COMMONWEALTH OF VIRGINIA

STANDARD CONTRACT

Contract Number: VTG-3266-2026

This contract entered into this 1 day of July 2026 by Consolidated Machine Corporation, d.b.a. Consolidated Sterilizer Systems, hereinafter called the "Contractor" and Commonwealth of Virginia, Virginia Polytechnic Institute and State University called "Virginia Tech."

WITNESSETH that the Contractor and Virginia Tech, in consideration of the mutual covenants, promises and agreements herein contained, agree as follows:

SCOPE OF CONTRACT: The Contractor shall provide specialized scientific equipment and instrumentation to Virginia Tech as set forth in the Contract Documents.

PERIOD OF CONTRACT: From July 1, 2026 through June 30, 2028, with four (4) X two (2) optional renewals.

COMPENSATION AND METHOD OF PAYMENT: The Contractor shall be paid by Virginia Tech in accordance with the Contract Documents.

CONTRACT DOCUMENTS: The Contract Documents shall consist of this signed contract, the VHEPC PAC Agreement, Request for Proposal (RFP) number 952642606 dated April 10, 2026, together with Addendum Number 1 To RFP dated April 24, 2026, the proposal submitted by the Contractor dated May 8, 2026 and the negotiation summary, all of which Contract Documents are incorporated herein.

ELECTRONIC TRANSACTIONS: If this paragraph is initialed by both parties, to the fullest extent permitted by Code of Virginia, Title 59.1, Chapter 42.1, the parties do hereby expressly authorize and consent to the use of electronic signatures as an additional method of signing and/or initialing this contract and agree electronic signatures (for example, the delivery of a PDF copy of the signature of either party via facsimile or electronic mail or signing electronically by utilizing an electronic signature service) are the same as manual executed handwritten signatures for the purposes of validity, enforceability and admissibility.

Initial: GF / DS: RN
(Initials)

In WITNESS WHEREOF, the parties have caused this Contract to be duly executed intending to be bound thereby.

Contractor
By: Signed by: Gary Fowles 1C9F6CB14F0248F... (Signature)
Gary Fowles Eastern Regional Manager
Name and Title

Virginia Tech
By: DocuSigned by: Reed Nagel 5EF51DA320D049B...
Reed Nagel
Assistant Vice President and
Director of Procurement

AGREEMENT
PUBLICLY ACCESSIBLE CONTRACT

This Agreement executed this 1 day of July, 2026 by and between Virginia Polytechnic Institute and State University ("the University") and Consolidated Machine Corporation, d.b.a. Consolidated Sterilizer Systems ("Supplier").

TERM

The term of this Publicly Accessible Contract ("PAC") shall remain in effect until the expiration or termination of the Primary Agreement.

WITNESS

WHEREAS, the University and Supplier have executed an agreement, VTG-3266-2026 dated July 1, 2026 (the "Primary Agreement"), and included in the Primary Agreement is a third party access / cooperative procurement clause. Now therefore, the University and Supplier agree to the specific terms that will allow third-party access to the Primary Agreement, and based on other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

I. Supplier will:

- A. Allow third parties to obtain goods and services from Supplier in accordance with the terms and pricing of the Primary Agreement ("Third-Party Access").
- B. Pay the Virginia Higher Education Procurement Consortium ("Consortium") one percent (1%) of all revenue received by Supplier from non-Consortium entities through Third-Party Access (the "PAC Annual Fee"). The PAC Annual Fee will be paid in exchange for marketing services provided by the University and the Consortium described in Section II.
- C. Fully support this marketing relationship by promoting the availability of the Third Party Access to non-Consortium entities; and
- D. Provide quarterly reports detailing the amount of revenue received from non-Consortium entities through Third-Party Access.

II. The University will ensure the Consortium:

- A. Promotes the Primary Agreement and Third-Party Access on its website and through other channels (e.g., conferences) to non-Consortium members; and
- B. Maintains a Supplier-approved version of the Supplier's logo on the Consortium website.

III. Payment

A. Supplier shall remit the PAC Annual Fee to the Consortium no later than August 31st of each year. The University and Consortium will share the payments equally and allocate payments to the appropriate accounts.

If the Primary Agreement expires or terminates before August 31st, Supplier shall remit the PAC Annual Fee no later than 45 calendar days from expiration or termination date of the Primary Agreement.

B. Supplier shall remit the PAC Annual Fee by check in U.S. dollars. Checks will be made payable to the University of Virginia and sent to:

Procurement Office Manager
Procurement and Supplier Diversity Services
University of Virginia, Carruthers Hall
PO Box 400202
1001 N. Emmet Street
Charlottesville, VA 22904

Note 'PAC payment' on check.

IV. Notices

Any notice required or permitted to be given under this Agreement will be in writing and will be deemed duly given: (1) if delivered personally, when received; (2) if sent by recognized overnight courier service, on the date of the receipt provided by such courier service; (3) if sent by registered mail, postage prepaid, return receipt requested, on the date shown on the signed receipt: or (4) if sent by electronic mail, on the next business day of the receiver. All such notices will be addressed to a party at such party's address as shown below.

If to the University:

Reed Nagel, Director of Procurement
procurement@vt.edu
540-231-6221
300 Turner Street NW Suite 2100
Blacksburg, VA 24061

If to Supplier: x

Name: Gary Fowles
Address: 3 enterprise dr. Suite C Billerica Ma 01821

Email: gary.fowles@consteril.com

ACCEPTANCE

For
Virginia Polytechnic Institute & State University

DocuSigned by:
Reed Nagel
5EF51DA320D049B...

Reed Nagel
Director of Procurement

7/6/2026
Date

For Supplier

Signed by:
Gary Fowles
1C9F6CB14F0248F...

Name: Gary Fowles
Title: Eastern Regional Manager

7/2/2026
Date

Agreement #: VTG-3266-2026-PAC

Request for Proposal # 952642606

For

Specialized Scientific Equipment & Instrumentation

April 10, 2026

Note: This public body does not discriminate against faith-based organizations in accordance with the *Code of Virginia*, § 2.2-4343.1 or against a bidder or offeror because of race, religion, color, sex, sexual orientation, gender identity, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment.

RFP # 952642606, Specialized Scientific Equipment & Instrumentation

INCLUDE THIS PAGE WITH YOUR PROPOSAL, SIGNATURE AT SUBMISSION IS REQUIRED

DUE DATE: Proposals will be received until **May 11th, 2026 at 3:00 PM**. Failure to submit proposals to the correct location by the designated date and hour will result in disqualification.

INQUIRIES: All inquiries for information regarding this solicitation should be directed to Levi Henry, Phone: (540) 231-7852 e-mail: lhenry29@vt.edu. All inquiries will be answered in the form of an addendum. Inquiries must be submitted by 3:00 PM on April 24, 2026. Inquiries must be submitted to the procurement officer identified in this solicitation.

PROPOSAL SUBMISSION:

Please note, proposal submission procedures have changed effective March 2023.

Proposals may NOT be hand delivered to the Procurement Office.

Proposals should be submitted electronically through Virginia Tech's procurement portal. This portal allows you access to view business opportunities and submit bids and proposals to Virginia Tech digitally and securely.

Proposals must be submitted electronically at:
https://bids.sciquest.com/apps/Router/PublicEvent?CustomerOrg=VATech

Vendors will need to register through this procurement portal, hosted by Jaggaer. **It is encouraged for all vendors to register prior to the proposal submission deadline to avoid late submissions**. Registration is easy and free. If you have any challenges with the registration process, please contact Jaggaer Support at 1-800-233-1121 or procurement@vt.edu.

Click on the opportunity and log in to your vendor account to begin preparing your submission. Upon completion, you will receive a submission receipt email confirmation. Virginia Tech will not confirm receipt of proposals. It is the responsibility of the offeror to make sure their proposal is delivered on time.

Hard copy or email proposals will not be accepted. Late proposals will not be accepted, nor will additional time be granted to any individual Vendor.

Attachments must be smaller than 50MB in order to be received by the University.

In compliance with this Request For Proposal and to all the conditions imposed therein and hereby incorporated by reference, the undersigned offers and agrees to furnish the goods or services in accordance with the attached signed proposal and as mutually agreed upon by subsequent negotiation.

AUTHORIZED SIGNATURE: _____ Date: _____

[INCLUDE THIS PAGE]

I. PURPOSE:

A. Background: The Virginia Higher Education Procurement Consortium (VHEPC), on behalf of participating member institutions, is issuing this Request for Proposal (RFP) as part of a coordinated R&D sourcing initiative designed to modernize and streamline research-related contract coverage.

VHEPC represents public institutions of higher education and seeks to establish competitively awarded, category-based contracts that support the diverse and evolving research needs of its members. These contracts are intended for use by VHEPC participating institutions and may also serve as nationally accessible cooperative contracts for eligible public agencies that elect to utilize them.

Historically, research-related procurements have often been addressed through individual contract actions or sole-source justifications based on specialized needs. This initiative replaces fragmented approaches with structured, transparent, and scalable competitive procurement aligned to defined R&D categories.

The objective of this RFP is to establish a pool of qualified firms within the specified category that can provide reliable, compliant, and cost-effective solutions to VHEPC members while maintaining flexibility necessary for research environments.

This RFP is targeted for offerors providing specialized scientific equipment and instrumentation, which is defined as capital or system-based scientific, engineering, and research equipment, including highly specialized instruments and integrated systems. This category also includes incidental services such as installation, configuration, calibration, training, and equipment-specific maintenance that are inseparable from the acquisition and operation of the equipment.

B. Coordinated Multi-Institution Model

Multiple R&D RFPs are being issued concurrently by designated lead institutions within VHEPC. Each RFP corresponds to a distinct and clearly defined category of goods or services.

Each participating institution serves as the issuing authority for its assigned category. However, awarded contracts are intended for use by eligible VHEPC members in accordance with the terms of each solicitation.

This coordinated approach:

- Distributes administrative responsibility across institutions
- Aligns evaluation with subject-matter expertise
- Replaces numerous individual contracts with structured category-based coverage
- Preserves continuity of research operations

C. Category-Based Structure

This RFP corresponds to the following category: **Specialized Scientific Equipment & Instrumentation.**

Each category is defined based on the primary value delivered, whether capital equipment, consumable products, regulated research inputs, labor-based services, or software platforms.

Category definitions are consistent across all coordinated RFPs to ensure clarity and prevent duplication.

D. Vendor Response Guidance (Important)
Vendors are advised that multiple R&D RFPs are being issued simultaneously under this coordinated initiative.

To prevent duplication and ensure efficient evaluation:
- Vendors should submit a proposal in response to only one RFP category.
- Vendors offering products or services that could reasonably align with more than one category should select the RFP that best represents their primary line of business.
- Vendors should not submit identical or substantially similar proposals to multiple RFPs under this initiative.

If a vendor is uncertain which category is most appropriate, the vendor is strongly encouraged to contact Ryan Balber, VHEPC Director at rbalber@virginia.edu for guidance. VHEPC reserves the right to redirect or reassign proposals if a submission is clearly misaligned with the category scope.

E. Scope Intent
This RFP is intended to establish competitively awarded contracts within the defined category to:

- Reduce reliance on sole-source justifications
- Improve transparency and audit defensibility
- Provide predictable and sustainable contract coverage
- Support diverse and evolving research needs across participating institutions

The resulting contracts are not intended to limit research flexibility, but rather to provide structured, compliant procurement pathways.

F. Coordination and Consistency
While issued by a designated lead institution, this RFP is part of a broader, coordinated VHEPC initiative. Category definitions, evaluation principles, and vendor response guidance are aligned across all related solicitations.

This structure ensures vendors experience a unified and organized market approach despite multiple issuing institutions.

G. Open Enrollment/Additional Opportunities
This RFP establishes an initial award group. Following the initial award, the University reserves the right to open an additional RFP at its sole discretion to establish additional agreements for these goods and/or services, which may occur annually or as operationally needed.

During any subsequent open enrollment period:
- Firms not previously awarded may submit proposals.
- Proposals will be evaluated using the same published criteria.
- Additional contracts may be awarded to qualified Firms.

II. SWaM BUSINESS PARTICIPATION:

The mission of the Virginia Tech supplier opportunity program is to foster opportunity in the university supply chain and accelerate economic growth in our local communities through the engagement and empowerment of high quality and cost competitive SWaM, and local suppliers. Virginia Tech encourages prime suppliers, contractors, and service providers to facilitate

participation through partnerships, joint ventures, subcontracts, and other inclusive and innovative relationships.

For more information, please visit: https://www.sbsd.virginia.gov/

III. CONTRACT PERIOD:

The term of this contract is for two years, or as negotiated. There will be an option for four (4) two-year renewals, or as negotiated.

IV. EVA BUSINESS-TO-GOVERNMENT ELECTRONIC PROCUREMENT SYSTEM:

The eVA Internet electronic procurement solution streamlines and automates government purchasing activities within the Commonwealth of Virginia. Virginia Tech, and other state agencies and institutions, have been directed by the Governor to maximize the use of this system in the procurement of goods and services. *We are, therefore, requesting that your firm register as a vendor within the eVA system.*

There are transaction fees involved with the use of eVA. These fees must be considered in the provision of quotes, bids and price proposals offered to Virginia Tech. Failure to register within the eVA system may result in the quote, bid or proposal from your firm being rejected and the award made to another vendor who is registered in the eVA system.

Registration in the eVA system is accomplished on-line. Your firm must provide the necessary information. Please visit the eVA website portal at http://www.eva.virginia.gov/pages/eva-registration-buyer-vendor.htm and **register both with eVA and Ariba**. *This process needs to be completed before Virginia Tech can issue your firm a Purchase Order or contract.* If your firm conducts business from multiple geographic locations, please register these locations in your initial registration.

For registration and technical assistance, reference the eVA website at: https://eva.virginia.gov/, or call 866-289-7367 or 804-371-2525.

V. CONTRACT PARTICIPATION:

It is the intent of this solicitation and resulting contract to allow for cooperative procurement. Accordingly, any public body, public or private health or educational institutions, or Virginia Tech's affiliated corporations and/or partnerships may access any resulting contract if authorized by the contractor.

Participation in this cooperative procurement is strictly voluntary. If authorized by the Contractor, the resultant contract may be extended to the entities indicated above to purchase at contract prices in accordance with contract terms. The Contractor shall notify Virginia Tech in writing of any such entities accessing the contract, if requested. No modification of this contract or execution of a separate contract is required to participate. The Contractor will provide semi-annual usage reports for all entities accessing the Contract, as requested. Participating entities shall place their own

orders directly with the Contractor and shall fully and independently administer their use of the contract to include contractual disputes, invoicing and payments without direct administration from Virginia Tech. Virginia Tech shall not be held liable for any costs or damages incurred by any other participating entity as a result of any authorization by the Contractor to extend the contract. It is understood and agreed that Virginia Tech is not responsible for the acts or omissions of any entity, and will not be considered in default of the contract no matter the circumstances.

Use of this contract does not preclude any participating entity from using other contracts or competitive processes as the need may be.

VI. STATEMENT OF NEEDS/SCOPE OF WORK:

A. Discounts/Logistics: Deep discounts off list are expected. Except for special handling, prices should be inclusive of delivery (FOB Destination).

B. Sales representation: Provide a plan for sales representation. We recognize that not all institution accounts will warrant full-time on-campus representation. Provide a narrative on how you propose to provide this service.

C. Product Satisfaction: The Contractor should act as a customer advocate and coordinator for communications and is responsible for performance and problem resolution. Customer satisfaction will be a determining factor in measuring the Contractor's performance.

D. Warranty: All products purchased under this contract will minimally include the Original Equipment Manufacturer's warranty which will pass directly to Virginia Tech. Products which fail after acceptance and installation will be covered under warranty. Products which are inoperative at installation will either be replaced by the Contractor or repaired under warranty. The decision to replace such products or accept warranty repair will be at the sole discretion of Virginia Tech, except in the event Virginia Tech fails to provide timely notice of product failure to the Contractor. The Contractor should provide contact information for requests for warranty services for all equipment sold under the contract. Any maintenance agreements available from the Contractor should be provided to Virginia Tech as an option and priced as discounted off list price.

E. Sustainability: The Contractor is encouraged to address environmental concerns related to the purchase of recycled products, reductions of operating and maintenance costs, improved energy efficiencies, reduction of waste, use of 'green' products, and efforts to reduce consumption of energy, water, and materials.

F. Minimum Order: There shall be no minimum order requirement.

G. Quarterly Reporting Requirements

1. Reporting Obligation
   The awarded Contractor shall provide quarterly sales reports to VHEPC for the duration of the contract.

   Reports are mandatory regardless of sales volume and must be submitted even if there were no purchases during the reporting period (in which case a “zero sales” report shall be submitted).

   Reports shall be submitted electronically no later than thirty (30) calendar days following the end of each calendar quarter.

2. Reporting Format
   All reports must be submitted using the VHEPC Unified Quarterly Reporting Template provided as an attachment to this RFP.

   Contractors shall not modify the structure, column order, or formatting of the template. Alternative reporting formats will not be accepted.

   The template includes:
   - A “Quarterly Reporting” tab for VHEPC member purchases
   - A “Non-Member Reporting” tab for purchases made by entities accessing the contract under the Publicly Accessible Contract (PAC) structure

3. Member Reporting Requirement
   The “Quarterly Reporting” tab shall include item-level detail for all purchases made by VHEPC participating institutions during the reporting period.

   Each transaction line shall include, at minimum:
   - University
   - PO Number
   - Order Date
   - Invoice Number
   - Invoice Date
   - Department
   - Vendor SKU (if applicable)
   - Product Category
   - Item Description or Service Description
   - Manufacturer Name (if applicable)
   - Manufacturer Number (if applicable)
   - Unit of Measure
   - MSRP (if applicable)
   - Contract Price
   - Net Price
   - Quantity (or Hours for services)
   - Extended Volume (total invoiced amount)

   Summary-only reporting is not acceptable.

4. Non-Member (PAC) Reporting Requirements
   If the Contractor elects to permit third-party access under the Publicly Accessible Contract (PAC) structure, the Contractor shall also complete the “Non-Member Reporting” tab.

   The Non-Member Report shall include all item-level transactions associated with non-VHEPC entities that accessed the contract during the reporting period.
   The Non-Member Report shall serve as the basis for PAC Annual Fee calculation in accordance with the PAC Agreement.

   If no non-member sales occurred, the Contractor shall indicate “No Sales” on the Non-Member Reporting tab.

5. Submission Method
   Quarterly reports shall be submitted electronically to:

   VHEPC Contract Administrator
   Anu Mathew
   amathew@virginia.edu

   Reports must be submitted in Excel format and shall clearly identify in the title of the excel file:
   - Vendor Name
   - Contract Number
   - Reporting Period (Quarter Ending)

6. Use of Reported Data
   Reported data may be used by VHEPC for:

   - Spend analysis and reporting
   - Pricing consistency review
   - Identification of cost savings opportunities
   - Contract performance monitoring
   - PAC Annual Fee verification

   Reported data will be treated as confidential to the extent permitted by applicable law.

7. Failure to Comply
   Failure to provide accurate and timely quarterly reporting may result in:
   - Withholding of contract renewal or extension
   - Suspension of third-party access privileges
   - Audit review
   - Termination for default in cases of repeated non-compliance

H. Publicly Accessible Contract (PAC) Requirement (see **ATTACHMENT C** for PAC Agreement)

1. Mandatory Execution of PAC Agreement
   As a condition of award, all Offerors awarded a contract under this RFP shall execute the VHEPC Publicly Accessible Contract ("PAC") Agreement.

   Execution of the PAC Agreement is mandatory and is not subject to post-award negotiation.

   The PAC Agreement shall be incorporated by reference into the resulting contract.

2. Optional Third-Party Access
   The PAC Agreement provides a mechanism through which eligible public entities that are not VHEPC participating institutions may elect to access the awarded contract.

   Participation in third-party access is voluntary for the awarded Contractor.

   An awarded Contractor may elect whether to permit third-party access under the PAC structure. Such election shall be documented at the time of contract execution or amended thereafter by mutual agreement.

   No guarantee of third-party usage is made or implied.

3. PAC Annual Fee
   If an awarded Contractor elects to permit third-party access and receives revenue from non-VHEPC entities under the PAC structure, the Contractor shall remit a Publicly Accessible Contract Annual Fee equal to one percent (1%) of revenue received from such non-VHEPC entities, in accordance with the PAC Agreement.

   The PAC Annual Fee:
   - Applies only to revenue received from non-VHEPC entities utilizing third-party access
   - Does not apply to purchases made by VHEPC participating institutions
   - Shall not be invoiced or passed through as a separate line item to participating institutions

   Offerors shall incorporate any anticipated PAC-related costs into their proposed pricing.

4. Reporting and Reconciliation
   Contractors electing to permit third-party access shall submit quarterly Non-Member (PAC) reports in accordance with the RFP Reporting Requirements section.

   Reported data shall serve as the basis for PAC Annual Fee calculation.

   VHEPC reserves the right to reconcile reported revenue against PAC fee remittance.

5. Future Open Enrollment Applicability
   All firms awarded under future open enrollment generations of this RFP shall be subject to the same PAC execution requirement.

VII. PROPOSAL PREPARATION AND SUBMISSION:

A. Specific Requirements

Proposals should be as thorough and detailed as possible so that Virginia Tech may properly evaluate your capabilities to provide the required goods or services. Offerors are required to submit the following information/items as a complete proposal:

1. Provide a summary overview of the company, including qualifications and experiences, geographical operations, unique services provided to the higher education marketplace and any envisioned company changes including planned technological advances and acquisitions.

2. List all contact information for ordering, invoicing, customer service, etc.

3. Describe delivery options and policies including special handling charges, installation and training if required for the items being offered. **All orders shall be FOB destination**. Include information regarding delivery costs and/or free delivery. Specify costs in Attachment B Pricing Schedule.

4. Specify typical turnaround time for delivery (standard, rush, etc.) for the items being offered.

5. Describe return policy (including replacement of defective, broken, or damaged items) and identify any associated costs. Any costs to be specified in **Attachment B Pricing Schedule**.

6. Provide sample quote and invoice. Quotes shall include manufacturer list price and contracted discount price.

7. Identify any other goods or services offered to Virginia Tech and associated costs as specified in **Attachment B Pricing Schedule**.

8. Participation of SWaM Business:

   If your business cannot be classified as SWaM, describe your plan for utilizing SWaM subcontractors if awarded a contract. Describe your ability to provide reporting on SWaM subcontracting spend when requested. If your firm or any business that you plan to subcontract with can be classified as SWaM, but has not been certified by the Virginia Department of Small Business and Supplier Diversity (SBSD), it is expected that the certification process will be initiated no later than the time of the award. If your firm is currently certified, you agree to maintain your certification for the life of the contract. For assistance with SWaM certification, visit the SBSD website at http://www.sbsd.virginia.gov/

9. The return of the Submission Instruction page and addenda, if any, signed and filled out as required.

D. General Requirements

1. RFP Response: In order to be considered for selection, Offerors shall submit a complete response to this RFP to include;

   a. **One (1) electronic document** in WORD format or searchable PDF of the entire proposal as one document, INCLUDING ALL ATTACHMENTS must be uploaded through the Virginia Tech online submission portal. Refer to page 2 for instructions.

      Any proprietary information should be clearly marked in accordance with 2.d. below.

   b. Should the proposal contain **proprietary information**, provide **one (1) redacted electronic copy** of the proposal and attachments **with proprietary portions removed or blacked out**. This redacted copy should follow the same upload procedures as described on Page 1 of this RFP. This redacted copy should be clearly marked *"Redacted Copy"* within the name of the document. The classification of an entire proposal document, line item prices and/or total proposal prices as proprietary or trade secrets is not acceptable. Virginia Tech shall not be responsible for the Contractor's failure to exclude proprietary information from this redacted copy.

      No other distribution of the proposals shall be made by the Offeror.

2. Proposal Preparation:

   a. Proposals shall be signed by an authorized representative of the Offeror. All information requested should be submitted. Failure to submit all information requested may result in Virginia Tech requiring prompt submission of missing information and/or giving a lowered evaluation of the proposal. Proposals which are substantially incomplete or lack key information may be rejected by Virginia Tech at its discretion. Mandatory requirements are those required by law or regulation or are such that they cannot be waived and are not subject to negotiation.

b. Proposals should be prepared simply and economically providing a straightforward, concise description of capabilities to satisfy the requirements of the RFP. Emphasis should be on completeness and clarity of content.

c. Proposals should be organized in the order in which the requirements are presented in the RFP. All pages of the proposal should be numbered. Each paragraph in the proposal should reference the paragraph number of the corresponding section of the RFP. It is also helpful to cite the paragraph number, subletter, and repeat the text of the requirement as it appears in the RFP. If a response covers more than one page, the paragraph number and subletter should be repeated at the top of the next page. The proposal should contain a table of contents which cross references the RFP requirements. Information which the offeror desires to present that does not fall within any of the requirements of the RFP should be inserted at an appropriate place or be attached at the end of the proposal and designated as additional material. Proposals that are not organized in this manner risk elimination from consideration if the evaluators are unable to find where the RFP requirements are specifically addressed.

d. Ownership of all data, material and documentation originated and prepared for Virginia Tech pursuant to the RFP shall belong exclusively to Virginia Tech and be subject to public inspection in accordance with the Virginia Freedom of Information Act. Trade secrets or proprietary information submitted by an Offeror shall not be subject to public disclosure under the Virginia Freedom of Information Act. However, to prevent disclosure the Offeror must invoke the protections of Section 2.2-4342F of the Code of Virginia, in writing, either before or at the time the data or other materials is submitted. The written request must specifically identify the data or other materials to be protected and state the reasons why protection is necessary. –The proprietary or trade secret material submitted must be identified by some distinct method such as highlighting or underlining and must indicate only the specific words, figures, or paragraphs that constitute trade secret or proprietary information. The classification of an entire proposal document, line item prices and/or total proposal prices as proprietary or trade secrets is not acceptable and may result in rejection of the proposal.

3. Oral Presentation: Offerors who submit a proposal in response to this RFP may be required to give an oral presentation of their proposal to Virginia Tech.—This will provide an opportunity for the Offeror to clarify or elaborate on the proposal but will in no way change the original proposal. Virginia Tech will schedule the time and location of these presentations. Oral presentations are an option of Virginia Tech and may not be conducted. Therefore, proposals should be complete.

VIII. SELECTION CRITERIA AND AWARD:

A. Selection Criteria

Proposals will be evaluated by Virginia Tech using the following:

Criteria	Maximum Point Value
1. Quality of products/services offered and suitability for the intended purposes	25
2. Qualifications and experiences of Offeror in providing the goods/services	25
3. Specific plans or methodology to be used to provide the Services	25
4. Cost (or Price)	15
5. Participation of SWaM Business	10
Total	100

B. Award

Selection shall be made of two or more offerors deemed to be fully qualified and best suited among those submitting proposals on the basis of the evaluation factors included in the Request for Proposal, including price, if so stated in the Request for Proposal. Negotiations shall then be conducted with the offerors so selected. Price shall be considered, but need not be the sole determining factor. After negotiations have been conducted with each offeror so selected, Virginia Tech shall select the offeror which, in its opinion, has made the best proposal, and shall award the contract to that offeror. Virginia Tech may cancel this Request for Proposal or reject proposals at any time prior to an award. Should Virginia Tech determine in writing and in its sole discretion that only one offeror has made the best proposal, a contract may be negotiated and awarded to that offeror. The award document will be a contract incorporating by reference all the requirements, terms and conditions of this solicitation and the Contractor's proposal as negotiated.

Virginia Tech reserves the right to award multiple contracts as a result of this solicitation.

IX. INVOICES:

Invoices for goods or services provided under any contract resulting from this solicitation shall be submitted by email to vtinvoices@vt.edu or by mail to:

Virginia Polytechnic Institute and State University (Virginia Tech)
Accounts Payable
North End Center, Suite 3300
300 Turner Street NW
Blacksburg, Virginia 24061

X. METHOD OF PAYMENT:

Virginia Tech will authorize payment to the contractor as negotiated in any resulting contract from the aforementioned Request for Proposal.

Payment can be expedited through the use of the Wells One AP Control Payment System. Virginia Tech strongly encourages participation in this program. For more information on this program please refer to Virginia Tech's Procurement website: http://www.procurement.vt.edu/vendor/wellsone.html or contact the procurement officer identified in the RFP.

XI. ADDENDUM:

Any **ADDENDUM** issued for this solicitation may be accessed at https://bids.sciquest.com/apps/Router/PublicEvent?CustomerOrg=VATech. Since a paper copy of the addendum will not be mailed to you, we encourage you to check the web site regularly.

XII. COMMUNICATIONS:

Communications regarding this solicitation shall be formal from the date of issue, until either a Contractor has been selected or the Procurement Department rejects all proposals. Formal communications will be directed to the procurement officer listed on this solicitation. Informal communications, including but not limited to request for information, comments or speculations regarding this solicitation to any University employee other than a Procurement Department representative may result in the offending Offeror's proposal being rejected.

XIII. CONTROLLING VERSION OF SOLICITATION:

The posted version of the solicitation and any addenda issued by Virginia Tech Procurement Services is the mandatory controlling version of the document. Any modification of/or additions to the solicitation by the Offeror shall not modify the official version of the solicitation issued by Virginia Tech Procurement Services. Such modifications or additions to the solicitation by the Offeror may be cause for rejection of the proposal; however, Virginia Tech reserves the right to decide, on a case by case basis, in its sole discretion, whether to reject such a proposal.

XIV. TERMS AND CONDITIONS:

This solicitation and any resulting contract/purchase order shall be governed by the attached terms and conditions, see Attachment A.

XV. CONTRACT ADMINISTRATION:

A. The individual user departments at Virginia Tech shall be identified as the Contract Administrators and shall use all powers under the contract to enforce its faithful performance.

B. The Contract Administrators in each user departments shall determine the amount, quantity, acceptability, fitness of all aspects of the services and shall decide all other questions in connection with the services. Contract Administrators, or designees, shall not have authority to approve changes in the services which alter the concept or which call for an extension of time for this contract. Any modifications made must be authorized by the Virginia Tech Procurement Department through a written amendment to the contract.

C. Levi Henry, Senior Contracting Officer, Procurement, shall oversee the contract in its entirety and will serve as the point of contact for issues involving this contract.

XVI. ATTACHMENTS:

Attachment A - Terms and Conditions
Attachment B - Pricing Schedule
Attachment C – PAC Agreement

ATTACHMENT A

TERMS AND CONDITIONS

RFP GENERAL TERMS AND CONDITIONS

See:
https://www.procurement.vt.edu/content/dam/procurement_vt_edu/docs/terms/GTC_RFP_02182022.pdf

ADDITIONAL TERMS AND CONDITIONS.

1. **ADDITIONAL GOODS AND SERVICES**: The University may acquire other goods or services that the supplier provides other than those specifically solicited. The University reserves the right, subject to mutual agreement, for the Contractor to provide additional goods and/or services under the same pricing, terms and conditions and to make modifications or enhancements to the existing goods and services. Such additional goods and services may include other products, components, accessories, subsystems, or related services newly introduced during the term of the Agreement.

2. **AUDIT**: The Contractor hereby agrees to retain all books, records, and other documents relative to this contract for five (5) years after final payment, or until audited by the Commonwealth of Virginia, whichever is sooner. Virginia Tech, its authorized agents, and/or the State auditors shall have full access and the right to examine any of said materials during said period.

3. **AVAILABILITY OF FUNDS**: It is understood and agreed between the parties herein that Virginia Tech shall be bound hereunder only to the extent of the funds available or which may hereafter become available for the purpose of this agreement.

4. **CANCELLATION OF CONTRACT**: Virginia Tech reserves the right to cancel and terminate any resulting contract, in part or in whole, without penalty, upon 60 days written notice to the Contractor. In the event the initial contract period is for more than 12 months, the resulting contract may be terminated by either party, without penalty, after the initial 12 months of the contract period upon 60 days written notice to the other party. Any contract cancellation notice shall not relieve the Contractor of the obligation to deliver and/or perform on all outstanding orders issued prior to the effective date of cancellation.

5. **CONTRACT DOCUMENTS**: The contract entered into by the parties shall consist of the Request for Proposal including all modifications thereof, the proposal submitted by the Contractor, the written results of negotiations, the Commonwealth Standard Contract Form, all of which shall be referred to collectively as the Contract Documents.

6. **IDENTIFICATION OF PROPOSAL**: Virginia Tech will only be accepting electronic submission of proposals. All submissions must be submitted to the Virginia Tech online submission portal. Upon completion you will be directed to your Submission Receipt. Virginia Tech will not confirm receipt of proposals. It is the responsibility of the offeror to make sure their proposal is delivered on time. **Attachments must be smaller than 50MB in order to be received by the University.** Proposals may **NOT** be hand delivered to the Procurement Office.

7. **NOTICES**: Any notices to be given by either party to the other pursuant to any contract resulting from this solicitation shall be in writing via email.

8. **SEVERAL LIABILITY:** Virginia Tech will be severally liable to the extent of its purchases made against any contract resulting from this solicitation. Applicable entities described herein will be severally liable to the extent of their purchases made against any contract resulting from this solicitation.

9. **CLOUD OR WEB HOSTED SOFTWARE SOLUTIONS**: For agreements involving Cloud-based Web-hosted software/applications refer to link for additional terms and conditions: https://www.procurement.vt.edu/content/dam/procurement_vt_edu/itprocurement/Data_Security_FERPA_Addendum_2024.docx.

10. **ADVERTISING:** In the event a contract is awarded for supplies, equipment, or services resulting from this solicitation, no indication of such sales or services to Virginia Tech will be used in product literature or advertising. The contractor shall not state in any of the advertising or product literature that the Commonwealth of Virginia or any agency or institution of the Commonwealth has purchased or uses its products or services.

11. **ELECTRICAL INSTALLATION:** All equipment/material shall conform to the latest issue of all applicable standards as established by National Electrical Manufacturer's Association (NEMA), American National Standards Institute (ANSI), and Underwriters' Laboratories, Incorporated (UL) or other Nationally Recognized Testing Laboratories (NRTL) currently listed with the US Department of Labor. All equipment and material, for which there are NEMA, ANSI, UL or other NRTL standards and listings, shall bear the appropriate label of approval for use intended.

12. **INSURANCE**

    By signing and submitting a Proposal/Bid under this solicitation, the offeror/bidder certifies that if awarded the contract, it will have the following insurance coverages at the time the work commences. Additionally, it will maintain these during the entire term of the contract and that all insurance coverages will be provided by insurance companies authorized to sell insurance in Virginia by the Virginia State Corporation Commission.

    During the period of the contract, Virginia Tech reserves the right to require the contractor to furnish certificates of insurance for the coverage required.

    INSURANCE COVERAGES AND LIMITS REQUIRED:

    A. Worker's Compensation - Statutory requirements and benefits.

    B. Employers Liability - $100,000.00

    C. General Liability - $2,000,000.00 combined single limit. Virginia Tech and the Commonwealth of Virginia shall be named as an additional insured with respect to goods/services being procured. This coverage is to include Premises/Operations Liability, Products and Completed Operations Coverage, Independent Contractor's Liability, Owner's and Contractor's Protective Liability and Personal Injury Liability.

    D. Automobile Liability - $500,000.00

    E. The contractor agrees to be responsible for, indemnify, defend and hold harmless Virginia Tech, its officers, agents and employees from the payment of all sums of money by reason of any claim against them arising out of any and all occurrences resulting in bodily or mental injury or property damage that may happen to occur in connection with and during the performance of the contract, including but not limited to claims under the Worker's Compensation Act. The contractor agrees that it will, at all times, after the completion of the work, be responsible for, indemnify, defend and hold harmless Virginia Tech, its officers, agents and employees from all liabilities resulting from bodily or mental injury or property damage directly or indirectly arising out of the performance or nonperformance of the contract

13. **LABELING OF HAZARDOUS SUBSTANCES**: If the items or products requested by this solicitation are "Hazardous Substances" as defined by the # 3.1-250 of the Code of Virginia (1950), as amended, or # 1261 of Title 15 of the United States Code, then the offeror/bidder, by submitting its Proposal/Bid, certifies and warrants that the items or products to be delivered under this contract shall be properly labeled as required by the foregoing sections and that by delivering the items or products the offeror/bidder does not violate any of the prohibitions of # 3.1-252 of the Code of Virginia or Title 15 U.S.C. # 1263.

14. **LICENSE TO USE VIRGINIA TECH LICENSED INDICIA**: By signing and submitting this Proposal/Bid, the offeror/bidder agrees that if it is awarded a purchase order/contract as a result of this solicitation, it will follow the procedures outlined by Virginia Tech's Licensing and Trademarks Administration to become a licensed vendor authorized to use Virginia Tech licensed trademarks indicia identified in the solicitation and to follow all procedures for submitting artwork for product for approval prior to producing any product with Virginia Tech indicia. As a licensed vendor, the offeror/bidder will be required to pay the university's standard royalty rate for similarly licensed vendors. *More information on the licensing process and application can be found at: http://clc.com/Licensing-Info.aspx*.

15. **ORDERS**: Applicable departments, institutions, agencies and Public Bodies of the Commonwealth of Virginia may order by issuing a purchase order against any contract resulting from this solicitation.

16. **PRICE ESCALATION/DEESCALATION**: Price adjustments for changes in the contractor's price of materials, labor and transportation may be permitted. Request for price adjustments for any other reasons will not be granted. No price increases will be authorized for 365 calendar days after the effective date of the contract. Contractor shall give not less than 30 days advance notice prior to the annual renewal of the contract of any desired price increase.

    The Contractor shall document the amount and proposed effective date of any general change in the price of materials, labor and transportation. Documentation shall be supplied with the contractor's request for increase which will (1) verify that the requested price increase is general in scope and not applicable just to Virginia Tech, and (2) verify the amount or percentage of increase which is being passed on to the contractor by the contractor's suppliers. Failure by the contractor to supply the aforementioned verification with the request for price increase will result in a delay of the effective date of such increase. The Virginia Tech Procurement Department may verify such change in price independently. The Virginia Tech Procurement Department may make such verification as it deems adequate. However, any increase which the Virginia Tech Procurement Department determines is excessive, regardless of any documentation supplied by the contractor, may be cause for cancellation of the contract by the Virginia Tech Procurement Department. The Virginia Tech Procurement Department will notify the contractor in writing of the effective date of any increase which is approved. However, the contractor shall fill all purchase orders received prior to the effective date of the price adjustments of the old contract prices.

    "Across the Board" price decreases are subject to implementation at any time and shall be immediately conveyed to Virginia Tech. The contractor is further advised that price decreases which affect the price of materials, labor, and transportation are required to be passed on to Virginia Tech immediately. Failure to do so will result in action to recoup such amounts.

17. **SPECIAL OR PROMOTIONAL DISCOUNTS:** The Contractor shall extend any special promotional sale prices or discounts immediately to Virginia Tech during the term of the contract. Such notice shall also advise the duration of the specific sale or discount price.

18. **SIDEWALK POLICY:** Driving on sidewalks is allowed when there is no other way to get a needed vehicle to a designated place or building on campus. The vehicle operator shall be made aware that extreme caution shall be used to operate the vehicle in a way that will not be a hazard or hindrance to pedestrians using the walk. The contractor shall be responsible for any damage to turf and anything that is located adjacent to the walk. Parking an unattended vehicle on a sidewalk is strictly prohibited by State Law. The contractor is allowed to park a vehicle on a sidewalk if there is no other way to perform necessary work. The procedure to obtain a permit to operate a vehicle on sidewalks is the same as for the turf as outlined in Turf Policy. Any vehicle parked illegally on sidewalks shall be subject to ticketing, fines and towing if necessary.

19. **TURF POLICY:** Parking or driving on campus turf or sidewalk is strictly prohibited, except as specifically directed or otherwise allowed by the Physical Plant Grounds Department. In this case, a

turf permit must be obtained from Virginia Tech Parking Services and displayed by the vehicle. Turf parking is not allowed under the canopy of any tree on campus. Any vehicle parked illegally on turf or sidewalks shall be subject to ticketing and fines.

20. **WARRANTY (COMMERCIAL):** The contractor agrees that the supplies or services furnished under any award resulting from this solicitation shall be covered by the most favorable commercial warranties the contractor gives any customer for such supplies or services and that the rights and remedies provided therein are in addition to and do not limit those available to Virginia Tech by any other clause of this solicitation.

Attachment B

Pricing Schedule

The offeror shall provide pricing using the template below as applicable. The pricing schedule should include percentage off list price for specific manufacturer/product lines and/or categories. The “volume tier” section is intended to allow the offeror to provide volume-based incentives if applicable.

Equipment Category	Manufacturer	Model	List Price	Discount %	Net Price	Installation Cost	AVG Lead Time (Days)	Volume Tier (if applicable)

Attachment C
AGREEMENT
PUBLICLY ACCESSIBLE CONTRACT

This Agreement executed this [Date] day of [Month, Year] by and between [VASCUPP MEMBER NAME], ("the University") and [Supplier NAME] ("Supplier").

TERM

The term of this Publicly Accessible Contract ("PAC") shall remain in effect until the expiration or termination of the Primary Agreement.

WITNESS

WHEREAS, the University and Supplier have executed an agreement, [CONTRACT NUMBER], dated [CONTRACT DATE] (the "Primary Agreement"), and included in the Primary Agreement is a third party access / cooperative procurement clause. Now therefore, the University and Supplier agree to the specific terms that will allow third-party access to the Primary Agreement, and based on other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

I. Supplier will:

- A. Allow third parties to obtain goods and services from Supplier in accordance with the terms and pricing of the Primary Agreement ("Third-Party Access").
- B. Pay the Virginia Higher Education Procurement Consortium ("Consortium") one percent (1%) of all revenue received by Supplier from non-Consortium entities through Third-Party Access (the "PAC Annual Fee"). The PAC Annual Fee will be paid in exchange for marketing services provided by the University and the Consortium described in Section II.
- C. Fully support this marketing relationship by promoting the availability of the Third Party Access to non-Consortium entities; and
- D. Provide quarterly reports detailing the amount of revenue received from non-Consortium entities through Third-Party Access.

II. The University will ensure the Consortium:

- A. Promotes the Primary Agreement and Third-Party Access on its website and through other channels (e.g., conferences) to non-Consortium members; and
- B. Maintains a Supplier-approved version of the Supplier's logo on the Consortium website.

III. Payment

- A. Supplier shall remit the PAC Annual Fee to the Consortium no later than August 31st of each year. The University and Consortium will share the payments equally and allocate payments to the appropriate accounts.

If the Primary Agreement expires or terminates before August 31st, Supplier shall remit the PAC Annual Fee no later than 45 calendar days from expiration or termination date of the Primary Agreement.

B. Supplier shall remit the PAC Annual Fee by check in U.S. dollars. Checks will be made payable to the University of Virginia and sent to:

Procurement Office Manager
Procurement and Supplier Diversity Services
University of Virginia, Carruthers Hall
PO Box 400202
1001 N. Emmet Street
Charlottesville, VA 22904

Note 'PAC payment' on check.

IV. Notices

Any notice required or permitted to be given under this Agreement will be in writing and will be deemed duly given: (1) if delivered personally, when received; (2) if sent by recognized overnight courier service, on the date of the receipt provided by such courier service; (3) if sent by registered mail, postage prepaid, return receipt requested, on the date shown on the signed receipt: or (4) if sent by electronic mail, on the next business day of the receiver. All such notices will be addressed to a party at such party's address as shown below.

If to the University:

[Lead School Procurement Director]
[Lead School Procurement Address & Contact Info]

If to [Supplier]:

[Supplier Contact]
[Supplier]
[Address]
Email: [Supplier Email]

ACCEPTANCE

For [Lead Institution]	**For [Supplier]**
[Lead Procurement Director]	[Supplier Contact]
[Lead Job Title]	[Supplier Contact Title]
Date	Date

Agreement #: [Contract-Number]-PAC

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
PROCUREMENT DEPARTMENT

ADDENDUM NO. 1

DATE:	**April 24, 2026**
TO:	**All Offerors**
FROM:	Levi Henry, Senior Contracts Officer
TOTAL PAGE(S):	**2**
SOLICITATION TITLE:	Specialized Scientific Equipment and Instrumentation
SOLICITATION NUMBER:	952642606

I. CLARIFICATIONS AND ADDITIONAL INFORMATION

1. The VHEPC Quarterly Reporting Template referenced in the RFP is included as an attachment as part of this addendum. ***Please note that not all fields are required, and we are flexible in allowing the offeror to do the best they can to provide the data as it applies to their product/service offering.

II. REQUESTS FOR INFORMATION

1. We utilize a standardized pricing model that structures pricing by supplier and product line, providing a defined range of minimum and maximum discount percentages within each category. As a result, pricing components such as list price, net price, and installation costs may not be applicable. Will this pricing approach be acceptable for the RFP?

   Yes, this is acceptable just please clearly indicate the discount percentages as part of your pricing approach.

2. Section 10 of Attachment A prohibits stating in our literature that any Commonwealth agency or institution has purchased or uses its products. Are contractors permitted to advertise the agreement itself in its literature? In the PAC it states the University will promote the PAC, but can the contractor promote it as well?

   Yes, contractors are permitted to advertise the agreement itself in its literature. Virginia Tech and VHEPC will both work in conjunction to promote the PAC, and we highly encourage the contractor to promote the PAC as well.

3. *The link in Attachment A appears to be inactive. Please confirm if the doc in the following link is correct:*
   https://www.procurement.vt.edu/content/dam/procurement_vt_edu/docs/terms/RFP-General-Terms-And-Conditions.pdf

   Please use the following link instead:
   https://www.procurement.vt.edu/content/dam/procurement_vt_edu/docs/terms/RFP-General-Terms-And-Conditions.pdf

4. We are seeking clarification regarding invoicing requirements under this contract. Specifically, Section 1X states: “Invoices for goods or services provided under any contract resulting from this solicitation shall be submitted by email to vtinvoices@vt.edu.” Could you please confirm whether this means that all invoices from all participating entities must be submitted to Virginia Tech’s Accounts Payable, or whether this requirement applies only to VT.edu, with other entities receiving invoices directly?

   This section refers strictly to Virginia Tech invoices. Other entities shall be invoiced directly and do not need to be sent to Virginia Tech.

Proposal Summary:

Consolidated Sterilizer Systems began 79 years ago as a “Made in the USA” company and today has more than 15,000 installations in 66 countries. Consolidated sterilizers offer a range of solutions to meet the most demanding applications in clinical, animal and life science, biotechnology, pharmaceutical, and commercial/industrial applications. CSS thrives in tough and challenging situations where space, customer demands, and applications are challenging. We design our customer manufactured products around four basic concepts: Reliability, Serviceability, Functionality, and Cost Effectiveness.

CSS provides sterilizers for small and medium labs, Healthcare, and biocontainment (BSL-3). Our sizes range from 100L-1,000L. CSS offers hinged or sliding vertical doors, single door and pass-thru configurations, integral steam generators, nickel clad or stainless-steel chamber, and a 15-year warranty on every chamber. Water is the life blood of any steam sterilizer. Water quality is important to both effectively sterilize and a robust operating sterilizer overtime. If your supply water needs treatment CSS offers water purification systems configured specifically for your customer’s application and in a small footprint. CSS offers custom designed carts and carriages for all sizes of our autoclaves.

There are four main reasons why CSS autoclaves are the #1 choice for labs:

1. Intuitive easy-to-use controls
    a. CSS units are not overly engineered or complicated. The streamlined controls offer robust flexibility that is simplistic and not overly complicated.
    b. The touchscreen offers a shortcut for “favorites cycles”
    c. Up to 50 programmable cycles. Choose from pre-set industry standard cycles or easily create your own cycle recipe.
2. Lowest total cost of ownership
    a. All of our autoclaves are built using non-proprietary, off-the-shelf parts.
    b. LOWER cost than proprietary parts found on competitor units
    c. Easy to obtain parts for a CSS autoclave
    d. Preventative Maintenance Kits are available for cost-effective and easy maintenance and repair.
    e. Units can be serviced by third-party service providers or your in-house service team, thereby making repairs quick, efficient and affordable.
3. Built-in energy saving features
    a. CSS is so committed to the U.S. Green Building Council that we include a water-eco saving package on EVERY sterilizer. Our sterilizers offer LEED points through four major areas: water efficiency, materials and resources, energy and atmosphere, and innovative design.

b. We also proudly display the ACT label on every sterilizer.
c. CSS built-in water and energy saving features include:
    i. Auto Idle Shutoff
    ii. EcoJacket
    iii. EcoCalendar
    iv. Hood Control
    v. WaterEco
d. Energy savings implications with Steam Control is about 25,000kWh/year
    i. Night/Weekends Off saves 60% consumption
    ii. Saves $2,068/unit (not including HVAC savings)
    iii. 20 gal/day Water is on when probe is above 140F
    iv. 75-99% savings

4. Each autoclave is custom and made to order. We consult with general contractors, architects, owners, and end users without overcomplicating sterilizer build design. This is done in 4 ways:
    i. Compile accurate specifications centered around user application.
    ii. Recommend layout and customize build based on plan drawings
    iii. Identify logistical or installation barriers
    iv. Simplify configurations to provide a simple, easy to use autoclave
    v. CSS builds each autoclave to the customer specifications and to accommodate the customer's unique lab space and application.
        1. Customizations include; steam generator location (underneath, above or next to the chamber, autoclave frame width, drainage (sump pump), controller and door mounting, plumbing location, custom carts and shelving, shelving height, sampling port location, extra sampling ports, custom sterilization cycles, and validation testing for your specific needs

RFP # 952642606, Specialized Scientific Equipment & Instrumentation

INCLUDE THIS PAGE WITH YOUR PROPOSAL, SIGNATURE AT SUBMISSION IS REQUIRED

DUE DATE: Proposals will be received until **May 11th, 2026 at 3:00 PM**. Failure to submit proposals to the correct location by the designated date and hour will result in disqualification.

INQUIRIES: All inquiries for information regarding this solicitation should be directed to Levi Henry, Phone: (540) 231-7852 e-mail: lhenry29@vt.edu. All inquiries will be answered in the form of an addendum. Inquiries must be submitted by 3:00 PM on April 24, 2026. Inquiries must be submitted to the procurement officer identified in this solicitation.

PROPOSAL SUBMISSION:

Please note, proposal submission procedures have changed effective March 2023.

Proposals may NOT be hand delivered to the Procurement Office.

Proposals should be submitted electronically through Virginia Tech's procurement portal. This portal allows you access to view business opportunities and submit bids and proposals to Virginia Tech digitally and securely.

Proposals must be submitted electronically at:
https://bids.sciquest.com/apps/Router/PublicEvent?CustomerOrg=VATech

Vendors will need to register through this procurement portal, hosted by Jaggaer. **It is encouraged for all vendors to register prior to the proposal submission deadline to avoid late submissions**. Registration is easy and free. If you have any challenges with the registration process, please contact Jaggaer Support at 1-800-233-1121 or procurement@vt.edu.

Click on the opportunity and log in to your vendor account to begin preparing your submission. Upon completion, you will receive a submission receipt email confirmation. Virginia Tech will not confirm receipt of proposals. It is the responsibility of the offeror to make sure their proposal is delivered on time.

Hard copy or email proposals will not be accepted. Late proposals will not be accepted, nor will additional time be granted to any individual Vendor.

Attachments must be smaller than 50MB in order to be received by the University.

In compliance with this Request For Proposal and to all the conditions imposed therein and hereby incorporated by reference, the undersigned offers and agrees to furnish the goods or services in accordance with the attached signed proposal and as mutually agreed upon by subsequent negotiation.

AUTHORIZED SIGNATURE: Gary K. Fowles Date: 5/8/2026

[INCLUDE THIS PAGE]

CONSOLIDATED STERILIZER SYSTEMS

Sales Rep	**Jim Walker**	Quote #	**19103-1**
Sales Rep Phone #	**(336) 580-4111**	Quote Date	**April 20, 2026**
Sales Rep Email	**jimw@aresscientific.com**	Expiration Date	**June 30, 2026**

Quote To:
Thermo Fisher Scientific
Gianluca LaPalombella
587 Industrial Park
Wilson, NC 27893
(224) 230-3313
gianluca.lapalombella@thermofisher.com

Ship To:
Thermo Fisher Scientific
Gianluca LaPalombella
587 Industrial Park
Wilson, NC 27893
(224) 230-3313
gianluca.lapalombella@thermofisher.com

We are pleased to submit the following quotation for your consideration:

Line	Description	Qty.	Extended Price
1.0	**Model PT-SR-26B : 26" × 26" × 49" chamber pass-thru sterilizer** with the following features:	**1**	**$138,406.64**
	Selected Options		
	316L Stainless Steel Chamber with 304L Stainless Steel Jacket Standard Finish (Passivated Chamber) Stainless Steel Recessed Panel at One End and Cabinet at the Other End Left Door Hinge at Load End and Left Hinge at Unload End Stainless Steel Generator - Large 39 kW Generator: 480 Volts, 3 Phase Loading Cart, Two (2) transfer carriages, and chamber tracks - One for Dirty Side Loading Cart, Two (2) transfer carriages, and chamber tracks - One for Clean side X1 Controls: 7" Color Touchscreen, up to 50 programmable cycles Primary Controls Mounted on Unload End Thermal Printer Double Door Interlock System Controls: 110 Volts, 60 Hz (Standard) Password Protection (up to 50 users & passwords) and Lockable Cycle Parameters Dual Controls (includes secondary 7" touchscreen) Emergency Stop Button SteriNET Dataport - USB Effluent Decontamination System (includes 50 filters) Cross Contamination Bioseal Stainless Steel Piping, Valves & Fittings in contact with Process Steam Gravity Air Removal with Economy Post-Vacuum Drying System Automatic Jacket Blowdown for Liquids Cycle WaterEco® Water Conservation & Monitoring System		
	Standard Features		
	Double Door Configuration EcoCalendar & Auto Idle Shut-Off capability for energy efficient control of steam ASME (American Society of Mechanical Engineers) U-1 Code Stamping 1/2" Thermocouple Port UL, cUL Listed Hinged, Fully opening, manual door CSS Starter Kit including C3 cleaner and scrubbing pads, a pair of autoclave gloves, printer paper and printer ribbon (if applicable), and electronic manuals		

CONSOLIDATED STERILIZER SYSTEMS

Installation for Line 1 Installation Level 4 (Turnkey): Includes receiving sterilizer, uncrating, setting into place, leveling, final assembly, final utility connections, start-up, and user training. Does not include permitting, inspections, or building modifications, unless previously approved by CSS. Prior to installation, the customer is responsible to provide utility connections within 5 feet of the sterilizer.	**$19,704.30**

Pricing Summary	
Total Base Configuration Price	**$138,406.64**
Additional Options Total	**$0.00**
Installation Total	**$19,704.30**
Shipping & Handling: FOB Destination **Freight charges include dock to dock shipment. Customer is responsible for offloading delivery from truck unless installation includes receiving or otherwise specified. A raised loading dock or forklift (or other means to offload the truck), as well as pallet jack are required at the delivery location. Additional services such as liftgate, short truck, inside delivery, or guaranteed shipments not included unless otherwise specified.** Please contact Consolidated if additional services are required. Due to market conditions, Shipping and Handling is an estimate only. Applicable rates at the time of shipment will be applied and added to invoice(s). Freight amount is based on all items shipping together. Split shipments will incur additional freight costs.	**$2,873.00**

Grand Total: $160,983.94

Thank you for your interest in Consolidated Sterilizer Systems! For questions about your quotation, please contact your sales representative, Jim Walker, at (336) 580-4111.

Consolidated recommends a Preventative Maintenance inspection by an authorized service team once every 300 cycles or once per year, whichever comes first. For more information on preventative maintenance please visit our website https://consteril.com/support-and-services/sterilizer-maintenance/ or contact your sales representative.

Terms and Conditions:

***Domestic Quote Terms/Warranty:** https://www.consteril.com/domestic-quote-terms-and-conditions/
***International Quote Terms/Warranty:** https://www.consteril.com/international-quote-terms-and-conditions/

Quotation does not include applicable Sales/Use taxes. The purchaser will be invoiced for such taxes unless exempt.

Quotes are valid for 30 days, and are based on delivery within 9 months of the quotation date.

Financing Option: Financing is available through CIT Bank with flexible terms (12-72 months). Apply online and receive eligibility within minutes: https://consteril.directcapital.com/

CONSOLIDATED STERILIZER SYSTEMS

Please email purchase orders to sales@consteril.com - Purchase orders must reflect our remit-to address to be accepted.
Please remit payment to **3 Enterprise Road, Suite C, Billerica, MA 01821.**

CONSOLIDATED STERILIZER SYSTEMS

Quality Manual

TITLE:

Quality Manual

DOC. NO.:	Rev.
Q93424	**02**

REVISION HISTORY

Revision	Change Details	Date	ECO
01	Initial Release	1/8/2024	534
02	Update section 3 to remove “I don’t know why” Update section 5.3 to add a new released procedure Incoming Inspection Procedure Non-ASME	5/05/2025	652

INDEX:

Appendix B: Sequence and Interaction of QMS Processes

1. NOTIFICATION OF THE FOOD AND DRUG ADMINISTRATION

1.1. Consolidated Sterilizer System will promptly inform the Food and Drug Administration as applicable, of any significant change to the company that may include the following items:

1.1.1. Changes in the location of the firm,
1.1.2. Change in ownership of the firm,
1.1.3. Change in Management Representative and/or Official Correspondent,
1.1.4. Change in trade name or reorder numbers,
1.1.5. Changes in US FDA Establishment type (e.g. manufacturer, specification developer, etc.)
1.1.6. Significant changes in the Quality Management System

2. Scope

2.1. This Quality Manual describes the Quality Management System (QMS) of Consolidated Machine Corp with the business trade name Consolidated Sterilizer Systems. (CSS). Consolidated Machine Corp will be referred by its business trade name Consolidated Sterilizer Systems (CSS) in this document.

2.2. This Quality Manual applies to all finished medical devices and related processes regulated by FDA CFR Part 820, Quality System Regulations.

2.3. CSS is a privately held corporation located at 3 Enterprise Road, Suite C, Billerica, MA 01821.

2.4. CSS designs and develops, manufactures, and markets products and related accessories for sterilization.

2.5. The QMS is practiced in compliance with the standards listed below, and is appropriate for the specific medical devices produced by Consolidated Sterilizer Systems.

3. Exclusions and Non-Applicable Requirements

None. All QMS requirements of FDA 21 CFR Part 820, Quality System Regulations, are applicable to CSS's QMS.

4. Definitions and Acronyms

Refer to the definitions defined in FDA 21 CFR Part 820, Quality System Regulations.

5. Quality Management System

5.1. General Requirements

5.1.1. \The requirements within this Quality Manual only applies to the healthcare products designed and manufactured by CSS. The Quality System Regulations (FDA QSR) will be referred to as the 'Standards' throughout this Quality Manual. Other Standards and regulations may be applicable to specific processes of the QMS, these will be identified in the appropriate QMS procedures. CSS maintains the effectiveness of the QMS in accordance with the requirements of the Standards and any applicable regulatory requirements.

5.1.1.1. FDA 21 CFR Part 820, Quality System regulations: Good Manufacturing Practice for Medical Devices (FDA QSR's)

5.1.2. CSS has determined:

5.1.2.1. The processes needed for the QMS and the application of these processes taking into account the roles undertaken by CSS.

5.1.2.2. Applied a risk-based approach to the control of these processes, as applicable.

5.1.2.3. The sequence and interaction of these processes is shown as a flowchart in Appendix B and then the requirements of the FDA QSR's cross-referenced to CSS Procedures in Q93438 Quality System Index.

5.1.3. For each QMS process CSS has done the following:

5.1.3.1. Determined the criteria and methods needed to ensure that both the operation and control of these processes are effective;

5.1.3.2. Ensured the availability of resources and information necessary to support the operation and monitoring of these processes;

5.1.3.3. Implemented actions necessary to achieve planned results and maintain the effectiveness of these processes;

5.1.3.4. Set up monitoring and measuring as appropriate to analyze each process, and

5.1.3.5. Established and maintains records needed to demonstrate conformance to the Standards and applicable regulatory requirements.

5.1.4. To ensure continued compliance of the QMS processes CSS assesses changes as follows:

5.1.4.1. Evaluates them for their impact on the QMS;

5.1.4.2. Evaluates them for their impact on the components and devices produced under the QMS; and

5.1.4.3. Controls their implementation to ensure continued compliance with the requirements of the Standards and applicable regulatory requirements.

5.1.5. Nay process outsourced by CSS that may impact the conformity of the components and devices manufactured. CSS ensure proper control over such processes by controlling the suppliers as defined in P43405-01 Purchasing Procedure and P93403-01 Supplier Qualification and Management Procedure. The controls will be proportionate to the criticality of the supplier and the ability of the supplier to meet the customer's requirements.

5.1.6. CSS has a procedure for the validation of the application of computer software used in the QMS, P93431-01 Validation Procedure. Such software will be validated prior to initial use and, as appropriate, after changes to such software or its application.

5.1.6.1. The specific approach and activities associated with software validation and revalidation will be proportionate to the risk associated with the use of the software.

5.1.6.2. Records of validation and revalidation activities will be maintained.

5.2. Documentation Requirements

5.2.1. General

5.2.1.1. The CSS QMS documentation includes the following:

5.2.1.1.1. This Quality Manual (Q93424) which is a collection of the QMS Policies including the Quality Policy.

5.2.1.1.2. Documented Procedures that provide details as to how CSS implements the QMS Policies and identify the quality records that are generated for each process as required by the Standards and, as applicable, regulatory requirements.

5.2.1.1.2.1. Procedures may also identify other records determined by CSS to be necessary to ensure the effective planning, operation, and control of its processes.

5.2.2. Quality Manual

5.2.2.1. This Quality Manual includes the following:

5.2.2.1.1. The Scope of the CSS QMS, including details of and justification for any exclusions or non-application;

5.2.2.1.2. References to the procedures of the QMS where they are applicable; and,

5.2.2.1.3. Provides a description of the interaction between the processes of the QMS in Appendix B.

5.2.2.1.4. The hierarchy of QMS documentation is shown in the image in Appendix A.

5.2.2.1.4.1. The QM, Procedures and quality records are explained in the previous section.

5.2.2.1.4.2. Work Instructions provide additional detail for Procedure activities, as needed.

5.2.2.1.4.3. When filled out, forms provide quality records.

5.2.3. Device Master Record (DMR)

5.2.3.1. CSS maintains a Device Master Record (DMR) for every medical device as part of the P93448-01 Design Control. The DMR includes or references the location of the following at a minimum:

5.2.3.1.1. Device specifications including appropriate drawings, component specifications, and software specifications

5.2.3.1.2. Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

5.2.3.1.3. Quality assurance procedures and specifications including acceptance criteria

5.2.3.1.4. Packaging and labeling specifications, including methods and processes used.,

5.2.3.1.5. Installation, maintenance, and servicing procedures and methods.

5.2.4. Document Controls

5.2.4.1. Documents of the CSS QMS are controlled according to P92542-01 ECO Change Order (ECO) & Document Control Procedure, and P93445 Quality Records Procedure. Records are a special type of document and are controlled as defined in Section 4.2.5 of this Quality Manual. P92542-01 defines the document controls needed to:

5.2.4.1.1. Review and approve documents for adequacy prior to issue;

5.2.4.1.2. Review, update as necessary, and re-approve documents;

5.2.4.1.3. Ensure that the current revision status of and changes to documents are identified;

5.2.4.1.4. Ensure that relevant versions of applicable documents are available at points of use;

5.2.4.1.5. Ensure that documents remain legible and readily identifiable;

5.2.4.1.6. Ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the QMS are identified and their distribution controlled;

5.2.4.1.7. Prevent deterioration or loss of documents; and,

5.2.4.1.8. Prevent the unintended use of obsolete documents and apply suitable identification to them.

5.2.4.2. CSS ensures changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decision.

5.2.4.3. The period for which at least one copy of obsolete documents is retained is inherent to the retention period for ECO's (Engineering Change Orders) as defined in P93445-01 Quality Records Procedure. The document retention period defined ensures that documents to which devices have been manufactured are retained for at least the lifetime of the device plus ten years .

5.2.5. Control of records

5.2.5.1. Quality records (QRs) are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS.

5.2.5.2. P93445-01 Quality Records Procedure defines the process used by CSS for the following:

5.2.5.2.1. Controlling the identification, storage, security and integrity, retrieval, retention time and disposition of records;

5.2.5.2.2. CSS would only receive confidential health information as part of the P93423, Complaint Handling Procedure. The process is designed to only require general information, not confidential information;

5.2.5.2.3. Ensuring the legibility, identification and ability to retrieve quality records;

5.2.5.2.4. Making corrections to quality records as defined in the procedure for good documentation practices P93741-01; and,

5.2.5.2.5. Retaining finished device records for at least the lifetime of the medical device plus ten years as defined in P93445-01 Quality Records Procedure.

5.3. To follow is a list of Procedures that describe the processes to be used to satisfy the Policies described in Section 4 of this Quality Manual.

5.3.1.	Q93438	Quality System Index
5.3.2.	P93405-01	Purchasing Procedure
5.3.3.	P93892-01	Incoming Inspection Procedure Non-ASME
5.3.4.	P93403-01	Supplier Qualification and Supplier Controls
5.3.5.	P93431-01	Validation Procedure
5.3.6.	P92542-01	Engineering Change Order (ECO) & Document Control Procedure
5.3.7.	P93445-01	Quality Records Procedure Data Control
5.3.8.	P93445-01	Quality Records Procedure
5.3.9.	P93741-01	Good Documentation Practices
5.3.10.	P92543-01	Engineering Documentation Procedure
5.3.11.	P92665-01	Engineering Drawing Standard Procedure
5.3.12.	P93393-01	Corrective and Preventive Action Procedure
5.3.13.	P93394-01	Internal Audit Procedure
5.3.14.	P93395-01	Recall Procedure
5.3.15.	P93402-01	Training Procedure
5.3.16.	P93403-01	Supplier Qualification and Management Procedure
5.3.17.	P93404-01	Software Development Procedure
5.3.18.	P93407-01	Nonconforming Material Procedure
5.3.19.	P93423-01	Complaint Handling Procedure
5.3.20.	P93425-01	Risk Management Procedure

5.3.21. P93429-01 Management Review Procedure
5.3.22. P93431-01 Validation Procedure
5.3.23. P93440-01 Calibration Procedure
5.3.24. P93442-01 Device Master Record
5.3.25. P93444-01 Device History Record
5.3.26. P93445-01 Quality Record Procedure
5.3.27. P93447-01 Production Specification – Healthcare Sterilizer
5.3.28. P93448-01 Design Controls
5.3.29. P93454-01 HC Sterilizer Risk Management Plan
5.3.30. P93517-01 HC Sterilizer Risk Analysis
5.3.31. P93520-01 Unique Device Identifier (UDI) Procedure
5.3.32. P93521-01 Shipping Procedure
5.3.33. P93685-01 Inspection and Testing Procedure
5.3.34. P93740-01 Contract Review Procedure
5.3.35. P93744-01 Service Procedure
5.3.36. P93745-01 Electronic Back up Procedure
5.3.37. P93751-01 Storage and Handling Procedure
5.3.38. P93438-01 Quality System Index Procedure
5.3.39. P93755-01 Identification and Traceability Procedure
5.3.40. P93751-01 Storage and Handling Procedure
5.3.41. P93754-01 Process Control Procedure
5.3.42. P93441-01 Preventive Maintenance
5.3.43. P93743 -01 Returned Material Authorization Procedure

6. Management Responsibility

6.1. Management Commitment

6.1.1. To provide evidence of its commitment to the development and implementation of the QMS and the maintenance of its effectiveness, the management of CSS has done the following:

6.1.1.1. Communicated to the organization the importance of meeting customer requirements as well as applicable regulatory requirements;
6.1.1.2. Established the Quality Policy;
6.1.1.3. Ensured that Quality Objectives are established;
6.1.1.4. Conducted Management Reviews; and
6.1.1.5. Ensured the availability of resources.
6.1.1.6. Appoint a Management Representative

6.2. Customer Focus

6.2.1. The management of CSS ensures that customer requirements and applicable regulatory requirements are determined and met by participating in the P93448-01 Design Control procedure. CSS ensures customer needs are met by ensuring methods for Purchasing (P93405-01) are documented and customer feedback is reviewed per the Complaint Handling Procedure(P93423-01).

6.3. Quality Policy

6.3.1. CSS has documented and communicated a Quality Policy. Management ensures that the Quality Policy does the following:

6.3.1.1. Is applicable to the purpose of the organization;
6.3.1.2. Includes a commitment to comply with requirements and to maintain the effectiveness of the QMS;
6.3.1.3. Provides a framework for establishing and reviewing quality objectives;
6.3.1.4. Is communicated and understood within CSS and,
6.3.1.5. Is reviewed for continuing suitability.

6.3.2. The CSS Quality Policy

"Consolidated Sterilizer Systems is dedicated to the development and manufacture of steam sterilizer products that comply with customer needs and regulatory standards, are safe and effective, and significantly contribute to the quality of care given to patients. Consolidated Sterilizer Systems is committed to continual improvement of its products, services, and Quality Management System."

6.4. Planning

6.4.1. Quality objectives

6.4.1.1. Management will ensure that Quality Objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization.
6.4.1.2. Quality Objectives will be established, reviewed, and updated during Management Review Meetings (P93429-01).
6.4.1.3. Quality Objectives will be measurable and consistent with the Quality Policy.

6.4.2. QMS Planning

6.4.2.1. CSS Management ensures the QMS is carried out to meet the requirements of the Standards, regulatory requirements, and the CSS Quality Objectives, and that the integrity of the QMS is maintained when making changes that could impact the QMS.
6.4.2.2. CSS will manage significant changes to ensure the QMS is not negatively impacted during implementation of a significant change. Significant changes can be managed using a quality plan, an ECO, or a corrective or preventive action depending on the complexity of the change.

6.5. Responsibility, authority and communication

6.5.1. Responsibility and authority

6.5.1.1. An organization chart and Job Descriptions detailing the responsibilities and authorities of personnel are defined, documented, communicated, and maintained. The organization chart shows the interrelationship of personnel who manage, perform, and verify work affecting product quality. QMS procedures provide additional detail of responsibilities. The organization chart clearly shows management has given employees the independence and authority needed to perform their tasks.

6.5.2. Management representative

6.5.2.1. CSS has appointed the CEO as the Management Representative. The Management Representative, irrespective of other responsibilities has responsibility and authority that includes the following:
6.5.2.1.1. Ensuring that processes needed for the QMS are documented;
6.5.2.1.2. Reporting to top management on the effectiveness of the QMS and any need for improvement; and

6.5.2.1.3. Ensuring the promotion of awareness of applicable regulatory requirements and QMS requirements throughout CSS.

6.5.3. Internal communication

6.5.3.1. Top management ensures that appropriate communication processes are established within CSS and that communication takes place regarding the effectiveness of the QMS.

6.5.3.1.1. Initial employee training, and the need for updated training when documents of the QMS are revised, currently serve as CSS's ongoing communication method. (defined in P93402-01 Training Procedure and P92542-01 ECO Change Order (ECO) & Document Control Procedure

6.5.3.1.2. Management Review also serves as a communication means. (P93429-01 Management Review).

6.6. Management review

6.6.1. General

6.6.1.1. The CSS management review process is documented in P93429-01 Management Review. Top management reviews CSS's QMS at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The Review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

6.6.1.2. Records from Management Review are maintained.

6.6.2. Review input

6.6.2.1. Inputs to Management Review will include the following at the least.

6.6.2.1.1. Feedback;
6.6.2.1.2. Complaint handling;
6.6.2.1.3. Reporting to regulatory authorities;
6.6.2.1.4. Audits;
6.6.2.1.5. Monitoring and measurement of processes;
6.6.2.1.6. Monitoring and measurement of product;
6.6.2.1.7. Corrective actions;
6.6.2.1.8. Preventive actions;
6.6.2.1.9. Follow-up actions from previous management reviews;
6.6.2.1.10. Changes that could affect the QMS;
6.6.2.1.11. Recommendations for improvement;
6.6.2.1.12. Applicable new or revised regulatory requirements

6.6.3. Review output

6.6.3.1. Outputs from Management Review Meetings will be recorded and include the input reviewed. The Minutes will include any decisions and actions related to the following that resulted from the Meeting.

6.6.3.1.1. Improvements needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes;
6.6.3.1.2. Improvement of product related to customer requirements;
6.6.3.1.3. Changes needed to respond to applicable new or revised regulatory requirements;
6.6.3.1.4. Resource needs.

7. Resource management

7.1. Provision of resources

7.1.1. CSS has determined and provided the resources needed to:

7.1.1.1. Implement the QMS and to maintain its effectiveness;

7.1.1.2. and meet applicable regulatory and customer requirements.

7.1.2. The organization, through the management review process, identifies the need for acquisition of necessary resources such as human resources, equipment, processes, suppliers, and facilities.

7.1.3.

7.2. Human resources

7.2.1. CSS ensures that that personnel who perform work affecting product quality are competent on the basis of appropriate education, training, skills and experience. Detailed job descriptions are available for each position, and these are used to select appropriately qualified individuals.

7.2.2. The training process described in P93402-01 addresses the following:

7.2.2.1. Determining the necessary competence for personnel performing work affecting product quality;

7.2.2.2. Providing training or taking other action to achieve or maintain the necessary competence;

7.2.2.3. Evaluating the effectiveness of the actions taken using a method that is proportionate to the risk associated with the work for which the training or other action is being provided; and,

7.2.2.4. Ensuring personnel are aware of their relevance and the importance of their activities and how they contribute to the achievement of the quality objectives; and

7.2.2.5. Maintaining appropriate records of education, training, skills and experience.

7.2.3. Training effectiveness is evaluated by a number of different methods, depending upon the type of training conducted to the risk associated with the work. Such effectiveness checks may include but not limited to observing daily job performance, competency testing, appropriate on-the-job training documentation, internal audit results, and corrective actions.

7.3. Infrastructure

7.3.1. CSS documents the requirements for infrastructure needed to achieve conformity to product requirements, prevent product mix-ups, and ensure orderly handling of product as defined in P93448-01 Design Controls and P93754-01Process Controls. Infrastructure includes the following, as appropriate.

7.3.1.1. Buildings, workspace and associated utilities;

7.3.1.2. Process equipment (both hardware and software); and,

7.3.1.3. Supporting services (such as transport, communications, or information systems).

7.3.2. CSS will document the requirements for maintenance activities, including the interval for performing maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. The need for these activities would be determined during design transfer to production as defined in P93448-01 Design Controls or as new equipment is introduced to CSS operations as described in the P93441-01 Preventive Maintenance. As appropriate, these requirements will apply to control of the work environment and monitoring and measurement as well.

7.4. Work environment and contamination control

7.4.1. Work Environment

7.4.1.1. CSS determines the requirements for the work environment needed to achieve conformity to product requirements as defined in P93448-01 Design Controls and P93754-01 Process Controls.

7.4.1.2. CSS ensures that preheat temperature for welding is specified and that the maximum interpass temperature is in accordance with the requirement.

7.4.1.3. CSS does their manufacturing in an environment appropriate for capital equipment manufacture requiring significant metal work, plumbing and electrical, not requiring cleanliness standards (e.g. Controlled Environment Rooms (CER)).

7.4.2. Contamination control

7.4.2.1. CSS does not receive or introduce potentially contaminated product which could affect the work environment, personnel and product.

7.4.2.2. CSS does not manufacture sterile medical devices.

8. Product realization

8.1. Planning of product realization

8.1.1. CSS plans and develops product as defined in P93448-01 Design Controls. Planning of product realization is consistent with the requirements of other processes of the QMS.

8.1.2. P93425-01 Risk Management, defines how CSS manages risks during product realization. Records of risk management activities are maintained as defined in this procedure.

8.1.3. As part of product realization CSS determines the following, as appropriate.

8.1.3.1. Quality objectives and requirements for the product;

8.1.3.2. The need to establish processes and documents and to provide resources specific to the product, including infrastructure and work environment;

8.1.3.3. Activities and acceptance requirements for verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product; and,

8.1.3.4. The records needed to provide evidence that the realization process and resulting product meet requirements.

8.1.4. The outputs of the product realization process will be documented in a form suitable for CSS's method of operations as defined in P93448-01 Design Controls.

8.2. Customer-related processes

8.2.1. Determination of requirements related to product

8.2.1.1. CSS determines the following requirements related to product.

8.2.1.1.1. The customer-specified requirements including those for delivery and post-delivery activities;

8.2.1.1.2. The requirements not stated by the customer, but necessary for specified or intended use, as known;

8.2.1.1.3. Applicable regulatory requirements related to the product;

8.2.1.1.4. Any user training needed to ensure specified performance and safe use of the medical device; and,

8.2.1.1.5. Any additional requirements determined by CSS.

8.2.1.2. The method for doing this is documented in P93740-01 Contract Review Procedure

8.2.2. Review of requirements related to product

8.2.2.1. CSS reviews the requirements related to product prior to committing to supply product to the customer and ensures the following:

8.2.2.1.1. Product requirements are defined and documented:

8.2.2.1.2. Order requirements differing from those previously expressed are resolved;

8.2.2.1.3. Applicable regulatory requirements are met;

8.2.2.1.4. Any user training needed to ensure specified performance and safe use of the device is available or planned to be available; and,

8.2.2.1.5. CSS has the ability to meet the defined requirements.

8.2.2.2. Records are kept of the review and actions arising from the review.

8.2.2.3. If the customer provides no documented statement of requirement, the customers' requirements will be documented and confirmed prior to order acceptance.

8.2.2.4. When product requirements are changed, CSS ensures that the relevant documents are amended and that relevant personnel are made aware of the changed requirements.

8.2.2.5. The review process is documented as defined in P93740-01Contract Review Procedure.

8.2.3. Communication

8.2.3.1. CSS communicates with its customers regarding the following according to the Procedure listed:

8.2.3.1.1. Product information

8.2.3.1.2. Enquiries, contracts or order handling, including amendments

8.2.3.1.3. Customer feedback (P93423-01), including complaints.

8.2.3.1.4. Advisory notices (P93423-01 Complaint Handling Procedure).

8.2.3.2. As needed, CSS will communicate with regulatory authorities in accordance with regulatory requirements as defined P93423-01 Complaint Handling Procedure and P93395-01 Recall.

8.3. Design and development

8.3.1. General

8.3.1.1. CSS's P93448-01 Design Controls defines CSS's procedure for product design and development.

8.3.2. Design and development planning

8.3.2.1. CSS plans and controls the product design and development process. As appropriate, design and development planning documents will be maintained and updated as the design and development progresses.

8.3.2.2. During design and development planning CSS documents the following:

8.3.2.2.1. The design and development phases;

8.3.2.2.2. The review(s) needed at each design and development phase;

8.3.2.2.3. The verification, validation, and design transfer activities that are appropriate at each design and development phase;

8.3.2.2.4. The responsibilities and authorities for design and development;

8.3.2.2.5. The methods to ensure traceability of design and development outputs to design and development inputs; and,

8.3.2.2.6. The resources needed, including necessary competence of personnel.

8.3.3. Design and development inputs

8.3.3.1. CSS determines the inputs relating to products requirements and maintains records of the design inputs. The design inputs will include the following.

8.3.3.1.1. Functional, performance, usability and safety requirements, according to the intended use;

8.3.3.1.2. Applicable regulatory requirements and standards;

8.3.3.1.3. The applicable output(s) of risk management (P93425-01);

8.3.3.1.4. As appropriate, information derived from previous similar designs; and,

8.3.3.1.5. Other requirements essential for the design and development of the product and processes.

8.3.3.2. Design input requirements will be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

8.3.3.3. Design inputs are reviewed for adequacy and approved.

8.3.4. Design and development outputs

8.3.4.1. Design and development outputs shall contain the following as described in P93448 Design Controls.

8.3.4.1.1. Meet the input requirements for design and development;

8.3.4.1.2. Provide appropriate information for purchasing and production provision;

8.3.4.1.3. Contain or reference product acceptance criteria; and,

8.3.4.1.4. Specify the characteristics of the product that are essential for its safe and proper use.

8.3.4.2. The outputs of design and development will be in a form suitable for verification against the design and development inputs and be approved prior to release.

8.3.4.3. Records of the design and development outputs will be maintained.

8.3.5. Design and development review

8.3.5.1. At suitable phases of the design and development process, design reviews will be held in accordance with planned and documented arrangements. The purpose of a design review is:

8.3.5.1.1. To evaluate the ability of the results of design and development to meet requirements; and,

8.3.5.1.2. To identify and propose necessary actions.

8.3.5.2. Participants in design reviews will include representatives of functions concerned with the design and development phase being reviewed, an independent reviewer (an individual who does not have direct responsibility for the design phase being reviewed), and specialist personnel, as needed.

8.3.5.3. Records of the results of reviews and any necessary actions will be maintained and include the identification of the design under review, the participants involved, and the date of the review.

8.3.6. Design and development verification

8.3.6.1. Design and development verification is performed in accordance with planned and documented arrangements to ensure that the design and development outputs satisfy the input requirements.

8.3.6.2. CSS documents verification plans including methods, acceptance criteria and, as appropriate, statistical techniques with a rationale for the sample size chosen.

8.3.6.3. If a CSS product is designed to interface with other medical devices already in commerce, verification plans will include confirmation that the design outputs meet design inputs when interfaced as intended.

8.3.6.4. Records of the results and conclusions of the verification and necessary actions will be maintained.

8.3.7. Design and development validation

8.3.7.1. Design and development validation is performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

8.3.7.2. Plans for design validation will be documented and include methods, acceptance criteria and, as appropriate, statistical techniques with a rationale for the sample size chosen.

8.3.7.3. Design validation will be conducted on representative product such as initial production units or their equivalent. The rationale for the choice of product used for validation will be recorded.

8.3.7.4. As part of design and development validation CSS performs clinical evaluations or performance evaluations of the medical device in accordance with regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

8.3.7.5. When CSS products are designed to be connected to, or have an interface with, other medical devices, validation will confirm that the requirements for the specified application or intended use have been met when so interfaced.

8.3.7.6. Validation will be completed prior to release for use of the product to the customer.

8.3.7.7. Records of the results and conclusion of validation and necessary actions will be maintained.

8.3.8. Design and development transfer

8.3.8.1. CSS has documented a process for the transfer of design and development outputs to manufacturing or 'design transfer' in P93448-01 Design Controls. The design outputs will be verified as suitable for manufacturing before becoming final production specifications and CSS will verify that production capability can meet product requirements.

8.3.8.2. The results and conclusion of design transfer will be recorded.

8.3.9. Control of design and development changes

8.3.9.1. CSS has documented procedures to control design and development changes in P93448-01 Design Controls and P92542-01 ECO Change Order (ECO) & Document Control Procedure. The significance of changes will be determined with respect to product function, performance, usability, and safety, as well as applicable regulatory requirements (essential requirements) for the medical device and its intended use.

8.3.9.2. When design and development changes are identified the changes will be reviewed, verified, validated, as appropriate, and approved, before implementation.

8.3.9.3. The review of design and development changes will include evaluation of the effect of the change on constituent parts and product in process or already

delivered; inputs or outputs of risk management; and, the product realization processes.

8.3.9.4. Records of changes, their review and necessary actions will be maintained.

8.3.10. Design and development files

8.3.10.1. CSS maintains a Design History File (DHF) for each medical device type or medical device family. The DHF includes or references the records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

8.4. Purchasing

8.4.1. Purchasing process

8.4.1.1. CSS has documents P43405-01 Purchasing Procedure, P93403-01 Supplier Qualification and Management Procedure and P93685-01 Inspection and Testing, to ensure that purchased product conforms to specified purchasing information.

8.4.1.2. CSS evaluates and selects suppliers according to P93403-01 Supplier Qualification and Management Procedure, from which to purchase materials according to P43405-01 Purchasing Procedure. The criteria for selecting suppliers include the following.

8.4.1.2.1. The supplier's ability to provide product that meets CSS's requirements;

8.4.1.2.2. The performance of the supplier;

8.4.1.2.3. The effect of the purchased product on the quality of the medical device; and,

8.4.1.2.4. Is proportionate to the risk associated with the medical device.

8.4.1.3. CSS plans the monitoring and re-evaluation of suppliers according to P93403-01 Supplier Qualification and Management Procedure. The Supplier's ability to meet requirements for the purchased product is monitored through the records of the Nonconforming Materials Procedure (P93407-01).

8.4.1.4. Non-fulfillment of purchasing requirements will be addressed with the supplier proportionate to the risks associated with the purchased product and any risk to compliance with regulatory requirements using the P93407-01 Nonconforming Materials Procedure and P93393-01 Corrective Action Procedure. As applicable these processes will provide input into the supplier re-evaluation process and/or the incoming inspection process.

8.4.1.5. Records are kept of the evaluation, selection, monitoring and re-evaluation of supplier capability and/or performance, and any actions resulting from these activities.

8.4.2. Purchasing information

8.4.2.1. According to P43405-01 Purchasing Procedure purchasing information will describe or reference the product to be purchased including the following.

8.4.2.1.1. Product specifications;

8.4.2.1.2. Requirements for product acceptance, procedures, processes, and equipment;

8.4.2.1.3. Requirements for qualification of supplier personnel; and,

8.4.2.1.4. QMS requirements.

8.4.2.2. CSS ensures the adequacy of specified purchasing requirements prior to their being communicated to the supplier according to P43405-01 Purchasing Procedure.

8.4.2.3. Purchasing information includes, as applicable, a written agreement that the supplier notify CSS of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified requirements.

8.4.2.4. CSS defines the requirements for traceability as applicable in purchasing records. Records of purchasing are maintained.

8.4.3. Verification of purchased product

8.4.3.1. The process used by CSS to receive purchased product to ensure the product meets specified purchasing requirements is defined in P93685-01 Inspection and Testing. The extent of verification activities is based on the supplier evaluation results (P93403-01) and proportionate to the risks associated with the purchased product (P93425-01).

8.4.3.2. When CSS is informed of changes to the purchased product, CSS will determine if the changes affect the product realization process or the medical device.

8.4.3.3. If CSS or its customer intends to perform verification at the supplier's premises CSS will state the intended verification activities and method of product release in the purchasing information.

8.4.3.4. Records of the verification of purchased product will be maintained.

8.5. Production and Service provision

8.5.1. Control of production and Service provision

8.5.1.1. Production of CSS devices is planned, carried out, monitored and controlled to ensure that product conforms to specification, in accordance with P93754-01 Process Controls procedure. As appropriate, production controls include the following.

8.5.1.1.1. Documentation of procedures and methods for the control of production;

8.5.1.1.2. Qualification of infrastructure;

8.5.1.1.3. Implementation of monitoring and measurement of processes parameters and product characteristics;

8.5.1.1.4. Availability and use of monitoring and measuring equipment;

8.5.1.1.5. Implementation of defined operations for labeling and packaging; and,

8.5.1.1.6. Implementation of product release, delivery and post-delivery activities.

8.5.1.2. CSS establishes and maintains a record in accordance with section 4.2.5, control of records, through P93445-01 Quality Records Procedure. The records for each medical device that provide traceability to the extent specified in 7.5.9., traceability, through P93754-01 Process Controls Procedure. Records identify the amount manufactured and amount approved for distribution through P93444-01 Device History Record Procedure. The records are verified and approved before products are moved to finished goods and become available for commercial distribution.

8.5.2. Cleanliness of product:

8.5.2.1. CSS product is a non-sterile product. CSS develops and documents the requirements for cleanliness of the product through P93448-01 Design Control Procedure and P93425-01 Risk Management, and are provided to the customer

with the product. Requirements for cleanliness of the product during manufacturing are in accordance with P93754-01Process Controls Procedure.

8.5.3. Installation activities:

8.5.3.1. CSS develops and documents requirements for the medical device installation and acceptance criteria for verification of installation, as appropriate, in accordance with P93448-01 Design Control Procedure and P93744-01 Service Procedure.

8.5.3.2. If installation of the medical device is allowed to be performed by an external party other than CSS or its contractors, CSS develops and documents the requirements for the medical device installation and acceptance criteria for verification of installation, as appropriate, in accordance with P93448-01 Design Control Procedure and P93744-01 Service Procedure.

8.5.3.3. Records of medical device installation and verification of installation performed by the organization or its supplier are maintained in accordance with P93445-01 Quality Records Procedure.

8.5.4. Servicing activities:

8.5.4.1. CSS develops and documents servicing requirements for the medical device in accordance with P93448-01 Design Control Procedure and P93744-01 Service Procedure. These documents address as required, servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.

8.5.4.2. CSS analyzes records of service activities to determine if the information is to be handled as a complaint in accordance with P93423-01 Complaint Handling Procedure**.**

8.5.4.3. CSS analyzes records of service activities, as appropriate, for input to improve processes in accordance with P93429-01 Management Review Procedure.

8.5.4.4. CSS analyzes record of service activities using appropriate statistical method, when necessary, in accordance with the Corrective and Preventive action to identify potential cause of nonconformity and other quality problems.

8.5.5. Particular requirements for sterile medical devices:

The products manufactured by CSS are not required to be sterilized so these QMS requirements are not applicable to the CSS QMS.

8.5.6. Validation of processes for production and service provision

8.5.6.1. When a process for production ‘cannot be’ or ‘is not’ verified by subsequent monitoring or measurement and, as a consequence, deficiencies could become apparent only after product is in use, this process will be validated as defined in P93431-01 Validation Procedure. Validation will demonstrate the ability of the process to achieve planned results consistently.

8.5.6.2. P93431-01 addresses validation methods including the following.

8.5.6.2.1. Defined criteria for review and approval of the processes;

8.5.6.2.2. Equipment qualification and qualification of personnel;

8.5.6.2.3. Use of specific methods, procedures and acceptance criteria;

8.5.6.2.4. As appropriate, statistical techniques with rationale for sample sizes;

8.5.6.2.5. Requirements for records;

8.5.6.2.6. Revalidation, including criteria for revalidation; and,

8.5.6.2.7. Approval of changes to the processes.

8.5.6.3. If CSS should introduce software for use in production provision it would need to be validated as defined in P93431-01.

8.5.6.3.1. This software will be validated prior to initial use and, as appropriate, after changes to such software or its application.

8.5.6.3.2. The specific approach and activities associated with software validation and revalidation will be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.

8.5.6.4. Records of the results and conclusion of validation and necessary actions from the validation will be maintained.

8.5.7. Particular requirements for validation of processes for sterilization and sterile barrier systems

The products manufactured by CSS are not required to be sterilized so these QMS requirements are not applicable to the CSS QMS.

8.5.8. Identification

8.5.8.1. Finished device identification numbers are assigned during the product development process as detailed in P93448-01 Design Controls Procedure, this includes any regulatory requirement for unique device identification (i.e. UDI number (reference P93754-01 Unique Device Identifier (UDI Procedure)). These identifiers are used throughout product realization (receipt, production and distribution).

8.5.8.2. The use of part identifiers is detailed in QMS procedures and then required on quality forms as applicable. Parts are assigned a part number as appropriate in accordance with the Identification and Traceability Procedure PP93755-01.

8.5.8.3. Product status with respect to monitoring and measurement is maintained in accordance with P93439-01 Process Control Procedure. Finished devices will be released in accordance with P93685-01 Inspection and Test Procedure.

8.5.8.4. The returned material process defined in P93743 -01Returned Material Authorization Procedure ensures that returned devices are identified and distinguished from conforming product.

8.5.9. Traceability

8.5.9.1. General

8.5.9.1.1. Traceability requirements according to applicable regulatory requirements are identified during the design and development process defined in P93448-01 Design Control Procedure implemented and in accordance with Identification and Traceability P93755-01.

8.5.9.2. **Particular requirements for implantable medical devices**

CSS products are not implantable medical devices so these QMS requirements are not applicable to the CSS QMS.

8.5.10. Customer property

8.5.10.1. CSS has no reason to be provided customer property for use or incorporation into the CSS product, this requirement is not applicable to the CSS QMS.

8.5.10.2. If CSS should have customer-owned equipment on-site, the required equipment controls will be negotiated with the customer using a quality agreement or a similar contract.

8.5.11. Preservation of product

8.5.11.1. P93751-01 Storage and Handling Procedure and P93754-01Process Controls define the processes used by CSS for preserving the conformity of product to requirements during processing, storage, handling and distribution. Preservation applies to the constituent parts of a medical device.

8.5.11.2. CSS protects product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling and distribution by:

8.5.11.2.1. Designing and constructing suitable packaging and shipping (P93448-01 Design Control Procedure).

8.5.11.2.2. No special conditions exist for preservation of CSS product.

8.6. Control of monitoring and measuring equipment

8.6.1. CSS determines the monitoring and measurement to be undertaken and the monitoring and measurement equipment needed to provide evidence of conformity of product to requirements. This is defined in P93685-01 Inspection and Test Procedure and includes the following:

8.6.1.1. How equipment will be calibrated or verified;

8.6.1.2. That the monitoring and measurement needed can be carried out in a manner that is consistent with the monitoring and measurement requirements.

8.6.1.3. That the equipment is calibrated, or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification will be recorded;

8.6.1.4. That when equipment requires adjustments, such adjustments and readjustments will be recorded;

8.6.1.5. That the calibration status of equipment is clearly identified;

8.6.1.6. That equipment, as applicable, is safeguarded from adjustments when that adjustment could invalidate the measurement result;

8.6.1.7. That equipment is protected from damage and deterioration during handling, maintenance and storage;

8.6.1.8. Definition of actions to be taken when equipment is found out of calibration; and,

8.6.1.9. Calibration records to include results, conclusion and necessary actions.

8.6.2. Out of tolerance will be investigated to assess the potential impact on the product. CSS has documented a procedure to be used for the validation of software used in the monitoring and measurement of requirements, P93431-01 Validation Procedure. This Procedure addresses the following:

8.6.2.1. The need for the software to be validated prior to use and, as appropriate, after changes to the software or its application;

8.6.2.2. The specific approach and activities associated with the validation or revalidation which will be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications; and,

8.6.2.3. The records to be maintained.

8.7. Refer to Q93438 Quality System Index for a list of Procedures that describe the processes to be used to satisfy the Policies described in Section 7 of this Quality Manual.

9. Measurement, analysis and improvement

9.1. General

9.1.1. CSS plans and implements the monitoring, measurement, analysis and improvement processes needed for the following.

9.1.1.1. To demonstrate conformity of product – CSS ensures conformity of the product to specifications according to:

9.1.1.1.1. P93685-01 Inspection & Test Procedure

9.1.1.1.2. P93431-01 Validation Procedure

9.1.1.1.3. P93429-01 Management Review

9.1.1.2. To ensure conformity of the QMS - CSS ensures conformity of the QMS according to:

9.1.1.2.1. P93429-01 Management Review

9.1.1.2.2. P93394-01 Internal Audit

9.1.1.3. To maintain the effectiveness of the QMS – CSS maintain the effectiveness of the QMS according to:

9.1.1.3.1. P93429-01 Management Review

9.1.1.3.2. P93394-01 Internal Audit

9.2. Monitoring and Measurement

9.2.1. Feedback

9.2.1.1. CSS gathers and monitors information related to whether CSS has met customer requirements as defined in P93423-01 Customer Complaint. This analysis incudes data from production and post-production.

9.2.1.2. Feedback data is reviewed during Management Review (P03429-01) as a means of assessing the effectivity of the QMS. The results of this analysis may serve as input into the risk management process (P93425-01) for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

9.2.2. Complaint handling

9.2.2.1. CSS has documented their complaint handling process in P93423-01 Complaint Handling Procedure. This procedure ensures that complaints are addressed in a timely manner.

9.2.2.2. P93423-01 addresses the following requirements and responsibilities at a minimum.

9.2.2.2.1. Receiving and recording information;

9.2.2.2.2. Evaluating information to determine if the feedback constitutes a complaint;

9.2.2.2.3. Investigating complaints (if no investigation, justification will be documented);

9.2.2.2.4. Determining the need to report the information to the appropriate regulatory authorities;

9.2.2.2.5. The handling of complaint-related product: and,

9.2.2.2.6. Determining the need to initiate corrections or corrective actions (and documentation of such)

9.2.2.3. If an investigation determines activities outside CSS contributed to the complaint, relevant information will be exchanged between CSS and the external party involved.

9.2.2.4. Complaint handling records are defined in P93423-01 and maintained.

9.2.3. Reporting to regulatory authorities

9.2.3.1. CSS determines if applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities in accordance with.

9.2.3.1.1. P93423-01 Complaint Handling Procedure

9.2.3.1.2. P93395-01 Recall Procedure

9.2.3.2. Records are maintained of any reporting to regulatory bodies.

9.2.3.3. Reports to regulatory bodies are reported at Management Review (P93429-01).

9.2.4. Internal audit

9.2.4.1. CSS performs Internal Audits (IAs) according to P93394-01 Internal Audit Procedure. P933394-01 addresses the responsibilities and requirements for planning and conducting IAs and recording and reporting IA results.

9.2.4.2. IAs are performed at planned intervals to determine if the QMS;

9.2.4.2.1. Conforms to planned and documented arrangements, the requirements of the Standards, CSS QMS requirements, and applicable regulatory requirements; and,

9.2.4.2.2. Is effectively implemented and maintained.

9.2.4.3. P93394-01 addresses the following requirements for IAs:

9.2.4.3.1. IA planning, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous IAs;

9.2.4.3.2. The audit criteria, scope, interval and methods;

9.2.4.3.3. Qualifications of auditors and the conduct of audits to ensure objectivity and impartiality;

9.2.4.3.4. IA records; and,

9.2.4.3.5. The need for actions on IA findings to be taken without undue delay.

9.2.5. Monitoring and measurement of processes

9.2.5.1. CSS applies suitable methods for monitoring and, as appropriate, measurement of the quality management system processes in accordance with the following procedures:

9.2.5.1.1. P93429-01 Management Review

9.2.5.1.2. P93394-01 Internal Audit

9.2.5.2. P93429-01 and P93394-01 demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is be taken, as appropriate, in accordance with P93393-01 Corrective and Preventive Action Procedure.

9.2.5.3. CSS chooses the appropriate analysis method to demonstrate the ability of a process to achieve planned results. This may be defined in a process procedure, in a quality objective, or as part of the Management Review process.

9.2.5.4. When planned results are not achieved, correction and corrective action will be taken, as appropriate.

9.2.6. Monitoring and measurement of product

9.2.6.1. CSS performs inspection of the characteristics of the product to verify that the product requirements have been met in accordance with P93685-01 Inspection and Test Procedure and P93439-01 Process Controls procedure. The characteristics of the product being monitored and measured were determined as

part of the design and development process (P93448-01 Design Controls Procedure).

9.2.6.2. Records are maintained of all inspections performed to provide evidence of conformity. The records identify acceptance activities and the person authorizing release of product, dates performed, results, signature of the inspector, and, as appropriate, the test equipment used to perform the inspection activities.

9.2.6.3. Product release will not proceed until product release has been successfully performed.

9.3. Control of nonconforming product

9.3.1. General

9.3.1.1. Where applicable CSS procedure P93407-01 Nonconforming Material Procedure, describes how potentially nonconforming product should be managed including moving it to a quarantined area, or identifying as quarantined, to prevent its unintended use or delivery. CSS has documented procedures for managing nonconforming product found before delivery and after delivery. These procedures address the controls and related responsibilities and authorities for the identification, segregation, evaluation and disposition of nonconforming product.

9.3.1.2. The evaluation of a nonconformance will include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

9.3.1.3. Records of the nature of the nonconformities and any subsequent actions taken, including the evaluation, any investigation and the rationale for decisions will be maintained.

9.3.2. Actions in response to nonconforming product detected before delivery

9.3.2.1. Nonconforming product detected before delivery is managed according to P93407-01 Nonconforming Material Procedure. This product can be dispositioned as follows:

9.3.2.1.1. Return to the vendor

9.3.2.1.2. Scrap

9.3.2.1.3. Use as is (Concession approval as needed)

9.3.2.1.4. Rework

9.3.2.1.5. Other (i.e. Sort)

9.3.2.2. Nonconforming product will only be accepted by concession if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession will be maintained.

9.3.3. Actions in response to nonconforming product detected after delivery

9.3.3.1. When nonconforming product is detected after delivery or use has started, CSS will take action appropriate to the effects, or potential effects, of the nonconformity. CSS has documented P93423-01 Complaint Handling Procedure to define corrective actions and reporting as applicable. Records of the actions taken will be maintained.

9.3.3.2. CSS has documented P93395-01 Recall Procedure to define when advisory notices or recalls are required if nonconforming product is detected after delivery or use has started and how to manage those notices according to regulatory

requirements. This procedure can be put into effect at any time. Records of actions relating to advisory notices will be maintained.

9.3.4. Rework

9.3.4.1. If disposition of nonconforming product involves rework, CSS will perform the rework in accordance with documented procedures that take into account the potential adverse effect of the rework on the product. Rework instructions will undergo the same review and approval as the original procedure.

9.3.4.2. Upon completion of the rework, product will be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

9.3.4.3. Records of rework will be maintained.

9.4. Analysis of data

9.4.1. CSS document P93429-01 Management Review procedure provides the requirements for, collecting and analyzing appropriate data to demonstrate suitability, adequacy and effectiveness of the QMS. The procedure includes how to determine the appropriate methods to use, including statistical techniques and the extent of their use.

9.4.2. CSS will include analysis of data from the following sources at a minimum and provide the results to management review (P93429-01).

9.4.2.1. Customer feedback

9.4.2.2. Conformity to product requirements

9.4.2.3. Characteristics and trends of processes and product, including opportunities for improvement

9.4.2.4. Supplier Performance

9.4.2.5. Audits

9.4.3. If a data analysis shows that the QMS is not suitable, adequate or effective, CSS will review the analysis result to determine if it is an opportunity for improvement. Any negative trends in quality data will lead to actions.

9.5. Improvement

9.5.1. General

9.5.1.1. CSS identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the QMS as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post market surveillance, analysis of data, corrective actions, preventive actions and management review**.**

9.5.2. Corrective action

9.5.2.1. CSS will take actions to eliminate the cause of nonconformities in order to prevent recurrence as defined in P93393-01 Corrective and Preventive Action Procedure (CAPA). Any necessary corrective actions are taken without undue delay. Corrective actions are proportionate to the effects of the nonconformities encountered.

9.5.2.2. P93393-01 ensures that CSS does the following with respect to corrective actions:

9.5.2.2.1. Review quality data to identify nonconformities including complaints;

9.5.2.2.2. Determines the cause(s) of nonconformities;

9.5.2.2.3. Evaluates the need for action to ensure that nonconformities do not recur;

9.5.2.2.4. Plans and implements the actions needed, including appropriate documentation updates;

9.5.2.2.5. Verifies that the corrective action does not adversely affect the ability of CSS products to meet applicable regulatory requirements or safety and performance requirements; and,

9.5.2.2.6. Reviews the effectiveness of the actions taken.

9.5.2.3. CSS documents the result of any investigation performed and the actions taken. These records are maintained.

9.5.3. Preventive action

9.5.3.1. CSS is proactive in defining potential nonconformities and determines the actions necessary to prevent their occurrence. Preventive actions are proportionate to the effects of the potential problems.

9.5.3.2. P93393-01 Corrective and Preventive Action Procedure ensures that CSS does the following with respect to preventive actions;

9.5.3.2.1. Reviews quality data to identify potential nonconformities;

9.5.3.2.2. Evaluates the need for action to prevent occurrence of nonconformities;

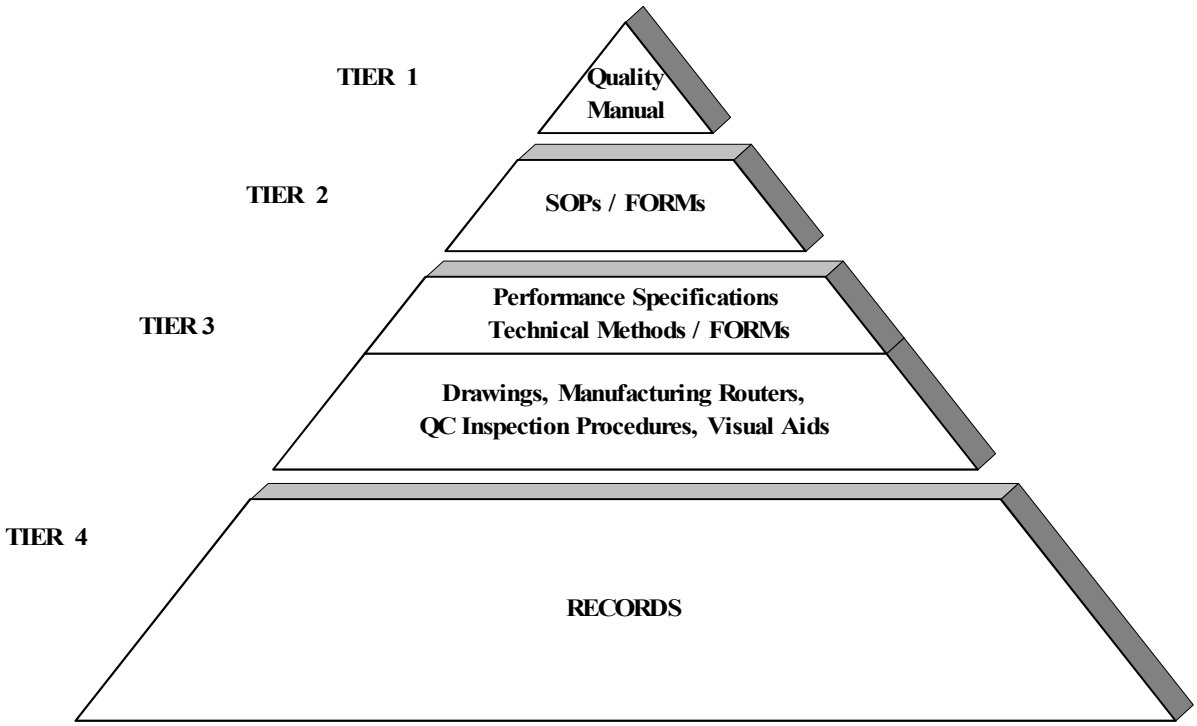
9.5.3.2.3. Plans and implements the actions needed, including appropriate documentation updates;

9.5.3.2.4. Verifies that the corrective action does not adversely affect the ability of CSS products to meet regulatory requirements or safety and performance requirements; and,

9.5.3.2.5. Reviews the effectiveness of the actions taken, as appropriate.

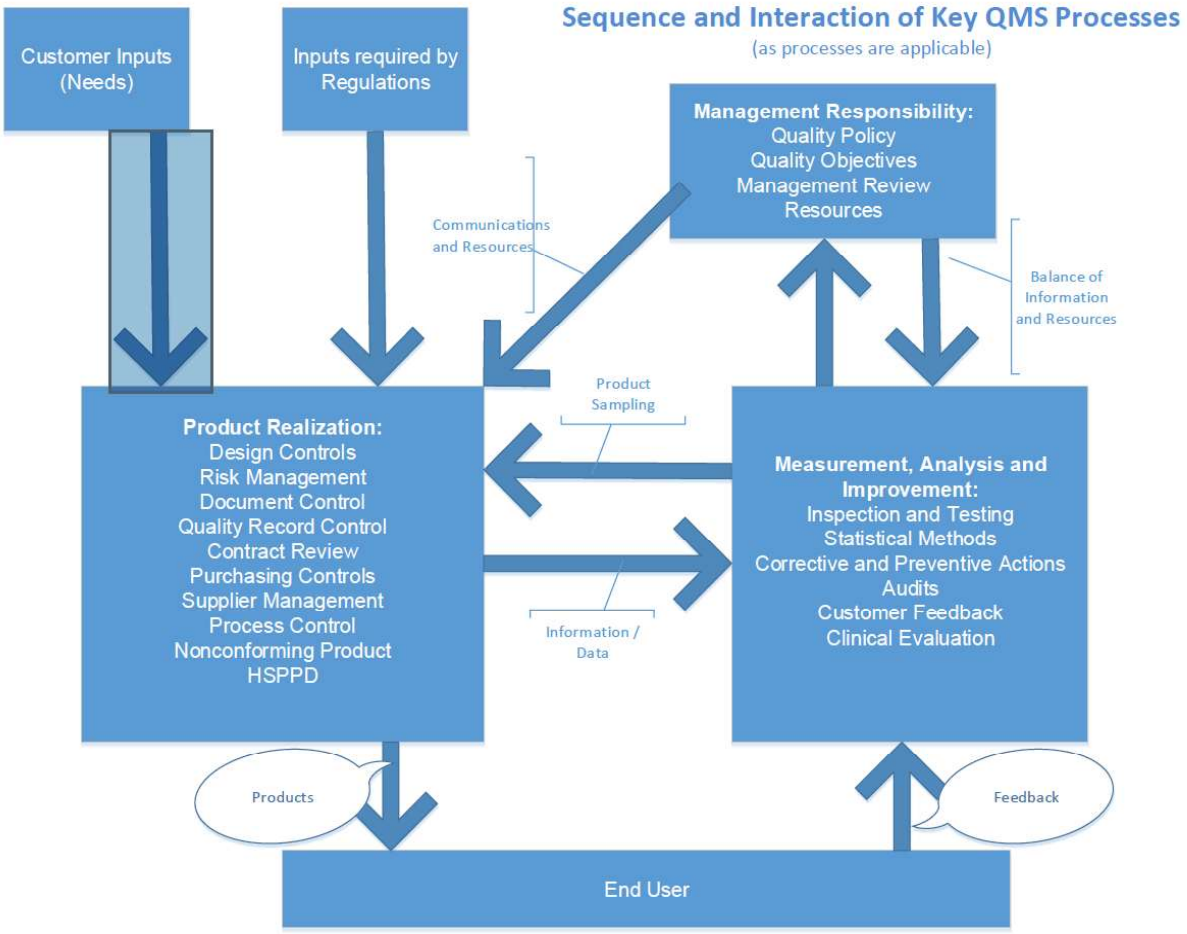
9.6. Refer to Q93438 Quality System Index for a list of Procedures that describe the processes to be used to satisfy the Policies described in Section 8 of this Quality Manual.

APPENDIX A



TIER 1 is the Quality Manual. It describes the overall quality system in accordance with the stated quality policy and US FDA QSR requirements and any additional country specific/regulatory requirements.
TIER 2 is the Operational Procedure System.
TIER 3 provides detailed specifications, procedures and work documents.
TIER 4 provides record and documentation required to meet the quality system requirements.

APPENDIX B



CONSOLIDATED STERILIZER SYSTEMS

Equipment and Vessel Warranty Statement

Limited Warranty

Each Consolidated Stills & Sterilizers ("CSS") Steam Sterilizer is warranted against manufacturer defects in workmanship and material for one (1) year from installation and start-up of the equipment or fifteen (15) months from the ship date, whichever occurs first. All warranties are for the original purchaser.

In addition, CSS pressure vessels are warranted against structural failures for ten (10) years. The vessel will be repaired or replaced at the sole discretion of CSS on a prorated basis. The only extension of this warranty occurs when the unit has been maintained, as described below*, by a CSS authorized service group during the entire life of the unit. At this time the vessel warranty will be extended from ten (10) years to fifteen (15) years.

If damage occurs during shipping/transportation to the purchaser, CSS must be notified immediately upon the unit's arrival. Bill of lading must be noted "damaged upon receipt" by the person taking receipt and signing for the unit upon arrival. CSS accepts no responsibility for transit or movements during a return or delivery.

* All maintenance records must be present at time of claim. A CSS authorized service group shall have performed preventive maintenance on this unit, following CSS maintenance guidelines, a minimum of two (2) times each year with no more than six (6) months between inspections. The customer shall have followed the suggestions of the CSS authorized service group. Operator and service maintenance guidelines are located in the operator and service manual.

What This Warranty Does Not Cover:

1. Service calls to correct an installation performed by someone other than a CSS authorized service representative.
2. Service calls to correct facility wiring, plumbing, or water issues.
3. Consumable items such as, but not limited to, door-gaskets, filters, valve-kits, fuses, lamps, heaters and strainers.
4. Damage or defects caused by: acts of God, labor disputes, utility malfunction, or use of parts other than Consolidated authorized parts.
5. Any misuse or abuse to the sterilizer will void any warranty including, but not limited to, inadequate utilities such as poor (i.e. out of specifications) water quality, electricity, steam, etc.
6. Failure to follow recommended maintenance guidelines will void warranty. Obtaining a proper operator training class on maintenance responsibilities shall be the sole responsibility of the owner or facility owner of this equipment.
7. Damage or defects to stainless steel vessels caused by bleach-containing hypochlorites, corrosive chemicals, acids or seawater.
8. CSS assumes no liability for consequential damages of any kind.
9. In the event that the sterilizer and/or pressure vessel needs to be sent back to the CSS factory for modifications, repairs, or replacement it is the sole responsibility of the owner to remove, package, and ship the unit back to CSS. Re-installation is also the sole responsibility of the customer.

How Do I Contact Service?

Contact CSS at 617-782-6072 x1900. Please have your Serial # and Model # available when calling. All returns must be made under a Return Materials Authorization (RMA) assigned by CSS. Replaced parts will become property of CSS.

What Will Consolidated Do?

CSS will evaluate the claim in a timely manner and make any necessary repairs at the sole discretion of CSS.

Purchaser's sole remedy under this warranty is limited to repair or replacement of the defective equipment or product at the sole discretion of CSS. CSS shall in no event be liable in respect to loss of business or profits on any similar or dissimilar consequential or incidental damages or losses arising out of, or in connection with, this equipment.

No waiver or modification of any provisions of this warranty will be binding upon Consolidated unless agreed to, in writing, by a duly authorized official of CSS. CSS does not authorize any person or company to create any warranty obligations on its behalf.

Attachment B
Pricing Schedule

The offeror shall provide pricing using the template below as applicable. The pricing schedule should include percentage off list price for specific manufacturer/product lines and/or categories. The "volume tier" section is intended to allow the offeror to provide volume-based incentives if applicable.

Equipment Category	Option Name	Manufacturer	Model	List Price	Discount %	Net Price	Installation Cost	AVG Lead Time	Volume Tier (if applicable)
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	26AV	$ 75,353	15%	$ 64,050.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	26BV	$ 82,765	15%	$ 70,350.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	2-SSR-2A	$ 97,218	15%	$ 82,635.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	2-SSR-3A	$ 111,424	15%	$ 94,710.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-24A	$ 80,912	15%	$ 68,775.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-24B	$ 85,112	15%	$ 72,345.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-24C	$ 95,365	15%	$ 81,060.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-24D	$ 101,665	15%	$ 86,415.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-24E	$ 107,594	15%	$ 91,455.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-24F	$ 115,747	15%	$ 98,385.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-26A	$ 92,771	15%	$ 78,855.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-26B	$ 97,588	15%	$ 82,950.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SR-28B	$ 122,442	15%	$ 104,076.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SSR-2A	$ 59,171	15%	$ 50,295.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	PT-SSR-3A	$ 68,682	15%	$ 58,380.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-24A	$ 65,965	15%	$ 56,070.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-24B	$ 69,671	15%	$ 59,220.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-24C	$ 77,082	15%	$ 65,520.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-24D	$ 83,506	15%	$ 70,980.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-24E	$ 89,559	15%	$ 76,125.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-24F	$ 97,588	15%	$ 82,950.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-26A	$ 72,141	15%	$ 61,320.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-26B	$ 80,171	15%	$ 68,145.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SR-28B	$ 105,371	15%	$ 89,565.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SSR-2A	$ 51,018	15%	$ 43,365.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: 7" Color Touchscreen, up to	Consolidated S	SSR-3A	$ 58,182	15%	$ 49,455.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	X1 Controls: Top Mount 7" Color Touchsc	Consolidated S	3AV	$ 61,518	15%	$ 52,290.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Nickel Clad Chamber with Carbon Steel Ja	Consolidated S	Consult Facto	Consult factory for price			TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	26AV	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	26BV	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	2-SSR-2A	$ 5,327	15%	$ 4,527.60	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	2-SSR-3A	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	3AV	$ 2,816	15%	$ 2,394.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-24A	$ 6,288	15%	$ 5,344.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-24B	$ 6,288	15%	$ 5,344.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-24C	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-24D	$ 6,856	15%	$ 5,827.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-24E	$ 10,438	15%	$ 8,872.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-24F	$ 11,006	15%	$ 9,355.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-26A	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-26B	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SR-28B	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SSR-2A	$ 2,668	15%	$ 2,268.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	PT-SSR-3A	$ 2,816	15%	$ 2,394.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-24A	$ 6,288	15%	$ 5,344.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-24B	$ 6,288	15%	$ 5,344.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-24C	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-24D	$ 6,856	15%	$ 5,827.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-24E	$ 10,438	15%	$ 8,872.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-24F	$ 11,006	15%	$ 9,355.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-26A	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-26B	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SR-28B	$ 5,868	15%	$ 4,987.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SSR-2A	$ 2,668	15%	$ 2,268.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 304L S	Consolidated S	SSR-3A	$ 2,816	15%	$ 2,394.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	26AV	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	26BV	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	2-SSR-2A	$ 7,436	15%	$ 6,321.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	2-SSR-3A	$ 7,189	15%	$ 6,111.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	3AV	$ 3,965	15%	$ 3,370.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-24A	$ 7,016	15%	$ 5,964.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-24B	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-24C	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-24D	$ 9,042	15%	$ 7,686.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-24E	$ 12,217	15%	$ 10,384.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-24F	$ 13,156	15%	$ 11,182.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-26A	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-26B	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SR-28B	$ 7,523	15%	$ 6,394.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SSR-2A	$ 3,718	15%	$ 3,160.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	PT-SSR-3A	$ 3,965	15%	$ 3,370.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-24A	$ 7,016	15%	$ 5,964.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-24B	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-24C	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-24D	$ 9,042	15%	$ 7,686.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-24E	$ 12,217	15%	$ 10,384.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-24F	$ 13,156	15%	$ 11,182.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-26A	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-26B	$ 7,152	15%	$ 6,079.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SR-28B	$ 7,523	15%	$ 6,394.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SSR-2A	$ 3,718	15%	$ 3,160.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	316L Stainless Steel Chamber with 316L S	Consolidated S	SSR-3A	$ 3,965	15%	$ 3,370.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	2 Shelves - 1 Extendable Bottom Shelf & 1 Extendable Up		All Other Mode	$ 2,718	15%	$ 2,310.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	2 Shelves - 1 Extendable Bottom Shelf & 1 Extendable Up		20x20 chambe	$ 1,322	15%	$ 1,123.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	2 Shelves - 1 Extendable Bottom Shelf & 1 Extendable Up		PT-SR-24F, SR	$ 5,435	15%	$ 4,620.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	2 Shelves - 1 Stationary Bottom Shelf & 1 Extendable Upp		20x20 chambe	$ 1,001	15%	$ 850.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Top Chamber with 2 Standard Shelves, Bottom Chamber		Tower Models	$ 1,371	15%	$ 1,165.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Chamber Tracks Only		All Models	$ 1,618	15%	$ 1,375.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		26AV	$ 7,474	15%	$ 6,352.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		26BV	$ 7,474	15%	$ 6,352.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		3AV	$ 6,874	15%	$ 5,843.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-24A	$ 7,171	15%	$ 6,095.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-24B	$ 6,856	15%	$ 5,827.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-24C	$ 7,189	15%	$ 6,111.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-24D	$ 8,524	15%	$ 7,245.00	TBD	60-90	Case by Case-please Call

1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-24E	$ 9,623	15%	$ 8,179.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-24F	$ 11,476	15%	$ 9,754.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-26A	$ 7,474	15%	$ 6,352.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-26B	$ 7,474	15%	$ 6,352.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SR-28B	$ 9,648	15%	$ 8,200.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SSR-2A	$ 6,226	15%	$ 5,292.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Transfer carriage, and chamber tracks		SSR-3A	$ 6,874	15%	$ 5,843.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-24A	$ 10,753	15%	$ 9,140.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-24B	$ 10,290	15%	$ 8,746.50	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-24C	$ 10,790	15%	$ 9,171.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-24D	$ 12,001	15%	$ 10,200.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-24E	$ 14,447	15%	$ 12,279.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-24F	$ 17,220	15%	$ 14,637.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-26A	$ 11,210	15%	$ 9,528.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-26B	$ 11,210	15%	$ 9,528.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SR-28B	$ 14,465	15%	$ 12,295.50	TBD	TBD	TBD
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SSR-2A	$ 9,357	15%	$ 7,953.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Loading Cart, Two (2) transfer carriages, and chamber tra		PT-SSR-3A	$ 10,327	15%	$ 8,778.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		26AV	$ 14,941	15%	$ 12,699.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		26BV	$ 14,941	15%	$ 12,699.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		3AV	$ 13,743	15%	$ 11,681.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-24A	$ 14,329	15%	$ 12,180.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-24B	$ 13,712	15%	$ 11,655.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-24C	$ 14,379	15%	$ 12,222.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-24D	$ 17,053	15%	$ 14,495.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-24E	$ 19,246	15%	$ 16,359.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-24F	$ 22,933	15%	$ 19,493.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-26A	$ 14,941	15%	$ 12,699.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-26B	$ 14,941	15%	$ 12,699.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SR-28B	$ 19,289	15%	$ 16,395.75	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SSR-2A	$ 12,452	15%	$ 10,584.00	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Two (2) Loading Carts, Two (2) Transfer Carriages, Cham		SSR-3A	$ 13,743	15%	$ 11,681.25	TBD	60-90	Case by Case-please Call
1. Sterilizer Base Price and Controls and FOB Destination	Top Chamber with Standard Shelving, Bottom Chamber w		Tower Models	$ 6,899	15%	$ 5,864.25	TBD	60-90	Case by Case-please Call
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Negotiation Questions

1. **Virginia Tech question:** Describe delivery options and policies including special handling charges, installation and training if required for the items being offered. All orders shall be FOB destination.

   Response:
   Delivery is through shipping freight company from Boston to your location and is quoted on sale by sale. Installation of our units can be included in quote pricing by Consolidated Sterilizer or the End user can provide their own option of direct contract. We recommend using our installer as they are certified and trained on our equipment and start up and training will be included in that cost.

2. **Virginia Tech question:** Specify typical turnaround time for delivery (standard, rush, etc.) for the items being offered.

   Response:

   Specify typical turnaround time for delivery (standard, rush, etc.) for the items being offered. Post PO, a rush delivery is 30-60 days. Standard is 60-90, however that is subject to change based on the order.

3. **Virginia Tech question:** Cost to the University is a major component of this solicitation and one of the 5 factors considered during the award process. Please submit your best and final pricing/discount structure for consideration.

   Response:

   Attached with this questionnaire is the pricing matrix laid out for your review. Discount structure is the highest across the entire USA Consolidated Sterilizer footprint.

4. **Virginia Tech question:** Are the prices provided with your proposal as favorable (or more favorable) as pricing provided to other Higher Educational Institutions?

   .Response:

   Pricing for Virginia Tech, all locations, will be 15% discount on all our manufactured products. This is the single most aggressive discount in all of our contract offerings across all customer bases in the USA

5. **Virginia Tech question:** Do you agree to provide invoices with payment due thirty (30) days after receipt of invoice or goods/services, whichever is later?

   Response:

   Yes! We are committed to a NET THIRTY timeline and will allow for 30-day post Invoice schedule.

6. **Virginia Tech question:** If awarded a contract, do you agree to limit price increases to no more than the increase in the Consumer Price Index, CPI-W for the

latest twelve (12) months for which statistics are available at the time of renewal or 3 percent, whichever is less?

Response:

We so Agree on your request regarding price increase limitations outlined in the above question.

7. **Virginia Tech question:** If awarded a contract, are you willing to hold prices firm for the initial contract period and the first renewal term?

   Response:
   Per your question above, we affirm to hold prices firmly for the initial contract period and the first renewal term.

8. **Virginia Tech question:** Are you registered with and willing to participate in the eVA internet procurement solution described in the terms and conditions of the RFP?

   Response:
   Yes, We are registered with and willing to participate in the eVA Internet procurement solution described in terms and conditions of the RFP.

9. **Virginia Tech question:** Are the prices for all goods/services listed in your proposal inclusive of all applicable eVA system transaction fees?

   Response:

   Yes all prices for goods and services listed in proposal are inclusive of eVA system transaction/fees.

10. **Virginia Tech question:** Are you willing to provide a report at the end of each Virginia Tech Fiscal Year detailing the money saved by the University by utilizing this contract? Virginia Tech's Fiscal Year ends June 30th of each year.

    Response:
    We are willing to provide such a report following your June 30th Fiscal end of year, but require a 10-14 days.

11. **Virginia Tech question:** Do you agree that the initial contract period shall be two years?

    Response:

    We agree to this timeframe of two years.

12. **Virginia Tech question:** Upon completion of the initial contract period, do you agree that the contract may be renewed by Virginia Tech upon written agreement of both parties for four (4) two-year periods, under the terms of the current contract?

Response:
We agree to the above renewal schedule request regarding renewal timeframes.

13. **Virginia Tech question:** Prior to renewal do you agree to reevaluate pricing to be sure Virginia Tech is receiving the best possible discount or rate structure you can provide?

    Response:
    We agree to reevaluate the contract terms to stay in line with the best possible pricing and savings and rate structure we can provide. Virginia Tech will continue to receive our best pricing.

14. **Virginia Tech question:** Do you agree that you will be performing services as an Independent Contractor, Company, Corporation or other business entity and are not an employee of Virginia Tech or any other Commonwealth Entity?

    Response:
    Yes we understand the nature of our relationship with the University.

15. **Virginia Tech question:** Do you further agree that Virginia Tech will not withhold any income taxes from its payments to contractors nor will it provide any employment benefits to the contractor or contractor's employees?

    Response:

    Yes we acknowledge and agree in the above statement.

16. **Virginia Tech question:** Please describe your turn-around time if emergency services are needed.

    Response:
    Typically our service call turn around is between 24-72 hours, potentially sooner pending time report is received.

17. **Virginia Tech question:** How soon after contract award can you begin providing services?

    Response:
    We are ready to provide services on Day one after award.

18. **Virginia Tech question:** Do you acknowledge, agree and understand that your contract is not exclusive, and that Virginia Tech cannot guarantee a minimum amount of business if a contract is awarded to your company?

    Response:
    We acknowledge and agree to the statement above.

19. **Virginia Tech question:** Does the vendor acknowledge, agree, and understand that the terms and conditions of the RFP # 952642607 shall govern the contract if a contract is awarded to your company?

    Response:
    We acknowledge and agree to the above statement.

20. **Virginia Tech question:** If applicable, do you agree to become a certified SWaM vendor with the Virginia Department of Small Business and Supplier Diversity and maintain that certification throughout the term of this contract?

    Response:
    We do agree to the above statement and will do whatever we need to do to comply with requirements.

21. **Virginia Tech question:** Please submit a W-9 on the current IRS Form Revision, and a copy of your Certificate of Insurance that meets the requirements of the solicitation.

    Response: Attached