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# The role of the Polish Secondary Standard Dosimetry Laboratory in view of the requirements of the EC Directive 97/43 Euratom

Barbara Gwiazdowska, Wojciech Bulski

Motto: *„The research should concentrate on radiation energy deposition in materials similar to biological tissues and in tissues themselves. It should also concentrate on metrology matters which leaves much to be desired"*
Maria Skłodowska-Curie

*The aim of this paper is to present the history and experience of the Polish SSDL (Secondary Standard Dosimetry Laboratory). It also presents the propositions in the domain of quality assurance in radiotherapy in Poland, as fulfilling the requirements of the Directive 97/43 Euratom on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, which is obligatory for the countries of the European Union.*
*It has been pointed out that there are, among other provisions, two concepts concerning the quality assurance in application of radiation in medicine, mentioned by the Directive, a) inspection and b) clinical audit, which should be implemented by the Member States. In the process of establishing and implementing the Directive confusion may appear as to the difference between the two concepts of external audits. The role of the SSDLs in carrying out external dosimetry audits is presented. The history of the establishment of the Polish SSDL (Secondary Standard Dosimetry Laboratory) and its inclusion into the international network of laboratories coordinated by the International Atomic Energy Agency and the World Health Organization is presented as well as the resulting advantages, obligations and perspectives for further activities.*
*The main activities of the Polish have been presented, namely maintaining a data-base on the radiotherapy infrastructure in Poland, preparation of recommendations on dosimetry procedures and quality control, calibration of dosimeters, external postal quality audits of dosimetry, etc. These activities are illustrated with the results from the period 1991-2003.*
*Based on the solutions and results presented in this paper, the authors conclude that the Ministry of Health should grant the Polish SSDL with a suitable legal status for carrying out external audits nationwide, especially since, according to the Directive 97/43, clinical audits in radiotherapy have to include dosimetry audits.*

## Rola Polskiego Laboratorium Wtórnych Wzorców Dozymetrycznych w świetle wymagań Dyrektywy 97/43 Euratom Komisji Europejskiej

*Celem pracy jest przedstawienie dotychczasowej działalności Laboratorium Wtórnych Wzorców Dozymetrycznych i perspektyw dalszej jego działalności w dziedzinie zapewnienia jakości w radioterapii w Polsce na tle wymagań Dyrektywy EC 97/43 EURATOM, która obowiązuje kraje Unii Europejskiej, a dotyczy ochrony zdrowia ludności przed zagrożeniami wynikającymi z zastosowania promieniowania jonizującego do celów medycznych.*
*W pracy zwrócono uwagę na fakt, często błędnie interpretowany, że Dyrektywa wyróżnia dwa systemy: a) system inspekcji i b) system auditów – pomyślanych jako audity zewnętrzne. W pracy przytoczono opinie środowisk międzynarodowych o trudnościach w międzynarodowej unifikacji procedur dotyczących auditów oraz o roli jaką w tym zakresie (zwłaszcza w zakresie auditów dozymetrycznych) odgrywają Laboratoria Wtórnych Wzorców Dozymetrycznych.*
*Opisano historię powstania w Polsce Laboratorium Wtórnych Wzorców Dozymetrycznych (LWWD) i jego włączenia do międzynarodowej sieci laboratoriów, których funkcjonowanie jest koordynowane przez Międzynarodową Agencję Energii Atomowej i Światową Organizację Zdrowia, oraz wynikające stąd korzyści, obowiązki i perspektywy dalszego rozszerzenia działalności.*

Department of Medical Physics
Maria Sklodowska-Curie Memorial Cancer Center
and Institute of Oncology, Warsaw, Poland

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*Przedstawiono działalność LWWD w zakresie tworzenia bazy danych dotyczących infrastruktury i wyposażenia ośrodków radioterapii, przygotowania zaleceń dozymetrycznych, szkoleń fizyków oraz w szczególności kalibracji dawkomierzy terapeutycznych i przeprowadzania dozymetrycznych auditów zewnętrznych, z zastosowaniem detektorów termoluminescencyjnych i metody wysyłkowej. Działalność w zakresie kalibracji dawkomierzy ilustrują wyniki przeprowadzonych ostatnio pomiarów w wodzie i w powietrzu. Działalność w zakresie auditów dozymetrycznych zilustrowano wynikami za lata 1991-2003.*
*Na podstawie rozważań i wyników przedstawionych w pracy autorzy wnioskują, aby Ministerstwo Zdrowia nadało polskiemu LWWD legalny status na prowadzenie dozymetrycznych auditów, zwłaszcza, że audity kliniczne w radioterapii muszą, zgodnie z Dyrektywą 97/43, obejmować audity dozymetryczne.*

**Key words:** radiotherapy, dosimetry, audit, quality assurance
**Słowa kluczowe:** radioterapia, dozymetria, audit, zapewnienie jakości

## Introduction

Over the last years, the use of ionizing radiation in medicine has been a subject of extensive regulation as far as the radiological protection of patients is concerned.

The Council of the European Union having regard to the Treaty establishing the European Atomic Energy Community stressed in the Directive 97/43/EURATOM the responsibilities regarding individual medical exposures [1]. There are, among other provisions, two concepts concerning the quality assurance in application of radiation in medicine, mentioned by the Directive, inspection and clinical audit, which should be implemented by the Member States. In the process of establishing and implementing the Directive confusion may appear as to the difference between the two concepts. Some procedures for inspections and clinical audits may be in many situations similar, while the basic criteria used, the interpretation of the results, and authorities who apply them in practical situations are quite different [2].

In the Directive, inspection is defined as follows: *"Inspection is an investigation by any competent authority to verify compliance with national provisions on radiological protection for medical radiological procedures, equipment in use or radiological installations"*, and *"Member states shall ensure that a system of inspection enforces the provisions introduced in compliance with this Directive."*

In order to fulfil this requirement the relevant regulations should be established and monitoring should be conducted by appropriate authorities to determine whether radiation sources and methods are being used in accordance with the requirements. The most valuable element of compliance monitoring is on-site inspection. The purpose of the inspection is to verify that various detailed requirements for radiation protection are being met.

Two methods of verification can be used:

- assessments of documents, e.g. quality manual and documents being part of it, (QA – Quality Assurance programs, QC – Quality Control documents, safety guidelines, procedures, instructions, etc);
- verification measurements carried out by, or on behalf of the authority by persons (inspectors) who are fully independent from the controlled institution, and use methods as independent as possible from the methods applied in the institution. The verification measurements require high technical competence of the inspectors, thus outside experts may be used in some cases. The inspections should never replace any QC checks or measurements that are prime responsibilities of the controlled institutions. The non-compliance with specified conditions and requirements must lead to enforcement actions by the authority. The inspector may impose corrective requirements to the institution on the spot.

A clinical audit is defined in the Directive as: *"Systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care trough structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and application of new standards if necessary"*.

Although the notion "audit' is not new [3], introducing the "clinical audit" into the Directive 97/43 is a concept of high importance for the improvement of the quality of radiological medical procedures. According to the Directive: *"clinical audits shall be carried out in accordance with national procedures"*. The procedures of the implementation of a Clinical Audit are either in a planning stage or have already begun in the Member States, and it is to be expected that procedures will vary from country to country, as clinical audit mechanisms are still under development throughout Europe, and each country adapts the requirements of the Directive to local circumstances. It is stressed that technology can play an important role in developing and harmonizing radiation protection strategies in Europe. The member states thus have much freedom in interpreting what the contents and practical organization of these procedures should be [4-6].

According to the ISO quality system there are two kinds of audits: internal and external [7]. By "internal audits" all systematic self-assessments carried out by the institution are understood. The general understanding of the concept "external audit" implies that the review or assessment is carried out by auditors independent of the institution (department, laboratory at the institution) to be audited, i.e. the auditors should not be responsible for the procedures to be assessed. In ideal situation the audit should cover all steps of a complete radiological procedure (comprehensive audit). In reality, as a first

step, the weakest points in the chain of this procedure should be determined and thoroughly examined (partial audit). It is also part of general understanding, that the auditors have no power to enforce any actions or requirements on the basis of their findings. Their role is simply to produce an independent assessment, report the findings and recommendations to the head of audited institution, and leave him to decide on actions necessary for the findings. It is assumed to reduce the effort and intensity of inspections when an intensive and comprehensive system of clinical audits is established and well functioning.

Different approaches and different standards are used in different domains: radiological protection of workers (staff), radiological protection of patients in radiodiagnostics, and in radiotherapy (different for tele- and brachy-radiotherapy).

Radiological protection of the radiotherapy patient encompasses the achieving of the objective of the treatment, i.e. ensuring that the target tissue is given the prescribed dose while minimising the dose to surrounding healthy tissues and critical organs. The success or failure of radiotherapy depends upon the accuracy of dose delivery. The accuracy of dose delivery, which is a complex procedure (involving the determination of the doses, localisation of the tumour, treatment planning, and irradiation of the patient) depends on many factors, and is a major problem in radiation therapy. The organization of audits requires the elaboration of a suitable methodological approach, the determination of acceptable tolerance levels and standards for individual parameters which contribute to the cumulative effect of radiotherapy procedures. Criteria used when performing audits should be explicit, related to the important aspects of patient care and, if possible, these criteria should be measurable. It has been widely recognized that beam calibration (determination of the doses in reference conditions) is a key factor in reducing overall uncertainty, and that metrology institutions, such as Secondary Standard Dosimetry Laboratories (SSDLs) are usually competent in carrying out these procedures [8]. Teletherapy dosimetry audits have been widely performed by several national and international organizations covering approximately 60% of radiotherapy centres. The International Atomic Energy Agency (IAEA) together with the World Health Organization (WHO) have been performing postal audits using thermoluminescence dosimetry (TLD) since 1969. The European Society for Radiotherapeutic Radiology and Oncology (ESTRO) has set up a TLD postal dosimetry programme EQUAL (European Quality Audit Laboratory). About 3000 photon and electron beams have been checked since 1998 when the service started [6]. At present, the IAEA is in process of preparing the audit teams for testing and implementing the methodology developed for a comprehensive clinical audit and it will soon be able to respond to the demand of its Member States in this domain [9].

In Poland, the Parliamentary Act – "Atomic Law" [10] is being updated so that it will be in concordance with the Directive. According to this act, the designated inspectors of suitable national authorities will be responsible for carrying out inspections in radiotherapy departments.

The aim of the paper is to present the experience of the Polish SSDL, and to present the propositions in the domain of quality assurance, including external audits, in radiotherapy in Poland, as fulfilling the requirements of the Directive 97/43 Euratom.

**Historical background**

The Medical Physics Department (MPD) of the Centre of Oncology in Warsaw has a long tradition in controlling and supervising other institutions or performing the measurements for them. In 1937 the "Laboratory for Roentgen Rays Calibration" and the "Laboratory for Radioactivity Measurements" were created (as a part of the Physics Department), following the suggestion of Maria Skłodowska-Curie, the founder of the Institute. The scope of their activity was recommended in the Official bulletin of the Ministry of Social Assistance [11].

From 1940 to mid 1944, when scientific activity was forbidden under the German occupation, only the Laboratory for Roentgen-Rays Calibration was operational and the activity limited to measurements in hospitals and other medical establishments. According to the reports of C. Pawłowski (first head of the MPD), the Laboratory performed 642 measuring procedures ordered by external institutions, from 1937 till the end of the war [12].

In 1951, the Ministry of Health requested the creation of the Central Laboratory for Radiological Measurements in the MPD, which operated till 1960. During this period the Laboratory performed over 100 calibrations of radiotherapy dosimeters using a Victoreen dosimeter, granted by the UNRRA (United Nations Relief and Rehabilitation Administration). The dosimeter had an American certificate as the Secondary Standard. The Laboratory also performed about 200 measuring procedures for radiotherapy machines (dose rates in various configurations of high voltage, current, filters, half value layers, etc.) in other institutions, and about the same number at the Institute of Oncology. It controlled the leakage of radium tubes, radiation protection of rooms and personnel (till late fifties, when the new institution – the Laboratory for Radiological Protection was created and took over the duty of radiological protection measurements), and evaluated dosimetry methods and instruments [13]. For unknown reasons the Ministry of Health stopped this very important activity, in 1960.

When the first cobalt units were installed in Poland, it was clear that dosimetry became very important task not only from the point of view of accuracy but also from the point of view of greater probability of radiation accidents. In this situation, in 1966, the Ministry of Health

together with the Central Office of Measures, created the Secondary Standard Dosimetry Laboratories in 3 branches of the Institute of Oncology (Warsaw, Gliwice, Cracow). After a few years, the high cost of the equipment and lack of dedicated personnel limited the number of Laboratories to one (in Warsaw). The main duty of the Laboratory at that time was the calibration of radiotherapy dosimeters for the whole country.

In 1988, at the recommendation of the Central Office of Measures this SSDL was incorporated into the IAEA/WHO Network of SSDLs. (Membership in the network is open only to laboratories designated by appropriate national authorities). Apart from calibration of radiotherapy dosimeters, which constitutes its main duty, the SSDL meets most of the requirements and recommendations of the IAEA, especially those connected with external audits in radiotherapy.

In 1999, a Mutual Recognition Arrangement (MRA) was signed by representatives of national Metrology Institutes and the representative of the IAEA/WHO Network. According to an editorial note in the SSDL Newsletter [14]: *"An essential element of this agreement is the concept of the equivalence in measurements and comparability of national metrology services. The signing of the MRA places metrology of ionizing radiation in those countries having a laboratory member of the IAEA/WHO Network of the SSDLs at the level of international recognition, allowing for the worldwide mutual recognition of their national measurement standards and of the calibration and measurement certificates issued by their laboratories. This, naturally, imposes strict demands on the performance of the SSDLs, and will require a thorough review of the conditions of acceptability of results of the intercomparisons and quality audits organized by the Agency for the Network of SSDLs"*.

The Polish SSDL has been functioning for the whole period as a full member of the Network. To maintain the full membership the SSDL participates in quality audits established by the SSDL Network Secretariat [8], which include: (a) verification of radiation beam calibration procedure with TLD (results in Table I), and (b) verification of the SSDL calibration procedure with an ionization chamber.

**Table I. IAEA verification of the TLD calibrations performed by the SSDL**

A. Verification of the TLD calibration

| Year of irradiation | IAEA dose/SSDL stated dose for Co-60 | for X-15 MeV |
|---|---|---|
| 1994 | 1.00 | 1.02 |
| 1995 | 1.02 | 1.01 |
| 1996 | 1.00 | 1,01 |
| 1997 | 1.00 | 1.01 |
| 1998 | 1.00 | 1.00 |
| 1999 | 1.01 | 0.99 |
| 2000 | 0.99 | 1.00 |
| 2001 | 1.01 | 1.01 |
| 2002 | 1.00 | 0.99 |
| 2003 | 1.00 | 0.99 |

In almost all cases the difference between the doses measured at the SSDL and at the IAEA were below 1%, within the measurement uncertainty

## Present organization

The SSDL is incorporated into the structure of the MPD (Figure 1) and consists of three parts: the RTG Lab, the Co-50 Lab, and the TLD Lab.

The RTG Lab is equipped with:

– X-ray radiotherapy machine PANTAK with a PTS-Comet tube, generating X-ray beams in the range of 50-320 kV;

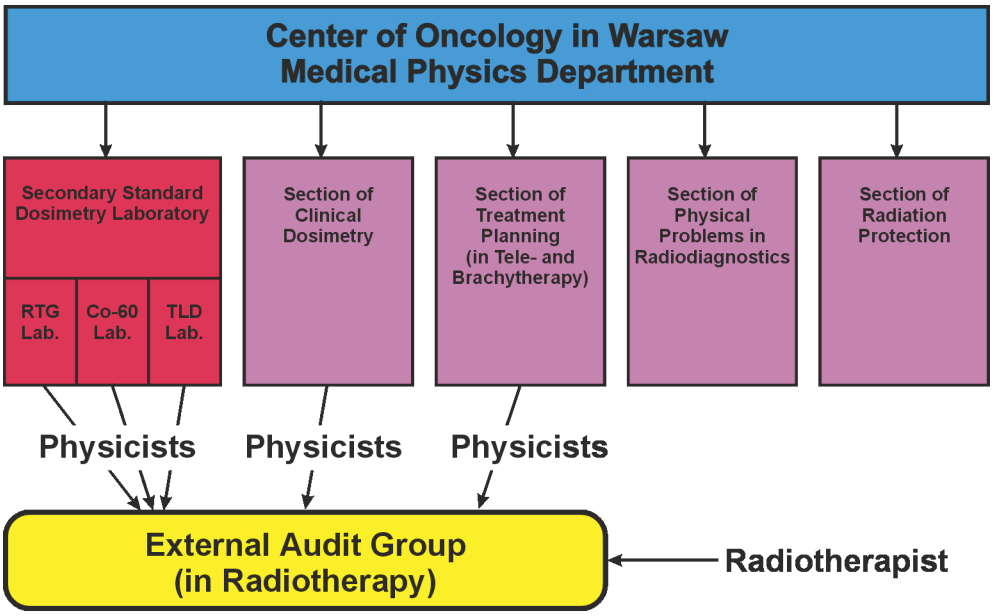


**Figure 1.** Organization of the SSDL, as incorporated into the structure of the MPD

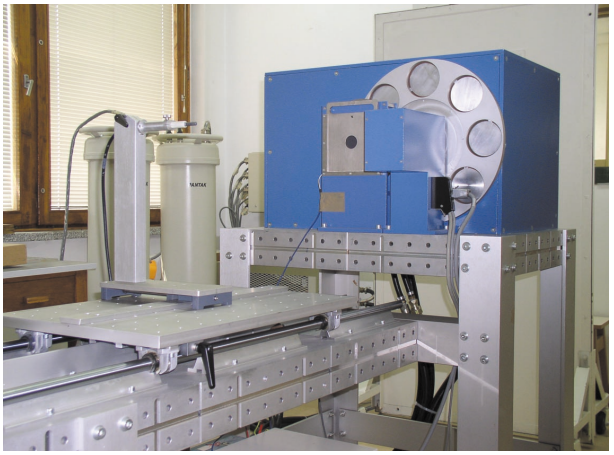

**Figure 2.** View on the installations in the RTG Lab. The measurement bench, rotational filter changer, and the chamber holders are seen in the forefront of the X-ray generator

– generator supplying a Varian OEG-50-2 tube for mammography calibration purposes;
– PTW – designed measuring cart for the positioning of the dosimeters (Figure 2);
– Keithley Electrometer type 6517A, with the chambers type NE 2571, used as a Secondary Standard Dosimeter.

The Co-60 Lab is equipped with:

– Theratron-780 unit with a Co-60 source of activity 3098 Ci (as of 01.01.2004);
– two Secondary Standard Dosimeters: Keithley Electrometers type 6517 and chambers type NE2571, NE2458 and NE2885;
– calibration measuring cart type IAEA-Heider System;
– water phantom type PTW 4322 (Figure 3).

The Theratron-780, decommissioned as a clinical unit, was installed for the SSDL purposes in 2002. All cylindrical ionization chambers are calibrated in its beam (earlier a Co-60 unit installed at the Radiotherapy Department was used). Only plane parallel chambers are now calibrated at the Radiotherapy Department in electron beam of a linear accelerator. The SSDL calibrates only these dosimeters, which have a valid certificate of type. The SSDL checks other types of measuring devices issuing a "measurement certificate" on request. The calibration procedure is performed according to the Standard PN-EN 60731 [15] and to the recommendations issued by the President of the Central Office of Measures [16].

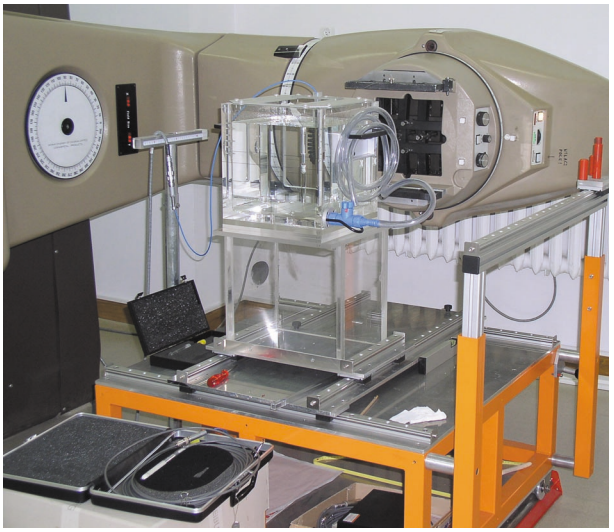

**Figure 3.** View on the installations in the Co-60 Lab. The measurement cart with designated water phantom and chamber holder in front of the Co-60 unit head

The TLD Lab is equipped with three TLD-readers:

– Harshaw B/C – Microlab,
– Laboratory Reader – Analyzer TL – RA94 (Poland), and
– PCL3-Fimel (France) – in operation since 2003.

The lithium fluoride (LiF) thermoluminescent virgin powder MT-F produced at the Institute of Nuclear Physics (Cracow, Poland), and waterproof plastic capsules from the IAEA are used for the audit purposes.

Apart from TLD readers, the laboratory is equipped with:

– reference-class Farmer dosimeter with an ionization chamber type NE 2571;
– reference-class Unidos dosimeter with Markus type chamber;
– two dosimetric film readers: Atrix Scan Microtek, and Lumiscan model 50/75 Lumisys Inc.; and
– Mosfet dosimeter reader – Thomson/Nielsen Mosfet 20 with detectors to be used in on-site audits.

Most of the equipment (measuring cart, water phantom, some of the dosimeters, Fimel TLD-reader) was supplied by the IAEA in the framework of a technical cooperation project (contract No POL/1/012). The film reader and mosfet detectors were acquired in the framework of a Research Contract of the State Committee for Scientific Research (No 6P05B 06721).

There is only one staff member, working full time for the SSDL – this person performs calibration of dosimeters; other staff members divide their duties between MPD and SSDL (if needed). Following the recommendation of the IAEA [17, 18], an External Audit Group in charge of TLD based quality assurance network in teleradiotherapy was established in 1999 (Figure1).

## SSDL activities

The main activities of the SSDL in the radiotherapy domain in Poland may be grouped as follows:

– collection of the data and up-dating of the radiotherapy infrastructure data-base;
– preparation of recommendations on dosimetry procedures and quality control;
– calibration of dosimeters;
– external postal quality audits of dosimetry;
– on-site quality audits;
– training of physicists and radiotherapists in order to adapt to the increasing complexity of modern radiotherapy procedures.

## Collection of data and up-dating of the radiotherapy infrastructure data-base

The establishment of a database on the infrastructure of radiotherapy in Poland is essential for the proper functioning of the SSDL, for obligatory action – calibration of dosimeters, and up to now for voluntary action – the audits. It also helps to asses the improvement in quality and adequacy of departmental equipment and staffing levels. The radiotherapy computerized database was created in 1993 (supported by a grant No 4.4048 92/C8222 of the State Committee for Scientific Research) and has been updated at the beginning of each year. The database contains information on radiotherapy treatment units, treatment planning systems, simulators, CT and MRI units, dosimeters, phantoms, and staffing levels.

In Poland, there are 69 teletherapy machines which generate about 220 different photon and electron beams. According to ESTRO each beam should be checked once every three years. This means that about 70 beams should be checked every year.

The distribution of radiotherapy machines in Poland, as of 01.01.2004, is presented in Figure 4. In Table II the equipment of teleradiotherapy departments (01.01.2004) is compared with the data of 1995 and 2000. Although some progress may be observed, Poland still belongs to a group of European countries with the smallest number of teleradiotherapy machines for every million of inhabitants.


**Figure 4.** Distribution of external radiotherapy units in Poland as of 01.01.04.

## Preparation of recommendations on dosimetry for radiotherapy

The recommendations worked out at the SSDL aimed at the implementation of them in every-day practice as guidelines for performing quality control and internal audits, by the staff of regional oncological centres. The following recommendations were published and distributed: recommendations for quality control of Co-60 units [19]; recommendations for quality control of linear accelerators [20]; recommendations for quality control of plane-parallel ionization chambers [21]; description of new dosimetric methods based on calibration of ionization chambers in water [22].

These recommendations cannot be imposed by the SSDL as obligatory, but some of them are being introduced into the regulations of the Ministry of Health (in preparation) and so they will become obligatory.

It should be mentioned that such recommendations are also prepared by other medical physics groups, e.g. the recommendations for quality control of brachytherapy equipment [23].

## Calibration of dosimeters

The SSDL performs in-air calibration of dosimeter and ionization chambers which are used in radiotherapy, at least every three years. Until the late 1980s, various dosimetry protocols were in use in Polish regional cancer centres, issued by following organizations: American Association of Physicists in Medicine – AAPM, International Atomic Energy Agency – IAEA, International Commission on Radiation Units and Measurements – ICRU, Nordic Association of Clinical Physicists – NACP. The differences in calibration coefficients, applied in various protocols, were investigated by the SSDL [24]. At present, only the IAEA protocols are used. This minimizes the differences between the results. Until 2003 the calibrations were performed in air (the Co-60 exposure calibration coefficient was determined and then air-kerma and absorbed dose to water calibration coefficients were calculated), according to the dosimetry protocol IAEA-TRS 277 [25]. Since the beginning of 2003, the calibration is performed both in air and in water

**Table II. Basic equipment at teleradiotherapy departments in Poland**

| Year | TRT centres | Co-60 units | Accelerators | Number of X-ray units | Simulators | TPS | Dosemeters |
|---|---|---|---|---|---|---|---|
| 1995 | 18 | 27 | 23 | 22 | 17 | 19 | 47 |
| 2000 | 21 | 22 | 43 | 9 | 30 | 45 | 64 |
| 2004 | 22 | 19 | 50 | 4 | 32 | 48 | 66 |

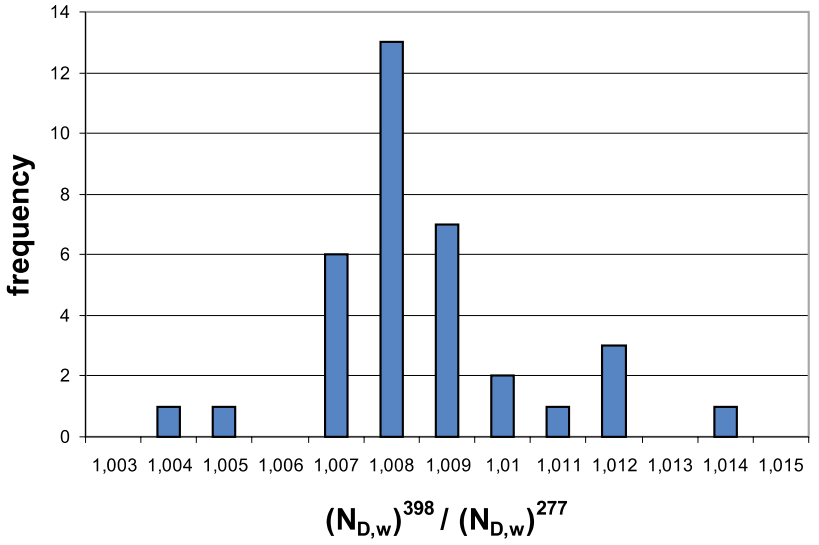


**Figure 5.** Distribution of the ratios of the calibration coefficients determined according to the IAEA protocols 398 and 277

(according to the recommendations of the IAEA) [26]. In the case of in water calibration the dosimetry protocols IAEA-TRS 398 [27] and IAEA-TRS 381 [28] are used, and the calibration coefficient to water is given to the user. In the orthovoltage range the system linearity and energy characteristics are determined [29]. The accuracy of the calibration coefficients evaluated by the SSDL is less than 3% (3 SD) for Farmer type chambers. The SSDL calibrates above 30 cylindrical chambers and above 10 plane-parallel chambers annually. In Figure 5 the distribution of the ratios of the calibration coefficients according to TRS 398 to those according to TRS 277 protocol is shown. Dose determination using TRS 398 gives coefficients up to 1% higher than those according to TRS 277. This is confirmed by other authors [30]. This may result in the dose given to the tumour being 1% lower than the prescribed dose.

The SSDL also calibrates chambers used for brachytherapy: (a) in orthovoltage X-ray beam (high voltage = 290 kV, HVL = 4 mm Cu), and (b) in Co-60 beam. Calibration coefficients for these two beams agree within 0.1–0.2%.

## External postal quality audits of dosimetry

External postal quality audits of dosimetry proved to be a very effective means of assuring the quality of an extremely important part of radiotherapy process. Most of such audits are performed using TLD detectors. In such investigations each radiotherapy centre taking part in the audit is provided with waterproof plastic capsules filled with LiF virgin powder. The participants are asked to irradiate the capsules to the prescribed dose in the conditions presented in detail in the instructions. At nearly the same time the SSDL irradiates the TLD capsules to the same dose, whose signal serves as the reference. In order to assure measurement accuracy, the investigation of the TLD system parameters is performed whenever any step of the procedure is changed (a reader is replaced, or the new batch of LiF powder is used) [31, 32]. A difference of ±3.5% between the dose reported by the participant and the dose measured by the SSDL is considered acceptance level (this also constitutes the intervention level). This value is consistent with the IAEA rules concerning audits of the SSDLs [33]. The adoption by the Polish SSDL, of an intervention level as low as ±3.5% was possible due to a relatively small number of radiotherapy centres and to an easy contact with them. Every centre which participates is identified be a code and all results are confidential.

The first study of TLD postal dose inter-comparison in Poland was organised by the SSDL in 1991 (supported by the IAEA, research contract No 6013/RB) [34, 35]. In 1994, the Polish SSDL joined the *pan-European Radiation Oncology Project for Assurance of Treatment Quality (EROPAQ)*. The SSDL participated in the organisation of the EROPAQ, taking responsibilities of the organisation of the audit in Poland, clearing up the deviations of the results beyond acceptance levels, undertaking corrective actions, and helping to re-measure and recalculate the doses when necessary [36, 37]. In 1999, the SSDL organised a third postal dose inter-comparison program for radiotherapy centres in Poland (supported by the IAEA, research contract No 10796/RO) [38, 39]. In all these 151 audits the doses were determined by the participants with an ionization chamber in reference conditions.

In Figure 6 distribution of deviations between the doses measured by the SSDL and the dose stated by the participants for those 3 runs are shown. All deviations beyond ±3.5% (19 cases out of 151) were analysed. Quite often it was very difficult to find a clear explanation. Most errors could be related to the incorrect geometry set-ups, insufficient care taken during the TLD irradiation, and especially in the first years, to the misinterpretation of the dosimetry protocol. Calculation errors were also common. In few cases there were problems with machine

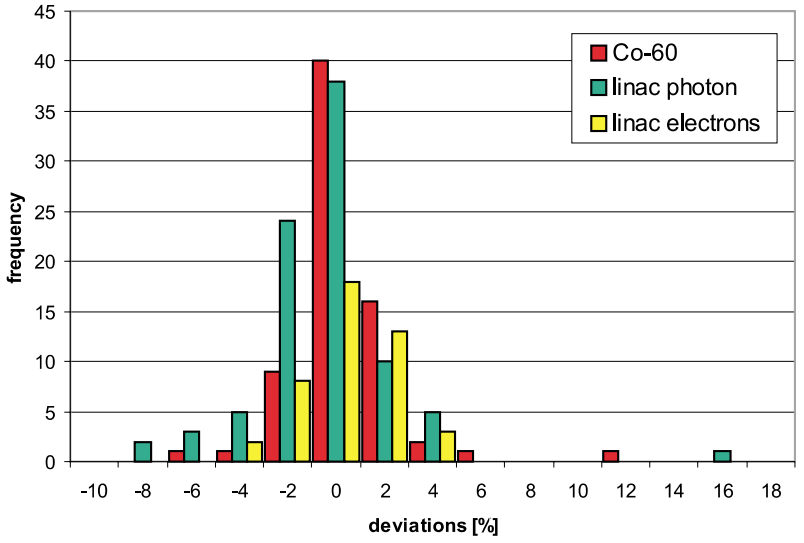


**Figure 6.** Distribution of deviations between the doses measured by the SSDL and the doses stated by participants (1991-2003)

performance, e.g. accelerator instability. It was extremely difficult, but in same cases possible, to estimate the number of patients, which could be improperly irradiated. The explanation of the deviations are given in other publications [35, 39]. Subsequent audits, started since 2001, include dosimetry checks of radiation beams in more complicated situations, e.g. encompassing the estimation of the dose by the radiotherapy treatment planning systems (TPS), measurements in non-reference conditions, in multileaf collimator (MLC) fields, etc., from which additional errors may originate. A number of such TLD audits have already been performed (Table III) and the parameters of the distribution of the results are given in Table IV.

**Table III. TLD postal audits performed by the SSDL at teleradiotherapy departments in Poland**

| Year | Number of beams audited in reference conditions for: | | |
|---|---|---|---|
| | Co-60 photons | Linac photons | Linac electrons |
| 1991-1993 | 11 | 11 | 12 |
| 1994-1995 | 32 | 24 | |
| 1999-2000 | 12 | 17 | |
| 2001 | **16** | | 32 |
| 2002/2003 | | **36** | |

The absorbed dose values were measured with ionization chambers, except for numbers in bold, when the absorbed dose values were determined by treatment planning systems.

## On-site quality audits

On-site quality audits have so far been carried out mainly during preparatory stages of the multi-centre prospective clinical trials. Such audits require teams of highly qualified experts who visit the audited centre and during several days check a number of parameters of various radiotherapy equipment. This generates high costs. Only radiotherapy simulators have been controlled and a verification of treatment plans (using mosfet detectors) has been performed in some centres up to now. Unfortunately these interesting results were not included in the publications of the results of the trials. Nevertheless they gave some indication as to the future development of the on-site audits.

## Training

The training of medical physicists is organized in a way to adhere to the increasing complexity of modern radiotherapy procedures. Recently, the implementation and use of the international code of practice based on standards of absorbed dose to water (not on in-air kerma) was the subject of a special training course organized for physicists dealing with dosimetry in all Polish radiotherapy centres.

**Table IV. Parameters of the distribution of the results of TLD postal audits (period 1991-2003)**

| | Ionization chamber measurements | | | TPS calculations | |
|---|---|---|---|---|---|
| | Co-60 | Linac photons | Linac electrons | Co-60 | Linac photons |
| No of beams | 55 | 52 | 44 | 16 | 36 |
| Mean | 0.50 | -0.95 | 0.29 | 0.38 | -0.1 |
| SD | 2.37 | 2.78 | 2.10 | 1.15 | 1.40 |
| No of deviations > 3.5% | 4 | 12 | 3 | 0 | 0 |

## Further developments

The SSDL pays particular attention to delivering services of a high standard. This year, steps were taken to have the entire MPD certified according to the ISO system applied in health care. As such certification does not demonstrate the competence of the laboratory to produce valid data and results, the Co-60 Lab (the main part of the SSDL) is getting prepared to meet the requirements for testing and calibration laboratories, that is the IS0/IEC 17025 standard [7]. The laboratory could then be accredited by the Polish Centre for Accreditation (PCA). This would be the first step for the SSDL to become a designated laboratory for ionizing radiation standards in radiotherapy in the future. Moreover, the SSDL, being incorporated into the IAEA/WHO network, is considered certified to perform secondary standard calibrations [14]. Other parts of the SSDL (the RTG and TLD Labs) are scheduled to apply for accreditation after fulfilling the requirements concerning proper housing and staffing, which for the moment have not been fully met. Nevertheless, the TLD Lab activities are carried out according to the Quality Manual and Maintenance Procedures prepared in compliance with the requirements of the IAEA [40], and the RTG Lab is functioning according to the regulations of the President of the Central Office of Measures [16].

Calibration of dosimeters is the main duty of the SSDL. Apart from calibration of therapy dosimeters, calibration of dosimeters used for checking the beams of therapy simulators and CT-scanners used in radiotherapy will be introduced at larger scale. This will make it possible for radiotherapy centres to fulfil the requirements of introducing a quality assurance systems [10]. The calibration of non-radiotherapy dosimeters needs more research and adequate procedures to be elaborated.

A new comprehensive programme for dosimetry audits in radiotherapy is being prepared, covering:

- determination of the dose, including non-reference conditions;
- control of the parameters of facilities producing input data for the treatment planning (CT-scanners and simulators);
- evaluation of the TPSs from the point of view of accuracy of the dose and dose distribution determination;
- control of patient irradiation (portal imaging, *in vivo* measurements, etc.).

In many cases, the whole programme requires a certain amount of research, or at least verification measurements to be performed (which in some domains has already been started). As the radiotherapy procedures become more and more complex, new methods of measurement or calculation emerge and require testing. Research in this area is being undertaken at the MPD. The SSDL's duty and responsibility is to select and introduce methods which are suitable for external audits, be it postal or on-site audits. Such methods are usually examined at the Centre of Oncology in Warsaw during internal audits. As mentioned above, the IAEA is in the process of developing a programme of comprehensive clinical audit for radiation therapy; this programme will be conducted by the IAEA team [9]. An important part of SSDL activity would be the preparation of the radiotherapy departments for such external audit.

On the basis of experience gained from the performed audits, guidelines and recommendations will be issued and distributed.

Over the last years, the demand for paramedical staff in medical physics has increased all over the world. The profession of medical physicist has recently been recognized in Poland [41], and a programme of specialization has been prepared to be carried out at selected hospitals, as is the case for specializations in medicine. The IAEA acknowledges a severe shortage of medical physicists both in developed and developing countries and note that a special category of affiliated member of the SSDL network may be used to provide training in dosimetry, and that opportunities exist for collaboration in setting training programmes [9]. It is expected that the Polish SSDL will participate in such programme.

## Conclusions

1. According to the Directive 97/43, all EU Member States have the freedom to choose the procedures for clinical audits but clinical audit in radiotherapy must include dosimetry audit.
2. Dosimetry procedures play an essential role in radiotherapy and the results of these partial audits may serve as representative, measurable indicators of the quality of dosimetry as applied to radiotherapy.
3. Radiotherapy departments passing the external audits successfully are more likely to meet the requirements of inspections performed by the state authority.
4. The SSDL, through the affiliation to the IAEA/WHO network of SSDLs, is a link to the international system of dosimetry and plays an important role in assuring high quality of radiotherapy in Poland.
5. The Polish SSDL should be granted a suitable legal status for its activities through an adequate wording in the regulations prepared by the Ministry of Health, and should be granted funds for carrying out external audits nationwide; the costs of clinical audits should be covered by the hospitals audited.

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**Professor Barbara Gwiazdowska MD, PhD**
Department of Medical Physics
Maria Sklodowska-Curie Memorial Cancer Center
and Institute of Oncology
ul. Roentgena 5
02-781 Warszawa

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