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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

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National Cybersecurity Center of Excellence (NCCoE) Wireless Medical Infusion Pumps

use case for the health care sector

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites

organizations to provide products and technical expertise to support and demonstrate

security platforms for the Wireless Medical Infusion Pumps use case for the health care

sector. This notice is the initial step for the National Cybersecurity Center of Excellence

(NCCoE) in collaborating with technology companies to address cybersecurity

challenges identified under the Health Care Sector program. Participation in the use case is open to all interested organizations.

DATES: Interested parties must contact NIST to request a letter of interest template to be completed and submitted to NIST. Letters of interest will be accepted on a first come, first served basis. Collaborative activities will commence as soon as enough completed and signed letters of interest have been returned to address all the necessary components and capabilities, but no earlier than [PLEASE INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. When the use case has been completed, NIST will post a notice on the NCCoE Health Care Sector program website at https://nccoe.nist.gov/projects/use_cases/health_it announcing the completion of the use case and informing the public that it will no longer accept letters of interest for this use case.

ADDRESSES: The NCCoE is located at 9700 Great Seneca Highway, Rockville, MD 20850. Letters of interest must be submitted to HIT_NCCoE@nist.gov; or via hardcopy to National Institute of Standards and Technology, NCCoE; 100 Bureau Drive, MS 2002, Gaithersburg, MD, 20899. Organizations whose letters of interest are accepted in accordance with the process set forth in the SUPPLEMENTARY INFORMATION section of this notice will be asked to sign a Cooperative Research and Development Agreement (CRADA) with NIST.   A CRADA template can be found at: https://nccoe.nist.gov/library/nccoe-consortium-crada-example.

FOR FURTHER INFORMATION CONTACT: Gavin O'Brien via email at

HIT_NCCoE@nist.gov; by telephone 240-314-6815; or by mail to National Institute of

Standards and Technology, NCCoE; 100 Bureau Drive, MS 2002, Gaithersburg, MD,

20899. Additional details about the NCCoE Health Care Sector program are available at

https://nccoe.nist.gov/projects/use_cases/health_it.

SUPPLEMENTARY INFORMATION:

Background: The NCCoE, part of NIST, is a public-private collaboration for

accelerating the widespread adoption of integrated cybersecurity tools and technologies.

The NCCoE brings together experts from industry, government, and academia under one

roof to develop practical, interoperable cybersecurity approaches that address the real-

world needs of complex Information Technology (IT) systems. By accelerating

dissemination and use of these integrated tools and technologies for protecting IT assets,

the NCCoE will enhance trust in U.S. IT communications, data, and storage systems;

reduce risk for companies and individuals using IT systems; and encourage development

of innovative, job-creating cybersecurity products and services.

Process: NIST is soliciting responses from all sources of relevant security capabilities

(see below) to enter into a Cooperative Research and Development Agreement (CRADA)

to provide products and technical expertise to support and demonstrate security platforms

for the Wireless Medical Infusion Pumps use case for the health care sector. The full use

case can be viewed at: https://nccoe.nist.gov/projects/use_cases/health_it.

Interested parties should contact NIST using the information provided in the FOR FURTHER INFORMATION CONTACT section of this notice. NIST will then provide each interested party with a letter of interest template, which the party must complete, certify that it is accurate, and submit to NIST. NIST will contact interested parties if there are questions regarding the responsiveness of the letters of interest to the use case objective or requirements identified below. NIST will select participants who have submitted complete letters of interest on a first come, first served basis within each category of product components or capabilities listed below up to the number of participants in each category necessary to carry out this use case. However, there may be continuing opportunity to participate even after initial activity commences. Selected participants will be required to enter into a consortium CRADA with NIST (for reference, see ADDRESSES section above). NIST published a notice in the Federal Register on October 19, 2012 (77 FR 64314) inviting U.S. companies to enter into National Cybersecurity Excellence Partnerships (NCEPs) in furtherance of the NCCoE. For this demonstration project, NCEP partners will not be given priority for participation.

Use Case Objective: In the past, medical devices were standalone instruments that interacted only with the patient. Today, medical devices have operating systems and communication hardware that allow them to connect to networks and other devices. While this technology has created more powerful tools and improved health care, it has led to additional risks in safety and security.

The goal of this use case is to help health care providers secure their medical devices on an enterprise network, with a specific focus on wireless infusion pumps.[1] This use case begins the process to identify the actors interacting with infusion pumps, define the interactions between the actors and the system, perform a risk assessment, identify applicable mitigating security technologies, and provide an example implementation. Clinicians and patients rely on infusion pumps for safe and accurate administration of fluids and medications. However, the FDA has identified problems that can compromise the safe use of external infusion pumps. These issues can lead to over or under-infusion, missed treatments, or delayed therapy.

The publication of the use case is merely the beginning of a process that will identify research participants and components of a laboratory environment to identify, evaluate and test relevant security tools and controls. The approach may include: risk assessment and analysis, logical design, build development, test & evaluation and security control mapping. The output of the process will be the publication of a multi-part Practice Guide to assist the community in evaluating the security environment surrounding their infusion pumps deployed in a clinical setting.

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[1] For purposes of this notice, NIST is adopting the definition of external infusion pumps provided on the Food and Drug Administration (FDA) Protecting and Promoting Your Health website as:
"Medical devices that deliver fluids, including nutrients and medications such as antibiotics, chemotherapy drugs, and pain relievers, into a patient's body in controlled amounts. Many types of pumps, including large volume, patient-controlled analgesia, elastomeric, syringe, enteral, and insulin pumps, are used worldwide in health care facilities such as hospitals, and in the home."
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesand Supplies/InfusionPumps/

A detailed description of the Wireless Medical Infusion Pumps use case is available at https://nccoe.nist.gov/projects/use_cases/health_it

Requirements:

Each responding organization's letter of interest should identify which security platform component(s) or capability(ies) it is offering. Letters of interest should not include company proprietary information, and all components and capabilities must be commercially available. Components are listed in section two of the Wireless Medical Infusion Pumps use case (for reference, please see the link in the PROCESS section above) and include, but are not limited to:

1. Wireless infusion pump
2. Pump server
3. Network
4. Alarm manager
5. Electronic medication administration record (eMAR)
6. Point of care medication system
7. In hospital pharmacy system
8. Computerized physician order entry (CPOE)
9. IT security system
10. Network security system
11. Credentialing/credentialing server
12. Asset management and monitoring systems

Each responding organization's letter of interest should identify how their products address one or more of the following desired solution characteristics in the Security Control Map section of the Wireless Medical Infusion Pumps use case (for reference, please see the link in the PROCESS section above):

1. Automatic logoff
2. Audit controls
3. Authorization
4. Configuration of security features
5. Cybersecurity product upgrades
6. Data backup and disaster recovery
7. Emergency access
8. Health data de-identification
9. Health data integrity and authenticity
10. Malware detection/protection
11. Node authentication
12. Person authentication
13. Physical locks and devices
14. Security guides
15. System and application hardening
16. Third-party components in product lifecycle roadmaps
17. Health data storage confidentiality
18. Transmission confidentiality
19. Transmission integrity

Responding organizations need to understand and, in their letters of interest, commit to provide:

1. Access for all participants' project teams to component interfaces and the organization's experts necessary to make functional connections among security platform components

2. Support for development and demonstration of the Wireless Medical Infusion Pump capability in NCCoE facilities which will be conducted in a manner consistent with Federal requirements (e.g., FIPS 200, FIPS 201, SP 800-53, and SP 800-63)

Additional details about the Wireless Medical Infusion Pumps use case for the Health care sector are available at https://nccoe.nist.gov/projects/use_cases/health_it.

NIST cannot guarantee that all of the products proposed by respondents will be used in the demonstration. Each prospective participant will be expected to work collaboratively with NIST staff and other project participants under the terms of the consortium CRADA in the development of the Wireless Medical Infusion Pump capability. Prospective participants' contribution to the collaborative effort will include assistance in establishing the necessary interface functionality, connection and set-up capabilities and procedures, demonstration harnesses, environmental and safety conditions for use, integrated platform user instructions, and demonstration plans and scripts necessary to demonstrate the desired capabilities. Each participant will train NIST personnel, as necessary, to operate its product in capability demonstrations to the health care community. Following successful demonstrations, NIST will publish a description of the security platform and its performance characteristics sufficient to permit other organizations to develop and deploy security platforms that meet the security objectives of the Wireless Medical Infusion Pumps use case. These descriptions will be public information.

Under the terms of the consortium CRADA, NIST will support development of interfaces among participants' products by providing IT infrastructure, laboratory facilities, office facilities, collaboration facilities, and staff support to component composition, security platform documentation, and demonstration activities.

The dates of the demonstration of the Wireless Medical Infusion Pump capability will be announced on the NCCoE Web site at least two weeks in advance at https://nccoe.nist.gov/. The expected outcome of the demonstration is to improve

wireless medical infusion pumps across an entire health care sector enterprise.

Participating organizations will gain from the knowledge that their products are

interoperable with other participants' offerings.

For additional information on the NCCoE governance, business processes, and NCCoE

operational structure, visit the NCCoE Web site https://nccoe.nist.gov/.

Richard Cavanagh
Acting Associate Director for Laboratory Programs
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