

AN OVERVIEW OF PROTOCOL FOR QUALITY CONTROL TESTS FOR DIAGNOSTIC RADIOLOGY APPLIED BY ALBMEDTECH

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Abstract

The diagnostic radiology service, play a crucial role in examinations of patients with different diseases, being in some cases the main and only method in determining the diagnosis. Actually, medical imaging technology has evolved exponentially where multidetector row computed tomography, sophisticated angiography systems, AI algorithms and automation are being widely used. During a diagnostic procedure, the physical properties of X rays are used to obtain a diagnosis or to guide invasive devices through the body when an interventional procedure is performed. A malfunction of an X ray system can increase the radiation dose and affect the health of patients. For this reason, X ray machines are monitored periodically through strict quality control. To ensure that a X ray machine works in accordance with accordance with the clinical objective, national and international standards, thus providing diagnostic information of the required quality with the lowest patient exposure, it is necessary to design and implement the protocols for quality assurance and quality control to provide the information of optimal performance of a X ray equipment. These QA and QC tests of verifying accuracy of the voltage (kV), the stability of the repetition of the values of the voltage dependence of the power voltage change, the overall filtering and the exposure time etc., also helps the medical institutions to invest in maintenance of the diagnostics systems to meet the requirement approved by national and international bodies or organizations. In our country, a significant number of X ray systems used in diagnostic radiology departments are now part of a regular quality assurance program, under the monitoring and approval of the Albanian Radiation Protection Commission. In this work we represent a detailed procedure for QA and QC performance of X ray systems followed by Albanian Medical Technology (Albmedtech), which was drafted and improved in cooperation with the staff of Albmedtech based on the legal and by-laws in force as well as the logistical capacities that Albmedtech has in use. The need for such cooperation comes during the development of the project "Development of simulation and forecasting models and integration with the TCIA database of medical images", where in some diagnostic centers, especially public ones, a low level of awareness of the personnel was observed because of regarding the functional parameters of radiological equipment. the study showed that overall, the level of. Also, we analyze the diagnostic system in Albania by collecting information from the public and private sectors and presented a general picture of the situation of diagnostic equipment in Albania compared to OECD and COCIR standards. To address this issue, in collaboration with Albmedtech and Albanian Association of Medical Physics (AAMP), we supported the strengthening quality assurance and quality control in X ray diagnostics and in applying best practices for quality and safety in diagnostic radiology. Also, we developed a quality control procedure for diagnostic radiology equipment taking into consideration all the latest developments in the field, in order to have a better operation.

Keywords: Quality Assurance, Radiology, Diagnostic, Quality Control, Albmedtech, AAMP.

1. INTRODUCTION

The health system in Albania is a mixed system that combines elements of public and private healthcare provision (Ministry of Health). It is organized into primary, secondary, and tertiary levels of care. Primary healthcare is delivered through a network of health centres and clinics located in urban and rural areas.

Secondary and tertiary care is provided by hospitals, including regional and university hospitals. The public sector plays a significant role in healthcare provision, with the Ministry of Health being responsible for overall policy-making and planning.

Public health care service in Albania is free of charge and covers a range of services, including outpatient care, hospitalization, and medication. However, there are many efforts have been made to improve access to healthcare services, particularly in rural areas, there are still disparities in access between urban and rural populations.

Despite the great improvements, the health system in Albania faces several challenges, including limited healthcare infrastructure, shortages of medical professionals in certain regions, and the need for investment in modern medical equipment and technologies. In the last years, especially after the COVID 19 pandemic [2], the Albanian government has implemented various reforms aimed at improving the health system.

These reforms include efforts to enhance primary healthcare services, improve healthcare infrastructure, and strengthen the regulatory framework for healthcare providers. Over time, medical diagnostic technologies were further developed in Albania. The use of radiation for diagnosis, such as radiography and computed tomography (CT scan), became increasingly used.

Also, other diagnostic tools were developed, such as ultrasound (ultrasound), magnetic resonance (MRI), endoscopy, and many others. It has been estimated that medical diagnostics in Albania has made significant progress in recent years, however, as in many other countries, there are still challenges and room for improvement. Technological advances, investments in medical infrastructure and development of professional capacities are some of the focuses. Diagnostic imaging played an important role in diagnosis of patients affected by COVID – 19 [3],[7].

Diagnostic imaging system in Albania, uses a large variety of equipment. In total are in use around 28 MRI, 70 CT, 1 PET-CT, 50 CBCT and more than 500 conventional and digital radiography devices, fluoroscopy and mammography equipment.

Compared with OECD units per million population, the report of units per 1 million habitants in Albania is under the average number [9]. Every radiological equipment used in radiological centres must meet some of the parameters related to its functionality.

One of the main classifications used for radiological equipment is the time of use of the equipment [8]. National Bodies responsible for monitoring of quality of radiologic devices are Directorate of Radiation Protection and Radiation Protection Commission.

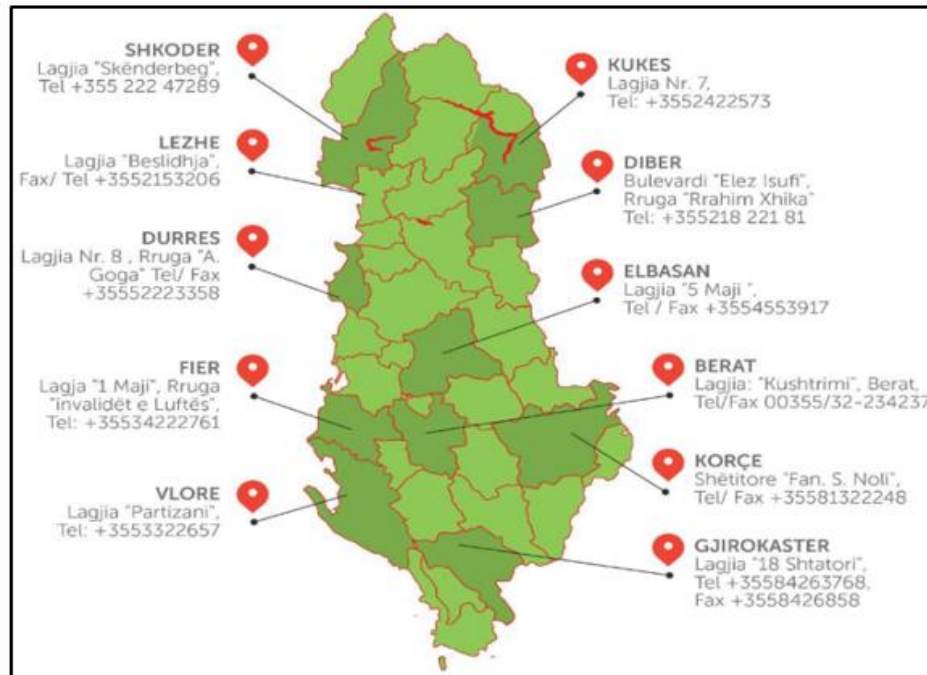


Fig 1: Map of regional hospitals in Albania, Health system in Albania, Ministry of Health [12]

Several laws and bylaws are approved to in order to ensure the quality of operation of medical equipment. Most important acts are: Law no. 8025, dated 9.11.1995, "On protection from ionizing radiation", as amended, Decision no. 404, dated 18.6.2014, on the approval of the regulation "On the basic rules of radiological installations in medicine", Decision no. 590, dated 18.8.2011, on the approval of the regulation "For the protection of employees professionally exposed to ionizing radiation", Decision no. 229 dated 20.3.2013, "For the approval of the regulation on safety against medical exposures with sources of ionizing radiation", Order no. 415 dates. 11.10.2011 of Ministry of Health, Rregulation.No.10 dt.7.1.2010 "For licensing and inspection of activities with sources of ionizing radiation", Guideline no. 1526.1 dated 13.04.2012, "Elements for recognition by RPC for legal and physical persons who perform measurements with ionizing and non-ionizing radiation, calibration of radiometric and radiation measuring equipment, training, and personal dosimetry service", Order of the Ministry of Health. No. 434 dt. 14.10.2015 "On education and training for protection and safety from ionizing radiation" etc [1] the reports and series published by IAEA and EFOMP are also applicable, such as "Handbook of Basic Quality Control Tests for Diagnostic Radiology" [4].

Based on the above legal and by-law framework, the assessment and quality control are carried out by companies or experts in the field, recognized and certified by the Radiation Protection Commission. Albmedtech is certified and operates in the evaluation of functional parameters of radiological equipment and their certification.

2. THE METHODOLOGY

With Albmedtech support, we performed site visit in 20 municipal and regional hospitals. During site visits, we reviewed the documentation, licensing acts, documents and other certifications performed by authorities, meeting with radiology departments and technicians etc. The measurement procedure was administered in collaboration with Albanian Medical Technology, Albmedtech, in accordance with the regulatory acts of Radiation Protection Office in Albania [10]. To evaluate the quality of the radiological equipment operating in different hospital centers is a relatively simple procedure but the problem lies in the fact that there is a lack of updated data at the national level that provide information in real time. For measurements of ionizing radiation values, we used Piranha Multi 657 [6], which is a device for measuring/analyzing X-radiation produced by radiological equipment. This device is manufactured by RTI Group, a world leader in quality assurance and dosimetry services for radiological systems. The complete equipment set includes the external Dose Probe detector along with cables/transmitters. Piranha multi measures the functional parameters of radiological equipment operating with X-rays, for quality control, including measurements of kerma, kerma rate, kVp, tube current, exposure time, brightness, illuminance and surface dose product according to manufacturer's specification. Most measurements and tests are managed such as: tube voltage, exposure time, dose and dose rate are measured for all types of modalities: conventional radiography, fluoroscopy, pulsed fluoroscopy, mammography, dental, panoramic dental, and CT. In one exposure, the detector measures tube voltage, time, dose, dose rate, HVL, and overall filtering evaluated in radiographic, fluoroscopic, dental, and CT exposures. In pulsed radiation, pulse dose and pulse rate are also measured. The internal Piranha detector is very sensitive and can measure tube voltage for outputs as low as 50 kV / 0.050 mA at 50 cm. Normally, the exposure time should be at least 5 ms to get a kVp value, but this depends on the waveform. In modern X-ray generators, the peak tube voltage can be measured with exposure times in steps of 1 ms. Doses and time values are given for even shorter exposure times. Estimates of total filtering and fast HVL are made from a single exposure using a combination of detector and filters in Piranha. In the case where overall filtration cannot be automatically estimated, a "standard" HVL measurement may be required. All measured values of kVp and dose measured with Piranha are automatically transferred to the actual radiation quality. This means that no manual corrections of the measured data are needed. During the site visit to the institution, the staff was equipped with the appropriate equipment for carrying out measurements according to the approved protocol. Always staff was equipped with a radiation dose reader/personal digital dosimeter for instant reading of the dose. The personal dosimeter was kept on at all times on the areas with ionizing radiation presence. Radiation values (accumulative dose) were recorded in a specific database and become an integral part of the personal data file for further analyses. Before starting the measurement procedure, we prepared several documents such are: the authorization sheet for carrying out measurements, measurement plan and templates. Also, we evaluated the documentation associated with a specific device, technical specifications, the latest equipment evaluations (QA and QC) and recommendations made from previous certification.

Table 1: Piranha MULTI, Specifications for Rad/Fluoroscopy measurement

Tube Voltage	35 – 160 kV ($\pm 1.5\%$)
PPV	Yes
Time	0.1 ms – 2000 s ($\pm 0.5\%$ or ± 0.5 ms)
Dose	1.3 nGy – 1500 Gy 150 nR – 150 kR. ($\pm 5\%$)
Dose Rate	15 nGy/s – 320 mGy/s ($\pm 5\%$ or ± 7 nGy/s) 1.7 μ R/s – 37 R/s ($\pm 5\%$ or ± 0.8 μ R/s)
Auto Compensation	All dose parameters are automatically compensated for using measured kVp and TF over their specified ranges.
HVL	0.72 – 13 mm Al ($\pm 10\%$ or ± 0.2 mm)
Total Filtration	1.0 – 90 mm Al ($\pm 10\%$ or ± 0.3 mm)
Pulses	1 – 65535 pulses (± 1 pulse)
Dose/Pulse	8 nGy/pulse – 0.9 Gy/pulse
Pulse Rate/Frequency	0.5 – 180 Hz
Pulse Width	4 ms – 2000 s
Piranha Multi, Specifications for CT, measurement	
Tube Voltage	45 – 155 kV ($\pm 1.5\%$)
Time	0.1 ms – 2000 s ($\pm 0.5\%$ or ± 0.5 ms)
Total Filtration	1 – 90 mm Al ($\pm 10\%$ or ± 0.3 mm)
HVL	0.72 – 13 mm Al ($\pm 10\%$ or ± 0.2 mm)
Pulses	1 – 65535 pulses (± 1 pulse)
Dose Rate Range	67 nGy/s - 2.2 Gy/s 0.46 mR/min - 15000 R/min
Inaccuracy	$\pm 5\%$ or ± 15 nGy/s
Spatial Resolution	0.25 mm
Air Kerma Rate	0.3 mGycm/s to 3 Gycm/s
Inaccuracy	$\pm 5\%$ or ± 0.03 mGycm/s
Radiation Quality	70 - 150 kV
Sensitivity	30 mGycm/nC

In total we tested 55 radiologic devices between 5 – 15 years old for 3 parameters: tube voltage, linearity and dose rate. 53 (96 %) passed the test. This means that despite the fact that the devices do not meet the COCIR Golden rules [5], they function in accordance with the standards and criteria established in the Albanian legislation for the functional parameters of radiological devices [1]. In parallel with equipment evaluation visit, we developed a detailed survey to obtain information on the professional training of radiological technicians, the level of radiological equipment they use in diagnostic centers, as well as the level of information technology, artificial intelligence they use in obtaining images, visualization, processing and optimization of their parameters [11].

3. RESULTS IN IMPROVEMENTS ON QUALITY CONTROL PROTOCOL

To perform quality control of radiologic devices with Piranha Multi, it's important to know that the device is designed to perform ionizing radiation measurements for a wide range of radiological equipment operating in the X-ray spectrum such is: X-ray, Cin-radiology - Pulsed radiation, Fluoroscopy, Pulsed fluoroscopy, Mammography, Dental x-ray, Panoramic (OPG) and CT [13]. There are several procedures and measurements options such are: Post Delay, Measuring Mode with three alternatives are possible Normal, Timed and Free run: Piranha continuously measures radiation without defined adiation levels (trig levels). The associated software "Ocean professional" supports a wide range of

measurements, document templates and reporting. Piranha Multi measures 8 parameters continuously and 3 waveforms from a single exposure: kVp, dose and dose rate, exposure time, HVL, estimate the total filtering and determine the waveform, mAs and mAs, pulses, kV waveform, waveform dose report, waveform, various pulsed fluoroscopy parameters. Below we represent the measurement protocol for radiography devices in accordance with Decision no. 404, dated 18.6.2014, on the approval of the regulation "On the basic rules of radiological installations in medicine".

3.1 Kilovoltage accuracy

The equipment in use enables the measurement of kV and dose correctly in the entire range from 20 to 155 kV, while the range of standard measurement values varies from 35 to 155 kV. Piranha uses 4 signals S1-S4 (produced by detectors D1 to D4 inside the device) and accurately calculates the corresponding tube voltage. Using these signals together, accurate dose and tube voltage readings are obtained. Since all signals are measured simultaneously and at high speed, Piranha automatically compensates kV and dose for waveform dependence and tube filtering. To determine the quality of the X-ray beam, the size kVp (kilovolt per peak) is used, which depends on the energy and penetration. The measurement of kVp in radiographic equipment is done directly. Piranha automatically detects and compensates for changes in radiation quality. Positioning the detector in the radiation field is easily done after checking that the detector area is fully and uniformly irradiated. Practically this means that the kVp value can be measured in the range of 1.0 to 50 mm of total filtration. Piranha is positioned at the front of the radiation beam according to the device configuration and through the "Position Check" option, it is checked if the placement and positioning geometry is within the measurement parameters. Low radiation fields are used to pinpoint the position. Although the detector is not sensitive to scattered radiation, it is attempted that the irradiated area of the detector is perpendicular to the field to minimize scattering. Also, the detector measures a wide band of values which makes it practically impossible that the signal level is not sufficient to get an accurate kVp value. The collimator is adjusted so that the radiation clearly covers the detector (the rectangle marked in the upper panel of Piranha). The recommended field is 20 × 40 mm and perpendicular to the surface of the detector. Radiography uses values of X radiation in the range from 35 to 155 kV.

For measurements of kilovoltage accuracy we recommended the following steps:

- Turn on Piranha according to the measurements methodology and ensure communication with the computer
- Is positioned on the patient's bed at the distance of the clinical examination
- A position check is performed at 70kV to confirm that the detector area is uniformly irradiated. Piranha automatically switches back to the previously selected kV level (configured for measurement)
- The kVp and mA (or mA / t) parameters are set according to the desired values.
- The exposure is realized.
- Values are read and recorded.

- The results are analyzed and processed and the corresponding report is generated along with the recommendations

Referring to the error interval, the measurement inaccuracy is calculated at the value of $\pm 1.5\%$ with an accuracy of up to 4 digits after the decimal point. Meanwhile, in the same measurement, other parameters are automatically evaluated for the same kV exposure. Based on the Regulation approved by DCM 404, the maximum deviation of the output voltage value must be less than 10% of the value indicated by the device panel. In the evaluation report attached to the evaluation certificate, the measured values and recommendations for the subject are given in detail if the values are within 10% of the allowed value.

3.2 Dependence with current change

In general, radiological equipment operates at a voltage of 220 V. The intensity passing through the filament of the X-ray lamp is measured in mA, while the acceleration voltage is measured in kV (or kVp). The relationship of kVp to current is such that when kVp increases mA decreases or when kVp decreases mA increases. This relationship is then translated into image quality in relation to its contrast. According to this relationship, when kVp increases, image contrast decreases and vice versa. Increasing the intensity increases the number of photons and thus increases the quality of the beam otherwise known as exposure. Piranha performs the measurement of these parameters automatically thanks to the 4 detectors it has. To see the dependence between kVp and current, several measurements are performed for different values of intensity for the value of 70 kV. The exposure time to make the measurement is between 0.5 - 64 ms while the recording time is up to 524 s. Measurements are recorded and presented graphically. For measurements with the external detector, the following procedure is followed as described above for Kilovoltage accuracy. An estimate of the dependence of kVp on the intensity is also calculated by analyzing the quality of the X-ray beam by measuring the dose under reference conditions from Piranha or Piranha dose probe. The analysis and comparison with the respective values is done automatically. Output doses mGy/mAs should be constant when kVp and distance remain constant. This parameter is estimated by calculating the linearity coefficient $L_{1-2} = |X_1 - X_2| / X_1 + X_2 < 0.1$ The maximum deviation of the voltage value should be less than 10% of the change of the current values.

3.3 Accuracy in voltage repetition

Measurements with piranha are performed to ensure there is accuracy in repeating certain voltage values using current in clinical parameters. First, Piranha is placed according to the above definitions. The measurement parameters of the device are determined similar to the clinical parameters. A series of measurements are performed starting from the lowest voltage to the highest one with an increase interval of 10kV (over 3 measurements). The measured voltages and respective dose values are recorded. The measured and set values must be less than 10%, while the voltage and dose changes must not be more than 5%, as determined in the above-mentioned regulation that for repeated measurements, the voltage deviation must be less than +5% of the average voltage value.

3.4 Total filtering

Measurements of general/ total filtration are made in one exposure. Inside the device there are several detectors and the total filtering is determined by a combination of these signals and the kV value. Using these four signals S1-S4 (from detectors D1 to D4) Piranha accurately calculates the corresponding tube voltage. The S3 signal is not affected by the moving filters and is designed to measure the dose. Basically, the detector packs consist of four separate electrometer channels connected to detectors D1, D2, D3, and D4 and a movable filter pack that can be changed to one of six positions, each a combination of different filters for the detectors. The reference depth for the detector's sensitive area is 10 mm below the surface of the Piranha's top panel. Detector D4 is placed directly below D3 with additional filter in between. The ratio between S3 and S4 is used to estimate the overall filtering for the range of radiographic equipment from 35 to 155 kV (35 - 75, 55 - 105, and 80 - 155 kV). Piranha makes it possible to measure fields, with a width of less than 3 mm, and low output levels down to approximately 1 $\mu\text{Gy} / \text{s}$. Piranha automatically compensates the kV and dose for the dependence of the waveform and tube filtering the detector is perfectly positioned and both detectors have the same radiation, the ratio between the two signals must be exactly "1.000". This is very useful information and testing this ensures that the measurement geometry is correct, giving reproducible readings. Piranha measures faster via the "one shot" method which is a standard additional information feature for kVp. Between 60 and 120 kV, general filtering is defined with a higher accuracy of 10%- or 0.3-mm Al. Outside this range, up to 50 kV and up to 150 kV, the overall filtering can be determined, however the inaccuracy increases. When the kV is lower than 50 kV or higher than 150 kV no overall filtering can be determined. In the Ocean program, the add filter option is selected and then the measurement is performed. A high signal level is used, ie 200 mA for 200 ms to obtain a stable result. It does not matter if measurements are made at a higher or lower kV since the main goal is to obtain a correct total filtration value. The total inaccuracy is about 0.3 \pm mm in the range from 2 to 10 mm and \pm 10% in the range from 10 to 25 mm. The purpose of this value is to always be able to calculate the kVp correctly and the dose value independent of beam filtering. Total filtering can also be obtained by measuring fast HVL using filters above the detector. Then the overall filtering is calculated from the HVL value automatically.

In the table of Piranha's respective intercepts and the external detector, the total filtering and HVL data are given or vice versa. Based on the Regulation approved by DCM 404, the total filtering for an X-ray beam must be no less than 2.5 mm Al or its equivalent. The measurement report refers to the value measured in HVL, fast HVL and total filtration.

3.5 Exposure time

The irradiation time or exposure time must be at least 5 ms to obtain a kVp value. In modern X-ray generators (high frequency with rapid rise and fall in tube voltage), the peak can normally be measured with exposure times as short as 1 ms. The purpose of this measurement is to verify that the exposure times set in the apparatus correspond to the effective time measured. The device is positioned as for a standard measurement procedure where the detector part is placed perpendicular to the tube. Several exposures

are performed at the reference voltage (70kV for traditional devices) with 100 mA and with time covering the necessary interval with which the device works. Time is measured for each exposure. Piranha also performs automatic measurement of recording time, where the range of values based on the device's manual for radiographic measurements is in the range 01 – 2000 s. Based on the acceptance criteria, the measured times must correspond to those indicated below 10%. For a dashboard exposure time greater than 100 milliseconds, the (real) output exposure time must be within +10% of the dashboard value.

3.6 Output radiation power

In order to evaluate the output radiation of the x-ray tube and its power, it is imperative that the equipment is tested and evaluated to operate in accordance with the manufacturer's parameters. The device must give the same radiation value for the same values of variable parameters. We also need to see the relationship of this radiation with the current and with the product of the current with time. Several measurements are performed simultaneously. In an exposure, the detector measures dose, dose rate for radiographic equipment, air kerma, dose level. Initially, the reference parameters/conditions are set - voltage 80 kV, 50 mA and total filtration 2.5mm Al distance 100 cm. The measurement of the dose and its level is done by Piranha automatically. Referring to the criteria defined in the Regulation approved by DCM 404, if the total filtration is taken to be 2.5mm Al, the output radiation must be greater than 25 $\mu\text{Gy/mAs}$ at a distance of 1m for a true voltage value of 80Kv. Based on the allowed parameters, the output radiation must be constant within + 20% values for repeated exposures under the same conditions (Voltage 80Kv, total filtering 2.5mm Al). While with the change of the current values, the radiation avoidance at the output must be less than +15%. The product of time x current is calculated and it is seen if the avoidance of outgoing radiation is less than + 20 %.

3.7 Matching the beam of light with the beam of x-rays

The coincidence of the defined field with the beam of light in any direction of the x-ray field in any fundamental direction should not exceed 3% of the distance from the focus to the center of the light field, and the sum of the deviations in the two perpendicular directions should not exceed 4%. The matching of the light beam with the x-ray beam is related only to the quality of the X-ray tube and it does not depend on other parameters such as kV, mAs and dose. For this reason, the test is done for different parameters, eg 50kV, 20mAs, 100 cm. Gafchromic film is placed under the above conditions. With the markers, the positions of the light are set by simultaneously setting the north-south and east-west orientations so that the film is analyzed as it is positioned on the device. The film is scanned and analyzed with ImageJ/Fiji or Matlab. Referring to the criteria, the compatibility of the defined field with the beam of light on each side of the X-ray field should not exceed 3% of the distance from the focus to the center of the light field and the sum of the deviations in the two perpendicular directions should not exceed 4%. The twist/rotation of the light quadrature and the X-ray quadrature are also analyzed.

3.8 Matching the x-ray beam center and image acquisition center

The compatibility of the X-radiation center (isocenter) with the detector center is a parameter that affects the quality of the image. The perpendicularity of the x-ray beam to the image receiver creates quality and does not distort the image obtained by exposure, but not only. Equally important is the alignment of the light cross with the center of the X cluster, as well as the alignment of its center with the center of the image receiver on the cassette.

The compatibility of the isocenter is related to the measurement above. In order to control these processes, an evaluation of the compatibility of the radiation field with the light field is performed, and then measurements are performed to verify the compatibility of the isocenter and deviations. With piranha, the collimator is adjusted so that the radiation clearly covers the detector (the rectangle marked in the upper panel of piranha). The recommended field is 20 × 40 mm and perpendicular to the surface of the detector.

When the x-ray beam axis is perpendicular to the imaging plane the center of the x-ray field and the center of the image acquisition must coincide within 2% of the focus-image acquisition distance. The alignment of the crosshair with the center of the X-ray beam should not vary by more than 1% of the focus-film distance.

3.9 Orthogonality of x-ray beam and image receiver

The X-ray beam and the receiver must be in a perpendicular position to each other. The perpendicularity of the X-ray beam to the film is very important in order not to create distortions in the image acquisition on the film. In normal measurements, the piranha detector is positioned perpendicular to the X-ray source. Depending on the angle of incidence of the radiation (for small values of the angle), piranha has different approaches. In the measurements performed, the device identifies the radiation angle, which for radiography is generally not a problem, since most measurements are performed in the center of the field, perpendicular to the incident radiation. The angle sensitivity for dose measurement and the detector's approach to positioning at different angles relative to non-perpendicular positioning makes it excellent for measurements being less affected by scattered (secondary) radiation coming from different angles as a result of interaction. In order to control this process, the angle between the central axis of the x-ray beam and the image acquisition plane (film) should not change more than 1.5 degrees for the 90° angles.

3.10 Collimation

The amount of radiation emitted by the patient is proportional to the dose received by the patient as well as the size of the X-ray field. This field must correspond to the minimum necessary to obtain the examination image. Collimation or incident beam limiting is used to accomplish this. The use of the collimator is intended to reduce all types of doses to the patient. The collimator determines the size of the field required for image acquisition. When the total field is larger than the image receiver, we have an unnecessary greater exposure of the patient. In order to measure and verify this parameter, the X-ray beam must be collimated in such a way that the total field of exposure for an image receiver

(film) at a fixed distance remains within the selected limit on the image receiver. The collimator is adjusted so that the radiation clearly covers the detector (the rectangle marked in the upper piranha panel). The recommended field is 20 × 40 mm and perpendicular to the surface of the detector. The values used for detector exposure are the clinical reference values. The displayed dose value has no energy dependence as it is automatically compensated for each KV exposure while the filtering and waveform are measured. The x-ray beam must be collimated in such a way that the total exposure field for an image receiver at a fixed distance remains within the selected limit on the image receiver. In automatic collimation, the x-ray beam should not change more than 2% of the focus-film distance with the sides of the film.

3.11 Control in automatic exposure and radiation leakage

The maximum focus load for graphics should be less than 600 mAs. The exposure time for a single exposure should be no more than 6s. In radiological equipment it is important to verify possible defects related to radiation flow/output. At the exit of the lamp, the X-ray should come out only in a certain window. With its closure, the radiation should be almost zero. If there is such a flow, however small, it affects the quality of the image by increasing the values of the scattered radiation. The change in film optical density between two exposures for the same automatic exposure control values, one with a short exposure time and the other with a long exposure time, should be less than 0.3 of the optical density value. For a given thickness of the object during the test, the maximum change in the optical density of the image as a function of the tube voltage values, which are used in practice, should not exceed the value of 0.3 of the optical density value. For a given voltage during the test, the maximum change in the optical density of the image as a function of thickness should not exceed the value of 0.3 of the optical density value. In order to control the process, the radiation coming out of the lamp box, measured at a distance of 1m from the source, should not exceed 1mGy/h. Since radiation values can be low, measurements are made with Piranha and Piranha Dose Probe to measure the lowest possible dose rate, up to 0.1 µGy/s. The protocol continues with other radiologic devices (Cin-radiology - Pulsed radiation, Fluoroscopy, Pulsed fluoroscopy, Mammography, Dental x-ray, Panoramic (OPG) and CT), in accordance with Decision no. 404, dated 18.6.2014, on the approval of the regulation "On the basic rules of radiological installations in medicine".

4. CONCLUSIONS

The process of measurements in the subject ends only when the representative has received all the information, performed the measurements and recorded the data in the computer. Based on the archived data, a large range of functionalities and reports are offered depending on the device, the technology it uses, the measured values, etc. With the recorded data, personalized reports are generated instantly.

Meanwhile, based on the results, limits/limits of acceptance and analyzes are determined according to the legal provisions in force. The requirements are in accordance with the criteria and requirements regarding the accuracy of the error and the technical and specific definitions of the device. At the end of each process, the final report is generated

which contains data on the evaluated subject, the device under evaluation, the measurement procedure, the analysis, the final evaluation, the summary and the recommendations.

Data is stored electronically and archived. If the subject is evaluated for the first time, his database profile is created and further access is granted (if required). This enables access for the subject to electronic data and ease of application in the future. The subject remains informed about the latest data about the device, the new testing time and other necessary notifications. A database of measurements is created for each subject by standardizing the formats for reporting and archiving. The data is automatically synchronized online for remote access by representatives of the diagnostics center. The connection to the online database for sharing data with other evaluation and monitoring institutions to see in real time the situation of the radiological equipment in relation to their functionality, enables real time monitoring.

At the end, the subject's certificate is generated and issued to him on the date of the performed evaluation and the duration of its validity. We recommend to the institutions that provide diagnostic services, the integration into the European assessment systems based on the self-declaration methodology.

Strengthening QA and QC systems providing real-time information. At the same time, it helps the institutions themselves to increase their capacities, knowing the new level compared to other institutions at the European level. The hospital centers, should increase the transparency to publish accurate data on the radiologic equipment in use and certification. It is confirmed that the level of diagnosis in the country is below the average level compared to the standardized COCIR's Golden rules but we but we found a noticeable improvement especially after the Covid 19 pandemic.

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Conflicts of interest

The authors declare no conflicts of interest.

References

- 1) Radioprotection office Regulation, 2014. Regulation for the basic rules of the installations radiologic in medicine.
- 2) Kamberi, Fatjona et al. "Impact of COVID-19 pandemic on mental health, risk perception and coping strategies among health care workers in Albania - evidence that needs attention." *Clinical epidemiology and global health* vol. 12 (2021): 100824. DOI: 10.1016/j.cegh.2021.100824
- 3) Hyka, N. et al. "How chest CT radiation dose of patients with confirmed COVID-19 will impact the cancer risk in the future." *Physica Medica* vol. 92 (2021): S230–S231. DOI:10.1016/S1120-1797(22)00497-5.

- 4) International Atomic Energy Agency, 2023. | Series: IAEA human health series, ISSN 2075–3772; no. 47 | Includes bibliographical references. Identifiers: IAEAL 22-01533 | ISBN 978–92–0–130322–6.
- 5) COCIR (2021), Medical Imaging Equipment Age Profile & Density, 2021 Edition
- 6) Piranha MULTI 2021, Piranha meters, https://rtigroup.com/wp-content/uploads/2023/01/The-RTI-Piranha-Family-Brochure-A4_converted-v10.pdf
- 7) Cappabianca, Pietro et al. “Universal Access to Advanced Imaging and Healthcare Protection: UHC and Diagnostic Imaging.” *Medical sciences (Basel, Switzerland)* vol. 9,4 61. 27 Sep. 2021, doi:10.3390/medsci9040061S.
- 8) A. Amundson et al., “Biological indicators for the identification of ionizing radiation exposure in humans,” *Expert. Rev. Mol. Diagn.*, vol. 1, no. 2, pp. 211-219, Jul. 2001.DOI: 10.1586/14737159.1.2.211, PMID: 11901816
- 9) The Organisation for Economic Co-operation and Development, OECD 2021. <https://data.oecd.org/searchresults/?q=MEDICAL+IMAGING>
- 10) ALBMEDTECH (2021), Albanian Medical Technology, Albmedtech “Measurement methodology for certification of radiologic devices”, <https://albmedtech.com>
- 11) AI4MED (2023) Artificial intelligence for medicine, <https://ai4med.net>
- 12) Ministry of Health, Health system in Albania, <https://shendetesia.gov.al/organizimi-i-sistemit-shendetesor/>
- 13) Bente et al. “Radiographic and fluoroscopic X-ray systems: Quality control of the X-ray tube and automatic exposure control using theoretical spectra to determine air kerma and dose to a homogenous phantom.” *Journal of applied clinical medical physics* vol. 22,8 (2021): 204-218. DOI:10.1002/acm2.13329.