treatment in accordance with these standards as a basis for CSAT certification. These standards address patient admission requirements, medical and counseling services, drug testing, and other requirements. The final rule also established an accreditation requirement. Each OTP is required to obtain and maintain accreditation from an accreditation organization approved by SAMHSA under 42 CFR part 8. Accreditation organizations that provide OTP accreditation under the final rule are required to apply for and obtain SAMHSA approval. Under 42 CFR 8.3(a)(3), each accreditation organization must develop a set of accreditation elements or standards together with a detailed discussion of how these elements will assure that each OTP surveyed by the accreditation organization is meeting each of the Federal opioid treatment standards. The Federal Guidelines for Opioid Treatment are intended to guide accreditation organizations in preparing their accreditation standards. In addition, the Guidelines provide useful elaborations on the regulatory standards set forth under 42 CFR part 8.

As such, the updated guidelines will assist both accreditation organizations and OTPs in complying with regulatory requirements. Prepared initially in 1997, the Federal Opioid Treatment Guidelines, originally titled *Guidelines for the Accreditation of Opioid Treatment Programs,* are being updated to reflect new information and research in the field of opioid assisted treatment. CSAT convened an expert panel to provide the draft guideline now being circulated for comment. CSAT is soliciting comments on the guideline from the public, and expects comments from OTPs, accreditation organizations, patients, the medical community and other interested parties. All comments submitted no later than 60 calendar days from the date of publication in the **Federal Register** will be considered.

Summer King,

Statistician.

[FR Doc. 2013–11637 Filed 5–15–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2013–0036]

Cooperative Research and Development Agreement (CRADA) Opportunity With the Department of Homeland Security for the Development of a Foot-and-Mouth Disease 3ABC ELISA Diagnostic Kit

AGENCY: Science and Technology Directorate, Plum Island Animal Disease Center, Department of Homeland Security.

ACTION: Notice of intent.

SUMMARY: The Department of Homeland Security Science and Technology Directorate (DHS S&T), through its Plum Island Animal Disease Center (PIADC), is seeking industry collaborators to aid DHS S&T in developing an ELISA diagnostic test that it capable of obtaining a U.S. regulatory license to detect antibodies to at least one of the Foot and Mouth Disease virus (FMDV) non-structural proteins (NSP): 3A, 3B, or 3C. This new FMDV 3ABC ELISA may be used in the event of a real or suspected outbreak of Foot-and-Mouth Disease (FMD) in order to differentiate infected from vaccinated, non-infected animals (DIVA).

The role of the industry collaborator(s) in this CRADA will be to develop and validate the FMDV 3ABC ELISA assay in collaboration with DHS S&T and the United States Department of Agriculture Animal and Plant Health Inspection Service Foreign Animal Disease Diagnostic Laboratory (USDA APHIS FADDL) at PIADC, and with other U.S. laboratories that are associated with USDA, such as the National Animal Health Laboratory Network (NAHLN). Components of a prototype assay, developed by USDA, Texas Veterinary Medical Diagnostic Laboratory, and a 3rd party fee-for-service contractor, will be made available to the industry collaborator(s). The goal of the CRADA is to submit a data package to USDA APHIS Center for Veterinary Biologics (CVB) in order to obtain a U.S. regulatory license for use under the direction of USDA administrators of the FMDV 3ABC ELISA in the U.S. (See CVB Veterinary Services Memorandum No. 800.73 for ''General Requirements for Immunodiagnostic Test Kits for the Detection of Antibody or Antigen.'') The assay must also successfully identify and test a reference panel of sera provided by OIE (World Organisation for Animal Health) as tested in a U.S. Reference Laboratory, e.g., USDA APHIS FADDL.

DHS S&T is seeking CRADA collaborators that own or have access to the technological components for, have the technological expertise in, and have proven track records of success in the fields of diagnostic test kit research, development, and the obtaining of USDA licensure for the detection of antibodies to viral antigen(s). CRADA collaborators must indicate if they are currently or may be funded by the Federal government, and, if yes, they must include a discussion of how proposed CRADA work and Federal government-funded work would not be duplicative.

The proposed term of the CRADA can be up to thirty (30) months.

DATES: Submit comments on or before June 17, 2013.

ADDRESSES: Mail comments and requests to participate to Dr. Angela Ervin, (ATTN: Angela Ervin, 245 Murray Lane SW., Washington, DC 20528–0075). Submit electronic comments and other data to *Angela.Ervin@hq.dhs.gov.*

FOR FURTHER INFORMATION CONTACT:

Information on DHS CRADAs: Marlene Owens, (202) 254–6671.

SUPPLEMENTARY INFORMATION:

Assay Requirements

1. Ideally a competitive ELISA (an assay in which a molecule in the test sample competes against a reagent provided in the kit for binding to the target) for FMDV NSPs that will differentiate FMDV infected from FMDV vaccinated animals (DIVA) (specifically cattle) and can be made commercially by the CRADA partner or by another entity and upon request by USDA APHIS, be supplied to USDA APHIS FADDL and accredited state laboratories within the National Animal Health Laboratory Network.

2. The ideal assay will have the following characteristics:

a. Diagnostic sensitivity of at least 96% for all seven major serotypes of FMDV, including detection of cattle antibodies to FMDV within 7 to 10 days post-infection.

b. Diagnostic specificity of at least 96%, ideally >99% with respect to viruses that cause FMDV look-alike clinical signs, such as Vesicular Stomatitis Virus, Swine Vesicular Disease Virus, Bovine Rhinovirus, Seneca Valley Virus.

c. Compatibility with serum samples from U.S. national cattle (beef and dairy) and domestic swine herds, and ideally with other species that are susceptible to FMDV, e.g., sheep, goats, feral swine, buffalo, deer, antelope, etc.

d. Assay time not exceeding 4 hours from start of incubation to beginning of reading the plate.

e. 96 well modular format.

f. Positive control (produced from non-FMDV infected animals, e.g., hyperimmunized with synthetically made FMDV peptides/proteins) and negative control (produced from naïve animals) for each plate.

g. Compatibility with Biosafety Level 2 (BSL–2) laboratory requirements, i.e., will not contain any reagents considered to be select agents or potentially contaminated with select agents.

3. Transportability under cold chain (1) to USDA APHIS PIADC, (2) upon USDA APHIS administrator request approved laboratories within the National Animal Health Laboratory network, and (3) outside of the US without special restrictions.

DHS S&T Role (includes but not limited to)

1. As necessary, coordination of development and commercialization access to critical assay components such as the recombinant 3ABC* protein (* indicates that the 3C protein has a mutation in the active site) and a FMDV-specific monoclonal antibody, which may be negotiated through intellectual property licenses with 3rd parties who control rights to these assay components. DHS will supply data from testing a prototype assay, but DHS will not supply historical background or any proprietary information.

2. Coordination of testing and evaluation of samples from U.S. cattle and swine vaccinated with FMD molecular vaccines.

3. Coordination of testing and evaluation of true positive samples from U.S. cattle and swine that were experimentally infected. A maximum of 500 samples can be tested.

4. If requested, coordination of testing and evaluation of true positive and true negative samples from other FMDV susceptible U.S. domestic species.

5. If requested, coordination of testing and evaluation of serum samples from FMDV susceptible U.S. wildlife species.

6. The actual testing of samples listed above mainly by scientists in USDA APHIS FADDL or by partners in laboratories that USDA APHIS FADDL and DHS S&T will identify, e.g., the NAHLN.

Period of Performance

If CRADA collaborator(s) is (are) selected, a comprehensive data package to obtain a USDA license for the FMDV 3ABC ELISA for use in cattle should be submitted to USDA APHIS CVB within 30 months of the CRADA award date. The submission must adhere to the requirements in USDA APHIS CVB Veterinary Services Memo No. 800.73 and other applicable CVB 9CFR requirements for diagnostic kits and reagents. The assay must also successfully identify samples in a reference panel of sera provided by OIE (World Organisation for Animal Health) as tested in a U.S. reference laboratory, e.g., USDA APHIS FADDL. Because these reference panels are provided on a yearly basis to FMD world reference laboratories, the testing and analysis of results may extend beyond the 30 month Period of Performance. Nevertheless, results should be made available within 2 months of the availability of reference panels.

Selection Criteria

The Plum Island Animal Disease Center (PIADC) reserves the right to select CRADA collaborators for all, some, or none of the proposals in response to this notice. PIADC will provide no funding for reimbursement of proposal development costs. Proposals (or any other material) submitted in response to this notice will not be returned. Proposals submitted are expected to be unclassified.

PIADC will select proposals at its sole discretion on the basis of:

1. How well the proposal communicates the collaborators' understanding of and ability to meet the CRADAs goals and proposed timeline.

2. How well the proposal addresses the following criteria:

a. Capability of the collaborator to provide equipment and materials for proposed testing.

b. Capability of the collaborator to meet the requirements for development, validation testing and analysis, and submission of supporting data and documents fulfilling the CVB requirements for licensure in the U.S.

c. Preliminary data or results which support the assay requirements outlined above.

Participation in this CRADA does not imply the future purchase of any materials, equipment, or services from the collaborating entities, and non-Federal CRADA participants will not be excluded from any future PIADC procurements based solely on their participation in this CRADA.

Authority: CRADAs are authorized by the Federal Technology Transfer Act of 1986, as amended and codified by 15 U.S.C. 3710a. DHS, as an executive agency under 5 U.S.C. 105, is a Federal agency for the purposes of 15 U.S.C. 3710a and may enter into a CRADA. DHS delegated the authority to conduct CRADAs to the Science and Technology Directorate and its laboratories.

Dated: May 9, 2013.

James Johnson,

Director, Office of National Laboratories.

[FR Doc. 2013–11693 Filed 5–15–13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2013–0078]

Privacy Act of 1974; Department of Homeland Security/U.S. Immigration and Customs Enforcement—014 Homeland Security Investigations Forensic Laboratory System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to establish a new Department of Homeland Security system of records titled, ''Department of Homeland Security/U.S. Immigration and Customs Enforcement—014 Homeland Security Investigations Forensic Laboratory System of Records.'' This system of records allows the Department of Homeland Security/U.S. Immigration and Customs Enforcement to collect and maintain records by the Homeland Security Investigations Forensic Laboratory (HSI–FL). The HSI–FL is a U.S. crime laboratory specializing in scientific authentication; forensic examination; research, analysis, and training related to travel and identity documents; latent and patent finger and palm prints; and audio and video files in support of law enforcement investigations and activities by DHS and other agencies. To facilitate forensic examinations and for use in forensic document training, research, and analysis, the HSI–FL maintains case files, a case management system, an electronic library of travel and identity documents (Imaged Documents and Exemplars Library), and a hard copy library referred to as the HSI–FL Library. Additionally, the Department of Homeland Security is issuing a Notice of Proposed Rulemaking elsewhere in the **Federal Register** to exempt this system of records from certain provisions of the Privacy Act. This newly established system will be included in the Department of Homeland Security's inventory of record systems.