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Perspective Approaches to Classification of Radiation Accidents in Radiology on the Example of Computed Tomography

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Abstract. Radiation accidents in radiology are becoming more common in the recent years in the international practice. However, the data on the radiation accidents in the Russian Federation is limited, mostly due to lack of proper classification of different radiation and non-radiation emergency situations and significant consequences for the medical facilities reporting on a radiation accident. This study was aimed at introducing and adapting modern international approaches to handling radiation accidents and incidents into the Russian radiation protection practice in radiology based on the example of computed tomography. Proposed classification was verified via anonymous survey on a base of a multi-disciplinary medical research center.

INTRODUCTION

According to the existing Russian radiation protection regulations, radiation accident is a loss of control of an ionizing radiation source due to equipment malfunction, improper actions of workers (personnel), natural disasters or other reasons that could lead or led to the exposure of public and workers above the established standards or to radioactive contamination of the environment [1]. That definition cannot be fully applied to the medical exposure, since it is not possible to establish dose limits for patients and cases of overexposure of workers are seldom. In accordance with [2], the definition of the radiation accident includes loss of control of a radiation source, violation of the limits and/or conditions of normal operation of a radiation source, unauthorized access to radioactive source, radioactive substances and radioactive waste, loss and/or theft of the radioactive sources, radioactive substances and radioactive waste, or staff errors, as a result of which any of the following consequences occur: predicted doses to individuals from public exceed the dose limits established by radiation safety standards [3]; unplanned staff exposure exceed the dose limits established by the radiation safety standards. This definition does not consider the features of medical exposure and is not suitable for the regulation of medical radiation accidents as well.

However, the analysis of published data indicates that the number of radiation accidents in medicine has increased significantly in the recent years [4]. The structure of radiation accidents in 1980-2013 is presented in Table 1.

Radiation accidents in medicine in 2010-2013 compose more than 80% of all radiation accidents. Unfortunately, there are no reliable data on radiation accidents in medicine in the Russian Federation due to the lack of proper regulation and accident reporting.

TABLE 1. Trends and structure of radiation accidents in international practice [1].

Type of source of ionizing exposure	Time period			
	1980-1989	1990-1999	2000-2009	2010-2013
Industrial	91	49	22	7
Medical – radiation therapy	35	63	72	32
Medical – interventional examinations	16	98	55	25
Orphan sources	12	12	5	2
Military sources	2	2	-	-
Other	16	13	4	-

According to the data from the database of radiation accidents and incidents, established in Institute of Radiation Hygiene after P.V. Ramzaev (a subsystem of the automated radiation exposure monitoring system of Rospotrebnadzor (one of the regulatory bodies in the field of radiation protection)), in 2012-2019 only 34 radiation accidents in medicine were identified: 26 cases of detection of after radionuclide therapy patients with ambient dose equivalent rate exceeding the established criteria [3]; 4 cases of loss/theft of radiation sources (2 radionuclide, 2 generating); 2 cases of depressurization of the closed radionuclide source (breakage of vials with radiopharmaceutical) and 2 cases of patient overexposure due to technical malfunction of the radiation therapy unit (^{60}Co sources). That data is clearly underestimated and does not consider the whole variety of emergency situations (radiation accidents) in medicine.

It should be noted that according to the Russian radiation protection regulations, assignment of the event to the radiation accident entails serious consequences. In accordance with the decree of the Chief State Sanitary Doctor of the Russian Federation No. 11 "On the submission of extraordinary reports on emergency situations of a sanitary and epidemiological nature in the field of public health " and the order of Rospotrebnadzor No. 968 "On improving the response in the event of a radiation accident " for each radiation accident, it is necessary to present a report on the occurrence of an emergency situation to the territorial bodies on sanitary and epidemiological supervision within 2 hours after establishing the fact of an emergency, with a copy of the report sent to the Institute of Radiation Hygiene after prof. P.V. Ramzaev for registration in the database of radiation accidents and incidents. Based on the report, the regulatory bodies make management decisions, usually associated with an extraordinary inspection of the facility. These reports should be compiled for all types of radiation accidents (0-7 levels in accordance with the INES scale) [5].

Additionally, in the regulatory and methodological documents of Rospotrebnadzor, there is no classification of radiation accidents according to the degree of impact on staff / public / patients (incident, incident, etc.). The term "incident" was introduced in NP-014-16 [2] as a radiation accident, during which there was a loss of control of the source of ionizing radiation, which did not lead to overexposure of the public and staff above the established dose limits (which is not fully suitable for medical exposure, where, as a rule, patients are overexposed).

Hence, the aim of the current study was to develop a harmonized approach to the identification and reporting of the various types of radiation accidents in medicine on the example of the computed tomography examinations. The existing Russian and international approaches to the radiation accidents in medicine were analyzed, new classification of the radiation accidents and incidents was proposed and verified based on the survey conducted on the base of a multi-disciplinary federal diagnostic center.

MATERIALS AND METHODS

Computed tomography (CT) was selected for the study as X-ray examination with different possible emergency situations that can be attributed to radiation accidents / incidents and cases of unnecessary exposure of patients. In addition, the specificity of certain types of CT examinations (multiphase examinations with the use of contrast agents) determines the possibility of developing negative health consequences for patients not associated with X-ray exposure – for example, allergic reactions to the administration of a contrast agent.

The international practice [6-8], is commonly based on the concept of unintentional or accidental medical exposure, arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error. These situations include any diagnostic X-ray examinations performed for wrong patient or wrong anatomical region (tissue), exposing patient with a single dose or total dose, significantly different from the values predictively assessed by radiologist/medical physicist, or which may lead or led to unreasonable side-effects, as well as any equipment failures, accidents, errors, failures or other situations. At the same time, the main emphasis for the system of united and accidental medical exposure is not on informing the regulatory authorities, but on the development of an internal quality control system within a medical facility aimed at preventing emergencies. These approaches have not been implemented in Russian regulatory and methodological documents yet. All possible emergency situations were divided into radiation and non-radiation in accordance with paragraph 6.19 of SanPiN 2.6.1.1192-03 [9]. Radiation emergency situations were divided into accidents and incidents in accordance with Annex 2 of NP-014-16 [2]. Radiation accidents include only the situations that have led to exposure of personnel or the public in doses above the dose limits established by radiation safety standards; or exposure of patients exceeded the standard (typical) dose by more than a factor of 10 or led to the development of deterministic effects. Such situations include exposure of patients with a dose exceeding the corresponding standard (typical) dose for a selected CT examination (CT scan protocol) by more than a factor of 10; single exposure of patient with effective dose exceeding 200 mSv; development of deterministic effects in the patient (alopecia, erythema, etc.) after the CT scan; and inadvertent exposure of the embryo or fetus in doses exceeding 100 mGy. It is necessary to inform the territorial regulatory bodies about such situations and perform corresponding corrective measures with the involvement of external organizations.

Radiation incidents were divided into two categories depending on the cause of the patient overexposure: justified exposure in abnormally high doses and unjustified conduction of CT examinations. The first category includes such situations as performing a CT scan on the wrong anatomical area and / or with the wrong CT scan protocol; exposure of patients with a dose exceeding the corresponding standard (typical) dose for this CT examinations (CT scan protocol) by more than a factor of 3 but less than a factor of 10; unintentional irradiation of the embryo or fetus at a dose not exceeding 100 mGy. The second category includes performing a CT scan to the wrong patient; equipment malfunction that led to the inability to complete the CT scan; performing unjustified CT examination; and performing a CT scan on a faulty/non-calibrated CT unit, resulting in poor diagnostic quality of CT images. The first category of radiation incidents most closely matches the category “accidental exposure”; the second - “unintended exposure” [6-8]. All numerical criteria for classifying an emergency situation as radiation accident / incident were adapted from [10]. All radiation incidents should be registered within the medical organization, with the corresponding corrective measures applied, but no mandatory notification of regulatory bodies is required.

Non-radiation accidents were divided on the degree of potential harm (consequences for health) of the patient. The first category includes situations with the heavy consequences for the health of the patient (anaphylactic shock after administration of the contrast agents, patient trauma or death due to fire or electric shock, mechanical injury due to a malfunction in the computer tomograph). The second category includes situations in which health effects could have occurred, but did not occur: extravasal administration of a contrast agent; the patient gets stuck in the gantry of a computed tomograph; failure of the mechanical parts of the computed tomograph during the examination. Regulatory bodies must be notified of non-radiation accidents of the first category; accident of the second category should be registered at the level of the medical facility.

RESULTS AND DISCUSSION

The proposed classification was validated on the base of a multi-disciplinary medical research center based on the anonymized survey of the staff of the CT and X-ray diagnostic departments. 20 radiologists participated in the survey. The survey was conducted using dedicated questionnaires, aimed at identifying the prevalence and severity of different emergency situations. The results of the study are presented in Tables 2, 3.

According to Tables 2, 3, situation referred to the category of radiation accidents (severe overexposure of the patient or exposure of the pregnant patient) are quite seldom, encountered less than once per year. Radiation incidents are more frequent, being commonly encountered once per quarter or even once per week. The most frequent incidents are related to unjustified CT examinations (performed without any referrals or self-referred by the

patient). Non-radiation accidents are less frequent, but the majority of the respondents indicated such situation happening at least once per year.

TABLE 2. Results of the survey on radiation and non-radiation incidents and accidents in CT.

Question	How frequently do you encounter the following situations:					
	Never encountered such situation	Less than once per year	At least once per year	At least once per quarter	At least once per week	At least once per day
Radiation accidents						
Development of the deterministic effects after the CT examination	19 (95%)	-	-	-	1 (5%)	-
Identification that the patient is pregnant after (or during) the CT examination	16 (80%)	4 (20%)	-	-	-	-
Radiation incidents: patient overexposure						
Conducting CT examination of the wrong patient	5 (25%)	9 (45%)	2 (10%)	4 (20%)	-	-
Conducting CT examination of the wrong anatomical region	4 (20%)	11 (55%)	4 (20%)	2 (5%)	-	-
Conducting CT examination of the larger anatomical area than intended (accidentally)	6 (30%)	6 (30%)	5 (25%)	2 (10%)	-	1 (5%)
Significant overexposure of the patients (intended/unintended)	3 (15%)	4 (20%)	4 (20%)	7 (35%)	2 (10%)	-
Performing CT examination using the incorrect protocols	7 (35%)	4 (20%)	7 (35%)	2 (10%)	-	-
Radiation incidents: unjustified exposure						
Conducting CT examination without proper referral	3 (15%)	3 (15%)	2 (10%)	5 (25%)	6 (30%)	1 (5%)
Conducting CT examination according to the self-referral of the patient	4 (20%)	1 (5%)	2 (10%)	5 (25%)	7 (35%)	1 (5%)

TABLE 3. Results of the survey on radiation and non-radiation incidents and accidents in CT.

Question	How frequently do you encounter the following situations:					
	Never encountered such situation	Less than once per year	At least once per year	At least once per quarter	At least once per week	At least once per day
Radiation incidents: unjustified exposure						
Performing the same CT examination multiple times due to the errors in the referral system	10 (50%)	8 (40%)	1 (5%)	1 (5%)	-	-
Repeating CT examination due to the errors in PACS or during image transfer	8 (40%)	4 (20%)	3 (15%)	5 (25%)	-	-
Performing CT examination without contrast even if it was included in the referral	4 (20%)	5 (25%)	6 (30%)	5 (25%)	-	-
Inability to continue the CT examination due to the malfunction of the CT unit	6 (30%)	4 (20%)	4 (20%)	6 (30%)	-	-
Non-radiation accidents						
Development of the acute allergic reactions (anaphylaxy) after the ingestion of the contrast media	1 (5%)	6 (30%)	11 (55%)	2 (10%)	-	-
Necessity to perform emergency first aid to the patient during CT examination	7 (35%)	9 (45%)	3 (15%)	1 (5%)	-	-
Non-radiation incidents						
Extravasation of the contrast media	3 (15%)	1 (5%)	6 (30%)	9 (45%)	1 (5%)	-

CONCLUSION

This study allowed developing a harmonized approach for the identification and classification of the radiation accidents and incidents in radiology on the example of computed tomography examinations. The proposed structure of radiation and non-radiation incidents and accidents includes all possible emergency situations specific to the computed tomography. The results of the validation of the proposed approach on the base of the multi-disciplinary medical research center indicate that the majority of the emergency situations occur in everyday radiological

practice on a relatively frequent basis. Such situations should be registered at least on the level of a medical facility with the aim of strengthening radiation safety culture and improving the quality of diagnostic radiology. Less restrictive approach for the reporting on the accidents will reduce the pressure from the regulatory bodies.

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