**IAEA-TECDOC-1565** 

# Validation Procedures of Software Applied in Nuclear Instruments

Proceedings of a Technical Meeting held in Vienna, 20–23 November 2006



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#### FOREWORD

The IAEA has supported the availability of well functioning nuclear instruments in Member States over more than three decades. Some older or aged instruments are still being used and are still in good working condition. However, those instruments may not meet modern software requirements for the end-user in all cases. Therefore, Member States, mostly those with emerging economies, modernize/refurbish such instruments to meet the end-user demands. New advanced software is not only applied in case of new instrumentation, but often also for new and improved applications of modernized and/or refurbished instruments in many Member States for which in few cases the IAEA also provided support.

Modern software applied in nuclear instrumentation plays a key role for their safe operation and execution of commands in a user friendly manner. Correct data handling and transfer has to be ensured. Additional features such as data visualization, interfacing to PC for control and data storage are often included. To finalize the task, where new instrumentation which is not commercially available is used, or aged instruments are modernized/refurbished, the applied software has to be verified and validated.

A Technical Meeting on "Validation Procedures of Software Applied in Nuclear Instruments" was organized in Vienna, 20–23 November 2006, to discuss the verification and validation process of software applied to operation and use of nuclear instruments. The presentations at the technical meeting included valuable information, which has been compiled and summarized in this publication, which should be useful for technical staff in Member States when modernizing/refurbishing nuclear instruments. 22 experts in the field of modernization/refurbishment of nuclear instruments as well as users of applied software presented their latest results. Discussion sessions followed the presentations. This publication is the outcome of deliberations during the meeting. The IAEA thanks all the participants for their active participation in the meeting. Special thanks are here for H. Rongen for his preparation.

The IAEA officer responsible for this publication was H. Kaufmann of the Division of Physical and Chemical Sciences.

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# SUMMARY

#### 1. Introduction

Nuclear instruments are the fundamental tools for deriving benefits from any application of nuclear science and technology. Most applications involve the detection and surveillance of radiation, data acquisition and data processing, while the user profile can vary from academic researchers, healthcare professionals, industrial technologists, and environmental scientists to radiation protection and reactor personnel. The International Atomic Energy Agency regularly assists Member States in the acquisition, maintenance, repair, modification and refurbishment of nuclear instruments. In this respect, Member States have an interest in the building up of capacity for self-reliance and sustainable activities.

Almost all modern instruments are nowadays driven by microprocessors or microcontrollers. This brought a new component for the design and use of such equipment; the software. This new component, as any other part of the systems, must work properly for avoiding wrong measurements or even incidents or accidents. Consequently it is necessary to develop procedures and methodologies for assuring that this new part of the equipment will properly work.

Improper software, which can lead to inaccuracy of the whole system, can be identified and corrected through proper verification and validation of every step of the development. Therefore software validation is a key aspect of quality control, enhancing the reliability of the operation of instruments and of the data obtained.

The refurbishment of nuclear instruments (NI) deals with typical nuclear applications like single-channel analyzer (SCA), multi-channel analyzer (MCA) and counting systems. This kind of nuclear data acquisition is the basis for environmental monitoring, human health instrumentation, nuclear research and nuclear technology based industrial applications. In refurbishment of NI the use of a PC and/or embedded micro controllers ( $\mu$ C) inside the instruments brings many advantages to the instruments. Using this approach the software running on the PC/ $\mu$ C determines the functionality of the instruments and can add new or extended functionality to the NI under refurbishment, like improved throughput, reduction of human error by automated data acquisition, date storage and traceability. But these advantages can be limited or even lost if the development is not handled according to proper method and/or that the potential problems of the application are not fully understood.

Several national institutes worldwide made attempts to refurbish or already refurbished their nuclear instruments to meet the current end-user demands like automatic control, data acquisition, and evaluation towards the traceability of data. The refurbishment/modernization of equipment improves the quality of the measurements and, in many cases, allows the continuation of vital activities that would be stopped due to the unavailability of the proper high cost instruments. Since refurbishment/modernization is performed using microprocessors and microcontrollers, to assure the overall quality of the "new equipment", it is necessary to perform the verification and validation of the software developed for these applications.

The IEEE STD 1012-1998 treats the "verification" and "validation" as separate terms which should be considered by software developers. Detailed information can be obtained from: (http://standards.ieee.org/reading/ieee/std\_public/description/se/1012-1998\_desc.html)

The following paragraphs present a brief summary of the standard.

Software verification is the test that the specified requirements have been fulfilled. A continuous verification during the process of development ensures that the product at each development phase meets requirements given by the specification. Therefore the verification is the test that the product was built right. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated.

Software validation refers to the process of evaluating a computer based system at the end of its development, to ensure that it is free from failures and complies with its requirements (paper 1).

Validation is the test that the particular requirements for a specific intended use are fulfilled.

This validation occurs through the utilization of various test procedures throughout the development of the product. Even it is more or less impractically to test software with all possible input data and all execution paths, the process of validation should assure that the software and the whole system delivers correct results within the range of usage given in the specification of the product.

In this publication, the terms verification and validation are used interchangeably, as it is seen as a single concept and mentioned by the term V&V.

The process of V&V takes places at several levels during the software development.

Intensive component tests should be done for every software component (a subroutine for a mathematical algorithm). Software components (units, module) should be tested separately, by stimulation with given input data, and by checking the expected output values. This leads to a set of tested software building blocks which can be used in different application.

The integration tests checks the interaction of several software components which are integrated together. This testing proceeds until the entire system has been integrated.

System tests are used to test the complete system, verifying that the overall system meets its specified requirements. Reference measurement systems are needed, enabling users and developers to test software themselves by comparing measurement data and calculated results to data generated using an "industrial standard" hardware. A final acceptance test determines whether or not the system satisfies its acceptance criteria of the end user (customer).

There are typical techniques which can be applied to the various testing levels outlined above.

This publication describes current activities in the field of software verification and validation procedures applied to data acquisition/evaluation software as utilized in MCAs and nuclear counting systems. These NI are mostly applied in environmental monitoring, nuclear spectroscopy, industrial applications, etc.

In addition to the IEEE STD 1012-1998, the software applied in nuclear instruments has to be verified and validated to the specific requirements of the nuclear instruments. The dedicated QC procedures for various nuclear instruments are described in the next section.

# 2. Modernization/refurbishment and software validation of nuclear instruments performed in Member States

This section provides information on performed modernization/refurbishment with the individual validation process for the stated nuclear instruments or of the validation procedure (process) for dedicated nuclear spectroscopy software.

# 2.1. Modernization of TLD readers

A thermo-luminescence dosimeter (TLD) reader (Harshaw Model: 2271 & 2000B) which was used by the Atomic Energy Authority (AEA) of Sri Lanka was recently modernized (paper 15). For this purpose the instrument was interfaced to the universal data acquisition module (UNIO-52) (paper 18), which is controlled through virtual instrument software to provide data traceability as needed by end users.

Correctness and consistency of the results and functioning of the system were verified with electrical reference signals. The accuracy of the results of radiation dose measurements was also verified by using exposed TLDs which were irradiated in a SSDL facility. Comparison of the results with the modern computerized TLD system also verified the accuracy of the results. With these evidences, it was concluded that the validity was given for software and suitability of the TLD system for reading TLD cards for measurement of radiation dose.

This instrument is currently used as a backup system at the Radiation Protection Division of the AEA.

It is known that other brands of TLD readers are being modernized in Latin American countries using a similar approach.

#### 2.2. Nuclear spectroscopy software packages for quantitative analysis

Continuous evaluation and verification of nuclear spectroscopy software and the quantitative analysis is needed to ensure high quality analytical results.

In order to extract maximum performance/information from nuclear spectrometry systems, reliable software is an absolute necessity. In this respect, validation procedures for analytical software involve the verification and validation of the spectra data and the analytical methods used.

Comparison methods have been used as a tool to validate nuclear analytical software packages. Such a work has been done at Nuclear Technology Development Centre of the National Nuclear Energy Commission (CDTN/CNEN) in Brazil for the validation of  $k_0$ \_IAEA software (paper 2).

Reference or standard spectra have been used to evaluate the performance of conventional spectrum analysis algorithms (peak search, base line subtraction, peak area integration and multiple fitting) at the Atomic Energy Commission of Syrian Arab Republic (AECS) (paper 5).

Alternative evaluation by measurements of known samples has also been done at Malaysian Institute for Nuclear Technology (MINT), Malaysia (paper 6). In this method the performance tests of the used hardware must be carried out.

A special purpose data evaluation and analysis software applied to gamma-ray spectrometry has been developed and is being used in Nuclear Science and Technology Institute of the Atomic Energy Organization of Iran, Islamic Republic (NSTRI/AEOI) (paper 8).

A general data-acquisition board was used, to develop a MCA system in China Institute for Atomic Energy (CIAE), China. The whole system has been validated by using known sources  $(^{60}$ Co) (paper 11).

For gamma-efficiency calculations of semiconductor detectors in environmental radioactivity control and monitoring, the software ANGLE  $2.0^1$  and its experience were presented.

Software Development and Validation for Refurbishment of Nuclear Instruments (paper 17).

### 2.3. Environmental monitoring

A computer-controlled area radiation monitoring system was designed at the Nuclear Electronics Department of the Nuclear Research Centre for Agriculture and Medicine (NRCAM) of AEOI, Karaj. The system comprises a number of area radiation monitors, used for dose-rate measurements, connected to a central computer via a network. A user friendly graphical interface, written in Visual C, provides graphs and numerical data-bases of the acquired data. This system is being used successfully in the Cyclotron Department of the NRCAM/AEOI, Karaj since 2004 (paper 10).

A portable meteorological station including a nuclear radiation monitoring instrument based on a BASIC-8052 micro-controller has been designed and implemented at the Syrian Atomic Energy Commission (SAEC) site. The main objective was to design and construct a system which measures physical environmental parameters such as temperature, solar radiation, pressure, wind speed, rain fall and area dose rate. The measured data is in a good agreement with data acquired from similar commercial instruments available at the SAEC (paper 16).

#### 2.4. Refurbishment of whole body counter (WBC)

For the refurbishment of a WBC, a development of a new system to control the whole process in the WBC was done at MINT, Malaysia (paper 14). The refurbishment is based on the UnIO-52 board (paper 18) which is used for the bed positioning and data acquisition. A LabView based graphical-user interface was developed to control the whole system and to store the data for later use. A commercial MCA (Canberra) and spectra evaluation software (Genie-2000, Canberra) are used for the spectrum analysis because of its reliability requirements and was integrated into the LabView application. A software validation process was done to achieve a certain level of system's confidence and reliability before it can be permitted to use for investigation. As a conclusion, this WBC refurbishment was successfully completed and able to fulfill the national needs for the radiation and safety program.

<sup>&</sup>lt;sup>1</sup> This software was presented at the meeting by S. Jovanovic, Montenegro who is the developer of this commercially available software package.

# 2.5. Refurbishment of thyroid uptake and RIA systems

Thyroid uptake system, Probe Renogram (paper 12) and RIA counter (paper 13) have been refurbished using commercial available boards (UnIO-52, AccuSpec NaI) and locally made data acquisition boards to extend nuclear medicine service to the major population in Member States. The systems were refurbished with SCA and MCA techniques. Software for all the equipment was developed in C++ environment on the basis of users need. Software validation tests were performed by the software developer group for both hardware setup and also for the analysis of the acquired data. Quality control tests and total performance verification were done together with the end user using IAEA-TECDOC-602.

Several of these refurbished instruments are being used in different nuclear medicine centers in Bangladesh and Cuba.

# 2.6. Safety systems

For safety related systems, the required software has to be validated towards each of customers' specifications and/or regulations. For the software validation static analysis and dynamic testing were used.

In case of the nuclear power plant, Paks, Hungary (paper 7) the instrumentation and control (I&C) system for the safety and protection functions of the reactor, have been replaced within the scope of the reactor protection refurbishment (Reactor Protection System – RPS). The traditional, wired devices operating with relays were displaced with intelligent equipment of modular construction based on microprocessors corresponding to the then up-to-date technical and technological requirements. The significant modification affected both the hardware and software and required various tests. Verification and validation procedures were applied in the different phases of the design and during the implementation.

# 2.7. Specific consideration for modernization/refurbishment of nuclear instruments (NI) or for advanced design of nuclear instruments

In this section specific considerations are stated.

# 2.7.1. Basic requirements

Quality control of the front-end electronic in NI has to be considered for modernization, refurbishment and for newly designed NI. Test procedures for homogeneity tests of photomultipliers as well as linearity tests for the amplifier(s) and ADC(s) must be performed (paper 3).

# 2.7.2. Simulation

Simulation of physical and technical process helps to understand complex and sophisticated instruments like a PET. Proper simulation helps to reduce the hardware and software verification and validation time (paper 4).

# 2.7.3. Newly designs of NI

For dedicated nuclear instruments such as personal radiation detection systems or for safety related systems poor software can cause very critical errors. The software applied in such instruments has to be tested, verified and validated having no critical error (paper 9).

### 3. Verification and validation (V&V) procedures used

Software V&V is mostly based on a requirements specification (RS) (paper 1). The RS is the basis for the development of a new system and describes the need of the end user. Therefore, the RS is also the basis for the V&V process. The RS identifies the inputs, outputs, and test data to be used as well as the acceptance criteria for the validation.

V&V activities are performed by the code developer or by an independent V&V team. In most cases of code development, the V&V tests are carried out by the code developer. The final system evaluation should be at least supplemented or completely performed by a separate (different and independent persons) V&V team.

The code or software under test is validated when tests results are shown to meet criteria within a previously stated range.

- V&V is a rigorous engineering discipline;
- V&V encompasses *all* life cycle of software;
- V&V tasks and their intensity vary with integrity level;
- Other technical methods support the V&V tasks.

Results should be documented and reported. Each V&V activity should produce a report describing the tests itself and the positive and negative results of the analysis or testing performed. Checklists for each test of the V&V process, containing questions that must be answered, can help to establish reproducible V&V results.

The verification and validation (V&V) techniques used in the different applications described above can be grouped in three categories:

- (1) Evaluation of spectrum analyzing software.
- (2) Validation and verification of software-controlled nuclear instruments.
- (3) Validation and verification of software for safety related systems.

# **3.1.** Evaluation of spectrum analyzing software

In this case a V&V process is applied to existing code. The purpose for the V&V in this case is to determine whether the software produces valid response when applied to problems in some domain. This can be achieved by comparing the results from the software under test against results taken from a reference system. The reference system itself must be a proofed and validated system. The software under test is validated, when tests results are shown to meet criteria within a stated range, compared to the reference system.

Spectra analyzing software can be thoroughly tested and evaluated either by utilization of reference spectra data or by reference samples used in an inter-comparison method.

- Usage of reference spectral data and compare with the known analysis results;
- Usage of a certified source or reference sample and compare the results.

# **3.2.** Validation and verification of software-controlled nuclear instruments

Because of the variety of nuclear instruments, the meeting concluded that for each nuclear instrument controlled by software, an individual (and even different) test programme (procedure) for the validation of the system has to be established.

For the V&V of software controlled nuclear instruments the interaction between the software itself and the instrument hardware must be taken into account and tested. Therefore, some basic hardware validation checks must be performed before the software V&V process. The following tests should be implemented to validate the proper operation of the system.

These are:

- Count accuracy;
- Time accuracy;
- Non- Linearity tests (integral and differential);
- Peak shift versus count rate;
- FWHM versus count rate;
- Minimum detectable activity;
- $CHI^2$  Test.

These basic system tests should be performed periodically in order to assure a technical quality assurance (QA) of the used hardware.

The software V&V process includes techniques like visual code checking, software reviews, data stimulation and system validation. The most effective way to find anomalies at the component level is inspection. The verification of source code includes the manual code inspection (Walkthrough). On the other hand, inspection is not applicable at the system level when the software gets already very complex. During system testing, given input values are traced through the test software items (components) to assure that they generate the expected output values, with the expected intermediate values along the way. Mathematical algorithms are analyzed by test data, which can include estimation of execution times and estimation of system resources. Therefore, a database with test data sets has to be built up. With this method test cases (program feed with test data) are executed and the results are evaluated and compared to their expected values.

Test procedures for software V&V:

- Verification of software modules (subroutines, for example where mathematical equations are executed);
- Variable checking
  - (variable length differs from compiler to compiler);
- Coverage analysis (all possible software branches are covered with code);
- Software inspection (Walkthrough);
- Stimulation of software modules with known stimuli data;
- Stimulation of the complete application with known stimuli data;
- Memory usage (static and dynamic memory, Stack, etc.);
- Performance testing / Critical timing analysis (Real-time requirements, response times);
- Validation of the complete system that it satisfies the end user requirements.

This testing proceeds until the entire system has been integrated and accepted by the customer. The test results must be documented in a test report.

Finally a demonstration of the complete system and reference measurements taken with another proofed system (reference system) gives the assurance of properly implemented software.

#### **3.3.** Validation and verification of software for safety related systems

In this meeting a special session was devoted to safety related systems. V&V for safety related systems must follow a strict systematic approach for improving the reliability of computer codes and reduce the risk of incorrect application. The V&V activities can be performed in parallel with the code development and should be finalized with an end test for the validation of the whole system. In this regard, the validation and verification has to follow national regulations, of proper execution of the safety guidelines. These regulations determine the level and modality of V&V efforts. It was mentioned that general safety systems must be checked to cover all possible scenarios of risks.

# 4. Further requirements for V&V

Verification and validation of software applied to NI should also be accompanied by a suitable quality assurance (QA) programme. A software quality assurance plan (SQAP) has been established at the National Institute of Nuclear Research [Instituto Nacional de Investigaciones Nucleares {ININ}] in Mexico (paper 1) for the QA of the validation of software systems. It can be applied for the development or refurbishment of nuclear equipment that includes software sections. The SQAP provides information on performing the V&V process which includes: the level of effort, the range of acceptance, the activities for V&V, the needed tools, the documentation, and finally the name(s) of the person(s) responsible for the tests.

The use of the SQAP in the development of software for nuclear applications helps to obtain a high quality software product that fulfills all the requirements established by the user.

#### 5. Trends in software development and research

There is a general tendency for using simulator, emulator and debugger techniques for all kind of development. Using simulator from early software development stages helps to avoid general software failures by the simulation of all software behavior before and during the implementation stage.

During implementation and coding of the software, debuggers can be used to test software step by step (single line stepping) and check for the status of the processor, the memory allocation and also values of variables (data) at breakpoints. The debugging process helps to confirm the correct operation of a program or to identify the source of errors. The debugging feature is an integral part of many programming environments like "C" compilers.

Build-in-self-test (BIST) is a mechanism which, coded within the application software, provides automated functions which verifies all or a portion of the internal functionality of the system. BIST functions can be designed to perform field-diagnostics of individual devices or entire systems. For example, at power-up time, a system could acquire a set of data and perform the CHI<sup>2</sup> test in order to make a limited self-diagnostic. Failure of the diagnostic is reported to the user.

#### 6. Future / further needs of the Member States

In the future, the software V&V process should be a part of each refurbishment and development project and should be well-matched to the requirements and also taken into account the availability of test instruments in Member States. According to the problems identified during the meeting, a short checklist, like a guideline, for the different V&V procedures, may help to fulfill the process. An expansion or reference for each of the guidelines can be included. Those guiding principles should include techniques such as various sorts of simulations, interface verification, walk-through, etc. Only by implementing of V&V it can be ensured that the software has the required quality and meets the specification.

The Member States expressed the need for certified sources. Because of the different applications single isotope sources are needed for the software validation of systems under test.

The validation process should be carried out according to V&V standards. Therefore, further education and training on software V&V techniques according to national and international standards and applied to NI are needed. This will improve the skills in the area of V&V.

Modern software development environments include software simulators and debugging techniques. These can be used to verify software components and modules before their implementation in the complex application. Training on software simulators and debugging techniques should be considered.

Inter-comparison exercises of software are a useful tool for the validation of spectra evaluation software. With this method not only the software itself but also the procedure for the software validation is verified. The method is based on digital data and therefore, a good traceability is possible. Therefore inter-comparison exercises will improve the validation process in MS.

The above mentioned needs or improved V&V methods can be met through CRP, technical meeting, training, etc.

Development of complex reference spectra permits a validation of analytical software for very complex spectra (multi-plates). Such spectra should be available on the internet for download.

# References to the submitted papers

Paper 1:	Quality assurance for validation of software applied to nuclear instruments E. Gaytan-Gallardo, T. Rivero-Gutierez
Paper 2:	Validation of the k <sub>0</sub> _IAEA software at CDTN/CNEN, Brazil <i>M.A.B.C. Meneze, R. Jacimovic</i>
Paper 3:	Basic steps in validation of software for nuclear instruments <i>R. Engels</i>
Paper 4:	Hard- and software requirements for nuclear instruments, e.g. for the ClearPET Neuro Scanner <i>K. Ziemons</i>
Paper 5:	A comparison of some softwares used for processing HPGe gamma spectra <i>A. Aba, M. Tlas, W. Doubal</i>
Paper 6:	Method of software validation for <sup>137</sup> Cs and <sup>226</sup> Ra activity measurements in environmental samples using gamma spectrometry system <i>Z. Ahmad, M.W. Yii, A.K. Ishak</i>
Paper 7:	The V&V process of the reactor protection system refurbishment in NPP Paks <i>B. Doszpod</i>
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Paper 15:	Refurbishment and modernization of a thermo-luminescence dosimeter system using LabView virtual instrument software and validation of its results <i>C. Kasige, P.D. Mahakumara</i>
Paper 16:	Software and hardware validation for meteorological station <i>A. Al Mohammad</i>

- Paper 17: Software development and validation for refurbishment of nuclear instruments *Abdul Karim, Rashid Qamar, M. Idris Khattak, M.I. Mahmood, M. Tahir Khaleeq*
- Paper 18: A hard- and software platform for refurbishment of nuclear instruments *H. Rongen*

# Quality assurance for validation of software applied to nuclear instruments

#### E. Gaytán-Gallardo, T. Rivero-Gutiérrez

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**Abstract:** A software quality assurance plan (SQAP) has been established at the National Institute of Nuclear Research in México for validation of software systems, it can be applied for the development or refurbishment of nuclear equipment that includes software sections. The use of the SQAP in the development of software for nuclear applications helps to obtain a high quality software product that fulfills all the requirements established by the user. The SQAP is complemented with the following five procedures that help on its application: Specification of Software Requirements, Software Design and Development, Software user Documentation, Software Configuration Management and Software Verification and Validation.

#### 1. Introduction

The development of complex instrumentation used in modern nuclear applications includes generally a hardware section, an acquisition and processing section and a software section. There is also a strong interdisciplinary collaboration of specialists in this area to fulfill this task. The main goal in producing software applied to nuclear instruments is to create a product that performs according to the user requirements, if the software is developed using good software engineering practices, we can assure that this goal is reached efficiently. The development of software for most of the nuclear instruments or applications, such as safety systems, medical physics, nuclear medicine, reactor control system, etc., is considered as critical systems, due to the fact that failures can result in significant economic losses, physical damage or threats to human life.

For validation of software applied to nuclear instruments, a Software Quality Assurance Plan (SQAP) has been developed at the National Institute of Nuclear Research in Mexico. Five procedures complement the SQAP application. The Software Requirements Specification procedure indicates the points necessary to obtain: system requirements, user requirements, general and specific requirements. In the Software Design and Development procedure, design is a multi-step process in which data design, architectural design, interface design and procedural design are employed; development consists in to develop and document correctly the software code. The Software User Documentation procedure indicates accurately how to write the user manual for the system. The Software Configuration Management defines how to record the components of the Software life cycle and how to process the system changes. The Software Verification and Validation procedure is applied to all components of the Software cycle life. First, the components are verified by means of technical revisions or testing. Each one of the results of the verification must be accorded with the points to apply, as indicated in the procedures. When the verification has been completed, a validation certificate is written and the software is delivered to the users.

#### 2. Software quality assurance plan

The SQAP [1] has been developed, taking as reference the IEEE standard [2], the Technical Report from IAEA [3], regulatory guides from the Nuclear Regulatory Commission [4] and Software Engineering books from Sommerville and Pressman [5, 6]. Software quality assurance is the process of defining how software quality can be achieved and is primarily concerned with defining, selecting or developing procedures that help in the realization of the software product assuring a high quality. The SQAP encompasses procedures for software requirements analysis, design, development, verification, testing strategies, documentation and validation for the effective application of methods and tools. The establishment and execution of this quality assurance plan is necessary for quality control, it provides an independent check on the software development process. Quality assurance is important for all software systems but it is more important for safety-critical systems due to accidents that might occur if the system is unsafe. The SQAP could be supported too with a Software Process Model [7]. The figure 1 shows the procedures and deliverables of the SQAP. In the next paragraphs each one of the procedures are described.

#### 2.1 Software configuration management

The Software Configuration Management procedure [8] has been developed having as reference the IEEE standard [9], it identifies software configuration items, defines how to record the components of the Software life cycle and how to process the system changes; how to relate the components and the methods used to identify different versions of the system. The changes of the functional and physical characteristics of the system are identified and documented, because, as they evolve, generate the need to create different versions of software.

#### 2.2 Software requirements specification (SSR)

This procedure has been developed having as reference the IEEE standard [10], it indicates the points necessary to obtain: system requirements, user requirements, general and specific requirements. The requirements are established in this point and accepted by the user [11]. After to have the software requirements it is necessary to create a document that describes exactly what the user wants. The requirements are modelled by graphical diagrams.



Figure 1. Diagram of the Software Quality Assurance Plan (SQAP)

In software systems for nuclear applications in which there is a strong interaction with hardware, it is essential that the system operation is always safe and the software requirements are critical in safety and successful project development. Some examples of these kinds of systems are: data acquisition and control systems, monitoring systems, safety systems, etc. The figure 2 shows a methodology to follow in order to get the software requirements [12].

The requirements identification allows the analyst to gather and understand the requirements. The feasibility study is made to estimate whether the user needs may be satisfied using existent software and hardware technologies, the feasibility report helps to decide if we must go ahead with a more detailed requirements analysis. The requirements analysis helps the analyst to understand the system to be built through discussions with users and tasks analysis; this involves the development of system models and prototypes. The requirements specification consists on to translate the information gathered during the analysis activity into a document that defines a set of requirements, the prototype created is used as a basis for writing the requirements specification for a safe critical system. The requirements validation is the processes that checks and ensures that the requirements specification is realist, consistent and complete. An especial emphasis is made about software requirements because the correction of errors in this level is less expensive than when they are discovered in posterior levels or when the software product is delivered.



Figure 2. Software Requirements Methodology.

#### 2.3. Software design and development

The design transforms the analysis model into a design model that serves for software development. Design is a multi-step process in which Data Design, Architectural Design, Interface Design and Procedural Design is employed [13]. The data design translates the data objects defined in the analysis to data structures that reside within software. The architectural design uses the characteristics of the information flow described in the analysis model to obtain the program structure. The interface design takes programs of internal and external interfaces and the user interface design. The design notation, together with the structured programming concept permits to develop the procedural design facilitating the code translation. Development is the process of converting a requirements specification into an executable system. This procedure has been developed having as reference the IEEE standard [14].

#### 2.4. Software user documentation

The software user documentation procedure indicates how to write the user manual [15] the user manual contains information for: the use of the document, general use of the software, information on software commands, error messages and terminology. This procedure has been developed having as reference the IEEE standard [16].

#### 2.5. Software verification and validation

The verification and validation is applied to all components of the Software cycle life. First, the components are verified by means of technical revisions or testing. Each one of the results of the verification must be accorded with the points to apply, as indicated in the procedures. The verification and validation are realized to ensure that software conforms to its specifications and to meet the needs of the system users. All documents generated in the system are checked. The system is tested to the users, examining the outputs of the software and its operational behaviour [17]. When the verification has been completed, a validation certificate is written and the software is delivered to the users. Verification and validation start with software configuration management, continue with requirements reviews and finish trough design and code inspections to product testing. The verification and validation process for software developed for nuclear instruments has much in common with that for any other software; however the costs and consequences of this kind of software could be much greater.

For the software test, component and integration testing are used. During the integration testing, individual components are tested and integrated to complete the whole system in order to ensure that the software requirements have been met. The tests are made by using black-box testing that consists in the analysis of its inputs and the related outputs. This procedure has been developed having as reference the IEEE standard [18].

#### 3. Training in the use of the SQAP

The SQAP is the establishment of framework of organizational procedures in order to obtain high quality software. In practice there are much more to ensure that the following of these procedures. For application of the SQAP it is necessary to develop a quality culture. In systems for nuclear instruments it is necessary to train the software developers in the application of this plan in order to: a) realize a software configuration management, b) understand the user requirements and establish a system specification that defines the system to be implemented, c) avoid mistakes during the development by the application of a detailed software design, d) detect and remove errors applying the verification and validation procedure, and e) limit the damage caused by operational failures when the system is in use. To reach this objective a training manual has been developed [19] and a course has been imparted to people who develop software for nuclear instruments or applications in the National Institute of Nuclear Research in México.

#### 4. Study cases

The SQAP has been applied successfully in the development of the following systems: Grain Size Analyzer [20], System for the Measurement of X-Rays with PIN Diodes [21], Refurbishing of a Freeze Drying Machine used in Nuclear Medicine for Radio-pharmaceuticals Production [22] and a System for the Calibration of X-Ray Measuring Instruments [23].

#### 4.1. Grain size analyzer

In this system the image of the material is acquired, filtered and also convolution is applied. After that the threshold values are identified, the results of the threshold process is a binary image with pixel values of ones and zeros. The grains are represented by the connected pixels of ones, and the background is represented by the zeros. The light can be adjusted to get the maximum contrast between the background and the particles you wish to count. Partially visible grains that touch the edge of the field of view are removed. Analysis results are displayed in an easy to read format. A histogram of grain sizes in values as well as minimum, maximum, average grain size, field area, and total area measured are provided as per current specification.

#### 4.2. System for the measurement of X rays with PIN diodes

A system for the X ray measurements (dose and exposure) for the Detectors Laboratory and the Secondary Standard Dosimetry Laboratory (SSDL) of the National Institute of Nuclear Research in México has been developed. The detectors used in the measurements are PIN type silicon diodes and their output is a charge or current signal, this signal is converted to voltage with a preamplifier. The output is proportional to the X ray intensity and associated energy. The PIN type silicon diodes employed for the measurement of X-ray have different filters, one of tungsten and another of aluminum. The X ray measurement system was partially supported by International Atomic Energy Agency (ARCAL LIII project).

# 4.3. Refurbishing of a freeze drying machine used in nuclear medicine for radiopharmaceuticals production

The refurbishing of a freeze drying machine used in the radiopharmaceuticals production, applied in nuclear medicine in the Radioactive Materials Department of the National Institute of Nuclear Research in México, was realized. The freeze drying machine was acquired in the 80's decade and some components started having problems. Then it was necessary to refurbish this equipment by changing old cam-type temperature controllers and outdated recording devices, developing a sophisticated software system that substitutes those devices. The system is composed by a freeze drying machine by Hull, AC output modules for improved temperature control, a commercial data acquisition card, and the software system.

#### 4.4. System for the calibration of X-ray measuring instruments

A software system that facilities the calibration of X ray measuring instruments used in medical applications is presented. The Secondary Standard Dosimetry Laboratory (SSDL) of the National Institute of Nuclear Research in México, supports activities concerning with ionizing radiations in medical area. One of these activities is the calibration of X ray measuring instruments, in terms of air kerma or exposure by substitution method in an X ray beam at a point where the rate has been determined by means of a standard ionization chamber. A software system has been developed, to automate this process, the calibration system is composed by an X ray unit, a Dynalizer IIIU, an X ray meter by RADCAL, a data acquisition card, the software system and the units to be tested and calibrated.

#### 5. Future work

It is important to consider the creation of a Software Engineering Laboratory at the National Institute of Nuclear Research as future work, and have training in the Software Engineering area, that permits to develop software applied to nuclear instruments with high quality. With respect to the freeze drying machine, next activity is to upgrade completely this equipment, considering the vacuum system, pressure sensors, water systems and electrical connections applying the Software Quality Assurance Plan.

#### 6. Conclusions

The development of software for nuclear applications requires a detailed plan of quality assurance that helps to validate the resulting product. This goal will be reached with the application of the SQAP in the National Institute of Nuclear Research in México, but it is important first to develop a quality culture, training the software developers. The SQAP helps to improve the quality of the software product, and permits to save costs and time, avoid physical damage or threats to human life. The Software Requirements Specification is an essential part in the record of needs in order to accomplish the analysis of requirements in safety system software. It is the base for the development of the software and should exhibit characteristics such as correctness and completeness that will facilitate the implementation of the software system. The development of software systems for refurbishing is very important in countries as México, because it allows converting old equipment in a modern system, where the main differences are the added capabilities of data acquisition and processing. automated control, internet monitoring, data storage and monitoring of process status. The refurbishing of the freeze drying machine shows that it is possible to refurbish old equipment, with the appropriate tools and developing specific software. This would give some more years of useful life to old equipment at a very low cost.

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# Validation of the k<sub>0</sub>\_IAEA Software at CDTN/CNEN, Brazil

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**Abstract.** The Laboratory for Neutron Activation Analysis, CDTN/CNEN acquired the  $k_0$ \_IAEA software package during the Workshop on Nuclear Data for Activation Analysis, 2005, held at the Abdus Salam International Centre for Theoretical Physics, Trieste, Italy. After the software being set up according instructions of the guidelines, a validation procedure was carried out at aiming at local laboratory validation of the  $k_0$ \_IAEA software. Several reference materials were analyzed by this software and the results compared to the KAYZERO/SOLCOI<sup>®</sup> version Windows, KayWin, a commercial program. The overall results pointed out that the  $k_0$ \_IAEA software is working properly but it still needs to be improved and the validation process is not complete as more reference materials should be analyzed. In spite of this fact, the overall results presented small uncertainties and they are also within the range of certified values uncertainties.

#### 1. Introduction

The Laboratory for Neutron Activation Analysis, LNAA/CDTN, located at Centro de Desenvolvimento da Tecnologia Nuclear (Nuclear Technology Development Centre) sponsored by Comissão Nacional de Energia Nuclear (Brazilian Commission for Nuclear Energy), CDTN/CNEN, has developed its activities since the starting up of the IPR-R1 TRIGA Mark I research reactor in 1960. Due to the growing need to determine several elements in only one sample meeting the clients' analytical needs, it was necessary to look for a more efficient method in order to avoid the need to prepare and measure several multi-elemental standards for each analytical sample. In 1995 the k<sub>0</sub>-standardization method of neutron activation analysis was introduced [1, 2] at CDTN/CNEN. In 2003 it was assisted by the KAYZERO/SOLCOI<sup>®</sup> software package [3] and improved in 2005 [4]. Its validation was established via the analysis of two matrix reference materials, one from the United States Geological Survey (GXR-6 Soil) [5] and the other from IAEA (IAEA/Soil-7) [6]. In 2006, the program was updated to version Kayzero for Windows, KayWin [7].

This paper is about the development of a validation procedure carried out at aiming at local laboratory validation of the  $k_0$ \_IAEA software package, other program about  $k_0$ -method. The specific objective was just to validate just the final elemental concentration calculated by the software.

#### 2. k<sub>0</sub>-standardization method

The  $k_0$ -standardization method [8, 9] is a "quasi" absolute technique in which instead of standards, neutron flux monitors are used. The unknown nuclear data are replaced by compound nuclear constants characterizing the nuclides, called  $k_0$  factors. The  $k_0$ -method requires good knowledge of spectral parameters of the neutron flux in irradiation channels of the reactor. Due to the powerful characteristic of this method on elemental concentration determination besides other applications, the method was widely accepted by neutron activation users. As it has several advantages as a non comparative method, it was set up in routine analytical analysis producing results with high accuracy and small uncertainties.

In 1992 the KAYZERO/SOLCOI<sup>®</sup> was introduced and in 2005 it was updated to version Windows, the KayWin. It was the first commercial program purchased by several laboratories achieving very good results. However, due to diversified reasons, several laboratories developed their own programs. Aiming at harmonizing the results produced by these "inhouse" software, the International Atomic Energy Agency, IAEA, made a new program, called  $k_0$ \_IAEA software package [10] available. It was freely distributed to more than 50 laboratories in 36 countries during a few training courses.

#### 3. Validation

Software has been proved as a relevant and useful tool in all fields of knowledge. However, day by day the dependence on this component has been increasing as well as software developers' responsibility to offer trustworthy products. Thereby, reliability in computerized data is one of the utmost qualities of software. One way to assure its quality is to perform the software validation, so that it can be demonstrated that software is reliable and reproducible in the hands of users (the staff in that laboratory or other places). It means that the software meets the requirements of a specific and determined use.

Some norms as ISO 8402:1994 [11] define software validation as "a part of the design validation for a finished device". The ISO/IEC 17025: 2005 [12] defines validation as "the confirmation by examination and the provision of effective evidence that the particular requirements for a specific intended use are fulfilled". Several validation techniques are described in the literature [13]. One of them, for instance, is a process usually informal – peer review – in which the software is tested by any member.

Concerning the  $k_0$ \_IAEA software package, the IAEA distributed the program to several laboratories [10] and has accepted suggestions from the users about the performance of the program. The program is still being improved. It may be one of the reasons why on the IAEA, up till now, has not suggested any procedure to validate the program. This is an informal way to validate the software – peer review – in which the software is tested by any member or user. Therefore, this procedure is in accordance with one of the processes described in the norm ISO/IEC 12207 [13].

On the other hand, the CDTN/CNEN established a management system for quality control based on the ABNT NBR ISO/IEC 17025:2005 norm, "General requirements for the competence of testing and calibration laboratories" [12]. This norm does not foresee how to validate software. It only guides the methods in general. Item 5.4.5 "Validation of methods", Note 2, page 15, determines that the calibration should be performed using reference materials

and results should be compared to other methods, besides other guidelines that are not related to software.

Based on these instructions, the procedure followed to validate the  $k_0$ \_IAEA software was to analyze several reference materials comparing the results obtained by this software to the certified values and also to the commercial KayWin software package, already established at the LNAA/CDTN. Therefore, the validation procedure for the software  $k_0$ \_IAEA software adopted was in accordance with the ISO/IEC 17025:2005 and with the ISO/IEC 12207.

# **3.1 Experimental Part**

The LNAA/CDTN acquired the  $k_0$ \_IAEA software package during the Workshop on Nuclear Data for Activation Analysis, 2005, held at the Abdus Salam International Centre for Theoretical Physics (ICTP, Trieste, Italy). The installation and calibration of the  $k_0$ \_IAEA version 1.02 software package at the CDTN followed the procedure suggested by Blaauw [14] and the program guidelines. Afterwards, the program version was updated to the version 2.0.

It is relevant to mention that both programs KayWin and  $k_0$ \_IAEA software, were calibrated with respect to energy versus channel number and peak width versus photon energy, using the same <sup>152</sup>Eu and background spectra. The same dimensions of the samples and detector as well as information about irradiation facilities were edited to both programs. In order to calculate the elemental concentration of the reference material in the KayWin and  $k_0$ -IAEA, the same files – net peak area (\*.PTF) and spectrum (\*.SPE) files – were used generated by HyperLab ver 2002.3 program [15]. It would have been possible to use the  $k_0$ \_IAEA program to generate these files, however, the use of the HyperLab assured that the elemental concentration was based on the same files in both programs.

The validation was established using two complex matrices as soil (GXR-6 [5], and IAEA/Soil-7 [6]) and sediment (BCR-320 [16]) due to the diversity of chemical elements and concentration. Another less complex matrix was also used, a vegetable matrix (GBW 07602 [17]). These reference materials were analysed in order to verify whether the experimental determinations of reactor parameters (f and  $\alpha$ ) and the detector calibrations were fully operational in the k<sub>0</sub>-standardization method.

Aliquots of about 200 - 300 mg of the reference material were weighed in pure polyethylene vials and inserted in another polyethylene vial intercalated with Al-(0.1%) Au discs (6 mm in diameter and 0.2 mm thick), alloy IRMM-530, from Central Bureau for Nuclear Measurements, Geel, Belgium, as monitors.

The samples were irradiated in the TRIGA MARK I IPR- R1 reactor located at CDTN/CNEN. The irradiation was for 8 hours in the channel IC-7, where the parameters f and  $\alpha$  [4] are 22.32 and -0.0022, respectively and the thermal neutron flux is 6.35 x 10<sup>11</sup> cm<sup>-2</sup> s<sup>-1</sup>, at 100 kW.

After 2-3 days, 8-10 and 21 days cooling time, the activities were measured on the HPGe detector, a coaxial detector – CANBERRA - with 15% relative efficiency at the 1332.5 keV gamma line of  $^{60}$ Co. The spectra were acquired by Genie PC program CANBERRA and applied the HyperLab ver 2002.3 program [15] for net peak area evaluation.

### 4. Results and Discussion

Table 1 shows the concentration values for reference materials – BCR-320, GBW 07602, GXR-6 and IAEA/Soil-7 obtained by both software and the certified values.

	GDW 0/002	GAR-0	IAŁA/S011-7
(River	(GSV-1,	(Soil)	
Sediment)	Vegetable)	220 + 11	1 4 + 1
± 3	< ]	$328 \pm 11$	$14 \pm 1$
$\pm 6$	$0.7 \pm 0.3$	$288 \pm 10$	$13 \pm 2$
$.7 \pm 3.4$	$0.95 \pm 0.08$	$330 \pm 25$	$13.4 \pm 0.85$
	-	$0.085 \pm 0.003$	-
	-	$0.058 \pm 0.003$	-
	-	$0.095 \pm 0.014$	-
	$19990 \pm 1652$	$16280\pm621$	-
	$18360\pm3342$	$17500\pm1200$	-
	$22200\pm700$	$18000 \pm 7000$	-
	$2.0\pm0.1$	$36 \pm 1$	$58 \pm 2$
	$2.0\pm0.3$	$27 \pm 1$	$47 \pm 6$
	$2.4\pm0.2$	$36 \pm 4$	$61 \pm 6.5$
	$0.46\pm0.02$	$14 \pm 1$	$9.2\pm0.3$
	$0.49\pm0.04$	$14 \pm 1$	$10 \pm 1$
	$0.39\pm0.03$	$13.8 \pm 1.0$	$8.9 \pm 0.85$
	$0.25\pm0.01$	$4.3 \pm 0.2$	$5.5 \pm 0.2$
	$0.25\pm0.04$	$3.4 \pm 0.2$	$5 \pm 1$
	$0.27\pm0.02$	$4.20 \pm 0.21$	$5.4 \pm 0.75$
	< 0.05	< 0.8	$1.1 \pm 0.1$
	$0.04\pm0.01$	$0.53\pm0.05$	$0.9 \pm 0.2$
	$0.037\pm0.002$	$0.76 \pm 0.03$	$1.0 \pm 0.2$
	$1073 \pm 43$	57660 ± 2021	-
	$1104 \pm 102$	55250 ± 1381	-
	$1020 \pm 40$	$55800 \pm 4100$	-
	< 0.1	$3.8 \pm 0.2$	$5.0 \pm 0.2$
	$0.14 \pm 0.03$	3.0 ±0.1	$4.0 \pm 0.1$
	$0.14 \pm 0.02$	$4.3 \pm 0.7$	$5.1 \pm 0.35$
	$7996 \pm 767$	$19820 \pm 942$	-
	8043 ± 1017	$26830 \pm 2227$	-
	8500 ± 300	$18700 \pm 400$	-
	$1.08 \pm 0.04$	$13.7 \pm 0.5$	$28 \pm 1$
	$1.1 \pm 0.1$	$12.3 \pm 0.4$	$27 \pm 1$
	$1.23 \pm 0.07$	$13.9 \pm 0.9$	$28 \pm 1$
	$10600 \pm 372$	$1036 \pm 40$	-
	$11250 \pm 1000$	$1310 \pm 56$	-
	11000 + 600	1060 + 90	-
	(River         Sediment) $\pm 3$ $\pm 6$ .7 $\pm 3.4$	Bernetics $(GSV-1, Vegetable)$ $\pm 3$ <1	OctorOctorOctorOctorSediment)Vegetable)(Soil) $\pm 3$ <1

# TABLE 1: ELEMENTAL CONCENTRATIONS DETERMINED BY KAYWIN AND $$\mathbf{k}_0\_$ IAEA SOFTWARE

El.	Software	BCR 320	GBW 07602	GXR-6	IAEA/Soil-7
		(River	(GSV-1,	(Soil)	
		Sediment)	Vegetable)		
Rb	KayWin	-	$3.5\pm0.5$	$84 \pm 4$	$51 \pm 2$
	k0_IAEA	-	$3.3 \pm 0.5$	$75 \pm 2$	$50 \pm 4$
	Cert. v.	-	$4.2 \pm 0.2$	$90 \pm 4$	51 ± 4.5
Sc	KayWin	$16 \pm 1$	$0.32\pm0.01$	$28 \pm 1$	9.1 ± 0.3
	k0_IAEA	$17 \pm 1$	$0.33\pm0.03$	$26 \pm 1$	$9\pm1$
	Cert. v.	$15.25\pm0.36$	$0.31\pm0.02$	$27.6\pm2.6$	$8.3\pm1.05$
Sm	KayWin	-	$0.16 \pm 0.01$	$2.5 \pm 0.1$	$4.9 \pm 0.2$
	k0_IAEA	-	$0.16\pm0.02$	$1.9 \pm 0.1$	$4.3 \pm 0.4$
	Cert. v.	-	$0.19 \pm 0.01$	$2.67 \pm 0.15$	$5.1 \pm 0.35$
Sr	KayWin	-	$296 \pm 12$	< 50	< 120
	k0_IAEA	-	$302 \pm 26$	$40 \pm 15$	$121 \pm 14$
	Cert. v.	-	$345 \pm 7$	$35 \pm 4$	$108 \pm 5.5$
Та	KayWin	-	-	$0.38\pm0.02$	$0.73\pm0.03$
	k0_IAEA	-	-	< 0.1	$0.69\pm0.04$
	Cert. v.	-	-	$0.485\pm0.030$	$0.8 \pm 0.2$
Tb	KayWin	-	-	-	$0.65\pm0.02$
	k0_IAEA	-	-	-	$0.5 \pm 0.1$
	Cert. v.	-	-	-	$0.6 \pm 0.2$
Th	KayWin	-	$0.38\pm0.02$	$5.2 \pm 0.2$	$8.2 \pm 0.3$
	k0_IAEA	-	$0.34\pm0.04$	$3.4 \pm 0.1$	$6 \pm 1$
	Cert. v.	-	$0.37\pm0.02$	$5.30 \pm 0.22$	8.2 ± 1.05
U	KayWin	-	-	$1.4 \pm 0.1$	$2.0 \pm 0.2$
	k0_IAEA	-	-	$1.1 \pm 0.1$	$2.1 \pm 0.1$
	Cert. v.	-	-	$1.54 \pm 0.07$	$2.6 \pm 0.55$
Zn	KayWin	$144 \pm 13$	$23 \pm 1$	$140 \pm 6$	$107 \pm 7$
	k0_IAEA	$167 \pm 12$	$23 \pm 2$	$134 \pm 4$	$113 \pm 8$
	Cert. v.	$142 \pm 3$	$20.6 \pm 1.0$	$118 \pm 17$	$104 \pm 6$

Cert. v., Certified value; -, not reported

To evaluate accuracy, the percentage of deviation of the experimental result compared to certified value was calculated. This evaluation is on Table 2.

Table 2 shows that only 3 chemical elements presented results from both programs with the same deviation (module): Sc (BCR 320), Co and Na (GXR-6). It is also shown that there are 50 pairs of results and 54% of them are within 95% confidence interval.

El.	Software	BCR 320	GBW 07602	GXR-6	IAEA/Soil-7
		(River Sediment)	(GSV-1,	(Soil)	
		,	Vegetable)		
As	KayWin	- 1.2	-	- 10.3	- 9.0
	k <sub>0</sub> IAEA	+ 4.9	- 25.0	+ 1.7	- 18.7
Au	KayWin			- 7.7	
	k <sub>0</sub> IAEA			+ 19.0	
Ca	KayWin		- 1.5	+ 1.9	
	k <sub>0</sub> IAEA		- 4.1	- 3.2	
Ce	KayWin		+ 3.3	- 13.9	- 9.2
	k <sub>0</sub> IAEA		- 6.7	+10.2	- 0.5
Со	KayWin		+ 5.9	- 12.9	- 9.4
	k <sub>0</sub> IAEA		+ 9.8	- 12.9	- 7.2
Cs	KayWin		- 4.0	- 7.3	- 15.7
	k <sub>0</sub> IAEA		- 16.0	+ 8.2	- 26.5
Eu	KayWin		-	-	- 19 1
	k <sub>0</sub> IAEA		- 22 3	+ 16.9	- 32.2
Fe	KavWin		-27	-75	-
-	k <sub>0</sub> IAEA		-49	- 8 9	-
Hf	KavWin		-	-99	- 8 9
	k <sub>0</sub> IAEA		- 35 7	+ 10.6	+ 12.2
Κ	KavWin		-72	-09	-
	k <sub>0</sub> IAEA		- 10.8	+33.0	-
La	KavWin		+2.8	- 8 7	-71
	k <sub>0</sub> IAEA		-42	+1.8	- 3 7
Na	KavWin		- 5 3	- 10 1	-
	k <sub>0</sub> IAEA		- 12.1	+10.8	-
Rb	KavWin		- 2.4	-2.5	- 12.7
	k <sub>0</sub> IAEA		+ 1.5	+9.6	- 14 9
Sc	KavWin	- 3 7	- 6 4	- 11.5	-63
	k <sub>0</sub> IAEA	+ 3.2	- 9 1	-75	- 15 3
Sm	KavWin		-2.0	-33	-76
	k <sub>0</sub> IAEA		+4.3	+18.0	-0.5
Sr	KavWin		+ 8.1	+ 8.1	-
	$k_0$ IAEA		+1.8	+ 1.8	- 4.6
Та	KayWin		-	+10.2	- 20.4
	k <sub>0</sub> IAEA		-	-	- 17.0
Tb	KayWin		-	-	- 28.1
	k <sub>0</sub> IAEA		-	-	- 36.7
Th	KayWin		- 8.0	- 6.1	- 16.5
	k <sub>0</sub> IAEA		- 9.1	+ 28.8	- 2.6
U	KayWin		-	- 2.6	- 8.1
	k <sub>0</sub> IAEA		-	+ 14.9	- 6.7
Zn	KayWin	- 9.7	+ 2.4	- 0.05	- 9.4
	ko IAEA	+83	- 1 9	- 3.8	-42

# TABLE 2: COMPARISON OF EXPERIMENTAL VALUES WITH CERTIFIED DATA,95% CONFIDENCE INTERVAL EXPRESSED IN PERCENTAGE

An example of the comparison between each software data with certified values is in Figure 1, IAEA/Soil-7. The objective was to verify if the results obtained from the two software were consistent inside expanding 95% confidence interval (95% confidence interval of reference material and given uncertainty by software used). In Figure 1 it can be seen that only Hf data obtained by the k<sub>0</sub>-IAEA do not passed above criteria.



Figure 1. Comparison between experimental data obtained by KayWin and  $k_0$  IAEA software to certified values for IAEA/Soil-7.

Observing the results from Table 2, it is possible to know how many results show a deviation lower than 5%, between 5 and 10% and higher than 10% for both software. Table 3 summarizes the percentage of deviation from the certified values. The values of percentage used for this calculation come from Table 2.

TABLE 3:	PERCENTAGE (	ΟF	RESULTS	CONCERNING	DEVIATION	FROM
	CERTIFIED VALU	ES				

Range	KayW	<b>in</b>	k <sub>0</sub> _IAEA		
	# of results	%	# of results	%	
> 10%	12	23.53	24	43.6	
$5\%$ < value $\le 10\%$	22	43.14	11	20.0	
$0\% \leq \text{value} \leq 5\%$	17	33.33	20	36.4	
Total	51	100.0	55	100.0	
## 5. Conclusions

The four reference materials were irradiated, analysed by gamma spectrometry and had their spectra analyzed under the same conditions. Only the elemental concentrations were calculated using two different software, the KayWin and the  $k_0$ \_IAEA programs, aiming at validating the  $k_0$ \_IAEA program, in local Laboratory for Neutron Activation Analysis, CDTN/CNEN.

The overall results point out that the  $k_0$ \_IAEA program is working properly but it still needs to be improved. Table 3 shows that  $k_0$ \_IAEA produced 56.4% of the elemental concentration results with a deviation from the reference material lower than 10%, while KayWin, 76.44%. In spite of this fact, the overall results presented small uncertainties and they are also within the range of certified values uncertainties.

The validation process is not completed as more reference material should be analyzed. Analysis of other several reference materials are already being carried out at LNAA/CDTN.

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# Basic steps in validation of software for Nuclear Instruments

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**Abstract:** This paper describes different test procedures for scintillation materials where one can measure the light output or other important parameters. It also describes to use of a two-dimensional motion unit for position dependent scanning of photomultipliers applying a thin light. The motion unit can be modified and used for testing a complete detector system (or multiple head) or a single detector (or single head) with a radiation source. Standard readout electronic like a high precision Single-Channel or Multi-Channel-Analyzer is described to make preliminary tests and to check those detector systems. NIM modules from different companies, generators, simulators describes to test and to stress the whole electronic chain, up to the end-user software to check the whole system with known pulses.

#### 1. Introduction

In Jülich we have much experience on developing detector systems, in the neutron as well as in the gamma sector, for more than over 30 years. We always include certain inspection points in our developments, where we can test and document the quality of our systems. These points are very important to have short setup times at the final place where the system will be installed. We have different test procedures available for Scintillation – Systems with photomultipliers or with semiconductors. With slightly modifications at our place it is even possible to test a lot of other detector - system for nuclear measurements.

In the last decade a lot of nuclear instruments were equipped with modern readout systems. Such systems could be driven by Microcontrollers, PCs or other high level architectures for the control, data acquisition and data processing. Furthermore, nowadays users want to have a standardized remote control of those system, based on actual standards like DIN, IEEE, or other world wide known standards.

In order to put such systems into operation, a thorough test of all system components is necessary. But different objectives also require different testing strategies. However, before any software validation can be carried out, a test of hardware is mandatory. Here, the procedures are the same as it was during the last decades. In principle one has to go through the following steps: Inspection, Analysis, Testing and Final Demonstrations to the end user. This could also end in a certificate for such systems.

In Jülich we have much experience in developing those systems, in the neutron as well as in the gamma sector, for more than over 30 years. We always include certain inspection points in our developments, where we can test and document the quality of our systems. These points are very important to have short setup times at the final place where the system will be installed. Different test procedures are available for scintillation systems with photomultipliers or with semiconductors. With slightly modifications at our place it is even possible to test a lot of other detector - systems for nuclear measurements.

## 2. Homogeneity of photomultipliers

In Nuclear- Instruments and experiments one is continuously interested in large area detectors with appropriate spatial resolution. In many applications a resolution of a few percent of the linear dimension of the detection area is sufficient.

The following example experiment was made with the position sensitive HAMAMATSU R3292 tube.

For optical tests a pulsed LED emitting blue light was used. The photo cathode was illuminated either locally with a light spot of less than 1mm with a collimated ray or homogeneously within a selected area with a diffuse ray. This experimental setup is shown in Figure 1.



Figure 1. Schematic drawing of the PM test with a collimated beam.

By scanning the PM with the LED, which emits collimated light pulses, the step size and the scan area was varied within a wide range. For these experiments the light pulse intensity was adjusted to be approximately the same as for a  $\text{Li}^6$  glass scintillator. The scans restricted to the central part of the PM showed a fairly homogenous detector response with fluctuations of the pulse height within a factor of three (see Figure 2).



Figure 2. Homogeneity Scan of a R3292 Tube from Hamamatsu.

## 3. Scintillator light output

The optimization of light output and energy resolution of scintillators is of special interest for the development of Nuclear Instruments in the medicine as well in the material research. These statistical reliable results are concerning optimal surface treatment of scintillation crystals and the selection of reflector material. For this purpose, raw, mechanically polished and etched crystals can be combined with various reflector materials (Teflon tape, Teflon matrix, BaSO<sub>4</sub>) and exposed to a source. In order to ensure the statistical reliability of the results, groups of different crystals were measured for all combinations of surface treatment and reflector material.



Figure 3. Pulse height spectra as measured at the Cf source with a <sup>6</sup>Li borate, a <sup>6</sup>Li glass and a <sup>6</sup>Li iodide scintillator under identical condition. There are vertical shifts of the pulse by Gammas from the Cf source.

The Figure shows the pulse height spectra of the three scintillators as measured with the <sup>2,2</sup>Cf source. The pulse height from <sup>6</sup>Li borate is 4.8 times larger than the pulse height from <sup>6</sup>Li glass and 0.55 times smaller than from <sup>6</sup>Li iodide. The pulse height distribution as measured with <sup>6</sup>Li borate is considerably broader than that measured with <sup>6</sup>Li glass. This is a consequence of the limited optical transparency of the <sup>6</sup>Li borate scintillator.

#### 4. Hardware test procedures

#### (a) Amplifier

The amplifier is one of the most important components in a pulse processing system for applications in counting, timing, or pulse-amplitude (energy) spectroscopy. Normally, it is the amplifier that provides the pulse-shaping needed to optimize the performance of the analog electronics. When the best resolution is needed in energy or pulse-height spectroscopy, a linear pulse-shaping amplifier is the right solutionThe linear pulse-shaping amplifier can also be used in simple pulse-counting applications.

The linear, pulse-shaping amplifier must accept the output pulse shapes provided by the preamplifier and change them into the pulse shapes required for optimum energy spectroscopy. Two general types of charge-sensitive preamplifiers are in common use: the resistive-feedback preamplifier, and the pulsed-reset preamplifier. Each of these places slightly different demands on the amplifier's functions.

Before amplification, the pulse-shaping amplifier must replace the long decay time of the preamplifier output pulse with a much shorter decay time. Otherwise, the acceptable counting rate would be severely restricted.

The energy information represented by the amplitudes of the steps from the preamplifier output has been preserved, and the pulses return to baseline before the next pulse arrives. This makes it possible for an analog-todigital converter (ADC) to determine the correct energy by measuring the pulse amplitude with respect to the baseline. With the shorter pulse widths at the amplifier output, much higher counting rates can be tolerated before pulse pile-up again causes significant distortion in the measurement of the pulse heights above baseline.

The simplest concept for pulse shaping is the use of a CR high-pass filter followed by an RC low-pass filter. Although this rudimentary filter is rarely used, it encompasses the basic concepts essential for understanding the higher-performance, active filter networks. This pulse-shaping technique can be used with scintillation detectors. For that application, the shaping time constant  $\tau$  should be chosen to be at least three times the decay time constant of the scintillator to ensure complete integration of the scintillator signal. The disadvantage in using CR-RC shaping with scintillation detectors is the much longer pulse duration compared with that of single-delay-line shaping.

On silicon and germanium detectors, the electronic noise at the preamplifier input makes a noticeable contribution to the energy resolution of the detector. This noise contribution can be minimized by choosing the appropriate amplifier shaping time constant.

Both an Oscilloscope and an MCA are necessary to find extraneous of noise. Each must be used to check the other because each may be its own noise source.

## (b) ADC

The ideal A/D converter produces a digital output code that is a function of the analog input voltage and the voltage reference input.

The code width of a given output code is the range of analog input voltages for which that code is produced. The code widths are referenced to the weight of 1 least significant bit (LSB), which is defined by the resolution of the converter and the analog reference voltage.

Resolution and accuracy are terms that are often interchanged when the performance of an A/D converter is discussed. The resolution of an A/D converter is specified in bits and determines how many distinct output codes  $(2^N)$  the converter is capable of producing. For example, an 8-bit A/D converter produces 256 different, output codes.

Integral nonlinearity, or INL, is a result of cumulative DNL errors and specifies how much the overall transfer function deviates from a linear response. INL is sometimes simply referred to as the linearity of the converter. The INL specification tells the designer the best accuracy that the A/D converter will provide after calibrating the system for gain and offset. INL can be measured in two ways. The first method used to determine INL is the end-point method. For the end-point method, the locations of the first and last code transitions for the converter are determined and a linear transfer function based on the endpoints is derived. The end-point nonlinearity is determined by finding the deviation from the derived linear transfer function at each code location. The second method used to determine INL is the best-fit method. The best-fit response is found by manipulating the gain and offset for the measured transfer function, comparing against a linear transfer function, and balancing the total positive and negative deviations. As the transfer functions indicate, the end-point method provides more conservative results, so the designer should always determine the method used to specify the INL. The maximum positive and negative INL are usually specified for stated operating conditions. Furthermore, graphs indicating the INL for each code are sometimes given in the device data sheet. Like DNL graphical data, the INL graphical data can be used to analyze the quality of the A/D converter.

The test procedure for Amplifier (e.g. Signal to Noise ratio), ADCs (INL and DNL) and the digital part (performance measurements) of such system are important to know and well explained in the common literature. You have to think of system tests where you have to test the pulse processing, gamma-sensitivity, maximal count rate, coincidence time, dead-time and dead time correction. Those procedures are well known and already explained in IAEA documents or in the IEEE Test Procedures for Photomultipliers for Scintillation Counting and Glossary for Scintillation Counting Field.

## 5. Examples

#### (a) Thyroid scanner

A 2-dimensional detector system for improved thyroid I-131 scintigraphy was developed. It has a sensitive area of  $4x4cm^2$  and consists of a lead-collimator and an array of 10x10 BGO crystals combined with a position sensitive photomultiplier. The detector design aims at a high spatial resolution. Therefore, interfering penetration and scattering effects of the gammaquants have been reduced by arranging the BGO crystals in a lead matrix and the choice of an appropriate thickness for the collimator septa. In order to avoid dead areas on the detector due to lead absorption, the whole system is moved step-wise during measurements and the consecutive scans are composed to a final image.



Fig. 3. Construction of the improved thyroid up-take system.

The performance of the detector was tested using a I-131 filled phantom of 100mm diameter and 3mm height. An average sensitivity of about 500 counts/min per MBq could be achieved, which seems to be suitable for patient-friendly acquisition times. For the determination of the spatial resolution, a I-131 filled line source with a width of 0.9mm has been used. The resulting line spread function had a FWHM of 3.8mm. This represents a considerable improvement compared to existing systems and lead to favorable results in first patient measurements.

## (b) Large area detector

During the upgrade of the small angle neutron scattering instrument KWS-1 at the research reactor FRJ-2, the 15 years old detector system has been replaced. While the Anger camera based concept of the detector remained unchanged, the signal and data processing branch has been completely revised. Because of higher count rate requirements, a highly configurable parallel readout electronics has been developed aiming at counting rates of several 100 kHz.

The whole detector system has been recently installed at KWS-1 and measurements to study the system performance have been carried out. The linearity and spatial resolution of the new detector have been determined by an analysis of the acquired image taken with a hole diaphragm in front of the scintillator. The overall system dead time has been measured by comparing the detector count rates at several scattering intensities to the count rates achieved with a fission chamber. At last, scattering patterns of well-known samples have been taken in order to prove the quality of the acquired images.

#### 6. Conclusion

This paper pointed out different test procedures for Detector Systems in NI and made some examples. We can test e.g. scintillation materials where we can measure the light output or other important parameters. In our Lab we have a two-dimensional motion unit which we can use for a position dependent scanning of photomultipliers with a thin light. Moreover, this unit can be modified and used for testing a complete detector system or only detector head with one of our radiation sources. All other standard readout electronics like a high precision Single-Channel or Multi-Channel-Analyzer are available to make first test and check on those detector systems. We have NIM modules from different companies, generators, simulators to test and with which we can stress the whole electronic chain up to the end user software to check the whole system with known pulses. Even small phantoms are available or can be fabricated at our workshop.

Those test procedures are important to make sure that the whole system is working properly. Only if you know the hardware is working correct and in the range of the specification, you can start with the validation of the software.

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# Hard-and software requirements for nuclear instruments e.g. for the ClearPET Neuro Scanner

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**Abstract.** In engineering and manufacturing, quality control and quality engineering are involved in developing systems, which ensure that products or services are designed and produced to meet or exceed customer requirements and expectations. Software validation is a part of the design validation for a finished device, but is not separately defined in a quality system regulation.

In practice, software validation activities may occur both during, as well as at the end of the software development life cycle to ensure that all requirements have been fulfilled. Since software is usually part of a larger hardware system, the validation of software typically includes evidence that all software requirements have been implemented correctly and completely and are traceable to system requirements.

The Central Institute for Electronic is a scientific and technical joint facility of the Research Centre Jülich (FZJ) with important investigation and development works on the field of analog and digital electronics, measurement and control engineering, nuclear electronics as well as on-line data processing hardware and software. The research priorities of the institute consist of research and development in close collaboration with other institutes in order to suit the needs of the overall research programme of the FZJ. In the last few years one of our main focus is the development and construction of a high resolution and high sensitivity small animal PET (positron emission tomograph) system for brain studies with non-human primates and rodents, called ClearPET Neuro. This project is proposed by working groups of the Research Center Jülich (FZJ) and by working groups of the Crystal Clear Collaboration (CCC). The aim of this project is to apply the non-invasive PET technique to in vivo investigations of signal transduction in non-human primates under physiological conditions.

There are user needs and intended uses for a finished device, but the medical users do not specify whether those requirements are to be met by hardware, software, or some combination of both. Therefore, simulation studies are considered for geometric design, timing information and data acquisition and should be the base for a validation procedure.

## 1. Introduction

The same design engineers that use a wide variety of software design tools must use hardware to test prototypes. Commonly, there is no good interface between the design phase and testing/validation phase, which means that the design usually must go through a completion phase and enter a testing/validation phase. Issues discovered in the testing phase require a design-phase reiteration. Test plays a critical role in the design and manufacture of today's electronic devices. As designs iterate through this build-measure-tweak-rebuild process, the designer needs the same measurements again. In addition, these measurements can be complex by requiring frequency and amplitude. Simulation will help to check the system and to understand the data that are collected. Virtual instrumentation software flexibility and virtual instrumentation hardware modularity could accelerate the development cycle.

The ClearPET<sup>TM</sup> project is proposed by working groups of the Crystal Clear Collaboration (CCC), namely the Vrije Universiteit Brussel (VUB), the CERMEP & Université Claude Bernard - Lyon1 (UCBL), the European Organisation of Nuclear Research (CERN), the Institute for Nuclear Problems in Minsk, the Université de Lausanne, and the Research Center Juelich (FZJ). While in recently developed dedicated small animal positron emission tomograph (PET) systems a high spatial resolution of about ~1.5mm was the main research interest, it has become clear that it is equally important not to sacrifice the sensitivity of the scanners since the specific activity of the radiotracers used may be limited. In order to achieve high sensitivity and maintain good uniform spatial resolution over the field of view in high resolution PET systems, it is necessary to extract the depth of interaction (DOI) information and correct for spatial degradation. It has been shown, that a phoswich design with two different types of scintillators is capable to provide this information. In CCC, we are developing a 2nd generation high performance PET scanner, called ClearPET<sup>TM</sup>, using new technologies in electronics and crystals to design and build a total of five more or less identical small animal PET scanners for the associated medical institutes.

Design optimization for the first PMT ClearPET<sup>™</sup> camera is done with a Monte-Carlo simulation package implemented on GEANT. The GEANT package is a design tool for detector development in middle and high energy physics, which was developed since the 70s at CERN (Geneva, Switzerland). Simulation allows to study and check several designs in consideration to given technical specifications before the first detector module is assembled. However, it is very important to validate simulation results by comparing with measurements using a first prototype.

#### 2. Materials & methods

In a first iteration the prototype scanner is based on a multi-channel photomultiplier tube solution. For an optimum readout the dual layer of crystals is coupled directly to the PMTs. The dual layer phoswich matrices consist of 8x8 LSO and LuYAP crystal elements. The growth of the lutetium Perovskites is a delicate process. A way to overcome the temperature and stoechiometry stabilization problem is to grow mixed Perovskite crystals using yttrium ions. It's an obligation to get  $Lu_{0.7}Y_{0.3}AP$  in the production phase. For the first prototype a mixture in density between 6.5g/cm3 and 7.1g/cm3 is reached which could be related to a lower lutetium contribution as foreseen. The light yield is about 1/3 of LSO and has two components in its decay: one fast component with 23ns decay time and a slow component with 200ns decay time. The crystals are grown with the Czochralski method in the Bogoroditsk Techno Chemical Plant (BTCP) in Russia. The LSO is obtained from the commercial company CTI, now Siemens Medical Solution.

The crystal latter being closest to the PMT. The PMTs have a sensitive area of 18.1x18.1mm<sup>2</sup> well suited for the crystal matrices. Each crystal element is mechanical polished on all 8 sides and has a face surface of 2.0x2.0mm<sup>2</sup> and the element pitch is 2.3mm. The length of the crystals for the different ClearPET designs varies between 8 and 10mm. 64 crystals are assembled and glued with Barium Sulfate powder for each layer. A light shielding mask is glued on the multi-channel PMT to correct for variation in the sensitivity of the 64 channels in the range of 20%.

A detector cassette was designed by arranging a unit of four multi-channel PMTs (R7600M64, Hamamatsu) in-line including the corresponding front-end electronic: analog

and decoder boards in front, one FPGA board, one slow control and finally an opto link transmitter board to send the data from the gantry to the first preprocessing PCs. Each PMT anode is connected to a comparator and an address decoder. They reduce the 64 comparator outputs to a position code consisting of two 6bit numbers, indicating the highest and the lowest address of the pixels that generated a trigger. The comparators trigger if the anode signal exceeds the threshold voltage. Thus, simultaneous triggers in different pixels which might be generated by scatter or crosstalk can be detected. In this case the two addresses are not equal. Simultaneous triggers on the same PMT provide less precise position information. Therefore an adaptive threshold control has been implemented. A fraction of the dynode signal is added to the threshold for the comparators to gives a clear indication of the highest amplitude in the matrix block and reduces crosstalk effects.

A preamplifier is connected to the dynode signal of the PMT. This photodetector signal is continuously sampled by free running ADC's at a sampling rate of 40MHz with a resolution of 12bit. Prior to digitization the pulse has to pass a low pass filter in order to satisfy the Nyquist theorem. The samples are pushed through a shift register. Each scintillation pulse is represented by 16 samples, thus covering a time window of 400ns. When a pulse is detected the corresponding 16 samples are saved and will be analyzed further on preprocessing PC's. The data package consists the position code, the PMT identification number and a 48bit time mark additionally. The clock is synchronous for all cassettes in order to allow the time mark to be used for later coincidence detection. The obtained digital pulse data will provide the information about energy, timing and scintillator type.

While the energy is given by the integral value of all 16 samples the coincidence time estimation is done with respect to the time of the first sample of each record. The starting time is obtained by calculating the intersection of the line through the rising edge with the baseline of the pulse. The time between the first sample and this point is then added to the preliminary time mark from the cassette. Thus a much more precise time mark for the pulse starting time is obtained. In the output data it appears as a 38bit number with 0.5ns resolution.

The layer identification in the phoswich detector is done by the ratio of the last sample of the pulse to the integral value. While both scintillators have a rather short main decay time LuYAP has an additional slow decay time component in the range of 250ns which is not present in LSO. This allows a rather simple discrimination of the pulses because the slow decay time is still present at the end of the recorded time window when LSO pulses have already returned to the baseline. In order to be independent of the pulse height the last sample os the recorded time window is normalized by dividing it by the integral of the sampled pulse. The value is compared to a threshold to identify the crystal layer. A separation test has been shown a reliability of 99,2% of the Lu<sub>0.7</sub>Y<sub>0.3</sub>AP pulses.

#### 3. The ClearPET Neuro scanner

The current system consists of 80 detector modules enclosed on 20 cassettes and arranged into a 4-ring configuration with a variable opening between 13.0 and 30.0 cm diameter and 11.0 cm axial extent. In total the system has 10240 crystals and 5120 pixels. Every other cassette is shifted by 7mm,  $\frac{1}{4}$  of a PMT length to linearize the axial sensitivity profiles of the scanner. The gantry allows rotation over 360 degrees of the detector cassettes around the field of view as well as tilting by 90 degrees. This design is essential for the measurement of non-human

primates in an upright sitting position. The rotation capabilities are used to fill the 3D sinograms.

The rotate able gantry measures 120cm in diameter and 50cm width and houses the detector cassettes. The entire gantry was mounted on a rack. A small animal bed or a monkey seat can be mounted in a fixed position to the rotateable gantry. A cabinet that houses the preprocessing electronics and power supplies is separate from the gantry. Figure 1 shows a photograph of the system setup in the Institute for Medicine.



Figure 1. A photo of the ClearPET Neuro gantry with a small animal bed in front.

All measured or simulated singles are recorded and coincidences are identified by software offline. An advantage of that is that the coincidence window and the dimensions of the field of view can be adjusted easily. The limitation is the event rate per cassette of 0.5 million events per second. The events are stored in a list mode file format (LMF) on a dedicated RAID system. All list mode data were sorted in 3D-sinograms and reconstructed with the Maximum Likelihood Estimation type algorithm implemented in the open source software STIR: Software for Tomographic Image Reconstruction library.

## 4. Results and Discussion

Our simulation studies for the ClearPET<sup>TM</sup> Neuro scanner show good agreement with experimental results which form the base for the aspired ClearPET<sup>TM</sup> design. As an example of these studies the non-linear axial sensitivity profile could be reproduced (see fig. 2) and is caused by the gaps between the PMTs. This effect leads to the global ClearPET<sup>TM</sup> scanner design decision that every other detector cassette is shifted by <sup>1</sup>/<sub>4</sub> of a PMT center-to-center

distance in axial direction. Thus, the sampling of the axial FOV becomes more homogeneous. Furthermore the perfect agreement between the simulated and measured intrinsic resolution affirms the expectation of a better intrinsic resolution of the ClearPET<sup>TM</sup> system in comparison with the commercial small animal PET systems. This gives a reasonable impact for the total sensitivity and spatial image resolution of all ClearPET<sup>TM</sup> scanner designs.



Figure 2. Normalized measured and simulated a) axial and b) radial sensitivity profile using an energy threshold of 300keV. High fluctuation caused by the axial gaps between the crystal matrices in axial direction.

## 5. Conclusion:

The simulation of physical and technical processes help to understand the acquire data of such a complex system. In addition this can help to reduce the hardware and software verification and validation time. It is necessary and important to verify each module and higher level of integration separately.

At the end the whole system has to been validated based on the requirements fixed at the beginning. The characterisation of medical devices has to been done in a standardized procedure described by NEMA protocols. The results and the procedures have to been written into a standardized document for further quality controls.

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## A comparison of some softwares used for processing HPGe gamma spectra

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**Abstract**. The analytical performance of seven available gamma analysis software packages in radiometrics laboratory of the Atomic Energy Commission of Syria (AECS) has been compared. The comparison includes, full energy peak position, precision and accuracy of the peak-area calculations and deconvolution performance of the multiple peaks; nine test spectra mathematically produced by the IAEA known as G series (1100-1400) were used for this purpose. A utility function that takes into account the accuracy of peak intensities and peak positions has been suggested and applied to the output of each gamma analysis package.

The obtained results were used to rank the studied software packages according to their analytical performance as shown Table 1.

Keywords: Gamma Analysis Spectrum; HPGe detector; analytical performance; utility function

#### 1. Introduction

Gamma ray analysis software packages are very important tool in any radiometric laboratory. They are being used in such important applications such as environmental studies, low level activity determination, neutron activation analysis, and a number of medical applications. The software in use varies in design and construction; they are available as commercial, non-commercial (e.g. specially developed by the laboratory, stand-alone packages), and integrated data acquisition and analysis software [1, 2, 3]. Each software implements a special mathematical algorithm that differs from the other. Even different versions of the same program will not give precisely the same results. Software also plays an important role in the laboratory's QA program i.e. the computer program should be evaluated to check that consistent and accurate results are obtained [4]. The ANSI N42 standard recommends a number of tests for automatic peak finding, independence of peak-area from peak-height-to-baseline ratio, and doublet peak finding and fitting [5]. It is, however, not a simple matter to evaluate the quality of results from analyses of gamma spectra since true results do not generally exist [6]. The ideal test spectrum would have both large and small peaks on both

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high and low continuum backgrounds. This spectrum will test the ability of the software to find and accurately measure peaks in a range of spectrum environments without reporting spurious peaks. There would need to be a test for doublet resolution, with a range of peak separations and peak ratios. In order to be assured that the analysis program would not be confused by spectral artifacts such as backscatter peaks and Compton edges, these should also figure somewhere within the spectra.

In 1977 the International Atomic Energy Agency (IAEA) organized the G-1 intercomparison of methods for processing Ge gamma spectra and this intercomparison was based on test spectra for which the true results are known [7].

This study about software comparison was intended to provide information about software currently used in gamma spectrometry laboratories in (AECS). The results of this study will hopefully enable users in different laboratories to learn more about their own software, and to assess and improve the quality of their gamma spectrometric analysis.

## 2. Material and methods

#### 2.1. Software packages

Table 2 represents the seven gamma analysis software packages that have been compared including name of software, its version, and its mode of operation (which is either programs can be run only in batch mode i.e. no interaction with the user, or programs are operated in interactive mode that is user controls the analysis procedure either by using menus or graphics or both during the run).

#### 2.2. Test Spectra

The IAEA G1 test spectra are a set of nine spectra distributed originally in 1976 as an intercomparison exercise. The spectra were prepared by measuring pure radionuclides with high precision using a detector of a 60 cc Ge(Li) detector of resolution 2.8 keV. Spectra were recorded in 2000 channels with gain of about 0.5 keV/channel giving a range of about 1000 keV. The G1100 reference spectrum contains 20 peaks; each peak contains near to 65,000 counts and can be measured with an uncertainty of about 0.4%. The G1200 spectrum contains 22 peaks, all shifted and attenuated relative to G1100, many peaks are difficult to detect, and this spectrum serves as a very good tool to test the peak search performance. The G1300 to G1305 spectra used as a consistency test spectra; each one contains 22 peaks and derived from the G1100 reference spectrum, but subjected to the 'noise generation' process separately.

Some peaks are attenuated and shifted, and in one spectrum a peak in the area of Compton edge was added to check the performance of the software package to analyze the peaks located near the Compton edge. The G1400 test spectrum used for deconvoltion peak performance, the spectrum contains nine peaks well defined doublet peaks formed by shifting and attenuation peaks from G1100.

#### 2.3. Performance criteria

A Utility Function (UF) defined as

$$UF = \frac{QI}{RSE} \times 100$$

where QI is the Quality index defined as :

$$QI = \frac{m}{n} \quad \left(m \le n\right)$$

Where m is the number of the detected peaks, and n is the actual number of peaks in the test spectrum.

*RSE* is the relative standard error and defined as:

$$RES = \sqrt{\frac{\sum_{i=1}^{m} (R_{MESURED} - 1)^2}{m}} \times 100$$

where  $R_{MESURED}$  is the ratio between the measured and reference peak area.

The UF is applied to all results obtained for peak search performance, consistency spectrum analysis performance, and deconvolution performance of the software packages.

The maximum value of the UF means the best performance of the software package. The calculated values of the UF were used to rank the analytical performance of the software packages.

#### 3. Results and discussion

#### 3.1. Peak search performance test

The out put results of each software package of peak search performance using the G1200 spectrum is used to calculate the UF value. Figure 1 shows the UF for the compared software packages. It should be noted that the UF values are an absolute values which implies the output of the QI that related to the number of peaks found by the software, and the RSD of the area calculation of the detected peaks. Two software packages MicroSAMPO and InterWinner show the best performance for the peak search test. This can be explained by the fact that these two packages allows the user to control the peak search parameters and enable him to choose the exact channel to insert or delete a peak, this is absolutely true for MicroSAMPO and to some extent for InterWinner and GammaTrac. On the other hand, it is very hard, for the other packages, to control the parameters which enable the user to insert or

delete a peak, or to determine the peak intervals and the suitable mathematical function for area calculation.

## **3.2.** Consistency performance

Consistency performance of the software is carried out by analyzing the spectra G1300-1305, where the UF value represents the mean and its related standard deviation of the six out put results of the test spectra G1300-G1305. UF calculated values of this performance test are shown in figure 2. It is very clear that the package with the ability to control the parameters fitting is always shows the best performance (MicroSAMPO). Moreover, Anges and GammaTrac packages showed good performance also, this may be explained by the fact that the peaks in the test spectra have enough counts to be detected, in addition to the fitting algorithm in both packages depend on the Gaussian shape. Figure 3 shows the results of UF for the performance of the software package to analyze the peaks located near the Compton edge. It is clear that, InterWinner, MicroSAMPO, Anges, and GammaTrac, have better performance than the other packages, for the same reason mentioned before.

## **3.3. Deconvolutin performance**

Deconvolution performance test of the software packages was carried out using the spectrum G1400. The UF calculated values are shown in figure 4. The best performance was the FitzPeak and MicroSAMPO, these two softwares have several mathematical fitting functions which enable the user to choose the most suitable one to calculate the expected number of peaks in a single interval [8]. The InterWinner software has a limited flexibility to change the fitting parameters comparing with the previous two softwares. The other packages have very limited mathematical fitting functions that can be controlled by user to carry out the deconvolution.

## 4. Conclusions

A classical spectrum analysis algorithms (peak search, base line subtraction, peak integration, multiplet fitting) of seven gamma software packages have been tested. A simple utility function was applied to the output results of the analysis reference spectra in order to rank the software packages according to their analytical performance. The ranking method of the software packages are in agreement with the expectation of the users (at AECS labs) of these packages. Hence, this simple UF can be used as an easy tool to check the classical analytical performance of the gamma software packages. The obtained results showed that the most powerful package in performance analysis is the one with most interactive mode of operation. Further, the software package that includes a variety of mathematical fitting function has good analytical performance. Finally, achieving a good analytical performance depends mostly on the user experience in analyzing gamma spectra, in addition to good understanding the software package.

## TABLE 1: ANALYTICAL PERFORMANCE OF GAMMA SOFTWARE PACKAGES

Full Energy Peak		Precision and Accuracy			Deconvolution		
<b>Position Test</b>		of	the peak-area Test	<b>Performance Test</b>			
1	MicroSampo	1	Interwiner	1	Fitzpeak (Demo version)		
2	Interwiner	2	MicroSampo	2	MicroSampo		
3	Gamma Trac	3	Anges (IAEA)	3	Anges (IAEA)		
4	Anges (IAEA)	4	Fitzpeak (Demo version)	4	Interwiner		
5	Fitzpeak (Demo version)	5	Gamma Trac	5	Aptec		
6	Gannas (IAEA)	6	Gannas (IAEA)	6	Gamma Trac		
7	Aptec	7	Aptec	7	Gannas (IAEA)		

# TABLE II. GAMMA ANALYSIS SOFTWARE PACKAGES USED IN THE OMPARISON

Software Package	Version & developer	Mode of Operation	
GammaTrack	Version 1.21, by Oxford	Interactive	
	Instruments Ins. Nuclear		
	measurements group.		
	Tennessee, USA		
GANAAS	Version 3.3, by physics	batch mode	
	section, IAEA, Vienna		
(Aptec) OSQ/Professional	Version 6.31, by Aptec	batch mode	
	engineering LTD, Canada		
MicroSAMPO	Version 1.2, by P. A& J.S,	Interactive	
	Canberra, USA		
InterWinner	Version 4.16, by Eurisys	Interactive	
	Mesures, France		
ANGES	Version 1, by physics	Interactive	
	section, IAEA, Vienna		
FitzPeak	Version 3.27, Evaluation	Interactive	
	copy, Jim Fitzgerald, JF		
	Computing Services,		
	Oxfordshire, UK		



Figure 1. UF calculated values of peak search performance test.



Figure 2. UF calculated values of consistency performance test.



Figure 3. UF calculated values of analyzing the peaks located near the Compton edge test.



Figure 4. UF calculated values of deconvolution performance test.

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# Method of software validation for <sup>137</sup>Cs and <sup>226</sup>Ra activity measurements in environmental samples using gamma spectrometry system

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Abstract. Nowadays, nuclear analytical technique instruments usually come along with the commercial software to do analysis and generate report. Despite the advantages and attractive features of the computerized system, this software needs to be validated first to find its reliability and also to ensure the quality of the analysis results. A gamma spectrometry counting system equipped with commercial gamma-ray spectrum analysis software was used to study its reliability in identifying and calculating the radionuclide activity, automatically. To do so, a reference material, IAEA Soil-6, was counted with the system one hour each week for thirty consecutive weeks. The activities of the two certified radionuclides, <sup>137</sup>Cs and <sup>226</sup>Ra, inside the reference material were calculated automatically by the provided software. These values were compared with the values obtained by manual calculation. Energy peaks used were 661.6 keV for <sup>137</sup>Cs, and 295.2 keV, 351.9 keV and 609.3 keV for <sup>226</sup>Ra. In automatic calculation, the analysis software will normally mark the energy peaks with a preset tolerance of 1 keV in order to obtain the peak area. However, in the manual calculation, the spectrum collected was analysed visually and peak was marked from the peak centroid to the left and right of the peak until its baseline. The activity was then calculated based on the peak area using the normal activity calculation equation. The study found that around 70% of the results generated by the analysis software were inside the recommended value at 95% confidence level. However, u-score calculation showed no significant bias (u < 2.58) in the data set except for 1 ( $^{226}$ Ra) or 2 ( $^{137}$ Cs) data only. On the other hand, all manual calculation data were found to be within the 95% confidence level.

Keywords: Gamma Spectrometry System, <sup>137</sup>Cs, <sup>226</sup>Ra.

#### 1. Introduction

Most nuclear analytical instruments nowadays are supplied with the commercial software to help users to perform analysis of the raw data or spectrum and generate reports. Among such instruments is gamma spectrometry counting system that is used to identify gamma-emitting radionuclides quantitatively. A modern gamma spectrometry is normally equipped with commercial gamma-ray spectrum analysis software to automatically identify and calculate the radionuclide activity. With the advent of computer technology, data analyses become much faster and easier compared to when it was first invented. Computer software has the advantage of resolving overlapping peaks by fitting analytical curves to the collected data and also handling large amounts of data very rapidly and accurately.

A gamma spectrometry counting system is normally supplied with MCA emulation software, as a standard accessory, and the gamma-ray spectrum analysis software, as an optional

accessory. The MCA emulation software is the basic software that enables the system to distribute pulses collected in memory based on distribution of the number of pulses with respect to pulse height. This distribution will usually be displayed as a spectrum [1]. This type of software has limitations as the establishment of energy and efficiency calibration, the analysis of spectrum such as, peak identification, marking of peak areas, and activity calculation, have to be done manually. Whereas, the gamma-ray spectrum analysis software is capable of analysing  $\gamma$ -spectrum for photo-peak position and relative intensity of the respective photo-peak that is proportional to the measured radio-nuclides activities. The software then automatically calculates the activity of the respective radio-nuclides in samples based on the ready built-in library [1]. Nowadays, while purchasing a gamma spectrometry system, both emulation software and gamma-ray spectrum analysis software are supplied together as a standard package. Despite the advantages and attractive features of the computerized system, the gamma-ray spectrum analysis software needs to be validated to ensure its reliability to produce accurate and precise results.

Validation of analytical method is an obligation laid down in ISO/IEC 17025 International Standard, which provides general requirements for the competence of any testing and calibration laboratories. The entire analytical process starting from sampling, sample preparation and storage until the final determination of radionuclide concentration inside the sample is subjected to rigorous quality control and quality assurance including validation [2].

To ensure that the commercial gamma-ray spectrum analysis software performs as it is intended, an experiment was conducted to demonstrate the reliability of this software. In this study, a gamma spectrometry system with its commercial analysis software was used.

## 2. Experimental

## 2.1 Sample preparation

The sample used for this study was reference material, IAEA Soil-6. The material was dried in an oven at 105 °C until constant weight. It was packed properly into a 350 ml plastic container until the density was approximately 1 g/cm<sup>3</sup> and then sealed with PVC tape to ensure it was airtight. This sample was kept in a dry cabinet for a month to allow <sup>226</sup>Ra and its daughters to reach secular equilibrium before being used to measure the activities of <sup>137</sup>Cs and <sup>226</sup>Ra.

## 2.2 Counting system

The high-purity germanium (HPGe) detector<sup>2</sup> was calibrated using a customized gamma multinuclide standard of 1.0 g/cm<sup>3</sup> epoxy matrix in a 350 ml plastic container (Source No. 1206-12), prepared by Isotope Products Laboratories, United States of America. The peak resolution at FWHM for <sup>60</sup>Co at 1333 keV was 1.70 keV. The performance of this instrument was monitored regularly to ensure its fitness and reliability [3].

<sup>&</sup>lt;sup>2</sup> EG & G Ortec, 25 % efficiency P-type detector

#### 2.3 Sample counting and spectral evaluation

The sample was counted for an hour every week for thirty consecutive weeks. The <sup>137</sup>Cs peak was identified at its single energy line of 661.6 keV. Meanwhile, <sup>226</sup>Ra was detected using the most abundant equilibrium daughters' energy lines, i.e. <sup>214</sup>Pb (295.2 keV and 351.9 keV) and <sup>214</sup>Bi (609.3 keV) [4]. These peaks were marked manually from the peak centroid to the left and right until its baseline following the guideline given by Gilmore and Hemingway [5], and IAEA [6]. The specific activities of <sup>137</sup>Cs and <sup>226</sup>Ra in the sample were calculated manually. Background area was marked on a background spectrum within the same marking region used for the sample photo-peak. This is to ensure that a more representative background within the region of the peak can be estimated. The background spectrum was collected weekly by counting a blank deionised water sample. The complete calculations of the activity of a specified nuclide at the time of sampling with a time difference of t<sub>1</sub> between sampling and starting the measurement are made by means of Equation 1 [6] below:

$$A_{st} = \frac{R_n m_f \lambda t e^{\lambda t_1}}{\varepsilon P_{\gamma} m_{\mu} m_F \left(1 - e^{-\lambda t}\right)} \dots \dots \dots (1)$$

where:

- A<sub>st</sub> is the mean activity concentration at sampling time (Bq/kg wet mass),
- R<sub>n</sub> is the net count rate of nuclide n (counts/s),
- $m_{\rm f}$  is the mass of sample after ashing (kg),
- $\lambda$  is the decay constant (s<sup>-1</sup>),
- t is the counting time (s),
- $t_1$  is the time between sampling and the start of the measurement (s),
- $\epsilon$  is the efficiency of the system at that nuclide energy,
- $P_{\gamma}$  is the emission probability of the gamma line corresponding to the peak energy,
- $m_{\mu}$  is the mass of ashed sample used for measurement (kg),
- $m_F$  is the mass of wet sample used for measuring or ashing (kg).

The results calculated manually were compared with those values generated automatically from the analysis software<sup>3</sup> using the same equation.

<sup>&</sup>lt;sup>3</sup> Analysis Software was Gamma Vision-32, Version 6.01

#### 3. Results and Discussion

From the reference material certificate, the average values for <sup>137</sup>Cs and <sup>226</sup>Ra were given as 53.65 Bq/kg and 79.9 Bq/kg, respectively, and the range for <sup>137</sup>Cs and <sup>226</sup>Ra at 95% confidence level were between 51.43 to 57.91 Bq/kg and 69.6 to 93.4 Bq/kg, respectively. In this study, thirty sets of spectrum data were collected, beginning March until September 2006. The activities for both radionuclides, i.e. <sup>137</sup>Cs and <sup>226</sup>Ra, were calculated automatically using the gamma-ray spectrum analysis software. Both radionuclides in the same spectrum were also manually marked and their activities were calculated. The values obtained from both approaches were plotted, as shown in Figure 1 and Figure 2.



*Figure 1. Comparison of*<sup>137</sup>*Cs specific activity calculated manually and using software.* 



*Figure 2. Comparison of*<sup>226</sup>*Ra specific activity calculated manually and using software.* 

Figure 1 shows that all (100%) the <sup>137</sup>Cs activity calculated manually are within the recommended value at 95% confidence level, as compared to 70% (21 data) of <sup>137</sup>Cs activity calculated by the gamma-ray spectrum analysis software. By excluding the data that fails the Grubbs' outlier test [7], the <sup>137</sup>Cs average activity is  $54.16 \pm 1.88$  Bq/kg and  $55.91 \pm 2.56$  Bq/kg for manual and automatic calculation, respectively. Meanwhile, for <sup>226</sup>Ra, as shown in Figure 2, all (100%) the manually calculated values fall within the recommended value as compared to only 77% (23 data) obtained from the analysis software. Also, by excluding the data fails outlier test, the <sup>226</sup>Ra average activity is  $75.0 \pm 2.8$  Bq/kg and  $72.4 \pm 4.3$  Bq/kg for manual and automatic calculation, respectively. The average values for both radionuclides using manual and automatic calculation show little differences. To determine how significant the difference between the measured values and the certified value, U-score for each single data was calculated using Equation 2 below:

$$U - score = \frac{|value_{certified} - value_{measurement}|}{\sqrt{\sigma_{certified}^2 + \sigma_{measurement}^2}} \dots (2)$$

Where  $value_{certified}$  is the certified value of radionuclide as in certificate and  $value_{measurement}$  is the measured value. The  $\sigma_{certified}$  is the uncertainty of the certified value and  $\sigma_{measurement}$  is the uncertainty of the measured value.

A U-score of 1.95 > u > 1.64 means the measured value probably does not differ significantly from the certified value. A U-score of u <1.64 means that the value measured does not differ significantly from the certified value [8]. The interpretation of U-score values is summarized in Table I.

The calculated U-score values for both <sup>137</sup>Cs and <sup>226</sup>Ra activity using manual calculation are all less than 1.64 (Refer Table II and Table III in Appendix). On the other hand, there are four values for <sup>137</sup>Cs and six values for <sup>226</sup>Ra in gamma-ray spectrum analysis software results giving a U-score of more than 1.64. This shows that the gamma-ray spectrum analysis software produce some bias from the certified value and is less reliable in spectrum analysis when compared with the manual calculation. Generally, the deviation is considered small, as almost all of the data has a U-score value of less than 2.58. However, among these data, there is one set of data, collected on the 3<sup>rd</sup> of April that is significantly different between the activity calculated manually and those from gamma-ray spectrum analysis software. This could be due to several factors as discussed below.

Condition	Probability	Status		
u < 1.64	Greater than 0.1	The reported value does not differ significantly from the certified value		
1.95 > $u > 1.64$ Between 0.1 and 0.05		The reported value probably does not differ significantly from the certified value		
2.58 > u > 1.95	Between 0.05 and 0.01	It is not clear whether the reported value differ significantly from the certified value		
3.29 > u > 2.58	Between 0.01 and 0.001	The reported value is probably significantly different from the certified value		
u > 3.29	Less than 0.001	The reported value significantly differs from the certified value		

#### TABLE I:PHYSICAL MEANING OF THE U-SCORE VALUES

The first reason might be due to the different approach used in marking the region of interest for a radionuclide peak in the software analysis compared to the manual analysis. Basically, in the gamma-ray spectrum analysis software calculation, a peak will be marked based on a preset marking region from the centroid of energy peaks with a tolerance of 1 keV. When there is a shift in peak energy while counting is in progress then there is a probability that the software would not be able to locate the peak or the software could not mark the peak completely until the edge. However, this phenomenon rarely occurs while counting is in progress because the photo-peak usually will not shift very much from its original peak position unless there is a massive change in environmental conditions [3]. This would not happen in manual observation, where a spectrum is viewed and marked manually according to the guideline [5, 6].

Another reason might be due to a photo-peak being overlooked by the gamma-ray spectrum analysis software. This is because the peak search is not as straightforward as generally thought. Theoretically, peak search is performed based on seeking a number of channels that each of them is successively significantly greater, in the statistical sense, than its previous neighbour. When there is a consistent rise, a corresponding series of channels with significantly falling contents might be sought as a peak. The pattern of rise and fall would then indicate the presence of a fall, and could be used to determine the peak limits. However, when only a few channels are statistically different from their neighbours and there is no consistent sequence of statistically significant differences, such a simple algorithm fails. But the human eye and brain can still detect the peak easily [5]. This phenomenon could be the explanation for the failure in software calculation for spectrum collected on the 3<sup>rd</sup> of April 2006.

Another possible reason could be caused by broad peak and poor resolution. When a measured peak is too broad due to a peak shift while counting is in progress because of the instability in power supply or the detector is not cold enough or a change in the room temperature, the preset marking region in the spectrum analysis software will not be able to mark a peak to its edge. This, indirectly, will cause an error in total counts, which will eventually direct the software to report a wrong value. This differs from the manual marking, where every peak is marked to the best possible edge of the peak.

Data presented in this paper is only preliminary. Few more set of data are required to confirm the reliability of the gamma-ray spectrum analysis software. These can be done by extending the similar analysis on different gamma spectrometry systems using different reference materials with multiple ranges of energies.

## 4. Conclusions

The comparison of manually calculated to the automatically produced results by analysis software is one of the validation procedures for gamma spectrometry system. In this case, a reference material containing radionuclide of interest is used. From the study that had been carried out, it can be concluded that the values obtained from the analysis software do sometimes deviate from the manually calculated value. Only 70% of <sup>137</sup>Cs activity and 77% of <sup>226</sup>Ra activity calculated by the spectrum analysis software are within the recommended values of 95% confidence level, but all the manual calculations are within the range. This shows that there is still some limitation in the spectrum analysis. Unless the limitations of the analysis software, as described above, can be resolved or improved, manually peak search, marking and calculation will still remain as the preferred option for calculating the gamma radionuclides activity. A further work is required to determine the actual cause of the deviation and to find ways to overcome the analysis software problems.

## 5. Appendix

	Manual			Spectrum analysis software		
Date	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score
03/15/06	52.37	3.92	0.30	45.95	3.51	1.99
03/21/06	55.72	4.19	0.46	53.81	4.20	0.04
03/27/06	52.10	3.93	0.36	50.20	3.92	0.81
04/03/06	55.19	4.96	0.30	0.59	0.04	32.74
04/10/06	54.08	4.88	0.08	57.09	3.86	0.82
04/17/06	56.49	5.01	0.54	56.86	3.91	0.76
04/24/06	54.93	4.96	0.25	56.13	3.72	0.61
05/02/06	51.73	4.56	0.40	52.76	3.76	0.22
05/08/06	55.90	5.01	0.43	58.52	3.61	1.23
05/15/06	56.28	4.88	0.51	55.25	3.91	0.38
05/23/06	51.97	4.58	0.35	53.38	3.65	0.07
05/29/06	54.77	4.91	0.22	57.68	3.59	1.02
06/05/06	54.97	4.93	0.25	56.97	3.80	0.80
06/12/06	52.22	4.74	0.29	54.77	3.49	0.29
06/19/06	51.67	4.71	0.40	52.76	3.56	0.23

TABLE II:<sup>137</sup>CS ACTIVITY FOR BOTH MANUAL AND SPECTRUM ANALYSIS<br/>SOFTWARE CALCULATION

	Manual			Spectrum analysis software		
Date	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score
06/26/06	57.37	5.12	0.69	27.85	4.11	5.84
07/03/06	52.37	5.08	0.24	54.77	4.54	0.23
07/10/06	57.01	5.09	0.63	59.08	3.85	1.30
07/17/06	54.39	4.90	0.14	57.40	3.58	0.96
07/24/06	53.86	4.88	0.04	55.30	3.70	0.41
07/31/06	56.86	5.07	0.60	58.85	3.82	1.25
08/07/06	54.48	4.91	0.16	54.99	3.69	0.33
08/14/06	52.13	4.55	0.31	55.00	3.51	0.35
08/21/06	56.70	5.03	0.58	60.67	3.69	1.74
08/28/06	51.55	4.65	0.43	51.71	3.83	0.47
09/04/06	52.74	4.73	0.18	56.02	3.85	0.57
09/12/06	52.34	4.77	0.26	54.26	3.74	0.15
09/18/06	55.00	4.95	0.26	57.11	3.84	0.83
09/25/06	55.27	5.01	0.31	57.91	3.86	1.02
10/02/06	52.48	4.86	0.23	60.30	3.79	1.61

 TABLE III:
 226 RA ACTIVITY FOR BOTH MANUAL AND SPECTRUM ANALYSIS

 SOFTWARE CALCULATION

	Manual			Spectrum analysis software		
Date	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score
03/15/06	78.70	4.66	0.11	68.72	3.94	1.57
03/21/06	79.60	4.84	0.03	78.06	3.46	0.27
03/27/06	73.57	4.46	0.49	67.53	3.09	1.84
04/03/06	73.68	5.82	0.48	2.93	1.00	12.72
04/10/06	76.36	5.94	0.27	72.74	3.25	1.06
04/17/06	77.26	6.07	0.20	70.43	2.85	1.43
04/24/06	78.37	6.12	0.12	71.90	2.90	1.21
05/02/06	76.72	5.93	0.25	74.21	3.08	0.85
05/08/06	74.47	5.82	0.42	73.21	3.26	0.99
05/15/06	76.70	5.90	0.26	70.75	2.88	1.38
05/23/06	71.04	5.55	0.67	65.86	3.06	2.10
05/29/06	76.19	6.03	0.29	75.18	4.46	0.64
06/05/06	73.03	5.81	0.52	71.54	3.12	1.24
06/12/06	77.00	6.07	0.23	71.36	2.88	1.29
06/19/06	71.48	5.71	0.64	66.06	3.16	2.05
06/26/06	76.46	6.04	0.26	70.76	5.54	1.12
07/03/06	75.38	6.18	0.34	73.13	4.75	0.89

	Manual			Spectrum analysis software		
Date	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score	Measured activity (Bq/kg)	Unc. 1s (Bq/kg)	U-score
07/10/06	77.56	6.05	0.18	74.59	4.76	0.70
07/17/06	73.12	5.78	0.54	73.72	3.12	0.92
07/24/06	70.55	5.59	0.75	70.25	3.04	1.44
07/31/06	70.20	5.59	0.76	64.98	2.75	2.27
08/07/06	74.06	5.81	0.45	73.49	3.21	0.95
08/14/06	76.39	5.88	0.28	76.25	4.27	0.50
08/21/06	70.27	5.58	0.74	66.85	3.03	1.95
08/28/06	74.74	5.90	0.41	74.41	3.27	0.81
09/04/06	70.94	5.65	0.69	70.11	3.02	1.47
09/12/06	75.34	5.94	0.35	73.58	3.20	0.94
09/18/06	75.21	5.90	0.36	78.83	4.67	0.14
09/25/06	75.87	5.97	0.30	77.36	4.59	0.34
10/02/06	80.05	6.29	0.02	84.28	3.13	0.65

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# The V&V process of the reactor protection system refurbished in NPP Paks

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**Abstract.** Between 1999 and 2002, on the four units of the Paks Nuclear Power Plant the obsolete relay-based I&C system providing the safety and protection functions of the reactor have been replaced within the scope of the reactor protection refurbishment by using an up-to-date digital (processor-based) system

The old protection system consisted of several subsystems operating in parallel. Each subsystem had its own sensors, transmitters, inputs as well as actuators and outputs. In the new system, these autonomous subsystems are integrated. Therefore, the refurbishment means a change not only in the (processor-based) tools used, but also in the modified structure of the reactor protection system. Various operational experiences, international recommendations and analyses necessitated also some functional modifications.

The significant modification affecting both hardware and software required various testing, verification and validation procedures in the different phases of design and implementation.

First the requirements were specified in natural language, then graphically (using the Synoptical Functional Diagrams). This document served as a basis for implementation.

The process was implemented on two separate, independent tools and sites.

The first tool was the Full Scope Unit Simulator at the Paks NPP, where the coding and comprehensive testing of the protection functions were performed in the GRASS development environment.

The other tool to implement the same function was the SPACE at the SIEMENS site. Testing was performed on the real hardware within the Factory Acceptance Tests (FAT).

Additionally, also in the simulator centre Paks NPP installed a representative configuration of the reactor protection system, which facilitates testing the real TXS hardware in simulated process environment. (This environment makes possible – through the connection to the simulated technology – carrying out closed loop tests.)

After the design and commissioning process also it is required to perform the periodic testing of the system already in operation. Testing is performed using a separate, independent tool called Test Machine.

## 1. The scope of the refurbishment

Between 1999 and 2002, on the four units of the Paks Nuclear Power Plant the I&C system providing the safety and protection functions of the reactor have been replaced within the scope of the reactor protection refurbishment. The traditional, wired devices operating with relays were displaced with intelligent equipment of modular construction based on microprocessors corresponding to the then up-to-date technical and technological requirements, as well as with such technical solutions which were newer than the earlier applied ones.

The SIEMENS (Framatome, Areva) TELEPERM XS product range was applied during the refurbishment.

The commissioning procedures accomplished on the unit 1, then during the following years also on the other units took place as a result of a long progress of analysis, decision making,
planning and development; the individual phases and steps of these work processes were executed under checking and testing carried out with intensive caution.

The old protection system included more sub-systems which were operated parallel. Separate autonomous protection systems existed in the reactor according to the technological signals, such as the Reactor Technological Protection System – RTPS, the Neutron Monitoring System – NMS, the Emergency Core Cooling System – ECCS, the Diesel Load Sequencer – DLS, the Reactor Power Limiting System – RPLS and the Steam Generator Protecting System – SGPS.

All of these sub-systems were provided with own sensors, remote transmitters, inputs, as well as own executive devices and outputs.

These autonomous sub-systems were integrated in the new system. The advantage of the integration is that the number of the sensors, remote transmitters and inputs was reduced successfully at a significant extent because these elements became common; likewise certain actuating units and executive devices also became common. In this manner the structure of the system became more embraceable and clearer, consequently the cabling and assembly (etc.) became more simply, which resulted in significant cost reduction.

The new reactor protection system consists of three trains of equal construction. Every train includes two independent branches, or in other words, diverse computers. All of the three trains receive the analog and binary signals coming from the technology, as well as the operator's commands, then they generate the own output signals from the incoming signals on the basis of predetermined logical operations (functions). The initiation signal of the actuators is generated from these output signals on the basis of majority voting.

Every train sends the parameters measured by themselves to the other two trains. (The A diverse branch sends them to the A only, and the B diverse branch sends them to the B only.) In this manner all of the three trains choose from the same input data the most appropriate ones on the basis of the same algorithm for further processing. This ensures that in the case of normal, trouble-free operation all of the three trains calculate with the same input value and give equal commands.

Therefore, the refurbishment means a change not only in the (processor-based) tools used, but also in the modified structure of the reactor protection system.

In addition, various operational experiences, international recommendations and analyses necessitated also some functional modifications:

- the ÜV-2 functions were cancelled (9)
- functions were modified (21)
- new functions were introduced (18)

Summary of the above described: In the original RPS there were 69 start-up conditions, where in the new RPS more than 80 start-up conditions have been implemented.

In accordance with the significant modifications concerning equally the hardware and the software, in the phases both of the design and the implementation, consequently test, verification and validation (V&V) procedures had to be carried out extended to the entire

system construction in order to confirm that the refurbished system performs accurately the tasks according to the specifications even in the case of an arbitrary input state.

# 2. The V&V process

First the requirements were specified in natural language, then graphically (using the Synoptical Functional Diagrams). This document served as a basis for implementation.

The process branches out here. The implementation took place on two different, independent tools and localities.

The first tool was the reactor unit simulator at the Paks NPP, where the coding and comprehensive testing of the protection functions were performed in the GRASS development environment. Different experts were involved in the relevant test phases (I&C) and process engineers and operators, etc.).



GRASS	Graphic Simulation System
SPACE	Specification And Coding Environment
RC	Representative Configuration
SFD	Synoptical Functional Diagram
ProfiSIM	Simulation and Code Generating
	Environment (Formalised Functional
	Specifcation)

Figure 1. The V&V Process.

The other tool to implement the same function was the SPACE (Specification and Coding Environment – the SIEMENS Teleperm XS graphic programming surface) at the SIEMENS site. The same protection function was implemented in the SPACE following the Synoptical Function Diagram, and it was tested on the real hardware already within the framework of the Factory Acceptance Test (FAT) at the manufacturer's site in Germany.

As shown in the *Figure 1*. the tests covering different scopes overlap or include each other, thus ensuring the reliability of the V&V process.

As a unique test facility, the Paks NPP developed an own test environment by means of building up the Representative configuration. One train of the Representative configuration is entirely identical with a real unit train, and it is connected to the unit simulator through an interface. However, the two side trains, so called emulators are not complete. They do not contain physical inputs; they receive the technological parameters through a communication line only. The communication both within the real train and between the trains is identical with that of the unit.

This environment makes possible – through the connection to the simulated technology – carrying out closed loop tests.

The simulator can be operated by means of virtual switches in the following three main modes of operation:

- (1) The old reactor protection logic links with the simulated technology in a closed loop. This operational mode ensured that in the temporary period of the refurbishment (operating the previous system parallel with the new one in some units) carrying out the training specified for the operator personnel was possible even on the old system.
- (2) The new protection logic (GRASS model) links with the simulated technology in a closed loop (software in the loop), while the inputs of the old logic are connected and their outputs are disconnected.
- (3) The representative configuration links with the simulator in a closed loop (hardware in the loop), while the inputs of the GRASS model are connected, and its outputs are compared automatically with RC outputs continuously.

The renewal of the Representative configuration and in connection with it that of the simulator entailed numerous advantages:

- Faster and more accurate technological model.
- Continuous training of the operator personnel both on the old and the new system.
- Training of the operating and maintenance personnel of control engineering.
- Independence of developing the reactor protection functions.
- Possibility of open and closed loop test.
- Comparability of behaviour of the software model (GRASS) and the TXS hardware (RC).
- Test capability of the human machine association surface.
- Test capability of the operating processes.
- Possibility of validation of later modifications, changes.

Parallel to the tests executed on the simulator, similar tests are performed in the Test Field within the FAT.

The ProfiSIM system developed in Paks is the other device for encoding the protection functions, which system accomplishes the Formalised Functional Specification (FFS) on the one hand, consequently it has a documenting property, and, on the other hand, it generates a program code automatically for the SPACE (Specification And Coding Environment – the SIEMENS Teleperm XS graphic programming surface). By means of so called cloning automatisms the ProfiSIM system ensures that both the redundant trains within the individual units and the software in the four units are identical. As an additional service the system provides an offline test facility which can be implemented even in the planning phase.

# **3.** Tests during the operation

The test procedures described so far were applied during development of commissioning processes, however, the modernization of the Reactor Protection System brought new possibilities and methods also in the field of operating tests.

In the beginning the standing-points of the Paks NPP Ltd. and the SIEMENS were different in relation to the necessity of the testability.

International standards (IEC880, IAEA recommendations) contain specifications on the testability of intelligent, programmed systems providing safety functions, in reference to which the Paks NPP Ltd. built the testability requirements in the own documents from the beginning. According to this the testability and its development aspects are specified by the *Planning principles* document, for example, in an accentuated manner.

Likewise the standing-point of the SIEMENS was rejected by the Paks NPP Ltd., according to which the operating tests can be accomplished by means of the test functions integrated in the system built up from the Teleperm XS elements. Through the application of these integrated test modes of operation information could be obtained merely on that the processors comply with the expected requirements in test state but it could not be confirmed whether returning into the normal operational mode these test modes of operation exist.

The *Testability requirements* document was worked out with taking into consideration the above mentioned, as well as the conception of the periodic test, which describes that the defect-free operation must be confirmed through the tests carried out beside the external intervention of the user, and accomplished at a defined periodicity.

Differently from the self-diagnostic methods, the tests accomplished periodically require a methodology developed in a special manner and external, independent test equipment.

The periodical test of the Reactor Protection System (carried out in operating or inoperative state of the unit) is facilitated by the appropriate building-up of the user software and an external, independent test device, the so called **Test Machine** (TM).

On the basis of the RPS to be tested the following test types were developed:

- <u>NF</u> test of analog modules and computers (<u>NF tests</u>),
- <u>TS</u> Test of input modules of computers (<u>TSIM tests</u>),
- TS function and output test of computers (<u>TSF tests</u>),
- <u>VT</u> output test of computers (<u>VTOUT tests</u>).

In addition there is a special test type accomplished during the unit outage, the

• Unit start-up, in other words "Inoperative unit" (or <u>OUTAGE</u>) tests.

The purpose of the tests, and the scope of the system elements to be tested, respectively, was determined in such a manner that the complete signal flow is covered, therefore the test types overlap each others.

# Designing and Developing of Data Evaluation and Analysis Software Applied to Gamma-Ray Spectrometry

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**Abstract.** This study is intended to design and develop software for gamma spectral data evaluation and analysis suitable for a variety of gamma-ray spectrometry systems. The software is written in Visual C++. It is designed to run under Microsoft<sup>®</sup> Windows<sup>©</sup> Operating System. The software is capable of covering all the necessary steps for spectral data evaluation and analysis of the collected data. These include peak search, energy calibration, gross and net peak area calculation, peak centroid determination and peak width calculation of the derived gamma-ray peaks. The software offers the ability to report qualitative and quantitative results. The analysis includes:

- Peak position identification (qualitative analysis) and calculating of its characteristics,
- Net peak area calculation by subtracting background,
- Radioactivity estimation (quantitative analysis) using comparison method for gamma peaks from any radioisotopes present during counting,
- Radioactivity estimation (quantitative analysis) after efficiency calibration,
- Counting uncertainties calculation,
- Limit of detection (LOD) estimation.

# 1. Introduction

Gamma-ray spectrometry is a well-established tool for basic research and has a great variety of applications. High resolution gamma-ray spectrometry is a convenient method for measuring the activity of radioactive nuclei emitting gamma and/or X-rays. In laboratory conditions samples are placed close to the sensitive volume of the detector and the gamma and/or X-ray spectra are measured. In the spectrum all the photons that interact with the material within the sensitive volume of the detector are counted and registered. Since radioactive atoms emit a discrete spectrum of photons, photo-peaks in the spectrum occur at individual photon energies due to interactions leading to full absorption of the photon energy within the sensitive detector volume.

After the measurement is completed, the peak areas in the spectrum have to be calculated and corrected for counting losses. The corrected peak areas are proportional to the number of radioactive atoms that have decayed in the sample during the measurement.

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There are three available types of computer programmes for nuclear spectrometry:

- (1) MCA emulators, which are concerned mainly with the acquisition of the spectrum data. They emulate the functions of the hard-wired multichannel analyzer.
- (2) Off-line programs, which are intended to perform full calibration and analysis of spectra which have been acquired either by an MCA Emulator program or by hard-wired analyzer and stored on disk.
- (3) Dual-purpose programs, which combine the two functions. Spectra may be analyzed subsequent to acquisition within the same program.

# 2. Experimental

The gamma-ray spectrometry software has been designed and developed for gamma spectral data evaluation and analysis. The software is written using Visual C++ and runs under Microsoft<sup>®</sup> Windows<sup>©</sup> operating system. The software exploits all the capabilities of MS Windows technology such as point-and-click simplicity in task executions, intelligent mouse pointer and so on.<sup>1</sup>

The main tasks of the developed gamma-ray spectrometry software:

- Determines peak position in the spectrum
- Performs energy calibration and plots energy calibration curves.
- Locates peaks in the spectrum using region-of-interest (ROI)
- Determines corresponding energy to each gamma-ray peak (energy calibration)
- Estimates the areas of the peaks in the spectrum (calculates gross and net peak areas)

The program subsequently:

- Corrects for counting losses due to dead time and random summing
- Makes corrections for radioactive decay from a reference time, such as sample collection time or irradiation time. This function is useful in neutron activation analysis method.
- Converts peak areas to activity (or concentration depending upon usage) by direct comparison with a reference spectrum (quantitative analysis report using standard sample spectrum for selected gamma-ray energies)
- Determines peak width (full width half maximum; FWHM) and efficiency calibration coefficients
- Estimates a limit of detection when appropriate peaks are not detected
- Identifies nuclides in the spectrum after energy calibration using internal library
- Presents final reports, both qualitative and quantitative printed reports

In the software an active peak search is included. The software locates peaks using channel differences. The pattern of rise and fall indicate the presence of a peak. Energy calibration is performed before acquisition of the spectrum as part of the setting up procedure. ROI could

be selected using peak search function. ROI could also be set manually for each individual peak. Using the ROIs the software can then calculate and subsequently print out, peak areas corrected for the background continuum and a peak area uncertainty. To estimate the gamma-ray energy represented by the peak we must have a means of determining the position of the peak centroid to within a fraction of a channel. The peak centroid is calculated as follows:

$$Centroid = I = \frac{\sum C_i i}{\sum C_i}$$
(Eq. 1)

where  $C_i$  is the count in the  $i^{th}$  channel.

In order to do peak area measurement, the Total Peak Area and Covell methods have been used as the standard methods for peak area estimation for single un-interfered peaks. The Covell method was used in the early days for measuring peaks areas in NaI scintillation spectra. The gross area of the peak is:

$$G = \sum_{i=L}^{U} C_i \qquad (\text{Eq. 2})$$

The background under the peak is estimated as:

$$B = n \frac{(C_{L-1} + C_{U+1})}{2}$$
 (Eq. 3)

where n is the number of channels within the peak region and  $C_{L+1}$  and  $C_{U+1}$  are the counts in the channels immediately beyond the lower and upper edge channels L and U. This background is estimated mathematically and is simply the mean background count per channel under the peak multiplied by the number of channels within the peak region.

The background region estimated using the channel contents at the upper and lower edges of the peak region is shown in Fig. 1.

The net peak area, A is calculated as:

$$A = G - B = \sum_{i=L}^{U} C_i - n \frac{(C_{L-1} + C_{U+1})}{2}$$
 (Eq. 4)

The standard deviation  $\sigma_{\scriptscriptstyle A}$  of peak area is calculated using the following formula:

$$\sigma_A = \left[ A + B \left( 1 + \frac{n}{2m} \right) \right]^{1/2}$$
 (Eq. 5)

where n is the number of channels within the peak region and m is the number of channels within upper and lower background regions.

All measured activities are corrected for radioactive decay to a point in time:

$$R_0 = R_t \exp\left(\frac{\ln 2}{T_{1/2}} \times t\right)$$
 (Eq. 6)

where  $R_t$  and  $R_0$  are the disintegration rates at time t and at the reference time and  $T_{1/2}$  is the half-life of the nuclide.

Unlike many spectrum analysis programs, the present software makes specific provisions for direct comparative analysis. This function is in particular suitable for neutron activation analysis.

The sample peak count rate is simply compared with those of a standard or reference material samples:

$$C_{sam} = \frac{R_{sam} \times C_{std}}{R_{std}}$$
(Eq. 7)

where the  $C_{sam}$  and  $C_{std}$  represent activities or concentrations of sample and standard and the  $R_{sam}$  and  $R_{std}$  are the sample and standard peak count rates, respectively.

For calculation of full-energy peak efficiency the following equation was used:

$$\varepsilon = \frac{C}{S \times P_{\gamma}}$$
(Eq. 8)

where C is the full-energy peak count rate in count per second(cps), S the source activity in disintegrations per second (Becquerels; Bq) and  $P_{\gamma}$  is the probability of emission of the particular gamma-ray being measured. The software plots efficiency curve for the full energy gamma-rays.

The software is capable of deducing the FWHM of the identified peaks as a function of energy using the following simple equation:

$$FWHM = 0.939 \times \frac{A}{C_T - C_0}$$
(Eq. 9)

where A is the area of the peak and  $C_T$  is the estimated peak height derived from counts in peak centroid (Eq. 1). To estimate peak height at peak centroid:

$$C_{T} = \exp\left[\frac{\ln(C_{L} - C_{0}) - F\ln(C_{U} - C_{0})}{(1 - F)}\right]$$
(Eq. 10)

where  $F = \left[\frac{L - \overline{x}}{U - \overline{x}}\right]$ , L and U are the channels at either side of the centroid,  $\overline{x}$ . C<sub>0</sub> is the peak background, based upon the average background level above and below the peak.

The detection capability of any measurement process is one of its most important performance characteristics. In low activity measurement by gamma-ray spectrometer it is necessary to determine limits of detection (LOD). An empirical expression for LOD measurement in Bq/kg or Bq/g of solid sample has been used in the software.

$$LOD(Bq/kg) = (2.71 \times 3.29) \times \frac{((A_b \times LT_s) + 2B_s)^{1/2}}{LT_s \times M_s \times P_s \times \varepsilon}$$
(Eq. 11)

where:

 $A_b$  = net peak area of background measurement (cps)

 $LT_s = live time of sample measurement (s)$ 

 $B_s$  = peak base of measured sample (counts)

 $M_s = mass of sample (kg)$ 

 $P_{\gamma}$  = probability of emission

 $\varepsilon$  = full-energy peak efficiency

all parameters for the particular gamma-ray.

Nuclide identification is included in the software using an internal library. (Fig. 2)

Fig. 3 shows a typical gamma-ray spectrum presented in main menu of the software.

The software produces two different final reports, qualitative and quantitative analysis reports.

The complete overall procedure for performing a full spectrum analysis of nuclides present in the spectrum, follow the flowchart given in Fig. 4.

# **3.** Conclusions

A Gamma-ray Spectrometry Software has been designed and developed for gamma spectral data evaluation and analysis. The software is written in Visual C++ and runs under Microsoft<sup>®</sup> Windows<sup>©</sup> Operating System. The software determines peak position, energy calibration, locating peaks in the spectrum using region-of-interest and calculates the energy of the gamma-ray each peak represents. It also estimates the areas of the peaks in the spectrum and performs counting losses and decay corrections. Furthermore, the software converts peak areas to activity by direct comparison with a reference spectrum and creates efficiency, peak width (energy resolution) and efficiency calibration coefficients. It also estimates a limit of detection and identifies nuclides in the spectrum after energy calibration using internal library. Finally it presents final results including both qualitative and quantitative printed reports.

The software will be developed further and will be commercially available for gamma-ray spectrometry applications.



Figure 1. Calculation of peak area using the upper and lower edges of the peak region.



Figure 2. A typical gamma-ray spectrum presented in main menu of GRSS, including the Isotopes Library.



Figure 3. A typical gamma-ray spectrum presented in main menu of GRSS, including the Info Peak view.



Figure 4. Full spectrum analysis flowchart.

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# Software and algorithms for PDS-100 personal radiation detector

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**Abstract:** This paper presents the validation and verification (V&V) process of a newly designed personal radiation detection instrument used for a so-called "moving curtain" to enhance the control over illegal trafficking of nuclear materials. Therefore, the instrument has to meet all related ANSI and similar IAEA standard requirements. Since V&V is an expensive task, targeting the verification effort to the important to verify the having no critical errors. The software was divided to importance blocks, by error consequences. The critical significance blocks are data acquisition and data processing units, alerts management unit and parameters verification. Parameters verification included tests such as acceptable limits verification, accuracy verification, system behavior and different parameters conditions and incongruity between parameters.

#### 1. Introduction

Illegal trafficking of nuclear materials and other radioactive materials has been an issue of concern in the last decade and required for enhanced control and security of nuclear and radioactive materials. In response to that threat, an integration approach for the protection against nuclear terrorism has been adopted and activities concerned with physical protection of nuclear material have been taken by worldwide agencies. The firs combating line against illicit trafficking and movement of radioactive materials is designated to Personal Radiation Detectors (PRD). These instruments worn by law enforcement personal in the course of their regular duties constitute a flexible "moving curtain" enhancing the detection capability of sites as airports and seaports.

In order to enhance the control over illicit trafficking of radioactive materials, the USA Department of Homeland Security (DHS) developed the ANSI N42.32 group of standards.



The performance criteria for the PRD are described in those standards. The PDS-100 is a PRD type instrument developed by Rotem with assistance of NRCN engineers, designed to meet all the ANSI and similar IAEA standard requirements. PDS-100 is a smart, small and lightweight radiation monitor that provides fast approach to a suspected radiation source.

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# 2. Description

The PDS-100G is the latest generation of gamma and gamma/neutron personal radiation detectors. These sensitive pocket-sized instruments are designed to detect, locate and quantify any radioactive materials, such as Special Nuclear Materials (SNM), and to respond to incidents involving Radiological Dispersal Devices (RDD). The PDS-100 includes innovative algorithms in order to limit any false alarms. The PDS-100G/GN instruments are ideally suited for first responders, hazard-material border/inspection personnel and for security of critical infrastructures.

Designated, sophisticated, real time software was developed for the PDS-100. Measurements are made by distinguishing four levels of radiation energy and gathering gamma and neutron counts. Neutrons are distinguished from gamma pulses according to the pulse amplitude. The algorithm for gamma alert considers dose rate increase over background and statistical calculations for count rate. The neutron alert algorithm calculated both the neutron count rate and the ratio of high energy gamma counts to neutron counts. The instrument software provides fast alert for neutrons and for gamma radiation increase, with very low false alert rate. In conjunction with proper filtering and appropriate conditions, the PDS-100 complies and in some cases surpasses the ANSI N42.32 demands To achieve dose rate measurements up to 10mR/h the instrument software includes dead time compensation factors for different radiation intensities.

# **3.** Validation and verification

The validation and verification (V&V) process was carried out during the development to ensure the high quality of the final product. Validation is the process of evaluating a system to determine whether it satisfies specified requirements. The validation process applied to the PDS-100 provided evidence that the software satisfy system requirements such as solving the right problem, correctly modeling physical laws, confirming the use, the proper system assumptions and satisfying intended use and user needs.

The validation requirement of satisfying intended use and user needs is not an obvious requirement. Nevertheless, this requirement is critical since even first-rate device with an excellent performance used incorrectly by the user can produce more harm the benefit.

Since V&V is an expensive task, targeting the verification effort to the important to verify the having no critical errors. The software was divided to importance blocks, by error consequences. The critical significance blocks are data acquisition and data processing units, alerts management unit and parameters verification. Parameters verification included tests such as acceptable limits verification, accuracy verification, system behavior and different parameters conditions and incongruity between parameters.

# 4. Evaluation of data acquisition and processing

For evaluation of data acquisition, detectors and electronics response to all required radioactive sources should be record. This data is evaluated for correct statistics, energies,

accuracy, linearity, saturation etc. The acquired data can be used for further simulation on fast PC instead of the embedded system.



Figure 1. Data recording concept.

The evaluation of data processing and the algorithms should start from using previously acquired data and to be carried out on the PC. At the start, the use data from previously developed comparable instruments is possible. When available, use the data acquired by the developed instrument is used for more accurate evaluation.



Figure 2. Data processing concept.

Evaluation of data should verify handling of not expected and incorrect inputs, optimize performance (while keeping in mind the embedded system), simulate and validate on PC, verify filters and DSP blocks, and analyze the obtained results. When evaluation of data is performed on PC, graphs and statistics are easily obtained. The results and the conclusions are

effortlessly documented when comparing to performing the same on embedded system. Afterwards the software is coded on the embedded system. Most of the PC verifications should be performed again and relevant embedded verifications must be performed as well. Sub blocks and accuracy should be compared on PC and on the embedded system to have similar results.

#### 5. Writing the code

The code and the hardware should be written or designed in maintainable matter. Providing the code and the design as reusable modules, save budget and V&V in further developing projects. Providing an extensible design for later feature improvements, can save budget and Verification effort in present project as well. Although developing thus requires additive time and effort, the development is carried out better with fewer errors.

Today more and more systems are build using COTS products. Reuse of software and algorithms can be based on previous instruments, scientific routines, in-house software and Commercial of the Shelf (COTS) software. Reusable software generally require less verification effort. On the other hand, different V&V should be performed. It is vital to identify all assumptions and constrains of the original software, input and output ranges, accuracy, designated hardware and different system demands such as memory constrains.

#### 6. Additional development

Ai instrument must have a self-test to verify correct and reliable performance. The self-test should be executed at start and during operation. The PDS-100 continuously performs a self-test for battery voltage, counts in range test (no too high and no too low), internal temperature monitoring and other internal tests. In the event of a malfunction, the PDS-100 will display an appropriate error message.

As a part of requirements validation of the intended use of PDS-100 the software maintains two user profile modes of operation *routine* profile and *expert* profile. In the *routine* profile the instrument is operated at the simplest manner as a monitoring, alerting and searching device carried on the operator's belt. Alternatively, the *expert* profile, which is dedicated for professional radiation control personnel, includes display of radiological units of uSv/h or uR/h, spectrum acquisition capability, flexible parameters adjustment etc.

The firmware of the PDS-100 can be remotely updated by downloading newer versions from the internet. The firmware update feature enabling update of the instrument firmware via the PDS-100 IRDA interface, without opening the instrument case. Firmware update is performed with the aid of the PDS Loader software tool, which is used to download a HEX file to the instrument. To make the firmware update procedure as safe and robust as possible it is done in two steps. At first the new hex file is transferred into the PDS-100 EEPROM which is used to store the PDS-100 event log and acquired spectra. This step overwrites any stored event or spectra data but does not over write the existing firmware. This way the PDS-100 remains functional even if something goes wrong during the firmware transfer process. In the second step the new firmware is copied from the EEPROM to the internal flash memory, this effectively replaces the PDS-100 firmware. The second step is done automatically inside the PDS-100 and therefore with as small as possible chance for failure. In any case the firmware

update does not overwrite the boot loader firmware which is responsible for the firmware update process.

The developed PC software provides fast, simple, reliable and fail safe calibration procedure based on statistical analysis of the calibration data. The software enables remote operation, including spectrum deriving and management of data such as parameters, alarms, event times and any other data measured by the PDS-100. The software also enables remote operation, including spectrum deriving and management of data such as parameters, alarms, event times and any other data measured by the PDS-100.

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# Design and implementation of an optimized network for a computer controlled radiation monitoring system

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**ABSTRACT:** A new design of hardware and software required for networking a computer controlled radiation monitoring system is presented. This radiation monitoring system comprises a network of area radiation monitors connected to a central computer via an interface module. The monitors are employed for area dose-rate measurement and controlled via the network. For increasing distance between monitors and central control and reducing transmission error a kind of bus networking which is controlled by the interface module is used. The interface module is mainly designed for network control and acts as the bus master. By using this interface module, there is no need to equip dose monitors with any interface cards. Communication between the monitors and bus master is carried out by two transmission lines for send and receive, using RS485 standard to get benefit of a low cost and simple hardware. In this communication platform a new practical protocol is used to reduce the transmission error. This kind of networking seems to be an optimum solution for distributed monitoring systems.

Keywords: Monitoring System, Area Radiation Monitor, Data Transfer and Bus Networking

# 1. Introduction

An area radiation monitoring system comprises number of area radiation monitors, used for area dose-rate measurement. Depending on vastness of monitoring area, for example a laboratory, a building or a research center, proper number of area radiation monitors should be used for correct monitoring. In order to read dose-rates of different places in the monitoring area as well as setting up the area radiation monitors with desired set-points from a central location, connecting these monitors together and to a central computer via a network is essential. Such systems have been produced by few companies, such as Genitron Instruments [1].

This paper presents networking concept of a computer controlled radiation monitoring system, which is designed for area radiation monitoring in a radio pharmaceuticals production laboratories. The central computer of the system is used as the main controller and user interface. This computer collects the measurements of the area radiation monitors (called terminals) via an interface module and stores them in dedicated log files. The graphical user interface (main software) is written in Visual C [2], and some of its features are:

- On-line presentation of terminal's data (Fig.1).
- Graphical or numerical presentation of a terminal's data in a particular hour, day, month or year (Figs.2, 3).

A complete area radiation monitoring system, as explained above (Figs.1,2,3), is designed and fabricated at the Nuclear Electronics Department of the Nuclear Research Center for Agriculture and Medicine (NRCAM), and is being used in the Cyclotron Department of the NRCAM (Fig.4).



Figure 1. Main page of the system graphical user interface.



Figure 2. Dose-rate measurements of a terminal shown as a graph by graphical interface.



*Figure 3. Numerical presentation of a terminal reading for a particular data.* 



Figure 4. Area radiation monitors are being used in the hot-cell laboratory of the Cyclotron Department at NRCAM, Karaj.

# 2. General Description

The system hardware (Fig.5) includes:

- Number of area radiation monitors (terminals), used for dose-rate measurement,
- A central computer, used as main controller and user interface,
- An interface module, used as network controller and interface between the central computer and the terminals.



Figure 5. General block diagram of the system hardware.

Number of the terminals (n) can be increased up to 256, depending on vastness of monitoring area. A new terminal can simply be added to the network by serially connecting it to the data bus at the nearest point. These terminals are microprocessor-based instruments using an embedded software and a sensitive Geiger-Muller radiation detector to measure and display dose-rate with resolution of  $0.1\mu$ Sv/hr. The terminals communicate with the interface module to transmit measured values and receive control commands and set-points.

The interface module is also a microprocessor-based instrument which performs few tasks such as: network management, data transmission management, data buffering and storing data for a limited time period. Storing data in the interface takes place when the central computer is off or damaged. The central computer, used as the main controller and user interface, performs various tasks such as: data processing, data management, building data bases, storing processed data in dedicated log files (in \*.mdb format), on-line display of data in numerical or graphical shapes, and displaying logged data in a particular hour, day, month or year (Fig.2). In this paper a new, easy to implement and economical procedure for networking the area radiation monitors (terminals) of the above system is presented.

# 3. Network backbone

Presented network is sort of bus-networking, in which the terminals are connected to the interface module via a serial bus. Two separate transmission lines are considered for send and receive using RS485 standard (Fig.6). In This standard the maximum length for direct cabling between a terminal and the interface module could be 4000 feet [4].



Figure 6. Connection of the terminals to the interface module via two separate send and receive lines on a serial bus.

Each transmission line consists of a twisted pair wire, used for differential signaling (Fig.7). The twisted pair cable, recommended for RS485 communications, trends to cancel commonmode noise and causes cancellation of the magnetic fields generated by the current flowing through ach wire [3].

The standard CAT5 cable is used for network wiring to get benefit of its twisted pair wires as well as having the send and receive wires in a single cable.



*Figure 7. Electronic circuit used for conversion from TTL to RS485 and vice versa; A & B are differential lines in RS485 standard.* 

Regarding that in this system the terminals' measuring period is 4 seconds, a suitable buadrate for data transmission should be selected enabling complete transmission of terminals' data and other essential data and commands in this period. For example for buad-rate of 4800 bit/s, given 256 terminals and 3 bytes for measured dose-rates added by a terminating bit for each byte, total data transmission time would be:

(256\*3\*9) / 4800 = 1.5 second

Assuming that remaining time to 4 second would be used for transmission of essential commands and/or data, such as: control bytes, set-point values and checking the correctness of transmitted data, this speed (4800 bps) satisfies 4 second sampling period of the system.

Comparing to guaranteed speed in RS485, which is 10 Mbps for 4000 feet or some 1200 m [3, 4], the selected speed is relatively low. Knowing that the transmission distance can be increased for lower speeds, the distance from a terminal to the interface can be greater than 1200 m up to few kilometers. In case of having distances more than few kilometers, simple repeaters using two ADM485 ICs [3] for each transmission line, send and receive, can be employed (Fig.8).



*Figure 8. Simple repeaters can be used for data recovery in long distances.* 

# 4. Data transmission protocol

As the terminals' network is based on serial bus, data interference may occur when two or more terminals try to send data on the receive line concurrently. An appropriate protocol is presented to solve this problem and manages the data transmission in general. In this protocol, the communication between the terminals and the interface takes place on two separate transmission lines (send and receive) and always starts by the interface. Actually, the interface is the bus master and the terminals are slaves. The terminals are always in stand-by mode (waiting mode) to receive first command from the interface. This command gives permission to a particular terminal to communicate with the interface; getting data from the send line or putting data on the receive line. Figure 9 shows the command/data stream on the send line. The following steps explain the communication algorithm, shown in Fig.10:

- (1) The interface (bus master) puts a 9 bit packet on the data bus (send line) as starting command, where its first 8 bit specifies the terminal number and the 9<sup>th</sup> bit is set to 1.
- (2) All terminals are in waiting mode, so that their serial input is set in order to accept all 9 bit packets with its 9<sup>th</sup> bit set to 1. So, all terminals would receive first command and read the terminal number.
- (3) The specified terminal, if the terminal number is valid, sends back the received packet to the interface and gets ready to receive next packet with its 9<sup>th</sup> bit set to 0. Other terminals will remain in waiting mode and do not receive the subsequent packets with their 9<sup>th</sup> bit set to 0. So, they do not get involved and step in communication process.
- (4) As shown in Fig.8, second 9 bit packet is also a command which shows the data flow direction, to or from the terminal. This could be commands such as: dose-rate request, alarm state request and sending set-points.
- (5) Depending on this command, data is sent by the interface to the active terminal or vice versa, on send and receives lines.
- (6) When the required data is collected from the active terminal and also new set-points is sent to it, the communication ends.
- (7) At the end of communication the active terminal goes to waiting mode again, that is, accepts 9 bit packets with its 9<sup>th</sup> bit set to 1.
- (8) Then next terminal is ordered to start communication and so on.

As shown in the protocol algorithm in Fig.10, in communicating process the receiving device (terminal or interface) always send back its received packet to the sender. This is a procedure for checking that if a packet is correctly received by the receiver or not?



Figure 9. Data stream from the interface to a terminal.

#### 5. Discussion

Using RS485 standard for data transmission simplified the required hardware for system networking and increased acceptable distance for direct cabling from the terminals to the interface, up to few kilometers. Presented network management and transmission protocol requires simple hardware and offers a reliable and data transfer. In this hardware 8051

microcontrollers, used in the terminals and the interface module, are connected together as a network using RS485 standard and CAT5 cable.

Therefore, the presented system is: simple, practical, easy to implement, reliable, capable of adding new terminals (up to 256) to the network with no need to significant changes in either hardware or software, and, capable of increasing the distances between terminals and the interface, which is typically placed in the central control location, up to few tens of kilometers using simple and cheap repeaters.

The system can be developed and modified by adding capability of connecting each terminal to the local area network (LAN), if exists. In this case the terminals will get an IP and communicate with a central computer using TCP/IP. This computer, which accommodates the main software and acts as the main controller, can be connected to the LAN in any place in the intranet or internet.



Figure 10. The algorithm of communication between the interface and a terminal.

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# Validation of software applied to virtual nuclear instruments

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**Abstract:** This article mainly introduces what virtual nuclear instrument is, the significance and necessity of validation procedures of software applied to virtual nuclear instrument, software verification and validation procedures, and the test strategy. We also combine with virtual multichannel analysis system to introduce the test steps of applied software in detail. In general, the test used was divided into four steps as follows: unit test, integrated test, system test, validated test. In a word, the quality of software is life of nuclear instrument, however, how to improve the quality of software; strict validation is the most important aspect.

#### **1. Virtual Instrument**

Virtual nuclear instrument is a new concept for an instrument which results from the combination of computer technology and one electronic module capable to convert any physical unit into electronically readable information for further process. This is the major breakthrough and one even can say it is a "revolution" in the nuclear instrumentation field. Virtual instrument is a new generation of instrument resulting from: the first generation instrument—analog instrument; the second generation—the discrete components instruments; the third generation –digital apparatus; the fourth generation—intelligent equipment.

#### 2. Difference between virtual nuclear instrument and traditional nuclear instrument

Virtual instrument is virtual instrument techniques applied to nuclear field. The main functions of traditional nuclear instrument consist of three major components—signal acquisition, data analysis and processing, the result output, only the manufactures can define, create the functions, users can not change anything. Along with the development of the microelectronic technology, computer technology, software technology, network technology, and along with these technologies have been plenty used in measurement and instrument, the data analysis, data processing and output functions have thoroughly been handed over to the computer-based software, the signal acquisition and control can be made into one plug-in board, which can be inserted into the computer bus expanded slot, or appropriative instrument plug-in plank, or plug-in box. Computer screen also can be used to imitate various types of instrument and control panel directly and easily, display outputs in various forms. All of these would constitute a computer-based digital nuclear measurement instrument—virtual nuclear instrument. In this virtual nuclear instrument system, hardware simply solve the signal input and output, we can thoroughly use the same hardware system to develop different instruments

by development different software, the functions and size of the system can be changed easily by software modification. Software system is the core of the virtual instrument, it can define different instruments, and therefore it can be said that "Software is Instrument".

# 3. The necessity and significance of software validation applied to virtual nuclear Instrument

As far as software development is concerned, general so-called "quality assurance" refers to test and check the software after it finish, but in fact that can guarantee what? For example, a software product has been completed, a number of errors were found in tests, if these errors can be modified by only changing a small number of program code, it may do not a matter, but if the core of the software should be modified to fix these errors, we can not image how much workload we should do, maybe to redesign the software rather than to fix these errors. As we know each product has it's own defective, we should find the defective as early as possible in the course of developing, improving the quality of software in this way is more effective than testing after it has been completely finished. So if we want to achieve high quality software, what we should do is to design the quality control into the whole process of software development, it is more important than only setting up quality assurance department, or whom to report, or what is the independent test, or what kind of comment we should do, and etc.

I think you must agree to the view about that quality control is designed in the whole process of software development, but how to judge that quality control has been merged into the design at first? One important idea is that we should focus on the quality in the entire cycle of product development, from affirming the requirement of the software, to deliver it to users. If we focus on quality at every stage of software development, we need one management flow, most of improved software development management model (like CMM an ISO9000) are the effective and correct flow. High quality software will be inevitably produced if we follow these flow.

# 4. Validation, verification, test of virtual nuclear instrument

#### 4.1 Validation

At every stage of software life cycle, validation is recognized that to test if the developing software unit at the end of each stage meets its requirements described in the file system at the beginning of software life cycle.



Figure 1. Validation.

# 4.2. Verification

At every stage of software life cycle, verification is referred to that if software at the end of each stage meets its specifications defined at the end of the last phase.



Figure 2. Verification.

Software tests can be used for verification, but also for validation.

# 5. Software testing strategy

The software testing strategies and methods and techniques are varied.

The software testing technologies can be classified from different point of view: from the perspective of the need for the implementation of software, can be divided into static test and dynamic test; from the perspective of the internal structure of the system and algorithms, can be divided into white box testing and black box testing.

White-box testing, also known as structural test logic-driven testing or program-based testing, it is based on the internal characteristics of program.

Black-box testing: from the perspective of the user, also called functional testing, data-driven testing or based on specifications or user manuals test, it is based on the external characteristic of program.

Static methods: mean that don't execute program itself, only thoroughly analysis or testing the grammar, structure, procedures, interfaces of original program to check the validity.

Dynamic methods: mean by executing program, inspect the difference between running results and expected results, at the same time, analyze the capability of running efficiency and haleness, this method is composed of three parts: constructing test program, executing program, analyzing the output result of program.

# 6. Testing steps of software applied to virtual nuclear instrument

In general, the testing steps are divided into four steps: unit test, integration test, system test and validation test.

# Unit test

Also known as module test, its aim is to find various errors within modules - the smallest unit of the software. Unit test often use the white-box testing (structural testing) technology, a number of modules within the system can be tested in parallel.

#### Integration test

Also known as assembly test, after unit test, they need to be linked according to the design structure diagram for integration test. Integration test is a systematic test technology for assembly software, its aim is to find interface errors.

#### System test

After software thoroughly completed, it must operate with its other parts. System test include recovery test, security test, intensity test and performance test.

#### Validation test

Also known as eligibility test, which test the developed software whether meet the user's requirement. Validation test should check whether software carry on work according to the requirements of contract, or meet the validation standard of software document.

# 7. Virtual multi-channel analysis system: Example to describe the system testing and the validation testing

# 7.1. Virtual multi-channel analysis system

The whole system is divided into three parts:

- Data display.
- Data acquisition.
- Data processing and control.



Figure 3. Main Program Interface.

# 7.2. System test

# Testing the MCA using a Co-60 source

Test conditions with the test set-up as shown in figure 4:

- Probe: HPGe detector
- Radioactive source: <sup>60</sup>Co
- Main amplifier: Canberra Model 2025
- High voltage supply: Canberra Model 2105; high voltage setting: 3000 volts.


Figure 4. Test set-up for MCA test.

- (1) As shown in figure 5.: Measuring time: 1000 seconds; Sample rate: 13MHz; lower threshold (LLD): 0.3V
- <sup>60</sup>Co spectrum: 1173.2 keV at channel 1309; channel content: 114965 counts; 1332.5 keV at channel 1487; channel content: 98695 counts;



Figure 5. Measuring time: 1000 seconds; Sampling rate: 13MHz; lower threshold: 0.3V.

(2) As shown in figure 6: Measuring time: 1000 seconds; Sampling rate: 20MHz; lower threshold: 0.3V

<sup>60</sup>Co spectrum: 1173.2 keV at channel 1310; channel content: 70490 counts; 1332.5 keV at channel 1487; channel content: 61567 counts;



Figure 6. Measuring time: 1000 seconds; Sampling rate: 20MHz; lower threshold: 0.3V.

The spectrum energy calibration curve is show below in figure 7.



*Figure 7. Energy calibration curve using the* <sup>60</sup>*Co source.* 

<sup>60</sup>Co spectrum results:

The full width at half Maximum (FWHM) for the 1332.5 keV peak is 211 channels, or in the corresponding energy value: 1.90 keV

Figure 8 shows a <sup>60</sup>Co spectrum measured with the AccuSpec MCA from Canberra.



*Figure 8.* <sup>60</sup>*Co spectrum measured with the AccuSpec MCA from Canberra.* 

The resolution for the 1332.5 keV line is 1.85 keV when measured with the commercial Canberra MCA  $\,$ 

To permit a comparison of the two systems, the test conditions were the same. For the Canberra MCA the resolution was 1.85 keV where the resolution for the virtual system was 1.90 keV.

Resume: The virtual multi-channel analyzer will meet the needs of many users.

## Count/timing accuracy versus countrate

Test condition:

- Signal Source: BNC slip pulse generator
- Counter: EE3376 programmable counter
- Pulse Amplitude: 3V
- Risetime: 0.5 microsecond
- Sampling frequency: adjusted from 1 kHz to 20 kHz.

The table 1 compares the count accuracy of the commercial counter content with the virtual instrument.

Time	Pulser Frequency [kHz]	Software threshold setting	Counter Content [counts]	Software Counting [counts]	Counting error [%]
5s	1.0	0.2 V	314851	314384	0.15
5s	2.0	0.2 V	587904	583339	0.78
5s	2.5	0.2 V	698753	696326	0.35
5s	10.0	0.2 V	3011754	2286958	24.06
5s	10.0	0.5 V	3041419	3014941	0.87
5s	15.0	0.7 V	4482201	3635833	18.88
5s	20.0	0.7 V	6028871	3640445	39.62
5s	23.0	0.6 V	6883399	3398148	50.63

## TABLE I: COUNT/TIMING ACCURACY

From the above table one can conclude that with a proper threshold setting and a pulser frequency below or equal to 10 kHz the counting error is below 1%. Therefore, the virtual multi-channel analyzer is suitable for the routine nuclear pulse measurement when the countrate is below 10kcps.

## 7.3. Validation test

The virtual multi-channel analyses system realize the bipolar nuclear pulse signal acquisition and signal pulse amplitude analyses, real-time display, pretreatment of spectrum data, off-line read and write, and so on.

The resolution of the <sup>60</sup>Co 1332.5 keV peak measured by virtual multi-channel analyzer (V-MCA) system is almost the same as it was measured by the commercial AccuSpec multi channel analyzer. This meets most of the customer's demand.

In the case of the counting test, when pulse frequency is 10K or below, the system dead time is zero or very little. The deviation between software counting and counter content is small and it will meet the general measurement requirements.

But there are still some limitation in the V-MCA, more experiment should be done, the V-MCA system need to be improved.

## 8. Conclusions

The quality of software is the life of nuclear instrument. Software tests and validation is the guarantee for its quality and therefore, one has to pay more and more attention to this task. To improve the quality of software product, a strict validation is very important.

# Software validation for refurbished nuclear equipment

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**Abstract.** Software validation is an important tool used to assume the quality of device software, software automated operation and software for self diagnostics. Software validation can increase the usability and reliability of the devises, resulting in decreased failure rate, fewer recalls and correction action, less risk to user and patients for medical devises, reduce long term costs by making it easier and less costly to reliably modify software and revalidate software changes.

In recent years a large number of nuclear equipment were refurbished at the nuclear refurbishing laboratory of Bangladesh Atomic Energy commission. The equipments are thyroid uptake system, probe renogram, gamma cameras and RIA counter. All these were tested for QA/QC according to IAEA protocol. Beyond the IAEA TEC-DOC 602 software validation tests were performed. Software for all these equipment were classified into three categories, such as self test, calibration & setup, data collection from the sensor and finally the analysis software like activity in a specific volume, blood flow, image reconstruction & processing etc. All refurbished equipment before going to use for medical purposes it was decided to test the developed software as a part of validation check. As the software module of each component is different especially for medical equipment, total test volume is very high. For a single equipment like gamma camera a large number of protocols presents for diagnosis in addition to hard ware control, calibration, quality control auto peak detection and positioning etc. To reduce the volume of tests for refurbished equipment special selection procedure were applied on the basic of hardware replacement. It was observed that replacement of high speed hardware, the equipment have generated the same result as the original ones does. Due to absence of references data, original position of each equipment could not be assessed after refurbishment.

## 1. Background

Nuclear radiation is a part of life today. Human beings are exposed to nuclear radiation from the beginning of life and after knowing the interaction of nuclear radiation and biological system, people are using the material for the benefit of the society. Nuclear particle detection systems called the Nuclear Instrument are the fundamental tools for the driving benefits from the application as well as from the safety point of view of the human health. After the discovery of radio activity and x-ray, scientists are giving tremendous effort to develop high quality detection and measurement system. Although the basic principal remain same, the associated electronics are improving day by day. Many manufacturer came in to market with new product. Funding for new equipment is big problem for a developing country like Bangladesh. For the expansion of nuclear medicine a large number of new expensive equipment are being procured and on the other hand a few old equipment refurbished with digital technology to meet the demand of the nuclear medicine department. The equipment include thyroid uptake system, probe renogram, RIA counter and a few gamma camera.

# 2. Objective

The objective of this paper can be listed as follows:

- Methods of the refurbishing of the equipment.
- Evaluation of the performance.
- Verification of the equipment performance characteristic.
- Validation test of the developed software which includes the limitation of the performance.

# 3. Method of refurbishment

## 3.1. Thyroid uptake system

Thyroid uptake system is a machine which directly tests the functional behavior of the thyroid gland. It consist of a scintillation detector, a collimator with mechanical stand, signal processing electronics and display out put. Fifty percent price goes to mechanical devises and rest goes to electronics. Approximate price of a thyroid up take system is about US\$10 000. Although most of the nuclear medicine departments are reluctant to use a thyroid uptake system but still most of the developing countries prefer to use thyroid uptake system for the preliminary assessment of the gland. It is very easy, safe, non invasive and inexpensive test for the thyroid gland.



Figure 1. The basic blocks of an aged thyroid uptake system.

Due to recent development of digital electronics most of the companies uses computer for the processing of signal to generate desired output. Total software was developed in the laboratory and all the necessary test were performed.



Figure 2. Block diagram of refurbished thyroid uptake system.

## 3.2. Probe renogram

Probe renogram is a device which performs the function of the kidneys. Renogram is known as a safe, easy and inexpensive test of the kidneys so far the function of kidneys are concern. But most of the hospitals prefer conventional gamma cameras to test the renal function test as it has several advantages

It is like a duel channel uptake system which has two detectors which collect the signal from two kidneys and displays two time activity curve. The system was refurbished with two Canberra Accuspec NaI Plus card whish contain amplifier, pre amplifier power supply, high voltage up to 1000 V, 100MHz Wilkinson ADC and 64KB on board memory. These were ISA slot board both can run under DOS and Windows.



Figure 3. Block diagram of probe renogram.

## 4. Software development

Both uptake and renogram software were developed initially on DOS environment and the second version was released under windows environment. The software was developed for the collection of data from the detector and displaying of image including hardware control like setting of high voltage, amplifier gain etc. The software has the provision for continuous display of spectrum so that during acquisition the user can see the window setting. The uptake system has the provision for two system of calculation such as standard sample method and the decay correction method. Both the method are equally accepted to the nuclear medicine community.

#### 5. Validation procedure for thyroid uptake system software and renogram

#### 5.1. Purpose

- To test the software for the detection of different isotope gamma energy peak.
- To test the peak-shift if any in the spectrum.
- To test the count rate linearity for the whole system.
- To test the resolution with different count rate.
- To check the calculation for the report.

#### **5.2.** Validation test procedure

- Step 1 Standard certified source was placed in the detector as described in the detector manual.
- Step 2. High voltage, amplifier gain, ADC etc were set as per instruction available in the doc.
- Step 3. Acquisition of spectrum were collected for each source.
- Step 4. Peak channel number was recorded for each isotope.
- Step 4. Auto peak search programme was run for energy calibration.
- Step 5. Calculation of result were performed manually from the data from each channel of MCA.
- Step 6. Printing of report were checked as per instruction such as: date, time, patient record, etc.

## 5.3. Validation result

From the study it is seen that the uptake system produced the result equally good as commercial available product like Atomlab9000 or Capintec2000. About the hardware, it is observed that with the commercial grade card count rate linearity is very high but the systems with the locally developed card, at high count rate experiences some count loses which was compensated through software. The software point of view it has no limitations to use in clinical purposes.

## 6. RIA System

RIA system was also refurbished with locally developed add on card. Unlike thyroid uptake system or renogram it is developed using a single channel analyzer. It is a multi detector(12 to 16) single channel analyzer which count the events simultaneously to reduce the counting time. The basic difference is that the system is a long range of count rate, so for curve analysis log scale is used to find unknown concentration in the sample.

## 6.1 Validation procedure, test of software in the area of RIA.

## 6.1.1. Purpose

- To test the software used for the analysis of different human hormone of human body using RIA technique in general.
- To test the count repetition rate in each channel.
- To test the count rate linearity in each detector channel.
- To test the curve fitting capability of the software.

## 6.1.2. Equipment

It is a multi detector gamma counter works in parallel to count labeled radio activity (I-125 or Co-57). Computer software collect data from the counter port of the equipment and generates graphs (generally in log scale) for the known value and finds the unknown value from graph. It is a very low concentration graph and the known sample number is also limited, so, decision making to generate graph is very important. Quality control is very important in these are especially for the software. A sample test procedure is as follows.

## 6.1.3. Test Procedure

- Step 1 Set up of the whole system was done for the assay.
- Step 2 Assay were performed with fresh kit with unknown QC sample.
- Step 3 Assay with fresh kit with unknown QC sample performed manually in graph paper taking the count from the counter of the same machine.
- Step 4 Results were compared.

## 7. Remarks

A few gamma cameras were refurbished using Gamma PF card to extend the life of the system. All the required software was developed locally and the validation tests were done. Gamma camera is a very complicated system and the volume of software is very big and have a different component like control software, self diagnostic software and clinical software. For every organ there are different modules of software and the procedure for validation is also different. Clinical software of gamma camera is appeared to be beyond the scope of the meeting so detail validation procedure is not included in this document.

# Software for thyroid uptake equipment based on PC

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**ABSTRACT.** DETECT<sup>©</sup> software was designed and developed as an integral part of a measurement detection system that allows carrying out Thyroid Uptakes functional studies. The whole system consists of a Personal Computer connected with a radiometric block based on a UnIO52 board, for the acquisition of counts to be processed. The application software is responsible for the control and monitoring of the equipment operation as well as the statistical analysis. It also includes a database where the information of the patient under study is stored. The software was designed according to the principles of Object Oriented Programming (OOP) with a graphic user interface (GUI) under "MS-Windows" environment. Quality control tests, according to international standards, have been performed to the equipment. Software Features: measurement of batch of samples, and statistical analysis, determination of the measurement time for the study, spectrum display of counting or percent of uptake, database to store patient and measurement data, calibration option, help menu.

#### 1. Introduction

Diseases caused by a malfunction of the Thyroid gland are very common. Any General Hospital assists dozens of such cases weekly and there are some places where those diseases are endemic.

Iodine Thyroid uptake is used as diagnostic and therapeutic method in medical practice (nuclear medicine) since the decade of the 50ties. These studies are indicated in all such cases in which it is desired to evaluate the functional state of the Thyroid gland as: Hyperthyroidism, Diffuse Toxic Goitre, Nodular Goitre, Thyroid's Cancer and others, allowing therapeutic results evaluation and <sup>131</sup>I treatment planning.

In Nuclear Medicine, Iodine Thyroid Uptake studies are carried out in order to assess the functional state of the gland by measuring the absorption level of a radioisotope and the variations of its concentrations on time.

Iodine Thyroid Uptake study consists in the oral administration to patient of a radioactive iodine preparation. The radioactive substance is chemically attracted to the gland and produces an emission that can be found by using a detector of ionizing radiations. The Thyroids Iodine concentration degree, as well as its variations on time reflects gland functioning. [1-3]

In this paper, the DETECT<sup> $\odot$ </sup> software [4] designed and developed to be an integral part of the measurement – detection system [5-6] that allows carrying out Thyroid Uptake functional studies is presented. In its development were taken into account medical practice in realization of Iodine Thyroid Uptake Studies in a way to implement and to promote good

medical practices [7]. With present advances in medical electronic instrumentation and the growing processor power, the inclusion in the software of functions that go beyond the primitive functionality and increase the easy of use or friendliness and diagnostic capabilities is a must, to keep in pace with the state of the art and the expectations of the users.

## 2. Materials and methods

Typically, every week, a batch of up-to 100 samples of a radioactive Iodine solution is prepared with an activity range from 7 to 10  $\mu$ Ci each [12] However, each solution of this batch must be within 5% tolerance. This batch is analyzed statistically: the Arithmetic mean of counting, the Standard Deviation, and the Coefficient of Variation are calculated. If the coefficient is bigger or equal to 5%, the batch of samples is rejected because of bad preparation. On contrary case, it is determined a Pattern Sample, it is calculated the Confidence Interval and the Disposable Samples are determined.

Based on the Pattern Sample, the measurement time is determined for all the samples of the batch. Once, the patient ingested the radiopharmaceutical it begins the process of serial measurements. These are carried on at 2, 4, 6, 24, 48, 72 and 96 hours. At 2 and 24 hours, an evaluation of the patient is performed and a decision can be taken as shown in the following table:

Evaluation at 2 hours						
Uptake %	Diagnosis	Decision				
From 0 to 4	Hypothyroidism	Measurement goes on				
From 5 to 16	Euthyroidism	End of study				
Bigger than 16	Hyper-thyroidism	Measurement goes on				
Evaluation at 24	hours					
From 0 to 9	Hypothyroidism	End of study				
From 10 to 50	Euthyroidism	End of study				
Bigger than 50	Hyper-thyroidism	Measurement goes on, to calculate Effective Mean Life (EML)				

TABLE I: CLASSIFICATION OF PATIENTS ACCORDING TO UPTAKE PERCENT

DETEC-PC is the measurement-detection system developed to work with the DETECT software. The application software controls the operation of the system. It runs in a Personal Computer and its most modern version communicates with the UnIO52 board through a USB port.

The measurement-detection system consists on a detector connected to a nuclear amplifier and its output, in turn, to the discriminator input on the UnIO52 board. For nuclear applications this board has 2 analog and 2 digital Single Channel Analyzers (SCAs), and one analog Multi-channel Analyzer input. One of the analog SCA inputs receives shaped nuclear pulses from the amplifier. The high voltage for the detector is also controlled by a DC signal generated in the  $UnIO52^5$ .

The software was designed according to the principles of Object Oriented Programming (OOP) using C++ language [9-12], with a graphic user interface (GUI) under "MS-Windows" environment, allowing access to all machine resources normally available to users.

In order to insert a product into the system of Public Health in Cuba it is must to have developed it according to a Quality Assurance System. National authorities exercise a systematic control to institutions to check the state of their QA system. Also, DETEC-PC software was developed taking into account that for medicine applications, it is necessary to fulfill medical good practices.

For all these reasons, DETEC-PC software has the following security checks:

- Measurement of a batch of samples and all its statistical processing. This feature allows checking the quality of the samples and of the preparation procedure itself.
- Chi Square Test. Everyday the software checks if Chi Square Test was completed. The system becomes not operative if the test was not successfully accomplished.
- Test of communication. If the software does not detect the presence of the measurement system, a message to the operator is displayed and the application waits until the connection is established.
- Accidental power loss in the measurement module. If a temporary disconnection occurs, the measurement is discarded and a message appears indicating that it is necessary to repeat the last one.
- Data integrity checking. Every measurement to the patient is repeated three times. In case of a spurious value, the measurement is discarded and must be repeated.
- Automatic storage of relevant information concerning to the good performance of the system.
- An option for energy calibration is implemented. Furthermore, every 7 days, the software notifies that a calibration process is due.

## 3. Results

In the system main window menu bar, the following options were defined: File, Measurement Modes, Statistical Analysis, Calibration and Help.

Its working area is divided in three panels:

Measurement data panel, spectrum data panel and patient's data panel.

## 4. System analysis

The whole software can be divided in three main subsystems:

- Measurement subsystem.
- Statistical analysis subsystem.
- Calibration subsystem.

<sup>&</sup>lt;sup>5</sup> UnIO52 board was developed by Heinz Rongen, Forschungszentrum Jülich, ZEL, and was distributed to Members States of ARCAL by IAEA.

## 4.1. Measurement subsystem

The subsystem has to fulfill the following:

- Control and monitoring of the measurement unit.
- Two measurement modes: Stopping by Time and Stopping by Counting. These modes were implemented through menu bar options and combo list boxes in the measurement panel of the system principal window.
- It is defined as Measurement Interval the time, in hours, elapsed after the ingestion of the radiopharmaceutical, to the moment in which it is established to carry out the measurement.
- Measurements are carried out for growing values of Measurement Intervals.
- It is defined a database where are stored the patient data and measurement data. Each registry from the table contents the following information: Name, Age, Sex, Clinic History (CH), Date of beginning of study, Time, Kind of spectra and measured values for each interval. To insert a patient in the database must be specified his Clinic History number. On the contrary, case measurements could be carried on, but information will not be saved in the database.
- A patient can be introduced into the database in two ways: either when it is going to be measured for the first time or through the button "To Insert patient into the DB".
- The information of a patient can be loaded in the system on two ways: when its measurement it is going to be carried out, then the system automatically will search for the data of such patient trough the database and will show it on the screen, adding finally the outcome of the measurement in the interval in question. If the search trough the DB fails, then in that very moment is inserted. The second way is through the button "Load patient from DB". If the patient is not found, then it will be notified trough a screen message.
- For a patient to be eliminated from the database is necessary to specify the password that allows to erase information.
- Visualization on the screen of two kinds of spectra: Counting Spectrum and Percent Uptake Spectrum.
- Taking into account the characteristics of measurement intervals that: first three are carried out at 2 hours intervals, then the next at 24 hours, and from so on with a frequency of 24; it was decided to show the spectrum in two parts: in the first the axis correspondent al time in hours has a range from 0 to 8 and in the second a range from 24 to 96. These two spectrum zones are swapped through a button.
- The option of visualizing the full spectrum with measurements of all intervals was implemented through a measurement panel command button.
- Primary evaluation of measurement results at 2 and at 24 hours.

## 4.2. Statistical analysis subsystem

In this subsystem all statistical parameters mentioned before are calculated. The results of statistical processing are displayed in a screen window and are saved to a file in disk.

## 4.3. Calibration subsystem

The Calibration option allows obtaining energy spectrum of the radioisotope by sweeping the lower threshold with a fixed threshold window. This makes possible to set optimum spectrometric parameters for measurement and to correct any shifting that had happen in these values.

The system help gives information about application different options and facilitates knowledge of medical and nuclear concepts related to the study.

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Figure 1. Main window of the software.

## 4.4. Software features

The application software "DETEC" has the followings features:

- Measurement of a batch of samples and performing all its statistical processing;
- Determination of the Measurement time to employ in the study;
- Displaying of Spectrum in counting or in percents of uptake;
- A database where patient and Measurement data are stored;
- Automatic Database information handling, from the Clinic History number;
- Evaluation, at 2 and 24 hours Measurement and according to the calculated percent of uptake value, suggestion of a decision making;
- Calculation of EML, in those cases in which is necessary;
- A calibration option;
- An "on line" help.

## 5. Discussion

## 5.1. Model of objects

It was defined the abstract class EQUIPO as root to the hierarchy, its attributes are: date, time, threshold window, high voltage and gain.

Subclasses are CALIBRACION, LOTE\_MUESTRAS, and CAPTACION\_IODO. CALIBRACION class attributes are: calibration spectrum number of points, values for this spectrum and maximum counting position. LOTE\_MUESTRAS class attributes are: batch size (quantity of samples), batch measurement time and counting values of these samples. CAPTACION\_IODO class attributes are: measurement mode, pattern sample counting, and measurement time to measure patients and counting value that is obtained of such measurement on an interval.

Subclasses are PCO\_ESTAD\_IODO and PACIENTE. PCO\_ESTAD\_IODO class attributes are: arithmetic mean, standard deviation, variation coefficient, interval of confidence limits and pattern sample number. PACIENTE class attributes are: patient personal data, its Clinic History number, measurement interval, the set of all measured values at different intervals and the kind of spectrum.

CAPTACION\_IODO and LOTE\_MUESTRAS are intermediate classes and CALIBRACION, PCO\_ESTAD\_IODO and PACIENTE are terminal classes that form the leaves of hierarchy, being the same concrete classes. This hierarchic organization is complex because there are multiple inheritances being PACIENTE class daughter of two parents.

It is defined in the EQUIPO class a pure virtual function: **Medir** which functionality is defined in descendant classes and in each one of them is different. This method in the CALIBRACIÓN class measures the pattern source. In the LOTE\_MUESTRAS class measures a batch of samples. In the CAPTACION\_IODO class measures time to reach base counting to determinate patient measurement time and in the PACIENTE class measures emitted radiations from patient's Thyroids gland.

## 5.2. Case studies

As a final step for the QA, it was necessary to carry out a cases study as a validation of the whole system. This study will be described in detail somewhere else. In it, it was compared the data obtained from a group of patients using thyroid uptake with the results from T3,T4 and TSH hormone tests in blood using RIA. This documentation was forwarded to the regulatory authorities also with the acceptance test of the system.

## 6. Conclusions

The application software design follows the concepts of OOP with its inherent characteristic of code reusability, allows creating new application codes for others studies with minimal effort, for that it will just have to add new specific classes for future new applications and these new classes will inherit from the existing ones.

In the design of the "DETEC – PC" have been taken in account the requirements of easiness of use and the good medicals practices.

It was possible to obtain a medical registry for this application, as a result of a proper observance of the requirements of the regulatory authority and the implementation of a QA system according to international standards.

#### ACKNOWLEDGEMENT

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# Refurbishment of the whole body counter bed-type ND7500 using rectangular (NaI) scintillation detector and development of integrated system software

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Abstract. The refurbishment activity is to develop a one man-machine operation consist of hardware upgrading and software development. During the hardware upgrading, two colorized 3" x 5" cvlindrical NaI(Tl) detector replaced with a single 3" x 5" x 16" rectangular NaI(Tl) detector and a detector's stage was designed along with a re-engineered of the initial bottom shielding. A surface protection was also fabricated from Perspex with a 5 mm thickness to be put on top of detector's surface for its safety. The motor controller for bed control is not function properly as its only works when a switch is press to move it to the front and back while the previous software for this system is totally not functioning and the user need to take the data manually and used an old Acquisition Interface Module (AIM) system that was no longer practical for today used. This was solved by a development of a new software system to control the whole process in the WBC, which includes a motor positioning system, data acquisition system and data storage for analysis using UnIO52 board and LabView. A well-known Genie-2000 package used for the spectrum analysis was integrated with a LabView. A software validation experiment was done to achieve a certain level of system's confidence and reliability before it can be permitted to use for medical investigation. This refurbished WBC was tested using a certified multi-nuclide standard source with a contained radioactivity of 3.094 µCi and able to view a set of spectrum in the range of 50 keV until 2000 keV. A CHI square test using Cs-137 was done on the system (result: 13.955) and the NIM system (result: 9.987) that were simultaneously started and satisfactorily within 3.325 and 16.919 as stated in IAEA TECDOC.

Keywords: Refurbishment, Whole Body Counter, UnIO52, LabView and Genie-2000 package.

## 1. Introduction

The whole body counter (WBC) Bed Type ND7500 was savaged from Institute of Medical Research (IMR) in 1987. This WBC is totally inoperable due to its counting system failures and lack of technical and operation manual that burned during fire on IMR. The WBC ND7500 initially consists of two main systems, which are the mechanical system and the nuclear counting system. The mechanical system consists of a movable bed and a stepper motor while the nuclear counting system is a NIM Bin system that consist of two Harshaw 3" x 5" cylindrical NaI(TI) detectors, NIM Bin and nuclear instrument modules (Figure I).

The idea of refurbishing of this WBC had been proposed during the Non RCA-RAS/4/023 Formulation Meeting for Refurbishment of Nuclear Instrument at Sri Lanka in 2002 but there was no vigorous action taken due to a final specification either to choose HpGe or NaI detector. Finally, a single 3" x 5" x 16" rectangular NaI(Tl) detector was then recommended by IAEA expert to replace both cylindrical Na(Tl) detectors. At the end of 2004, this recommended detector was purchased and this 1970's technology WBC model ND7500 had been refurbished in 2005.

## 2. Development process and method

The refurbishment of the WBC basically consists of the hardware and software development, and the upgrading activities. The completed refurbished WBC was validated using Cs-137 standard gamma source (number 1026-64-2) and CHI square test method.

# 2.1. Hardware upgrading

A plateau test was carried out on the Up and Down detector and based on curve from the plotted graph, the Up detector is still operable while the Down Detector is not considerably operable anymore. This is also based on facts of the low count rate produced by Down detector, which in average less 89 % in comparison with the Up detector at the same high voltage. Both detectors produced a broad spectrum, which is a poor resolution when both of their signals deposited to multichannel analyzer (MCA). During IAEA expert visit on July 2003, these detectors were dismantled and verified cannot be use any longer due to a colorized crystal that affected the detector's resolution and performance.

The recommended detector, a single 3" x 5" x 16" rectangular NaI(Tl) has a totally different dimension compares to the initial 3" x 5" cylindrical NaI(Tl) detectors and in addition with its 5" x 16" detection area a re-engineering work was done on an existing shielding to accommodate the new detector.







Figure II. Modified bottom shielding to accommodate the 3"x5"x16" rectangular NaI(Tl) detector.

Based on the studies of the detector's radioactivity detection capability (using detection positioning tests), the bottom shielding which is 10.3 cm away from bed surface was selected to be re-engineered (the upper shielding is 65.0 cm away from bed surface).

As shown in figure II, a tunnel was made into the bottom shielding to accommodate the  $3^{"} \times 5^{"} \times 16^{"}$  detector. A detector platform had been made which is shown in figure III, to support the detector's body. This detector also been protected with a surface protection for safety enhancement. The surface protector was fabricated from Perspex with a 5 mm thickness to be put on top of detector's surface for its safety.

Due to the detector's length, part of the detector as shown in Figure II looks out of the modified bottom shielding. Therefore, an additional shielding from lead blocks arrangement as shown in figure IV was built up, to cover the protruding body.



Figure III. Detector supported by detector platform and a detector surface protection.

Figure IV. Lead block arrangement to shield the protruding detector body.

## 2.2. Software development

The initial system does not have any software to control the whole WBC system. The user had to take data and analyze them manually. The motor controller for the bed movement did not properly function. The bed control had to be made manually by pressing switches for the forwards and backwards bed movements. That means the user had to set the bed position manually which are based on previous experiences and the therefore, the bed position and bed control was not integrated into the data acquisition system.

These problems had been solved by the development of a new software and interface system for WBC that includes a motor positioning system, data acquisition system and data storage for analysis using LabView. The Software used for the quantitative gamma analysis is based on the well known Genie-2000 package which controls also the commercial multi channel analyzer (MCA). The Software integration between Genie-2000 and LabView was carried out to make sure that only a one man-machine interface is used by the WBC-operator to control the whole system. The software development for this refurbishment activity focused on the following:

- Control of all operations from the main window under LabView;
- Control of stepper motor with the needed interface (variable speed);
- Display of bed position versus countrate;
- Start and stop commands for the commercial MCA under Genie-2000 but controlled by Labview via a software command;
- creation of the needed files for data trace ability, later.

A controller box was built, to interface the PC with stepper motor positioning system, data acquisition, and data displays which consists of an AC power supply, DC power supply, motor booster driver and the UnIO52 interface board designed by IAEA as shown in the following figure V.



Figure V. Block diagram of a controller box.

The WBC scanning program developed, is a system which has incorporated the function of: Multi-Channel Analyzer (MCA), Single Channel Analyzer (SCA), bed positioning display and scanning time/length and presents those data simultaneously in a window with various frames.

The patient details and the required input details must be made by the user. This program will auto generate the folder and the patient file name in a background function where after the scan all data are stored. This program is built in sequence process.

First it creates a global variable for all the shared data. Then, the program checks the status of home limit switch for current position. Scanning will only start when the bed is at the rightend position. Scanning will start when the user push the start button from the PC. The data acquisition and MCA program will run and display the spectrum in real time. After the scan is completed, the system will automatically save all the data taken including the generated graphs in html format to save storage space. A print function is also created for the user (operator) to print the report immediately, when needed. The program includes the feature of a three dimensional display of the scan (scan length, energy and activity) on line, which is a good feature when a suspicious peak is observed during the full scan so that immediately after the scan a detailed investigation can be made when needed.

This system allows that both MCAs, the commercial Genie-2000 and the MCA incorporated in the UnIO work simultaneously. The Genie-2000 software will not be visible for the user but runs automatically in the background. Nevertheless, the acquired data from the Genie-2000 program are archived in the folder where all patient data are stored, for future analysis.

## 3. Validation test

After the refurbishment task was accomplished, this WBC was tested using a certified multi nuclide standard source number 1120-75-1 with a contained radioactivity of 3.094  $\mu$ Ci to obtain the detecting capability of the refurbished WBC. This multi nuclide standard source contained 10 radio nuclides, which is <sup>241</sup>Am, <sup>109</sup>Cd, <sup>57</sup>Co, <sup>123m</sup>Te, <sup>51</sup>Cr, <sup>113</sup>Sn, <sup>85</sup>Sr, <sup>137</sup>Cs, <sup>88</sup>Y and <sup>60</sup>Co.

A CHI square test, which is a QC test were carried to the system to indicate the proper operation the WBC counting system by applying a 10.59  $\mu$ Ci Cs-137 standard source number 1026-64-2. A set of 10 measurements were taken simultaneously with the WBC counting system and a commercial NIM counting system for comparison the results.

With this method the count accuracy, the correct counting time could be verified and validated.

## 4. Results and discussion

The following figure shows a set of spectrum in the of 50 keV until 2000 keV successfully viewed by a commercial Genie-2000 software when the refurbished WBC was tested using a certified multi nuclide standard source number 1120-75-1 with a contained radioactivity  $3.094 \mu$ Ci.



*Figure VI. Spectrum from certified multinuclide standard source number 1120-75-I taken with the Canberra MCA system.* 

The following tables show, CHI square test results for NIM system (Table 1) and WBC counting system (Table 2) and that are simultaneously started to take a set of 10 measurements using 10.59  $\mu$ Ci Cs-137. Results for both systems are 9.987 respectively 13.955, which are within 3.325 and 16.919 as stated in IAEA TECDOC-602.

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TABLE 1:	CHI SQUARE TEST RESULTS			TABLE II:	CHI SQUARE TEST RESULTS			
	FOR NIM	SYSTEM.			FOR GENIE 2000.			
+		1						
	Counts,			No.	Counts, C	C - C <sub>Av</sub>	$(C - Av)^2$	
No.	С	$C$ - $C_{Av}$	$(C - Av)^2$	1	453559	741.2	549377.44	
1	478296	536.7	288046.89	2	453220	402.2	161764.84	
2	477598	161.3	26017.69	3	453193	375.2	140775.04	
3	477587	172.3	29687.29	4	452782	35.8	1281.64	
4	478966	1206.7	1456124.89	5	451204	1613.8	2604350.44	
5	476843	916.3	839605.69	6	452465	352.8	124467.84	
6	478464	704.7	496602.09	7	453097	279.2	77952.64	
7	478313	553.7	306583.69	8	453506	688.2	473619.24	
8	477626	133.3	17768.89	9	453593	775.2	600935.04	
9	476974	785.3	616696.09	10	451559	1258.8	1584577.44	
10	476926	833.3	694388.89	Average, Av	452817.8	$\Sigma(C - Av)^2$	6319101.6	
Average, Av	477759.3	$\Sigma(C - Av)^2$	4771522.1	CHI square				
CHI square				result	13.955			
result	9.987					1		

The following tables show a comparison of CHI square results between Genie 2000 (table III) and UniIO52 (table IV) in the condition of 10.59  $\mu$ Ci Cs-137 passed through the detector where table bed position 60cm to 120 cm from home position. Results for both systems are 5.128 respectively 8.502, which are within 3.325 and 16.919 as stated in IAEA-TECDOC-602.

TABLE III: CHI S		SQUARE TEST RESULTS		5 TAE	TABLE IV:		CHI SQUARE TEST RESULTS		
FOR		JENIE 2000.			F		'OR UnIO52.		
No.	Counts, C	C - CAv	SQR(C - Av)	N	э.	Counts, C	C - CAv	SQR(C - Av)	
1	451516	436.8	190794.24	1		514193	286.1	81853.21	
2	452812	859.2	738224.64	2		515912	1432.9	2053202.41	
3	451890	62.8	3943.84	3		514117	362.1	131116.41	
4	451498	454.8	206843.04	4	ļ	513835	644.1	414864.81	
5	452565	612.2	374788.84	5	;	515227	747.9	559354.41	
6	451897	55.8	3113.64	6	5	514345	134.1	17982.81	
7	451898	54.8	3003.04	7		514204	275.1	75680.01	
8	452046	93.2	8686.24	8	;	514757	277.9	77228.41	
9	452279	326.2	106406.44	9	)	514682	202.9	41168.41	
10	451127	825.8	681945.64	1	0	513519	960.1	921792.01	
Average	451952.8	$\Sigma(C - Av)^2$	2317749.6	Avera	nge	514479.1	$\Sigma(C - Av)^2$	4374242.9	
CHI	square			CHI		Square			
	Result =	5.128				Result =	8.502		



Figure VII. MINT Whole Body Counter system software.

The refurbishment tasks were successfully completed and the in-house software shown in figure VII meets user's specification and operates simultaneously with the commercial Genie-2000 software, without any complication. Table V below shows the features of the initial system and the system after refurbishment and upgrading.

Initial System	Refurbish/Upgrade
2 unit 3" x 5" NaI(Tl) detector	1 unit 3" x 5" x 16" NaI(Tl) detector
	1 unit detector surface protection
2 unit HVPS	1 unit HVPS
2 unit PAA	1 unit preamplifier
	1 unit amplifier
2 unit ADC	1 unit MCA
1 unit AIM	
Motor Driver	Multipurpose Controller
Data acquisition software	Multitask main software
2 unit lead shielding (up and bottom	1 unit lead shielding
shielding)	1 unit detector stage

TABLE V:	COMPARISON OF	THE INITIAL	SYSTEM AN	ND THE I	REFURBISH
	SYSTEM.				

#### 5. Conclusions

A selected single 3" x 5" x 16" rectangular NaI(Tl) detector to replace the two old 3" x 5" cylindrical Na(Tl) detectors (which were faulty) is the best decision in term of detecting capability and detection area geometry. The new rectangular NaI(Tl) detector was successfully installed as the re-engineered bottom shielding was able to accommodate its dimension horizontally. A test measurement of the installed detector, using the MCA Genie 2000, was done. The detector efficiency was measured with available sources (30 nano Ci could be easily identified as a peak). The QC test was performed with a certified multi-nuclide standard source with a CHI square test result of 13.955, which is within the acceptable range as stated in IAEA-TECDOC-602. Furthermore, the development of the new MINT whole body counter software enhances the acquisition and control system capability, as a one-man operation system, including a systematic data records. The new features permit a reduction in the operation costs and increase in the job efficiency (evaluation efficiency).

However, further investigations have to be made regarding activity detection limits with the same test and experimental setup but using a real phantom instead of the used radioactive test sources. The remaining task of this refurbishment project is for the user to test and to use the facility and to give feedback for improvement(s) when needed.

As a conclusion, this WBC refurbishment was successfully completed and able to fulfill the national needs for the radiation and safety program.

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# Refurbishment and modernization of a thermo-luminescence dosimeter system using LabView virtual instrument software and validation of its results

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Abstract: A Thermo-Luminescence Dosimeter (TLD) system (Harshaw Model: 2271 & 2000B) which was used by the Atomic Energy Authority of Sri Lanka was recently refurbished and modernized by interfacing a Data Acquisition Module (UNIO-52) which is controlled through a virtual instrument software interface providing solutions to many existing deficiencies. The photomultiplier tube current and the current signal of the temperature sensor of the heater element of the TL chip were digitized by ADC 0 and ADC 1 of the UNIO 52 respectively. The LabView Software tool was used for the visualization of the glow curve (GC) from the output of ADC 0 and the time-temperature profile (TTP) from the output of ADC 1 on the same display. Radiation dose was calculated from integrated area of the GC within the recommended temperature range for the TL material used. The GC was visualized on the display from the average value of the previous ten consecutive readings of the output of the ADC\_0. Each reading was taken at every 0.25s. The GC area was calculated by taking the summation of data points displayed within the specified range of temperature. Validation of the software was carried out by applying an external triangular waveform from a Function Generator (TTi model: TG 4001) and DC voltage from a Power Supply (TTi model: PL3200MD), one at a time, directly to the analogue inputs of the UNIO-52. The amplitude of triangular wave with period of 10s, and DC voltage inputs were varied in steps and the integral calculation was carried out by software. The theoretical value of the GC area was calculated by summing up the values of 40 data points ( $10s \times 4$  points/s = 40) during the period of 10s. Accuracy of the time scale was measured by varying the period of the triangular wave form. Linearity of response and reproducibility of results were also examined by replacing the PMT signal with the triangular wave form and DC voltage signal through a precision resistor. Results showed a good accuracy and reproducibility. The accuracy of TLD dose results was verified by using a standard dosimetry calibration facility. Comparison of the results with a commercially available modern computerized TLD System (Harshaw model: 4500) also verified the validity of the results.

#### 1. Introduction

The Thermo-Luminescence Dosimeter (TLD) system consisting of a detector/dosimeter identifier, Harshaw model 2271[1], herein after referred to as "Detector", and an Automatic Integrating Pico-ammeter[2], herein after referred to as "Pico-ammeter" used for reading the TLD cards for evaluation of occupational radiation doses in a large scale personal dosimetry program was refurbished and modernized by interfacing a Data Acquisition Module (model:UNIO-52)[3], herein after referred to as "DAM", controlled through a LabView virtual instrument software interface[4].

User-friendly virtual instrument software windows including quality assurance and quality control features of the system ensure easy operation and evaluation of results, and the accuracy and reliability of results.

## 2. Brief description of the TLD system

The photomultiplier tube (PMT) in the Detector senses the thermo luminescence emitted by a given dosimeter during the heating process. The resulting PMT output current signal is connected to the Pico-ammeter. The integral of this current signal represents the charge in coulombs, which is directly proportional to the quantity of radiation exposed by a respective TLD card. The Pico-ammeter integrates the low level current signal from the detector producing a digital charge signal and displays digital value on a four digit seven-segment display, along with the appropriate range legend. The counter incorporates a preset table feature to ensure counting continuously when automatic range changing occurs. Four reed-relays activated by the range logic circuit, select a resistor value into the feedback network that determines the gain of the electrometer. Each feedback-range-resistor is shunted by a capacitor designed to maintain a response time of about 1ms.

## 3.1 Modification of circuits in the pA-meter and interfacing with the DAM

Two ADCs (ADC\_0 & ADC\_1), 4 digital Inputs (TTL) and 6 digital outputs (TTL) of the DAM developed under the IAEA RAS/4/023 project was used for this modernization task. The output voltage signal of the Electrometer in the Pico-ammeter was connected to the input of the ADC\_0 of the DAM through a potential divider constructed using standard resistors, which limit the output to 5V of the maximum inputs limit of the ADC\_0.

The Pico-ammeter has 4 ranges that change automatically with the amount of the value of the TL current by an arrangement of relay switch system. Each range-select indicator-LED was connected to each bit of the four lower bits of Port\_B of the DAM as shown in fig. 2 to enable the software to identify the active range during measurements.

## **3.2** Modification of circuits in the fetector and interfacing with the DAM

 $S_2$  logic level at the TP1404 of 1400 Boards of the Detector (figure 55 in page 107 of the service manual of the Detector) was made permanently high level to read other types of TLD cards, which do not have optical identification code numbers. Control command-signals for reading the background, reference light and sequential movement of TLD cards, start, stop, clear from the Detector to the VG96 connector of the DAM were connected to the Circuit Board-200 of the Main chassis of the Detector. Controlling commands were generated through the lower 8 bits of the 16-bit digital input/ output (TTL) of the DAM. This analogue voltage signal (0 – 1.5V) corresponding to the temperature of the heater element (hot finger) was connected to the ADC\_1 of the DAM.

## 4.0 Software development

## 4.1 Microcontroller program

Software program for AN2131 Microcontroller on the UNIO52 module was programmed using the RIDE 51 C-compiler. The RIDE 51 compiler compiles the program written in C language to machine-code and generates the files \*.lst, \*.hex, \*.aof.

#### 4.2 Software for controlling the system

The software was written to calculate the output of the ADC\_0, resulting from the output voltage signal of the electrometer, by multiplying with the appropriate range factor that was identified by the software through the value of Port\_B and visualized on the display after smoothing the data. The user-friendly software environment for data acquisition, visualization and data storage, re-evaluation of the GC and control of the instrument and QA/QC features were prepared in several steps using the Lab View software tool. The flow chart of the steps is shown in fig 3.



Figure 2. Block diagram the modernized TLD system.

When the controlling software starts, the \*.aof file generated by RIDE 51 compiler sends to AN2131 Microcontroller of the DAM through USB connection. Then the Background and Reference Light readings are taken out automatically. If there is a large deviation of the readings from the previously stored data, program provides facility to repeat the measurement. If the readings are within the acceptable limit (normally  $\pm 10\%$  or less), provision has been provided to save these readings in a record file in the PC. Software is prepared in such a way that after finishing this step, the main-menu window of the controlling software was appeared. All necessary facilities are available in this window so as to set up the

parameters according to the type of the TLD used, select the path for saving data, view performance records, re-evaluate the glow curves, analysis of results by subtracting the background reading and printing results. Calibration factor in the set-up menu was protected by a password.



<sup>1</sup> Ref. LT: Reference Light. <sup>2</sup> Rec. file: Record File in which data are recorded. <sup>3</sup> BG: Background reading.



## 5.0 Validation of software and results

During the structured and software document development process, the corrections and consistency of each and every steps of the software program that can be tested with numerical inputs were examined. After completing the software program, testing and verification of function of the system that was specified during the system design were done and consistency of results was examined. Execution of each branch of the software program as indicated in the flow chart in fig. 3 was examined and the consistency of execution of each branch was also tested and verified.

## 5.1 Testing of the ADCs

A simple software program was written to display the output values of the ADCs of the DAM and accuracy of the outputs of the two ADCs were examined by applying a dc voltage source. The results of both ADCs found to be within the significant levels ( $\pm 16$ ).

## 5.2 Verification of calculation of glow curve area

The glow curve (GC) was visualized on the display from the average value of the previous ten consecutive readings of the output of the ADC\_0. Each reading was taken at every 0.25s. The GC area was calculated by taking the summation of data points displayed within the interested temperature range. After verification of the accuracy of the ADCs, calculation of the GC by the software program was examined by applying an external triangular wave form (clamped wave form by setting the offset an half of it's amplitude) from a function generator (TTi model: TG 4001) and DC voltage from a power supply (TTi model: PL3200MD), one at a time, directly to the analogue inputs of the DAM. The amplitude of triangular wave form with period of 10s and DC voltage inputs were varied in steps and the integral calculation by software for each input was obtained. The theoretical value of the GC area was calculated by summing up the values of 40 data points during the period of 10s. The results show in the graphic 1. The highest error observed for both triangular and DC inputs was -2.6%. The reproducibility of the system was tested and the highest value of the coefficient of variance was found to be 0.18%.



Graphic I. Accuracy of calculation of glow curve area bysSoftware for DC input.

#### 5.3 Accuracy of the time scale

Two cursors that can be moved along the time scale are available to select the glow curve area within the temperature range specified for the TLD. Minimum division of the time scale was 0.25 Seconds. Verification of the accuracy of time scale was examined by applying an external triangular wave form used in the section 5.2 with same integral of input wave form for different periods. (i.e. Period x Amplitude = Constant for each measurement). During this measurement, +1% error of integral outputs over the period of 8s and below 8s with respect to 10s period was observed.

## 5.4 Verification of the results of radiation dose measurements

Linearity of TL response of the system was examined using TLD cards, which were exposed to known radiation doses using a second standard dosimetry calibration facility. The results of the refurbished system compared to the new Harshaw model 4500 were in good agreement. The highest error detected in the system in the low dose ranges, below 1mSv, is +16% which is within the accepted limits for personal monitoring requirements [5]. This error could be further reduced by applying a correction factor considering behavior of the nonlinearity function with respect to dose.

#### 6. Conclusion

In this system, non linearity of time scale does not affect on dose measurements as the relative measurements are done for a particular time period (~10s) for evaluation of radiation dose. The reported errors are associated with the uncertainty of the test and measuring instruments used for validation. Correctness and consistency of the results and functioning of the system with external electrical input source were verified. The accuracy of the results of radiation doses measurements was also verified by using standard calibration facility. Comparison of the results with the modern computerized TLD system also verified the validity of the results. With these evidences it was concluded the validity of software and suitability of the TLD system for reading TLD cards for measurement of radiation doses.

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# Software and hardware validation for meteorological station

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**Abstract:** Software has become almost an essential part of any scientific system in recent years. This made many systems easier to use, more reliable and more flexible. However the increasing complexity of this software is itself a potential source of errors that can remain undetected. Users and developers of such systems need to be aware of the risks involved and take appropriate precautions. Validation and testing is a way of investigating and proving the integrity and fitness for purpose of the (software parts of the) measurement system. Also, software validation is considered as a critical tool used to assure the correct operation and functionality of the system.

## 1. Introduction

For each application, software components from many sources and some time different inputs may be used to form a specific environment. In general, Designing the software follows the main five stages:

- Design: "What software should do and how it should do it".
- Codes: "involves the use of HL/LL languages".
- Test: "running software under known conditions with defined inputs and documented outcomes that can be compared to their predefined expectations".
- Integration: "How the software integrates with hardware".
- Acceptance: "by the user of the instrument".

In our commission, we have designed and implemented several projects in the field of control and interfacing for different applications. For example, a portable meteorological station plus nuclear radiation monitoring system using a BASIC8052 microcontroller has been designed. The aims of this project were firstly, the lack of the country for such system which measures all physical and environmental parameters such as; temperature, solar radiation, pressure, wind speed, rain fall in addition to radiation monitoring channel, and secondly the high cost of such systems with other technical and research reasons inspired us to design and implement such station in our commission. Radiation measurements are not usually available in similar meteorological station.

Furthermore, several similar projects on automation and interfacing were designed and implemented in our commission. These include:

- Automatic sample changer for MCA CANBERRA S35+.
- Control of test instrument (HP4280A) using the GPIB port controller and PC/AT.
- Computer controlled dosimeter and beam calibration.
- Construction of a sample holder/changer controlled by computer to be used as an aiming beam target of CO2laser.
### 2. Experimental

As any modern project it consists of two main parts: Hardware and Software

### 3. The hardware part

Consists of three boards as shown in figure 1:

- Signal conditioning board
- Data acquisition board
- Single board computer



Figure 1. Block diagram of the meteorological station.

### 3.1. Signal conditioning board

Contains 9 channels, 7 of them were used to connect pressure, temperature, relative humidity, rainfall, wind speed and direction, in addition to radiation sensor (figure 2)

Since the nature of such sensors are not the same (some of them are digital and some are analogue) therefore, the output signal of such sensors must be conditioned and/or amplified in this signal conditioning board.



Figure 2. Block diagram of the signal conditioning board.

### **3.2. Data acquisition board**

All sensors output signals were converted into digital and counted in this board using 8254 Timer/Counter chip.

### 3.3. Single board computer (SBC)

Based on the 8052-BASIC Microcontroller. With some needed components (RAM & ROM) for Data and Program Storage. In addition to serial port to communicate with PC for Programming, Debugging, Testing and Saving measurement results fig. (1).

### 4. The Software Part

A controlling program written in BASIC-8052 language was stored in the system EPROM. The software was developed to be user friendly and to give maximum information with minimum complexity.

- It is not possible to validate software without predetermined and documented software requirement, these include the following:
- System inputs: (setting time and date, starting measurement time, number of samples, sampling time....)
- System outputs: (physical measured values, temperature, ..).
- Software performance:
- Reliability
- Timing: is derived from the built-in timer, which was enough for the nature of the measured parameters.
- Software interaction with the user: using any terminal program to input/output data.
- Errors and how to handle errors.
- Intended operating environment: using terminal program compatible in any operating system (DOS/Windows 9x/Xp) environment.
- All ranges, limits, defaults, and specific values: where considered properly during defining parameters.

### 4.1. The software contains the following subroutines:

### 4.1.1. Initialization

- (1) Giving the initial value of the station's parameters(Start measurement date and time, sensors calibration parameters).
- (2) Addressing all channels counters and ports(8254 chip control word, 8255 chip control word).

### 4.1.2. Parameters input

This subroutine calculates sampling and storage times in addition to the total measurement time.

- (1) Sampling time: equals to the time interval between two separated samples. This time can be chosen between 1 second to 5 minutes depending on the accuracy required.
- (2) Storage time: During this time, samples values are accumulated in a special accumulator and the number of samples are counted in a special sample counter. At the end of this time the average of these samples is computed and stored in a corresponding memory location.
- (3) Total measurement time.

### 4.2. Data acquisition

In this subroutine, the program takes one value at the end of each sampling time for every channel. An averaging and filtering processes are carried out at the end of each storage time to increase the accuracy and to reduce the nonlinearly effects.

Also eliminates the effect of any faulty measurements in the meteorological signals, during the storage time.

### 4.2.1. Storage

In this subroutine, the program stores the average values of the measured samples for each channel at the end of each storage time in a 32 Kbytes Non Volatile RAM

### 4.2.2. Display

In this subroutine, the results stored in the RAM can be displayed on a portable PC screen through a serial communication unit (RS232).

### 5. Results

Figures 3 and 4 show the physical parameters measured by the designed Meteorological station:



*Figure 3. The physical parameters measured by the designed meteorological station (Temperature, humidity, wind speed and direction).* 



Figure 7. Chart showing measured values of (a) temperature (°C), humidity (%), wind speed ( $m \ s^{-1}$ ) and wind direction, and (b) atmospheric pressure (mb). Sampling time: 5 seconds; storage time: 2 minutes; total measurement time: 2 hours.

#### 6. Conclusions

- In this project, software validation was taken into account, to increase the device usability and reliability. The overall performance of the station was tested for a period of about twelve months. In addition, the measurements were compared with the measurements of a standard METOS meteorological station (type MET93V2, Austrian-fabricate). The reported results taken from both stations showed a good agreement with a deviation less than 1 to 2%.
- The design was simple; in electronic circuits and control program.
- High accuracy in the measurements.
- Low power consumption.
- Nuclear radiation can be monitored.

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# Software development and validation for refurbishment of nuclear instruments

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**ABSTRACT.** Refurbishment of Nuclear Instruments is achieved by redesigning and developing intelligent analytical software. A discussion on software developed and validated for the refurbishment of some nuclear instruments including Inductively Coupled Plasma Optical Emission Spectrometer, Energy Dispersive Spectrometer, Charged Particle Accelerator and  $\alpha$ - $\beta$  counting system is presented in this paper. Software validation for each case is performed by comprehensive software testing, inspection, analysis, and performing other verification tasks at each stage of the software development activity. This indigenous work has provided an excellent experience to refurbish nuclear instruments by developing software and applying validation procedures.

### 1. Introduction

Nuclear Instruments (NI) automated with computers and used for research and development are very costly. As the information technology is progressing very fast, these computers have become obsolete and cannot be utilized properly. Also, these instruments cannot be repaired due to unavailability of their spares and documentation. Data acquisition, data logging and data processing to refurbish such instruments is need of the day. It can be achieved by interfacing PC's with the instruments, redesigning their hardware modules/ spares and by the development of new control/ analytical software. It helps in enhancing the life of these precious instruments and supports for further improvements in redesigning the NI. Pakistan is much benefited from the IAEA project (RAS/4/023) on Repair and Refurbishment of NI. Our scientists have made a step forward and refurbished these instruments by developing new control/ analytical software to meet the requirements of the end users in different laboratories. The developed software for each system is validated, using various standard validation procedures and by utilizing the experience of working of the end user on multi-functioning NI. An overview of data acquisition and data processing to develop application software and its validation is presented in the following sections.

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## 2. Software development and validation of refurbished inductively coupled plasma optical emission spectrometer (ICP-OES)

ICP-OES originally equipped with PDP-11/23 Plus is an expensive multi-element analytical instrument. It is a complex machine consisting of both spark and excitation sources in combination with a monochromator and a polychromator. This spectrometer is composed of two parts, control electronics for the spectrometer and acquisition of data (analog to digital conversion). A microprocessor called, Instrument Control System (ICS) [1] is interfaced by parallel and a serial link (RS 232) to the control electronics of the spectrometer. Another serial link allows for a dialogue, according to a well established protocol between the PDP-11/23 Plus and ICS. PDP-11/23 Plus has become obsolete whose failure could make the whole system useless.

It was decided to develop a control/analytical software compatible with the provided data processing system (DPS). A PC-based data processing software (PCDPS) was developed and tested without interrupting the routine usage of ICP-OES for chemical analysis. PDP-11/23 Plus has been replaced by a PC and PCDPS performs data acquisition and analysis in both modes (ICP and spark) with operational control diagnosis. PCDPS communicates with the spectrometer via ICS which controls the spectrometer's operations. ICS and PC are connected through an asynchronous serial line operating at a baud rate of 2400. Here, PC operates as the master and thus data are only transferred on request from PC for all communication between PC and ICS. ICS is activated in accordance with a particular protocol which consists of commands of ICS, data and checksum. The term, checksum is a three ASCII digits, representing the hundreds, tens and units, which is computed by addition module 256 of the ASCII character values of all the characters in the command except the checksum and the terminating carriage return. In the development of PCDPS software, ICS protocols are programmed according to a particular scheme and depending upon the task to be performed by the ICS for analysis. To understand this scheme, consider an example of the development of 'Status Logging' program to monitor status channels of the spectrometer. On execution of this program, PC sends a set of ICS protocols such as 'ms' and 'rs' according to a particular format to ICS. 'ms' instructs ICS to measure the spectrometer status channels and store these values in the ICS status buffer. In response to this protocol, ICS gives the alarm status. Another ICS protocol 'rs' is used to get the current value of the selected status channel stored in the ICS status buffer. The results obtained by the analytical programs by PCDPS are within the standard deviation of those obtained by PDP.

There are different procedures to validate the developed software for any instrument or otherwise. Validation at command level by calculating the checksum is one of the procedures which is adopted here. PCDPS was developed in an environment when PDP-11/23 Plus was running in parallel. Any sample was analyzed by DPS and also by PCDPS. The obtained results of PCDPS were only accepted when they were within the standard deviation of the results obtained by DPS. Comparison of results for regression analysis of a sample is given in the table I which shows the validity of the results and that of the developed software. Standard error of estimate obtained from DPS was 0.0051 and the standard error of estimate obtained from DPS was 0.0051 and the standard error of estimate obtained mandatory at the completion of each analytical, diagnostic and control program.

Name	Intensity		Concentration		True Concentration		Calculated Concentration		Concentration Error	
	DPS	PCDPS	DPS	PCDPS	DPS	PCDPS	DPS	PCDPS	DPS	PCDPS
AN101	3.6058	3.6058	0.0008	0.0008	0.0008	0.0008	0.0029	0.0029	0.0021	0.0021
7PN19G	4.4025	4.4025	0.0102	0.0102	0.0102	0.0102	0.0045	0.0045	-0.006	-0.0057
4AN54D	14.8178	14.8178	0.0322	0.0322	0.0322	0.0322	0.0356	0.0356	0.0034	0.0034
5AN55D	14.9016	14.9016	0.0324	0.0324	0.0324	0.0324	0.0359	0.0359	0.0035	0.0035
1AN51E	16.7593	16.7593	0.0407	0.0407	0.0407	0.0407	0.0437	0.0437	0.0030	0.0030
2AN52E	25.3216	25.3216	0.0953	0.0953	0.0953	0.0953	0.0877	0.0877	-0.008	-0.0076
3AN53E	45.9016	45.9016	0.2491	0.2491	0.2491	0.2491	0.2503	0.2503	0.0012	0.0012

TABLE I: REGRESSION RESULTS COMPARISON OBTAINED BY DPS AND PCDPS

## 3. Software development and validation of refurbished energy dispersive spectrometer (EDS)

EDS attached with scanning electron microscope (SEM) [2] was used for micro structural characterization and elemental analysis. Microprocessor attached with the system was used to store and analyze data of a spectrum generated by EDS, which became faulty. So, EDS is refurbished by acquiring and storing data on PC via PCA-8000, Nucleus MCA card and a software package was developed for elemental analysis. Energy line library [3] containing all the X ray emission lines shorter than 50Ű are created for analysis of the spectrum. The data is manipulated to eliminate fluctuation present in the data and to have only the trend movement using a nine point moving average smoothing technique [4–5]. This is carried out throughout the data excluding four points from each end. Two modes of peak identification, manual peak and auto peak are introduced. Formulation of a nine-point moving averages smoothing technique to minimize the errors associated with inaccurate description of the data is given by:

$$channel(i) = \frac{\sum_{j=i-4}^{i+4} channel(j)}{9} \quad -----(1)$$

where, starting channel# $+4 \le i \le last channel#-4$ .

Area under a curve [6] is computed by summing the counts over all the channels within a region marked by the user. The background contribution is subtracted from the calculated

area. This area is then multiplied by efficiency factor, supplied by the user. The formula for calculation of area is:

Net Area = 
$$\left\{\sum_{k=i}^{j} \left(counts(k) - background(k)\right)\right\}$$
 \* efficiency factor -----(2)

where,

$$\sum_{k=i}^{j} background(k) = \sum_{k=i}^{j} \left\{ \frac{counts(f) - counts(i)}{channel(f) - channel(i)} (channel(k) - channel(i)) + counts(i) \right\}$$

Composition is computed with the help of following formulae:

*wt* % *of an elem* = 
$$\left(\frac{Net Area}{Total Net Area of selected region}\right) * 100 -----(3)$$

Vol % of an elem = 
$$\left(\frac{wt \% of the elem}{\max \# of elems + total wt \% of total all selected elem}\right) * 100 ---(4)$$

The software has a calibration algorithm to calculate the energy curve. The algorithm provides two-point energy calibration, a minimum energy calibration point (initial energy in keV.) and a maximum energy calibration point (final energy position) to be defined by the user. Lower & upper energies must be known before calibration of a standard. After calibration it represents energy vs counts. Electron Microscope has a knob which provides various ranges to capture the data. When a spectrum of a particular standard is obtained at a certain range, the same range must be entered for analysis otherwise results will be incorrect. An auto-peak-identification technique was developed in which first of all maximum counts say  $C_{max}$  at a certain energy level  $E_{max}$  excluding noise peak in the given spectrum are searched. Then background is computed as

$$Background = \frac{C_{\max}}{100} * 5.----(5)$$

Seven energy levels on each side of  $E_{\max}$  with different counts are found. Let  $E_{l_1}, E_{l_2}, \dots, E_{l_7}$  be energy levels to the left of  $E_{\max}$  having counts  $C_{l_1}, C_{l_2}, \dots, C_{l_7}$ , which are different from each other. Similarly, if  $E_{u_1}, E_{u_2}, \dots, E_{u_7}$  are energy levels to the right of  $E_{\max}$  having counts  $C_{u_1}, C_{u_2}, \dots, C_{u_7}$ , respectively. The peak width is calculated as

*Peak Width* = 
$$E_{u_7} - E_{l_7}$$
.-----(6)

If this peak-width is < 40 channels then this energy level with counts  $C_{\text{max}}$  is declared as a peak. After identification of a peak, all the elements present at that energy level are displayed on

the screen with the help of line spectrum library. If more than one element are present at a particular peak one can tour through each element with the help of Up/Down cursor keys. The actual element is confirmed by comparing the values of  $K_{\alpha}$ ,  $K_{\beta}$ ,  $L_{\alpha}$ ,  $L_{\beta}$  etc. given in a line library. It means that if all other secondary peaks are also present in the spectrum then that particular element is confirmed.

Validation of software is achieved by using the standard mathematical techniques as explained above to identify an element. Validation of data which is very important and is the base of elemental analysis without which the whole software is aberrant is performed by a nine point moving averages smoothing technique [4-5], which is carried out throughout the data excluding four points from each end. Certification of the end-user is given a primary importance for identification of elements and their composition in a sample to be analyzed by the developed software. The method of comparing the results, achieved by the newly developed software with SEM and the reference information of the sample works properly and this method was applied for validation of software.

# 4. Software development and validation of refurbished charged particle accelerator (CPA)

CPA was originally manual driven and used for mass analysis, mass spectrometry and ion implantation [7]. Mass analysis deals with the removal of gas impurties and higher ion charges of ion beam produced by ion source through ExB Velocity Filter's electrostatic and magnetic field. Mass spectrometry is performed by identification of the emitted particles like atoms, ions, molecules and clusters from the target detected through Faraday Cage (FC) or Channel Electron Multiplier (CEM). FC is used to measure the charge particle current in the range  $10^{-6}$  to  $10^{-9}$  amperes while CEM is used below the above mentioned range. Ion implantation changes the surface characteristics like resistivity, hardness, structure, roughness and optical transmission.

CPA was refurbished [8] to replace paper chart recorder, counter and other measuring instruments by developing software, CPA-Lab Automation with on-line graphics and print option facility. Data acquisition, data processing and data logging is performed according to the standard specifications and end-user requirements in LabView environment. Mass analysis is achieved by using the formula (7) to control ExB Velocity Filter's electrostatic field through the locally developed software. Mass spectrometry is achieved by the measurement and identification of the emitted particles from the target by applying the formula (8) and other options of the software. This software is also capable of measuring the current from the target for the evaluation of ion implantation. The whole system is described in Figure 1.

Software validation and verification (V&V) [10] has been accomplished by applying following techniques. Empirical formulae (7) and (8) are formulated by giving different values of the parameters to verify the raw data by hands on calculations. The empirical formula that gives the analog output (in volts) is given as

where *E* is end point with in the range  $0 \le \le \le 5$ , *S* is starting point within the range  $0 \le \le \le 5$ , *I* is iteration number and *N* is total number of iterations. Mass reference value and values of lower and higher mass are used for the experiment of mass spectrometry. These values are chosen from the Particle Physics Standard Data on the basis of expected behavior of ions or charged particles and used in the formula (8) to calculate mass values *P* in atomic mass units. Indices of maximum peak value is identified by the software to be a valid peak, if it lies in the range of lower and higher mass values.

$$P = (M * (V^{2})) / (X^{2}))$$
(8)

where M is mass reference value, V is the indices of the maximum peak and X is the current iteration number. Software testing was performed in the laboratory using function generator with different parameters for the accuracy of the results. Afterwards, CPA-Lab Automation software is installed and interfaced with CPA for on-line testing and verification. Graphical User Interface (GUI) was developed to achieve maximum perceptive Human Computer Interaction and presentation of the real time data and control parameters. Facilities like report generation, good performance, easy data entry, visual data representation, printing after completion of every spectrum and single point information are provided to achieve the reliability of the software. To be more care full and to reduce the risk of malfunctioning or failure, the developed software has been debugged appropriately. Supervisory committee has checked and verified the proper functioning of the software and its validation. Analysis was performed by applying various limit checks at different locations for smooth running of the software. Comparisons of results with other measuring instruments have been also performed to meet V&V of the acquired data according to the end-user specifications. The compared results are given in table II.

Sr. No.	Sour	ce (CPA) g Instrument	<b>CPA-Lab</b> Automation		
	Multimeter (FC)	Oscilloscope (CEM)	AI	Counter	
	Volts	MHz	Volts	MHz	
1.	0.105	1.502	0.104	1.503	
2.	0.304	1.802	0.303	1.802	
3.	0.506	2.002	0.505	2.001	
4.	0.703	2.303	0.702	2.302	
5.	0.901	3.702	0.899	3.702	
6.	1.001	3.002	1.002	3.001	
7.	1.299	3.301	1.298	3.301	
8.	1.50	3.402	1.501	3.401	
9.	2.00	3.501	2.001	3.499	

TABLE II: COMPARASION OF ANALOG/DIGITAL INPUT VIA CPA



Figure 1. Schematic diagram for data acquisition and control of CPA.

### 5. Software development and validation of refurbished $\alpha$ - $\beta$ counting system

Alpha, beta counting system as explained in the Figure 2 has low background and very high sensitivity performance. The system consists of a phoswich scintillation detector [11], surrounded by a low-active lead shielding and a cabinet with the associated electronics. There is a sample changer assembly in which proposed samples run step by step and finally stay in a chamber which is a counter part of the detector with a photo multiplier tube. This unique detector allows  $\alpha$ ,  $\beta$  radiations to be counted. The detector has two terminals one for High Voltage (H. V.) and the other for the output to be fed into a pre-amplifier where signals are amplified up to an extent and then fed to a Pulse Shape Analyzer (PSA). One output of PSA is given to SCA (Single Channel Analyzer) and other two signals are fed to a measuring channel FHT 7000 [12] which is an acquisition and processing unit for pulse trains, analog values and digital signals which also controls sample changer assembly. FHT 7000 is itself, a complete old designed computer with a built in thermal printer. Measuring channel, FHT 7000 became faulty and unable to do the job. This obsolete measuring channel was refurbished [13] by:

- Interfacing a PC through a locally designed/fabricated buffer unit with the IAEA UnIO-52 micro-controller module.
- Development of control software (in C-language) under the Lab VIEW environment.



*Figure 2. Schematic diagram for data acquisition and control of*  $\alpha$ *-\beta counting system.* 

Validation and verification of the Software was performed by comparing the results, obtained by measuring a sample with FHT 7000 and with hands-on calculations. In our institute, the  $\alpha$ ,  $\beta$  counting system is only used for  $\beta$  counting. Hence,  $\beta$  calibration was done with Sr<sub>90</sub> with 1.42\*10<sup>4</sup> disintegration per minute (dpm). As the instrument is very old its calculated efficiency factor reduces to  $\approx 22.5\%$ . All calculations and validation of the software is made by considering the above points also. Comparison of  $\beta$  counting is shown in Table III.

### TABLE III: COMPARASION OF $\boldsymbol{\beta}$ COUNTING WITH REFURBISHED SYSTEM

Sample No.	$\beta$ counting with FHT 7000	$\beta$ counting after refurbishment
	(CPM)	(CPM)
1st time	3211	3208
2nd time	3200	3202
3rd time	3230	3207
Average	3213	3205

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### A Hard- and software platform for refurbishment of nuclear instruments

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**Abstract:** Refurbishment of nuclear instruments (NI) based on PC and/or an embedded micro controller ( $\mu$ C) inside the instruments brings many advantages to the instruments. Using this approach the software running on the PC/ $\mu$ C determines the functionality of the instruments and can add new or extended functionality. To deal with a wide range of NI, a uniform hardware platform was developed. This  $\mu$ C based data-acquisition system can work as an embedded standalone controller inside the NI and uses the universal serial bus (USB) to communicate with a Host-PC for further data processing, visualization, data storage and documentation. A set of functions and packages commonly used in refurbishment of NI are available and can be used together with the hardware for a refurbishment. This hard- and software platform can be used as a "building block" for a wide range of nuclear application.

#### 1. Introduction

Refurbishment of nuclear instruments (NI) deals with typical nuclear applications like singlechannel analyzer (SCA), multi-channel analyzer (MCA) and counting systems. These kind of nuclear data acquisition is the basis for environmental monitoring, human health instrumentation, nuclear research and nuclear technology based industrial applications. In refurbishment of NI the use of a PC and/or embedded micro controllers ( $\mu$ C) inside the instruments brings many advantages to the instruments. Using this approach the software running on the PC/ $\mu$ C determines the functionality of the instruments and can add new or extended functionality, like improved throughput, reduction of human error by automated data acquisition, date storage and traceability, to the NI under refurbishment. But these advantages can be negated if the development is not handled in a methodical way and the potential problems of the application are not understood.

### 2. Verification and validation

A poor software implementation can lead to inaccuracy of the whole system that could have been avoided. Therefore the implemented software must be verified and validated at every step of the development. The IEEE STD 1012-1998 [1] treats the "verification" and "validation" as separate terms.

**Software verification** is the test that the specified requirements have been fulfilled. A continuous verification during the process of development ensures that the product at each development phase meets requirements given by the specification. Therefore the verification is the test that the product was built right. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated.

**Software validation** refers to the process of evaluating a computer based system at the end of its development, to insure that it is free from failures and complies with its requirements.

Validation is the test that the particular requirements for a specific intended use are fulfilled.

This validation occurs through the utilization of various test procedures throughout the development of the product. Even it is more or less impractically to test software with all possible input data and all execution paths, the process of validation should assure that the software and the whole system delivers correct results within the range of usage given in the specification of the product.

In the following we will use the Terms verification and validation interchangeably, as if it is a single concept and mention this by the term V&V. The process of V&V takes places at several levels during the software development.

Intensive **component tests** should be done for every software component (a subroutine for a mathematical algorithm). Software components (units, module) should be separately tested by stimulation with given input data and by checking the expected output values. This leads to a set of tested software building blocks which can be used in different application.

The **integration tests** checks the interaction of several software components which are integrated together. This testing proceeds until the entire system has been integrated.

**System tests** are used to test the complete system, verifying hat the overall system meets its specified requirements. Reference measurement systems are needed, enabling users and developers to test software themselves by comparing measurement data and calculated results to data generated using an "industrial standard" hardware. A final acceptance test determines whether or not the system satisfies its acceptance criteria of the end-user (customer).

There are typical techniques which can be applied to the various testing levels outlined above.

The inspection includes visual code checking, software reviews and technical reviews. The most effective way to find anomalies at the component level is inspection. On the other hand, inspection is not applicable at the system level when the software gets already very complex. During system testing, given input values are traced through the test items (components) to assure that they generate the expected output values, with the expected intermediate values along the way. Mathematical algorithms are analyzed by test data, which can include estimation of execution times and estimation of system resources.

This testing proceeds until the entire system has been integrated and accepted by the customer.

Finally a demonstration of the complete system and reference measurements taken with another proofed system (reference system) gives the assurance of proper implemented software.

Development and validation time can be shortened and simplified when using pre-tested hardware- and software components.

### 3. Hardware building blocks

The computer systems, including embedded controllers within the instrument, used in measurement applications and the related software must be fit for the purpose of the application. This fitness for purpose can be degrade if data processing software implements unreliable algorithms, or if the particular needs of measurement are not fully taken into account at the design stage. To deal with a wide range of NI, a uniform hardware platform and a set of software modules were developed.

The developed hardware is based on a set of microcontroller modules [8]. These modules provide a complete modern microcontroller system including memory, serial IO and a fast communication channel in a standardized foot print. Depending on the application a module with CAN (controller area network), USB (universal serial bus) or Ethernet can be chosen.



Figure 1. The USB (left) and the Ethernet (right) based microcontroller module.

The modules can be used to control purpose build hardware or, in combination with the Universal Input/Output (UnIO52) base-board, as a platform for the refurbishment of nuclear instruments.

### 4. UnIO52 DAQ board

For the refurbishment of NI some more data-acquisition and control tasks have to be solved. Beside of the SCA or MCA a typical refurbishment of NI includes the control of the instrument and the acquisition of environmental parameters like temperatures, pressures or other physical units and



Figure 2. The UnIO52 DAQ board.

the control of the instrument like the movement control of a motor. For this, a unique hardware platform [7] which can be used for the refurbishment of several NI was developed and introduced in the Member States (MS). The UnIO52 board comes with analog and digital input and outputs, providing sufficient IO channels for general purpose DAQ task. A motor controller can drive stepper motors of up to 2 Amps. For nuclear applications two SCA with programmable lower- and upper limit and two digital (TTL compatible) counting inputs are available. A fully digital MCA with 1 K channels allows also spectral analysis of nuclear events. A LCD display and a keyboard can be connected to the board, allowing user input/output in standalone application of the board.

This  $\mu$ C based data-acquisition system can work as an embedded standalone system inside the NI and uses the USB or Ethernet channel to communicate with a Host-PC for further data processing, visualization, data storage and documentation.

This unique hardware can be used as a "building block" for a wide range of nuclear application. All components are user programmable and the firmware can be downloaded at runtime of the application. The application specific programming of the board defines the behavior of the board inside of a refurbishment application. Therefore the "Software defines the Instrument".

### 5. Software Building Blocks

Furthermore a today application is mostly PC based and needs a graphical user interface to interact with the user. This includes the visualization of the acquired data, data processing and data storage for traceability of the results. With this approach, using the PC as the central host computer for visualization and user interface, the software creates a "Virtual Instrument" (VI) based on universal data acquisition hardware. The concept of VIs is also the idea of the graphical programming system LabVIEW (©National Instruments). The approach of graphical programming allows the preparation of software building blocks which are well tested. This allows the Re-Use of software components.

A set of functions and packages commonly used in refurbishment of NI are available and can be used together with the hardware building blocks for the refurbishment of a NI.

This hard- and software platform can be used as a "building block" for a wide range of nuclear application. To validate the system, the development of the software must be accompanied with verification tests, in order to ensure the correctness of the system.



Figure 3. Pre-tested software components for UnIO52.

### 6. Refurbishment example

In cooperation with the Malaysian Institute for Nuclear Technology (MINT), the IAEA and the Forschungszentrum Jülich (FZJ), a bed whole body counter (WBC) was refurbished using the UnIO52 board. An existing bed WBC with stepper motor bed movement was connected to

a commercial high power stepper motor driver controlled by the UnIO52 board. Limit switches for the bed end-position allows the system to find the zero point for the calculation of the position. The detector electronics consisting of a pre-amplifier, a shaping-amplifier and a high voltage supply is placed in NIM modules. The Gaussian shaped pulse is feed to the UnIO52 board utilizing the analog SCA and MCA input. With the developed software the events can be counted while the bed is moving and can be displayed as a curve with relation to the bed position. When а contamination is found the detector is placed at this position and a spectroscopy analysis, using the



Figure 3. Refurbished bed WBC at MINT.

MCA, can be performed in order to specify the nuclear isotopes.

The UnIO52 board, the high power stepper motor driver and a suitable power supply was build into a rugged housing. A local LCD display shows the current position of the bed and the SCA count rate. The complete System is connected to the PC using the USB bus.



Figure 4. UnIO52 board, power supplies and stepper motor driver (left) mounted in a rugged cabinet (right).

The software written allows the entry of patient data, the scan range in cm and the scan speed.



Figure 5. Graphical user interface for the refurbished WBC.

Different graphs show the result of the SCA over the scanning distance and also the MCA spectrum. After the scan is completed, a report with patient data and scan results will be printed and saved in a databank.

In order to validate the System, reference measurements were done with standard MCA board installed in the PC. Therefore the spectra data from the developed system could be compared with the spectra acquired with the GENIE200 system. By integration the MCA events inside a window also the SCA function can be tested and validated.

### 7. System validation

Basic validation steps should be made such as counting and timing accuracy, integral nonlinearity (INL), energy resolution and CHI square test.

The CHI square test shows any instability in a complete system, when results outside the limits

Counting accuracy

- Fixed gating time
- compare counts with a reference counter
- Timing accuracy
  - nuclear pulser, fixed frequency
  - increase counting time, check linearity

• Integral non-linearity (INL)

- nuclear pulser, linear amplitude ramp
- Energy resolution

 $Resolution = \frac{FWHM}{PeakEnergy} \times 100\%$ 

• CHI<sup>2</sup> test  $\chi^2 = \frac{\sum (x_i - \overline{x})^2}{\overline{x}}$ 



To determine the accuracy of the hardware, basic tests must be done. Using pre-tested hardware and software components for data acquisition, processing and also for the graphical visualization, allows the developer to concentrate on the application to be done and allows an error detection in early states of the development. The interaction of the different components should be tested by running the system with known input signals and observing the behavior of all output data by graphical presentation of the results. Known input signals can be generated by simulators, function generators or a nuclear pulser for NI applications. Also all output signals and controls should be measured and validated with reference measurement tools like multimeters or a oscilloscope.

Even when pre-tested software components are used, the interaction between them and the overall system performance must be checked. This includes the communication protocol with the host system, the needed real time requirements (speed of the application) and also the memory usage of the system. This is true especially in the case when using a Microcontroller, because of the limited resources of memory and processing power of such a controller.

Finally the process of validation of the system should end in a good documentation where all tests and results are described and compared to reference measurements.

Due to the complexity of software, a seemingly small local change may have a significant global system impact. When any change (even a small change) is made to the software, the validation status of the software needs to be re-established.

Whenever software is changed, a validation analysis should be conducted not just for validation of the individual change, but also to determine the extent and impact of that change on the entire software system. Based on this analysis, the software developer should then

conduct an appropriate level of software regression testing to show that unchanged but vulnerable portions of the system have not been adversely affected. Design controls and appropriate regression testing provide the confidence that the software is validated after a software change.

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