DOE-ID NEPA CX DETERMINATION
Idaho National Laboratory

CX Posting No.: DOE-ID-INL-20-015

SECTION A. Project Title: Materials and Manufacturing to Address Supply Chain Issues Related to COVID-19

SECTION B. Project Description and Purpose:

Under the proposed action, Idaho National Laboratory (INL) will collaborate with 15 national laboratories[1] and local hospitals (Idaho Falls Community Hospital/Mountain View Hospital and Eastern Idaho Regional Medical Center) to develop, demonstrate, and make operational key technologies needed to address medical supply chain issues with Corona Virus Disease (COVID)-19. The task force, taking guidance from both public and private shareholders (government, health care providers), has identified three health care supply chain challenges and have assigned teams to rapidly address the issues. These issues include surgical masks and face shields, ventilator systems and consumables (swabs, test kits). To respond to needs, INL can rapidly design and manufacture prototype parts and verify its performance. Once the protypes are validated (phase 1) efforts will shift to production considerations (tooling, material selection, supply chain engagement).

The proposal has three phases described below:

Phase 1: Rapid Prototype Development
In 3 weeks, the team will design, manufacture and evaluate prototype masks, ventilator parts and systems, reverse engineer and prototype test kits and difficult to resource consumable products such as swabs. Each of these areas consists of subject matter experts coordinating with public health care professionals verifying proposed solutions are scalable and achieve the target requirements. INL will share data, designs, requirements and results.

Phase 2: Testing, Evaluation and Transition to Production
As the project transitions from phase 1 to phase 2, efforts will transition from rapid prototyping to design for manufacturing considerations for industrial production. For each of the task areas, material considerations and manufacturing requirements such as tooling will be designed, tested and delivered to industrial manufacturing partners. Low production runs will be conducted and tested for performance.

Phase 3: National Lab Manufacturing Network
Phase 3 efforts will focus on establishing a national network of manufacturing research capabilities, connecting INL resources to enable rapid response to future manufacturing supply chain crisis.

Regulatory Engagement
Each of the activities include engagement with public health care providers who understand the needs and public regulatory providers to understand the risks. Given the dynamics of the outbreak, and the changing landscape of what is required and what is needed, INL will operate to verify optimal solutions for protecting public health. In some task areas, INL will integrate FDA approved technologies, e.g. in ventilators, to verify adherence to regulations.

Task 1: Masks/Shields
Efforts will focus on the design, rapid prototyping and testing of reusable and sterilizable N95 masks and face shields. The final design will be publicly released in two forms. One will be for the general public to use if they wish to help with low production. INL will publish all computer aided design data, manufacturing specifications and bill of materials. The second design will be based on commercial manufacturing processes (injection molding, vacuum forming) equipment for high production rates. The team will design the tooling, manufacture using either additive or conventional manufacturing and distribute to manufacturers for mass production. The program will leverage capabilities to identify medical providers in their area and injection mold and vacuum forming companies. INL will help manage the manufacturing and distribution.

Task 2: Ventilators, Air Purifiers and Small Part Production and Repair
There are anticipated to be three strategies to address the need for ventilators and respirators. The first strategy is to help close national gaps in the manufacturing supply chain. There are considerable manufacturing capabilities at INL that can help with surge capabilities in small, low volume parts or tooling. The second strategy is to enable modifications to current systems such as adapting CPAP systems to be respirators or enabling a single respirator to service multiple patients. Finally, there is considerable design and systems integration capabilities at INL that can help enable rapid, low cost solutions for new ventilation systems (e.g. IPV) in collaboration with small businesses and regional hospitals. Efforts during the first phase will focus on having task groups addressing each of these areas with rapid prototyping and testing. Second phase efforts will start to evaluate production needs, strategic partnerships and production opportunities. Air Purification units will also be explored to reduce airborne pathogens in critical infrastructure that may be respired from a ventilated patient, or perspired from patients and infected personnel using Pulsed Electric Fields (May induce RF fields and emissions of ozone).

Task 3: Consumables and Plastic Extraction Kits PCR assay
As clinical laboratories around the world have begun testing for SARS-CoV-2, the virus that causes COVID-19 disease, the country has encountered a new crisis: a shortage of the consumables such as test kits and swabs required to obtain the necessary sample. The swabs are called nasopharyngeal swabs, or NP swabs. These are by majority manufactured in China and Italy, presenting challenges to the existing supply chain. INL's objective is to utilize 3D printing

[1] Ames Laboratory, Argonne National Laboratory, Idaho National Laboratory, Los Alamos National Laboratory, Lawrence Berkley National Laboratory, Lawrence Livermore National Laboratory, National Energy Technology Laboratory, National Renewable Energy Laboratory, Oak Ridge National Laboratory, Pacific Northwest National Laboratory, Princeton Plasma Physics Laboratory, SLAC National Accelerator Laboratory, Sandia National Laboratory, Savanah River National Laboratory, Kanas City National Security Campus

along with scalable manufacturing to rapidly create swabs and swab replacements. Efforts will focus on design, simulation, rapid prototyping and testing of swabs that meet requirements (e.g., mechanical stiffness and flexibility, achieves adequate uptake of nasal fluid secretion, materials do not inhibit PCR, swab serves its purpose with actual viral testing, etc.). There are two necessary kits for COVID-19 diagnosis, one is to isolate viral RNA from the clinical samples and the other is to carry out quantitative PCR (qPCR) to detect the presence of SARS-CoV-2 RNA. RNA extraction kits and accessories that enable effective deployment (swabs, etc.) have quickly become the limiting factor for qPCR testing of SARS-CoV-2. The shortage of extraction kits for RT-PCR testing impedes the efforts to fight COVID-19. Efforts will focus on the design, prototyping, characterization and validation which will be followed by design and manufacturability for mass production. The project will engage with health care professionals to help in the co-design the manufacturing of the plastic extraction kits.

The advanced design and manufacturing initiative at INL focuses on research and development (R&D) on advanced manufacturing solutions for materials used in demanding or harsh environments. INL's advanced manufacturing effort encompasses advanced computer science, visualization and data, applied materials science and engineering, biological and bioprocess engineering, chemical and molecular science, chemical engineering, condensed matter physics and materials science, cyber and information science, large-scale facilities/R&D facilities/advanced instrumentation, mechanical engineering and design, and nuclear engineering.

The proposed action uses facilities at the Research and Education Campus (REC) to perform:

- process discovery and development
- R&D design
- mockup
- fabrication
- testing
- analysis
- intensification and scale-up studies.

To support advanced manufacturing techniques, INL will utilize computer-aided drawing, engineering and manufacturing, high performance computing, additive-manufacturing processes, novel fabrication and joining processes, intelligent production systems, control systems to monitor processes and advanced platform technologies to manufacture materials.

SECTION C. Environmental Aspects or Potential Sources of Impact:

Air Emissions

Project activities have the potential to release hazardous and chemical contaminants into the air. Regulatory requirements will be determined prior to commencing modification of facilities using the APAD process.

Project activities have the potential to release refrigerants, ozone, and greenhouse gases.

Generating and Managing Waste

Industrial waste in the form of plastic, packaging material, Resource Conservation and Recovery Act (RCRA) empty chemical containers, etc. will be generated during the project.

Hazardous waste generation has the potential to be generated from adhesive waste, cleaning solvents, and spill material.

All waste generated during the project will be characterized, stored, and disposed at the direction of Waste Generator Services (WGS).

Releasing Contaminants

Chemicals will be used and will be submitted to chemical inventory lists with associated Safety Data Sheets (SDSs) for approval prior to use. The Facility Chemical Coordinator will enter these chemicals into the INL Chemical Management Database. All chemicals will be managed in accordance with laboratory procedures. When dispositioning surplus chemicals, project personnel must contact the facility Chemical Coordinator for disposition instructions.

Although not anticipated, there is a potential for spills when using chemicals. In the event of a spill, notify facility environmental staff. If environmental staff cannot be contacted, report the release to the Spill Notification Team (208-241-6400). Clean up the spill and turn over spill cleanup materials to WGS.

Using, Reusing, and Conserving Natural Resources

All applicable waste would be diverted from disposal in the landfill when possible. Program personnel would use every opportunity to recycle, reuse, and recover materials and divert waste from the landfill when possible. The program would practice sustainable acquisition, as appropriate and

practicable, by procuring construction materials that are energy efficient, water efficient, are bio-based in content, environmentally preferable, non-ozone depleting, have recycled content, and are non-toxic or less-toxic alternatives.

SECTION D. Determine Recommended Level of Environmental Review, Identify Reference(s), and State Justification: Identify the applicable categorical exclusion from 10 Code of Federal Regulation (CFR) 1021, Appendix B, give the appropriate justification, and the approval date.

For Categorical Exclusions (CXs), the proposed action must not: (1) threaten a violation of applicable statutory, regulatory, or permit requirements for environmental, safety, and health, or similar requirements of Department of Energy (DOE) or Executive Orders; (2) require siting and construction or major expansion of waste storage, disposal, recovery, or treatment or facilities; (3) disturb hazardous substances, pollutants, contaminants, or Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)-excluded petroleum and natural gas products that pre-exist in the environment such that there would be uncontrolled or unpermitted releases; (4) have the potential to cause significant impacts on environmentally sensitive resources (see 10 CFR 1021). In addition, no extraordinary circumstances related to the proposal exist that would affect the significance of the action. In addition, the action is not "connected" to other action actions (40 CFR 1508.25(a)(1) and is not related to other actions with individually insignificant but cumulatively significant impacts (40 CFR 1608.27(b)(7)).

References: 10 CFR 1021, Appendix B to subpart D, items B3.6, "Small-scale research and development, laboratory operations, and pilot projects" and B2.4, "Equipment qualification."

Justification: The proposed R&D activities are consistent with CX B3.6 "Siting, construction, modification, operation, and decommissioning of facilities for small-scale research and development projects; conventional laboratory operations (such as preparation of chemical standards and sample analysis); small-scale pilot projects (generally less than 2 years) frequently conducted to verify a concept before demonstration actions, provided that construction or modification would be within or contiguous to a previously disturbed area (where active utilities and currently used roads are readily accessible). Not included in this category are demonstration actions, meaning actions that are undertaken at a scale to show whether a technology would be viable on a larger scale and suitable for commercial deployment;" and

B2.4 "Activities undertaken to (1) qualify equipment for use or improve systems reliability or (2) augment information on safety-related system components. These activities include, but are not limited to, transportation container qualification testing, crane and lift-gear certification or recertification testing, high efficiency particulate air filter testing and certification, stress tests (such as ''burn-in'' testing of electrical components and leak testing), and calibration of sensors or diagnostic equipment."

Is the project funded by the American Recovery and Reinvestment Act of 2009 (Recovery Act) ☐ Yes ☒ No

Approved by Jason Sturm, DOE-ID NEPA Compliance Officer on: 03/30/2020