

Document Title	Technical Specification: Radio-TLC Imaging Scanner and Radio-chromatography Software
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APPROVAL & DISTRIBUTION

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1 BACKGROUND

This specification describes the technical requirements for a radio-TLC imaging scanner and radio-chromatography software used for the certification of molybdenum-99 in the RadioAnalysis laboratory (hereinafter referred as the “system”).

The main aim of this BID is to solicit quotations and proposals for the (1) Demonstration of a fully functional system, (2) Supply of all relevant instrumentation, software and accessories, (3) Installation and testing and (4) Training and After sales support (Maintenance plan). The outcome of this BID will be used by Necsa to determine how to proceed with the process of establishing a potential contract. The Service Provider will be evaluated based on compliance to specification for the required instrument. 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.

2 SCOPE CLARIFICATION

2.1 Testing and Acceptance for fully functional system

This task involves the following actions:

- Meeting requirement to supply, install, acceptance testing.
- Factory Acceptance Test (FAT): The system, prior to shipment, shall be tested for conformance with manufacturer’s performance specifications and the minimum requirements specified herein.

2.2 Supply of all relevant instrumentation and accessories


This task involves the following actions:

- Acquiring and supply of all necessary equipment, instrumentation and accessories required for the full functioning of the system from the manufacturer site to Necsa site
- Securing any documentation for the transportation of equipment from manufacturer’s site to Necsa site.

2.3 Installation, testing and verification

This task involves the following actions:

- Performing equipment installation, testing it and executing and or supplying all necessary verifications/tests in accordance with applicable accreditation requirements such as those of ISO 17025.
- Install the system such that it is in a functioning condition ready for commissioning.
- Participation of Necsa technicians and scientist during installation, testing and verification as a form of skills transfer.
- Possible onsite infrastructure modifications, electrical, plumbing and air conditioning (hence need for pre-site inspection).
- The Service Provider shall ensure that all required materials are available before attempting installation.
- The Service Provider shall install the System at Necsa.
- On-site acceptance test (SAT): The System, after installation, shall be tested by the Service Provider together with Necsa personnel to demonstrate that the performance meets the manufacturer’s performance specifications and the minimum requirements specified by the End-user.

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- h) The results of the testing of the system shall be documented by the Service Provider in an acceptance protocol that shall be signed by the end-user.

2.4 Training and After-sales support

This task involves the following actions:

- The Service Provider shall provide training to Necsa personnel with daily operation of the System, immediately after installation.
- Onsite training at the Necsa facility on troubleshooting and preventative maintenance required for daily operation.
- Conclusion of a binding agreement with respect to after sale support and Maintenance Plan. The supplier must have technical knowledge to advise and assist with support.
- The Service Provider shall provide a complete set of operation and servicing manuals and technical drawings in the English language.
- The Service Provider shall identify support contacts.

3 PROJECT REQUIREMENTS

3.1 General requirements

This task involves the following actions:


- The key staff of the interested service provider (i.e. Project Manager) must have a minimum of 10 Years of work experience in radio-analytical instrumentation (Nuclear analytical) and technical knowledge of operation of the instruments.
- The response to this BID must indicate project time frames from start to finish.
- Interested service provider must have a certified ISO 9001 Quality Management System or equivalent.
- Interested service provider must provide a certificate or letter of authorisation being a sole supplier or distributor in South Africa which should outline the extent of authorisation (should not only be sales but should include technical services and application).
- 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.
- Certificate of competency for the supplier technicians and those of the local service provider of the instrumentation system. If local technicians not currently certified, a programme of training with clear timeframes to be provided.
- Interested service provider should be willing to make an oral presentation of his/her proposal to this BID to Necsa at no cost to Necsa.

3.2 Technical requirements

Performance specifications of the Imaging Scanner are indicated in Table 1:

Table 1: Performance Specifications and requirements

Parameter	Expected Performance
Sensitivity (10 min analysis)	100 to 1000 dpm
Resolution	0.5 to 3 mm
Linearity	± 1 mm
Background	Less than 0.15 cpm per mm
Software	100% GMP compliant
Power	220 V / 50 Hz

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Gas supply	P10 counting gas regulated to 20-30 psi
PC Requirements	Windows 10 Pro 64Bit, I5.I7 processor, 4GB me 250 GB HDD/SSD, 15" full HD non-touch disp USB ports

** Refer Appendix 1 for completion of checklist*

3.3 Instrument system components

Necsa seeks to procure a radio-TLC imaging scanner to be used for certification of the radiochemical purity of the molybdenum-99 produced at NTP. Specifications of the required system are detailed in the paragraph below:

The system shall meet the following functional and technical requirements:

- a) **Performance specifications:** The system shall achieve the minimum performance as indicated in Table 1. This shall be confirmed by QC tests before shipment and installation.
- b) **Number of TLC plates:** The system should be able to accept one TLC plate.
- c) **Control of system:** Easy to use instrument control.
- d) **Technical requirements:** The system shall be supplied with:
 - A calibration plate,
 - P-10 gas regulator,
 - A high resolution collimator,
 - A high efficiency collimator,
 - Built-in sample changer,
- e) **Computer:** See Table 1
- f) **Software:** See 3.4
- g) **Uninterruptable power supply:** Sufficient to operate the system for 5-10 minutes in the event of power failure.

3.4 System Management Software

System Management Software shall be supplied along with the instrument and shall have the following features:


- a) Automatic execution of workflows e.g. full processes of measurement, evaluation and quality control.
- b) Automatic generation of a report which cannot be changed by the user.
- c) Built-in user management and access protection in compliance with GMP standards.
- d) The software will be installed on a fully functioning desktop computer sourced through the Necsa IT department, which complies with the specifications as indicated in Table 1.

3.5 Accessories, Materials and Consumables

Interested service provider must provide a list of all necessary critical components, accessories, materials and consumables required in order for the systems to be functional and productive

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

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- f) The Service Provider shall supply the System with a comprehensive warranty, valid for one (1) year from the date of signing the acceptance protocol by the end-user.
- g) The Service Provider shall clearly note the manufacturer's guarantee conditions, the preventive and corrective maintenance contract to ensure continuous operation of the System.
- h) The Service Provider shall provide two (2) years of support.

3.7 Quality and Compliance Requirements

- a) The System, for shipment to NECSA, shall be packed in accordance with international standards applicable for the shipment of this kind of equipment.
- b) The System shall be manufactured, shipped and installed in accordance with the Service Providers' ISO quality assurance system or an equivalent quality system. The Service Provider shall document the compliance with this quality assurance system.
- c) The equipment shall have all safety markings and operating instructions in the English language.

4 TERMS AND CONDITIONS

4.1 General requirements


- a) The supplier should install the equipment at user site, Building P1600 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 suppliers' 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.

6 APPENDICES

Please confirm the specifications of the quoted system by completing the checklist below. Please respond with **YES/NO** in the Compliance column.

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APPENDIX 1 : Technical Specification Radio-TLC Imaging Scanner and Radio-chromatography Software

Company		
Instrument Model		
Parameter	Specification	Compliance (YES/NO)
1. Performance specifications		
Sensitivity (10 min analysis)	100 to 1000 dpm	
Resolution	0.5 to 3 mm	
Linearity	± 1 mm	
Background	Less than 0.15 cpm per mm	
2. System requirements		
Power	220 V / 50 Hz	
Gas supply	P10 counting gas regulator to 20-30 psi	
Number of TLC plates accepted	One	
Calibration plate	Included	
Collimator	High resolution, High efficiency	
Sample changer	Built-in	
3. Software		
Workflow executions	Measurement, evaluation and quality control	
GMP compliant	User management and access protection	
Life time license	Included	
4. PC requirements		
Operating system	Windows 10 Pro or latest	
Processor	I5, 2.66 GHz or faster, 32 or 64 bit dual core	
RAM	4GB or more	
Hard drive	250 GB, HDD/SSD,	
Display	15" full HD, non-touch	
USB	3 USB ports (mouse, USB-software adaptor, USB dongle)	
Connection	LAN or WIFI	