

information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 3090-0283, Contractor Information Worksheet; GSA Form 850 in all correspondence. The form can be downloaded from the GSA Forms Library at <http://www.gsa.gov/forms>. Type GSA 850 in the form search field.

Dated: November 25, 2015.

David A. Shive,

Chief Information Officer.

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BILLING CODE 6820-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-16-0046]

Agency Forms Undergoing Paperwork Reduction Act Review

The Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of

responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (OMB Control No. 0923-0046, Expiration, 2/29/2016)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Navajo Nation is the largest Alaska Native/American Indian Reservation in the United States. From 1948 to 1986, many uranium mining and milling operations took place in the Navajo Nation, leaving a large amount of uranium contamination on the reservation. The House Committee on Oversight and Government Reform requested that federal agencies develop a plan to address health and environmental impacts of uranium contamination in the Navajo Nation.

As a result in 2013, ATSDR and its research partners (University of New Mexico Community Environmental Health Program [UNM-CEHP], Navajo Area Indian Health Service [NAIHS], Navajo Nation Department of Health [NNDOH], Navajo Nation Environmental Protection Agency [NNEPA], and Navajo culture and language specialists) initiated a research study titled "Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation" (OMB Control No. 0923-0046; expiration date 02/29/2016). The goal of the research is to better understand and prevent unfavorable child and maternal health outcomes potentially related to prenatal exposures to uranium. As ATSDR has received supplemental funding to continue the study, a three year extension for PRA clearance is requested to allow further recruitment of mother-infant pairs.

Participants include Native American mothers from age 14 to 45 with verification of pregnancy who have

lived in the study area for at least 5 years. Also, participants must consent to receive prenatal care and deliver at one of the healthcare facilities that are taking part in the study.

Since 2013, over 525 mother-infant pairs and over 160 fathers have been enrolled. Biological sample analysis, surveys, and developmental screenings are performed for each participant. An estimated 675 biomonitoring samples have been analyzed for 36 metals/metalloids including uranium, arsenic, lead and mercury. Home environmental assessments (HEAs), conducted by field research staff, consist of gamma radiation surveys, indoor air radon tests, and dust sample analysis of the participants' primary residence during pregnancy, and over 400 HEAs have been completed to date. Mothers must be present at home when field research staff conduct the HEA. Study participants receive report back letters on their biomonitoring and HEA results to inform them of uranium and other heavy metals in their bodies and in and around their home environment.

The survey instruments for pregnant mothers include the following: Eligibility Form, Mother Enrollment Survey, Ages and Stages Questionnaire (ASQ), Mullen Scales for Early Learning (MSEL), Postpartum Survey (2 months), Postpartum Survey (6,9,12 months), Food Frequency Questionnaire/WIC Intake Form, and Home Environmental Assessments. An enrollment survey for fathers who agree to participate is also administered. Follow-up assessments including the Ages & Stages Questionnaire and biomonitoring at 2, 6, 9 and 12 months are currently being conducted for the 387 infants delivered to date.

Community Health and Environmental Research Specialists (CHERS) administer the surveys using a CDC-approved electronic data entry system. Survey instruments are used to collect demographic information and to assess potential environmental health risks and mother-child interactions. The final format of the survey instruments is based on review and input from the Navajo Nation community liaison group and associated Navajo staff to address issues such as cultural sensitivity, comprehension, and language translation.

There is no cost to the respondents other than their time to participate in the study. The total estimated annual burden hours equals 4,455.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden response (hours)
Mothers	Eligibility Form	750	1	5/60
	Mother Enrollment Survey	550	1	2
	Ages and Stages Questionnaire (2,6,9,12 months)	500	4	15/60
	Mullen Scales of Early Learning	500	1	20/60
	Postpartum Survey (2 months)	500	1	1
	Post-partum Survey (6, 9, 12 months)	500	3	15/60
	Food Frequency Questionnaire/WIC Intake Form	500	1	45/60
	Home Environmental Assessment	550	1	1
Fathers	Father Enrollment Survey	550	1	90/60

Leroy A. Richardson,

Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3329-PN]

Medicare and Medicaid Programs: Application From the Institute for Medical Quality for Initial CMS- Approval of Its Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare and
Medicaid Services, HHS.

ACTION: Notice with request for
comment.

SUMMARY: This proposed notice
acknowledges the receipt of an
application from the Institute for
Medical Quality (IMQ) for recognition
as a national accrediting organization
(NAO) for Ambulatory Surgical Centers
(ASCs) that wish to participate in the
Medicare or Medicaid programs.

DATES: To be assured consideration,
comments must be received at one of
the addresses provided below, no later
than 5 p.m. on January 4, 2016.

ADDRESSES: In commenting, please refer
to file code CMS-3329-PN. Because of
staff and resource limitations, we cannot
accept comments by facsimile (FAX)
transmission.

You may submit comments in one of
four ways (please choose only one of the
ways listed):

1. *Electronically.* You may submit
electronic comments on this regulation
to <http://www.regulations.gov>. Follow
the "Submit a comment" instructions.

2. *By regular mail.* You may mail
written comments to the following
address ONLY: Centers for Medicare &
Medicaid Services, Department of
Health and Human Services, Attention:
CMS-3329-PN, P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed
comments to be received before the
close of the comment period.

3. *By express or overnight mail.* You
may send written comments to the
following address ONLY: Centers for
Medicare & Medicaid Services,
Department of Health and Human
Services, Attention: CMS-3329-PN,
Mail Stop C4-26-05, 7500 Security
Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively,
you may deliver (by hand or courier)
your written ONLY to the following
addresses:

a. For delivery in Washington, DC—
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Room 445-G, Hubert
H. Humphrey Building, 200
Independence Avenue SW.,
Washington, DC 20201.

(Because access to the interior of the
Hubert H. Humphrey Building is not
readily available to persons without
Federal government identification,
commenters are encouraged to leave
their comments in the CMS drop slots
located in the main lobby of the
building. A stamp-in clock is available
for persons wishing to retain a proof of
filing by stamping in and retaining an
extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, 7500 Security
Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your
comments to the Baltimore address, call
telephone number (410) 786-9994 in
advance to schedule your arrival with
one of our staff members.

Comments erroneously mailed to the
addresses indicated as appropriate for

hand or courier delivery may be delayed
and received after the comment period.

For information on viewing public
comments, see the beginning of the
SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

Cindy Melanson, (410) 786-0310.
Patricia Chmielewski, (410) 786-6899.
Marie Vashbinder, (410) 786-8665.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All
comments received before the close of
the comment period are available for
viewing by the public, including any
personally identifiable or confidential
business information that is included in
a comment. We post all comments
received before the close of the
comment period on the following Web
site as soon as possible after they have
been received: [http://
www.regulations.gov](http://www.regulations.gov). Follow the search
instructions on that Web site to view
public comments.

Comments received timely will also
be available for public inspection as
they are received, generally beginning
approximately 3 weeks after publication
of a document, at the headquarters of
the Centers for Medicare & Medicaid
Services, 7500 Security Boulevard,
Baltimore, Maryland 21244, Monday
through Friday of each week from 8:30
a.m. to 4 p.m. To schedule an
appointment to view public comments,
phone 1-800-743-3951.

I. Background

Under the Medicare program, eligible
beneficiaries may receive covered
services from an Ambulatory Surgical
Center (ASC) provided certain
requirements are met. Section
1832(a)(2)(F)(i) of the Social Security
Act (the Act) establishes distinct criteria
for facilities seeking designation as an
ASC. Regulations concerning provider
agreements are at 42 CFR part 489 and
those pertaining to activities relating to
the survey and certification of facilities
are at 42 CFR part 488. The regulations
at 42 CFR part 416 specify the