
	Technical Specifications for the Supply, Installation and Commissioning of a Dosimetry System and Associated Services for Individuals, Workplace and Environmental Monitoring	DOC. No.	NLS-BUS-SPE-0001
		Rev.	1.0

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Approval & distribution

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1. INTRODUCTION

1.1 Purpose

Necsa Laboratory Services is expanding its scope of services offering by adding dosimetry services based on the latest technology. The main aim of this dosimetry system technical specification and associated requirements is to serve as basis to invite qualifying products and services providers to submit quotations and proposals for the supply, installation, commissioning, and after sale services for a new Dosimetry system for individuals, workplace and environmental monitoring.

1.2 Objectives

This specification document sets out the scope of required services and deliverables used to invite services providers to submit proposals covering (1) delivery of a fully functional system, (2) supply of all necessary equipment, instrumentation, software and accessories, (3) installation, testing and validations, (4) commissioning, training and after sale support of a new Dosimetry system. That is, potential services providers shall make use of this specification to gain an understanding of the problem(s) and envisaged solutions, conditions of services, and other essential requirements. This specification document also provides layout to be followed by bidders with respect to the submission of responsive proposals.

2. THE SCOPE OF REQUIRED PRODUCTS AND SERVICES

The dosimetry system supplier must supply the system that meet the technical specification, installation acceptance and testing criteria, commissioning and licensing of radiation dosimetry unit and the associated software, the environmental operating conditions, as well as the after-sale services that are summarized in Appendix A. The prospective supplier must return, along with the tender returned proposal, the technical datasheets and compliance matrix for all proposed, instruments, equipment and software as evidential support that the system being offered meets the listed criteria.


2.1 Products and services delivery requirements

The following are technical requirements for the delivery of the Dosimetry system, critical accessories, and all necessary associated services for a functional dosimetry system that meets the technical specifications given in this scope of required products and services specification document.

2.2 Dosimetry system components

Necsa Laboratory Services wants to procure a Dosimetry instrumentation systems composed of the readers, detectors, annealing, internal irradiator, readout and dose calculation. The system shall be supplied with the following integrated components:

- i) Barcode scanning device,
- ii) Electric pin cutter for dosimeter holders, and
- iii) Calibration and Quality control kits,

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Reading/annealing machine must be capable of reading a minimum of 300 badges per hour (an alternative number close to this will also be considered for acceptance). The reader must be upgradable to a higher loading capacity to accommodate potential increases in the demand for the service.

The dosimeters must have an internal radiation source as (^{137}Cs). This must include the software for operating irradiator, and it must meet the requirements for radiation protection safety standards.

The technical specifications and performance requirements are summarized in Appendix A, Section 4.2.1 and 4.2.2. The shipment requirements are provided in Section 4.4 of Appendix A.

2.3 System management software

The supplier must provide a complete set of all the required software to operate the system as one package. The software must have a provision to allow the end user Administrator (or designate) to modify algorithm according to customer's needs when required. The software must include bar code reader for dosimeter or able to read in binary numbers.

The system to have security fixtures to manage unauthorised login by amongst other things assigning to users with special login employee PIN, password and or use of fingerprints for authentication of users.

2.4 Accessories, material and consumables

The supplier must provide a list of all necessary critical components, accessories, materials and consumables required for the dosimetry system to be functional and productive. The list should be grouped on applicable period, meaning (1) number required at start, (2) number required on monthly basis and lastly (3) on an annual basis. Further indications of the technical and performance requirements and provided in Appendix A, Section 5.2.3.

2.5 Installation, calibrations and validations testing


The supply of all necessary equipment, instrumentation, accessories as well as the commissioning, training and after-sale technical support are detailed in Section 4.3 of Appendix A.

2.6. Warranties, guaranties and performance

The supplier must provide a clear description of the nature of standard warranty of instrumentation and equipment as well as a description of the supplier return Policy that satisfies the following requirements (Appendix A, Section 4.3.3).

3. PROPOSAL GENERAL REQUIREMENTS AND ADDITIONAL ACCEPTANCE CRITERIA

The supplier interested in rendering the specified Dosimetry system and associated services must submit a concise written proposal that addresses the requirements for the scope of work and deliverables that are summarized in Appendix A of the scope of work and technical specification document.

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4. APPENDIX A: TECHNICAL SPECIFICATIONS

4.1 Format of the respond and key requirements of the deliverables

The service provider is required to make use of the following matrix table as a key when responding to the key requirements for the provision of a fully functional, adequately tested, commissioned and warranted Dosimetry system and accessories system.

Response	Description
YES	Required items are delivered as standard system part and/or service and can be demonstrated as such by the supplier. When not part of the standard system the item and/or service are provided at no additional cost to the customer
NO	Requirement cannot be met – not without substantial changes and setting-up at an additional cost


4.2 Technical Requirements Questionnaire Table

This table must be completed and submitted as one of the compulsory documents. Any cell not marked yes or no, it will be counted as “NO”. The first section of the questionnaire is weighing 50% meaning scoring obtained here will be awarded 50% thereof. Same applies to the following two sections.

4.2.1 Dosimetry system properties

[50%]


# Entry	Parameters	Description of required performances	Responses (YES/NO)
4.2.1.1	Dose Range	The system meets provision of IEC 62387:2012 (see Annexure B in Section 5 of the Technical Specifications)	
4.2.1.2	System upgrade	The system is upgradable in terms of throughput and includes annealing system as well as in-built software to calculate a dose from each reading (excluding from the LMS).	
4.2.1.3	Types of measured radiation	H _p (10) Whole Body: Photon + Beta H _p (10) Whole Body: Neutron H _p (0.07) Skin: Photon and Beta H _p (0.07) Extremity Hand: Photon H _p (0.07) Extremity Hand: Photon + Beta H _p (0.03) Extremity Eye: Photon + Beta H*(10) Ambient Dose: Photon	
4.2.1.4	Test Type	H _p (10) Whole Body Deep Dose H _p (0.07) Whole Body Skin Dose H _p (0.07) Extremity Hand Dose H _p (0.03) Extremity Eye Dose H*(10) Ambient Dose for area and environmental monitoring	
4.2.1.5	Dosimetry Services/Types of Dosimeters	Whole Body Dosimeter, Extremity Dosimeter (Finger ring and/or wrist); Eye Dosimeter; and Environmental/Area Dosimeter	

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# Entry	Parameters	Description of required performances	Responses (YES/NO)
4.2.1.6	Energy Range	The system meeting Maximum Energy Range as per IEC 62387:2012 (see Annexure C in Section 6 of the Technical Specification Document)	
4.2.1.7	Minimum reading throughput	Reading a minimum of 300 Dosimeters in one hour (or equivalent).	
4.2.1.8	Minimum processing loading capacity	One magazine must carry a minimum of 50 dosimeters for a single processing throughput (6 x magazines) (or equivalent)	
4.2.1.7	Dosimeter life span	Minimum of 3 years life span (or 12 use cycles) guaranteed or better or closer	
4.1.2.9	Manufacturing Certification	Manufactured under ISO 9001 guidelines or any available standards and Dosimetry System accredited to IEC 62387:2012 or equivalent	
4.1.2.10	Through put	The system is able to produce a minimum of 300 dosimeters per hour [alternative figures closer to this will also be considered as compliant]	
4.1.2.11	Quality Checks	The system has a mechanism to perform quality checks for analysis of dosimeters as well as preventing tempering with dosimeters.	
4.1.2.12	Dosimeter Packaging	Water and dust resistant	

4.2.2 System management software [built-in in the dosimeter reading machine for processing dosimeters] [25%]

# Entry	Software	Description of required performance	Responses (YES/NO)
4.2.2.1	Reader Software	Software test/validation certificate by a third party	
		Perform Calibration and Linearity settings	
4.2.2.2		Capability for standard measurements such as mSv/a	
4.2.2.3		Set QC measurements and limits	
4.2.2.4		Generate reports (i.e. Calibration, QC, Dose results)	
4.2.2.5		Assign and modify badge information	
4.2.2.6		Access equipment information and detector parameters	
5.2.2.7		Able to perform Dose calculation	
4.2.2.8		Transfer files (excel spreadsheet including CSV format)	
4.2.2.9		Bidder able to access the system (via a software application) remotely to assist end user when problems are encountered	
4.2.2.10	Network connectivity	Systems operating components must provide for network connectivity and allow download of information from the system to the typical Microsoft applications such as Excel or Word, etc.	

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# Entry	Software	Description of required performance	Responses (YES/NO)
4.2.2.11	PC and relevant software	PC and relevant software to run auto self-testing and adjustments of the system at start-up, able to control the dosimeter processing algorithm to provide relevant result and report	
4.2.2.12	Access to original copies of system software	The system management software shall be provided on CD/DVD or means made for the user to download it from the OEM's website at no additional cost.	
4.2.2.13	Operational Manual	Able to provide end user with an operational manual written in English.	

4.2.3 Quality and compliance requirements

[25%]

# Entry	Description of the requirements	Responses (YES/NO)
4.2.3.1	The supplier has a certified quality management system issued by an accredited certification body. Copies of valid certificates to be provided as supporting documentation.	
4.2.3.2	The supplier must confirm that the dosimeter complies with the requirement IEC 61508 (Functional Safety of Electrical/ Electronic/ Programmable Electronic Safety-related Systems) IEC's Electromagnetic Compatibility (EMC) requirements. Supporting document to be provided.	
4.2.3.3	The supplier will assist the end-user with local dosimetry operational required manufacturer paper (when required for authentication purposes by SAHPRA and the DOH).	
4.2.3.4	Confirmation that the key staff of the interested service provider (i.e. project leader) have a record of accomplishment (5 years minimum) of work experience in the field of dosimeter systems supply & installations. Provide abbreviated CV as supporting document.	
4.2.3.5	If not the OEM, interested supplier must provide a certificate or letter of authorisation being an agent which should outline the extent of authorisation (which must include technical services and system applications). If submitting as OEM, full marks will be allocated.	
4.2.3.6	If not OEM, interested supplier must sought a confirmation letter from the OEM that in case the appointed agent goes under for whatever reason, the OEM undertakes to appoint a replacement within a period of 6 months and that the OEM will directly take over all actions related to "warranty after-sale support" during the period of non-availability of a local service provider of their product. If submitting as OEM, full marks will be allocated.	
4.2.3.7	Office management configuration (also referred to as Laboratory Management System):	
4.2.3.8	Badge receiving, reading, annealing, assignment, labelling and archiving. The software must be upgradable. Data reviewing and reporting	
4.2.3.9	Able to Install and Commission the system on Necsa site such that it is ready for commercialization	
4.2.3.10	Able to provide training for technicians, scientist and management on operation of the system.	
4.2.3.11	Able to provide written guidance and assisting with system calibration and validation data sets needed for ISO 17025 accreditation – as well as inter-lab comparison tests.	
4.2.3.12	Able to provide after sale support and associated warranties aligned to defined scope of work	