

1. **Contracting Office Address: 10903 New Hampshire Ave, WO62 RM 4215, Silver Spring, MD, 20993**
2. **Solicitation Number: 75F401-24-Q- 1279135**
3. **Subject: Custom fabricated phantom for Breast CT**
4. **Classification Code: 6640**
5. **NAICS Code: 334516**
6. **Response Date: 7/31/2024 at 11:59PM EDT** due via email to the Primary Point of Contact listed in the sam.gov webpage for this combined synopsis-solicitation.
7. **Description:**

(i) Disclaimer: This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in FAR Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; proposals are being requested and a written solicitation will not be issued.

The overall objective of the requirement is to procure an anthropomorphic breast phantom that will allow Food and Drug Administration (FDA) researchers to develop and compare new methods for testing performance for breast CT systems. The end result of this requirement if the contract is successful will be the development of new approaches for objectively assessing image quality of breast CT systems. These new testing methods could potentially reduce the burden of sponsors that submit new technology to the FDA for approval and accelerate the introduction of new breast imaging products to the general public. New testing methods will be published as an OSEL regulatory science tool.

(ii) This acquisition is issued as a **Request for Quote (RFQ)**.

(iii) The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular 2024-05

(iv) For purposes of this acquisition, the associated NAICS code is 334516. The small business size standard is 1,000 employees. This action is being solicited as a sole source.

(v) Line-Item Structure: The following is a list of line-item number(s) and items, quantities and units of measure, (including option(s), if applicable) and should be reflected in the Offeror's quote/proposal:

Line Item 0001: Custom fabricated phantom for Breast CT

(vi) Specifications/Requirement: The contractor shall provide:

Fabricated anthropomorphic breast CT phantoms to evaluate dedicated breast CT systems.

Salient characteristics of the desired breast CT phantom are that they have anthropomorphic uncompressed breast structure and accurately model the structure of real breast tissue and x-ray attenuation properties of different tissue types.

The set of contrast mammography phantoms must include:

- Anthropomorphic breast background structure as specified by a virtual digital breast phantom that will be supplied by the FDA in their Github site (<https://github.com/breast-CT-phantom/>)
- The phantom containing material that mimics x-ray attenuation properties of fibroglandular tissue, adipose tissue and skin over the energies typically used in breast CT imaging (for example, a 60 kilovolt (kV) x-ray spectrum).
- The base material of the phantom should be composed of at least 80% Cellulose-Polymer composite.
- Phantom resolution in the x,y direction (parallel to chest wall in the prone position) $\leq 200 \mu\text{m}$
- Phantom resolution in the z direction (chest to nipple) must be $\leq 100 \mu\text{m}$
- At least two replaceable slabs that can be inserted into the center portion of the breast phantom and that contain numerous (>10) mass lesions per slab. These slabs will be specified by a virtual digital slab phantom supplied by the FDA in their Github site.
- The phantom slabs in the prone position must be held together tightly by a magnetic mount.
- Product description and specification

(vii) Delivery: Delivery is required by 90 days after award. Delivery shall be made to:

POC: To be identified at time of award.

FDA White Oak campus

10903 New Hampshire Avenue

WO62 RM 4215

Silver Spring, Maryland 20993

Acceptance shall be performed at the delivery locations. The FOB point is DESTINATION.

(viii) The provision at 52.212-1, Instructions to Offerors – Commercial DEVIATION 2018-O0018, applies to this acquisition. The following addenda have been attached to this provision:

In addition to the requirements set for the in FAR 52.212-1, all offers responding to this solicitation must provide their business size in relation to the NAICS code contained in this solicitation and shall identify any socioeconomic categories to which they belong.

(ix) Evaluation Criteria - The specific evaluation criteria to be used are as follows:

Lowest Price Technically Acceptable

(x) Offerors shall include a completed copy of the provision at FAR 52.212-3 (with its Alternate I), Offeror Representations with its offer.

(xi) The clause at 52.212-4, Contract Terms and Conditions - Commercial Items, applies to this acquisition. The following addenda have been attached to this clause.

(xii) The clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders - Commercial Items applies to this acquisition. The following additional FAR clauses cited in this clause are applicable:

52.204-10 REPORTING EXECUTIVE COMPENSATION AND FIRST-TIER SUBCONTRACT AWARDS (JUN 2020)

52.209-6 PROTECTING THE GOVERNMENT' INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT (NOV 2021)

52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (FEB 2024)

52.222-3 CONVICT LABOR (JUN 2003)

52.222-19 CHILD LABOR--COOPERATION WITH AUTHORITIES AND REMEDIES (FEB 2024)

52.222-21 PROHIBITION OF SEGREGATED FACILITIES (APR 2015)

52.222-26 EQUAL OPPORTUNITY (SEP 2016)

52.222-35 EQUAL OPPORTUNITY FOR VETERANS (JUN 2020)

52.222-36 EQUAL OPPORTUNITY FOR WORKERS WITH DISABILITIES (JUN 2020)

52.222-37 EMPLOYMENT REPORTS ON SPECIAL DISABLED VETERANS, VETERANS OF THE VIETNAM ERA, AND OTHER ELIGIBLE VETERANS (JUN 2020)

52.222-50 COMBATING TRAFFICKING IN PERSONS (NOV 2021)

52.225-5 TRADE AGREEMENTS (NOV 2023)

52.225-13 RESTRICTIONS ON CERTAIN FOREIGN PURCHASES (FEB 2021)

52.232-33 PAYMENT BY ELECTRONIC FUNDS TRANSFER—CENTRAL CONTRACTOR REGISTRATION (OCT 2018)

(xiii) The following additional contract requirement(s) or terms and conditions apply:

52.204-7 SYSTEM FOR AWARD MANAGEMENT (OCT 2018)

52.204-13 SYSTEM FOR AWARD MANAGEMENT MAINTENANCE (OCT 2018)

52.204-16 COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING (JUL 2016)

52.204-18 COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE (JUL 2016)

52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

52.232-40 PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS
SUBCONTRACTORS (DEC 2013)

353.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations
(Dec 15)

252.239-73 **Electronic and Information Technology Accessibility Notice (Dec 15)**

(xiv) This acquisition is rated under the Defense Priorities and Allocations System
(DPAS) as N/A

(xv) Date, Time, and Place offers are due: **Offers due via email to**
joshua.reid@fda.hhs.gov **no later than (NLT) 4:30 PM EST on 1 August 2024**

(xvi) Name and phone number of the Individual to Contact for Information Regarding the
Solicitation: **Joshua Reid, 954-271-9362**