classes:

- secure storage radiation doses received during imaging explorations, that are considered personal data and are treated as confidential citizens' information;
- radiation doses management concerning the radiation safety of the citizens;
- logical security: authentication, digital signature, confidentiality.

Integration of PKI infrastructures is intended to supply a high level of security for the whole system including access to databases through various applications and also to ensure the confidentiality of citizens' personal data stored on cards and in a central data base.

II. RADIATION DOSES

A third of the Computed Tomographies performed in United States seems to be useless regarding the new medical information. A recent study [1] reveals by generalization that 4 million Americans are exposed to a cumulative effective dose of radiation that exceed the maximum allowed dose and 28% of them by Computed Tomography (CT) exposure to radiation [2].

In Romania, statistics show that three million people are investigated by radiographies and CTs and the investigations by radiological methods strongly increase the cumulative radiation dose of the patients. So, despite the great concern of radiation exposure, the doctors are not very careful when they prescribe such imaging investigations. The radiographies, mammographies, CT-s and other Xrays investigations can save our life but their high level radiation doses can affect our health. Despite the skyrocketing volume of imaging investigations with radiation risk there is a major lack in monitoring and track the cumulative radiation doses of the patients that are usually treated and evaluated in many health services all over the country.

Cosmic rays, alpha, beta, gamma and X-rays are well known ionizing radiation. Generally, any charged particle moving at relativistic speed is considered ionizing radiation. Neutrons form a particular case because they are ionizing radiation at any speed. Radio waves, microwaves, infrared light and visible light are normally considered non-ionizing radiation, although very high intensity beams of these radiations have similar properties to ionizing radiation.

The Sievert (Sv) is the International System of Units (SI) derived unit of radiation dose. Confusion can be caused as there are two more different radiation units: Gray and J/Kg. The Gray is used with quantities of absorbed dose in any material, while the Sievert is used with equivalent, effective and committed dose in biological tissue. An older unit for the equivalent dose, still used in the United States, is the Rem. One Sievert equals 100 Rem. The Rad is a deprecated unit of absorbed radiation dose, defined as one centiGray.

The International Commission on Radiological Protection (ICRP) recommends that the public limit of artificial irradiation should not exceed an average of 1 mSv efective 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 [3].

Typically doses from natural or artificial radiation sources are shown in table I [4].

TABLE I
DOSES RECEIVED FROM NATURAL AND ARTIFICIAL SOURCES

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

Radiation is a natural phenomenon in our environment. There are forms of invisible radiation from space and natural radioactive substances in the earth, in the air, in the water, in our food, all known as natural background radiation.

Prescribing radiological imaging investigation methods such as computed tomography must be a serious decision. Common CT doses are shown in Table II [5], [6], [7], [8].

Generally speaking ionizing radiation can be harmful and even lethal for humans. In Table III typically effects are shown.

Sometimes ionizing radiation can have health benefits such as radiation therapy used in cancer's treatment. Overall, it is known that 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.

Passing different materials, the radiation may damage their structure. In biological materials such as human cells and tissues sometimes the damage can occur to critical elements such as the DNA molecules which store the repair mechanisms. Usually they succeed to repair the damage or if they don't, the cells are sacrificed. It is also possible that the DNA may be misrepaired and such mutated cells will also die. There is a small possibility that the cell survives and the mutation in the DNA is replicated as the cell divides. This can be the start of a multi-step process that could eventually lead to formation of a cancer [9].

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

TABLE III
THRESHOLD RADIATION DOSES FOR HUMAN BODY

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

In our country, the current medical practice uses paper forms for recording different types of investigations and their individual radiation absorbed dose. The women are particularly questioned about a possible pregnancy every time. The patients often sign a formal agreement.

Modern radiological apparatus for Computerized Tomographies or scintigraphies can provide the total radiation doses during a particular investigation.

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 stores 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 from the same country or from abroad do not have computerized radiological apparatus that can provide the radiation dose. 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.

Generally, modern equipment of radiological investigations is continuously reducing the total dose of radiation due to improved films, 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 an increased annual collective dose.

The performed pilot survey in the Central Military Emergency Universitary Hospital Dr. Carol Davila from Bucharest, has revealed many cases of over passing the maximum cumulative dose only during one single hospitalization. These cases have been investigated by computerized tomography and scintigraphy and no by classical radiological methods. For a computed tomography the radiation dose can be ten times greater than for a chest radiography. Chest X ray is considered as the standard reference in comparing radiation doses and it brings 0.02 mSv. The usage of two-dimensional images of the distribution of radioactivity in tissues after the internal administration of a radiopharmaceutical imaging agent increases the cumulative dose. The conclusions are shown in Fig. 1 and in Fig. 2.

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 doctor with 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 provides 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 stores 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 ensures 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 stores 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 is 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 is recorded on the patient's card.

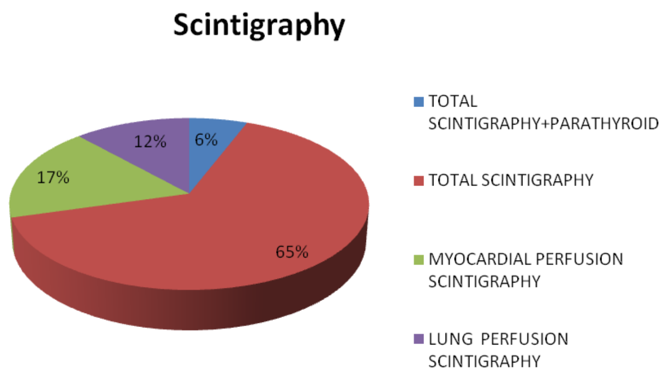

Fig. 1. Performed types of scintigraphies and their incidence.

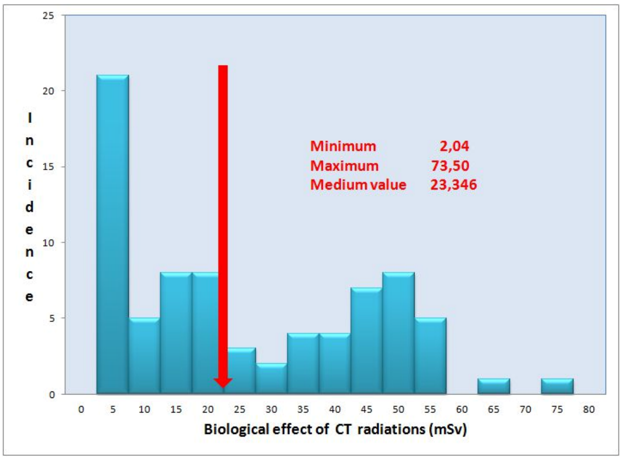

Fig. 2. Cumulative radiation doses received by patients in Computerized Tomographies.

Next time when the patient goes to the doctor with the card, this information will be stored in both in the local and in 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 components:

- Smart cards dedicated to patients: Citizen Radiation Safety Card – CRSC
- Professional Radiation Safety Card – PRSC – intended to medical and investigation laboratories personnel
- Smart card readers and writers in order to record and retrieve the information about the type of investigations and the specific emitted doses
- A data base that records all the necessary information in order to replicate a lost or destroyed card but also this database provides the possibility of collecting data about the patients on several criteria, it provides the possibility of standard or customized reports' creation
- 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.

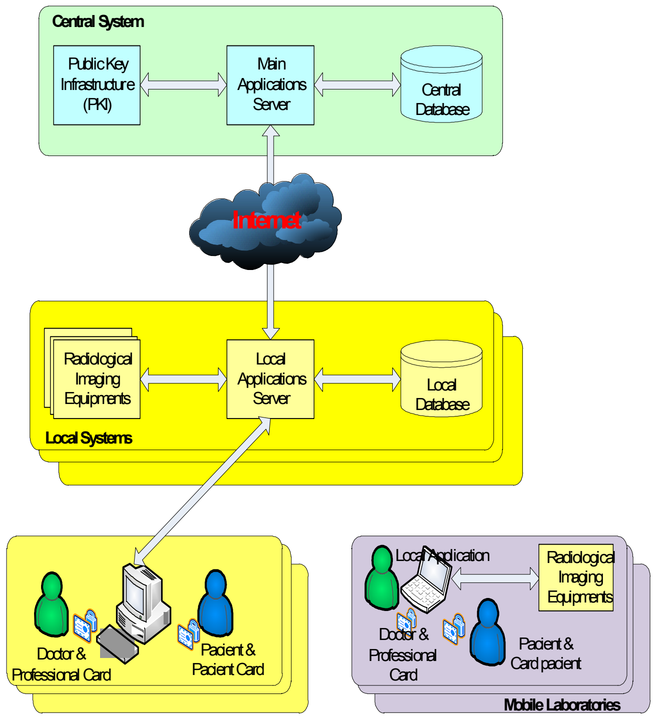

Fig. 3. The architecture of the integrated system.

The system's general architecture, shown in Fig. 3, is the conceptual model that defines the structure, behavior, and more views of the system and it has the main components:

- Public Key infrastructure used for electronic smartcards operation;
- The center for personalizing cards where the cards are created;
- The system for the management of the digitized certificates E-HEALTH CMS;
- The servers for the local databases and the central database.
- Applications and web services for the interface with the integrated system, electronic cards and medical equipements;
- On card Applications called JavaCard applets.

In this project a single public key infrastructure is implemented, as shown in Fig. 4, with two distinct units: an administration unit called ADMIN SUB-ROOT and an operational unit called OPER SUB-ROOT.

ROOT CA, is the certification authority of the PKI.

ROOT CA has a pair of RSA keys. The RSA is an algorithm for public-key cryptography. The keys are 2048 bits length, and the certificate is a self signed one. This certificate is used in order to sign the three subordinate units.

ADMIN SUB-ROOT simulates the certification authority. It also uses RSA keys on 2048 bits.

OPER SUB-ROOT simulates the certifying authority, the root of the operational unit.

The project consortium proposes itself to develop a system based on smart that integrates all activities with risks of

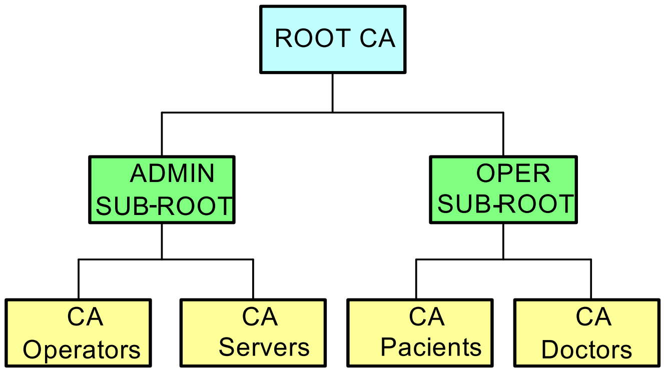

Fig. 4. The single key infrastructure with two units.

radiations, not only the patients investigated by 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 – dedicated to patients;
- Professional Radiation Safety Card – PRSC – intended to medical and investigation laboratories personnel.

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