

Request for Project Information: MTEC-25-03-BloodBag

Request for Project Information



Solicitation Number: MTEC-25-03-BloodBag

“Single Blood Donor Collection and Storage Bags Manufactured in Continental United States (CONUS)”

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: November 6, 2024

Project Information Paper Due Date: January 6, 2025
Noon Eastern Time

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The Medical Technology Enterprise Consortium (MTEC), in support of the U.S. Army Medical Research and Development Command (USAMRDC), and Defense Health Agency (DHA), is excited to post this Request for Project Information (RPI) focused on surveying the current manufacturing capabilities of single blood donor/storage bags within the bounds of the contiguous United States.

PURPOSE OF THE PROJECT INFORMATION PAPER:

This Request for Project Information (RPI) contains background material and guidance for the preparation of project information papers to MTEC. Project Information Papers will be reviewed by the Sponsor and used in a manner that shapes DHA efforts in this technology space. The results of the Project Information Paper submission will serve to assess the development landscape and potentially focus efforts that will follow.

As a note: This RPI is issued solely for information and planning purposes and does not constitute a solicitation. Neither unsolicited proposals nor any other kind of offers will be considered for award in response to this RPI. Responses to this notice are not offers and will not be accepted by the government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RPI. All information received in response to this RPI that is marked "Proprietary" will be handled accordingly.

FOCUS AREA OF INTEREST:

In accord with the Department of Defense (DoD) 2022 National Defense Strategy identifying Building Enduring Advantages, there is an effort to invest in manufacturing capabilities within the continental United States (CONUS) as part of efforts to bolster the Defense Industrial Base (DIB) and securing domestic supply chains. In recent years, there has been a shortage of much needed blood storage bags, and this is acute within the DoD system where there is a requirement for singly wrapped blood bags for use in far forward situations.

"Today's DIB requires additional investment from private and government sources to modernize infrastructure and capacity to provide military capabilities at the speed and scale necessary for the U.S. to prevail in a near-peer conflict. To adapt and fortify our existing capabilities and capacities, the Department needs to focus on investment and to buy down supply chain risk and expand capacity."

DoD's diverse warfighting capabilities means that Sailors, Marines, Soldiers, Airmen, Guardians and Joint Special Operations Service members operate in a vast array of challenging, remote, and austere environments. In forward positions there is a high probability of traumatic injury and wounds leading to blood loss. Hemorrhage is the leading cause of death in combat zone

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trauma. The gold standard for immediate treatment of hemorrhage is transfusion of whole blood however, the availability of whole blood and conventional blood products on forward missions is challenging. In recent years there have been supply chain disruptions across the continuum of military and civilian products. This includes components used in the manufacture of blood bags from the polymer components to the anticoagulant/preservative solutions within the bag. This has resulted in shortages of single blood storage kits most often used in austere environments especially for walking donors. According to the US Food and Drug Administration Center for Biologics Evaluation and Regulation for regulated products shortages website, the shortage of series of blood collection bag kits and products is described as ongoing. Shortages of ingredients, components and manufacturing supplies, and release timing issues are intermittent and unpredictable. Product may be placed on allocation as necessary to manage reduced or unavailable supply. This vital product is needed in steady supply to meet the needs of aiding wounded warriors within the golden hour, or sooner, out in the field at the point of injury with donated blood. Our approach is to stand up or bolster domestic production.

The Government seeks Project Information Papers regarding the development of a prototype system detailing the following:

- Production of a bag within the contiguous United States within 2 years of award that meets the following existing specification:
 - Individually wrapped single aseptic collection bag
 - Compliant with FDA (21 CFR 864.9100), ISO 10993 and 3826, USP and MIL 810H standards and guidance.
 - Supports whole blood donor phlebotomy of 500mL (+/-10%, 450-550 mL) or 450 mL (+/-10%, 405-495 mL).
 - Contains a solution of anticoagulant and preservatives meeting the USP standards that allows for storage of blood for at minimum 21 days up to 35 days.
 - Foil wrapping that is easy to open requiring no tools and if practical, textured for better grip with brightly marked notches not only at the corners but also in the center of the packaging.
 - The manufactured bags should have a shelf life of 18 - 24 months at room temperature.
 - Appropriate fatigue and distortion testing.
 - Experience designing medical devices specifically blood products and adhering to verification and validation guidance.
 - Within 2 years, capability to manufacture no less than 10,000 standard blood donor/storage bags per year and have a surge capability plan during times of increased demand for full single blood bag kits with compliant materials and processes.
- Any established current Good Manufacturing Practice (cGMP) ready methods with fully designed hardware and functional disposables.
 - Manufacturers implementing GMP that require financial assistance to meet all requirements of the U.S. Food and Drug Administration (FDA) with clear standard

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operating procedures and compliance documentation (21 CFR 864.9100) shall provide appropriate substantiating information, including a workflow for obtaining GMP certification.

- Demonstrable redundancy in sourcing of raw materials from multiple vendors.
- A notional rough order of magnitude estimate of proposed program cost inclusive of any cost share and other funding sources that the offeror has secured.

REQUIREMENTS OF THE PROJECT INFORMATION PAPER:

Project Information Papers should clearly describe expertise in each of the aforementioned areas as it relates to the manufacturing of blood bags. Interested parties are encouraged to submit Project Information Papers using the template included in **Addendum 1 of this RPI**.

MTEC is seeking input from both MTEC members and non-members via a project information paper to be considered by the government. Project Information Papers will be shared with the reviewers under non-disclosure agreements.

Project Information Papers may be submitted at any time during the submission period but no later than the due date and time specified on the first page of this RPI using BIDS: <https://submissions2.ati.org/AT12/Portal.nsf/Start?ReadForm>. See **Addendum 2 of this RPI** for further information regarding BIDS registration. **MTEC membership is NOT required for submission of Project Information Paper.**

MTEC:

The MTEC mission is to assist the U.S. Army Medical Research and Development Command (USAMRDC) and the Defense Health Agency (DHA) by providing cutting-edge technologies and supporting life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters' health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses, small businesses, "nontraditional" defense contractors, academic research institutions and not-for-profit organizations.

POINTS OF CONTACT:

For inquiries, please direct your correspondence to the following contacts:

- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@ati.org

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- All other questions should be directed to the MTEC Program Manager, Mr. Evan Kellinger, mtec-sc@ati.org

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Addendum 1 – Project Information Template

[Up to 10-page limit with 3-5 pages dedicated to technical capabilities; 1-2 pages on the proposed product including renderings and at least one page on the rough order of magnitude financials to achieve the goals. Times New Roman 11 point (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. These project information submissions will be shared with the Sponsor; therefore, all information must be **nonproprietary**. Project Information Paper should be submitted as a Word (*.docx) or PDF (*.pdf) document using the template provided in this RPI.]

Title: [Insert descriptive title of project]

Point of Contact: [Insert name, organization, email address, phone number]

Technology: [Provide a clear description of why and how the proposed technology or project fits into the described focus area of this RPI. Describe how the technology addresses the programmatic need.]

Objectives: [Provide a clear description of the objectives and aims for the proposed project.]

Technical Approach: [Provide an overview of the technical strategy to be employed during the project to achieve the abovementioned objectives. Provide a proposed period of performance. List milestones and deliverables from the proposed work.]

Technical Maturity: [Summarize the current maturity of the project, including any supporting data or information. Respondents are also encouraged to detail any expertise, capabilities, or recourses that would be used to support the development of the proposed project.]

Anticipated Regulatory and Commercialization Strategy: [Provide a brief description of the anticipated regulatory pathway and commercialization plans, as applicable. Include information on any previous interactions with the FDA.]

Personnel: [Briefly state the qualifications of the key personnel to perform the work.]

Estimated Funding Required to Advance Project: [Please estimate the required funding needed for each major task that advances the project into its next stage of development/milestone dependent upon its current maturity. Do not provide budget detail – only provide a total estimated budget for each major milestone. This information will be used to provide the Sponsor with a reasonable

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representation of the amount of funding required to advance the project.]

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Addendum 2 – BIDS instructions:

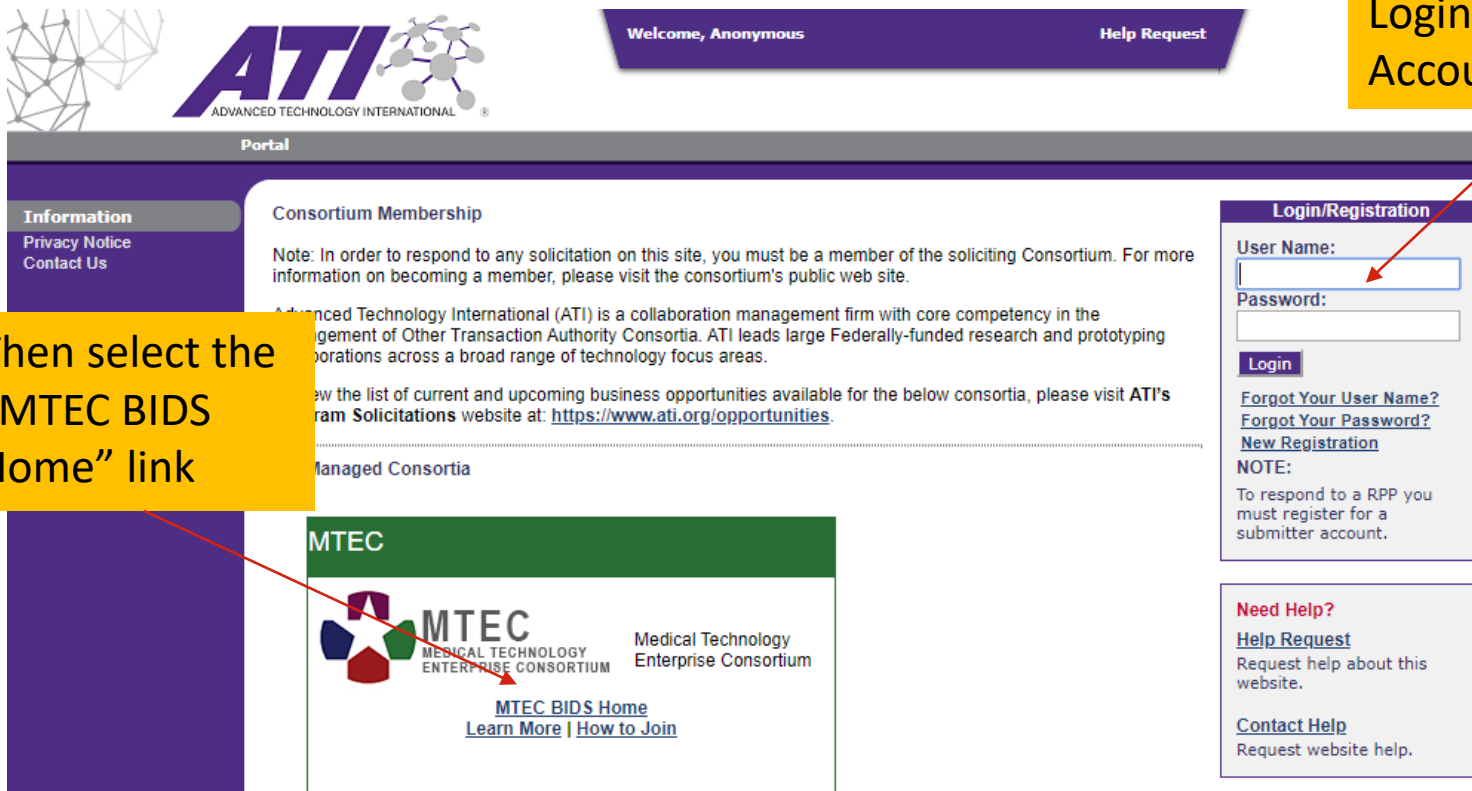
THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE THE PRESENTATION BELOW.

MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

[HTTPS://AT12.ACQCENTER.COM](https://at12.acqcenter.com)

Navigate to the MTEC BIDS site and login. After login select the “MTEC BIDS Home” link.



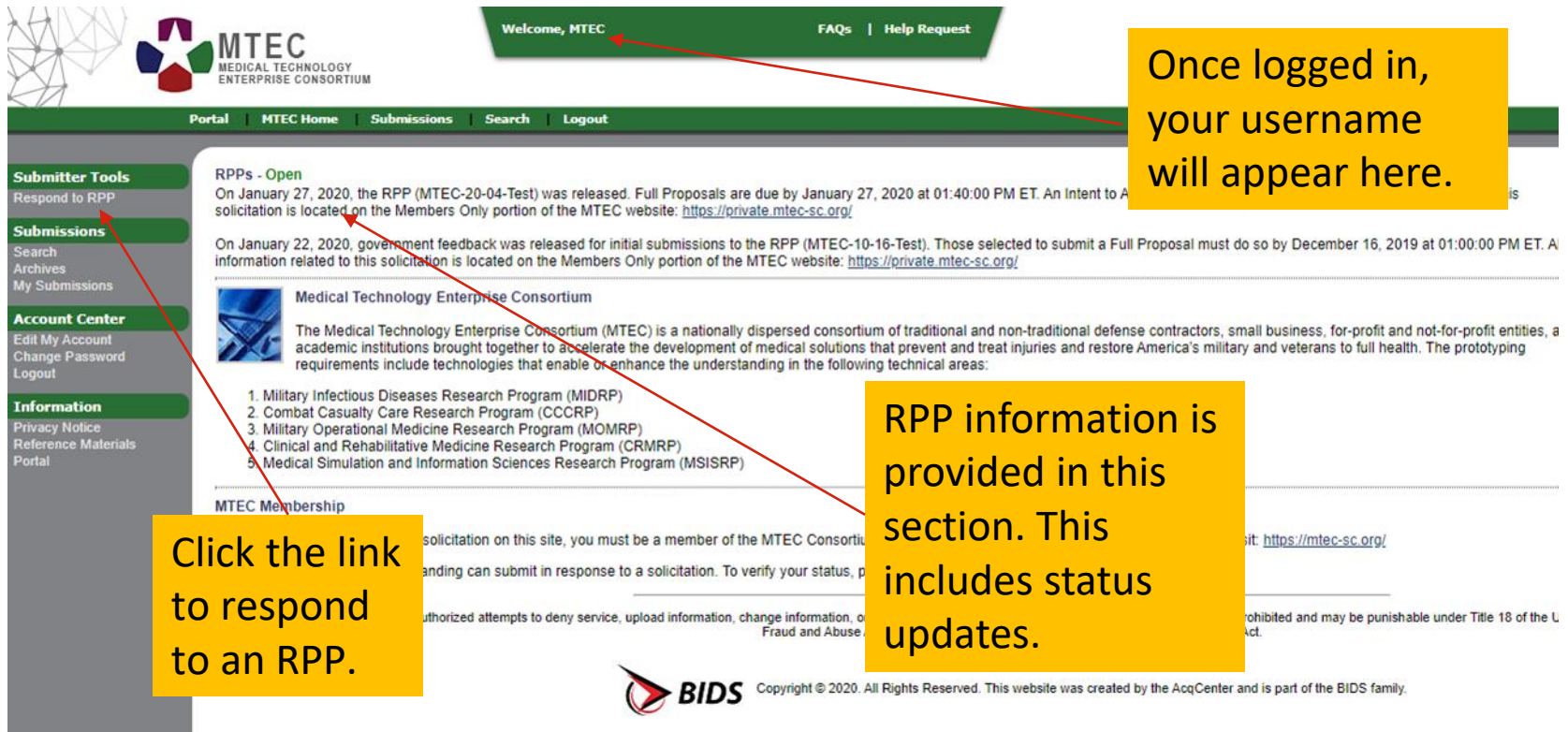
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and a "Help Request" link. Below this is a "Portal" header. The main content area is divided into several sections: "Information" (Privacy Notice, Contact Us), "Consortium Membership" (Note: In order to respond to any solicitation on this site, you must be a member of the soliciting Consortium. For more information on becoming a member, please visit the consortium's public web site. Advanced Technology International (ATI) is a collaboration management firm with core competency in the management of Other Transaction Authority Consortia. ATI leads large Federally-funded research and prototyping operations across a broad range of technology focus areas. View the list of current and upcoming business opportunities available for the below consortia, please visit ATI's Program Solicitations website at: <https://www.ati.org/opportunities>), and "Managed Consortia". A prominent feature is the "MTEC" section, which includes the MTEC logo and the text "Medical Technology Enterprise Consortium". Below this, there is a link for "MTEC BIDS Home" with sub-links for "Learn More" and "How to Join". On the right side, there is a "Login/Registration" section with input fields for "User Name:" and "Password:", a "Login" button, and links for "Forgot Your User Name?", "Forgot Your Password?", and "New Registration". A "NOTE:" section states: "To respond to a RPP you must register for a submitter account." Below this is a "Need Help?" section with links for "Help Request" (Request help about this website.) and "Contact Help" (Request website help.).

Login to your BIDS Account.

Then select the “MTEC BIDS Home” link

SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.

Select the “Respond to RPP” link under the submitter tools



Once logged in, your username will appear here.

Click the link to respond to an RPP.

RPP information is provided in this section. This includes status updates.

Welcome, MTEC FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

Submitter Tools
Respond to RPP

Submissions
Search
Archives
My Submissions

Account Center
Edit My Account
Change Password
Logout

Information
Privacy Notice
Reference Materials
Portal

RPPs - Open
On January 27, 2020, the RPP (MTEC-20-04-Test) was released. Full Proposals are due by January 27, 2020 at 01:40:00 PM ET. An intent to award solicitation is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

On January 22, 2020, government feedback was released for initial submissions to the RPP (MTEC-10-16-Test). Those selected to submit a Full Proposal must do so by December 16, 2019 at 01:00:00 PM ET. All information related to this solicitation is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

Medical Technology Enterprise Consortium
The Medical Technology Enterprise Consortium (MTEC) is a nationally dispersed consortium of traditional and non-traditional defense contractors, small business, for-profit and not-for-profit entities, and academic institutions brought together to accelerate the development of medical solutions that prevent and treat injuries and restore America's military and veterans to full health. The prototyping requirements include technologies that enable or enhance the understanding in the following technical areas:


1. Military Infectious Diseases Research Program (MIDRP)
2. Combat Casualty Care Research Program (CCCRP)
3. Military Operational Medicine Research Program (MOMRP)
4. Clinical and Rehabilitative Medicine Research Program (CRM RP)
5. Medical Simulation and Information Sciences Research Program (MSISRP)

MTEC Membership

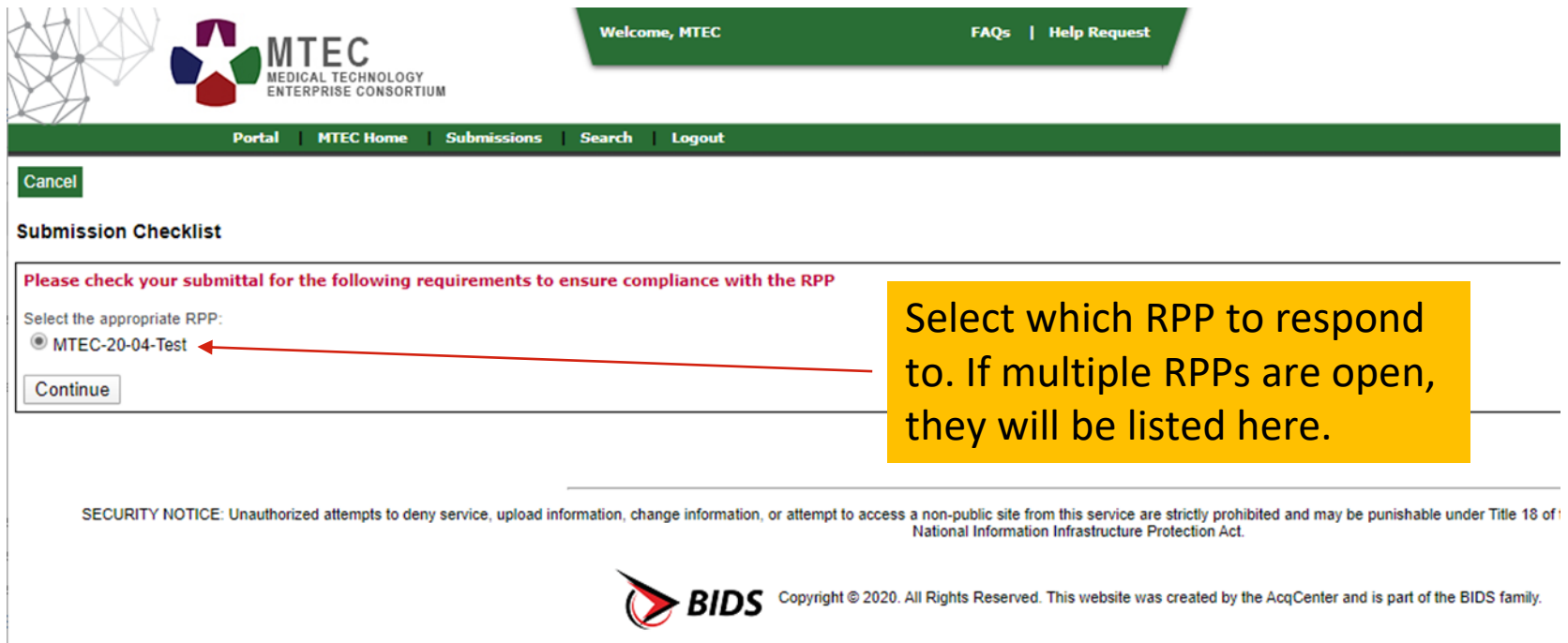
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

standing can submit in response to a solicitation. To verify your status, please visit: <https://mtec-sc.org/>

authorized attempts to deny service, upload information, change information, or engage in any activity prohibited and may be punishable under Title 18 of the U.S. Code, Chapter 115, Section 2385, Fraud and Abuse.

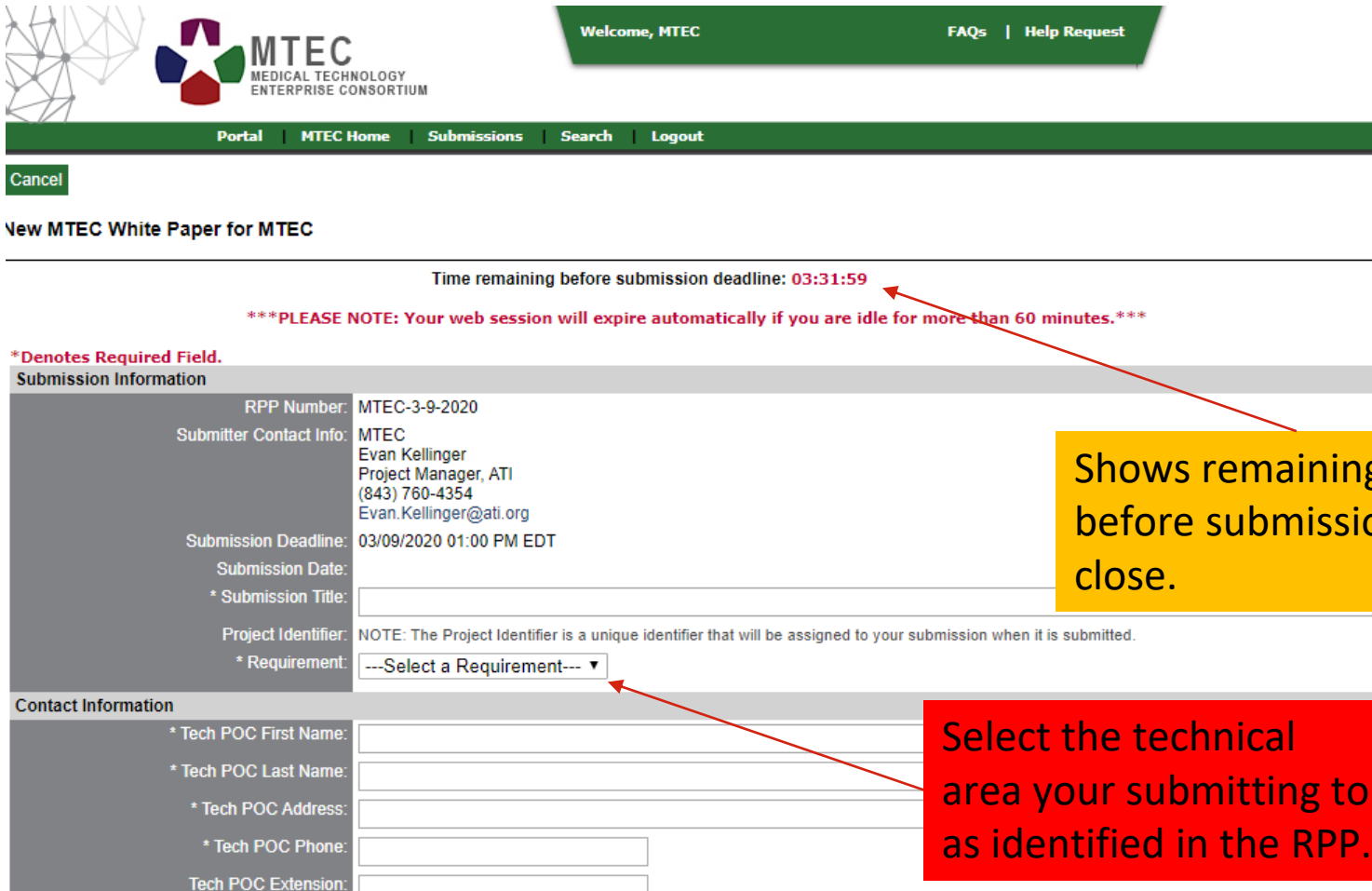
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Select which RPP you will be responding to.



The screenshot shows the MTEC submission checklist interface. At the top, there is a green navigation bar with the MTEC logo and the text "Welcome, MTEC" and "FAQs | Help Request". Below this is a dark green bar with navigation links: "Portal", "MTEC Home", "Submissions", "Search", and "Logout". The main content area has a "Cancel" button and a "Submission Checklist" section. The checklist contains the text "Please check your submittal for the following requirements to ensure compliance with the RPP" and "Select the appropriate RPP:". Below this text is a radio button selection for "MTEC-20-04-Test", which is highlighted with a red arrow. A "Continue" button is located below the selection. A yellow callout box on the right side of the screenshot contains the text: "Select which RPP to respond to. If multiple RPPs are open, they will be listed here." At the bottom of the page, there is a "SECURITY NOTICE" and the BIDS logo with the text "Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family."

Complete the submission form.



The screenshot shows the MTEC submission form interface. At the top, there is a green navigation bar with the MTEC logo and text: "Welcome, MTEC" and "FAQs | Help Request". Below this is a secondary green bar with navigation links: "Portal | MTEC Home | Submissions | Search | Logout". A "Cancel" button is visible on the left. The main content area displays "New MTEC White Paper for MTEC" and a countdown timer: "Time remaining before submission deadline: 03:31:59". A red note states: "***PLEASE NOTE: Your web session will expire automatically if you are idle for more than 60 minutes.***". A section titled "*Denotes Required Field." contains a "Submission Information" section with the following fields: "RPP Number: MTEC-3-9-2020", "Submitter Contact Info: MTEC, Evan Kellinger, Project Manager, ATI (843) 760-4354, Evan.Kellinger@ati.org", "Submission Deadline: 03/09/2020 01:00 PM EDT", "Submission Date:", "* Submission Title:" (text input), "Project Identifier: NOTE: The Project Identifier is a unique identifier that will be assigned to your submission when it is submitted.", and "* Requirement:" (dropdown menu showing "---Select a Requirement---"). Below this is a "Contact Information" section with fields for "* Tech POC First Name:", "* Tech POC Last Name:", "* Tech POC Address:", "* Tech POC Phone:", and "Tech POC Extension:". Two callout boxes provide instructions: a yellow box points to the timer with the text "Shows remaining time before submission close.", and a red box points to the requirement dropdown with the text "Select the technical area your submitting to as identified in the RPP."

Proposal Submission BIDS

Complete the submission form by uploading the required documents and click submit.

File Attachments	
Required Files:	White Paper No file uploaded Upload White Paper (Allowed file types: pdf, doc, docx; Size Limit: 5mb)
Agreements	
*Classified Information:	I certify no classified information is contained in the information being submitted. <input type="checkbox"/> Agree
*Submitter Agreement:	I understand The Government intends to use the Consortium Management Firm, ATI, to assist in the processing of Submitter's proposals to this RPP as indicated in the MTEC Base Agreement. The Consortium Management Firm shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of a Submitter's proposal and the subsequent contract administration if the proposal is selected for award. A Submitter indicates concurrence with the aforementioned CMF responsibilities. Additionally, the Government (CSP) to assist in the submitted proposals' evaluation. The CSP will be required to submit to the Submitter reflecting the effort they will supply to support this RPP. The Submitter's submission of a proposal with the aforementioned Consortium Management Firm responsibilities and the use of CSP. Finally, the Consortium leadership may be provided, at their request, top-level data and metrics on submissions for their use in monitoring the effectiveness of submission processes and the level of participation by members in the RPP. Information will only be released with Government approval. A Submitter's submission under this RPP indicated concurrence with the aforementioned release of information to the Consortium leadership. <input type="checkbox"/> Agree

Upload documents in this section.

Submit

Once the submission form is completed select submit.

SECURITY NOTICE: Unauthorized attempts to deny service, upload, or delete data on this non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the National Information Infrastructure Protection Act.

Proposal Submission BIDS

Once you have successfully submitted a proposal, you will receive a notification with your submission number (ex. MTEC-23-24-Everest-045).

- Submission documents can be modified anytime prior to the due date and time from your BIDS account.
- To make changes to your submission, prior to the due date/time, select the submission link from the home page and navigate to your submission.

Please note: For RPPs that are two stages (i.e. White Paper to Full Proposal) only the account that submitted the stage 1 proposal (the White Paper) will be allowed to submit for stage 2 (the Full Proposal), if selected.

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.