The influence of legislative changes on quality and costs in radiotherapy

Marta BOGUSZ-CZERNIEWICZ, Adam ŚWIEŻEWSKI, Julian MALICKI

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Marta Bogusz-Czerniewicz
The Greater Poland Cancer Centre,
Department of Training,
Scientific Cooperation
and Quality Assurance

Address for correspondence:
Marta Bogusz-Czerniewicz
The Greater Poland Cancer Centre,
Department of Training,
Scientific Cooperation
and Quality Assurance
15th Garbary St.
61-866 Poznań
e-mail marta.bogusz@wco.pl

SUMMARY

BACKGROUND: On 24 December 2002, in compliance with Euratom Directive 97/43, the Minister of Health issued an ordinance on rules and regulations of safe application of ionising radiation for medical purposes and methods of internal control over observance of the rules and regulations. The ordinance obliges managers of institutions which apply ionising radiation for medical purposes (radiotherapy, X-ray diagnostics, nuclear medicine) to implement, maintain and develop the Quality Management System (QMS). On 25 August 2005, the Minister of Health issued an ordinance on rules and regulations of safe application of ionising radiation with reference to all types of medical exposure which overruled the ordinance of 24.12.2002.

AIM: The purpose of this paper was (i) the comparative analysis of the aforementioned ordinances in the context of three selected aspects: internal audits, external audits and the system of quality management, and (ii) the analysis of the rise in labour costs, services, depreciation and materials in 2002–2005, as a result of the implementation of the aforementioned legal rules and regulations.

MATERIALS AND METHODS: A comparative analysis of the two a fore mentioned ordinances of the Minister of Health was performed: concerning (i) external clinical audits, (ii) internal clinical audits and (iii) requirements of the quality management system. The total cost of implementation of such rules and regulations (in particular the cost of the Quality Management System) has been calculated based on an analysis of labour costs, depreciation, materials and services in 2002–2005.

RESULTS: Legislative changes in the scope of safe application of ionising radiation for medical purposes enhance not only the organisation of health care institutions applying radiotherapy, but also the rise in costs of the organisations as a result of implementation of the changes, e.g. through (i) the costs of salaries for work groups or consulting companies implementing QMS, (ii) costs of external services, dosimetric audits by independent calibration laboratories, (iii) costs of QMS certification, (iv) awards and bonuses for internal auditors, (v) costs of service contracts, etc.

CONCLUSIONS: The implementation of the quality management system, modernisation of technical infrastructure, systematic controls and measurements of apparatuses and procedures, more effective work organisation, repeatability, regularity and homogeneity not only enhance the quality of medical service, but also the costs in radiotherapy.

KEY WORDS: cost, radiotherapy, quality

BACKGROUND

During the last few years radiotherapy quality assurance and control has become an issue arousing stronger and stronger interest among representatives of Polish government agendas, as well as managers of health care institutions.

The obligation to elaborate and implement a system of quality management or a quality assurance programme defined as a system of activities ensuring a required standard of radiological care and efficiency of the process of radiotherapy treatment was introduced to Polish law by virtue of Art. 7, clause 2 of the Atomic Law Act of 29 November 2000 [1, 2, 3, 4, 5, 6].

The incident in Białystok[1], which took place in February 2001 made the state authorities and organisational units management who applied radiotherapy conscious of the seriousness of the situation and the necessity to adjust their activities in units they managed to current quality standards concerning radiological safety.

As a result the Ministry of Health undertook the following activities:

1. Commissioning the State Consultant of Oncological Radiotherapy to prepare a General Outline of a Long-Term (until 2010) Governmental Research and Implementation Project in the scope of Improvement of Quality and Accessibility of Medical Services Applying Ionising Radiation and the Radiological Protection of Patients and Personnel. The project would contain information on the state of Polish radiotherapy, the needs of oncological centres, personnel education and training, as well as development plans as to radiotherapy infrastructure, and modernisation and replacement of equipment.

2. By virtue of the Ordinance of the Minister of Health of 16.11.2001, the appointment of a Team of Experts responsible for the implementation of 97/43 Euratom Directive in the scope of personal protection against ionising radiation applied in medicine in compliance with Polish law. [7] The result of research conducted by the Team was a Directive elaborated and introduced on 24.12.2002 which concerned the rules and regulations for safe application of ionising radiation for medical purposes and the method of internal inspection over their observance (Official Gazette, No. 241, item 2098).

On 25 August 2005, another directive on rules and regulations of safe application of ionising radiation for any and all types of medical exposure was published. The directive provided a detailed description of the issue of the quality management system in radiotherapy and overruled the directive of 24 December 2002.

AIM

The Directive of 25 August 2005 is an accurate

[1] On 27.02.2001 malfunction of a Neptun 10P accelerator occurred. The reason for the malfunction was a fall in electric wiring voltage. Since analogical incidents took place before and allegedly did not trigger any change in parameters of the radiation beam (entries in inspection documentation were not conducted regularly, thus there was no reliable or comprehensive evidence that would confirm any inspection of the apparatus parameters periodically or temporarily in the case of the aforementioned incidents), on restoration of the voltage the treatment was carried on. As a result of no procedural actions being taken in the case of this incident, an overdose of radiation was applied in the treatment of 5 female patients.

Table 1. Comparative analysis of the ordinance of the Minister of Health of 24.12.2002 and the ordinance of the Minister of Health of 25.08.2005

Area under analysis	The ordinance of MH 24.12.2002	The ordinance of MH 25.08.2005
Clinical External audits	General rules and regulations of conducting an external audit (app. 13 Item 10.2)	Detailed rules of conducting a clinical external audit (§ 45)
	Type of audit: – periodical (once in 2 years), – comprehensive, – selective	**Type of audit:** – periodical (once in 3 years), – comprehensive, – selective.
	Scope of audit: – audit of procedures (technical, physical, therapeutic, dosimetric); – safe application of ionising radiation, including radiation beam dosimetry (conducted in compliance with the document of quality control system in radiotherapy The Document is introduced by the manager of an institution, in other words, the schedule, form, scope and regulations of audits are specified by the manager of institution (item 8, app. 13 And item 9 app. 13)	**Scope of audit:** – audit of procedures; – dosimetric audit.

Table 1. Cont.

	Detailed scope of audit procedures: 1. Qualification for radiation treatment; 2. Defining the scope of treatment 3. Positioning and immobilisation of a patient on a therapeutic table; 4. Radiotherapy simulation; 5. Radiotherapy planning (technique, principles of fractionation); 6. Radiation charts, pateints' records; 7. Radiation treatment implementation.	**Scope of audit:** – conformity of preformed procedures with the standard procedures, – correctness of evaluation of the condition of the patient, diagnosis, qualification to radiotherapy; – correctness of medical documentation, records (treatment plans, irradiation charts, equipment control charts), – control protocols of physical and techical parameters of therapeutic machines and schedules of equipment control, – validity of calibration certificates of dosimeters – techniques and methods of dose fractionation, – correctness of determination of geometrical fields, (target volume, organs at risk), – correctness of simulation, – correctness of 2D or 3D dose distribution, – performance of in vivo dosimetry, – results of internal tests of physical parameters of radiological equipment, – following lawful regulations, – the fulfillment of requirements resulted from previous internal or external clinical audit
	Responsibility (item 10.3 App. 13) – audits are conducted on special instruction of a proper Minister of Health by a team appointed by the Minister – on the initiative of the manager of the institution – on order of a provincial/state consultant within one of the european programmes – in case of radiation or radiotherapy incident a state oncological radiotherapy consultant orders an immediate external audit to be conducted in order to discover the reasons for and prevent future cases of radiation incidents (§ 49. 1)	**Responsibility:** – (§ 45. 1) For organisation and supervision – an oncological radiotherapy committee (a committee of procedures and external clinical audits of oncological radiotherapy) – § 45. 3. For conducting a clinical audit of procedures – audit team appointed by the committee of an oncological radiotherapy specialist and medical physicist, and, in justified cases, a medical engineer – § 49. 2. In case of radiation incidents or accidents a state oncological radiotherapy consultant orders an immediate external audit to be conducted in order to discover the reasons for and prevent future cases of radiation incidents
	The ordinance does not regulate the following matters: – explicit responsibility for external audits, – duty of reporting, – necessity of undertaking corrective or preventive measures in case of any non-conformities, – detailed rules of conducting an audit, – no execution proceedings in case of a failure to fulfil a duty to conduct audits or initial audit data verification proceedings, – no date of external audit determined. Any decisions regarding audits are taken by the institution manager by virtue of the QC document.	**The ordinance regulates:** – responsibility for supervision, organisation and conducting external audits (§45. 1), – duty of accounting and reporting: § 45. 5. Audit statement is submitted to the committee, the manager of a health care institution under audit and proper provincial oncological radiotherapy and medical physics consultants who supervise the process of following instructions of auditors, – necessity of undertaking corrective or preventive measures in case of any non-conformities, – detailed rules of conducting an audit, – audit data verification proceedings and execution proceedings in case of a failure to fulfil a duty to conduct audits, – date of external audit determined. According to § 59. 2 Until 31 december 2009.

Table 1. Cont.

Dosimetric external audits	**The ordinance does not regulate** It introduces a sole necessity of implementation of beam dosimetry audit (§ 53. 1) Realised by a team appointed by a proper health minister and does not specify the details of its implementation.	In § 45. 2 External clinical audit divides into: – audit of procedures, – dosimetric audit (annual) (§ 45. 7) Scope and term of the audit is announced to radiotherapy institutions at one year's notice. (§ 45. 8) Attendance required. (§ 45. 9) Conducted by laboratories that are part of IAEA and WHO networks or other laboratories accredited in the area of calibration.
Clinical internal audits	**Method:** Realised in the case of each patient in accordance with the protocol of audits	**Method:** § 9. 1 item 8 on the basis of internal clinical audits entered into QMS in radiotherapy
	Scope: Identical as in the case of external audits	**Scope:** Identical as in the case of external audits
	Responsibility: Employees appointed by the institution manager who are not directly involved in one or other stages of radiotherapy planning and implementation (app. 13 Item. 10.1)	**Responsibility:** The health care institution manager appoints an audit team of a radiotherapy specialist and a medical physicist, as well as a medical engineer if necessary (§ 44. 2).
	The ordinance does not regulate – frequency, – reporting, – term of internal audits implementation in the institution	**The ordinance regulates:** Frequency – at least once a year, on the written request of the health care institution manager (§44.1) **Reporting:** Reports include results of internal clinical audits and corrective and repair actions (§ 9. 1 item 9) – term of internal audits implementation until December 2006 (§ 59. 1).
QMS internal audits	**The ordinance does not regulate**	Annual schedule of internal QMS audits, a report of the internal audit; internal audits procedure; frequency of audits – once a year (app. 5.1.11)
Quality management system requirements	Compulsory QMS implementation until 31 December 2004 Compulsory QMS certification until 31 December 2005	compulsory QMS implementation until 31 December 2006 Optional certification
	QMS documentation contents (§ 9. 2) 1. Quality manual in conformity with PN-EN-ISO/IEC; 2. General procedures elaborated by virtue of norms; 3. Therapeutic protocols elaborated in compliance with requirements of the state radiotherapy consultant; 4. Radiological devices' operation manuals; 5. Information on results of preliminary and periodical tests of radiological and supporting devices; 6. Information on personnel qualifications and training; 7. Information on analysis of rejected test results and undertaken corrective and repair actions; 8. Information on periodical inspections of the system; 9. Standards of test result analyses. Additional obligation to keep a QC document – radiotherapy quality control system.	**QMS documentation contents (§ 9.1)** 1. Quality manual; 2. General procedures; 3. Therapeutic protocols elaborated in compliance with requirements defined in separate regulations; 4. Radiological devices' operation manuals; 5. Information on the method of testing of internal control of radiological and supporting devices' physical parameters; 6. Information on results of tests of internal control of radiological and supporting devices' physical parameters and acceptance tests; 7. Information on personnel qualifications and training; 8. Procedure of internal clinical audit; 9. Information on results of internal clinical audits and undertaken corrective and repair actions; 10. Information on periodical inspections of quality management systems; 11. Standards of test result analyses and following measures, as well as other documentation.

Table 1. Cont.

	Responsibility: A team appointed by the institution manager of at least two radiotherapy specialists, two medical physicists and one senior radiotherapy technician. No position of QMS manager Requirements of quality management and control system procedures are defined by appendix no. 13 To the ordinance (1 page)	**Responsibility:** Institution manager QMS manager General and detailed radiotherapy quality management requirements: I. General requirements II. Detailed requirements of radiotherapy quality management (teleradiotherapy and brachytherapy) are referred to in Appendix no. 5 To the ordinance (7 pages)

Table 2. Total cost of implementation of quality management system in 2002–2005 in thousands of US$ as exemplified by The Greater Poland Cancer Centre

Cost category	Specification	2002	2003	2004	2005
Labour cost	a part-time job (1/3) of a quality division manager	3.66	5.67	6.28	9,63
	Radiotherapy quality team (11 persons x 5h x 12 months)	7.11	9.38	9.53	9,91
	Creation of a position of coordinator of technicians' work (2 positions)	0.00	0.00	27.56	29,33
	Quality and logistics specialist	0.00	0.00	0.00	10,46
	QMS internal audits	0.00	1.23	1.23	1,64
	Quality Control Checks of medical documentation and radiation (5000 patients x 3 verifications x1 position of a physicist)	0.00	25.61	26.64	27,97
	Internal clinical audit (a radiotherapist and a physicist)	0.00	0.00	0.00	0,36
	External dosimetric audit (calibration laboratory IAEA or WHO) – once a year	0.00	0.00	0.00	0,18
Services	training in ISO 9001:2000 norm interpretation (2 persons)	0.00	0.71	0.00	0,00
	Training for auditors of internal ISO 9001:2000 norm (5 persons)	0.00	1.94	0.00	0,00
	Training for QMS attorneys of ISO 9001:2000 norm (3 persons)	0.00	1.35	0.00	0,00
	System certification performed by RQA unit	0.00	3.06	0.00	0,00
	Testing audit of a certifying unit (twice a year)	0.00	2.90	2.90	2,90
	Consulting services – current system audit	3.77	0.00	0.00	0,00
	Consulting services – trainings	3.71	0.00	0.00	0,00
	Consulting services – system documentation elaboration	3.81	0.00	0.00	0,00
	External clinical audit	0.00	0.00	0.00	3,23
	Equipment service (accelerators, planning system simulators)	657.97	681.94	667.61	675,66
	Elaboration and implementation of a module for ISO system documentation	0.00	0.00	0.00	0,97
Permanent measures	equipment depreciation in radiotherapy institution	572.56	681.98	1 537.32	1 876,12
Materials	replacing "white" polystyrene with "blue" one, price difference per 1 m^2 25.62, Annually ca. 50 M2 is used	1.28	1.28	1.69	1,69
	Costs of documentation-related office supplies	0.97	1.61	1.29	1,29
Total		1 254.84	1 418.67	2 282.05	2 651.32

guide to implementation of the system. It analyses in depth the rules which apply to keeping medical documentation of the radiation process, internal and external audits, and proceedings in case of radiation incidents, as well as being a collection of guidelines regarding implementation and maintenance of QMS in radiotherapy.

MATERIAL AND METHODS

With a view to examining the influence of legislative changes on the quality and costs in radiotherapy, a comparative analysis of the two following reulations has been carried out: -1) of 24 December 2002 on rules and regulations of safe application of ionising radiation for medical purposes and the method of internal control over their observance and 2) of 25 August 2005 within: (i) external clinical audits, (ii) internal clinical audits and (iii) requirements of the quality management system (Table 1).

The total cost of implementation of the regulations (in particular the Quality Management System) was calculated based on the analysis of labour costs, depreciation, materials and services in 2002–2005 (Table 2).

CONCLUSIONS

Legislative changes in the scope of safe application of ionising radiation for medical purposes not only enhance the improvement of organisation of health care institutions which apply radiotherapy, but also the rise in costs of institutions as a result of implementation of the changes, e.g. through:

– the rise in depreciation costs of modernisation and the purchase of new, highly specialist equipment,
– the rise in costs of service of specialist equipment due to the growing number of annual services (from 4 to 6),
– the rise in salaries due to the payment of awards and bonuses for conducting internal audits, creating new working positions (e.g. Quality Specialist, Coordinator of Technicians' Work, QMS Manager), creation of work groups, extending the scope of duties (e.g. audit, medical documentation and apparatus control),
– the rise in costs of external services (e.g. QMS implementation by consulting companies, dosimetric audits by independent calibration laboratories, external testing audits of certifying institutions),
– costs of QMS certification by certifying institutions (DEKRA, TÜV, LRQA, PCBC).

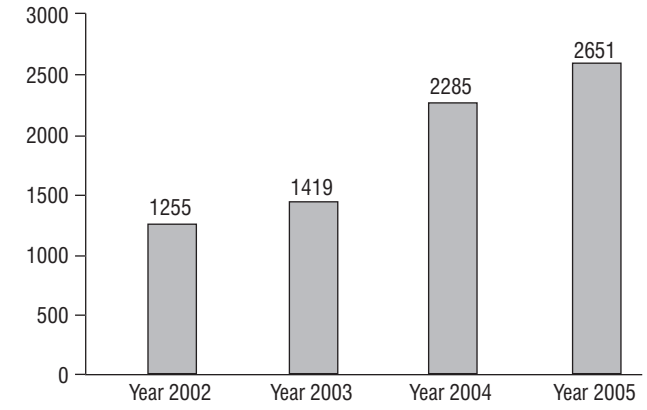

Fig. 1. The cost of QMS in radiotherapy in 2002–2005 in thousands of US$

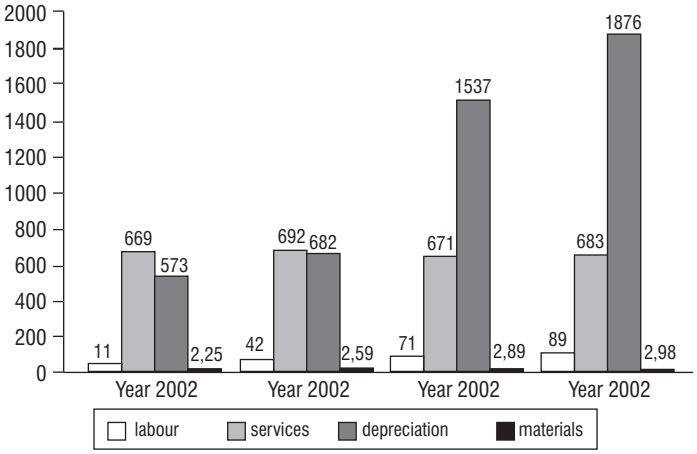

Fig. 2. Costs of labour, services, depreciation and materials resulting from QMS implementation in 2002–2005 in thousands of US$

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