CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM
FY23.3 Small Business Innovation Research (SBIR)
Proposal Submission Instructions

The approved FY23.3 topics included in the Chemical and Biological Defense (CBD) Small Business Innovation Research (SBIR) Program is provided in this document. Offerors responding to this Announcement must follow all general instructions provided in the Department of Defense (DoD) Program Announcement. Instructions detailing the CBD SBIR program requirements are provided below.

Proposers are encouraged to thoroughly review the DoD Program BAA and register for the DSIP Listserv to remain apprised of important programmatic and contractual changes.

- The DoD Program BAA is located at: https://www.defensesbirsttr.mil/SBIR-STTR/Opportunities/#announcements. Be sure to select the tab for the appropriate BAA cycle.
- Register for the DSIP Listserv at: https://www.dodsbirsttr.mil/submissions/login.

Please read the entire DoD Announcement and these CBD SBIR instructions carefully prior to submitting your proposal. Important programmatic changes have been incorporated as required by the SBIR and STTR Extension Act of 2022 (Pub. L. 117-183). Also, go to https://www.sbir.gov/about/about-sbir#sbir-policy-directive to read the SBIR/STTR Policy Directive issued by the U. S. Small Business Administration (SBA).

INTRODUCTION

In response to Congressional interest in the readiness and effectiveness of U.S. Nuclear, Biological and Chemical (NBC) warfare defenses, Title XVII of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103-160) requires the Department of Defense (DoD) to consolidate management and oversight of the Chemical and Biological Defense (CBD) Program into a single office – Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs. The Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD), located at the Defense Threat Reduction Agency (DTRA), provides the management for the Science and Technology component of the Chemical and Biological Defense Program. Technologies developed under the Small Business Technology Transfer (STTR) Program have the potential to transition to the Joint Program Executive Office for Chemical Biological Radiological and Nuclear Defense (JPEO-CBRND) if the appropriate level of technology maturity is demonstrated. The JSTO-CBD Science & Technology programs and initiatives improve defensive capabilities against Chemical and Biological Weapons of Mass Destruction. The SBIR portion of the CBD Program is managed by the JSTO-CBD.

The mission of the Chemical and Biological Defense Program is to ensure that the U.S. Military has the capability to operate effectively and decisively in the face of chemical or biological warfare threats at home or abroad. Numerous factors continually influence the program and its technology development priorities. Improved defensive capabilities are essential in order to mitigate the overall impact of chemical and biological threats. The U.S. military requires the finest state-of-the-art equipment and instrumentation available to permit our warfighters to 'detect to warn' and avoid contamination, if possible – and to be able to sustain operations in a potentially contaminated environment. Further information is available at the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs homepage at https://www.acq.osd.mil/ncbdp/cbd/

The overall objective of the CBD SBIR Program is to improve the transition or transfer of innovative Chem-Bio technologies to the end user – the warfighter – in addition to commercializing technologies within the private sector for mutual benefit. The CBD SBIR Program targets those technology efforts that

maximize a strong defensive posture in a biological or chemical environment using passive and active means as deterrents. These technologies include chemical and biological detection for both point and stand-off capabilities; individual and collective protection; hazard mitigation (decontamination); medical pre-treatments (e.g., vaccine development and delivery); medical therapeutics (chemical countermeasures and biological countermeasures); medical diagnostics; Digital Battlespace Management (aka information systems technology) to include but not limited to modeling and simulation (e.g., meteorological dispersion), disease surveillance, data fusion, and health & human effects to include wearable technologies.

All proposals submitted to the CBD SBIR program much comply to the terms of this Announcement. CBD SBIR reserves the right to limit awards under any topic, and only those proposals of superior scientific and technical quality, as determined by Technical Evaluation Team and the CBD SBIR program office will be funded. CBD SBIR reserves the right to withdraw from negotiations at any time prior to contract award. The Government may withdraw from negotiations at any time for any reason to include matters of national security (foreign persons, foreign influence or ownership, or other related issues).

Use of Foreign Nationals (also known as Foreign Persons), Green Card Holders, and Dual Citizens

See the "Foreign Nationals" section of the DoD SBIR Program Announcement for the definition of a Foreign National (also known as Foreign Persons).

ALL offerors proposing to use foreign nationals, green-card holders, or dual citizens, MUST disclose this information regardless of whether the topic is subject to export control restrictions. Identify any foreign nationals 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 the project. You may be asked to provide additional information during contract negotiations in order 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)).

Proposers responding to a topic in this BAA must follow all general instructions provided in the Department of Defense (DoD) SBIR Program BAA, paying special attention to the new requirements under the SBIR and STTR Extension Act of 2022 (Pub. L. 117-183). The Chemical and Biological Defense SBIR Program requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

Specific questions pertaining to the administration of the Chemical and Biological Defense SBIR Program and these proposal preparation instructions should be directed to: Ms. Abigail L. Roots, Chemical and Biological Defense SBIR/STTR Program Manager, JSTO-CBD, at dtra.belvoir.rd.mbx.jsto-cbd-chem-bio-defense-sbir@mail.mil.

PHASE I PROPOSAL GUIDELINES

The Defense SBIR/STTR Innovation Portal (DSIP) is the official portal for DoD SBIR/STTR proposal submission. Firms are required to submit proposals via DSIP; proposals submitted by any other means will be disregarded. Detailed instructions regarding registration and proposal submission via DSIP are provided in the DoD SBIR Program BAA.

Technical Volume (Volume 2)

The technical volume is not to exceed 20-pages and must follow the formatting requirements provided in the DoD SBIR Program BAA. No other information included in the other proposal volumes counts against the 20-page Proposal Technical Volume page limit. Pages provided in excess of this length will not be evaluated or considered for review. The proposal must not contain any type smaller than 10-point font size (except as legend on reduced drawings, but not tables).

Your entire proposal submission must be submitted electronically through the Defense SBIR/STTR Innovation Portal (DSIP) located at: https://www.dodsbirsttr.mil

A hardcopy is NOT required and will not be accepted by the Chemical and Biological Defense SBIR Program. Hand or electronic signature on the proposal is NOT required.

Any questions pertaining to the DoD SBIR/STTR submission system should be directed to DSIP Support: DoDSBIRSupport@reisystems.com

NEW: The maximum dollar amount for a Phase I proof-of-concept/feasibility study is $197,283.00 for a period of performance of up to six (6) months. **The CBD SBIR Program will not accept proposals exceeding $197,283.00 for the Phase I effort**. The total SBIR funding amount available for Phase II activities from a resulting Phase II contract is not to exceed $1,315,219.00.

Selection of Phase I proposals will be based upon the three (3) evaluation criteria discussed in this Program Announcement. The CBD SBIR Program reserves the right to limit awards under any topic, and only those proposals of superior scientific and technical quality in the judgment of the technical evaluation team will be funded. All SBIR contract awards, both Phase I and Phase II, are subject to availability of funding.

Companies should plan carefully for any research involving animal or human subjects, chemical agents, biological agents, etc. The brief Period of Performance available for a Phase I project precludes plans that include these elements, as all DoD requirements and necessary approvals associated with animal and/or human use must be strictly adhered to, and require considerable coordination and significant time for final protocol approvals. See "Additional Information" below for further information regarding all research that will include animal and/or human subjects.

Proposals not conforming to the terms of this Announcement, and any unsolicited proposals, will not be considered. All awards are subject to the availability of funding and successful completion of contract negotiations. The Chemical and Biological Defense Program is not responsible for any funds expended by the proposer prior to contract award.

Cost Volume (Volume 3)

The Phase I Base amount must not exceed $197,283.00. Total Base cost for Phase I must be clearly identified on the Proposal Cover Sheet (Volume 1) and in Volume 3.

Company Commercialization Report (CCR) (Volume 4)

Completion of the CCR as Volume 4 of the proposal submission in DSIP is required. Please refer to the DoD SBIR Program BAA for full details on this requirement. Information contained in the CCR will not be considered by the Chemical and Biological Defense Program during proposal evaluations.

Supporting Documents (Volume 5)

Offerors are welcome to provide Supporting Documents in this section, however these documents will not be considered by the Chemical and Biological Defense Program during proposal evaluations.

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.

Please note, under the SBIR and STTR Extension Act of 2022 and the SBA SBIR/STTR Policy Directive, proposals are required to include additional forms, to include the SBA-approved "Disclosures of Foreign Affiliations or Relationships to Foreign Countries" form. **NOTE:** Failure to submit the foreign disclosure form along with the proposal will automatically disqualify a SBC from receiving a SBIR award for that proposal.

DIRECT TO PHASE II PROPOSAL GUIDELINES

The Chemical and Biological Defense SBIR Program is not currently participating in any Direct to Phase II topics.

PHASE II PROPOSAL GUIDELINES

Phase II proposals may only be submitted by Phase I awardees.

Phase II is the demonstration of the technology that was found feasible in Phase I. Phase I awardees may submit a Phase II proposal without invitation; however, it is strongly encouraged that a Phase II proposal not be submitted until sufficient Phase I progress can be evaluated and assessed based on results of the Phase I proof-of-concept/feasibility study. Therefore, Phase II proposal may be submitted no sooner than five (5) months from date of Phase I contract award. **All Phase II proposal submissions must be submitted electronically through DSIP system: https://www.dodsbirsttr.mil**

At the DSIP website, Phase II proposals MUST be submitted to 'CBD SBIR' regardless of which DoD contracting office negotiated and awarded the Phase I contract. Additional instructions regarding the Phase II proposal submission process including submission key dates will be provided to Phase I awardees after the Phase I contract is awarded.

The Phase II proposal must include a concise summary of the Phase I project including the specific technical problem or opportunity addressed and its importance, the objective of the Phase I project, the type of research conducted, findings or results of this research, and technical feasibility of the proposed technology. Due to limited funding, the CBD SBIR program reserves the right to limit awards under any topic and only proposals considered to be of superior quality will be funded.

All proposers are required to develop and submit a commercialization plan describing feasible approaches for marketing and manufacturing the developed technology. Proposers are required to submit a budget for the entire 24-month Phase II Period of Performance. During contract negotiation, the Contracting Officer may require a Cost Volume for a base year and an option year; thus, proposers are advised to be aware of this possibility. These costs must be submitted using the Cost Volume format (accessible electronically on the DoD SBIR/STTR submission site). The total proposed amount should be indicated on the Proposal Cover Sheet as the Proposed Cost. At the Contracting Officer's discretion, Phase II projects may be evaluated for technical progress prior to the end of the base year, prior to extending funding for the option (second) year.

The CBD SBIR Program is committed to minimizing the funding gap between Phase I and Phase II activities. The CBD SBIR Program typically funds a cost plus fixed fee Phase II award at the discretion of the Contracting Officer, but may award a firm fixed price contract.

It is recommended that Phase II awardees have a Defense Contract Audit Agency (DCAA) approved accounting system. If you do not have a DCAA approved accounting system, this could delay/prevent a Phase II contract award. Visit https://www.dcaa.mil/Customers/Small-Business for more information on DCAA approved accounting systems.

DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TABA)
At this time, the CBD SBIR Program is not participating in the Technical and Business Assistance (TABA) Program.

EVALUATION AND SELECTION
All proposals will be evaluated in accordance with the evaluation criteria listed in the DoD SBIR Program BAA.

Proposing firms will be notified of selection or non-selection status for a Phase I award within 90 days of the closing date of the BAA. Notification will be provided via e-mail to the small business offeror – specifically to the Corporate Official (Business Point of Contact) and the Principal Investigator, as listed on the Cover Page (Volume I) of the proposal.

Upon written request via e-mail sent to dtra.belvoir.rd.mbx.jsto-cbd-chem-bio-defense-sbir@mail.mil, and within 30-days of non-selection, debriefing statements will be provided by the CBD SBIR Program Office. The debriefing statement will be provided only via reply e-mail to the Corporate Official and the Principal Investigator, as listed on the Cover Page (Volume I) of the proposal. Requests from the Offerer for further information after the debriefing statement will not be provided.

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 should be submitted to: Ms. Abigail L. Roots, Chemical and Biological Defense (CBD) SBIR Program Manager, Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD), dtra.belvoir.rd.mbx.jsto-cbd-chem-bio-defense-sbir@mail.mil.

ADDITIONAL INFORMATION

Fraud, Waste and Abuse

All offerors must complete the Fraud, Waste, and Abuse training (Volume 6) that is located on DSIP (https://www.dodsbirsttr.mil). Please follow guidance provided on DSIP to complete the required training prior to submitting proposals.

To Report Fraud, Waste, or Abuse, Please Contact:
DoD Inspector General (IG) Fraud, Waste & Abuse
Hotline: (800) 424-9098
hotline@dodig.mil

Additional information on Fraud, Waste and Abuse may be found in the DoD Instructions of this Announcement.

CBD SBIR Projects Requiring Animal Subjects

Refer to the DoD SBIR Program BAA for Research Involving Animal Subjects.

Companies should plan carefully for any research involving animal subjects, in addition to the use of any chemical or biological warfare agents, and use of any agents associated with "Dual Use Research of Concern (DURC)". The mandatory DoD level review of this research is typically a period of no greater than four (4) months.

Written authorization to begin animal research under the applicable protocol(s) proposed as part of the CBD SBIR program will be issued after the contract award in the form of an approval memo from the U.S. Army Medical Research and Development Command (MRDC), Animal Care and Use Review Office (ACURO), and the Research Oversight Board (ROB) of the Defense Threat Reduction Agency (DTRA), both of which provide DoD compliance oversight to the CBD SBIR program office.

The offeror is expressly forbidden from using or subcontracting for the use of animals in any manner prior to these approvals. Furthermore, modifications to approved protocols require review and approval by the ACURO prior to implementation.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award. The ACURO and DTRA ROB reviews are separate from, and in addition to, the responsible Institutional Animal Care and Use Committee (IACUC) review(s). Further information may be required if the proposal is successful.

CBD SBIR Projects Requiring Human Subjects, Human Anatomical Substances, and/or Human Data

Refer to the DoD SBIR Program BAA for Research Involving Human Subjects and Recombinant DNA Molecules.

Companies should plan carefully for any research involving human subjects, human data, and/or human biospecimens (human anatomical substances; e.g., blood, saliva, tissue), to include cadaveric specimens, hereafter referred to as "research", in addition to the use of any chemical or biological warfare agents, and use of any agents associated with "Dual Use Research of Concern (DURC)". The mandatory DoD level review of this research is typically no greater than four (4) months.

Projects under CBD SBIR awards involving the use of human subjects shall not be proposed for any Phase I Period of Performance, but may be proposed during the Phase II Period of Performance.

Written authorization to begin the research under the applicable protocol(s) proposed as part of the CBD SBIR program will be issued after the contract award in the form of an approval memo from the U.S. Army Medical Research and Development Command (MRDC), Office of Human Research Oversight (OHRO), and the Research Oversight Board (ROB) of the Defense Threat Reduction Agency (DTRA), both of which provide DoD compliance oversight to the CBD SBIR program office.

The offeror is expressly forbidden from beginning the research in any manner prior to these approvals. Furthermore, modifications to approved protocols require review and approval by the OHRO prior to implementation.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award. The OHRO and DTRA ROB reviews are separate from, and in addition to, the responsible Institutional Review Board (IRB) review(s). Further information may be required if the

proposal is successful.

CBD SBIR 23.3 Phase I Topic Index

CBD233-001 TITLE: Blister Chemical Warfare Agent Disclosure Spray System

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Biotechnology

OBJECTIVE: Develop a chemical warfare agent (CWA) disclosure spray system with the capability to visually disclose the location of blister CWA contamination on surfaces.

DESCRIPTION: Warfighters need to remove blister CWA contamination as quickly as possible and to reduce the logistical burden to warfighters for decontamination processes, perform a more targeted decontamination process through visualization and mapping of blister CWA contamination on surfaces (equipment, tactical vehicles, and weapons). There also is need to check surfaces post decontamination to confirm the area has been decontaminated to at or below detectable levels of blister CWA contamination. While there is previous research into colorimetric blister CWA mapping/detection, additional research and development is needed to improve sensitivity, ease of use, increase pot life, increase shelf-life, and incorporate these elements into a spray type application. This blister CWA disclosure spray prototype will enhance visual contamination mapping capabilities for both decontamination assurance and/or mapping to determine extent of contamination on surfaces to decrease the logistical burden to warfighters conducting decontamination operations and assure that the decontamination operations were complete, and the item is safe to use.

The objective of this project is the design and development of a system consisting of a fully formulated spray or other form factor and associated applicator capable of applying a liquid, foam or other medium on a surface to visually (human eye readable) indicate location of blister CWA contamination. The final prototype must identify less than 0.01 g/m2 levels of blister CWA and enable visual mapping of the location of blister CWA on surfaces in less than 5 minutes, post-application, in complex surface environments. The color change must remain visible for more than 10 minutes. It is anticipated a simple colorimetric reaction will not be sufficient to meet the sensitivity goal, and a description of how the sensitivity goal will be met is required in the proposal. The positive indication should be specific for blister CWA with low to no potential for false positive indication or environmental interference. Reaction schemes that produce a change in IR, colorimetric, fluorescent, or a combination of these responses for visual change/indication is acceptable. Using excitation light sources (e.g. flashlights) or other external means for visualization are acceptable. Solutions that require sampling, instrumentation, detectors or paper-based detection to measure the contamination are not acceptable. The desired system for the purposes of this SBIR is envisioned to be a small hand held sprayer with a positive response for blister agents on surfaces, with potential follow on (if successful) for larger scale applicators and scaling. Other requirements include not requiring an outside (e.g., electric, fuel, battery) power source, all required components for warfighter use (including water, if applicable) will be included in the kit (i.e. kit should be ready to use as supplied) and will weigh less than 5 pounds (including reagents), need for warfighters to mix reagents should be minimized, should be will be able to operate from 0-45 °C, one kit will cover at least 50 feet2 of surface, will not interfere with standard DoD detectors (such as, M8 paper, M9 paper, M256A1, or JCAD), will not create a hazard when exposed to standard decontaminants (such as, hot soapy water, high test hypochlorite, M100, M295, M333, or RSDL), will have an estimated shelf life of at least 5 years when stored under climate controlled conditions, and will have a pot life of at least 6 hours after components are mixed, will not cause degradation of military relevant surfaces (such as, CARC, MOPP suit fabrics, etc.) when reagent is left on these materials for 12 hours, and will not impact performance of military filters (such as N95, M61, etc.).

PHASE I: Establish and demonstrate proof of concept for blister positive response indication/reaction by developing robust reaction and verify ability of chemistry to identify the presence of simulants of blister CWA (target blister CWA is sulfur mustard, HD) in solution with sensitivity of sub-microgram per milliliter. Estimate potential for positive response visual indication and specificity for simulant/agent on

varying surface types and in varying environmental conditions. Estimate the logistical requirements of the proposed solution and how the requirements described above can be met.

PHASE II: Demonstrate system feasibility to include optimization of visual indicator, investigation of positive signal amplification, laboratory method validation, and user assessment. Verify ability of chemistry to identify the presence of HD in solution and on surfaces with sensitivity of sub-microgram per milliliter (solution) and less than 0.01 grams/m2 (surfaces). Verification of performance on surfaces will be conducted in multiple orientations of the test surface – horizontal, vertical and sloped at 45 degrees. Surfaces will be selected by the awardee and will be representative of military-relevant surfaces. Validate indication at sub-microgram/cm2 of HD. Live agent testing should be conducted as part of this phase of the work and will be conducted at an approved surety laboratory. Demonstrate how the requirements described above can be met. Provide a cost estimate per kit, primary cost drivers, and any anticipated supply chain issues. Scaling to work on sprayer and deliver 20 blister spray systems each containing the formulation, sprayer, and instructions for the warfighter.

PHASE III DUAL USE APPLICATIONS: PHASE III: Continue development and optimization of the prototype including optimizing formulation, continued laboratory testing, and applicator design. Successfully conduct user assessments and incorporate user feedback into optimized system design. Investigate and report requirements for formulation and applicator scaled manufacture.

PHASE III DUAL USE APPLICATIONS: This technology will be useful to civilian first responders for localizing contamination during civilian incidents.

REFERENCES:

1. Hurst, C.G. et al. Medical Aspects of Chemical Warfare - Vesicants. 2008. https://medcoe.army.mil/borden-tb-med-aspects-chem-warfare.;
2. Feng, W. et. al. Bifunctional Fluorescent Probes for the Detection of Mustard Gas and Phosgene. 2023. Anal. Chem. 2023, 95, 1755−1763. https://doi.org/10.1021/acs.analchem.2c05178.;
3. Chemical Agent Disclosure Spray, Agentase C2. https://www.flir.com/products/agentase-c2/?vertical=chem+bio&segment=detection.

KEYWORDS: vesicant; blister; HD; disclosure; decontamination; chemical warfare; hazardous materials

CBD233-002 TITLE: Polynomial-Curved Bespoke Prescription Lens for Respiratory Protection

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Biotechnology

OBJECTIVE: Develop a respirator lens that can provide visual correction on a polynomial curved surface (e.g. M50 respirator lens) with varied prescription strength as needed at either eye.

DESCRIPTION: Most single-lens full facepiece air-purifying respirators (APR) are unable to provide vision correction via the primary lens of the respirator due to its complex geometry and the requirement of providing different prescription strengths for each of the wearer's eyes. Instead, vision correction is traditionally provided through a vision correction assembly that is hung inside the respirator, close to the user's eyes. The vision correction assembly available for the M50 can accommodate lenses ranging from -10.00 to +8.00 Diopters in power. While the inserts offer vision correction functionality to the respirator, the accommodation of inserts increases eye relief and thus negatively impacts compatibility with external sighting systems.

This effort seeks to develop a prescription lens solution that can eliminate the need for an internal vision correction assembly building the visual correction directly into the primary lens of the respirator. These lenses would need to be made-to-order with specified diopter strengths available on either half of the respirator lens in order to accommodate conditions such as anisometropia which requires different prescriptions in each eye. The lens would also need to support a range of prescription strengths ranging from -10.00 to +8.00 Diopters and maintain the current shape and size of the primary lens of an M50. Since the primary lens of a full facepiece respirator is a part of the critical sealing surface, this lens will also need to have threat agent permeation resistance characteristics required by the NIOSH Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece APR. Durability and optical requirements shall compare favorably to existing military respirator materials and shall comply with the requirements set forth in MIL-STD 810G.

PHASE I: Investigate lens solutions that demonstrate two different prescription strengths on a single flat surface and provide eight (8) flat circular coupons (4" diameter, 0.05" thickness) that are resistant to chemical warfare agent materials as required by the NIOSH Statements of Standard for CBRN Full Facepiece APR to be subjected to government testing. Additionally provide two (2) coupons that demonstrate two different prescription strengths on a polynomial-curved surface, constructed using the same materials as the flat coupons.

PHASE II: Refine the material to develop a full respirator lens of size and shape equivalent to the primary lens of the M50 APR. This lens shall be resistant to chemical warfare agent materials, capable of providing a different prescription strength on each half and demonstrate equivalent optical properties to the primary lens of the M50.

PHASE III DUAL USE APPLICATIONS: PHASE III: Further improve and refine the lens material, demonstrating the ability to be integrated into a full facepiece APR. Additionally, demonstrate that the technology is durable and suitable for military combat applications.
PHASE III Dual Use Applications: Potential alternative applications include industrial, pharmaceutical, healthcare, international, and other commercial respiratory protection uses.

REFERENCES:

1. https://www.avon-protection.com/downloads/product%20datasheets/accessories/outserts/Avon-Protection_Vision-Correction-Assembly_Data-Sheet_EN.pdf ;
2. https://www.atec.army.mil/publications/Mil-Std-810G/MIL-STD-810G.pdf

KEYWORDS: individual protection; respiratory protective mask; protective eyewear; lens; prescription

CBD233-003 TITLE: Real Time Physiological Status Monitor for MicroClimate Control

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Biotechnology

OBJECTIVE: The Defense Threat Reduction Agency (DTRA) seeks to develop a ruggedized non-invasive real time physiological status monitor (RT-PSM) that can control an Army microclimate cooling system to mitigate thermal stress injuries, increasing mission performance and system efficiency.

DESCRIPTION: Warfighters operating in non-permissive environments in Level 1/A Personal Protective Equipment (PPE) are vulnerable to heat injuries. Even at low activity levels, mission performance and user health can be severely compromised. The requirements to wear PPE further exacerbates a Warfighter's thermal strain, diminishing the rejection of metabolic heat to the ambient environment. As a result, body heat is stored, core temperature rises, and physical and cognitive function can be significantly degraded. Depending on the environmental conditions, activity level, thermal characteristics of the protective clothing, duration of exposure, and individual tolerance to the heat, personnel may experience symptoms ranging from physical discomfort to more severe life-threatening conditions.
To mitigate these risks, current cooling solutions are being implemented under PPE utilizing a cooling vest and portable vapor compression system. This provides a steady state heat flux, which can be effective for shorter duration missions, but proves detrimental over longer missions due to inefficiencies in cooling the user. This is due to vasoconstriction within the skin limiting the effective heat transfer to reduce elevated core body temperatures. Utilizing heat stress biomarkers measured by a RT-PSM, a microclimate cooling system can increase cooling efficiency and time on target whilst minimizing power consumption and cognitive loading [1].

Current RT-PSMs utilize a combination of skin temperature, core temperature (typically estimated), heart rate, and skin heat flux to estimate the thermal strain [2]. When the data is fused, a general physiological strain index (PSI) can be calculated. Utilizing a generalizable modified PSI for the cooling system may not be satisfactory as individual thermal strains are so variable [3]. An innovative solution is required to ensure that reliable, valid metrics are being measured and tailored to each individual's needs based on their respective thermophysiological responses to the cooling garment.

In summary, the proposed sensor system should provide insight to the real time thermal strain of the end user using a novel combination of sensors. These sensors should then feed into an accessible algorithm that may be used for optimizing the control of a microclimate cooling system to ensure users can effectively perform their mission set while managing thermal strain.

PHASE I: The goal of the Phase I effort is to design and develop a RT-PSM sensor suite, algorithm, and Data Acquisition module by which thermal strain can be measured accurately. The proof of concept should demonstrate reliable signal sampling and sensor fusion in an output that is relevant for a liquid cooled vapor compression microclimate system. This includes investigation into relevant form factors by which the sensors can be implemented.

PHASE II: Develop integrated sensor suite and algorithm to perform cooling functions with simulated micro climate system optimizing for human performance. The proof of function system should be validated in a relevant environment. This validation should include the ability to modify algorithm outputs to tailor cooling system parameters for individual user optimization. By the end of Phase II the sensor suite and algorithm should be capable of providing relevant heat stress indicators and controlling a microclimate cooling system according to those metrics to reduce heat stress injury risk.

PHASE III DUAL USE APPLICATIONS: PHASE III: A Phase III effort would focus on ruggedization, reliability, and further algorithm optimization of the sensor solution for both Army and commercial

markets. Algorithms would be refined for reliability across larger subject populations and validated in simulated operational environments in conjunction with Army testing events.

PHASE III: DUAL USE APPLICATIONS: Multiple industries must contend with heat stress related injuries, such as construction, agriculture, and first responders. Coupling a reliable RT-PSM heat stress indicator with microclimate cooling system would increase safety, productivity, and mission duration.

REFERENCES:

1. Xu, Xiaojiang, et al. Simulation of a biofeedback microclimate cooling system using a human thermoregulation model. US Army Research Institute of Environmental Medicine Natick United States, 2017. ;
2. Lee, Jason KW, et al. "Biomarkers for warfighter safety and performance in hot and cold environments." Journal of science and medicine in sport (2022). ;
3. Buller, Mark J., Alexander P. Welles, and Karl E. Friedl. "Wearable physiological monitoring for human thermal-work strain optimization." Journal of applied physiology 124.2 (2018): 432-441.

KEYWORDS: Microclimate; PPE; Core Temperature; skin temperature; monitoring; cooling; control systems; algorithm

CBD233-004 TITLE: Breathable, Non-Fluorinated Chemical Barrier Materials

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Biotechnology

OBJECTIVE: Develop a non-fluorinated chemical protective material that meets the Class 3 requirements set forth in National Fire Protection Association (NFPA) 1994 standard.

DESCRIPTION: The Government requires ensembles that will meet the requirements for Class 3 protection as defined in NFPA 1994, Standard for Protective Ensembles for Hazardous Materials for First Responders to Hazardous Materials Emergencies and CBRN Incidents, 2018. Ensemble elements described in this standard include protective garments, protective gloves, protective hoods, and protective footwear with descriptions of all the properties and test methods required to meet Class 3 requirements. Of particular interest to this topic is the development of garment materials which are resistant to the chemical warfare agents (CWAs) and toxic chemicals listed in the standard. The threshold level of permeation resistance for Class 3 garment materials should be the cumulative permeation mass in one hour of less than 4.0 micrograms per square centimeter (µg/cm2) for distilled mustard, less than 1.25 µg/cm2 for Soman, and less than 6 µg/cm2 for toxic industrial chemicals when challenged with 10 grams per square meter (g/m2) of liquid challenge or with 40 ppm of vapor challenge.

Also of particular interest to this topic is the breathability of garment materials, as indicated by thermal and water vapor resistance measurements, with evaporative heat transfer (total heat loss) not less than 200 watts per square meter (W/m2) and evaporative resistance not greater than 30 pascal square meter per watt (Pa m2/W).

In addition to the requirements set forth in NFPA 1994, non-fluorinated ensemble materials are required. Environmental concerns with perfluoroalkyl and polyfluoroalkyl substances (PFAS) is leading to the discontinuation of numerous commercial products that have been utilized in chemical protective systems including ensemble components, coatings, and finishes. Non-fluorinated material alternatives are sought with this topic.

PHASE I: Demonstrate a fluorine-free garment material candidate that shows the NFPA 1994 required chemical resistance for one CWA simulant and two toxic industrial chemical liquids. Breathability must also be demonstrated. NFPA 1994 specified testing (ASTM F1868 and ISO 11092) may require more material than possible in the Phase I effort. Alternative methods may be proposed to provide acceptable estimates for breathability. Other physical properties are specified in NFPA 1994 (viral penetration, burst strength, puncture resistance, low temperature performance) and measured or addressed as possible in the Phase I effort to strengthen the feasibility for a Phase II effort. Chemical resistance and breathability are the key Phase I topic goals. At the end of the Phase I effort the candidate material should be able to be produced at a 6 inch by 6 inch swatch level and swatches made available for independent testing by the government. A preliminary scale-up method and a cost assessment should also be provided.

PHASE II: Optimize and scale candidate garment material to be able to produce enough material for prototype fabrication. Show chemical resistance to the CWAs and liquid and vapor challenges in NFPA 1994. Show breathability through the NFPA 1994 specified testing. Initiate garment fabrication and carry out all physical property testing (seam strength and closure strength in addition to those listed in Phase I). The Phase II effort should show a candidate garment material that meets the NFPA 1994 requirements and ready for scaling to production quantities. At the conclusion of Phase II, a sample of at least 12 inches wide and 5 yards in length of the optimized garment material should be delivered. A cost assessment for full scale production should also be provided.

PHASE III DUAL USE APPLICATIONS: PHASE III:

The successful Phase II material will be scaled to continuous production at full width (>40 inches) and integrated into Class 3 protective ensembles.

PHASE III DUAL USE APPLICATIONS:
In addition to military applications, Class 3 ensembles have a broad range of applications for the first responder for hazardous material and anti-terrorism situations.

REFERENCES:

1. NFPA 1994, “Standard for Protective Ensembles for Hazardous Materials for First Responders to Hazardous Materials Emergencies and CBRN Incidents”, 2018 ;
2. ASTM F1868, “Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate” ;
3. ISO 11092, “Textiles - Physiological effects - Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)”

KEYWORDS: chemical protective garment; permeation; breathable; chemical resistance; water vapor permeable; fluorine-free

CBD233-005 TITLE: Development of an early-warning biosensor based on the detection of helical structures in biomolecules

OUSD (R&E) CRITICAL TECHNOLOGY AREA(S): Biotechnology

OBJECTIVE: Develop sensing capabilities for the detection of airborne biological aerosols. The instrumentation must be capable of rapidly and continuously identifying bioaerosol particles based on the detection of helical structures present in biomolecules and discerning bioaerosols from the larger inorganic and organic background matrix via point detection at the location of the instrument in real time. The final device should be deployable on an unmanned platform such as unmanned aerial vehicle (UAVs) or unmanned ground vehicle (UGVs).

DESCRIPTION: A robust chemical-biological defense requires a fast, reliable, specific, and inexpensive biological aerosol threat detection system to prevent deadly contamination of soldiers and the general population. This requirement is critical for urban and/or battlespace settings where the atmosphere contains inorganic, organic, and biological particles with complex physico-chemical characteristics across orders of magnitude in size (0.1□100 microns [□m]). The detection of possible biological threat materials is limited by their small concentration within this ambient matrix containing materials of non-interest and interfering compounds. While sensor technology has improved over the last 20 years, threat detection remains a challenge in operational environments at mission-speed due to the complex and dynamic nature of the surrounding environmental media.

A fully operational biothreat detection system comprises trigger, rapid confirmer/identifier, sample collector, and final confirmer/identifier. Early triggers were mainly based on the detection of laser induced fluorescence (LIF) (e.g., BAWS, WIBS, UVAPS) and have become the industry standard, as they provide some level of correlation to the chemical nature of the bioaerosols, while upholding the ability of continuously operating at high throughput. However, despite decades of significant improvements, LIF-based early-warning systems exhibit shortfalls with respect to accuracy due to the existence of similar chromophores in both threat aerosols and innocuous background particles [1,2]. Furthermore, it has been shown that the fluorescence signal of a bioaerosol can be severely altered by changes in environmental conditions [3].

A recent surge in highly infectious diseases, as highlighted by the COVID-19 pandemic and respiratory syncytial virus infection (RSV), revived interest in the early detection and identification of health-threatening bioaerosols and various strategies including optical methods, such as elastic light scattering (ELS) were suggested as potential solutions. Widely used in atmospheric and planetary sciences, ELS generates the physical information useful for a particles' classification (e.g., size, morphology, refractive index) but is unsuitable for unambiguous chemical identification. However, some polarization containing elements of the scattering Mueller Matrix (S12, S34 and S14) enable retrieval of molecular conformation for complex biopolymers, and in limited instances circular intensity differential scattering (CIDS) was used to achieve characterization based on molecular or morphological chirality, without using fluorescent labels [4]. Furthering these capabilities, a recent study by Pan et al. demonstrated that CIDS measurements performed on a single airborne aerosol can distinguish particles with a helical structure (i.e., DNA and RNA) from background particles [5]. An ingenious design used in this work highlights opportunities for the development of a deployable compact device streamlining traditional bulky components, such as polarization modulator, lock-in amplifier, and rotation goniometer.

Leveraging these developments, detecting chirality in bioaerosols has the potential to generate an autonomous early-warning capability that could augment the Department of Defense's chem-bio defense effort by distinguishing biological threats from background particles. The sensing capability should overlap with the inhalable particle size and rely on contactless optical methods to sense biological

chirality. The system should have a continuous real-time monitoring (tens of thousands particles/sec) capability and, at a minimum, should be able to distinguish biological particles from inorganic or organic background.

PHASE I: Phase I entails the design of a concept for a rapid, chirality detecting early-warning biosensor. The study should lead to a laboratory demonstration that outlines major components of the system. The Phase I project should focus on the discrimination of bioaerosols from non-bioaerosols in the 0.1−100 μm particle size range, with accuracy >80%. The accompanying architecture required to integrate fast data analysis and machine learning for particle differentiation should also be included. The Phase I should also define a clear path forward for designing a prototype with low size, weight, and power (SWaP) to enable deployment on unmanned vehicles. Biological threats of all classes are of interest for sensing and identification. Examples include biological spores, such as anthrax or simulants thereof (that can be accessed by the small business offeror), and allergens like pollens.

The Phase I final report must explain in detail the detection method selected, software concepts, hardware requirements, and identify potential use cases and limitations.

PHASE II: Mature the concept into a pre-production portable instrument prototype integrating the capabilities outlined in the concept developed during Phase I.

The key deliverable of Phase II will be the demonstration of the system in a relevant environmental setting where the prototype is capable of sampling upwards of 10,000 particles per second and detecting biological particles to within 90% accuracy. Evaluation of the machine-learning particle-detection algorithms will be extended to multiple threat vectors. The system will be benchmarked against standard techniques of aerosol identification. An initial analysis of the commercial applications of the system will be conducted, focusing on the baseline cost of the system and the market space addressed by the technology development.

PHASE III DUAL USE APPLICATIONS: PHASE III: The small business will pursue commercialization of the technologies developed in Phase II for potential government and commercial applications. Government applications include rapid early-warning detection of biological threat aerosols.

PHASE III DUAL USE APPLICATIONS: The proposed method has the potential to be integrated into ongoing Department of Defense programs including the Nuclear, Biological and Chemical Reconnaissance Vehicle Sensor Suite Upgrade (NBCRV SSU) program and the Joint Biological Tactical Detection System (JBTDS) program. The system could similarly be installed on UAVs and UGVs used by other agencies responsible for early-warning biological threat surveillance such as the Department of Homeland Security (DHS). The successful product can also fulfill air quality environmental applications such as assessing pollutants, or other airborne pathogens driving highly infectious diseases for commercial applications and for use by government agencies including the U.S. Environmental Protection Agency (EPA).

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KEYWORDS: Biological Threat Detection; sensors; aerosols; environmental sampling; environmental surveillance