PRESOLICITATION NOTICE

Notice ID: NOI-FDA-132749

Subject: Annual Maintenance of the TESCAN Mira 3 Cryo SEM

SECTION 1 – IDENTIFICATION AND CLASSIFICATION CODES

Contracting Office: U.S. Food and Drug Administration, Office of Acquisitions and Grants Services (OAGS), CDER Acquisition Branch

NAICS Code: 334516 – Analytical Laboratory Instrument Manufacturing

Product Service Code (PSC): J065 (Maintenance/Repair of Equipment)

SECTION 2 – SET-ASIDE STATUS

A determination has been made by the Contracting Officer that competition to the maximum extent practicable is not feasible because only one source is reasonably available, consistent with RFO 12.201-1(c) and RFO 13.101(b). The intended award is single-source to Tescan USA, Inc., as the original equipment manufacturer (OEM).

All responsible sources that believe they can fully satisfy this requirement are invited to submit a capability statement. See Section 5 for details.

SECTION 3 – DESCRIPTION OF REQUIREMENT

Per RFO 5.101(c)(4)(i), the following description is provided to allow prospective sources to make an informed business judgment about this requirement.

The overall objective of the requirement is to establish a base and four option years maintenance award for the TESCAN SEM. The goal of the SEM service contract is to ensure timely service upon equipment malfunction and also timely preventive maintenance to manage overall operating costs for this equipment and preserve research project schedules. This is a renewal of a previous requirement.

The vendor will provide service coverage for the Mira-3 XMU and multiple components, some of which are In-beam SE detector, Motorozied Retractable Scintillator BSED (G3 and G4) etc.

The contractor provides all consumables needed for repairs and maintenance work.

SECTION 4 – INTENDED SOURCE AND BASIS FOR NONCOMPETITIVE ACTION

Pursuant to RFO 5.101(c)(4)(vii), the following identifies the intended source and explains why competition is not practicable for this requirement.

Intended Contractor:

Tescan USA, Inc.

765 Commonwealth Dr Ste 101

ALP: CDRH-2026-132749

Warrendale, Pennsylvania 15086

CAGE Code: 0FX68

The basis for limiting this solicitation to a single source is that only one source is reasonably available, consistent with RFO 13.101(b) and the single-source standard at RFO 12.201-1(c).

This procurement is to continue a service contract on the scanning electron microscope (SEM), TESCAN MIRA 3. This is a renewal of a previous requirement. A service contract has been in place for the TESCAN SEM in previous years. Timely service and preventive maintenance ensures this vital piece of equipment remains in operation.

Tescan has stated that it is the exclusive and sole North American representative for supplies, accessories and parts for its SEM's. It is the sole source provider of proprietary software necessary to operate or upgrade SEMs and it is the only authorized company providing certified engineers to service Tescan SEM's.

A written single-source justification has been prepared and approved in accordance with RFO 12.201-1(c) and RFO 13.101(b).

SECTION 5 – CONTRACT TYPE AND AWARD PROCEDURES

Per RFO 5.101(c)(4)(ii), the following describes the award procedures and anticipated award date for this action, which is valued above $25,000 but at or below the Simplified Acquisition Threshold (SAT).

Contract Type: Firm-Fixed-Price (FFP) Purchase Order

Procedures: Simplified acquisition procedures per RFO 12.201-1

Documentation: Award will be documented in accordance with RFO 12.204

SECTION 6 – SOURCES SOUGHT / CAPABILITY STATEMENTS

Pursuant to RFO 5.101(c)(4)(vi), all responsible sources that believe they can fully satisfy this requirement are invited to submit a capability statement or expression of interest.

Response Deadline: August 14, 2026, 10:00 AM Eastern Time

Submit to:

Contract Specialist, Aarati Singal at Aarati.Singal@fda.hhs.gov and

Contracting Officer, Sarah Hussain at Sarah.Hussain@fda.hhs.gov

Capability statements must address, at a minimum:

- Authorization status from Tescan USA, Inc. to distribute and service any MIRA 3 technology and its associated compatible components.
- Relevant prior contract performance: contract numbers, agency points of contact, dollar values, and period of performance.

Responses will be used solely to assess whether a competitive procurement is practicable. The Government will consider all capability statements received by the response deadline. A determination not to compete based on information received is solely within the discretion of the Government.

Capability statements submitted in response to this notice are not offers and cannot be accepted to form a binding contract. The Government is not obligated to issue a solicitation or award a contract as a result of this notice.

No phone calls will be accepted. All inquiries must be submitted in writing to the contracting officer.

SECTION 7 – QUALIFICATION REQUIREMENTS

Per RFO 5.101(c)(4)(viii), offerors are advised that award of a contract under this requirement is conditioned on the contractor's ability to demonstrate authorization from Tescan USA to perform modifications, installation, commissioning, and qualification of the subject equipment. Offerors lacking such authorization will not be considered responsible sources for this requirement.