Defense Health Agency
2024.4 Small Business Innovation Research (SBIR)
Proposal Submission Instructions

BAA Open: 27 March 2024
Topic Q&A close: 17 April 2024
BAA Proposal Submission Deadline: 14 May 2024 at 1200 EST

INTRODUCTION

The Defense Health Agency (DHA) SBIR Program seeks small businesses with strong research and development capabilities to pursue and commercialize medical technologies.

Proposers responding to a topic in this Broad Agency Announcement (BAA) must follow all general instructions provided in the Department of Defense (DoD) SBIR Program BAA. DHA requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

Only Government personnel will evaluate proposals submitted under this DHA SBIR solicitation. Specific questions pertaining to the administration of the DHA SBIR Program and these proposal preparation instructions should be directed to:

DHA SBIR Program Management Office (PMO)
Email: usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@health.mil

DIRECT TO PHASE II PROPOSAL GUIDELINES

15 U.S.C. §638 (cc), as amended by NDAA FY2012, Sec. 5106, and further amended by NDAA FY2019, Sec. 854, PILOT TO ALLOW PHASE FLEXIBILITY, allows the Department of Defense to make an award to a small business concern under Phase II of the SBIR Program with respect to a project, without regard to whether the small business concern was provided an award under Phase I of an SBIR Program with respect to such project. DHA is conducting a "Direct to Phase II" implementation of this authority for this 2024.4 SBIR Announcement and does not guarantee Direct to Phase II opportunities will be offered in future Announcements.

Each eligible topic requires documentation to determine that Phase I feasibility described in the Phase I section of the topic has been met.

Direct to Phase II Proposals are different than traditional DHA SBIR Phase I proposals. The chart below explains some of these differences.

	STANDARD DHA SBIR PROCESS	DHA D2P2 PROCESS
PHASE 1 FUNDING LEVEL	$250,000	None
PHASE 1 TECHNICAL *POP DURATION	6 months	None
PHASE 2 FUNDING LEVEL	$1,300,000	$1,300,000
PHASE 2 TECHNICAL *POP DURATION	24 months	24 months

*POP= Period of Performance

DIRECT TO PHASE II PROPOSAL GUIDELINES

Direct to Phase II proposals must include all volumes, not to exceed maximum page limit, and must follow the formatting requirements provided in the DoD SBIR Program BAA.

a. DoD Proposal Cover Sheet (Volume 1)

b. Technical Volume (Volume 2):

Part 1: Phase I Justification (20 Pages Maximum)

Part 2: Phase II Technical Proposal (40 Pages Maximum)

c. Cost Volume (Volume 3)

d. Company Commercialization Report (Volume 4)

e. Supporting Documents (Volume 5)

f. Fraud, Waste, Abuse (Volume 6)

Technical Volume (Volume 2):

Phase I Justification: Offerors are **required** to provide evidence that the scientific and technical merit and feasibility have been established as described in the topic's description and Phase I.

Technical Proposal:

1. Results of current work − Discuss the objectives of your effort, the research conducted, findings or results, and estimates of technical feasibility. provide evidence that the scientific and technical merit and feasibility have been established as described in the topic's description and Phase I.
2. Technical objectives and approach − List the specific technical objectives of the Direct to Phase II research and describe the technical approach in detail to be used to meet these objectives.
3. Work plan − The plan should indicate what is planned, how and where, a schedule of major events, and the final product to be developed.
4. Related work − Describe significant activities directly related to the proposed effort, including those conducted by the Principal Investigator, the proposing firm, consultants, or others. Report how the activities interface with the proposed project and discuss any planned coordination with outside sources. The proposers' awareness of the state-of-the art in the technology and associated science must be demonstrated.
5. Relationship with future research or Research and Development − State the anticipated results of the proposed approach if the project is successful. Discuss the significance of the effort in providing a foundation for a Phase III research or research and development effort.
6. Technology transition and commercialization strategy − Describe your company's strategy for converting the proposed SBIR research into a product or non-R&D service with widespread commercial use − including private sector and/or military markets. Note: The commercialization strategy is separate from the Commercialization Report. The strategy addresses how you propose to commercialize this research, while the Company Commercialization Report covers what you have done to commercialize the results of past awards.
7. Key personnel − Identify key personnel, including the Principal Investigator, who will be involved in the effort. List directly related education and experience and relevant publications (if any) of key personnel. A concise resume of the Principal Investigator(s) must be included.

8. Foreign Citizens – Identify any foreign citizens or individuals holding dual citizenship expected to be involved on this project as a direct employee, subcontractor, or consultant. For these individuals, please specify their country of origin, the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project. Proposing small business concerns frequently assume that individuals with dual citizenship or a work permit will be permitted to work on an SBIR project and do not report them. A proposal may be deemed nonresponsive if the requested information is not provided. Therefore, proposing small business concerns should report any and all individuals expected to be involved on this project that are considered a foreign national as defined in Section 3 of the BAA. You may be asked to provide additional information during negotiations to verify the foreign citizen's eligibility to participate on a SBIR contract. Supplemental information provided in response to this paragraph will be protected in accordance with the Privacy Act (5 U.S.C. 552a), if applicable, and the Freedom of Information Act (5 U.S.C. 552(b)(6)).
9. Facilities/Equipment – Justify items of equipment to be purchased (as detailed in the cost proposal), including Government Furnished Equipment (GFE). All requirements for government furnished equipment or other assets, as well as associated costs, must be determined and agreed to during contract negotiations. State whether the facilities where the proposed work will be performed meet environmental laws and regulations of federal, state (name) and local governments for, but not limited to, the following groupings: airborne emissions, waterborne effluents, external radiation levels, outdoor noise, solid and bulk waste disposal practices, and handling and storage of toxic and hazardous materials.
10. Consultants – Involvement of university, academic institution, or other consultants in the project may be appropriate. If such involvement is intended, it should be described in detail and identified in the Cost Volume.

Cost Volume (Volume 3):

The Cost Volume must contain a budget for the entire 24-month Direct to Phase II period. Proposals submitted under topic DHA244-D003 must not exceed the $1,300,000 proposed amount. Proposals submitted under topics DHA244-D001 and DHA244-D002 are candidates for an award proposed up to the maximum dollar amount of $3,000,000.
Costs must be separated and clearly identified on the Proposal Cover Sheet (Volume 1) and in the Cost Volume (Volume 3).

Please review the updated Percentage of Work (POW) calculation details included in section 5.3 of the DoD Program BAA. DHA will occasionally accept deviations from the POW requirements with written approval from the Funding Agreement Officer.

Travel must be justified and relate to the project needs for direct Research Development Test & Evaluation (RDT&E) Technology Readiness Level (TRL) increasing costs. Travel costs must include the purpose of the trip(s), number of trips, origin and destination, length of trip(s), and number of personnel.

Company Commercialization Report (Volume 4):

Completion of the CCR of the proposal submission in DSIP is required. Information contained in the CCR will be considered by DHA during proposal evaluations. Please refer to the DoD SBIR Program BAA for full details on this requirement.

Supporting Documents (Volume 5):

All proposing small business concerns are REQUIRED to submit the following documents to Volume 5:

1. Contractor Certification Regarding Provision of Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
2. Disclosures of Foreign Affiliations or Relationships to Foreign Countries
3. Disclosure of Funding Sources

Please refer to the DoD Program BAA for more information.

Fraud, Waste and Abuse Training (Volume 6)

DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TABA)

The DHA SBIR Program does not participate in the Technical and Business Assistance (formerly the Discretionary Technical Assistance Program). Contractors shall not submit proposals that include Technical and Business Assistance.

The DHA SBIR Program has a Transition Lead who provides technical and commercialization assistance to small businesses that have Phase I and Phase II projects.

EVALUATION AND SELECTION

The DHA SBIR Program will evaluate and select Direct to Phase II proposals using the evaluation criteria in the DoD SBIR Program BAA. Due to limited funding, the DHA SBIR Program reserves the right to limit awards under any topic and only proposals considered to be of superior quality will be funded.

Proposing firms will be notified via email to the Corporate Official of selection or non-selection status for a Direct to Phase II award within 90 days of the closing date of the BAA.

Non-selected companies may request feedback within 15 calendar days of the non-select notification. The Corporate Official identified in the firm's proposal shall submit the feedback request to the SBIR Office at usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@health.mil as specified in the non-select notification. Please note feedback is provided in an official PDF via email to the Corporate Official identified in the firm proposal within 60 days of receipt of the request. Requests for oral feedback will not be accommodated. If contact information for the Corporate Official has changed since proposal submission, a notice of the change on company letterhead signed by the Corporate Official must accompany the feedback request.

NOTE: Feedback is not the same as a FAR Part 15 debriefing. Acquisitions under this solicitation are awarded via "other competitive procedures". Therefore, offerors are neither entitled to nor will they be provided FAR Part 15 debriefs.

Refer to the DoD SBIR Program BAA for procedures to protest the Announcement.
As further prescribed in FAR 33.106(b), FAR 52.233-3, Protests after Award shall be submitted to:

Ms. Samantha L. Connors SBIR/STTR Chief, Contracts Branch 8
Contracting Officer
U.S. Army Medical Research Acquisition Activity
Email: Samantha.l.connors.civ@health.mil

AWARD AND CONTRACT INFORMATION

Direct to Phase II awards under topic DHA244-D003 will total up to $1,300,000 for a 24-month effort. Direct to Phase II awards under topics DHA244-D001 and DHA244-D002 will total up to $3,000,000 for a 24-month effort.

Contract awards will typically be Firm-Fixed-Price contracts. If a different contracting type is preferred, such as cost-plus, the rational as to why must be included in the proposal.

Awardees will be informed of contracting and Technical Point of Contact/Contract Officer Representative upon award.

ADDITIONAL INFORMATION

RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN SPECIMENS/DATA, OR ANIMAL RESEARCH

Prior to contract award when an IRB is indicated, proposers must demonstrate compliance with relevant regulatory approval requirements that pertain to proposals involving human subjects, human specimens, or research with animals. If necessary, approvals are not obtained within two months of notification of selection, the decision to award may be terminated.

Offerors are expressly forbidden to use, or subcontract for the use of, laboratory animals in any manner without the express written approval of the U.S. Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRDC ACURO to the recipient. Modifications to previously approved protocols require re-approval by ACURO prior to implementation.

Research under this award involving the use of human subjects, to include the use of human anatomical substances or human data, shall not begin until the USAMRDC's Office of Human Research Oversight (OHRO) provides formal authorization. Written approval to begin a research protocol will be issued from the USAMRDC OHRO, under separate notification to the recipient. Written approval from the USAMRDC OHRO is required for any sub-recipient using funds from this award to conduct research involving human subjects. If the Offeror intends to submit research funded by this award to the U.S. Food and Drug Administration, Offerors shall propose a regulatory strategy for review.

*NOTE: Exempt animal or human research use shall also reflect 'yes' on the proposal coversheet for USAMRDC ACURO and OHRO records.
Non-compliance with any provision may result in withholding of funds and or termination of the award.

FEDERAL FACILITY USE

The DHA SBIR Program highly discourages small business concerns (SBCs) from subcontracting to a federal facility and/or utilizing for testing due to the significant lead time required to secure approval, which could substantially delay the performance of the award.
Use of federal facilities is prohibited without an approved waiver from the DHA SBIR/STTR Office.

An SBC whose proposed work includes federal facility use is required to provide a written justification, uploaded to the Supporting Documents (Volume 5), that includes the following information:

1. An explanation of why the SBIR/STTR research project requires the use of the federal facility, including data that verifies the absence of non-federal U.S. facilities, in support of the overall mission and research area.

2. Evidence that there is no applicable U.S. facility that has the ability or expertise to perform the specified work.
3. Why the Federal Agency will not and cannot fund the use of the Federal facility or personnel for the SBIR/STTR project with non-SBIR/STTR money.

The DHA SBIR Program has the right of refusal. Companies that fail to meet requirements specified above will be at risk of delay to award or funding.

If the proposal is selected, the U.S. Army Medical Research Acquisition Activity (USAMRAA) will assist in establishing the waiver for DHA SBIR/STTR Office approval. If approved, the proposer will subcontract directly with the federal facility and not a third-party representative.

Transfer of funds between a company and a Military Lab must meet the following APAN 15-01 requirements (the full text of this notice can be found at https://usamraa.health.mil/SiteAssets/APAN%2015-01%20Revised%20Feb%202018.pdf):

(1) The DoD Intramural Researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the Extramural Research project. This letter must be provided to the Extramural Organization for inclusion in the proposal or application.

(2) The DoD Intramural Researcher must also coordinate with his/her local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. Where there are no DoD-established reimbursement rates [e.g., institution review board (IRB) fees, indirect cost rates, etc.], the Military Facility's RM office (or equivalent) must provide details of how the proposed rates were determined. The DoD Intramural Researcher must use the budget and justification form enclosed in APAN 15-01 when developing the estimated costs and provide it to the Extramural Organization for inclusion in the proposal or application.

(3) The Extramural Research proposal or application must include a proposed financial plan for how the Military Facility's Intramural Research costs will be supported [i.e., directly funded by DoD, resources (other than award funds) provided by the Awardee to the Military Facility, or award funds provided by the Awardee to the Military Facility (in accordance with the requirements below)].

(4) The DoD Intramural Researcher should also coordinate with his/her technology transfer office.

International Traffic in Arms Regulation (ITAR)
For topics indicating ITAR restrictions or the potential for classified work, limitations are generally placed on disclosure of information involving topics of a classified nature or those involving export control restrictions, which may curtail or preclude the involvement of universities and certain non-profit institutions beyond the basic research level. Small businesses must structure their proposals to clearly identify the work that will be performed that is of a basic research nature and how it can be segregated from work that falls under the classification and export control restrictions. As a result, information must also be provided on how efforts can be performed in later phases, such as Phase III, if the university/research institution is the source of critical knowledge, effort, or infrastructure (facilities and equipment).

END

DHA SBIR 24.4 Topic Index
Release 1

DHA244-D001	Sample Collection and Processing Methods to Support Battlefield Wound Infection Diagnostics (Direct to Phase II)
DHA244-D002	Innovative Solutions for Ethylene Oxide Mitigation Used in Sterilization Processes (Direct to Phase II)
DHA244-D003	Advanced Information Technology to Improve Mobility, Interoperability, and Survivability of Expeditionary Medical Command, Control, Communications, and Computers (Direct to Phase II)

DHA244-D001 TITLE: Sample Collection and Processing Methods to Support Battlefield Wound Infection Diagnostics (Direct to Phase II)

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Military Infectious Disease

OBJECTIVE: This topic is intended for technology proven ready to move directly into Phase II and is accepting Direct to Phase II proposals only. Develop a simple-to-use sample collection and processing method capable of preparing an adequate specimen for subsequent identification and accurate detection of specific fungal and/or bacterial species, such as Mucorales, Aspergillus spp., Fusarium spp, Pseudomonas aeruginosa, Escherichia coli (E. Coli), Staphylococcus aureus, and Streptococcus spp., that are often associated with complex battlefield wound infections for use in far-forward deployed environments.

DESCRIPTION: Battlefield wound infections are associated with significant morbidity and mortality (8-12% mortality). Early identification and treatment are critical to prevent loss of limb and/or loss of life. A Warfighter with blast and/or combat related wounds are exposed to various environmental pathogens to include bacteria and fungi in theater. Up to 32% of battlefield wound injures have been reported to develop follow-on infections with soft-tissue infections being the predominant (~66%). Current battlefield wound infection diagnostic capabilities are limited and comprised of traditional microbiology and culture procedures that yield diagnostic results in one (1) – three (3) days (i.e. bacterial infections) and potentially as long as six (6) weeks (i.e. fungal infections). These methods are insensitive and are heavily dependent on clinical and microbiological expertise. Furthermore, these capabilities are only located at higher roles of care, further from the point of injury and often delays treatment and medical intervention decisions. Proper sample collection methods and/or procedures are necessary to preserve the sample matrix to ensure high accuracy in sensitivity and specificity of the diagnostic test. Due to various factors of complicated wounds, the sample collection and processing method should take into consideration the complex nature of wound specimen types (biopsy, exudate, fluid aspiration) that can make sample processing more challenging.

Rapid diagnosis of battlefield infections in complex wounds closest to the point of injury significantly improves Solider outcomes in prolonged care and reduces morbidity and mortality for severely injured. Rapid diagnostics (<2 hours sample collection-to-result) located at the point of battlefield injury will reduce time-to-result by 2-3 days (at minimum). Rapid turnaround of test results directly improves patient outcomes and return to duty by enabling earlier and accurate treatment decisions and/or surgical interventions, especially in large-scale combat operations where medical evacuation may be degraded. And where evacuation is available, the most critical may be evacuated earlier to a higher role of care to receive advanced medical intervention that is not otherwise available in far-forward environments. However, simple-to-use capabilities that can accurately detect fungal and bacterial diseases in complex wounds has been challenged by the lack of effective sample collection and processing methods that can manage tissue and viscous fluids. Current market analysis has shown that rapid diagnostic capabilities lack the ability to conduct tissue homogenization procedures that are critical for isolation and accurate detection of bacterial and fungal species that are found in combat wounds.

The technology is not limited to but should consider, the factors below:
1. The technology must include a plan for FDA clearance.
2. Technology should have the ability to collect and process a clinical sample from a combat wound that can be used on a diagnostic platform capable of distinguishing between common clinical fungal and bacterial agents of infection with no downstream analysis required.
3. Technology solutions overall should require minimum logistical support, should be compatible with applications in wet/dry environments, and stable in long term storage including hot (~100℃) and cold temperature (-20℃).

4. Ease of use, technology should be operable with little training or background with unambiguous primary output.

Please Note - Technologies with the following features are not the primary focus of this topic:
1. Wound swabs (cotton-based or other similar swab applications)

PHASE I: This topic is intended for technology proven ready to move directly into Phase II. Therefore, the offeror must be able to demonstrate and provide documentation to substantiate that the scientific and technical merit and feasibility described in Phase I has been met and describes the potential commercial applications. Documentation should include all relevant information including, but not limited to technical reports, test data, prototype designs/models, and performance goals/results. Completed Phase I efforts should demonstrate a promising design with demonstrated performance (i.e. improved sample collection/processing to result time (less than 2 hours) and decreased logistical burden) superior to current standards (i.e. traditional microbiology and culture procedures) in the laboratory. Completed Phase I efforts should include the development of a study plan that includes identification of at least one traditional microbiology and/or culture procedure to use as a comparator along with the proposed sample collection method and/or procedure; the intended goal of having a comparator is to determine if the proposed sample collection method and/or procedure performs better than current standard methods/procedures and results in a superior test sample readout.

PHASE II: During this phase, the lead candidate sample collection method and/or procedure should further refine proof-of- feasibility and proof-of-concept to integration with a rapid diagnostic technology that can detect fungal and bacterial agents from samples to provide a positive/negative result (in less than 2 hours). Proof-of-feasibility and proof-of-concept studies should address the challenge of sample collection from combat wounds and sample processing to support rapid diagnostic capability requirements. Proposals may include early versions of sample collection methods and procedures. Sample collection methods and/or procedures developed should demonstrate feasibility of sample isolation and detection of bacterial and fungal agents (common to combat wounds) that can be integrated with relevant rapid diagnostic platforms. The rapid diagnostic technology should not require any downstream diagnostic requirements (i.e. a medical doctor/physician to interpret and/or read test result(s)); result output should be a definitive positive or negative readout for each bacterial or fungal target. Animal and/or tissue infection model(s) should be considered as a means of tissue collection for subsequent sample processing method(s) for detection of several bacterial and fungal agents. The sample collection method and/or procedure should preferably align with CLIA-waived complexity standards (not to exceed moderate complexity) to support use in a far-forward environment by individuals with minimal microbiology training. At this stage, offers may begin developing a quality control plan. The offeror shall propose a regulatory strategy and provide a plan on how FDA clearance may be obtained (this does not include consultation or engagement with the FDA). Sample processing and/or procedures should be drafted in a multimedia format that can translate into commercialization of the product into the market. Efforts must be made to ensure that the sample collection method and/or procedure is affordable and aligns with current market value.

At the end of phase II, a proof-of-concept prototype should be defined; however, the government is not requiring an initial production lot of the prototype sample collection and processing method technology to be provided at this time. The sample collection and processing method prototype should be defined to a point that enables/facilitates a future Phase III award that includes prototype scale up in preparation for clinical evaluation.

PHASE III DUAL USE APPLICATIONS: The goal of this phase is to secure an FDA approved sample collection method/procedure that is compatible/integrated with a rapid diagnostic capability that is either in development or is already FDA-cleared enabling early detection of fungal and bacterial infection in

combat wounds. Further development, testing and clinical evaluation of the sample collection method and/or procedure integrated with a rapid diagnostic technology in Phase II of this SBIR may be supported by BARDA, CDMRP, JWMRP, and other DOD opportunities. Once developed and demonstrated, the technology can be used commercially in both civilian and military settings to save lives. Market evidence supports use of the described capability in any civilian hospital where wound infection diagnostics are routinely performed. Wound cultures are a common and indispensable practice for diabetic chronic wound management, surgical site infections, and other circumstances involving persistent or severe infections. Similarly, Service Members are exposed to various organisms when deployed and suffer combat injuries that result in complicated wounds. If the sample collection method and/or procedure is transitioned into an Acquisition Program of Record, the Government may propose to the company to harmonize the technology design with other relevant products to meet additional DoD requirements.

REFERENCES:

1. Tribble DR, Ganesan A, Rodriguez CJ. Combat trauma-related invasive fungal wound infections. Curr Fungal Infect Rep. 2020 Jun;14(2):186-196. doi: 10.1007/s12281-020-00385-4. Epub 2020 Apr 16. PMID: 32665807; PMCID: PMC7360332.
2. Tribble DR, Murray CK, Lloyd BA, Ganesan A, Mende K, Blyth DM, Petfield JL, McDonald J. After the Battlefield: Infectious Complications among Wounded Warriors in the Trauma Infectious Disease Outcomes Study. Mil Med. 2019 Nov 1;184(Suppl 2):18-25. doi: 10.1093/milmed/usz027. PMID: 31778199; PMCID: PMC6886670.
3. Eardley WG, Brown KV, Bonner TJ, Green AD, Clasper JC. Infection in conflict wounded. Philos Trans R Soc Lond B Biol Sci. 2011 Jan 27;366(1562):204-18. doi: 10.1098/rstb.2010.0225. PMID: 21149356; PMCID: PMC3013428.
4. Murray CK, Roop SA, Hospenthal DR, Dooley DP, Wenner K, Hammock J, Taufen N, Gourdine E. Bacteriology of war wounds at the time of injury. Mil Med. 2006 Sep;171(9):826-9. doi: 10.7205/milmed.171.9.826. PMID: 17036599.

KEYWORDS: Sample collection, Infection(s), Fungal infection(s), Bacterial infection(s), Combat/Battlefield wound(s), Diagnostic(s), Clinical, Trauma

DHA244-D002 TITLE: Innovative Solutions for Ethylene Oxide Mitigation Used in Sterilization Processes (Direct to Phase II)

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Combat Casualty Care

OBJECTIVE: This topic is intended for technology proven ready to move directly into Phase II and is accepting Direct to Phase II proposals only. Develop innovative solutions that effectively mitigate ethylene oxide used as part of and generated during sterilization processes, promoting environmentally friendly and sustainable practices in the field of sterilization technologies.

DESCRIPTION: Approximately fifty percent of all sterile medical devices in the US are sterilized with ethylene oxide (ETO), which is highly effective at killing bacteria, viruses and other microorganisms (1,2). ETO is commonly used in the manufacturing of medical devices for its effective sterilization properties because it can sterilize heat - or moisture- sensitive medical equipment without harmful effects on the material used in the medical devices (1). The process involves exposing medical devices to ETO gas to eliminate microorganisms and to ensure product sterility. Medical devices are prepared for sterilization, loaded into a sealed sterilization chamber designed to maintain the appropriate conditions for the process, ETO gas is introduced into the chamber, penetrating the packaging, and reaching all surfaces of the medical devices and perturbing microbial DNA to prevent replication. After sterilization, the ETO gas is carefully removed from the chamber, and aeration processes may be employed to ensure residual ETO levels comply with safety standards. Once the sterilization process is complete, the medical devices remain unopened in order to maintain their sterility until use. It's important to note that while ETO is effective for sterilization, its use has raised environmental and health concerns, particularly due to its potential carcinogenicity. ETO toxicity has been established in a variety of animals and exposure can cause a multitude of serious symptoms, including cancer, nerve damage and spontaneous abortion (4). This has led to ongoing efforts to develop alternative sterilization methods with reduced environmental impact and health risks. Currently, there are no or limited commercially available products that can mitigate the ETO byproducts of medical device manufacturing. Current methods generate various byproducts, posing environmental concerns and potential cancer risks associated with exposure. The desired novel materiel solution should be compatible with current ETO sterilization equipment and focus on minimizing or eliminating ethylene oxide emissions during medical device sterilization. We are specifically seeking advancements in sterilization technologies that prioritize environmental sustainability and health, aiming to exclude methods that expose humans and the environment to residual ETO. The military's substantial investment in 3D printing and additive manufacturing reflects a strategic shift towards agile and on-demand production capabilities. However, the use of certain materials in these processes necessitates a crucial consideration: the need for safe ETO sterilization. As military applications often involve the production of critical components, ensuring the sterility of these items is paramount. ETO sterilization is particularly relevant in preserving the integrity of materials susceptible to heat or moisture damage during traditional sterilization methods. This dual focus on advanced manufacturing and sterilization underscores the military's commitment to not only innovation but also the quality and reliability of the products generated through these cutting-edge technologies. There is a plan for modernizing medical sterilization in an austere environment, and the DOD maintains an active technology watch program on emerging technologies in sterilization to enhance other surgical capabilities, including ETO sterilization.
The technology is not limited to but may consider the factors below:
1. The technology must consider a plan for FDA clearance and EPA review.
2. Technology should be capable of integrating into or compatible with current medical device manufacturing and sterilization processes without necessitating significant alterations to the existing sterilization processes and setup.
3. Technology should be capable of operating continuously and should not become the rate-limiting step to current standard manufacturing processes.

4. Engineering solutions overall should require minimum logistical support.
5. Technology should be operable with little training or background with unambiguous primary output.
Technologies that seek to use methods other than ETO sterilization are not the primary focus of this topic. To be clear, we are seeking strategies or technologies to reduce ETO emissions to as close to zero as possible from the ETO sterilization process. We are NOT seeking alternatives to ETO sterilization under this sterilization.

PHASE I: This topic is intended for technology proven ready to move directly into Phase II. Therefore, the offeror shall provide detail and documentations which demonstrates the accomplishment of a "Phase I-like" effort, including a feasibility study. This includes, insofar as possible, the scientific and technical merit of a prototype that will provide a novel ethylene oxide (ETO) mitigating solution for medical device sterilization that can be easily integrated into current medical device manufacturing processes. The solution should address cancer risks associated with ETO exposure without necessitating large modifications to current manufacturing processes and setups. Feasibility documentation of particular interest is prior evidence leading to:
• Evidence that the proposed solution will be viable with adequate risk mitigation.
• Design considerations to include sensors and other necessary instrumentation to detect, measure and warn of the presence of ETO or any other toxic byproduct of the sterilization process.
• Identification and analysis of potential challenges and risks associated with the implementation of the proposed solution.

Proposers should consider the additional challenges associated with testing potential solutions. Considerations may include working closely with a safety officer, use of a negative pressure chemical hood (lowered stash for safety and to increase the negative flow rate), evacuation of the test site area/building and other safety mitigation strategies as needed.

These deliverables collectively demonstrate the technical viability, feasibility, and strategic planning necessary for the successful development of the ethylene oxide byproduct mitigation solution.

PHASE II: The Phase II focus is on comprehensive development and refinement of the ETO byproduct mitigation solution for medical device sterilization.
Key expectations include:
1. Prototype development
    • Develop a demonstration prototype to thoroughly examine various design approaches and refine them for the best outcomes. It's crucial to ensure that the prototype is compatible with a wide range of currently approved ETO sterilizers, catering to different types and models. Assumptions should be made based on the largest market elements to align with potential user needs and preferences.
2. Efficacy testing
    • Rigorous testing and validation of the solution's efficacy in mitigating ETO byproducts, with a particular emphasis on addressing health and environmental risks. Testing shows the equipment's ability to reduce ETO emissions from sterilization process to as close to zero as possible, surpassing current FDA/EPA standards. Device should not interfere with components already in use for sterility assurance level (SAL) that is the FDA standard for confirming the absence of microbes.
3. Regulatory Compliance
    • Develop a regulatory plan with relevant regulatory standards and requirements for medical device sterilization (2) to include current EPA standards (6).
4. Scale up strategy or commercialization plan.
    • Development of a scalable strategy for integrating the solution into diverse manufacturing processes without compromising efficiency Phase II expectations revolve around advancing from

proof-of-concept to a more mature and market-ready product, positioning the project for successful commercialization and broader impact in the medical device manufacturing industry.

PHASE III DUAL USE APPLICATIONS: Following the successful Phase II development, this ETO mitigation prototype may be poised to revolutionize sterilization practices across numerous sectors. According to the FDA, approximately 20 billion medical devices are sterilized each year using ETO, and for most of these devices, ETO is the only validated and viable sterilization method. That said, this product is expected to have customers in a full range of industries, and in fact medical sterilization only accounts for about 1% of all industrial uses of ETO. With its ability to enhance safety and reduce risks associated with ETO sterilization, this technology offers a versatile solution for industries reliant on ETO sterilization, including medical, pharmaceutical, food, laboratory, veterinary, cosmetic, and textile sectors. The primary objective beyond Phase III is to transition the ETO mitigation prototype from development to widespread implementation across diverse industries, to include the medical device industry. Plan may include exploring potential collaborations and partnerships with industry stakeholders, regulatory bodies, or research institutions. An effective commercialization plan provides evidence of following a comprehensive strategy outlining how the ETO mitigation solution will be brought to market. The small business should have plans to secure funding from non-SBIR government sources and/or the private sector to develop or transition the prototypes into a viable product for sale to the military and/or commercial markets. The positive impact of successfully implementing the ETO mitigation solution extends beyond industry standards, fostering a paradigm shift toward environmentally conscious and health-focused practices, ultimately contributing to a safer and more sustainable future for medical device manufacturing.

REFERENCES:

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KEYWORDS: Manufacturing-related, Ethylene Oxide, Byproducts, Sterilization, Mitigation, Environmental sustainability, Sterilization techniques, Green sterilization, Ethylene Oxide Emissions, Manufacturing processes, Sterilization equipment, Industrial production, Sustainable manufacturing, Ethylene Oxide treatment, Manufacturing practices

DHA244-D003 TITLE: Advanced Information Technology to Improve Mobility, Interoperability, and Survivability of Expeditionary Medical Command, Control, Communications, and Computers (Direct to Phase II)

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Combat Casualty Care

OBJECTIVE: This topic is intended for technology proven ready to move directly into Phase II and is accepting Direct to Phase II proposals only. Develop expeditionary and interoperable information technology (IT) to enable health care delivery (HCD), medical command and control (MEDC2), medical logistics (MEDLOG), and patient movement (PM) in austere and contested environments.

DESCRIPTION: No capabilities fully bridge the gaps between expeditionary medical (EXMED) units, civilian and military brick-and-mortar medical facilities, and other healthcare providers, such as civilian emergency medical service (EMS) providers. Although standards exist to facilitate data interchange, there are limited solutions that offer robust communications and computer IT packages to implement standards at all levels of care, across military and civilian healthcare organizations.

Currently, EXMED units, like many civilian EMS providers, present paper charts or verbal reports when transferring care. These methods of information exchange lead to errors, reducing timeliness and quality of care. Even within such units, medical functionality is not fully interoperable; for example, information from diagnostic equipment must be manually captured in electronic health records (EHR) [2]. Further, administrative and public health functions are often disconnected from EXMED and civilian care providers, limiting visibility of logistics needs (e.g., supply) and safety considerations (e.g., disease vectors). Agile and interoperable solutions are required to improve healthcare provision both on the battlefield and at home.

Mobile and rugged C2, communications, and computer (C4) IT solutions and medical applications are required to ensure uninterrupted and secure HCD within medical units and throughout the continuum, from en route care (ERC) provided during PM to hospital care. Solutions must enable interoperability across all medical and administrative functions (MEDLOG, MEDC2) and domains, securely connecting medical and support endpoints (e.g., laptops, mobile x-rays) to each other and the enterprise.

C4IT solutions must achieve interoperability by implementing joint/industry communications and health IT standards (e.g., United States Core Data for Interoperability [USCDI] [2]) and meeting cybersecurity requirements (e.g., National Institute of Standards and Technology [NIST] Risk Management Framework [RMF] [1]). EXMED C4IT solutions must be resilient, scalable, and extensible. Solutions must survive and operate with limited degradation in various environmental conditions, including climatic extremes, degraded/denied external communications, and in the face of threats such as cyber attacks. Scalability is required to ensure the solution can be tailored to meet the mobility and capacity needs of various medical units. Extensibility is critical to ensuring solutions can incorporate new functionality and additional interfaces as civilian and DOD medical technology improves. For example, C4IT must connect to various civilian health information and DOD networks (e.g., Joint Health Information Exchange). Resiliency and interoperability require an innovative application of networking/communications, artificial intelligence, data storage/management, and other technologies that facilitate realizing smart hospital [3] benefits in a distributed and expeditionary environment.

PHASE I: This topic is intended for technology proven ready to move directly into Phase II. Therefore, the offeror must be able to demonstrate and provide documentation to substantiate that the scientific and technical merit and feasibility described in Phase I has been met and demonstrates the accomplishment of a "Phase I like" effort, including a feasibility study. Documentation shall address employment of novel technologies or innovative applications of edge computing, asynchronous / store-and-forward

communications, data storage (e.g., data lakes), machine learning, or similar concepts to deliver a solution that provides secure and continuous operations in a hybrid cloud or distributed environment and maximizes interoperability both with enterprise solutions and between local endpoints. Conceptual design and feasibility studies do not need to be limited to military or medical applications. However, documentation should indicate applicability to EXMED operations described herein. Documentation should include the following:
(a) Preliminary data to support the security and efficacy of concepts
(b) Specifications that describe/illustrate mobility, modularity, scalability, extensibility, and resiliency of design
(c) Statistically significant performance data, if available
(d) Applicability to EXMED operations

PHASE II: The phase will include:
(a) Design refinement, specifying mobile and rugged EXMED C4IT, including:
    1. Structure: hardened enclosure, network components, endpoints, dependencies, and connectivity
    2. Functionality: security, enterprise and standalone operations, and wired and wireless connectivity
    3. Interfaces with Joint Operational Medicine Information Systems (JOMIS) [5], including solutions requiring client applications and browser-enabled access
    4. Security measures
    5. Standards and protocols
(b) Prototype implementation planning; includes risks, mitigations, timeline, cost, and critical design aspects
(c) Prototype development. Prototype must:
    1. Implement approved design
    2. Be transportable in and include a hardened 10-foot ISO container (or comparable)
    3. Include
        i. Mobile network infrastructure
        ii. Endpoints, minimally:
            a. Twenty mobile computing devices: a mix of laptops, tablets, and thin-clients
            b. Three printing and scanning devices
            c. One mobile x-ray
            d. One mobile diagnostic laboratory device
            e. Patient monitoring equipment for three patients
(d) Test planning and execution; includes reporting actual characteristics (e.g., security, interoperability, performance) and improvements required
(e) Transition planning; includes timeline, production and sustainment costs, production and commercialization risks

Required deliverables include one prototype as described herein, design and plans specified herein, regular progress reports (with risks, cost and schedule impacts, mitigations), and a final report (with findings and recommendations).

PHASE III DUAL USE APPLICATIONS: Using the results and progress made during Phase II, a Phase III effort will complete all required work to deploy the C4IT capability in an operational environment. This phase will include the following tasks:
(a) Engineering, production, and management support, including support to transition the solution to (or coordinate with) PMS 408 for further deployment and evaluation
(b) Optimization of design to develop commercially viable product that can also meet military requirements

1. Design must clarify modifications required to maximize commercial viability. Innovative approaches are required to ensure design is extensible and interoperable such that the capability can be marketed to a wide audience
    i. In addition to implementing specified standards, C4IT design should enable exchange consistent with standards developed by organizations like Digital Imaging and Communications in Medicine (DICOM), Health Level Seven International (HL7), and National Council for Prescription Drug Programs (NCPDP)
    ii. Design should employ technologies like machine learning and data lakes to collect and process unstructured data and structured data of various formats
    iii. Design should include creative approaches to enable rapid integration of new endpoints; endpoints may be vastly different in purpose and construct
2. Design must clarify modifications required to enable operations in military environments/conditions, including operations ashore in austere environments (e.g., little/no communications/connectivity provided by other organizations) and operations on aircraft and ships
    i. Modifications should detail requirements to fully implement interfaces/integration with JOMIS [5], including:
        a. Operational Medicine Care Delivery Platform (OpMed CDP)
        b. Military Heath System (MHS) GENESIS Theater (MHSG-T)
        c. Operational Medicine Data System (OMDS)
        d. Medical Common Operational Picture (MedCOP)
    ii. Modifications should detail requirements to
        a. Scale the system up (150-person team) or down (2-person team)
        b. Integrate new/alternative endpoints
        c. Employ new/alternative information exchange mechanisms to ensure interoperability with latest DOD enterprise information systems (IS), including administrative (i.e., non-health) IS.
    iii. Design must account for modifications to fully meet DOD cybersecurity per DODI 8510.01 [4] and enable operations on DOD networks afloat and ashore

(c) Optimization of plan to produce and sustain systems; plan must account for:
1. Timeline and cost to become production ready
2. Modernization of Phase II prototype to meet updated design
3. Production of three systems within twelve months of design optimization
4. Sustainment of four systems, to include maintenance of cybersecurity (e.g., software/firmware patches)
5. Modernization, production, and sustainment of additional systems to support various organizations/applications, within and outside the DOD

Potential commercial applications cover both medical and non-medical industries, including:
(a) Organizations requiring distributed operations or operations in austere environments, e.g., North Atlantic Treaty Organization (NATO) forces, including medical units; civilian and military support to disaster relief and humanitarian aid efforts; and mobile clinics/healthcare
(b) Industries that struggle with stovepipe systems, disparate/non-existent standards, or rapidly growing base of distributed users and require the ability to quickly integrate new technologies/endpoints

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KEYWORDS: command, control, communications, and computer (C4) systems; communication networks; artificial intelligence (AI) computing; smart technology; cloud computing; information technology (IT); health care technology; Joint Operational Medicine Information Systems (JOMIS)