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THE CONCEPT OF IMPLEMENTATION OF A CLINICAL AUDIT AS A TOOL FOR EVALUATING QUALITY MANAGEMENT IN X-RAY DIAGNOSTICS

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The article discusses the clinical implementation of internal audits in enterprises that use ionizing radiation in X-ray diagnostics. The legal aspects involved in conducting clinical audits and their implementation are presented. Rules which have to be obeyed during an audit of a quality management system are compared in an analysis with the rules accommodated during a clinical audit led by state authorities. This analysis presents some similarities between the analyzed forms of checking the management system's condition in X-ray diagnostics. In addition to similarities, there exist some differences also, and they are pointed out in this analysis, that is, elements that distinguish the audits from each other. Both a quality management system's audit and control components can be used for a clinical audit. The author designed a simple workflow during the internal clinical audit. The conclusions of the analysis will be the subject of further research.

Keywords: clinical audit, management, quality, X-ray imaging, X-ray facilities

1. INTRODUCTION

Technical progress in medicine makes X-ray examinations more and more popular, even in smaller medical facilities such as a dental practice. X-ray equipment emits harmful radiation, thus their usage and control procedures needed to be regulated.

According to the Euratom 2013/59 directive from 05.12.2013, which establishes the main protection regulations against the threat of X-rays, a clinical audit "means

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a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary". It means that an audit is done in the exact clinical area by experts and an auditor needs to be experienced in clinical practice (Kuźnicki, 2012, p. 170).

Nowadays, Poland faces problems inside auditing companies, which do not realize the difference between an audit and a control, and what is the influence of both forms on the quality management system. This article describes the differences and similarities between the forms of controlling management in X-ray diagnostics in accordance with a quality management system, and draws up a simple schematic of actions during the internal clinical audit.

2. CLINICAL AUDITS LAW REGULATIONS

In directive 2013/59/EURATOM it is noted that a clinical audit must be "done in accordance to national procedure". We must acquaint ourselves with regulations issued in Poland, which contain more rules about clinical audits. Table 1 summarizes them.

Table 1. Polish clinical audit regulations

Legal basis	Area of regulations	Section
Council Directive 2013/59/ Euratom	Clinical audit definition	Article 4 point 12
	Declaration of member state audits compliance with national procedures	Article 58 subpart e
Nuclear Law Journal 2014 item 1512	Clinical audit definition	Article 3 point 1
	Description of prevention against medical radiologic accidents, especially by performing consistency tests of radiologic devices, internal and external clinical audits and setting up a quality control system	Article 33c point 7
	Medical facilities are to pay for internal and external clinical audits	Article 33c point 8
	Declaration that the Minister of Health will describe the requirements (including frequency and conditions) for internal and external clinical audits, and subjects authorized to perform them (to ensure a high quality of medical services obeying European Community standards)	Article 33c point 9 subpart 10

Table 1. cont.

Nuclear Law Journal 2014 item 1512	Appointment of a commission for procedures and external clinical audits, especially: – Determination of the members of the commission – Description of commission working rules establishment – Description of commission tasks, with a map out in written radiological pattern procedures for standard medical examinations – Description of tasks for a medical facility including the examination procedures based on pattern procedures required by the quality control system – Health Ministry Journal publishes a registry of pattern procedures. – Description of a situation, when pattern procedures are to be checked, changed or deleted. – Description of rules for pull back permission to ensure medical services with ionizing radiation and rules to issue pull back permission – Description of frequency for external clinical audit, which is not rarer than every 4 years and contains a review of personnel qualifications, equipment, housing conditions, quality management systems and application of procedures in the meaning of medical procedures. – Description of detailed requirements for the content and form of pattern and diagnostic procedures (in accordance to EU recommendations).	Article 33 g
Regulation of the Minister of Health on conditions - The safe use of ionizing radiation for all types of medical exposure 2013 number 0 item 1015	Description of regulation contents, such as a consistency test for radiological equipment, internal and external audits for compliance with a patient's radiological protection requirements.	§ 1 point 9
	Description of actions to be taken in case of a regular exceeding of the reference level of doses (described in par. 2) during a previous clinical internal audit, especially recommendation of doses	§ 4 point 3
	Description of the contents of the quality management system documentation, especially: internal clinical audits and records of results, and archiving corrections and corrective actions	§ 8 point 1 subpart 6-7

Table 1. cont.

Regulation of the Minister of Health on conditions – The safe use of ionizing radiation for all types of medical exposure 2013 number 0 item 1015	Description of: – Audits frequency – Ability to appoint an auditing team, ability to change it, or non-adherence – Range of the internal clinical audit – Method of determining the scope and timing of the audit – Method of establishing the range and time of audit – Method and deadlines for the performance of tasks by the auditing team – Facility manager's responsibilities – Commission's tasks – Neutrality of auditors against an audited facility's manager – Confidentiality by the auditors – Role of regional consultants in the proper range of audit – Range of external audit	Chapter 8 Clinical internal and external audits

The table presents all components of clinical audits such as: the method of drafting an auditing team, and the composition, tasks and responsibilities are precise. Although not all regulated rules are implemented yet.

3. CLINICAL AUDIT CRITERIA

Internal clinical audits should be done at least once a year according to the Minister of Health of 26 April 2013. The publication of the consolidated text of the Regulation of the Minister of Health contains the conditions for the safe use of ionizing radiation for all types of medical exposure. In facilities where X-ray equipment is installed the facility manager selects at least two persons with different qualifications (precise in decree) to perform an audit. It is necessary to check the following (Journal of Laws 2014 item 1512):

– working with model procedures compatibility;
– discarded images analysis;
– method of proceeding with basic medical documentation;
– frequency and results of consistency tests for X-ray units;
– to values described as reference (appendix 2 to Ordinance).

A clinical audit's aim is to check the accuracy of making an X-ray diagnosis, its interpretation and reason to perform it. This valuation is done regarding the personnel and equipment involved in this procedure (Kuźnicki, 2012, p. 171). For

a good conduct of a clinical audit, specific criteria should be established on the basis of which is an assessment. These criteria concern:
– evaluation if received image is compliant with procedures,
– evaluation if image is interpreted correctly,
– assessment of the accuracy of the performed procedures,
– personnel evaluation,
– equipment evaluation.

An audits task is to collect objective proof of compliance with a functional system, not to search for inconsistencies. Cases of non-compliance with requirements are inconsistences, which give a chance to improve the system by using corrective actions and preventive actions to detect potential non-compliance.

4. TASKS OF THE AUDIT OF A QUALITY MANAGEMENT SYSTEM

The growing number of companies who implemented the ISO 9001 standard means this standard has improved. Table 2 presents the growth.

Table 2. Number of organizations using ISO 9001 worldwide (own work based on Łuczak, Kuklińska, 2007, p. 16 and www.irpoznan.com.pl.)

Standard	**ISO 9001**		
Year	2001	2005	2012
Number of companies using ISO 9001	44 388	776 608	about 1 100 000
Percent growth	–	94,3%	29,4%

The large growth in the last year is a result of the need and will to use tools, which is offered by the ISO 9001 norm. This means that the awareness of the necessity of systematization is increasing. A quality audit is an important part of quality management system implementation. Quality audits are used to verify the actual state in respect of quality management system requirements. The auditing process is crucial to ensure if the owned documentation is followed and implemented in the company. The audit used as a verification form is also a basic tool used to evaluate the efficiency and accuracy of the implemented quality management system (Gołaś, Mazur, 2011, p. 68). Additionally, an audit allows to verify whether the quality management system is used at all, and if its statements are respected (Jasiulewicz-Kaczmarek, Misztal, 2014, p. 87).

An audit as a constant-improvement mechanism allows to define inconsistency, helps to analyze reasons and to undertake corrective and preventive actions. Corrective actions are focused on eliminating the reason for inconsistency. Preventive actions are taken to eliminate the potential reason of inconsistency (Gołaś, Mazur, 2011, p. 69). Although we will want to avoid mistakes, we are not able to fully succeed in all undertaken actions. That is why finding inconsistencies is crucial and an audit allows for it as it is organized and occurs regularly. This means an audit mustn't be mistaken with an inspection, which gives answers as to whether something is right or wrong. An audit is an independent and objective evaluation done based on an analysis of the strengths and weaknesses of an organization, which allows to conclude what has to be changed in order to improve business (Gołaś, Mazur, 2011, p. 69).

Although organizations can use different audit schemes, every audit contains the following components (Jasiulewicz-Kaczmarek, Misztal, 2014, p. 87):

– audit's aim,
– audit's scheme and project,
– collection and allocation of sources,
– process and control of audit,
– passing feedback to people interested.

During an audit the following tools can be used (Gołaś, Mazur, 2011, p. 71):

– control list (interview),
– conversation with employee,
– observation of employees and their workplaces,
– analysis (documents, achieved results),
– conducting surveys.

Except for the above-mentioned tools, auditors should especially pay attention to the completion of tasks by workers, reviewing contents, procedures and other documents to get objective proof confirming that the quality management system is efficient.

The collected proof is evaluated by auditors, and includes the audit's adopted criteria that are input to the report (Jasiulewicz-Kaczmarek, Misztal, 2014, p. 89). This report is a record of the performed studies and conclusions, thus it must be done even if during the audit no inconsistencies were found (Jasiulewicz-Kaczmarek, Misztal, 2014, p. 90).

5. INSPECTIONS IN X-RAY FACILITIES

X-ray facilities are controlled in some aspects. Besides inspections done in every business (for example by the Internal Revenue Service), an X-ray room is controlled by sanitary and hygienic authorities, which inspect only a group of companies. Inspections done by the Radiation Hygiene department of the Provincial Sanitary and Epidemiological Station cover only X-ray facilities, what will be described

in the following part of the article. The Provincial Sanitary and Epidemiological Station inspects every facility which operates an X-ray (from small intraoral X-ray to CT for complete body examinations) not less than every 4 years. This inspection checks documents' (such as a quality book) accuracy and topicality, personnel qualifications and admission to work on an X-ray (including patient's protection exam retake every 5 years).

The quality management system on which Provincial Sanitary and Epidemiological Station relies should consist of only controlled contents. Table 3 shows that only the quality book is being controlled. But the Provincial Sanitary and Epidemiological Station does not require a quality book to have at least quality politics, which is one of most important parts of it. This case begs one question: Why do national authorities rely on a quality management system, and require a document which does not contain the mandatory contents?

Some specialists involved in safety in X-ray management (Kowski, 2015) state that the document which includes the basic information required by the 'Regulation of the Minister of Health on the conditions for the safe use of ionizing radiation for all types of medical exposure' does not have to be a quality book, but only a folder containing such data. This statement is correct, but inapplicable, because the last opinion is on the Provincial Sanitary and Epidemiological Station's side as the controlling organ.

Table 3. The conformity assessment of the quality management system in diagnostic radiology (own study based on the guidelines of the Provincial Sanitary-Epidemiological Station in Poznan)

Requirement	**Legal Basis**	**Number legal basis**
Quality Manual contains administrative information about individual health and its structure	If a medical care quality management system was introduced only on the basis of the Act of 29 November 2000. - Atomic Law, the quality book created in this unit is a brief description of the quality management system and shall include at least the following information: 1) the structure and administrative subordination; 2) clinical activities; 3) possessed and operated medical equipment; 4) the competence of personnel; 5) how to ensure the confidentiality of the information contained in medical records.	Annex Number 5 point 4 subpart 1-4 Journal of Laws 2013 item 1015
Quality Manual contains a range of clinical activities		
Quality Manual contains a list of owned and operated medical equipment		
Quality Manual contains the competence of staff		
Quality management system documentation in radiotherapy, nuclear medicine, diagnostic radiology and interventional radiology includes at least:		
Developed general procedures of supervision over documentation and supervision of records and forms necessary to maintain records	1) procedures of supervision over documentation and supervision of records and forms necessary to maintain records	§ 8.1.1 Journal of Laws 2013 item 1015

Table 3. cont.

Developed general procedures for internal audits	6) the procedure for conducting internal clinical audits	§ 8.1.6 Journal of Laws 2013 item 1015
Developed general procedures for dealing with inconsistent service, corrective and preventive action	7) records of clinical results of internal audits and undertaken corrective and repair actions	§ 8.1.7 Journal of Laws 2013 item 1015
Radiological equipment has an instruction manual	2) the operating instructions of radiological equipment and auxiliary equipment	§ 8.1.2 Journal of Laws 2013 item 1015
Documentation contains records of qualifications and training of staff	5) information regarding the qualifications and training of staff	§ 8.1.5 Journal of Laws 2013 item 1015
Developed rules for the operation of medical equipment and control and measurement, including the conduct of operational cards (should save any irregularities found during the operation and repair of all acts and regulations)	Healthcare provider implementing medical procedures in the field of radiology – diagnostic imaging is obliged to provide the following requirements, according to the scope of clinical activity and existing equipment:	Annex Number 5 point III subpart 4a Journal of Laws 2013 item 1015
Developed rules for the operation of medical equipment and control and measurement, including the principle of periodic internal control testing of physical parameters	4) The rules for the operation of medical equipment and control and measurement should include at least: a) conducting operational cards in which to save irregularities noticed during operation and any interference on repair and adjustment; b) periodically conducting field tests; c) the scope of training and authorization to operate the individual medical devices and control and measurement	Annex Number 5 point III subpart 4b Journal of Laws 2013 item 1015
Developed rules for the operation of medical equipment and control and measurement, including the scope of training and authorization to operate the individual medical devices and control and measurement		Annex Number 5 point III subpart 4c Journal of Laws 2013 item 1015
Quality management system documentation in radiotherapy, nuclear medicine, diagnostic radiology and interventional radiology includes at least:		
Developed rules of conducting and supervising documentation, including how to write or mark information related to the implementation of the procedure (in particular, patient administrative data, position and lateralization, the data on used equipment and used physical parameters and doses and identifiers of persons implementing)	A healthcare provider implementing medical procedures in the field of radiology - diagnostic imaging is obliged to provide the following requirements, according to the scope of clinical activity and existing equipment: 2) conduct and supervision of medical records should include at least the following: a) a method of recording and labeling information related to the implementation of the procedure, in particular the patient's administrative data, position and lateralization, the data on used equipment and used physical parameters and doses and identifiers of persons implementing; b) the manner and extent of medical archiving; c) terms of reference related to the exercise description outcome of the procedure and the issuing of outcome of the procedure	Annex Number 5 point III subpart 2a Journal of Laws 2013 item 1015
Developed rules of conduct and supervision of documentation, including the nature and scope of archiving medical records		Annex Number 5 point III subpart 2b Journal of Laws 2013 item 1015
Developed rules of conducting and supervising documentation, including the terms of reference related to the exercise description and the outcome of the procedure for issuing outcome of the procedure		Annex Number 5 point III subpart 2c Journal of Laws 2013 item 1015

Table 3. cont.

Developed procedures and instructions on how to perform field tests and use radiological equipment, assistive devices carried out by an individual healthcare provider on their own	3) the procedures and instructions on how to perform field tests and radiological equipment, assistive devices carried by an individual health care on their own	§ 8.1.3 Journal of Laws 2013 item 1015
Developed records of the results of tests carried out on radiological equipment, consumables and ancillary equipment, and acceptance testing	4) records of the results of operating radiological equipment and auxiliary equipment and acceptance tests	§ 8.1.4 Journal of Laws 2013 item 1015
Developed principles of records of periodic review of the quality management system	8) information on the periodic review of the quality management system made by the head of the healthcare provider	§ 8.1.8 Journal of Laws 2013 item 1015
Individual patterns elaboration records (cards, schedules, forms)	1) procedures of supervision over documentation and supervision of records and forms necessary to maintain records	§ 8.1.1 Journal of Laws 2013 item 1015
Developed rules of conducting and supervision of documentation, including how to ensure the confidentiality of the information contained in the medical records	If a medical care quality management system was introduced only on the basis of the Act of 29 November 2000. - Atomic Law, the quality book created in this entity is a brief description of the quality management system and shall include at least the following information: 1) how to ensure the confidentiality of the information contained in medical records.	Annex Number 5 point 4 subpart 5 Journal of Laws 2013 item 1015
Developed patient admission rules for implementation, registration and determination of the date and rules for the procedure	Healthcare provider implementing medical procedures in the field of radiology - diagnostic imaging is obliged to provide the following requirements, according to the scope of clinical activity and existing equipment: 3) handling of the patient should include at least the following: a) how to perform the procedure, b) course of action in the implementation process, taking into account the principles of radiological protection of the patient, c) the specific responsibilities of all persons involved in providing medical procedure, d) the procedure and responsibilities in the patient's life-threatening situation, e) the detailed rights and obligations related to the implementation of patient medical procedures within the unit and method of informing a patient about them	Annex Number 5 point III subpart 3 a-e Journal of Laws 2013 item 1015
Developed procedures for proceeding with the patient in the implementation of the procedure, taking into account the patient's radiological protection rules		
Developed detailed respective responsibilities of all persons involved in providing medical procedure when dealing with a patient		
Developed rules of procedure with the patient and responsibilities in the patient's life-threatening situation		
Developed specific rights and obligations related to the implementation of patient medical procedures in the individual and the way of informing the patient about them		

Table 3. cont.

Developed principles of analysis of the results inconsistent with assumed criteria, including the method of registering anomalous results, the way they describe and represent in analysis	Healthcare provider implementing medical procedures in the field of radiology - diagnostic imaging is obliged to fulfil the following requirements, according to the scope of clinical activity and existing equipment: 5) the principles of analysis of the results inconsistent with assumed criteria should include at least the following: a) the method of registering anomalous results, the way they describe and represent in an analysis, b) specifically described criteria for the recognition of the result to be inconsistent with expectations, c) the forms and course of action in conducting the analysis of anomalous results, with particular emphasis on corrective actions and preventive measures undertaken and their effectiveness.	Annex Number 5 point III subpart 5 a-c Journal of Laws 2013 item 1015
Developed principles of analysis of the results inconsistent with folded criteria, including strict criteria described recognizing the result to be incompatible		
Developed principles of analysis of the results inconsistent with assumed criteria, including forms and course of action in conducting the analysis of anomalous results, with particular emphasis on corrective actions and preventive measures undertaken and their effectiveness		

The documents and records presented in Table 3 are not the only regulations for a facility which applies for permission to use an X-ray. The remaining regulations are included in Ordinance and Nuclear Law; constant updates and differences in interpretation of actions creates an additional problem in this case.

6. SIMILARITIES AND DIFFERENCES OF VARIOUS FORMS OF CHECKING THE STATUS OF GOVERNANCE IN DIAGNOSTIC RADIOLOGY

One of the quality management system's elements needed to be implemented in a facility is clinical audits. It is crucial to point out that a clinical audit differs from a quality management system's audit. The differences are shown in Table 4.

Directive 2013/59/EURATOM states that a clinical audit is form of control. To explain this problem, Table 5 presents the differences between a clinical audit and a typical control.

Unfortunately, misunderstandings often occur in radiological surveillance, which are related to the control of the Provincial Sanitary-Epidemiological Station. During the evaluation, substantive elements of the quality management system should not be judged in organizations that use X-rays, but only the obligation to implement and maintain the quality management system and documenting the actions that result from the legislation should be analyzed (Kuźnicki, 2012, p. 170).

Table 4. Comparison of a clinical audit with a quality management system audit (own work based on Kuźnicki, 2012).

Quality system audit	Clinical audit
Verifies whether the system is compliant with the standard.	Verifies whether the system allows the facility to achieve its quality targets.
Used regulations: ISO 19011 Referenced Documents: ISO 9001 ISO 17025 ISO 15189	Applicable regulations: 1. Regulation of the Minister of Health on 18 February 2011. On the conditions for the safe use of ionizing radiation for all types of medical exposure (Journal of Laws 2013 item 1015). 2. Act of 29 November 2000. Nuclear Law (Journal of Laws 2014 number 0 item 1512).
Performed by an independent certification body (external audit).	Carried out by an independent body (not a certification) associated with health care
The possibility of obtaining a certificate of compliance with the standard.	Inability to obtain a certificate of compliance with the standard (lack standard).
No necessity for auditors who are professionals in the field of the auditee.	Require the presence of auditors who are professionals in the field of health.
The auditors do not necessarily have knowledge and experience in a particular field, but are supported by technical experts.	The auditors must have adequate knowledge and experience of clinical work.

Table 5. Comparison of a typical clinical audit and a control (own work based on Kuźnicki, 2012)

Control	Clinical audit
Run by the administration.	Run by the healthcare authority.
It refers explicitly to existing legislation.	It refers to the recognized standards for good practice.
An identified incompatibility enforces action on the part of the controlled entity.	Detected nonconformity does not force action by the auditee, any subsequent action is decided by the user.
Conclusions are saved in the form of statements and orders.	Conclusions are saved in the form of statements and recommendations.

Unfortunately there are misunderstandings due to the radiological supervision performed by the Provincial Sanitary-Epidemiological Station. Every control shouldn't evaluate the essential elements of a quality management system in X-ray facilities, but only analyze the implementation performed in accordance to regula-

tions, which obliges the facility manager to implement and control the quality management system as described (Kuźnicki, 2012, p. 170).

Though there exist differences between a clinical audit and a quality management system audit, inspection should analyze only (according to Kuźnicki, 2012, p. 170-171):

- usability and topicality of documents,
- ensure adequate resources for quality control system from the technical aspect (programs, tutorials, their implementation and results, equipment condition, and its compliance),
- application of proper quality control procedures in the clinical aspect (procedures, documentation and usage of results, personnel responsibilities),
- quality implementation and comparison (documented procedures, results, links, evaluations, implementation of recommendations, adaptation, management reviews, self-notes, audits, certifications, accreditations, law-compliance inspections),
- incidents and other aberrations from the established quality criteria (tutorials, notes, signalization, corrective and preventive actions) records,
- feedback, notes, actions (feedback from doctors, other workers, patients, other customers).

The above remarks could be understood as an evaluation of the topicality, proprietary, usability of documents and records aimed at increasing the safety and comfort level for personnel and patients in an X-ray facility.

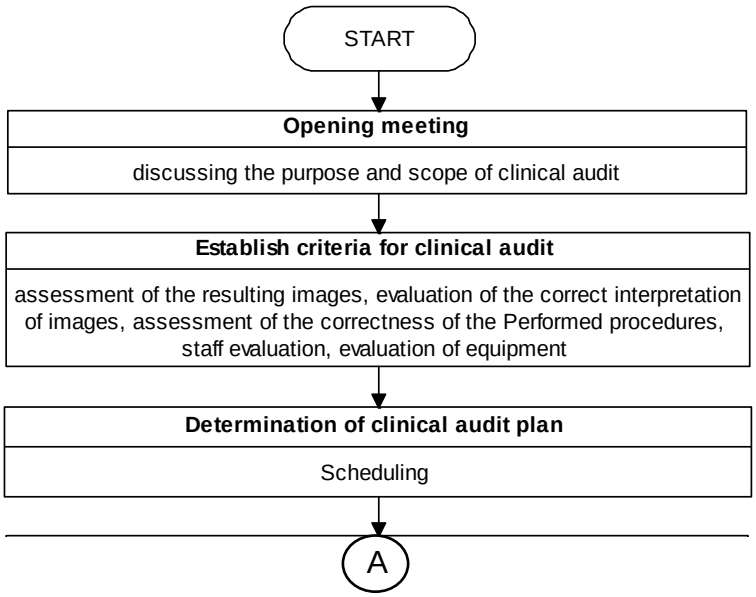

Fig. 1. Steps in the clinical audit (own study based on Journal of Laws 2014 item 1512 and Kuźnicki, 2012)

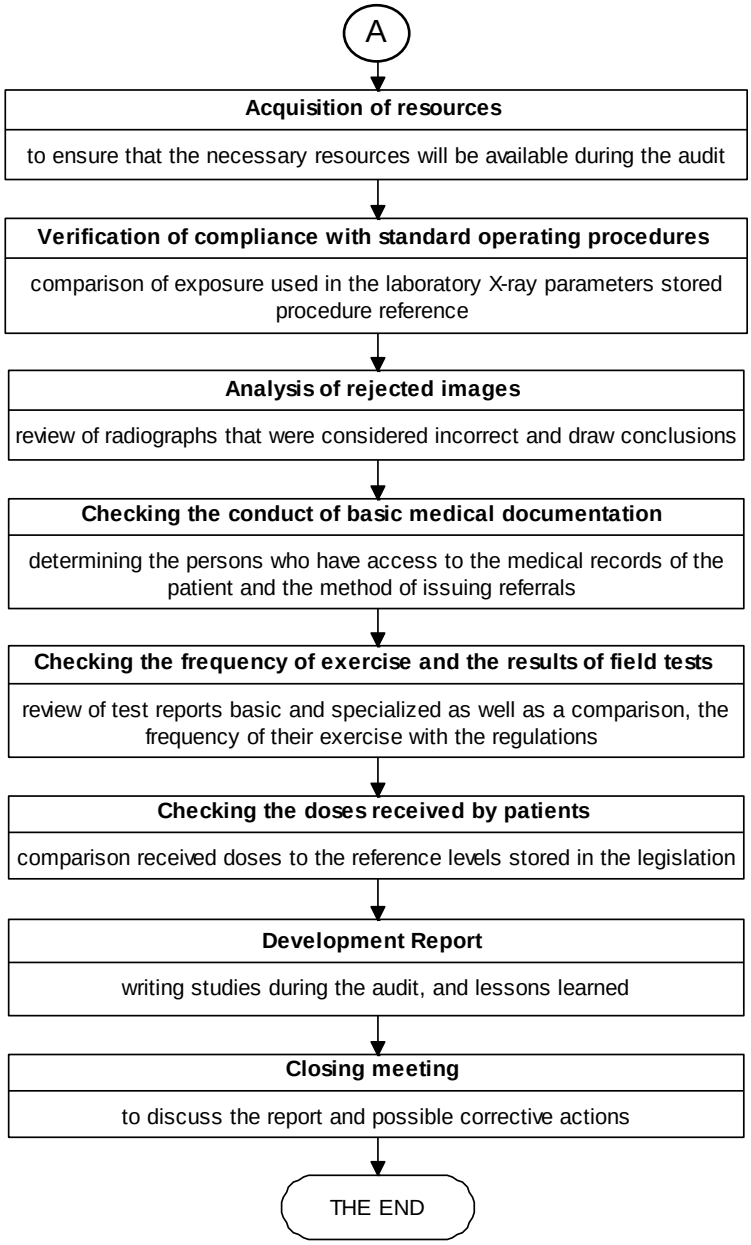

Fig. 1. Steps in the clinical audit, cont.

7. PROPOSAL FLOW CHART INTERNAL CLINICAL AUDIT

The above description concerns the internal clinical audit, the audit of the quality management system and the control. In order to facilitate the internal clinical audit, which is based on a quality management system, the author proposes a workflow. The block diagram combines elements of clinical and elements of quality management system. The diagram is a simplified picture of the proceedings during the internal clinical audit and is designed to help individuals who have a problem with performing an audit of its X-ray rooms and in particular in dental surgeries (Fig. 1).

The diagram shows the basic operation with a short explanation. As a result, it should be understandable to people who perform internal clinical audit for the first time. Often for people who are focused on carrying out its activities, they are not oriented in the provisions concerning ionizing radiation. Therefore, employed a radiological protection inspector to assist in security operations work on the X-ray. However, the responsibility for the internal clinical audit rests with the head of the organization. According to national regulations, the radiological protection inspector does not participate in the audit. Therefore, with the diagram in Figure 1 aimed at owners of an X-ray room and dental X-ray, one does not have to delve into incomprehensible to one rules.

8. CONCLUSIONS

All necessary regulations were stated to enable X-ray facilities to implement a quality management system. Although bigger X-ray facilities (clinics, hospitals) can proceed with internal clinical audits to help them, smaller facilities (such as a dental X-ray facility) using low power X-rays are in a difficult situation. For them it is even unknown how their entrances should be marked. ‘X-ray room’ applies to a room, which is equipped only in units dedicated to X-ray diagnostics. A dental cabinet is equipped with a wide variety of medical equipment such as a dental chair.

Besides small dental facilities’ problems, some doubts appear for the rest of companies as well. Undoubted is the fact that they need a prompt or methodology for them to follow, which is absent in current regulations. For many users, the issue is of auditing a clinical associate with not necessary bureaucracy, which charges companies using an X-ray. Clinical audits are detached from reality, but are a consequence of the quality management system, which every employer should implement (although this requirement is in opposition with the voluntary nature of a quality management system). A change in the clinical audits' perception is needed to make employees more willing to improve a customer's (patient's) service. The perception that a lot of commitments are a necessary evil, whose non-compliance

will lead to a fine, should be changed to the perception that clinical audits help in better fulfilling obligations and give benefits. That is why reality looks how can we observe now, probably because of a quality management system misunderstanding. To change it, proper direction should be given, and a proper methodology should be indicated to make clinical audits easier for companies to implement.

LITERATURE

1. Amin, P. (2001). *Clinical Audit, MedIND*, 8 (4), New Delhi.
2. Amstrong, N., Behan, A., Bolas, A. and others (2009). An Introduction to Audit Compliance With SI 478 (2002) In Dentistry, *Audit Subcommittee of the Dental Radiation Safety Committee of the HSE*, Dublin.
3. Council Directive 2013/59 / EURATOM of 5 December 2013. Laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation and repealing Directive 89/618 / Euratom, 90/641 / Euratom 96/29 / Euratom, 97/43 / Euratom and 2003/122 / Euratom.
4. Daly, M. (2008). *Healthcare Audit Criteria and Guidance*, Health Service Executive.
5. Devlin, J., Brady, A., O'Laoide, R. and others (2011). *Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine)*, Health Service Executive Faculty of Radiologists
6. European Commission (1996). *European Guidelines On Quality Criteria For Diagnostic Radiographic Images*, Luxembourg.
7. European Commission (2009). *Radiation Protection No. 159 – European Commission Guidelines On Clinical Audit For Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine And Radiotherapy)*, Belgium.
8. Gołaś, H., Mazur, A. (2011). *Implementation of Quality Management System*, Technical University of Poznan, Poznan.
9. International Atomic Energy Agency (2011). *Justification Of Medical Exposure In Diagnostic Imaging*, Vienna.
10. International Atomic Energy Agency (2015). *Radiation Protection In Medicine: Setting The Scene For The Next Decade*, Vienna.
11. Jasiulewicz-Kaczmarek, M., Misztal, A. (2014). *Design and integration of pro-quality management systems*, Technical University of Poznan, Poznan.
12. Kowski, R. (2015). *Training in the creation of working procedures*, Lodz Training and Consultation, Lodz.
13. Kuźnicki, J. (2012). Clinical audits in units that use ionizing radiation for medical purposes. In: G. Pawlicki (ed.), *Engineer and Physicist Medical*, 1 (4/2012), Wroclaw.
14. Łuczak, B., Kuklińska, D. (2007). *Audits and auditing*, Publishing School of Banking in Poznan, Poznan.
15. National Institute for Clinical Excellence (2002). *Principles for Best Practice in Clinical Audit*, Abingdon.

16. Proclamation of the Marshal of the Polish Seem on 17 September 2014. On the announcement of the uniform text of the Act – Nuclear Law (*Journal of Laws* 2014, item 1512).
17. Stassen, L.F.A. (edit.) (2009). IDA promoting best practice. In: *The Journal of the Irish Dental Association*, 55 (3), Dublin.
18. Statement of the Minister of Health of 26 April 2013. On the publication of the consolidated text of the Regulation of the Minister of Health on the conditions for the safe use of ionizing radiation for all types of medical exposure (*Journal of Laws* 2013, item 1015).
19. BS EN ISO 19011: 2012 Guidelines for auditing management systems.
20. Regulation of the Minister of Health of 21 August 2006. On the detailed conditions of safe use of radiological equipment (*Journal of Laws* 2006, No. 180, item. 1325).
21. Regulation of the Council of Ministers dated 18 January 2005. On ionizing radiation dose limits (*Journal of Laws* 2005, No. 20, item 168).
22. Wielkopolska Izba Rzemieślnicza w Poznaniu, Retrieved from http://www.irpoznan.com.pl (access 15.05.2015).

KONCEPCJA REALIZACJI AUDYTU KLINICZNEGO JAKO NARZĘDZIA DO OCENY POZIOMU ZARZĄDZANIA JAKOŚCIĄ W RENTGENODIAGNOSTYCE

Streszczenie

W artykule opisano problem wdrożenia wewnętrznych audytów klinicznych w przedsiębiorstwach wykorzystujących promieniowanie jonizujące w rentgenodiagnostyce. Przywołano prawne aspekty przeprowadzania audytów klinicznych oraz ich wdrażania. Dokonano analizy porównawczej reguł przeprowadzania audytów systemu zarządzania jakością z regułami przeprowadzania audytów klinicznych i regułami przeprowadzania kontroli organów państwowych. W konsekwencji tej analizy wskazano podobieństwa pomiędzy analizowanymi formami sprawdzania stanu systemu zarządzania w rentgenodiagnostyce. Zwrócono również uwagę na elementy odróżniające je od siebie, a także możliwość adaptacji elementów audytu systemu zarządzania jakością i elementów kontroli organów państwowych na rzecz audytu klinicznego. Opracowano prosty schemat postępowania podczas wewnętrznego audytu klinicznego. Wnioski z przeprowadzonej analizy stanowić będą przedmiot dalszych badań.

Słowa kluczowe: audyt kliniczny, zarządzanie, jakość, rentgenodiagnostyka, pracownia rtg