RESEARCH ARTICLE

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Quality Control of Brachytherapy Equipment in Kazakhstan: Current Stage and Minimum Requirements

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Abstract

Objective: Brachytherapy is used in 17 radiotherapy facilities In Kazakhstan. Each institution has an individual quality control (QC) program in place to ensure the safe and accurate delivery of the treatment dose to the patient. The main objective of this paper is to explore current approaches to quality control of brachytherapy in Kazakhstan and reduce potential discrepancies in testing frequency and tolerance limits by identifying a set of basic quality control requirements. **Materials and Methods:** A detailed brachytherapy quality control questionnaire was provided to 17 radiotherapy institutions for completion. A separate questionnaire was sent to two institutions associated with brachytherapy. Questions addressed safety aspects, radiation parameters, total time spent on quality control, and available imaging systems for dose determination. The results of the survey were compared with the recommendations set found in international brachytherapy quality control documents. **Results:** The results of the questionnaires revealed significant differences in the frequency and methods of testing. For example, only two of the 17 centers have at least some kind of quality assurance program for brachytherapy treatment. Only five centers have equipment with the help of which dosimetric control can be performed, and only two centers have local medical physicists performing this control. One of the centers is checked quarterly, while the other is checked only once a year. In the remaining 15 centers, dosimetric control is performed by specialists who recharge the source without providing any document or protocol. There were also significant differences in the amount of time spent on quality control, mostly related to the variety of approaches to quality control and differences in the availability of resources. Almost all centers (15 of 17) rely only on inspections from the radionuclide source supplier and do not monitor the dosimetric and mechanical parameters of the facility at all. **Conclusion:** Based on the results of the survey and comparison with international recommendations, a set of basic requirements for brachytherapy quality control is needed.

Keywords: Brachytherapy- Quality control- Radiation safety- Quality assurance

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Introduction

Brachytherapy is a method of radiation therapy in which a radionuclide source is temporarily or permanently placed in the patient's body (in or near the tumor) to reduce or destroy cancer cells, as opposed to external radiation therapy, in which radiation is generated from an external device and directed at the tumor in the patient's body. In Kazakhstan, approximately 2,000 patients in 17 radiotherapy facilities are treated annually with high dose rate (HDR) intracavitary brachytherapy. Unfortunately, due to certain circumstances, low dose rate brachytherapy has not taken root in Kazakhstan. The main reason is the high cost of resources for LDR brachytherapy.

The accuracy of brachytherapy dose delivery depends on many physical and technical parameters of the equipment used. According to generally accepted International Commission on Radiation Units and Measurements (ICRU) recommendations (Determination of Absorbed Dose in a Patient Irradiated by Beams of X or Gamma rays in Radiotherapy Procedures, 1976) in radiation therapy, the dose delivered to the patient should be within ±5% of the prescribed dose. Each step of radiotherapy should be performed with an error of less than 5%. A quality control program should be developed to ensure safe and accurate application of treatment and to prevent accidental overexposures. The goal of the quality control program is to maximize the likelihood that each individual treatment accurately meets the clinical intent of the radiation oncologist and that it is performed in a manner

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that maximizes the safety of the patient and others who may be exposed to ionizing radiation during the procedure. In Kazakhstan, each institution has developed its own quality control program for brachytherapy, following numerous recommendations published on the subject (Determination of Absorbed Dose in a Patient Irradiated by Beams of X or Gamma rays in Radiotherapy Procedures, 1976). In principle, quality control programs should not differ significantly from institution to institution.

Our group's study of current quality control practices showed that for radiation oncology equipment there are large differences in testing frequency, testing methods, and total time spent on quality control, largely due to differences in quality control approaches and differences in available resources, such as manpower, available dosimetry equipment, and access to new knowledge in treatment quality assurance. To achieve greater consistency between different quality control programs, a set of minimum quality control requirements was established across institutions, according to international recommendations, as the current regulatory framework for oncology services does not imply a specific list of control procedures or their frequency.

There are still no such national guidelines for quality control of radiotherapy devices. A scientific group of specialists involved in quality assurance of radiation therapy was established to gain an understanding of the current quality control situation of brachytherapy in Kazakhstan and to reduce deviations by formulating a set of minimum quality control requirements in a similar manner as has been done in other countries.

This article will discuss the current quality control stage of HDR brachytherapy, a comparison of current quality control practices with international guidelines, and an established set of minimum requirements for brachytherapy quality control.

Materials and Methods

In order to have an approaches of current quality control practices, an extensive questionnaire on quality control of brachytherapy systems was sent to all 17 radiotherapy institutions in Kazakhstan. The types of questions are shown in Table 1. Questions were on the frequency of testing, testing methods, time needed for testing, levels of safety systems and radiation parameters in brachytherapy, and availability of related imaging equipment (CT, MRI, ultrasound, C-arc). Also, there was a request for how many patients were treated and the amount of brachytherapy equipment (afterloaders, localizers and TPS).

Several international reports were reviewed regarding published quality control guidelines for brachytherapy equipment (Physics aspects of quality control in radiotherapy. Medical remote-controlled, automatically operated afterloading systems, consistency testing of equipment quality features. DIN. Berlin: Beuth, 1992; Clinical dosimetry, brachytherapy with gamma rays enclosed in radioactive substances. DIN. Berlin: Beuth, 1993; Medical electrical equipment, part 2: particular requirements for the safety of remotecontrolled automatically-driven gamma-ray afterloading equipment, 1996; Dutreix et al., 1994; Elfrink et al., 2002; Glasgow et al., 1993; IEC, 1989; Kubo et al., 1998; Kutcher et al., 1994; Nag et al., 1999; Nath et al., 1999; Nath et al., 1995; Nath et al., 1997; Williamson et al., 1994). The obtained data: query responses were compared with these recommendations. Based on this information, a set of minimum requirements for QC appropriate for the situation in Kazakhstan was formulated, which will be published as a methodology, based on which the regulatory documents in the field of cancer care for the population of Kazakhstan can be amended.

Results

The questionnaire was completed by 17 institutions. The results are presented in the form of table (Table 2). The following abbreviations are used: HDR (Ir) for high dose rate treatment using an Ir-192, HDR (Co) for high dose rate treatment using a Co- 60. Abbreviations used for testing frequencies: 3m for quarterly, 6m for every six months, and 12m for annual.

Unfortunately, at the time of the survey, only a small fraction of specialists in institutions of this type had any approaches of the need to develop at least their own quality control program for brachytherapy treatment.

Quality assurance in radiation therapy is realized through procedures that guarantee a consistent and safe dose delivery to the target volume with a minimum dose to normal tissues and minimum exposure of personnel and the public. Both clinical and physical aspects are involved. Key areas include clinical policies, planning and execution of exposures, a quality assurance program for facility and equipment performance, maintenance programs, and procedures for investigating accidental medical exposures. Such a comprehensive quality assurance program should be developed in accordance with the NSA (International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources., 1996) and World Health Organization (WHO) guidelines (Quality Assurance in Radiotherapy. A guide prepared following a workshop held at Schloss Reisensburg. , 1988). There are also ESTRO publications recommending the establishment of such a system (www.estro.be) (Practical guidelines for the implementation of a quality system in radiotherapy: a project of the ESTRO Quality Assurance Committee sponsored by "Europe against Cancer".. 1998; Thwaites et al., 1995).

For ease of actualization and ease of document control and audit, each written procedure should have limited objectives and a limited scope so that there is no cross-tasking. In addition to defining objectives and scope, each procedure should contain:

- A list of major responsibilities, identifying the person who has overall responsibility for the procedure;
- A list of all documentation that may be required to perform the procedure (e.g., work instructions and data sets);
- A list of documentation produced as part of the procedure;
- A brief description of the method, identifying

Table 1. Overview and Explanation of Questions Sent to Cancer Centers in Kazakhstan

The verification object	Explanatory question
Treatment	What type of contact radiotherapy do you perform in your Center? (localization and technique)
Equipment	What brachytherapy equipment do you have? (Manufacturer, year of manufacture and installation, radionuclide source used)
Related equipment	What type of imaging of critical organs and targets do you use? (Imaging methodology and purpose)
Personnel	Are your staff trained? (medical and physical-technical, what refresher courses and when did they take them?)
Technical services	Is there an annual service contract for brachytherapy equipment? (Does the terms of reference specify a mandatory quality control procedure at least once a year? If yes, can you provide a protocol?)
Work organization	Does your department have a clinical case review involving all staff involved? Is there any kind of recorded post-treatment follow-up of the patient? Is there a statistical analysis?
Quality control	Does your department have a quality control protocol for brachytherapy equipment approved by the head of the organization? If so, how often is it reviewed?

Table 2. Hospital survey results

Conducting brachytherapy	16 of 17
Planning equipment used	CT -2, C-arc – 3, Bibliography - 11
Availability of scheduled maintenance service	14 of 17
Staff training	0 of 17
Availability of a quality control program	2 of 17
Availability of dosimetric equipment	4 of 17
Conducting dosimetric measurements	2 of 17
Availability of quality control protocols from the radionuclide supplier	0 of 17

the individuals responsible for various aspects of the described work, the interaction between them, and the transfer of responsibilities to technicians and medical professionals from other levels (e.g., medical staff, physicists, technicians, and nurses) (Setting Up a Radiotherapy Programme. Clinical, Medical Physics, Radiation Protection and Safety Aspects., 2008).

The quality control program must define:

- The various tests to be performed;
- The equipment, including serial numbers, used to conduct the tests;
- The geometry of the tests;
- Frequency of tests;
- Responsible persons;
- Expected results;
- Tolerance values;
- Actions to be taken if tolerances are exceeded.

It should be emphasized that the tests should only be performed by qualified and experienced individuals, such as a medical physicist, but physicists may delegate the work to individuals they have trained. Regardless of who performs the tests, the physicist remains the responsible party to ensure that the equipment operates correctly. The physicist must also verify that the data in the irradiation planning system, as well as in any computer used to calculate irradiation times, and in the maintenance, log are correct and consistent.

Many international publications give recommendations on the frequency of certain quality control procedures, but do not describe the procedures themselves at all. In fact, for the entire quality assurance process, it is extremely important that absolutely all items be detailed, so that if the person responsible for these procedures is not available, any other technician can perform them. Some books give too long descriptions for the procedures to be carried out. We, in our work, still need to briefly describe the actions themselves and indicate the frequency of their performance, so that such a table does not look unwieldy for the convenience of using our method of brachytherapy device performance testing. The frequency of these tests can serve to create our own quality assurance protocol. It should be noted that all existing quality assurance rules in the regulations should be followed, however at first we have only focused on activity checks of the source after each replacement with an error of at least 5%. Increased frequency of testing is also required when the stability of the system is suspect or when a particular method of treating a patient requires special care ("A Practical Guide To Quality Control Of Brachytherapy Equipment, Venselaar, Pérez-Calatayud, ESTRO," 2004).

As a result, according to the recommendations of ("A Practical Guide To Quality Control Of Brachytherapy Equipment, Venselaar, Pérez-Calatayud, ESTRO," 2004), we have the following frequencies and tolerances of tests for quality control of HDR brachytherapy equipment, indicated in Table 3. The daily QC tests should be executed on a routine basis before treating the first patient of the day. Starting the treatment and signing the documents for that treatment, may implicitly assume that these daily tests were performed and that the results were satisfactory, according to a department's written policy. Other departments may wish to develop special daily check forms to record and sign for the execution of these tests on satisfactory completion. For most of the tests in Table 3, a

Table 3. Recommended Minimum Quality Control Procedures for Brachytherapy Equipment in Kazakhstan

Procedure description	Check frequency	Tolerance
Safety systems		
Warning light	Unit\3m	
Surveillance monitors	Unit\3m	
Emergency buttons	3m	
Interruption of treatment	3m	
Door lock	3m	
Power off	3m	
Fixation of applicators and catheters	6m	
Faulty catheter	3m	
Integrity of tubes and applicators	3m	
Checking the timer	Unit	
Radiation leak	12m	
Emergency equipment	Unit	
Working off emergency situations	12m	
Operation of manual source retraction	12m	
Checking Radiation with a Handheld Dosimeter	3m\12m	
Physical (dosimetric) parameters		
Source Calibration	3m	>5%
Source Positioning Accuracy	Unit\3m	>2mm
Checking the tube length	12m	>1mm
Timer linearity	12m	>1%
Timer persistence	Unit	

3 months interval is suggested because this is usually the frequency with which HDR sources are replaced. Some departments may apply a 4 months interval instead, if source replacement takes place only 3 times annually. The quality control checks, which are performed quarterly or with a lower frequency, must be explicitly logged in a logbook, which is kept by the physicist ("A Practical Guide To Quality Control Of Brachytherapy Equipment, Venselaar, Pérez-Calatayud, ESTRO," 2004). We also envisage using these types of tests and their frequency for brachytherapy machines with the Co-60 radionuclide source, taking into account the situation with respect to compliance with the quality control measures specified in Table 3.

Taking into account the recommendations of ("International Atomic Energy Agency, Setting Up a Radiotherapy Programme, Non-serial Publications, IAEA, Vienna ", 2008), which are almost identical to ("A Practical Guide To Quality Control Of Brachytherapy Equipment, Venselaar, Pérez-Calatayud, ESTRO," 2004), our scientific group allows a limit of 5% of the difference between the manufacturer's certificate and the local calibration to be used for source activity verification, as this is allowed for some radionuclides with long half-lives ("A Practical Guide To Quality Control Of Brachytherapy Equipment, Venselaar, Pérez-Calatayud, ESTRO," 2004).

Quality control of security systems

In general, the safety aspects of a remote afterloading device can be divided into interlocks, radiation protection, and emergencies. The quality control tests of these safety systems should prevent equipment failure and ensure the radiation safety of patients and staff. Quality control of safety systems often includes simple functional checks, which are carried out regularly during the operation of the treatment machine.

Interlocks are mechanisms that block the operation of the machine if any parameters are outside of the preset values. For example, if the radiation dose exceeds a preset limit, the system blocks the machine.

Radiation safety is a measure to protect the patient and staff from radiation. Safety systems must ensure that radiation doses are accurate and that repeated exposures are avoided. Radiation leaks must also be controlled to minimize environmental impact.

Emergency aspects are mechanisms that must be incorporated into the safety systems to prevent possible emergencies, such as machine failure or operator errors. These mechanisms must ensure that the machine stops safely in the event of unforeseen circumstances.

Quality control of safety systems is carried out in accordance with international standards and recommendations. These tests can include measurement of radiation dose, verification of dosage accuracy, verification of interlocks functionality and other functional tests. Regular quality control of safety systems is a prerequisite for patient and staff safety, as well as for compliance with international standards and regulations.

Thus, device safety is a priority in the treatment process, and training checks should be conducted systematically.

The current practice of source calibration in Kazakhstan

is that, with the exception of two recently purchased factory-calibrated devices from the manufacturer, there are simply no other instruments for measuring radionuclide activity used in brachytherapy. Only four out of seventeen organizations have well type chambers, but more than two years have passed since the factory calibration, and there is no possibility, primarily due to financial reasons, to send the measuring devices to a calibration laboratory that is located in another country. At the moment in the territory of the Republic of Kazakhstan there are no calibration laboratories that are engaged in such activities.

As a part of this research project, we want to cross-calibrate existing equipment in cancer centers, but such procedures will have no legal effect. And the accuracy of such calibration is would be low.

Studying the recommendations of IAEA, AAPM and ESTRO ("A Practical Guide To Quality Control Of Brachytherapy Equipment, Venselaar, Pérez-Calatayud, ESTRO," 2004; "International Atomic Energy Agency, Setting Up a Radiotherapy Programme, Non-serial Publications, IAEA, Vienna ", 2008; "International Atomic Energy Agency, The Transition from 2-D Brachytherapy to 3-D High Dose Rate Brachytherapy, IAEA, Vienna ", 2015)in the field of brachytherapy, our research group came to the conclusion that relying only on the certificate issued by the radionuclide manufacturer is impossible. Therefore, the need for internal activity controls is mandatory. In terms of the frequency of such checks, based on our own experience and in order not to overburden the physical and technical staff, we came to the conclusion that once a quarter would be sufficiently adequate period for both Ir-192 and Co-60.

Discussion

Quality control of brachytherapy includes quality control that should be standardized in all medical institutions. However, because of differences in guidelines, local conditions, such as differences in patient load and experience, there is considerable variation among quality control programs, and in some places there are no such programs at all. The diversity of protocols is probably due to differences in quality control approaches and differences in available resources, including manpower.

The main problem is the training of physical and technical specialists in radiotherapy departments. At the moment, medical physicists in the Republic of Kazakhstan do not bear any responsibility for providing a quality control program in medical institutions, according to regulatory documents. Thus, there is no compulsory methodology for checking dosimetric and mechanical parameters of radiotherapy units in the legislation, and international recommendations do not have the status of mandatory. In our opinion, this is a fundamentally wrong position, because it affects not only the level of training of local specialists, but also the level of services provided by medical organizations. In most medical centers of the country, quality control procedures are carried out by third-party organizations that have received a license for these activities, and in some organizations there are no supporting inspection protocols at all. While external verification by third party is a useful approach it should not replace the hospital own quality control program. The quality control program for brachytherapy devices to be developed by our specialists in the course of this work, based on international recommendations and in cooperation with experts in the field, should meet the requirements for implementing quality control procedures for most brachytherapy equipment currently available in the Republic of Kazakhstan.

We, as a working group, decided to create quality control guidelines that would include only mandatory regular tests for quality control, the results of which should be documented. No additional post overhaul inspections were considered. Therefore, the recommended frequency of inspections should only be considered a minimum, not an optimum period.

We see no reason to believe that the situation in institutions in Kazakhstan differs significantly from that in other developing countries, and the implementation of a national protocol could serve as a start in this direction. We hypothesize that the minimum requirements articulated in the national protocol would help reduce variation in quality control programs. In addition, it would be useful to examine differences in QC among institutions in other countries. The method described in the article, which involves the distribution and analysis of an extensive questionnaire, could lead to a critical revision of quality control protocols in the country.

In Conclusion, a study of quality control programs in the field of brachytherapy was conducted in 17 medical institutions of Kazakhstan specializing in radiotherapy. The results revealed considerable variation in the frequency of tests and even a complete lack of control procedures in some cases. The frequency of safety testing of systems and physical parameters ranged from daily inspections to inspections once a year.

Differences in quality control approaches, lack of training and available resources explain this diversity, which may not depend on the size of the institution. Based on the results of the survey and international recommendations, a set of minimum requirements suitable for the situation in Kazakhstan was developed. 20 test procedures are included, with an indication of the frequency of testing.

Unfortunately, in Kazakhstan there is no working group of specialists in physical and technical support of radiotherapy to develop unified standards for quality control procedures for radiotherapy facilities. This important issue should be raised at the highest level by heads of institutions of this type.

Author Contribution Statement

M.O. formulated the experimental design. A.T., O.S., and K.D., gathered data and interpreted results. N.G. provided guidance. The manuscript was written and edited by all authors. All authors read and approved the final manuscript.

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Ethical Declaration

This article does not contain any studies with human participants performed by the author.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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