TECHNICAL SPECIFICATION FOR REQUEST FOR INFORMATION (RFI) FOR THE ESTABLISHMENT OF A DOSIMETRY LABORATORY FOR INDIVIDUALS, WORKPLACE AND ENVIRONMENTAL MONITORING

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1. BACKGROUND

Necsa labs intends expanding its scope of offering by adding a state of the art dosimetry laboratory based on the latest technology. The main aim of this Request for Information (RFI) is to solicit quotations and proposals for the (1) demonstration of a fully functional system, (2) Supply of all relevant equipment, instrumentation, software and accessories, (3) Installation, testing and validations and (4) commissioning, training and after sale support of a fully functional Dosimetry Laboratory. The outcome of this RFI will be used by Necsa to determine how to proceed with the process of establishing a potential contract. This process might lead to an open or closed tender engagement. These technical specifications are very prescriptive however interested potential service providers may propose alternatives that differ from these specifications but such alternatives must be in line with intended purpose or produce better results. In such cases the respondent must clearly state such deviation and further provide justification in the proposal.

As an add-on to the above requested service, interested service providers will have also to acquire, supply and install equipment for analysis of passive radon dosimeters.

2. SCOPE CLARIFICATION

2.1 Demonstration of a Fully Functional System

This task involves the following actions:

a) Meeting requirement to supply, install acceptance testing commissioning and licensing of two radiation dosimetry monitoring units.

b) Taking a team of four Necsa experts into a site where there is a fully functioning system to demonstrate its functionalities.

c) Provide Necsa with dosimeters from a fully functioning lab for deployment at Necsa for a 30 day period, retrieval of such dosimeters, analysis thereof and provision of the results or proficiency test results.

2.2 Supply of all Relevant Equipment, Instrumentation and Accessories

The task involves the following actions:

a) Quantification, acquiring and supply of all necessary equipment, instrumentation and accessories required for the lab to be fully functional from the manufacture site to Necsa site.

b) Action also includes securing any documentation for the transportation of equipment from OEM site to Necsa site.

2.3 Installation, Testing, Calibrations and Validations

The task involves the following actions:

a) Performing equipment installation, testing it and executing and or supplying all necessary validations/tests in accordance with applicable accreditation requirements such as those of ISO 17025.
b) Participation of Necsa technicians and scientist during installation, testing and validation as a form of skills transfer.
c) Possible onsite infrastructure modifications, electrical, plumbing and air conditioning (hence need for pre-site inspection).

2.4 Commissioning, Training and After-Sale-Support

The task involves the following actions:

a) Commissioning the system such that it is ready for commercialisation.
b) Training technicians, scientist and management on daily operation of the system preferable at OEM facility or Necsa.
c) Conclusion of a binding agreement with respect to after sale support.

3. PROJECT REQUIREMENTS

The following are the requirements for the project:

3.1 General Requirements

a) The interested service provider must have a person registered/recognised as a Radiation Protection Specialist (RPS)/Medical Health Physicists by the relevant certification body such South African Radiation Protection Association or Health Professions Council of South Africa (HPCSA), South African Council for Natural Scientific Professions or equivalent competent regulatory body.

b) The Key staff of the interested service provider (i.e. Project Manager) must have a minimum of 10 Years of work experience in the field of Radiation Protection or Medical Health Physicists.

c) The Response to this RFI to be broken down to clearly indicate cost per project component shown in 2.1 to 2.4.

d) The Response to the RFI must indicate project time frames from start to finish.

e) Interested service providers are required to prepare a formal response following the format attached in Appendix 1 of this document.

f) Interested service provider must have a certified ISO 9001 Quality Management System or equivalent.

g) If not the OEM, interested service provider must provide a certificate or letter of authorisation being a sole supplier or distributer in South Africa which should outline the extent of authorisation (should not only be sales but should include technical services and application).

h) If not OEM, interested service provider must sought a confirmation letter from the OEM that in case the appointed distributer 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 "after sale support" during the period of non-availability of a local service provider of their product.

i) Proposed service level agreement for after sale support for a duration of three years (36 months) with a provision to engage in negotiations and consideration for renewal and with clear costing for each year.

j) Revenue model proved to be working profitable from existing users of the system.

k) Certificate of competency for the OEM technicians and those of the local service provider of the dosimetry system. If local technicians not currently certified, a programme of training with clear timeframes to be provided.

l) Interested service provider should be willing to make an oral presentation of his/her proposal to this RFI to Necsa at no cost to Necsa.

3.2 Technical Requirements

3.2.1 Dosimetry Performance/Desirable Dosimeter Properties

#	Parameter of interest	Expected Performance
1.	Dose Range	As per IEC 62387:2012 (Extended range) see **Appendix 4**
2.	Radiation Type	$H_p(10)$ 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
3.	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.	Dosimetry Services/Types of Dosimeters	Whole Body Dosimeter Extremity Dosimeter (Finger ring and/or wrist) Eye Dosimeter Environmental/Area Dosimeter
5.	Energy Range	Maximum Energy Range as per IEC 62387:2012 see **Appendix 5**.
6.	Minimum processing speed	High Volume Processing: Processing 500 Dosimeters in two and half hours. Low Volume Processing: Processing 50 Dosimeters in one hour.
7.	Minimum processing load	High Volume Processing Machine: 500 or more dosimeters in one load Low Volume Processing Machine: 100 dosimeters in one load
8.	Dosimeter life span	Minimum of 3 years life span or 12 use cycles
9.	Certification	Manufactured under ISO 9001 guidelines or any available standards and Dosimetry System accredited to IEC 62387:2012 or equivalent
10.	Dosimeter Packaging	Water and dust resistant
11.	Application/Industry	Medical Applications, Research Institutions, Safety & Security, Health Physics Applications, Mining Industry, Health Care, Universities, Laboratories, Veterinary, Dentists, Hospitals, X-Ray Technicians,
12.	Material	Lithium Fluoride, Calcium Fluoride, CaSO, LiBO, (LiF: Mg, Ti) or Silver activated phosphate glass ($AgPO_4$) or carbon-doped aluminium oxide (Al_2O_3:C) or equivalent
13.	Photon energy and angle of incidence	50 keV to 1,4 MeV and 0° to ± 60°
14.	Environmental Condition Tolerance range for dosimeters.	Ambient temperature should range between –15 °C to 50 °C or better Relative humidity should range between 40 % to 90 % RH or better Suitability for use in underground mining environment.
15.	Environmental Condition Tolerance range for readers.	Ambient temperature should range between +10 °C to +40 °C or better.

3.2.2 Dosimetry Instrumentation System Components

Necsa seeks to procure a Dosimetry instrumentation systems composed of elements such as detectors, readers, annealing, packaging, customer delivery & return, and storage, irradiation, readout and dose calculation. Specifications of these elements are detailed in the paragraphs below:

a) **Dosimeter detectors.** Dosimeter instrumentation measurement system should be empowered by fairly well known and reputable form of detectors in the field of Radiation Protection/Safety such as Lithium Fluoride or Calcium Fluoride, etc.

b) **High volume dosimeter card reader/machine** for automatic processing of dosimeter cards and single dosimeter chips for personal dosimetry, and environmental monitoring. The system should be simple to operate and easy to maintain with little or no need to have highly trained service personnel needed. Additional, the system should have a built-in self-diagnostics capability (to guarantee high measurement stability).

c) **Semi-Automatic Dosimeter Reading Machine (Low volume reader).** An additional reading machine is required as a back-up to the main one referred to in (b) above.

d) **Irradiator Machine** for irradiation of dosimeters with radiation source inside as (^{137}Cs). Irradiation of single elements or dosimeter cards. Programmable delivered dose by repeated irradiations. This will includes the software for operating irradiator. The irradiator must meet the requirements for radiation protection safety standards.

e) **Packaging and Labelling:** Means for sealing and labelling dosimeter in pouch or holder recommended by OEM supplier. Preferably, sealing and labelling should be automated.

f) **Software:** The service provider or manufacture must provide full required software to operate the system as one package. The software must have a provision to allow the end user or manufacturing 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.

g) **Quality Control Software:** QC software part of software package and calibration software.

h) **Backup Server:** Standards back up which can be integrated with Necsa serve.

i) **Operating Windows:** Window 7 or latest with windows

3.2.3 Laboratory Equipment

The system shall consist of:

No.	Item Name
1	Dosimeter dispensing cabinet
2	Cabinet suitable for Chest dosimeters
3	Cabinet suitable for Wrist dosimeters
4	Dosimeter preparation work station long table
5	Slot dimension to accommodate dosimeter cassette
6	RFID card reading processing time
7	Dosimeter dispensing time
8	Battery backup
9	Water phantom or slab phantom

3.2.4 System Management Software

System Management Software shall be supplied along with the dosimeter processing system and shall have the following features:

a) Provide real-time tracking of dosimeter badge as well as report on dosimeter not used, dosimeter not returned and dosimeter over used.

b) Maintains master register for dosimeters and Employees details such as employee name, employer name, employee exposure, employee No. with an option to add or delete or edit details contained in the register. The system must be able to allocate a unique identification number for registered radiation workers. The processed results must automatically store or allocated to the identification number assigned to radiation workers.

c) 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 finger prints for authentication of users.

d) The system must provide for internet connectivity and allow download of information from the system to the typical Microsoft applications such as Excel or Word, etc.

e) Special printer for radiation badge to print wearer's name plus serial number as well as barcode for easy traceability or any other information that the lab or lab customer might want it to be added to the badge.

f) PC or PCs to run automation for the entire dosimetry system.

g) The system should control dosimeter access, track when a dosimeter is picked up and returned and it should automatically record these transactions.

h) Occupational Health Information System/Dose Register System to keep doses of personnel for different customers for 40 years from date of de-registration.

i) System integration into existing related systems at Necsa such as LIMS and CRM.

j) Provision for both LAN and Wi-Fi connection to internet.

3.2.5 Accessories, Material and Consumables

Interested service provider must provide a list of all necessary accessories, materials and consumables required in order 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.

3.3 Warranties, Guaranties and Performance

a) Description of the nature of standard warranty of instrumentation and equipment.

b) Annual costs for extended warranty

c) Description of OEM return Policy.

d) Description of guarantees of continuous supply of consumables by OEM with or without the certified local supplier or distributer.

e) Description of previous successful installations projects including list of names of end-users, contact numbers, address and project amounts and size of the project.

f) Interested service provider must have executed successfully at least three orders of same or larger magnitude than this in the last 3 to 5 years locally or internationally.

3.4 Quality and Compliance Requirements

a) The Equipment shall be manufactured, packed and shipped in accordance with the Supplier's ISO9001 and ISO 13485 (or equivalent) quality assurance system.

b) The Equipment shall comply with the requirement IEC 61508 (Functional Safety of Electrical/ Electronic/ Programmable Electronic Safety-related Systems) IEC's Electromagnetic Compatibility (EMCI) requirements.

c) Where appropriate, all the items shall have compatible signals and common construction to simplify installation, operation, and maintenance.

d) The equipment shall have all safety markings and operating instructions in the English language.

e) The equipment shall be packed in accordance with Medical Devices Regulations or equivalent international standards applicable for the shipment of this kind of equipment to the User.

f) Inspection reports conducted by third party on functionality of the system.

g) Consideration and fulfilment of any applicable requirements for SAHPRA, NNR or any other relevant regulatory body.

h) The system must meet the criteria for proficiency Testing Scheme according to ISO 14146 requirements or meet criteria and requirements for any recognised standards such as ANSI 13.11.2009 etc.

i) The system must demonstrate the capabilities to pass the proficiency testing scheme conducted by any of the following with any of the following primary laboratories such as BIPM, NIST, NPL, PTB etc. or recognise laboratories.

3.5 Requirements for Additional Dosimetry System (Radon Dosimetry)

The equipment's required are as follows (this component can be outsourced if necessary):

a) Five micro scoping scanners each connected with computer

b) Software for operating the micro scope scanners

c) Puncher machine

d) Printer machine connecting to all five computers

e) Table with the following approximate dimension 0.9M by 3 M

f) Oven for boiling water

g) 500 passive detectors

h) Storage for passive detectors

i) Computer with software to enable processing, storage and displaying of data from the system and also keep an occupational dose register for all our customers for a period 40 years from the date of deregistration from our dosimetry system.

4 TERMS AND CONDITIONS

a) The supplier should install the equipment at user site, B-C-5 Building at Necsa and hand-over properly functioning system.

b) Pre-site inspection assessment shall be a requirement for prospective bidders/suppliers to ensure costing for possible infrastructure modifications in the proposal.

c) Hard copy as well as soft copy of detailed instruction, operation and maintenance manuals shall be supplied with the system and must be in English.

d) Any deviation in the quotation for the above-mentioned technical specifications must be clearly indicated.

e) Excellent quality material & workmanship shall be ensured.

f) The system management software should be provided on CD/DVD or means be made for the user to download it from the OEM's website at no additional cost.

g) Interested service provider must provide on-site training on the system.

5. ACCEPTANCE CRITERIA

The system will be accepted based on successful demonstration of intended functions of the system and satisfactory performance for one month from the date of installation.

5. APPENDICES

5.1 Appendix 1: Format for Response

a) Company overview/Profile

b) Competency Profile

c) Problem statement (Understanding of the Client Request)

d) Solution proposal to Customer Request

e) Costing and Timelines

f) References

g) Critical success factors

h) Contact details

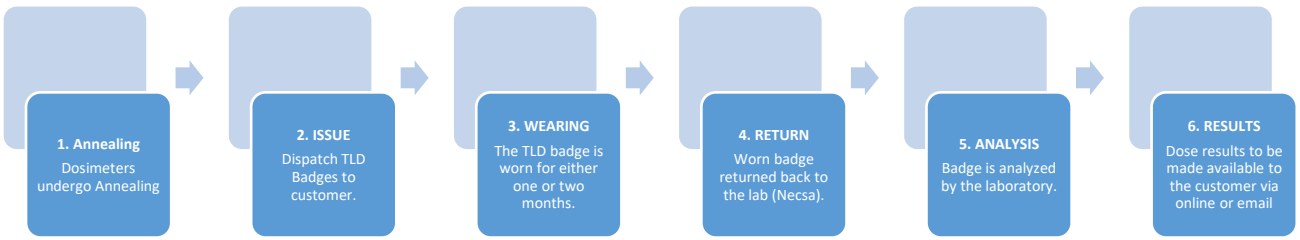
i) Additional Information

j) Appendices

- **Annexure 1**: Copies of Company Registration certificate, BBB-EE certificate, Tax Clearance Certificate, proof of registration into Treasury Central Database, certificate of qualifications for key personnel for project implementation
- **Annexure 2**: A table where interested service provider respond with a yes or no to each requirement listed from section 3 and 4.

5.2 Appendix 2: Process Flow Diagram

The anticipated process flow diagram for the dosimetry system to be delivered at Necsa is as follows:



5.3 Appendix 3: Floor Plans

Interested Service providers are welcome to make an appointment to view the facility where the two proposed dosimetry services will be located.

5.4 Appendix 4: Usage categories of passive dosimeters

Main Category	Symbol	Mandatory range of use	Optional extension		
			for energy range	for lower limit of dose range	for upper limit of dose range
$H_p(10)$ Photon radiation	G (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	E (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
Hp(0,07) photon radiation	S (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	
Hp(0,07) beta radiation	B (beta)	0,8 MeV (Emean) [a] 1 mSv to 10 Sv b	**l**: lower limit 60 keV (Emean)	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.

5.5 Appendix 5: Mandatory and maximum energy ranges covered by the standard

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]
Hp(10), H*(10)	80 keV to 1,25 MeV	12 keV to 10 MeV	-	-
Hp(3)	30 keV to 250 keV	8 keV to 10 MeV	0,8 MeV almost equivalent to an Emax of 2,27 MeV	0,7 MeVb to 1,2 MeV almost equivalent to Emax 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 source 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).