Request for Proposal

Radiopharmacy Equipment

December 13, 2012

Important Dates

Pre-Proposal Questions Due (no later than):
3:00 p.m. EST on Wednesday - January 2, 2013

Deadline for Receipt of Proposals:
3:00 p.m. EST on Thursday – January 10, 2013

A VASCUPP Member Institution
Issued by
Procurement and Supplier Diversity Services
Charlottesville, Virginia
A. GENERAL INFORMATION

Request for Proposal ("RFP") Name: Radiopharmacy Equipment

RFP Number: #FF121312

Issue Date: December 13 2012

Brief Description: The University of Virginia ("University") and its Department of Radiology ("Radiology") seek a qualified firm or firms to provide radiopharmacy equipment related to the production of Positron Emission Tomography ("PET") imaging drugs.

Preproposal Questions: Any questions concerning this RFP must be sent via e-mail, to the buyer listed below, no later than 3:00 p.m. EST on Wednesday, January 2, 2013 in order to guarantee a timely response prior to the proposal due date.

Proposal Due Date: 3:00 p.m. EST on Thursday, January 10, 2013

Firms will send one original electronic copy their proposal(s), formatted in Microsoft ("MS") Word or as a Portable Document Format ("PDF") file, to the e-mail address listed in the contact information box below. Additionally, firms will also send one complete hard-copy version of their proposal(s) to the physical address listed in the contact information box below. The University reserves the right to reject proposals received after the stated due date and time.

Any trade secrets or proprietary information submitted with a proposal (original or copy) for which the firm seeks protection from public disclosure must be clearly identified by the specific page and section number in the proposal and accompanied by a suitable justification requesting non-disclosure.

Negotiations: Negotiations, with University identified finalists, will be held via e-mail beginning the week of January 21, 2013 (a date which is subject to adjustment by the University).

Expected Award Date(s): Beginning January 28, 2013

Term of Agreement: The University will determine independently whether the University will issue a one-time only Purchase Order ("PO") to the Selected Firm or enter into a long-term Agreement with the Selected Firm. In the event multiple Selected Firms are chosen, this determination could vary, at the University's sole discretion, on a Selected Firm by Selected Firm basis. That being said, the term of a resulting any Agreement(s) resulting from this RFP will be for five years, with the ability to renew on the same or similar terms and conditions, for two additional one-year periods if mutually agreeable to the University and the Selected Firm. The Selected Firm and the University will mutually agree at least 180 days prior to each renewal period whether to renew the terms of the Agreement.
This RFP has been posted on Procurement and Supplier Diversity Services web site for your convenience. Addenda and attachments are posted if issued. The RFP can be downloaded at this web site: [http://www.procurement.virginia.edu/pagerfp](http://www.procurement.virginia.edu/pagerfp). It is the firm’s responsibility to ensure that the latest version of the entire RFP and related links are reviewed prior to submission of a proposal. We encourage you to check the web site frequently for any changes prior to the due date. Call (434) 924-1346 if you have trouble accessing the RFP from the web. For questions about the content of the RFP, contact the buyer listed above. Additional information can be found on Procurement and Supplier Diversity Services web site: [http://www.procurement.virginia.edu](http://www.procurement.virginia.edu).

For ease of reference, each firm or individual receiving this RFP is referred to as a “firm” and the firm(s) and/or individual(s) selected to provide goods and services for the University is referred to as the “Selected Firm.” This RFP states the instructions for submitting proposals and the procedure and criteria by which a firm may be selected.

**B. SCOPE OF GOODS & SERVICES**

The University and its Department of Radiology seeks a qualified firm to provide equipment, consumables and on-going services (the "Goods and Services") as part of research related to the current Good Manufacturing Processes ("cGMP") production of PET imaging drugs for use in human research and clinical care. This equipment will augment already installed chemical synthesizers and minicells. The two main synthesizers are a Siemens General Nucleophilic Reactions Module/Liquid Chromotography Purification Module ("GN/LC") and an Eckert & Ziegler methyl iodide/triflate - Pharmedracer system.

1. **Equipment**
   The University seeks the following equipment with the following highly preferred specifications:
   a. **Hot cell:**
      - A hot cell for the safe, sterile handling of PET drugs in a manner that complies with United States Food and Drug Administration ("FDA") guidance for cGMP.
      - Two manipulator arms
      - Means to transfer product from hot cell to adjacent minicell
      - Space for a dose calibrator
b. Dose dispenser for final formulations under cGMP conditions.

c. Gas Chromatography ("GC"):
   • Auto-injector
   • Firms should provide pricing for both an on-column and a split/splitless system

d. High Performance Liquid Chromatography ("HPLC"):
   • Auto-injector
   • 4 solvent injector or dual-pump system
   • Should include appropriate detectors:
     ➢ For PET and Single Gamma Emission Tomography ("SPECT") isotopes
     ➢ Ultraviolet-Visible ("UV-VIS")
     ➢ Light scattering detector.
     ➢ Electrochemical detector.

e. Thin Layer Chromatography: To include a radiochromatogram scanner (or equivalent equipment that provides a radiochromatogram) that can be used to measure radioactivity distribution in the developed TLC plate.

f. Benchtop Mass Spectrometer: To include both the ability to interface to HPLC, but also the ability to run in stand-alone mode.

g. High-purity nitrogen gas generator

h. Endotoxin test equipment.

i. Light Obscuration Particle Counter.

j. Sterility set up: To include incubator, temp monitoring, membrane filter integrity test equipment along with necessary supplies.

k. Gamma counter and a radioHPLC for metabolite analysis.

All equipment provided should include delivery and installation, training, defined warranty, Installation Qualification, Operational Qualification, Performance Qualification (validation of equipment — "IQ/OQ/PQ") documentation and drug master file (if available).

Firms may include one, some or all of the equipment listed in their proposal. However, all products should be listed separately in the #a thru #l order detailed above for ease of comparison.

2. Future Purchases

In the event that firms are interested in providing additional Goods and Services to the University and/or Radiology in the future, firms are encouraged to provide an appropriate discount schedule for those Goods and Services the firm would like to sell to the University in the future. These Goods and Services should encompass all goods and services the firm would like to sell to the University; including, but not limited to: the equipment detailed above, other equipment not included in this RFP, consumable supplies, parts, maintenance contracts/extended warranties and other goods and services offered by the firm.

While firms may format proposed discount schedules in any manner they choose, firms are encouraged to format their University pricing as a set discount percent off the manufacturer's suggested retail price (the "list price"). The methodology would facilitate incorporation into a
long-term Agreement. The list price may go up or down over time, but the set discount percent would remain constant throughout the term of the Agreement.

C. BASIS OF SELECTION

Proposals will be evaluated based upon the overall merits/value of the proposal including, but not limited to, price. The University will evaluate proposals, and if a firm is to be selected, select the firm on the basis of:

1. The firm's plan to provide the University with the Goods and Service as described in the Scope of Good and Services section along with the quality of the proposal; specifically, responsiveness to requirements and adequacy of information provided;
2. The firm’s experience in providing Goods and Services similar to those described in this RFP, to include the firm’s references from clients;
3. The firm’s financial proposal including, but not limited to: discounts, service charges, other charges or alternate financial models, and the contractual terms which would govern the relationship between the University and the Selected Firm.; and
4. The firm’s Small, Woman-owned and Minority-owned ("SWaM") businesses status and/or the firm’s plan for utilization of SWaM businesses. For more information about SWaM and the University’s SWaM plan, please see the letter in Attachment 1 and refer to the following site: www.procurement.virginia.edu/main/publicpostings/rfp/SWAMplan.pdf.

Note 1: A 10% minimum weight will be given to this criterion in evaluating proposals.

Note 2: Any questions related to SWaM business and SWaM subcontracting opportunities can be directed to Les Haughton, Director Supplier Diversity, at (434) 924-7174 or lh7sn@virginia.edu.

D. CONTENTS OF PROPOSAL

Proposals will be prepared simply and economically, providing a straightforward, concise description of capabilities to satisfy the requirements of the RFP. Emphasis will be on completeness and clarity of content, and will be organized in the order in which the requirements are presented in the RFP.

Unnecessarily elaborate brochures and other presentations beyond that sufficient to present a complete and effective proposal are not desired and may be construed as an indication of a firm’s lack of cost consciousness.

Elaborate artwork, expensive paper and bindings, and expensive visual and other presentation aids are neither necessary nor desired.

Firms will provide the following information:

1. A detailed description and the full specifications of the product/equipment proposed. Each firm will indicate in its proposal the firm’s ability to achieve/comply with each specification. In the event that the firm wishes to propose an alternate specification that, in any way, differs from the above specifications, the firm will detail the proposed change(s) and how the proposed change would compare to the listed specification. Proposals will be formatted in such a way to address each of the above specifications in a line-by-line process.
2. A brief history of the firm and its experience, qualifications and success in providing the type of product requested.
3. The estimated ship date of the product from the time of the order (i.e., 10 wks after order).
4. Information on the warranty associated with the product the firm is proposing and any extended warranty (include the price) that might be available.
5. The firm’s proposed price / fee for providing the Goods and Services, to include shipping charges (the University’s shipping terms are FOB Destination).
6. At least three references where similar goods and/or services have been provided. Include the name of the firm / organization, the complete mailing address, and the name of the contact person and telephone number.
7. The firm’s SWAM businesses status and/or how the firm intends to utilize SWAM firms in regards to this particular procurement.
8. Provide a list of institutions of higher education with which the firm has signed a term contract.
9. Provide the amount of annual sales the firm has with each VASCUPP Member Institution. A list of the VASCUPP Members can be found at https://vascupp.org.
10. Complete and return the information requested in Attachment 2, Firm Information.

**Virginia Freedom of Information Act**

Except as provided, once an award is announced, all proposals submitted in response to this RFP will be open to inspection by any citizen, or interested person, firm or corporation, in accordance with the Virginia Freedom of Information Act.

Trade secrets or proprietary information submitted by a firm prior to or as part of its proposal will not be subject to public disclosure under the Virginia Freedom of Information Act only under the following circumstances: (1) the appropriate information is clearly identified by some distinct method such as highlighting or underlining; (2) only the specific words, figures, or paragraphs that constitute trade secrets or proprietary information are identified; and (3) a summary page is supplied immediately following the proposal title page that includes (a) the information to be protected, (b) the section(s)/page number(s) where this information is found in the proposal, and (c) a statement why protection is necessary for each section listed. The firm must also provide a separate electronic copy of the proposal (CD, etc.) with the trade secrets and/or proprietary information redacted.

*If all of these requirements are not met, then the firm’s entire proposal will be available for public inspection.*

**IMPORTANT:** A firm may not request that its entire proposal be treated as a trade secret or proprietary information, nor may a firm request that its pricing/fees be treated as a trade secret or proprietary information, or otherwise be deemed confidential.
E. TERMS AND CONDITIONS

This solicitation and any subsequent award(s) are subject to:

- The Selected Firm registering as a vendor with the University of Virginia. [https://www.procurement.virginia.edu/pagevendorregistrationform](https://www.procurement.virginia.edu/pagevendorregistrationform).

- Unless otherwise deemed appropriate by the University, the Selected Firm(s) will enroll in one of the University approved methods for receipt of electronic payments. Accordingly, the Selected Firm agrees to accept Bank of America’s (“BoA”) ePayables® method of electronic payment or BoA’s PayMode® method of electronic payment.


  **Note:** Unless a firm expressly and specifically states its exception to any of the Preferred Provisions in its written proposal, then the proposal from the firm will automatically be deemed to include those Provisions.


F. OTHER INFORMATION

Additional Preferred Contractual Provisions:

1. **Insurance**

   Listed below is the insurance the Selected Firm must maintain under any Agreement resulting from this RFP. In no event should the Selected Firm construe these minimum required limits to be their limit of liability to the University. The Selected Firm will maintain insurance which meets or exceeds the requirements of the University with insurance companies that hold at least an A- financial rating with A.M. Best Company. No Agreement will be executed by the University until the Selected Firm satisfies the insurance requirements of the University. The Selected Firm may be required to provide the University with a valid Certificate of Insurance before providing any goods or services to the University. The University reserves the right to approve any insurance proposed by the Selected Firm. Additionally, the Selected Firm is responsible for identifying, securing, and maintaining insurance 1) required by regulation and 2) sufficient to protect the University from liability and damages resulting from the Selected Firm and any Subcontractors actions or inactions pursuant to this agreement.

   **Commercial General Liability:**

   The Selected Firm and any Subcontractor will provide a minimum combined single Limit of Liability for bodily injury and property damage of $2,000,000 per occurrence and a $2,000,000 general aggregate that includes products liability with coverage for the following:
Automobile Insurance:
The Selected Firm and any Subcontractor will provide a minimum combined single Limit of Liability for bodily injury and property damage of $1,000,000 per occurrence with the following coverages for vehicles operated by their employees:

- [X] Any Automobile
- [X] Owned and Non-Owned Automobiles
- [X] Transportation of Hazardous Substances

Umbrella/Excess Liability:
The Selected Firm, and any subcontractor, will maintain excess liability coverage of at least $3,000,000 per occurrence that provides coverage uniform with the underlying general liability insurance.

Professional Errors and Omissions Liability:
The Selected Firm will maintain professional errors and omissions liability coverage of at least $2,000,000 per claim.

*Additional Insured:
The University will be named as an Additional Insured, and the proper name is: "The Commonwealth of Virginia, and the Rector and Visitors of the University of Virginia, its officers, employees, and agents."

2. Formation of the Agreement with the Selected Firm
All proposals received will first be carefully evaluated by the University, and then the University intends to conduct negotiations with two or more firms. After negotiations have been conducted, if the University chooses to make award, the University will select the firm which, in its opinion, best meets the needs of the University. Alternately, if the University determines in writing and in its sole discretion that only one firm is fully qualified, or that one firm is clearly more highly qualified than the others under consideration, it may decide to negotiate and award an agreement to that single firm. In either event, the University intends to execute a mutually satisfactory written agreement which will reflect and largely incorporate this RFP as reconciled with any pertinent documents, such as the proposal submitted and relevant negotiation correspondence.

Because the University may choose to negotiate and award to a single firm, as discussed above, each firm must include in its written proposal all requirements, terms or conditions it may have, and should not assume that an opportunity will exist to add such matters after the proposal is submitted.

Any firm(s) invited to negotiations should note that the University reserves the right to begin negotiations by combining the best aspects of submitted proposals from all responding firms as the basis for subsequent formation of any Agreement resulting from this RFP.
Firms should also note that, as described above, certain matters will automatically be deemed part of the proposal.

3. **Term of Agreement**
   The term of any Agreement resulting from this RFP will be for five years, with the ability to renew on the same terms and conditions, for two additional one-year periods if mutually agreeable to the University and the Selected Firm. The Selected Firm and the University will mutually agree at least 180 days prior to each renewal period whether to renew the terms of the Agreement.

4. **Confidentiality**
   All firms responding to this RFP represent and confirm that the contents of the firm’s proposal(s) and any resulting Agreement are not confidential and will be open to the inspection of any interested person, firm or corporation, in accordance with the Virginia Freedom of Information Act.

5. **Account Manager**
   The Selected Firm agrees to provide a named individual (“Account Manager”) to implement, perform, and manage provision of the Goods and Services. The University must approve the appointment of the Account Manager prior to execution of any Agreement with the Selected Firm. The Account Manager will be the University’s primary contact, although the Account Manager will be assisted by other members of the Selected Firm’s staff in completing key activities.

   In the event that the Account Manager (or any other individual responsible for the University’s account) is no longer employed by the Selected Firm, is unavailable for any reason, or is performing in an unsatisfactory manner (as solely determined by the University); the Selected Firm will propose a replacement for that individual within a reasonable time frame, so as not to significantly delay the provision of the Goods and Services to the University. The University reserves the right to approve the replacement, or to cancel any resulting Agreement. If the University accepts a proposed replacement, the replacement will provide the Goods and Services at rates no higher than previously agreed and in accordance with all terms and conditions specified in the resulting agreement.

6. **Invoice Accuracy and Timeliness**
   It is the responsibility of the Selected Firm to ensure the accuracy, completeness, correct format, and timely submission of all invoices. The Account Manager, as referred to in the above mentioned section, will be responsible for all invoice coordination. Invoice errors may be reported, by the University, via e-mail to the Account Manager, or via telephone followed by confirming e-mail. The Selected Firm may not interrupt service to the University due to payment delays caused by the Selected Firm’s invoice errors. In addition, invoices are to be submitted on a timely basis (“timely” to be defined as no later than 60 days from the point at which the Goods and Services were delivered to the University). The University, in its sole discretion, may choose to reject any late invoices not submitted in this timely fashion.

7. **System Acceptance**
   “System Acceptance” will encompass testing and observation of the fully functional and operational System. The University’s Contract Administrator will determine if the System specifications have been met, shortly after installation and integration of the System. Warranty will begin as of the date of System Acceptance, and factors surrounding payment may be tied to System Acceptance. In the event
that the University does not accept the System, the University may elect to require the Selected Firm to provide a replacement System or terminate the Agreement or cancel the PO.

The University’s Contract Administrator will be the sole representative of the University and will have sole authority to act on the University’s behalf with regard to System Acceptance; however, that in the event of a dispute regarding any material aspect of System Acceptance unable to be resolved by the University’s Contract Administrator, then the procedures in the Procedure for Resolution of Contractual Claims will be followed.
Greetings:

The quality of service the University of Virginia is able to deliver to its customers is directly related to the excellent support we receive from you and many other outstanding suppliers of goods and services. Without you, we would not be able to fulfill our educational, health care and research missions. An important part of our procurement program involves our commitment to doing business with small, women- and minority-owned (SWaM) businesses. As one of our most important vendors, we look to you to help us achieve this objective.

We conduct substantial business with small firms. We have a particular institutional focus on developing long-term business relationships with minority-and women-owned businesses. We count on our majority firms to help us achieve our goal.

I seek your assistance in two areas. First, to the extent practical, I ask that you involve small, women-and minority-owned businesses in the delivery of services you provide to UVa. The office of Procurement and Supplier Diversity Services is ready to assist you in identifying qualified diverse business partners. Second, I seek your help in reporting your results through our quarterly subcontracting reports. The terms and conditions previously provided to your organization outlined this process.

This effort is important to us. We depend on you in so many ways – this is another way that we can partner with your company to make things better.

Sincerely,

Colette Sheehy
Vice President for Management and Budget
## Attachment 2

### Firm Information

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<th><strong>Full Legal Name</strong> <em>(Company name as it appears with its Federal Taxpayer Number):</em></th>
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**SWAM Information:**

Is the firm certified with the Commonwealth of Virginia’s Department of Minority Business Enterprises (DMBE)?

- [ ] Yes
- [ ] No

- Minority-Owned Business: [ ] Yes [ ] No
- Women-Owned Business: [ ] Yes [ ] No
- Small-Owned Business: [ ] Yes [ ] No

Is the firm registered as a vendor in the Commonwealth of Virginia’s e-procurement system (eVA)?

- [ ] Yes
- [ ] No

**Point of Contact for this Proposal:**

Name:  
Address:  

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