Request for Project Proposal (RPP)

Solicitation Number: MTEC-17-06 Prototype Development for Extracorporeal Life Support (ECLS)

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
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for the
Medical Technology Enterprise Consortium (MTEC)

Revision 3.0- April 4, 2017

Request Issue Date: March 28, 2017

Development Concept Paper/Proposal Due Date: April 28, 2017
12:00PM Eastern Daylight Time
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1 Executive Summary

1.1 Purpose
The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

(a) biomedical research and prototyping;
(b) exploration of private sector technology opportunities;
(c) technology transfer; and
(d) deployment of intellectual property and follow-on production.

This solicitation, issued by the MTEC Consortium Manager (CM), represents a Request for Development Concept Papers for MTEC’s support of the US Army Medical Materiel Agency (USAMMA) technology objectives. Strategic oversight for the award(s) supported by this RPP will be provided by USAMMA.

Military relevance is a critical component of proposal submission. The USAMMA is a unique and multifaceted organization that acts as the Army Surgeon General’s central focal point and Executive Agent for strategic medical logistics programs and initiatives. The Agency’s mission is to develop, acquire, provide, and sustain world class solutions and capabilities to enable medical readiness globally. Project Management Office, Medical Devices (PMO-MD) provides lifecycle management of advanced development and commercial medical devices supporting field medical organizations globally. This PMO provides oversight for technology, engineering, and manufacturing development efforts utilizing Defense Health Program (DHP) and Army Research, Development, Test and Evaluation (RDT&E) funds.

1.2 Request for Development Concept Papers
This MTEC Request for Development Concept Papers is focused on the design and prototyping of a device that addresses the combination of extracorporeal renal and lung support.

1.2.1 Background

Current military conflicts have exposed service members to complex injuries and combat polytrauma. The signature injuries currently seen are combinations of blast injuries (improvised explosive devices), penetrating wounds (projectiles and gunfire) and blunt force trauma, often accompanied by hemorrhagic shock and infection. Each of these injuries put casualties at risk of multisystem organ failure, but in combination have led to alarming rates of respiratory and renal failure. The use of conventional lung rescue strategies on standard ventilators, including lung
protective ventilation, airway pressure release ventilation (APRV- a ‘rescue’ ventilator mode) and proning, can prove challenging to rescue severe cases. Additionally, the lack of expertise, equipment, and resources limit therapeutic capability.

The physiologic burden of injury-related sequela is not limited to the lungs, as renal failure occurs in up to 12.5% of patients1 and contributes to mortality in nearly 30% of combat casualties.2 A combination of shock, prolonged hypotensive resuscitation, and tissue damage from a blast lead to rhabdomyolysis, acute kidney injury, and renal failure. Temporary renal replacement therapy can be lifesaving in these cases, as untreated traumatic renal failure has an unacceptably high mortality.3-5

In an effort to address these critical gaps in the most injured casualties, several strategies have emerged. An extracorporeal membrane oxygenation (ECMO) lung rescue team currently exists that can be launched from the US to any Role 3 facility on the battlefield. This team has the expertise and is equipped to be able to cannulate patients on site and initiate full ECMO. ECMO is a strategy to bring the blood of the patient outside of the body, through a circuit that will add oxygen and remove carbon dioxide, bypassing the compromised lung. ECMO generally requires large cannulas that can accommodate blood flows up to 5 L/min and requires specialized training. For renal failure, several Role 3 level assets have temporary renal replacement therapy (RRT) capability. Temporary RRT functions similar to ECMO, but operates at much lower blood flows (200-400 ml/min). Carbon Dioxide (CO₂) removal operates at similar flow rates as RRT and uses the same catheter sizes. This partial lung support can protect the lungs from injurious ventilation and has the potential to allow for avoidance of ventilation entirely. There are emerging uses for this therapy in trauma and combat casualty care, but it requires a more robust regulatory strategy at this time.

With the changing landscape of combat operations, and the mandate to provide up to 72 hours of prolonged care in the field, sicker patients will present to forward deployed medical treatment facilities (MTFs). These patients have potential for significant ischemia-reperfusion injury with resultant Acute Kidney Injury (AKI) and acute respiratory distress syndrome (ARDS). Therefore, there is a critical need to develop a single ‘bridge’ extracorporeal life support (ECLS) device that can be used in patients with both AKI and ARDS. The goal of this bridge therapy is to keep patients alive until more definitive support and transport can be achieved. This device must be able to

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fully support CO\textsubscript{2} removal while replacing the function of the kidneys through a standard dialysis catheter.

Though the military would most likely use the bridge ECLS device at a level 3 hospital facility, where more robust resources allow for adequate staffing, there may be a need to push farther forward, to the Role 2 if necessary, depending on the availability of evacuation assets. A device to meet the requirements would need to be lightweight, rugged, modular, and user-friendly for implementation in both the field and for transport during fixed or rotary wing medical evacuation. The device would also have to be designed for use by any critical care medical provider with minimal training. Ideally, such a device could be scalable, allowing for full ECMO capability at higher echelons of care.

Finally, the device would have to be air worthy. Air worthiness is determined using standards that allow equipment to be flown in air evacuation platforms, such as a sturdy frame that can withstand vibration, elevation changes, and rapid turning, a sealed container that can withstand environmental elements, and the low emission of electronic signals that do not interfere with airframe avionics. (These standards are available from the U.S. Army Aeromedical Research Laboratory (USAARL) at Fort Rucker, AL.)

1.2.2 Development and Award Approach:

This MTEC Extracorporeal Life Support (ECLS) Project will be executed in three phases:

PHASE 1: The first phase of the project is the submission of a development concept paper (proposal) that describes the:

Technical Proposal:

- Prototype design,
- Timeline for prototype development,
- Anticipated regulatory pathway, and
- Potential commercialization approach(es).

Cost Proposal:

- Projected cost for the development of detailed schematics and a breadboard prototype to be developed in follow-on phases of this project priced separately. Cost sharing requirements or outside funding contributions should also be noted here. If the cost exceeds $50k for the schematics and $170k for the prototype, the proposer should explicitly state willingness to incur additional costs at his/her own expense without reimbursement.

The technical proposal section of the development concept paper will not exceed 10 pages. Both the technical and cost proposals must comply with the mandatory format provided in the MTEC
Small Project Guide (SPG), which is available on the Members Only portion of the MTEC website at [www.mtec-sc.org](http://www.mtec-sc.org). Papers will be evaluated by a standard military evaluation board and no more than 10 will be selected to progress to Phase 2 of the project. If requested by the Offeror(s), the Department of Defense (DOD) or MTEC will provide feedback to the Offerors(s) on the rejected paper(s).

**PHASE 2:** MTEC will provide $50k to each awardee selected in Phase 1 to complete detailed engineering design ‘schematics’ that demonstrate an understanding of the request to develop a single ECLS device that can be used to treat both AKI and Acute Lung Injury (ALI). Awardees will have 45 days to prepare and submit their schematics. An outside panel of biomedical engineers and clinical specialists will evaluate the schematics for feasibility and completeness to address the intended clinical and operational goals. The MTEC will then select no more than 3 sets of schematics to progress to Phase III of the project. If desired, the Department of Defense (DOD) or MTEC will provide feedback on the schematics to be incorporated during Phase 3 of the project. If requested by the Offeror(s), the Department of Defense (DOD) or MTEC will provide feedback to the Offerors(s) on the rejected schematic(s).

**PHASE 3:** The MTEC will provide approximately $0.5 million dollars for the construction of up to 3 prototypes selected in Phase 2 (approximately $170k per prototype). Though the prototypes may not be finalized in terms of form, fit, and function, they should provide an indication of their capability to meet clinical and operational requirements as listed hereafter. The awardees will have 180 days to construct these prototypes. Upon completion, each prototype will participate in a performance challenge either in vitro or in vivo conducted by a DOD intramural lab. The three awardees will be expected to attend the challenge to setup, operate, and breakdown their prototypes. The evaluation criteria for, and description of, the challenge will be provided as soon as it is available.

**NOTE:** If there are no proposal submissions that sufficiently meet the requirements of this RPP, MTEC reserves the right to encourage several Phase 1 awardees to collaborate in Phase 2 to maximize performance across the greatest number of the requirements/goals/tasks outlined herein. MTEC may allocate Phase 2 funds to align with participation in such a collaboration.

**FOLLOW-ON:** The intent of the Government is to develop and procure such an ECLS device. Therefore, the Government reserves the right to continue development of an ECLS prototype resulting from this RPP through a separate Other Transaction Agreement (OTA) or other agreement as necessary. Obviously the degree that a prototype meets the stated clinical requirements as well as its utility in multiple field locations will dictate if further action is taken after this solicitation effort.

**1.3 Funding Availability and Type of Funding Instrument Issued/Effect on Timeline**

Approximately $1 million (FY16) funds will be available to support this effort as follows:
• Phase 1: Each development concept paper will be submitted at the proposer’s own expense.

• Phase 2: A total of $500k will be used to support this phase. Each awardee will receive $50k to develop schematics. Up to 10 awards will be made. The period of performance is 45 days.

• Phase 3: A total of $510k will be used to support this phase. Each awardee will receive $170k to complete the construction of an ECLS prototype device. Up to 3 awards will be made. The period of performance is 180 days. The evaluation of the prototypes submitted at the end of Phase 3 will commence upon completion of all 3 devices and will require no more than three months. Travel funds for participation in the performance challenge will be provided for team members to set up, operate, and breakdown their prototype devices. This is in addition to the $170k provided for prototype build. The 3 challengers will receive the results on the device challenge within 30 days post challenge test.

If fewer proposals are selected for award in each phase due to an insufficient number of proposal submissions or poor quality, then the funding may be increased per award to reduce the cost sharing burden (except for the statutory requirements of the OTA). All funding is intended for Research and Development and has a 2 year obligation period. As a result, MTEC must maintain strict oversight of timeline compliance to ensure that funding remains available for disbursement.

The intent of the Government is to develop and procure such an ECLS device for use within its deployed medical forces. However, future year Defense Appropriations Bills have not been passed as of the release date of this RPP. Therefore, there is no guarantee that additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment, and as always, funding of projects in response to this RPP is contingent upon the availability of federal funds for this program.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the OTA between the Government and MTEC. Subsequently, any proposal that is selected for award under this RPP will be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their proposals that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror
must state on the cover page of its proposals that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement No. 20XX-XXX.

Offerors are advised to check the MTEC website periodically during the proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

1.4 Proprietary Information
The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM 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 an Offeror’s proposal and the subsequent agreement administration if the proposal is selected for award. An Offeror’s submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities. Also, as part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private foundations that award grants for research and operate in research areas that are aligned with those of MTEC. These private foundations may be interested in reviewing proposals within their program areas, allowing for opportunities to attract supplemental funding sources. On your proposal Cover Page, please indicate your willingness to allow MTEC Officers access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit research project proposals, nor receive any research project funding through MTEC.

1.5 Offeror Eligibility
Offerors must be MTEC Members in good standing.

1.6 Inclusion of Non-traditional Defense Contractors
Proposals that do not include Non-traditional Defense Contractor participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award. Please see the MTEC SPG and RPP section 4 for additional details.

1.7 Cost Sharing
Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). The extent of cost sharing is a Factor in the evaluation of proposals (RPP Section 4.1). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution, a description of each cost share item proposed, the proposed dollar amount for each cost share item, and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor
rates, number of trips, etc.) for each cost share item. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

For additional information regarding Non-traditional Defense Contractors and Cost Sharing, please see the Cost Share Guidance document available on the Members-Only portion of the MTEC website www.mtec-sc.org.

1.8 Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee’s Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

Each offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), not both and submit a signed copy with the proposal. Summary explanations of each are provided below.

*Consortium Member Agreement (CMA)*

- Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the performing Member from licensing/commercialization of the technology, capped at 200% of funding provided. MTEC members receiving MTEC funding agreements for research projects will be required to execute an MTEC Royalty Agreement outlining the terms in more detail, to pay an additional 2% assessment fee on the award. (Per Section 11.17 Intellectual Property).

*Royalty Agreement*

- The awardee will be subject to a 10% royalty on all Net Revenues received from licensing/commercialization of the technology developed under the Research Project Award, capped at 200% of funding provided (Per Section 3.5 of the CMA).

*Additional Assessment Fee*

- Member agrees to pay an additional assessment fee of 2% to satisfy its obligations under Section 3.5 of the CMA. This is in addition to the 1% assessment fee for all Research Project Awards. Per Section 3.4 of the CMA, each recipient of a research project award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.
1.9 **Expected Award Date**
Offeror should plan on the period of performance beginning June 1, 2017. The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

1.10 **Anticipated Proposal Selection Notification**
As the bases of selections are completed, the Government will forward their selections to the MTEC CM to notify Offerors.

2 **Proposal**

2.1 **Proposals**
The Development Concept Papers in response to this RPP, must be received by the date on the cover page. Documents received after the time and date specified will not be evaluated.

The MTEC SPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC SPG is mandatory. MTEC will post any general questions received and corresponding answers (without attributable proprietary data) on the members only MTEC website.

2.2 **Proposal Submission**
Offerors must submit proposals via email to mtec-sc@ati.org.

2.2.1 **Submission Format**
Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

- **Full technical proposal submission (10-page limit):** One Word (.docx or .doc) or PDF file is required. Refer to the SPG for details related to the preparation of the technical proposal.

- **Cost proposal submission:** One Word (.docx or .doc) or PDF file for Section I: Cost Narrative required to describe the total costs expected throughout the phased plan and must include the cost-sharing component projected for each individual Phase of this solicitation, understanding that the award amounts are fixed. Separately, Section II: Cost Proposal Formats either in Excel (.xlsx or .xls) or PDF format is required and should include all costs provided by the applicant in pursuit of both Phases 2 and 3. Refer to the SPG for details related to the preparation of the cost data.
o Statement of Work (SOW) submission (1-page limit): One Word (.docx or .doc) file is required. Refer to the SPG for details related to the preparation of the SOW.

o Warranties and Representations: If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required. Refer to the SPG for details.

MTEC will email receipt confirmations to Offerors upon submission of proposals. Offerors may submit proposals in advance of the deadline.

3 Proposal Preparation Instructions

3.1 General Instructions
Development Concept Papers must be submitted, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The guidelines provided in the SPG are mandatory. Proposals shall reference this RPP number (MTEC-17-06-ECLS).

Payments will be made upon acceptance of the request for schematics, to assist in the development of those designs ($50K to a maximum of 10 awardees); and upon acceptance of the request for a prototype ($170K to a maximum of 3 awardees).

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC’s CM, with the approval of the Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as a result of this RPP.

3.2 Technical Proposal and Statement of Work

3.2.1 Technology Essential Characteristics

The overarching goal of this program is to provide a prototype for evaluation that complies with the following essential characteristics. The work will be conducted in three phases, as outlined in Sections 1.2 and 1.3 above. Development Concept papers submitted to MTEC should clearly state how the proposed research provides an innovative solution to integrating CO₂ removal and RRT into a single ECLS device with the ability to use each mode separately.

The Program Office envisions potential future battlefield scenarios of prolonged field care, which will result in the presentation of critically ill patients with AKI and ARDS far-forward on the battlefield. The response to this scenario will include deploying lightweight, rugged, user-friendly bridge ECLS devices to Field Hospitals (Role of Care 3) and to transport patients during fixed wing
medical evacuation. These devices will partially replace the function of the lungs for patients with ARDS or other types of pulmonary failure, and/or of the function of the kidneys for patients with AKI.

**Development Concept Papers must address the following essential characteristics for the combined ECLS device:**

1. Have a reasonable regulatory approach toward Food and Drug Administration (FDA) market authorized device for use in controlling CO₂ exchange in critically ill patients with ARDS and perform hemofiltration, hemodialysis and/or ultrafiltration in critically ill patients with AKI. The development concept papers must describe the methodology for the proposed approach and why they believe it will be successful.

2. Capable of various flow rates (150ml/min – 500 ml/min) and accommodate the use of a standard dialysis catheters (at least 13.5 F) and varying insertion lengths (15 and 24 cm).

3. Deliver a choice of therapies (including, but not limited to, continuous RRT and partial lung support) with the option of combined AKI and ARDS therapies being conducted simultaneously.

4. Lightweight (less than 45lbs) and rugged for battlefield use (withstand temperature extremes (hot & cold), drops/vibration, dust/rain/humidity as outlined in MIL-STD-810G). The device with its associated fluids and connections should be mountable onto a standard NATO litter system used to transport patients.

5. Operate on AC and DC power (11-28 Volt DC, 100/220 Volt AC 50/60Hz).

6. Operate using a rechargeable battery power source (battery life of a minimum of 8 hours when fully charged/hot swappable; objective is 12-24 hours).

7. User-friendly during initiation and maintenance of therapy, where target operators are Physician Assistants and/or General Physicians. Device should also be easy to maintain with the fielded equipment and the skills of biomedical equipment technician.

8. Should not require a large logistical footprint to use (supplies, fluids, minimal O₂, etc.).

9. Capable of passing airworthiness requirements for fixed and rotary wing medical evacuation. Airworthiness testing is conducted by the US Army Aeromedical Research Laboratory at Fort Rucker, AL.

10. Easy to transport and secure in place upon aircraft and in a medical treatment facility.

11. Patient data generated from the device should be transferable via either a tethered or wireless means to computer or hand held devices and should follow Health Level 7-related standards as defined by the DoD Healthcare Management System Modernization.

12. A description of lifecycle considerations should be included in the Development Concept Paper, such as, additional research and development costs, FDA requirements, ease of production, environmental exposure, versatility, modularity, maximum utilization of off-the-shelf components, initial acquisition cost, maintenance and repair requirements, operating and support costs, training requirements, technical support and recycle/disposal.

MTEC seeks Development Concept Papers from investigators comprising multi-disciplinary teams from a wide spectrum of disciplines including, but not limited to, engineering, translational research, and clinical research.
Proposed projects must be based on logical reasoning and sound scientific rationale. Please note that awards are not to be exploratory in nature and require a foundation of preliminary data. **Caveat:** Although the critical specifications of the combined renal and lung support prototype device are outlined above, we encourage you to submit even if you cannot currently meet all the specifications within this time frame. Though we are hopeful that all parameters can be met in a first time run, it may become apparent that we have overestimated the ability of consortium members to respond in full. We would potentially consider lesser responses based upon what parameters were met and the approach to meeting the others over time. However, it is expected that an Offeror’s approach to the prototype will demonstrate how to satisfy all of the critical specifications at some point in time.

Offerors are to propose a Milestone Payment Schedule for Phase 2 which should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone, and any cost share, if applicable. The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

Suggested timeline format may be used as shown in the table below:

<table>
<thead>
<tr>
<th>Milestone No.</th>
<th>Significant Event/Accomplishments Description of Deliverables</th>
<th>Due Date</th>
<th>Total Program Funds</th>
<th>Total Cost Share</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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<td><strong>Total</strong></td>
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</tbody>
</table>

### 3.2.2 Commercialization Plan and Regulatory Pathway

The successful Offeror will provide a description and justification of the anticipated regulatory pathway and Commercialization Plan. This section should be no more than 1 page of the total technical proposal page limit. The regulatory section will describe the strategy that will be adopted to reach FDA market authorization, any planned meeting agenda items that would validate that approach, any predicate device support, etc. The goal is to present a cogent approach that is based upon reasonable historical precedence.
The Commercialization Plan must concisely convey answers to the key questions outlined in the MTEC PPG. The Commercialization Plan should describe the strategy the Offeror will employ to move a technology to the military and relevant civilian market. The Commercialization Plan should provide a roadmap to convey how the Offeror may ultimately generate revenue and profits from the innovation, either from partnering to license and/or co-developing the technology, or continuing to develop internally with additional funds identified in conjunction with MTEC funding. The ability to demonstrate teaming partnerships where applicable is important in understanding the means in which such a technology will be commercialized. The Commercialization Plan should convey:

- The business opportunity enabled by the innovation;
- The compelling value proposition for the intended customer;
- The key points of a plan appropriate for the Offeror’s stage of development;
- The current and the anticipated commercial landscape;
- Pertinent information about intellectual property;
- A regulatory strategy and plan
- The planned indication for the product label, if appropriate;
- Transition plan (including potential funding and resources) showing how the product will progress to the next phase of development and/or delivery to the market after the successful completion of this award;
- The vision for the enterprise and how the proposed innovation fits into the future market.

3.3 Cost Proposal
MTEC will make sample cost proposal formats available on the members only MTEC website. Offerors are encouraged to use their own cost formats such that the actual cost and cost-sharing detail is provided. Costs for Phase 2 and Phase 3 must be priced separately. Refer to the MTEC SPG for additional details.

3.4 Proposal Preparation Cost
The cost of preparing proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

4 Selection

4.1 Proposal Source Selection
The Government will undertake proposal source selection. The proposal source selection will be conducted in accordance with the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

a) Select the proposal (or some portion of the proposal) for award
b) Reject the proposal

4.2 Evaluation Process

All development concept papers will be evaluated by a panel of subject matter experts that will make recommendations for funding based on criteria described below. Offerors submitting the best value proposals that meet the evaluation criteria will be selected for award. Negotiations with offerors may be entered if deemed necessary to clarify proposal information.

Factor 1: Nontraditional Defense Contractor/Cost Sharing
Factor 2: Technical Benefit.
Factor 3: Cost: Though the cost may be a fixed price for the schematics and prototype phases, it would be pertinent to understand the actual or total costs to determine the cost sharing and for comparison toward ultimate unit costs.

Nontraditional Defense contractor/Cost Sharing is a mandatory criteria based upon the use of the OTA vehicle, so it must be met to qualify. After this measure, Technical Benefit is more important than Cost.

4.2.1 Factor 1. Nontraditional Defense Contractor/Cost Sharing.

(1) Ratings. The following ratings will be used for Nontraditional Defense Contractor/Cost Sharing Evaluation:

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offeror proposing an MTEC research project meets at least one of the following:</td>
<td>Acceptable</td>
</tr>
<tr>
<td>• Offeror is a Nontraditional Defense Contractor</td>
<td></td>
</tr>
<tr>
<td>• Offeror’s proposal has at least one Nontraditional Defense Contractor participating to a significant extent</td>
<td></td>
</tr>
<tr>
<td>• Offeror provides at least one third of the total project cost as acceptable cost share</td>
<td></td>
</tr>
<tr>
<td>Offeror proposing an MTEC research project meets at least one of the following:</td>
<td>Marginal</td>
</tr>
<tr>
<td>• Offeror has at least one Nontraditional Defense Contractor participating, but additional detail is required to determine if nontraditional participation is significant</td>
<td></td>
</tr>
<tr>
<td>• Offeror has proposed cost share, but additional detail is required to determine if cost share is acceptable</td>
<td></td>
</tr>
<tr>
<td>Offeror proposing an MTEC research project does not meet any of the following:</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>• Offeror is a Nontraditional Defense Contractor</td>
<td></td>
</tr>
</tbody>
</table>
4.2.2 Factor 2: Technical Benefit  

(1) Ratings. The Technical Approach factor will be evaluated using the merit rating as shown below:

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding</td>
<td>Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.</td>
</tr>
<tr>
<td>Good</td>
<td>Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.</td>
</tr>
<tr>
<td>Acceptable</td>
<td>Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.</td>
</tr>
<tr>
<td>Marginal</td>
<td>Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.</td>
</tr>
<tr>
<td>Unacceptable</td>
<td>Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.</td>
</tr>
</tbody>
</table>

(2) Factor 2. Evaluation Process. The Offeror’s proposed solution will be assessed for the feasibility of design and the likelihood of successfully achieving the requirements of the technology of interest. This likelihood of success will be determined by considering the soundness
of the technical approach, including complete and clear processes to meet the prototype technology essential characteristics within the specified timeline, and provide a reasonable approach to regulatory requirements and commercialization plan. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and objectives, and the suitability of the proposed statistical plan. The proposed road map and SOW should provide a feasible plan for addressing the project’s objectives. Management controls and ability should be described throughout the development concept paper.

4.2.3 Factor 3: Cost Evaluation Factors
The Cost area will receive a narrative rating. The Government Technical Evaluators will assess cost realism as part of the source selection process. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror’s response to a Proposal Update Letter (PUL), if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

Completeness
The following will be evaluated:
- The degree to which the Offerors have provided all cost information requested in the RPP. Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.
- Substantiation of cost (i.e., supporting data and estimating rationale) for all elements.

Reasonableness
To be considered reasonable, the Offeror’s cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Realism
Estimates are “realistic” when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.
As part of its cost analysis, the factors of completeness, reasonableness, and realism will be reviewed as discussed below.

### 4.3 Best Value

The Government will conduct the source selection and MTEC CM will award the projects. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and revise any or all parts of the SOW. Offerors will have the opportunity to concur with the revised SOW and revise cost proposals as necessary.

#### Definitions

- **Strength** - An aspect of an Offeror’s proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

- **Weakness** - A flaw in the proposal that increases the risk of unsuccessful award performance.

- **Significant Strength** - An aspect of an Offeror’s proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

- **Significant Weakness** - A flaw that appreciably increases the risk of unsuccessful award performance.

- **Deficiency** - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

### 5 Points-of-Contact

All questions should be sent via email at mtec-sc@mtec-sc.org.

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Manager, Ms. Lisa Fisher.
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D.
- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director.
- All other questions should be directed to Ms. Polly Graham, MTEC Program Manager.
Once an Offeror has submitted a proposal, neither the Government nor the MTEC CM will discuss evaluation status until the source selection process is complete.