

**Department Of Veterans Affairs
TVHS Nashville and Murfreesboro Campus
Requirements for A/E Study and Design Services
Project 626A4-17-506
TVHS USP 800 Compliance Study**

I. GENERAL SCOPE OF WORK

The consultant shall study the Tennessee Valley Healthcare System (TVHS) pharmacy operations, infrastructure and processes in order to develop a successful plan to upgrade for USP 800 compliance at the Nashville and Murfreesboro Campus pharmacies (2 sites total, see a. and b. below). The TVHS USP 800 Compliance Study consultant shall provide all necessary architectural and engineering (A/E) services and testing necessary to completely assess the pharmacy Compounding Sterile Preparations (CSP) area and adjacent impacted spaces to arrive at optimal solutions. The A/E shall provide space planning, concepts, technical reports, layouts, calculations and sizing, narratives, scopes of work, estimates, scheduling/durations and staging / phasing plans. Professional disciplines include, but are not limited to, USP design specialist(s), architectural, life safety, mechanical, plumbing, electrical, communications, security / access controls, and industrial hygiene.

- a. TVHS Nashville Campus VA Medical Center, 1310 24th Avenue, South, Nashville, TN 37212.
- b. TVHS Alvin C. York VA Medical Center, 3400 Lebanon Pike, Murfreesboro, TN 37129.

II. STATEMENT OF PROJECT OBJECTIVES

It is the intent of the VA TVHS to be USP 800 compliant by July 2018. The containment facilities are currently operating under USP 797. The A/E conducting this study will fully investigate, survey, interview key personnel, document existing conditions, including all systems, equipment and processes, in order to gain the knowledge and insight necessary to prepare quality reports and documents. The study will conclude with the submission, evaluation and revision of Design Development 1 documents. The VA intends to use the study plans and documents as the basis for design to procure A/E services to produce construction documents.

- A. Upgrade by adding USP 800 compliance
- B. Promote uniformity between the two TVHS campuses
- C. Improve flow and alleviate congestion
- D. Improve processes and staff efficiency
- E. Reduce downtime and improve reliability
- F. Provide for program growth and evolution
- G. Provide secondary CSP provisions to be used temporarily during planned and unplanned outages.

IV. STATEMENT OF A/E TASKS

- A. Perform a complete assessment (functional, infrastructure, operational, etc.) at both facilities developing a minimum of three concepts for each campus to comply with USP 800, as well as USP 797. Each concept for each campus shall be unique, specific solution. A variance or modification to a concept is not unique and shall not be considered as another concept / alternative / solution. Substituting a constructed / built solution for a modular solution shall not be considered as another concept / alternative / solution (and vice versa).
- B. Evaluate all components, materials, supplies and equipment associated with the CSP. Present alternative options and "propose best practices."

- C. Study shall also weigh the benefits and risks of modular systems (manufactured offsite and assembled onsite) verses containment solutions that are totally constructed at the site.
- D. Provide dimensioned layouts of the space with flow diagrams, furniture placement, and equipment selection, incorporate utility tie-in locations, and address any impact moves or construction. This should be done to prove the validity of concepts, as well as the final solution(s).
- E. Provided complete working solutions that include impact, moves, phasing, and staging plan for upgrading the USP 797 pharmacy facilities by adding USP 800 compliance. Plan and design for any medical center spaces and operations impacted by the pharmacy upgrade. The TVHS Space Planner will not develop the plans, but will work with the consultant to determine the availability of space and evaluation the overall effects to services / spaces / functions.
- F. Once the design team comes to a consensus, selecting the best concept for each campus, the A/E shall fully develop the selected concept and provide complete corresponding Scopes of Work for each campus. The Scopes of Work shall be used as the basis for planning, budgeting and the procurement of A/E design packages for each campus.
- G. The A/E shall furnish all services for planning and a complete Schematic Design (SD) and Design Development 1 (DD1).
 - 1. Necessary site survey work and evaluation such as verifying existing conditions, verifying record drawings, and verifying and analyzing utility systems shall be accomplished in conjunction with preparation of Design Development. A/E shall furnish documentation and drawings of these findings, and address deficiencies in the design process.
 - 2. The complete site survey work shall include a thorough investigation of existing conditions to accurately document and convey space dimensions for measured drawings, all utilities for affected areas, and utilities that traverse through affected areas, typical construction type and variations, and finishes. This information provides the necessary base drawings for the Schematic Development phase of Design Development.
 - 3. Utility system verification shall include, but not be limited to, the necessary testing, adjusting, and/or balancing (TAB), temperature testing/surveillance, visual inspection, Direct Digital Controls frontend trending and other innovative measuring and testing methods of affected systems to ascertain the existing operating and performance conditions that will impact the design and construction process. Systems that are insufficient in capacity or are no longer supported by OEM parts shall be considered for expansion and/or replacement. Document existing conditions, proposed alternatives, and corrective actions.
- H. Design shall meet VA needs, VA space criteria, VA design alerts, and VA design standards while including applicable regulations and established VA standards, guidelines, criteria and design alerts.
- I. The A/E shall incorporate Energy efficiency and cost savings shall be considered in all design decisions. Design to applicable sections of the TVHS Energy Requirements and Design Guide for specific energy guidance. Design shall incorporate, but not be limited to:
 - 1. All components of the supply, ventilation, and exhaust systems will be evaluated and upgraded to meet hospital standards, increase functionality, energy efficiency and building envelope maintenance. Include Direct Digital Controls (DDC) and optimization controls. Whenever possible, exhaust systems shall be converted to return.
 - 2. Optimize reliability, stability, monitoring, and control. Integrate native BACnet DDC controls with existing DDC frontend systems. Provide strict control of processing environment (temperature, pressure relationships, and humidity, etc.).
 - 3. When observed, include design for replacement or repair of duct work/duct access doors/access panels that are leaking air. Duct work leakage objective is to obtain ASHRAE Standard 90.1, Seal Class A on major supply lines and Seal Class B on return and exhaust lines.

- J. The A/E shall form a design team consisting of key designers and key VA personnel, including affected users and services, and conduct meetings to accomplish a cohesive design that addresses facility issues and concerns. Design team meetings shall be held on site in conjunction with each phase of design and each submission. Additional meetings with individual user groups will be necessary to gather information and produce an effective design.
- K. The A/E shall provide multiple design concepts of the building interior as part of the Schematic Design phase. The A/E shall provide narratives and present the concepts to the VA Design Team and fully discuss the merits (pros and cons) of each. The design team will select the concept that will be fully developed during Design Development 1 (DD1).
- L. A/E shall develop and execute a Quality Assurance (QA) plan that demonstrates the team approach and methodology for study/design improvements and review, including well documented comments / issues and resulting corrections. The QA plan shall be submitted to the VA along with the design/study schedule and shall describe each QA task that will be taken during the development of the various phases of the study/design, including review of submissions. The design QA effort shall be led by a senior designer. The QA team shall include, at a minimum, another USP 797 / USP 800 specialist (meeting the criteria as the primary USP 797 / USP 800 specialist) and a senior engineer that is not performing actual design work on this project / study. Completion of each QA task shall be initialed and dated by the responsible QA team member. A 100% completed QA review shall be submitted with each A/E design submission, including the final DD1 package submission. Cost control shall be part of the QA process.
- M. The required stamp of the licensed architect and/or engineer of record will be considered as certification of compliance with the contract requirements for that document. The registered individuals who will stamp the final documents shall be the same lead designers that accomplish assessment and design work.
- N. A/E will coordinate with leading industry equipment manufacturers/vendor(s) to insure proper layout and support of equipment according to manufacturer's requirements. However, all selections must promote fair and open competition.
- O. Current facility planning has yielded a construction budget with a magnitude of \$1,000,000 to \$2,000,000 total for both campuses. Estimating and cost control shall be a part of every design phase and submission. A/E shall provide an independent estimate, arriving at a construction total for each campus.
- P. Planning and design shall incorporate appropriate safety factors and growth factors, typically 15% to 20%. Future growth shall be categorized at a minimum of 15% within a 5-year span with minimal replacement of equipment/components, rebuild, and disruption.
- Q. Minimize downtime to medical center and pharmacy operations
 - a. Individual Room or component failures must be rectified and corrected within 8 hours
 - b. System failures affecting multiple rooms or components resulting in failures / outages; downtime must be corrected within 24 hours
 - c. Components / equipment shall be easily replaceable / swappable.
- R. Other project constraints are considerations are as follows:
 - a. Expansion of building footprint at the Murfreesboro Campus may be possible. New square footage added to the building footprint shall be less than 1000 GSF.
 - b. New building square footage construction or expanding the building footprint is extremely limited at the Nashville Campus and shall not be considered.
 - c. Since immediate supervision of the CSP is required, solutions that do not create staffing inefficiencies are preferred. Solutions that minimize travel distances are preferred.

- d. The controlled area outside the containment rooms shall affectively limit traffic and cross contamination.

V. BASIS FOR DESIGN

- A. Department of Veterans Affairs standards may be obtained from the Internet at <http://www.cfm.va.gov/TIL/>.
- B. Department of Veterans Affairs Design Manuals. <http://www.cfm.va.gov/til/dManual.asp>
- C. Compliance with the Physical Security Design Manuals for VA Facilities. <http://www.cfm.va.gov/TIL/spclRqmts.asp>.
- D. Comply with VA HVAC Design Guidelines at <http://www.cfm.va.gov/til/dManual.asp>. Indoor air quality requirements must be met / maintained, such as outside air percentages, air changes / CFM, and humidity. Design shall maintain building envelopes to prevent moisture infiltration and possible mold growth.
- E. Comply with VA TIL, PG-18-3, Design and Construction Procedures <http://www.cfm.va.gov/TIL/cPro.asp>
 - a. Topic 1 - Codes, Standards and Executive Orders
 - b. Topic 2 - Drawings
 - c. Topic 15 - Energy efficient and sustainable design policy for new construction
 - d. Topic 16 - Sustainable buildings policy for new and Renovation construction
- F. Comply with VA TIL, PG-18-15, A/E Design Submissions and Review. <http://www.cfm.va.gov/til/aeDesSubReq.asp> (Click Vol. C Minor and NRM Projects).
- G. Comply with VA TIL, PG-18-2 Design Guide, 285 Sterile Processing Service and VHA DIRECTIVE 1116(2), dated 03/26/2016.
- H. The SPS Design Guide is available under Resources. <https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/10NC/RME/default.aspx>
- I. Any deviation from requirements, standards and guidelines shall be requested in writing and approved by VA. The deviation request shall include item for which deviation is requested and the reason or justification for deviation.
- J. New rooms and partitions shall be designed tight to reduce sound and air transfer. The target sound transmission class is 40 STC. This includes in-wall components such as doors, frames, boxes and glazing.
- K. Comply with TVHS Energy Requirements and Design Guide (revision September 2014, attached). See ASHRAE 90.1-2010 for energy requirements.
- L. Insure proper life safety and VA accessibility requirements. Code Analysis will be clearly defined on the Index Sheet of the Design Documents. There shall be a stamped Life Safety sheet as part of the final plan.
- M. The A/E shall implement cost control measures / processes / reviews that shall be implemented during every phase of planning and design.
- N. Comply with current applicable state, local, and federal codes, requirements and standards as well as codes/standards from other recognized authoritative bodies such as The Joint Commission. Other recognized bodies include but not limited to; Associated Air Balance Council (AABC), American Concrete Institute (ACI), Acoustical and Insulating Materials Association (AIMA), American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE), American Society of Mechanical Engineers (ASME), American Society for Testing and Materials (ASTM), Gypsum Association (GA), International Building Code (IBC), National Electric Code (NEC), NFPA, National Environmental Balancing Bureau (NEBB), International Plumbing Code (IPC), OSHA, Sheet Metal and Air Conditioning Contractors' National Association (SMACNA), and Uniform

Federal Accessibility Standard (UFAS), & American Barriers Act (ABA), Controlled Environment Testing Association (CETA) and United States Pharmacopeia (USP).

- O. Design shall consider industry standards and best practices, as well as facility standards, incorporating them to arrive at optimal design solutions.

VI. DETAILED SUBMISSION REQUIREMENTS

Program Guide PG-18-15, establishes the guidelines for the A/E submissions. Design shall be performed and submitted in accordance with VA A/E Submission Instructions for Minor and NRM Construction Program. Refer to (<http://www.cfm.va.gov/til/aeDesSubReq.asp>). These guidelines indicate a level for submission compliance, which may not be adequate for certain, types of design. In some instances in which critical decisions need to be made, sufficient and relevant information has to be provided timely in order for the design to progress to meet certain milestone dates. The level of applicability of the program guide depends upon the scope of work and the exclusions, which are herein specified. Questions in regards to the applicability of specific requirements shall be resolved with the COR prior to any submission deadline. Where “days” are stated, this refers to “calendar” not “work” days.

- A. At each submission, all drawings and support material shall be dated and appropriately labeled above the title block:

Work Element	Copies	Duration	Notes	Delivery
Kick-off Meeting & Initial Interview		1 Day		
Initial Site Survey & Interviews		3 Days		
Initial Survey Exit Interview Meeting		1 Day		Documented questions & answers/resolutions
Schematic Design (SD) and Assessment	4	30 Days	Plan on survey trips to site	Drawings of Existing Conditions for each trade/discipline
Follow-up Interviews and Surveys		4 Days		Documented questions & answers/resolutions
Conceptual and Schematic Submission Review Meeting	4	1 Day		Electronic copy & 3 Full Size & 1 Half Size hardcopy
Gov't Review		7 Days	Approved (signed by VA key personnel)	
Design Development 1 (DD1)		30 Days		
DD1 Submission Review Meeting	4	1 Day		Electronic copy & 3 Full Size & 1 Half Size hardcopy
Gov't Review		7 Days		
Final Revision and Reproduction		7 Days		
Final Review Meeting	4	1 Day	Approved (signed by VA key personnel)	Electronic copy & 3 Full Size & 1 Half Size hard copy
Total		93 Days		

- B. VA submission review comments may be verbal, noted directly on review sets, or written list. The A/E shall be responsible for compiling and addressing review comments. A/E shall produce and distribute meeting notes or minutes for VA review immediately after each submission review meeting.
- C. In addition to the deliverables identified in Section A of Detailed Submission Requirements above and in the Requirements for A/E Design Submissions in the VA Technical Information Library <http://www.cfm.va.gov/til/aeDesSubReq.asp>, please provide the following:
 - a. A/E furnish a separate stamped Life Safety sheet
 - b. Consultant QA mark-ups with each submission
 - c. A/E filled out checklists with each submission (see Program Design Guide, PG-18-15, Vol. C)
- D. For each submission, furnish electronic files in the latest version of Microsoft Office and Microsoft Word and/or AutoCAD 2016. Also submit 2 hardcopies of all drawings, 1 half set and 1 full set. Also, submit one full size hard copy of A/E DD submittal for energy review and comments.
- E. The final design document submission will include 1 full set and 1 half set of design documents including all disciplines/packages and will be sealed and signed by the Architects and Engineers of Record.
- F. The final design documents will incorporate all VA supplied comments from the earlier submission package reviews and will comply with the resultant contract requirements.
- G. If the submission documents are not complete, the A/E must resubmit the package in its entirety.
- H. Final selected concept documents shall be reproduced as part of the contract. One 1 full set and 1 half set of the Design Bid Documents are to be delivered to the COR. Electronic files of the Design Documents will be provided to the COR and Contracting Officer.
- I. Total time to accomplish Schematics and DD1 through final reproduced bid documents shall be 93 calendar days from the issuance of the Notice to Proceed. Each submission will require maximum 7 calendar days for VA review the consultant's submission package. A/E shall prepare a submission schedule based upon the submission table above so that the timeframes are met.

VII. MATERIALS TO BE FURNISHED TO THE SELECTED A/E BY VA

- A. Drawing Files – 2016 compatible AutoCAD files of the campus site plan and architectural floor plans are available. Station utility drawing file hard copies will be made available for the A/E to copy and scan. The accuracy of drawings is not guaranteed and shall be used for general information only. Actual conditions shall be field verified and drafted by the A/E.

Attachments:

 - a. Existing Architectural Floor Plan of Nashville VAMC, Building 1. (PDF and AutoCAD)
 - b. Existing Architectural Floor Plan of Murfreesboro VAMC, Building 3. (PDF and AutoCAD)
- B. Cut Sheets of major equipment
- C. The recent Pharmacy Test Report Number: 112816-01CR, Performed by Triangle Certification.
- D. TVHS Energy Conservation Project Requirements and Design Guide Sept. 2014.

IX. CONSULTANT AND DESIGNER QUALIFICATIONS

The consultant shall provide a team of professional designers and engineers that have worked together before on a USP 797 and USP 800 projects that capable of completing the work as specified. The consultant shall not make changes in personnel from those who are proposed without prior approval from the VA Contracting Officer and the Contracting Officer's Representative (COR).

- A. Firm must have completed a minimum of 3 years in design, construction, and/or certification of a USP 797 regulated space.
- B. Pharmacy Specialist must have:
 - 1. Direct experience with USP 800 and experience with USP797 regulated spaces.
 - 2. Licensed in United States and able to stamp designs / drawings.
 - 3. Demonstrated knowledge and understanding of USP 800 requirements. Designer shall be able to produce USP 800 credentials, training certificates/certifications, participation on USP 800 code boards, list of previous USP 800 design projects that he / she stamped, list of USP 797 design projects that he / she stamped, Referenced projects shall be listed shall include, at a minimum, facility name, location, project title and total project budget.
- C. Designers on the team must have...
 - 1. Licensed in United States and able to stamp designs / drawings.
 - 2. Experience with USP 800 and/or USP 797 design. Team members shall provide a list of USP 800 and/or USP 797 projects that they have stamped. The list shall include, at a minimum, facility name, location, project title and total project budget.

VIII. GEOGRAPHICAL LOCALITY

The A/E shall be geographically located within the United States.