



JOURNAL OF LAWS OF THE REPUBLIC OF POLAND

Warsaw, 20th of December 2022

Item 2683

REGULATION

OF THE MINISTER OF HEALTH¹

of 06 December 2022

on the detailed scope of internal and external clinical audits and the template of their reports²

Pursuant to Article 33x of the Act of 29 November 2000 on the Atomic Law (Dz.U. of 2021, item 1941, and of 2022, item 974), it is ordered as follows:

§ 1. This Regulation establishes:

- 1) detailed scope of internal clinical audits,
- 2) detailed scope of external clinical audits,
- 3) template of the report on the conducted internal clinical audit,
- 4) template of the report on the conducted external clinical audit.

§ 2. Internal and external clinical audits are conducted in the areas of:

- 1) X-ray diagnostics,
- 2) interventional radiology,
- 3) radiotherapy (radiation therapy),
- 4) nuclear medicine.

§ 3. 1. The scope of internal clinical audits shall include:

- 1) identification of the types of specific medical radiological procedures developed at the health care unit and subject to audit verification, hereinafter referred to as the "specific procedures", and indication of the number of applications of the specific procedures for each of the types indicated;
- 2) a review of the specific procedures referred to in point 1 to verify their correctness and timeliness, including:
 - a) an analysis of the specific procedures and their application practices, including the number of applications of specific procedures by adult patients and patients under 16 years of age, broken down by gender,

¹ The Minister of Health heads the department of government administration - health, pursuant to § 1(2) of the Regulation of the Prime Minister of 27 August 2020 on the detailed scope of activities of the Minister of Health (Dz. U. of 2021, item 932).

² This Regulation implements within its scope the Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ EU L 13, 17.1.2014, p. 1, OJ EU L 72, 17.3.2016, p. 69, OJ EU L 152, 11.6.2019, p. 128 and OJ EU L 324, 13.12.2019, p. 80).

- b) data to assess the magnitude of exposure of adult patients and patients under 16 years of age, broken down by gender, and a comparison of these magnitudes with the diagnostic reference levels specified in regulations issued pursuant to Article 33g (3) of the Act of 29 November 2000 on the Atomic Law, in cases where such levels have been defined;
- 3) a description of the findings of the audit, including recommendations for the health care unit, if any.
 2. The scope of the internal clinical audit referred to in § 2(1), in addition to the elements specified in paragraph (1), shall also include:
 - 1) verification of the analysis of rejected images,
 - 2) evaluation of whether descriptions of test results are in accordance with the established criteria,
 - 3) verification of the handling of medical records.
 3. The scope of the internal clinical audit referred to in § 2(2), in addition to the elements specified in paragraph 1, shall also include:
 - 1) as part of the review of specific procedures referred to in paragraph 1(2), verification of the correctness of the selection of the procedure, taking into account the absolute and relative contraindications to its use,
 - 2) analysis of the procedures in which unexpected clinical symptoms appeared as a consequence of the application of ionizing radiation,
 - 3) verification of the handling of medical records,
 - 4) determination of the number of procedures during the implementation of which the total amount of air kerma at the reference point exceeded 5 Gy or the total amount of the dose-area product (DAP) exceeded 500 Gy·cm².
 4. The scope of the internal clinical audit referred to in § 2(3), in addition to the elements specified in paragraph (1), shall also include:
 - 1) verification of the accuracy of referrals for treatment and qualification for radiotherapy;
 - 2) verification of the technique and method of fractionation of ionizing radiation dose;
 - 3) verification of the correctness of the designation of geometric areas (target areas, critical organ areas);
 - 4) verification of the correctness of patient positioning checks carried out;
 - 5) verification of two- or three-dimensional distribution of ionizing radiation dose in the planned volume of tissues and organs;
 - 6) verification of the performance of in vivo dosimetry in justified cases;
 - 7) verification of the accuracy of records in:
 - a) operation register,
 - b) treatment plan,
 - c) irradiation chart;
 - 8) verification of the implementation of the procedures for calibration of dose meters adopted at the health care unit;
 - 9) verification of the performance of dosimetry of treatment plans in dynamic techniques - in the case of radical radiotherapy.
 5. The scope of the internal clinical audit referred to in § 2(4), in addition to the elements specified in paragraph (1), shall also include:
 - 1) verification of the accuracy of referrals for examination and treatment,
 - 2) evaluation of the compliance of descriptions of test results with the established criteria,
 - 3) verification of the quality of the scintigraphic images obtained,
 - 4) verification of the correctness of labelling of radiopharmaceutical products - if this activity is carried out at the

health care unit,

- 5) verification of the handling of medical records.

§ 4. The scope of external clinical audits shall include:

- 1) a review of the specific procedures to be checked within the framework of the external clinical audit to verify their correctness and timeliness, with particular emphasis on procedures that have not been created on the basis of model medical radiological procedures for standard medical exposures;
- 2) evaluation of the health care unit's compliance with the requirements for conducting activities specified in either Article 33p(7) or Article 33q(7) of the Act of 29 November 2000 on the Atomic Law or in regulations issued pursuant to Article 33p(14) or Article 33q(13) of the Act of 29 November 2000 on the Atomic Law or in regulations issued pursuant to Article 33p(14) or Article 33q(13) of the Act of 29 November 2000 on the Atomic Law;
- 3) evaluation and comparison with recognized standards of other issues and matters relevant from the point of view of radiological protection of the patient related to the activities carried out by the health care unit.

§ 5. 1. The template of the report on the internal clinical audit of X-ray diagnostics, including dentistry and bone densitometry, and interventional radiology is specified in Annex No. 1 to the Regulation.

2. The template of the report on the conducted clinical internal audit in the field of radiotherapy is specified in Annex No. 2 to the Regulation.

3. The template of the report on the conducted internal clinical audit in the field of nuclear medicine is determined in Annex No. 3 to the Regulation.

4. The template of the report on the conducted external clinical audit is specified in Annex No. 4 to the Regulation.

§ 6. Internal and external clinical audits initiated and not completed by the date of entry into force of this Regulation shall be conducted in accordance with the existing regulations.

§ 7. This Regulation shall enter into force 14 days following its promulgation.³

Minister of Health: A. Niedzielski

³ This regulation was preceded by the Regulation of the Minister of Health of 18 February 2011 on the conditions for the safe use of ionizing radiation for all types of medical exposure (D. U. of 2017, item 884), which expired on 24 September 2022 in accordance with Article 37(2)(2) of the Act of 13 June 2019 amending the Atomic Law and the Fire Protection Act (Dz. U. item 1593, and of 2020, item 284).

TEMPLATE

REPORT ON THE INTERNAL CLINICAL AUDIT OF X-RAY (INCLUDING DENTISTRY AND BONE DENSITOMETRY) AND INTERVENTIONAL RADIOLOGY

1. GENERAL DATA

1.1 INFORMATION ABOUT THE HEALTH CARE UNIT:

1.1.a. Name of the unit:

1.1.b. Zip code:

1.1.C. City

1.1.d. Address:

1.1.e. Voivodship:

1.1.F. Register book number from the Register of Entities Performing Medical Activities:

1.2 DATE OF AUDIT: FROM **TO**

1.3 PERIOD TO WHICH THE AUDIT RELATES¹⁾: FROM **TO**

¹⁾ Pursuant to Article 33v (1) of the Act of 29 November 2000 on the Atomic Law (Dz. U. of 2021, item 1941, and of 2022, item 974), an internal clinical audit shall be conducted at least annually.

2. TYPE AND NUMBER OF SPECIFIC PROCEDURES PERFORMED IN THE UNIT

☐ Dental X-ray (without CBCT)	☐ Computed tomography
☐ Cone Beam Computed Tomography (CBCT)	☐ Cardiac interventional radiology
☐ Mammography	☐ Neurological interventional radiology
☐ Conventional radiography	☐ Interventional radiology - other
☐ Fluoroscopy	☐ Bone densitometry

3. THE SCOPE OF THE AUDIT, INCLUDING THE TYPE OF SPECIFIC PROCEDURES TO BE CHECKED AS PART OF THE AUDIT

4. A REVIEW OF THE SPECIFIC PROCEDURES TO BE CHECKED AS PART OF THE AUDIT

4.1. Analysis of specific procedures and the practice of their application, taking into account the scope of the internal clinical audit specified in § 3(2) or 3(3) of the Regulation of the Minister of Health of 6 December 2022 on the detailed scope of internal and external clinical audits and the template of their reports (Dz. U., item 2683)

4.2. Number of applications of specific procedures subject to audit

Specific procedure	Adult patients (over 16 years old)		Patients under the age of 16	
	female	male	female	male
1.				
2.				
3.				
4.				
5.				
...)				

4.3. Data to determine the magnitude of patient exposure in specific procedures subject to audit

Specific procedure	Typical dose or exposure magnitude of patients for specific age categories (expressed as DAP, surface input dose - D, CTDI, DLP or kV/mAs ²))										Measured quantity: ☐ DAP ☐ D ☐ CTDI ☐ DLP ☐ kV/mAs Unit:
	Adult patients (over 16 years old)		Patients under the age of 16 (F - female, M - male)								
			10 years old		5 years old		1 year old		newborn		
	female	male	F	M	F	M	F	M	F	M	
1.											
2.											
3.											
4.											
5.											
...)											

²⁾ In conventional radiography, in the absence of a dose recorder, give typical exposure parameters expressed as high voltage in kilovolts (kV) and current-time load in milliampereseconds (mAs).

4.4. Comparison of the magnitude of patient exposure in specific procedures to be audited with diagnostic reference levels (if such levels have been defined)

5. A DESCRIPTION OF THE CLINICAL AUDIT FINDINGS, INCLUDING ANY RECOMMENDATIONS TO CHANGE SPECIFIC PROCEDURES OR INTRODUCE NEW SPECIFIC PROCEDURES

☐ X-RAY DIAGNOSTICS (INCLUDING DENTISTRY AND BONE DENSITOMETRY)

	YES	NO	NOT APPLICABLE
Verification of the analysis of rejected images,	☐	☐	☐
Evaluation of the compliance of descriptions of test results with the established criteria	☐	☐	☐
Verification of the handling of medical records	☐	☐	☐

☐ INTERVENTIONAL RADIOLOGY

	YES	NO	NOT APPLICABLE
Verification of the correctness of the choice of the procedure, taking into account the absolute and relative contraindications to its use	☐	☐	☐
Analysis of the procedures in which unexpected clinical symptoms appeared as a consequence of the application of ionizing radiation	☐	☐	☐
Verification of the handling of medical records	☐	☐	☐
Determination of the number of procedures during the implementation of which the total total amount of air kerma at the reference point exceeded 5 Gy or the total value of the dose-area product (DAP) exceeded 500 Gy cm^2	☐	☐	☐

FINDINGS AND CONCLUSIONS

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6. PERSONS CONDUCTING THE AUDIT

Name and surname	Signature of person conducting the audit

TEMPLATE

REPORT ON THE INTERNAL CLINICAL AUDIT CONDUCTED IN THE FIELD OF RADIOTHERAPY

1. GENERAL DATA

1.1 INFORMATION ABOUT THE HEALTH CARE UNIT:

1.1.a. Name of the unit:

1.1.b. Zip code:

1.1.c. City

1.1.d. Address:

1.1.e. Voivodship:

1.1.f. Register book number from the Register of Entities Performing Medical Activities:

1.2 DATE OF AUDIT: FROM **TO**

1.3 PERIOD TO WHICH THE AUDIT RELATES¹⁾: FROM **TO**

2. TYPE AND NUMBER OF SPECIFIC PROCEDURES PERFORMED IN THE UNIT

☐ Teleradiotherapy - photons

☐ Brachytherapy

☐ Teleradiotherapy - gamma radiation (⁶⁰Co)

☐ Stereotactic radiosurgery

☐ Teleradiotherapy - electrons

☐ Intraoperative radiotherapy

☐ Hadron teleradiotherapy

☐ Other types of radiotherapy

¹⁾ Pursuant to Article 33v (1) of the Act of 29 November 2000 on the Atomic Law (Dz. U. of 2021, item 1941, and of 2022, item 974), an internal clinical audit shall be conducted at least annually.

3. THE SCOPE OF THE AUDIT, INCLUDING THE TYPE OF SPECIFIC PROCEDURES TO BE CHECKED AS PART OF THE AUDIT

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4. A REVIEW OF THE SPECIFIC PROCEDURES TO BE CHECKED AS PART OF THE AUDIT

4.1. Analysis of specific procedures and the practice of their application, taking into account the scope of the internal clinical audit specified in § 3(4) of the Regulation of the Minister of Health of 6 December 2022 on the detailed scope of internal and external clinical audits and the template of their reports (Dz. U., item 2683)

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4.2. Number of applications of specific procedures subject to audit

Specific procedure	Adult patients (over 16 years old)		Patients under the age of 16	
	female	male	female	male
1.				
2.				
3.				
4.				
5.				
...)				

4.3. Data to determine the magnitude of patient exposure in specific procedures subject to audit

Specific procedure	Typical fractional dose for specific age categories (absorbed dose in the disc area expressed in Gy)				Number of fractions
	Adult patients (over 16 years old)		Patients under the age of 16		
	female	male	female	male	
1.					
2.					
3.					
4.					
5.					
...)					

5. A DESCRIPTION OF THE CLINICAL AUDIT FINDINGS, INCLUDING ANY RECOMMENDATIONS TO CHANGE SPECIFIC PROCEDURES OR INTRODUCE NEW SPECIFIC PROCEDURES

	YES	NO	NOT APPLICABLE
Verification of the accuracy of referrals for treatment and qualification for radiotherapy	☐	☐	☐
Verification of the technique and method of fractionation of ionizing radiation dose	☐	☐	☐
Verification of the correctness of the designation of geometric areas (target areas, critical organ areas)	☐	☐	☐
Verification of the correctness of patient positioning checks carried out	☐	☐	☐
Verification of two- or three-dimensional distribution of ionizing radiation dose in the planned volume of tissues and organs	☐	☐	☐
Verification of the performance of in vivo dosimetry in justified cases	☐	☐	☐
Verification of the accuracy of entries in the operation record, treatment plan, irradiation chart	☐	☐	☐
Verification of the implementation of the procedures for calibration of dose meters adopted at the health care unit	☐	☐	☐
For radical radiotherapy - check the performance of dosimetry of treatment plans in dynamic techniques	☐	☐	☐

FINDINGS AND CONCLUSIONS

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6. PERSONS CONDUCTING THE AUDIT

Name and surname	Signature of person conducting the audit

TEMPLATE

REPORT ON THE INTERNAL CLINICAL AUDIT OF NUCLEAR MEDICINE

1. GENERAL DATA

1.1 INFORMATION ABOUT THE HEALTH CARE UNIT:

1.1.a. Name of the unit:

1.1.b. Zip code:

1.1.c. City

1.1.d. Address:

1.1.e. Voivodship:

1.1.f. Register book number from the Register of Entities Performing Medical Activities:

1.2 DATE OF AUDIT: FROM **TO**

1.3 PERIOD TO WHICH THE AUDIT RELATES¹⁾: FROM **TO**

2. TYPE AND NUMBER OF SPECIFIC PROCEDURES PERFORMED IN THE UNIT

☐ SPECT/SPECT-CT

☐ Therapy of benign thyroid disorders using iodine-131

☐ PET/PET-CT/PET-MRI

☐ Therapy of neoplastic lesions using iodine-131

☐ Other scintigraphic testing methods

☐ Therapy - other radiopharmaceuticals

¹⁾ Pursuant to Article 33v (1) of the Act of 29 November 2000 on the Atomic Law (Dz. U. of 2021, item 1941, and of 2022, item 974), an internal clinical audit shall be conducted at least annually.

3. THE SCOPE OF THE AUDIT, INCLUDING THE TYPE OF SPECIFIC PROCEDURES TO BE CHECKED AS PART OF THE AUDIT

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4. A REVIEW OF THE SPECIFIC PROCEDURES TO BE CHECKED AS PART OF THE AUDIT

4.1. Analysis of specific procedures and the practice of their application, taking into account the scope of the internal clinical audit specified in § 3(5) of the Regulation of the Minister of Health of 6 December 2022 on the detailed scope of internal and external clinical audits and the template of their reports (Dz. U., item 2683)

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4.2. Number of applications of specific procedures subject to audit

Specific procedure	Adult patients (over 16 years old)		Patients under the age of 16	
	female	male	female	male
1.				
2.				
3.				
4.				
5.				
...)				

4.3. Data to determine the magnitude of patient exposure in specific procedures subject to audit

Specific procedure	Typical activity given to the patient (per kg of body weight)										Type of radiopharmaceutical
	Adult patients (over 16 years old)		Patient under 16 years of age (W - female, M - male)								
	female	male	10 year old		5 year old		1 year old		newborn		
			F	M	F	M	F	M	F	M	
1.											
2.											
3.											
4.											
5.											
...)											

4.4. Comparison of the magnitude of patient exposure in specific procedures to be audited with diagnostic reference levels (if such levels have been defined)

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5. A DESCRIPTION OF THE CLINICAL AUDIT FINDINGS, INCLUDING ANY RECOMMENDATIONS TO CHANGE SPECIFIC PROCEDURES OR INTRODUCE NEW SPECIFIC PROCEDURES

	YES	NO	NOT APPLICABLE
Verification of the accuracy of referrals for examination and treatment	☐	☐	☐
Evaluation of the compliance of descriptions of test results with the established criteria	☐	☐	☐
Verification of the quality of the scintigraphic images obtained	☐	☐	☐
Verification of the correctness of labelling of radiopharmaceutical products - if this activity is carried out at the health care unit	☐	☐	☐
Verification of the handling of medical records	☐	☐	☐

FINDINGS AND CONCLUSIONS

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6. PERSONS CONDUCTING THE AUDIT

Name and surname	Signature of person conducting the audit

TEMPLATE

EXTERNAL CLINICAL AUDIT REPORT ON:

☐ **X-RAY DIAGNOSTICS AND INTERVENTIONAL RADIOLOGY**

☐ **RADIOTHERAPY**

☐ **NUCLEAR MEDICINE**

1. Date of the external clinical audit

The audit has been conducted fromto

2. GENERAL DATA

INFORMATION ABOUT THE HEALTH CARE UNIT:

2.1. Name of the unit:

2.2. Zip code:

2.3. City:

2.4. Address:

2.5. Voivodship:

2.6. Register book number from the Register of Entities Performing Medical Activities:

3. Information about the type of activities carried out by the health care unit, including an indication of the type of specific procedures performed at this unit

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¹⁾ Mark the appropriate range and delete as unnecessary.

4. The scope of the external clinical audit, including an indication of the type of specific procedures to be checked as part of the audit, and an indication of the specific procedures developed at the health care unit to be checked during the audit²⁾

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5. Review of specific procedures used in the health care unit and subject to verification within the framework of the audit, taking into account the scope of the external clinical audit specified in § 4 of the Regulation of the Minister of Health of 6 December 2022 on the detailed scope of internal and external clinical audits and the template of their reports (Dz. U., item 2683)

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6. Description of the findings of the audit with respect to the elements to be assessed, including any recommendations to the health care unit

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7. Person completing the report - LEAD AUDITOR

Name and surname	Signature of the lead auditor

8. Other members of the audit team

Name and surname	Signature of the audit team member

²⁾ In the case of an external clinical audit conducted in accordance with the plan for conducting external clinical audits referred to in Article 33w (8) of the Act of 29 November 2000 on the Atomic Law, the scope of the audit to be conducted shall be in accordance with the scope specified in the plan.