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|  <i>We're in your world</i> South African Nuclear Energy Corporation SOC Limited | 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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| Department | Necsa Laboratory Services (NLS) |
| TITLE: | Technical Specifications for the Supply, Installation, Commissioning and Training for a Dosimetry System and Associated Services for Individuals, Workplace and Environmental Monitoring. |
| Number | NLS-BUS-SPE-0001 |
| Revision | 1.0 |

Approval & distribution

| | NAME | SIGNED & Date |
|-------------|---|---------------|
| Prepared | MUSONZA MT Scientist: NLS/RAC | |
| Reviewed | KHAKA AS Section Head: NLS/RAC | |
| Reviewed | RAMATLHAPE I Scientist: RAC | |
| Reviewed | MATHIBE C Chief Scientist: CTS | |
| Recommended | MOALOSI EN Manager: RAC | |
| Approved | MOFOKENG A Acting Senior Manager: NLS/NOAM | |

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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 service 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 a 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 meets the technical specification, installation acceptance and testing criteria, commissioning and licensing of the radiation dosimetry unit and the associated software, the environmental operating conditions, as well as the after-sales services that are summarised 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 the required products and services specification document.

2.2 Dosimetry system components

Necsa Laboratory Services wants to procure a Dosimetry instrumentation system 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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The 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 upgradeable to a higher loading capacity to accommodate potential increases in the demand for the service.

This must include the software for operating the irradiator, and it must meet the requirements for radiation protection safety standards.

The technical specifications and performance requirements are summarised in Appendix A, Section 4.2.1 and 4.2.2.

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 the algorithm according to the customer's needs when required. The software must include a bar code reader for a dosimeter or be able to read in binary numbers.

The system needs 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, materials 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 by applicable period, meaning (1) number required at start, (2) number required on a monthly basis and lastly (3) on an annual basis. Further indications of the technical and performance requirements and provided in Appendix A.

2.5 Installation, calibrations and validation testing

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

2.6. Warranties, guarantees and performance

The supplier must provide a clear description of the nature of the standard warranty of instrumentation and equipment, as well as a description of the supplier's return Policy.

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 summarised in Appendix A of the scope of work and technical specification document. The documents can be submitted in person, by email or by post.

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4. APPENDIX A: TECHNICAL REQUIREMENTS QUESTIONNAIRE TABLE

4.1 Format of the response 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 parts 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, will be counted as “NO”. The first section of the questionnaire is weighing 50% meaning the score obtained here will be awarded 50% thereof. The 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 | Photons and Beta: 0.05 mSv to 10 Sv; Neutrons: 0.2 mSv to 1 Sv | |
| 4.2.1.2 | System upgrade | The system is upgradable in terms of throughput and includes an 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 response (mean energy) | Photons: 16 keV to 1250 keV; Beta: 680 keV to 2284 keV; Neutrons: 40 keV to 5000 keV | |
| 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) | |
| 4.2.1.9 | Linearity response | 0.05 mSv to 10 Sv: Standard deviation < 5% | |
| 4.2.1.10 | Measurement reproducibility | < 5% | |
| 4.2.1.11 | Angular response | Photons: $\pm 60^\circ$ from 16 keV; Beta: $\pm 45^\circ$ from 250 keV | |
| 4.2.1.12 | Angular dependency | Average deviation < 6 % | |

4.2.2 System management software [built-in into 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 | |
| | | 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) | |

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| 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 can access the system (via a software application) remotely to assist the 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. | |
| 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 results 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. | |

4.3 Quality and compliance requirements [25%]

| # Entry | Description of the requirements | Responses (YES/NO) |
|---------|---|--------------------|
| 4.3.1 | The supplier has a certified quality management system issued by an accredited certification body. Copies of valid certificates to be provided as supporting documentation. | |
| 4.3.2 | The supplier must confirm that the dosimeter complies with the requirements IEC 61508 (Functional Safety of Electrical/ Electronic/ Programmable Electronic Safety-related Systems) and IEC's Electromagnetic Compatibility (EMC) requirements. Supporting document to be provided. | |
| 4.3.3 | The supplier will assist the end-user with local dosimetry operational required manufacturer paper (when required for authentication purposes by SAHPRA and the DOH). | |

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| # Entry | Description of the requirements | Responses (YES/NO) |
|---------|---|--------------------|
| 4.3.4 | 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 an abbreviated CV as a supporting document | |
| 4.3.5 | If not the OEM, the 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. | |
| 4.3.6 | 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. | |
| 4.3.7 | Office management configuration (also referred to as Laboratory Management System): | |
| 4.3.8 | Badge receiving, reading, annealing, assignment, labelling and archiving. The software must be upgradable. Data reviewing and reporting | |
| 4.3.10 | Able to install and Commission the system on the Necsa site such that it is ready for commercialization | |
| 4.3.11 | Able to provide training for technicians, scientists and management on the operation of the system. | |
| 4.3.12 | Able to provide written guidance and assist with system calibration and validation data sets needed for ISO 17025 accreditation, as well as inter-lab comparison tests. | |
| 4.3.13 | Able to provide after -sales support and associated warranties aligned to the defined scope of work | |

5. ANNEXURE B – Dose range

Usage categories of dosimeters

| | | | |
|--|--|--|--------------------|
| | | | Optional extension |
|--|--|--|--------------------|

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| Main Category | Symbol | Mandatory range of use | for the energy range for the energy range | for the lower limit of the dose range | for the upper limit of the dose range |
|---------------------------------|---------------|---|---|---------------------------------------|---------------------------------------|
| $H_p(10)$ Photon radiation | (Gamma) | 80 keV to 1,25 MeV ^a 0,1 mSv to 1 Sv ^b | m (mid): lower limit 60 keV l (low): lower limit 20 keV h (high): includes 7 MeV | f: lower limit 0,01 mSv | a (accident): upper limit 10 Sv |
| $H^*(10)$ Photon radiation | (environment) | 80 keV to 1,25 MeV ^a 0,1 mSv to 1 Sv ^b | m (mid): lower limit 60 keV l (low): lower limit 20 keV h (high): includes 7 MeV | f: lower limit 0,01 mSv | A (accident): upper limit 10 Sv |
| $H_p(0,07)$ photon radiation | (Skin) | 30 keV to 250 keV 1 mSv to 10 Sv ^b | l : lower limit 20 keV n: lower limit 15 keV | g: lower limit 0,1 mSv | |
| $H_p(0,07)$ beta radiation | (beta) | 0,8 MeV (E mean) ^a 1 mSv to 10 Sv b | l : lower limit 60 keV (E mean) | g: lower limit 0,1 mSv | |

^a Mandatory energy range

^b Mandatory measuring range

Example 1: A personal photon dosimeter for a nuclear plant may be classified as Gmh.

Example 2: An environmental photon dosimeter for a location near a nuclear plant may be classified as Emhf.

Example 3: A personal photon-beta dosimeter for medical use may be classified as Sng-Blg.

6. ANNEXURE C – Energy range

| Measuring quantity | Mandatory energy range for photon radiation | Maximum energy range for testing photon radiation | Mandatory energy range for beta-particle radiation ^a | Maximum energy for testing beta-particle radiation ^a |
|-----------------------|---|---|---|--|
| $H_p(10), H^*(10)$ | 80 keV to 1,25 MeV | 12 keV to 10 MeV | - | - |
| $H_p(3)$ | 30 keV to 250 keV | 8 keV to 10 MeV | 0,8 MeV almost equivalent to an E_{max} of 2,27 MeV | 0,7 MeV to 1,2 MeV almost equivalent to E_{max} from 2,27 MeV to 3,54 MeV |
| $H_p(0,07), H'(0,07)$ | 30 keV to 250 keV | 8 keV to 10 MeV | 0,8 MeV almost equivalent to an E_{max} of 2,27 MeV | 0,06 MeV ^c to 1,2 MeV almost equivalent to E_{max} from 0,225 MeV to 3,54 MeV |

^a The following beta radiation sources are suggested for the different mean energies: For 0,06 MeV: 147Pm; for 0,8 MeV: 90Sr/90Y; for 1,2 MeV: 106Ru/106Rh.

^b For beta-particle radiation, an energy of 0,7 MeV is required to reach the radiation-sensitive layers of the eye lens in a depth of about 3 mm (approximately 3 mm of ICRU tissue).

^c For beta-particle radiation, an energy of 0,07 MeV is required to penetrate the dead layer of skin of 0,07 mm (approximately 0,07 mm of ICRU tissue).