the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is October 12, 2012 (2 weeks after the public meeting).

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section III of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted at *http://www.regulations.gov.*

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the public meeting on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting from the posted events list.)

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the event of an accident or terrorist attack that exposes a large population to radiation, an accurate assessment of the absorbed ionizing radiation dose received by victims will be essential for triage and medical management. Because there is currently no cleared or approved radiation biodosimeter for use in a mass exposure scenario, the development of proper radiation biodosimetry tools is a critical unmet public health need. However, because it is impossible to obtain samples that accurately reflect the intended use population of the device, validating the performance of radiation biodosimeters poses significant scientific and regulatory challenges. As such, FDA is holding this public meeting to obtain input from academia, Government, industry, and other stakeholders on the clinical application and scientific and technological challenges for performance validation of radiation biodosimetry devices. Individual perspectives from meeting participants may help to identify solutions for the scientific challenges associated with radiation biodosimetry development, and may clarify the regulatory path forward to ensure device safety and effectiveness and thereby provide significant clinical and public health benefits.

## II. Meeting Overview

The public meeting will consist of the following: (1) Presentations providing background on anticipated uses of radiation biodosimetry medical countermeasure devices, (2) the device design and performance evaluation challenges identified by FDA, (3) specific technology considerations in radiation biodosimetry, (4) an open public comment session, and (5) an open discussion on topics identified by FDA and those raised by the presentations (see section III of this document). The purpose of this meeting is for participants to share individual perspectives during the discussions. FDA is not seeking group opinions, recommendations, or advice on any matter. Additional information, including a meeting agenda, will be available on the Internet immediately after publication of this document in the **Federal Register.** This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov.* This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select the appropriate meeting from the list.)

## III. Topics for Discussion at the Public Meeting

The following questions represent the kinds of topics that will be discussed at the meeting.

1. Performance Evaluation for Radiation Biodosimetry:

A. What data would support the use of ex vivo radiation human samples in device performance validation?

B. What types of in vivo radiation human samples may be available to validate the performance of radiation biodosimeters?

C. What pre-clinical or clinical animal model testing might be necessary to demonstrate radiation biodosimeter performance?

D. Would a non-human primate pivotal clinical study be appropriate to support clearance/approval of biodosimetry MCM devices?

E. What data would support device applicability to both partial body and total body irradiation scenarios?

F. How should the impact of delays in sampling, delays in testing, combined injury, and other potential confounders on the performance of a radiation biodosimeter be assessed?

G. What challenges does the use of novel technologies bring to radiation biodosimetry development and performance validation?

2. Public Health Considerations for Radiation Biodosimetry:

A. What device design elements would address the need for rapid patient triage in a crisis scenario?

B. What device design elements should be included to account for the potential for high demand, device use by untrained medical personnel, and therapeutic decisionmaking based on limited resources?

C. What information should the Agency clarify in regards to the regulatory path forward for radiation biodosimetry MCM devices?

Dated: July 5, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–17082 Filed 7–12–12; 8:45 am]

**BILLING CODE 4160–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0004]**

### Statement of Cooperation Between the Food and Drug Administration and the Secretaria of Health of the United Mexican States: Safety and Sanitary Quality of Fresh and Frozen Molluscan Shellfish Exported From Mexico to the United States

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a Statement of Cooperation (SOC) between FDA and Secretariat of Health (SS) of the United Mexican States, through the Federal Commission for Protection from Sanitary Risks (COFEPRIS). The purpose of the SOC is to safeguard public health and to ensure the safety and sanitary quality of fresh

and frozen molluscan shellfish harvested from aquacultured and wild populations that are now or may be exported into the United States.

**DATES:** The arrangement came into effect on June 28, 2012 for 5 years.

**FOR FURTHER INFORMATION CONTACT:** Phyllis Marquitz, Latin American Office, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 3550, Silver Spring, MD 20993–0002, 301–796–8400, Fax: 301–595–7941.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the Agency is publishing notice of this MOU.

Dated: July 5, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

**BILLING CODE 4160–01–P**

**STATEMENT OF COOPERATION**
**BETWEEN**
**THE UNITED STATES FOOD AND DRUG ADMINISTRATION**
**AND**
**THE SECRETARIAT OF HEALTH OF THE UNITED MEXICAN STATES THROUGH THE FEDERAL COMMISSION FOR PROTECTION FROM SANITARY RISKS**
**COVERING THE SAFETY AND SANITARY QUALITY OF FRESH AND FROZEN MOLLUSCAN SHELLFISH EXPORTED FROM THE UNITED MEXICAN STATES TO THE UNITED STATES OF AMERICA**

The United States Food and Drug Administration (FDA), and the Secretariat of Health (SS) of the United Mexican States, through the Federal Commission for Protection from Sanitary Risks (COFEPRIS), hereinafter the "Participants,"

Desiring to safeguard public health and to ensure the safety and sanitary quality of fresh and frozen molluscan shellfish harvested from aquacultured and wild populations that are now or may be exported into the United States of America,

In keeping with the beneficial and cooperative work conducted under terms of the 2003 Memorandum of Understanding between the Department of Health and Human Services of the United States of America through the Food and Drug Administration and the Ministry of Health of the United Mexican States through the Federal Commission for Protection from Sanitary Risks covering the safety and quality of fresh and frozen aquacultured molluscan shellfish exported from the United Mexican States to the United States of America; and as extended in the 2008 Exchange of Letters concerning the safety and quality of fresh and frozen molluscan shellfish exported from the United Mexican States to the United States of America,

Recognizing that the COFEPRIS through the Mexican Shellfish Sanitation Program (MSSP), has an effective molluscan shellfish sanitary control system in place,

Acknowledging that the FDA recognizes the MSSP and finds that the MSSP adequately meets the U.S. National Shellfish Sanitation Program (NSSP) guidelines, and that COFEPRIS retains the overall responsibility for the MSSP and coordinates the participation of federal and state level Mexican government agencies in the MSSP to jointly ensure the safety of molluscan shellfish exported to the United States of America,

Recognizing that nothing in this Cooperative Arrangement will in any way abrogate the responsibility or authority of the FDA under Section 801 of the Federal Food, Drug and Cosmetic Act to examine, and, where appropriate, refuse admission of, any food product intended to enter the United States of America, or to comply with and enforce any other Law administered by the FDA,

The Participants have established the following understanding;

## SECTION I
## Purpose

The purpose of this Statement of Cooperation (Statement) is to assure that all molluscan shellfish exported from the United Mexican States to the United States of America are safe for human consumption, and that all MSSP guidelines for the harvest, processing, transport, and labeling of molluscan shellfish are in accordance with the provisions of the FDA's NSSP *Guide for the Control of Molluscan Shellfish,* and applicable requirements of the U.S. Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and Title 21 of the U.S. Code of Federal Regulations.

## SECTION II
## Definitions

For the purposes of this Arrangement the terms listed below will have the following meanings:

1. "Approved" is a sanitary classification used to identify a growing area (growing and harvesting) where the harvesting of aquacultured or wild population molluscan shellfish for direct marketing is allowed;
2. "Aquaculture" is the growing (cultivation) of seed or shellstock other than seed in natural or artificial growing areas, as well as the group of activities directed to its controlled reproduction, prefeeding and feeding, by using culturing techniques;
3. "Central File" is the area where the COFEPRIS keeps a copy of all MSSP-related information, data, reports, maps, minutes and final decisions, among others;
4. "Dealer" is a person or firm to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor;
5. "Depuration" is the process of reducing the pathogenic and indicator bacteria that may be present in shellstock by using a controlled aquatic environment approved and authorized by the MSSP as the treatment process;
6. "Harvest" (when used as a verb) is the removing of molluscan shellfish from growing areas under a fishing permit or license issued by the National Aquaculture and Fisheries Commission (CONAPESCA) and complying with MSSP provisions, or (when used as a noun) means any species of molluscan shellfish removed from growing areas under a fishing permit or license issued by the National Aquaculture and Fisheries Commission (CONAPESCA) and complying with MSSP provisions;
7. "Inspection and Surveillance" is the active control of molluscan shellfish harvest and transportation, including patrol of unapproved areas, to ensure that only molluscan shellfish from Approved areas are harvested, processed, labeled, and transported for export to the United States of America;

8. "Interstate Certified Shellfish Shippers List" (ICSSL) is the FDA publication of molluscan shellfish dealers, both domestic and foreign, who have been certified by a state or foreign shellfish control authority before FDA, and who abide to public health control measures that are specified in the FDA's *Guide for the Control of Molluscan Shellfish;*
9. "Lot of shellfish" is bulk shellstock or containers of a single species of shellstock containing no more than one day's harvest from a single defined growing area harvested by one identified harvester, and designated by a common container code or marking;
10. "Lot of shucked molluscan shellfish" is a collection of containers of no more than one day's harvest of a single species of shucked molluscan shellfish from a single defined growing area harvested by one identified harvester, produced under conditions as nearly uniform as possible, and designated by a common container code or marking;
11. "Marine biotoxin" is any poisonous compound produced by marine microorganisms and potentially accumulated by molluscan shellfish;
12. "Mexican Shellfish Sanitation Program" (MSSP) is the United Mexican States sanitary control system implemented by the COFEPRIS to assure the production of safe molluscan shellfish through the implementation of control measures described by the NSSP. Its operating principles and guidelines are set forth in the MSSP *Technical Guide;*
13. "Molluscan shellfish" is all edible species of oysters, clams, mussels, and whole or roe-on scallops harvested from aquacultured or wild population, whether shucked or as shellstock, fresh or frozen;
14. "National Shellfish Sanitation Program" (NSSP) is the federal/state cooperative program (domestic and foreign) between FDA and industry to ensure the safety and quality of molluscan shellfish intended for human consumption. The technical guidelines for ensuring the safety and quality of molluscan shellfish are set forth in the FDA's *Guide for the Control of Molluscan Shellfish;*
15. "Prohibited area" is a sanitary classification used to identify a growing area where the harvest of molluscan shellfish for any purpose, except depletion or gathering of seed for aquaculture, is not permitted;
16. "Relay" is the transfer of shellstock from areas classified as Restricted to areas classified as Approved for the purpose of reducing pathogens as measured by the coliform indicator group, or poisonous or deleterious substances (except biotoxins) that may be present in the shellstock, by using the ambient (Approved area) environment as the treatment process;
17. "Restricted area" is a sanitary classification used to identify a cultivation area (growing and harvesting) where harvesting aquacultured or wild-caught molluscan shellfish for direct marketing is not allowed, and where any harvesting activity is authorized by special license from COFEPRIS and with direct supervision by the state shellfish control authority, and from which all shellstock harvested are subjected to a suitable and effective treatment process approved by COFEPRIS through relaying or depuration;
18. "Sanitary survey" is the written evaluation report of all factors, including actual and potential pollution sources of direct or indirect impact and environmental

conditions which have a bearing on the water quality in a shellfish cultivating (growing or harvesting) area;

19. "Shellstock" is live molluscan shellfish in the shell; and
20. "Shucked shellfish" is the edible portion of molluscan shellfish that has been removed from the shell.

## SECTION III
## Responsibilities of the Participants

A. COFEPRIS

1. The COFEPRIS is responsible for coordinating and implementing the MSSP.

2. The COFEPRIS intends to:

   a. Maintain legal, administrative, and regulatory authority and infrastructure, including formal agreements with participating Mexican States, for the sanitary and safety control of fresh and frozen molluscan shellfish, whether shellstock or shucked shellfish, from aquaculture and wild populations, as provided in the MSSP;
   b. Ensure that the MSSP conforms to the NSSP, including but not limited to the following:
      i. Classify area of molluscan shellfish growing and harvest based on comprehensive sanitary surveys;
      ii. Prepare, evaluate, and approve sanitary survey reports for growing and harvest areas, and maintain a copy of each in the central file, including exhibits thereto;
      iii. Update all sanitary surveys annually and triennially to assure proper sanitary classification for each growing and harvest area;
      iv. Approve shellfish harvesting activities, supervise relay operations, and ensure proper labeling and identification of molluscan shellfish;
      v. Control molluscan shellfish harvesting and marketing to prevent shellfish from unapproved areas (areas classified as Restricted or Prohibited) from being mixed, commingled with or mislabeled as shellfish from Approved areas;
      vi. Restrict the harvest of molluscan shellfish from unapproved growing areas and take enforcement action against persons or companies harvesting from unapproved areas;
      vii. Prohibit and prevent the harvest of molluscan shellfish from growing and harvest areas affected by contamination or marine biotoxins emergencies, and rescind such prohibitions when causes for the emergency conditions have ended and analyses demonstrate that such areas and the shellfish therein meet MSSP approved area criteria;

viii. Recall or otherwise remove from the market any molluscan shellfish unsafe for human consumption;

ix. Maintain NSSP conforming laboratories certified to participate in the MSSP;

x. Verify annually that dealers of fresh and/or frozen molluscan shellfish exporting to the United States of America comply with MSSP technical criteria;

xi. Annually certify dealers exporting fresh and/or frozen molluscan shellfish to the United States of America for inclusion in the FDA's Interstate Certified Shellfish Shippers List (ICSSL);

xii. Forward electronically to FDA the filled-out Form FDA-3038, "Shellfish Dealer Certification," giving the name, location, and certification number for each of the MSSP certified dealers exporting molluscan shellfish to the United States of America;

xiii. Cancel the certification and notify FDA to revoke from the ICSSL, any dealer that:

a. Operates out of compliance with the MSSP;

b. Distributes molluscan shellfish harvested from unapproved MSSP areas;

c. Markets or tries to market in the United States of America molluscan shellfish not conforming to the U.S. Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, or title 21 of the U.S. Code of federal regulations; and

d. Fails to collaborate with COFEPRIS to recall molluscan shellfish deemed to be unsafe for human consumption;

xiv. Ensure that each container in a lot of shellstock or shucked molluscan shellfish marketed to the United States of America is properly labeled in accordance with MSSP criteria;

xv. Maintain a central file copy in English of all MSSP records, including growing and harvest area sanitary survey reports, control of harvest and patrol (inspection and surveillance) records, dealer inspections, laboratory evaluations, and enforcement actions, and make them available to FDA upon request;

xvi. Provide FDA evaluation reports, interpretations, laboratory quality assurance program information, and other molluscan shellfish program information to all Mexican federal and state government agencies having responsibility for the MSSP;

xvii. Review at least annually the level of conformity with NSSP requirements being enforced under the MSSP and provide FDA with a brief summary of the findings described in the written annual report;

xviii. Provide FDA with information concerning current and potential public health risks affecting molluscan shellfish intended for export to the United States of America;

xix. Upon written request from FDA, make arrangements to accommodate the travel and audit activities of FDA evaluation officials for conducting on-site inspections of the MSSP to be performed jointly with the COFEPRIS officials, and provide ground transportation as needed;

xx. Within 30 days from receipt of written notification from the FDA of MSSP deficiencies or other non-conformances with the NSSP, develop a written corrective action plan and submit this to FDA for review and concurrence;

xxi. Take appropriate preventative and corrective actions upon notice of any MSSP deficiency; and

xxii. Update the MSSP Technical Guide for consistency with the published NSSP *Guide for the Control of Molluscan Shellfish.*

c. Permit the harvest of molluscan shellfish for processing and/or shipping by MSSP certified dealers to the United States of America only from growing and harvesting areas approved by the COFEPRIS with concurrence from FDA.

3. The COFEPRIS intends to have specific laboratory procedures and qualified personnel to:

   a. Certify or otherwise ensure that laboratories participating in the MSSP substantially conform to NSSP requirements for laboratories and analysts;
   b. Periodically evaluate MSSP participating laboratories for conformance with MSSP provisions and NSSP requirements and observance of laboratory quality assurance procedures;
   c. Notify FDA of laboratories not in conformance with the NSSP;
   d. Maintain a marine biotoxin contingency plan and monitoring program in growing and harvesting areas where molluscan shellfish are harvested for export to the United States of America;
   e. Promote a split sample program among the MSSP laboratories for evaluating microbiological proficiencies among analysts and uniformity among laboratories; and
   f. Prevent laboratories not conforming to MSSP provisions or NSSP requirements from participating in the MSSP.

4. The COFEPRIS intends to have specific procedures and maintain a Standardization Officer for shellfish dealer inspections, trained and certified by FDA, to:

   a. Train and certify other government molluscan shellfish dealer inspectors as needed to meet inspection frequencies and standards;

b. Ensure that all molluscan shellfish dealers exporting to the United States of America are inspected at required frequencies and reliably comply with NSSP requirements;
c. Ensure that MSSP certified molluscan shellfish dealers are appropriately listed by FDA on the ICSSL;
d. Ensure that all action plans to correct deficiencies are appropriate for maintaining compliance with NSSP requirements; and
e. Ensure that all action plans are followed and all deficiencies are corrected by dealers in accordance with NSSP requirements.

5. The COFEPRIS intends to report to FDA any change in responsibility from the COFEPRIS to another authority within 30 days of such change.

B. FDA

FDA intends to:

1. Accept the United Mexican States as a participant in the NSSP and the Interstate Shellfish Sanitation Conference (ISSC), and in cooperative research programs, seminars, conferences, training courses, and other NSSP activities;

2. Accept Mexican shellfish dealers certified by the COFEPRIS for inclusion in the ICSSL, and publish the names, dealer types, locations, and certification numbers in the FDA ICSSL publication upon receipt of completed FDA Form 3038 from COFEPRIS;

3. Provide training and technical assistance to the COFEPRIS and the United Mexican States MSSP personnel upon request, subject to availability of resources for such purposes;

4. Give immediate written notice to the COFEPRIS of the reasons for any detention of certified molluscan shellfish shipments from the United Mexican States to the United States of America;

5. Participate with the COFEPRIS in joint evaluations of the MSSP to ascertain the level of conformance with the NSSP and with the responsibilities specified in this Statement; the FDA should pay round trip transportation expenses between the United States of America and the United Mexican States, air transportation inside the United Mexican States, and the per diem expenses of the FDA evaluation team while in the United Mexican States;

6. Within 30 days after a MSSP evaluation, notify the COFEPRIS of any NSSP deficiencies and request that the COFEPRIS of submitting to FDA within 30 days after notification, a written Corrective Action Plan for review and concurrence. If a Corrective Action Plan is not developed and submitted

within 30 days after notification, or if any deficiencies are not addressed and corrected in accordance with the Corrective Action Plan, FDA is to remove Mexican dealers from the FDA ICSSL and/or take other appropriate action to stop Mexican molluscan shellfish from entering the United States of America. In case of a serious public health threat, this 30 day period may be reduced or eliminated. Such action should remain in effect until all NSSP deficiencies have been corrected and FDA has determined that the MSSP is in conformance with the NSSP;

7. Remove individual Mexican dealers from the FDA's ICSSL when it is determined by FDA or COFEPRIS that the dealer is not in compliance with NSSP requirements or when an imminent health hazard exists with a dealer's product; and

8. Report to the COFEPRIS any transfer of responsibilities from FDA to another federal authority in the United States of America within 30 days of such transfer.

## SECTION IV
## Technical Information Exchange

The working language for documents exchanged under this Arrangement is English. The Participants plan to share technical expertise, provide assistance, and exchange information. Such collaboration may include, but is not limited to the following:

1. Exchange of information concerning proposed and final changes to MSSP operations and procedures including, among other things, the following:
   a. Sample methods and procedures;
   b. Methods of analysis;
   c. Methods of confirmation;
   d. Design of sanitary survey reports;
   e. Administrative procedures and changes thereto, sanitary standards and guidelines, reference standards, and nomenclature;
   f. Inspection procedures for growing and harvesting areas and dealers; and
   g. Inspection and surveillance procedures.

2. Written notification to the other Participant of any changes in liaison officials within 30 days of such change; and

3. Facilitating the exchange of information between the Participants and the federal and state agencies of the United Mexican States and the United States of America concerned with the introduction and proliferation of exotic organisms that might be carried by Mexican molluscan shellfish.

## SECTION V
## Liaison Officials

Unless and until changed pursuant to Section VI(2), the liaison officials will be:

A. For the COFEPRIS:

Comisionado(a) de Operación Sanitaria
Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS)
Secretaria de Salud
Avenida Monterrey No. 33, Tercer Piso
Col. Roma C.P. 06700
México, D.F., Estados Unidos Mexicanos
Telephone: 011 52 55 80 52 00 ext. 1254, 1230, 1263

B. For the FDA:

Director, Division of Seafood Safety, HFS-325
Office of Food Safety, Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740
United States of America
Telephone: 01 240 402 2300

The liaison officials may establish other contact points to facilitate the exchange of information and other operational activities.

## SECTION VI
## Final Provisions

This Statement comes in to effect as of the date of signature by both Participants and continues for five (5) years, period that may be extended upon the written consent of both Participants.

This Statement is to be evaluated by the Participants over such five-year period and may be amended upon mutual consent given in writing and specifying the effective date for such amendment.

All actions taken pursuant to this Arrangement are to be taken in accordance with the laws, regulations, and standards of the United Mexican States and the United States of America, and are subject to the availability of personnel, resources, and appropriated funds.

This Arrangement is not intended to create any obligation under international or other laws.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective government agencies, have signed this Arrangement.

SIGNED in the of Spanish and English languages.

Signed on behalf of FDA:

Deborah M. Autor, Esq.
Deputy Commissioner
Global Regulatory Operations and Policy
U. S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Tel. +1 301-796-4600
Fax. +1 301-595-7937

6/26/2012
Date

Signed on behalf of SS:

Mikel Andoni Arriola Peñalosa
Federal Commissioner
Federal Commission for the Protection against Sanitary Risk
Monterrey No. 33, Col. Roma
Del. Cuauhtémoc , México, D.F., 06700
Tel. +52 55 5080-5200

6/18/2012
Date

[FR Doc. 2012–17081 Filed 7–12–12; 8:45 am]
BILLING CODE 4160–01–C

## DEPARTMENT OF HEALTH AND HUMAN SERVICE

### Indian Health Services

**[HHS–2012–IHS–HLY–0001]**

### Healthy Lifestyles in Youth Project; Proposed Single Source Cooperative Agreement With National Congress of American Indians

*Application Due Date:* August 16, 2012.
*Review Date:* August 21, 2012.
*Earliest Start Date:* September 1, 2012.

### I. Funding Opportunity Description

The Indian Health Service (IHS) proposes a single source competing continuation cooperative agreement with the National Congress of American Indians (NCAI) for the purpose of continued implementation of the Healthy Lifestyles in Youth Project in selected Native American Boys and Girls Clubs of America. This program promotes healthy lifestyles among American Indian and Alaska Native (AI/AN) youth using the curriculum ''Together Raising Awareness for Indian Life'' (TRAIL) among selected Boys and Girls Club sites.

This program is authorized under the authority of the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001; and the Public Health Service Act, as amended, 42 U.S.C. 241(a). Under this cooperative agreement, IHS proposes to enter into a collaborative effort/initiative with NCAI, because of their unique experience partnering with the IHS and Boys and Girls Clubs of America in successfully establishing this program, as well as, their overall expertise and experience in addressing and evaluating healthy lifestyle techniques in AI/AN youth. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

The focus of the project continues to be on addressing healthy lifestyle development, emphasizing nutrition and physical activity for AI/AN children and youth 6 through 17 years of age. The long term goal is to prevent or delay the onset of obesity and related diseases such as type 2 diabetes. NCAI will continue partnering work with selected Tribal Boys and Girls Club sites to: (a) Provide health and physical education programs; (b) help youth achieve and maintain healthy lifestyles through participation in fitness programs; (c) help youth to acquire a range of physical skills; and (d) help youth develop a sense of teamwork and cooperation.

These early intervention strategies provide evidence based opportunities to reduce and/or halt the increasing trend of obesity and diabetes among youth and young adults. Clubs that develop a health promotion program that includes the TRAIL curriculum may help curtail the effects of unhealthy eating behaviors and lack of physical activity that can lead to obesity, diabetes, and other chronic diseases later in life. The T.R.A.I.L. curriculum was developed to provide information on good nutrition and to promote physical activity among youth participating in Tribal Boys and Girls Clubs. T.R.A.I.L. is a three-month (12 lessons) program that provides youth with a comprehensive understanding of healthy lifestyles in order to prevent diabetes. Woven throughout the program are self-esteem and prevention activities. Participants