

# Supporting Statement For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)  
Biomonitoring of Great Lakes Populations Program II

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## SECTION A. Justification

Date: March 20, 2015

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## TABLE OF CONTENTS

A. JUSTIFICATION.....	3
A.1. Circumstances Making the Collection of Information Necessary.....	3
A.2. Purpose and Use of Information Collection.....	4
A.3. Use of Improved Information Technology and Burden Reduction.....	7
A.4. Efforts to Identify Duplication and Use of Similar Information.....	7
A.5. Impact on Small Businesses or Other Small Entities.....	9
A.6. Consequences of Collecting the Information Less Frequently.....	9
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	9
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency	9
A.9. Explanation of Any Payment or Gift to Respondents.....	10
A.10. Assurance of Confidentiality Provided to Respondents.....	10
A.10.1. Privacy Impact Assessment Information.....	10
A.11. Justification for Sensitive Questions.....	18
A.12. Estimates of Annualized Burden Hours and Costs.....	19
A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	20
A.14. Annualized Cost to the Government.....	20
A.15. Explanation for Program Changes or Adjustments.....	21
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	21
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	22
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	22
LIST OF ATTACHMENTS.....	23

## A. JUSTIFICATION

### A.1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) for the *2013 Agency for Toxic Substances and Disease Registry (ATSDR) Biomonitoring of Great Lakes Populations Program II* (CDC-RFA-TS13-1302). The program requests Office of Management and Budget (OMB) approval for two years to complete information collection.

#### Background

In 2009, President Obama's Administration announced the Great Lakes Restoration Initiative (GLRI) to protect, restore and maintain the Great Lakes ecosystem. A task force of federal agencies developed milestones and outcome measures to make the five-year GLRI Action Plan ([http://greatlakesrestoration.us/pdfs/glri\\_actionplan.pdf](http://greatlakesrestoration.us/pdfs/glri_actionplan.pdf)) a national success. The GLRI Action Plan articulates the most significant regional ecosystem problems and the coordinated efforts to address them (GLRI Task Force, 2010). In conjunction with the White House Council on Environmental Quality and 11 other federal agencies, the U.S. Environmental Protection Agency (US EPA) was tasked with implementing the GLRI's billion dollar package of programs that aims to restore the Great Lakes ecosystems. As part of the GLRI Action Plan, the *Department of the Interior, Environment, and Related Agencies Appropriations Act of 2010* (Public Law 111-88; Attachment 1a), committed federal efforts to make the restoration of the Great Lakes a national priority. The ATSDR-GLRI program development began with external consultations in 2009 with the US EPA Great Lakes National Program Office (GLNPO), with state health departments, and with scientists at various workshops, fora, and conferences (further described in Section A.4).

The ATSDR Biomonitoring Program objectives are linked to the GLRI Action Plan focus area, "Toxic Substances and Areas of Concern." As a public health entity among the 12 GLRI Task Force agencies, this program also addresses the "Healthy People 2010" focus area related to Environmental Health Objective 8-25, "Reduce exposure of the population to pesticides, heavy metals, and other toxic chemicals, as measured by blood and urine concentrations of the substances or their metabolites." Measurable program outcomes are aligned with the following ATSDR performance goals: 1) Prevent ongoing and future exposures and resultant health effects from hazardous waste sites and releases; and 2) build and enhance effective partnerships. This program aims to provide a human exposure assessment among targeted subpopulations that will be concurrent with the onset of restoration activities.

Working directly with the US EPA under an Interagency Agreement, the ATSDR announced a new funding opportunity under the *2013 ATSDR Biomonitoring of Great Lakes Populations Program II*. The ATSDR is authorized to conduct this program under the *Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)*, as amended by the *Superfund Amendments and Reauthorization Act of 1986 (SARA)* (Attachment 1b). The ATSDR Great Lakes Biomonitoring Program awarded funds to The New York State Department

of Health (NYSDOH) to conduct this information collection (IC) under cooperative agreement #TS000194. The purpose of the current program is to evaluate body burden levels of priority contaminants in Great Lakes residents, particularly those who are at highest exposure risk, in an area that was not addressed in the original FY2010 CDC-RFA-TS10-1001 cooperative agreement program (*2010 ATSDR Biomonitoring of Great Lakes Populations Program* - OMB Control No: 0923-0044, expiration date 10/31/2015). The current proposed program period ends on 2 March 2016.

Onondaga Lake is a 4.5 square mile highly polluted Great Lakes Basin water body located in the City of Syracuse, the Towns of Salina, Geddes, and Camillus. The lake drains approximately 285 square miles of the surrounding areas. Because of extensive pollution, the lake was proposed to the National Priority List on May 10, 1993, and officially listed on December 16, 1994. The Onondaga Lake Superfund Site consists of the lake itself, seven major and minor tributaries, and upland sources of contamination to the site, of which there are eleven. The lake flows into the Seneca River, then into the Oswego River and ultimately Lake Ontario. As a result of past industry, Onondaga Lake waters are contaminated with mercury, and sediments are contaminated with polychlorinated biphenyls (PCBs), pesticides, creosotes, heavy metals (including lead, cobalt and mercury), polyaromatic hydrocarbons (PAHs) and volatile organic compounds such as chlorobenzene. Fish caught from Onondaga Lake have the highest mercury levels in NYS. Detailed information about the Onondaga Lake site history and current progress of remedial actions can be found at the EPA website, <http://www.epa.gov/region02/superfund/npl/onondagalake>.

NYSDOH will look at adults living in Syracuse, NY who are known to eat fish from Onondaga Lake. The NYSDOH biomonitoring program's two target subpopulations are: (1) the Burmese and Bhutanese refugee community in Syracuse who are known to eat a substantial amount of fish from Onondaga Lake (300 people); (2) an urban, subsistence population who rely on fish from Onondaga Lake as a source of food (100 people). NYSDOH study staff will work closely with local refugee and citizen support organizations to get people to take part in the study.

The 60-day Federal Register Notice was published on August 25, 2014 (Attachment 2) and is further discussed in Section A.8.

A data collection summary (Attachment 3) is provided as an index on the following topics and procedures:

- Subpopulation
- Outreach, Sampling, and Recruitment
- Response Rates
- Enrollment, Interview, Clinical Assessment, and Specimen Collection
- Tokens of Appreciation
- Laboratory Procedures
- Individual Results Reporting and Communications

## A.2. Purpose and Use of Information Collection

The ATSDR Great Lakes Biomonitoring Program II is an applied public health program that focuses on vulnerable or susceptible subpopulations with the potential for increased risk of exposure to persistent contaminants common to the Great Lakes watersheds and ecosystems. This surveillance project is designed to learn about levels of contaminants that can be detected in blood and urine of residents who consume fish from contaminated areas. This surveillance project is not investigating health outcomes or biological effects from such exposures. Project findings will be used to inform policy regarding reducing Great Lakes contaminants and exposures to contaminants.

The NYSDOH under a cooperative agreement with ATSDR will collect this data on a one-time basis. Under state code, the NYSDOH and associated environmental programs are responsible for addressing the public health concerns in the state and for issuing fish consumption advisories for their own water bodies. The state will use its own information to determine if select subpopulations living in the specified area have elevated exposures to Great Lakes contaminants. This information will be used by NYSDOH, ATSDR, and EPA to guide public health practice throughout the restoration process and into the future.

This ICR also represents the first time that the body burdens of a large panel of Onondaga Lake contaminants will be determined among lower income, urban, racial, and ethnic subpopulations with subsistence fishing customs and cultural fish diets. The targeted communities are particularly vulnerable to potential health risks related to eating locally caught fish due to proximity to the lake, contamination of the lake and fish they catch, a high proportion of fish in the diet, and social cultural isolation from sources of risk communication. (Derrick CG, 2008). As a means to promote trust with state health officials, collaborative community partnerships are beneficial when gathering health information from and intervening with vulnerable communities (Viswanatan M, 2004). The NYSDOH will work with their community partners to create culturally relevant educational and advisory messages on the risks and benefits of fish consumption diets in relation to chemical exposures. Therefore, this program will have direct utility in targeted outreach, education, and protection of potentially susceptible subpopulations that would otherwise be missed in general population biomonitoring studies.

Because the results of this ICR aim to inform the restoration process for specific subpopulations, the results from this nonresearch program are not intended to be generalizable beyond the target subpopulations living Syracuse, NY.

*Why this information is being collected.* Begun as a 2010 federal appropriation under Public Law 111-88, this effort is part of a national priority. It will provide a baseline assessment of the chemical exposures of specific susceptible Great Lakes Basin subpopulations as part of the FY10-FY14 GLRI Action Plan ([http://greatlakesrestoration.us/pdfs/glri\\_actionplan.pdf](http://greatlakesrestoration.us/pdfs/glri_actionplan.pdf)) and for future restoration activities in Syracuse, NY.

The GLRI Action Plan continues the legacy of the historic U.S.-Canadian International Joint Commission (IJC), established by the 1909 Boundary Waters Treaty to develop lakewide management plans. As such, the IJC committed to active ecosystem management under the 1978

Great Lakes Water Quality Agreement (GLWQA), and as amended in 1987. Under the GLWQA, a working list of criteria pollutants was established (<http://www.ijc.org/rel/agree/quality.html>). From this IJC list and for this GLRI activity, the ATSDR selected persistent toxic substances that were most feasible for biomonitoring (costs, established analytical methods, and human burden). Thus, the ATSDR program has required a core set of Great Lakes legacy contaminants for biomonitoring. In addition to the well-known toxicants like mercury, PCBs, and banned pesticides, there are chemicals of emerging concern that have been detected which may pose threats to the ecosystem. Therefore, NYSDOH has selected optional analytes, from among chemicals of local concern to test for among its target subpopulation. The state currently lacks this information necessary to inform jurisdiction-specific public health actions and environmental protections (see further discussion in Section A.10.1).

*Intended use of the information.* At the federal level, the ATSDR biomonitoring results will have direct utility in providing parallel human chemical exposure information to complement GLRI environmental monitoring of legacy and emerging contaminants in biota, sediments, and water quality. The Action Plan will target and remediate contaminated sediments and address other major pollution sources in order to restore and “delist” the most polluted sites in the Great Lakes Basin (GLRI, 2010). Under its relevant focus area, “Toxic Substances and Areas of Concern,” findings about human exposures from the *2013 ATSDR Biomonitoring of Great Lakes Populations Program II* will likewise inform federal, state, and tribal policies and programs responsible for controlling and reducing environmental pollution in the selected areas and Great Lakes Basins.

At the local level, determining which Great Lakes contaminants are entering human populations above background levels will also inform state health officials and their public health actions and advisories throughout the restoration process. The results of this ICR will inform prevention of ongoing or future human exposures for the specific subpopulations within the state’s jurisdiction.

The core program objective is to provide a current ‘snap shot’ of human exposure levels among susceptible subpopulations living in Syracuse, NY. The ATSDR will not make direct statistical comparisons between the urban subsistence anglers and the refugees from Syracuse or with external subpopulations. To the extent that there are resources available in the future, it may be possible to design follow up studies that can help us understand whether body burdens of the contaminants of interest are changing in the subpopulations of interest. These data will provide a baseline assessment for tracking restoration progress in future decades.

Specific public health uses of the exposure information are:

- To determine which chemicals get into the target populations and at what concentrations.
- For chemicals with a known toxicity level, to determine the prevalence of people with levels above those toxicity levels (e.g., a blood lead level greater than or equal to 10 micrograms per deciliter [ $\geq 10 \mu\text{g/dL}$ ]).
- To descriptively compare concentration levels in the target populations to available reference values such as National Health and Nutrition Examination Survey (NHANES) *Fourth National Report on Human Exposure to Environmental Chemicals*.
- To track, over time, trends in levels of exposure of the target populations.

It is not the ATSDR's intent to pool the data for analysis across subpopulations or previous programs. The ATSDR serves as the steward and coordinator of the program to ensure adherence to the goals and objectives of the GLRI and to ensure scientific integrity. The ATSDR has provided technical oversight to ensure scientifically valid sampling strategies, collection of a core set of precise analyte quantification (including laboratory SOPs and QA/QC protocols), and the collection of relevant questionnaire information on exposure pathways, demographics, and lifestyles.

ATSDR has fully executed Interagency Agreements with EPA for FY 2013 and FY2014 in place for funding this cooperative agreement program with NYSDOH.

### **A.3. Use of Improved Information Technology and Burden Reduction**

The program will record all responses using paper questionnaires. The instruments for the Burmese and Bhutanese will be asked by interpreters, recruited and trained from the partner community centers, along with trained study interviewers. Respondent driven sampling (RDS) is the sampling strategy for both the Burmese and Bhutanese subpopulation and the subsistence angler subpopulation. For RDS, participants do not have scheduled appointments. Sampling, screening, and recruitment occur simultaneously on scheduled screening days. Typically, a large volume of people present to screening venues at the scheduled opening time and need to be processed. Based on NYSDOH's experience with the FY10 biomonitoring program, the program determined that using paper questionnaires is the most efficient mode of data collection for this RDS-based study; particularly since over 65% of respondents will be non-English speaking. Consent forms that collect the signature of participants will be paper instruments and a copy will be given to each respondent.

### **A.4. Efforts to Identify Duplication and Use of Similar Information**

ATSDR has determined that no similar data currently exists. The ATSDR efforts to identify duplication of the proposed ICR included reviews of existing reports and publications, attendance at national meetings, and consultations with state and other agencies and community representatives. Specifically, ATSDR worked with the NYSDOH to identify whether the proposed ICR is duplicated for 1) the proposed subpopulations; 2) the specific area; and 3) for the proposed chemical contaminants.

#### ***Review of Institutional Reports and Published Literature***

This proposed ICR has two target subpopulations, both aged 18-69 years and who eat their catch: 1) refugees from Burma and Bhutan who live in the City of Syracuse; and, 2) urban subsistence anglers who live in the City of Syracuse.

The 1992-1995 New York Angler Cohort Study characterized exposure to PCB congeners, DDE, hexachlorobenzene (HCB), and mirex in approximately 18,000 western New York state anglers from 18 counties, aged 18 to 40 years, who consumed Lake Ontario sport fish and waterfowl. Lipid-adjusted serum values for PCB congeners and mirex were significantly correlated with an

index of fish consumption (Vena 1996, Bloom 2008). The *2010 ATSDR Biomonitoring of Great Lakes Populations Program* covered three of the original 18 counties, measured legacy Great Lakes contaminants from the 1992-1995 study, and expanded the list of measured contaminants to lead, mercury, DDT and emerging chemicals of concerns. The current catchment area is the City of Syracuse, NY located along the shores of Onondaga Lake and will contribute biomonitoring information on legacy Great Lakes contaminants and emerging chemicals of concern in the selected subpopulations.

### Consultations

Since 2009 and in preparation for the original program announcement, award, and administration of the cooperative agreements, ATSDR has had ongoing consultations with US EPA's GLNPO, state environmental public health officials, environmental health laboratory scientists, and other stakeholders to identify program needs and specifications for the *ATSDR Biomonitoring of Great Lakes Populations Program II*.

Table 2. *ATSDR External Consultations*

Name	Title	Phone	Email
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Edwin (Ted) Smith	Environmental Engineer	(312) 353-6571	<a href="mailto:smith.edwin@epa.gov">smith.edwin@epa.gov</a>

Since 2009, ATSDR has had ongoing consultations with CDC laboratory scientists to determine appropriate required and state-optional analytes for this program. The CDC National Center for Environmental Health (NCEH) Division of Laboratory Sciences (DLS) produces periodic biomonitoring reports and national reference values on the U.S. general population exposure to environmental chemicals, such as the *Fourth National Report on Human Exposure to Environmental Chemicals 2009* and the *Updated Tables, February 2015* (see <http://www.cdc.gov/exposurereport>).

Table 3. *Consultations with CDC NCEH Laboratories*

Name	Title	Phone	Email
Kathleen Caldwell, PhD	Inorganic and Radiation Toxicology Branch	(770) 488-7990	<a href="mailto:kcaldwell@cdc.gov">kcaldwell@cdc.gov</a>
Antonia Calafat, PhD	Organic Analytical Toxicology Branch	(770) 488-7891	<a href="mailto:acalafat@cdc.gov">acalafat@cdc.gov</a>
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*Ongoing Consultations with Cooperative Agreement Partners.* For the currently proposed ICR, ATSDR will continue to work with the state health department investigators and their consultants to adopt questionnaire items and data collection forms; select state-specific chemical analytes and laboratory standard operating procedures, among other protocol requirements that were developed as part of the *2010 Biomonitoring of Great Lakes Populations Program* (OMB Control No: 0923-0044, expiration date 10/31/2015). These consultations are further detailed in Section A.8.



## A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

## A.6. Consequences of Collecting the Information Less Frequently

The 2013 *Biomonitoring of Great Lakes Populations Program* is a one-time data collection. There are no legal obstacles to reduce the burden.

## A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

## A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. 60-day Federal Register Notice was published in the *Federal Register* on August 25, 2014, Vol. 79, No. 164, pp. 50649 (provided in Attachment 2, and available at <https://federalregister.gov/a/2014-20100>).

CDC's Information Collection and Review Office (ICRO) received one request for the 60-day package including information collection plan and instruments from a reporter, Mr. Glenn Coin, from Syracuse. ICRO provided Mr. Coin the materials that he requested. No other comments or inquiries were received during the public comment period.

B. Under cooperative agreement, the ATSDR has worked directly with the following state health department investigators, staff, and their consultants to obtain their views on the availability of data, the clarity of instructions and record keeping, disclosure, or reporting format, and on the data elements to be collected. The NYSDOH sought the input of fisheries and wildlife management, pollution prevention agencies, community representatives, university researchers, and other public health surveillance programs.

Table 4. *New York State Department of Health\**

Name	Title	Phone	Email
<i>NYSDOH Center for Environmental Health, Bureau of Environmental and Occupational Epidemiology</i>			
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\* An early consultant, Ms. Gomez is currently working at a new assignment within the NYSDOH.

## A.9. Explanation of Any Payment or Gift to Respondents

NYSDOH has advised the ATSDR that tokens of appreciation for participation in the form of gift cards will increase the ability of this program to recruit hard-to-reach eligible respondents and to collect more reliable information on the proposed susceptible subpopulations. The use of tokens of appreciation has been shown to benefit other studies among special, often under-represented, populations (Singer, 2002).

RDS uses a chain referral sampling strategy. Referred individuals can present to scheduled clinics anytime during the date/hours on their referral coupon. Eligibility screening, recruitment and all biomonitoring study information collection occur at a single visit. Referred individuals who complete the screening interview but are ineligible or refuse to participate will be given a small gift for their effort (i.e., a T-shirt and fishing license case with the fish advisory website link). Eligible respondents who provide informed consent and take part in the study will receive a \$75 gift card as a token of thanks when they exit the clinic. Along with the \$75 gift card, each respondent will be invited to refer others using a coupon ration system (Attachment 4). Those who agree can recruit up to three other eligible respondents. The NYSDOH will give a \$15 gift card per successful recruit as thanks for the referring respondent's willingness to assist.

## A.10. Assurance of Confidentiality Provided to Respondents

The NCEH/ATSDR PRA Contact has determined that the Privacy Act does not apply to this data collection. The data will not be collected, maintained, or disseminated by an ATSDR information system. All records from the NYSDOH will be delivered to ATSDR as de-identified records, where they will be retrievable by study ID number only.

### IRB Approval

The *2013 Biomonitoring of Great Lakes Populations Program* is a non-research public health program because the biomonitoring results will not be generalized beyond the City of Syracuse, NY, and the defined subpopulations under study; therefore, CDC/ATSDR IRB approval is not required (Attachment 5a). The NYSDOH has reviewed and obtained its own local non-research determination (Attachment 5b). Although not human subjects as defined under 45 CFR 46 (for research only), the state interprets its own responsibilities to its respondents in a broader context.

### A.10.1. Privacy Impact Assessment Information

## Overview of the Data Collection System

NYSDOH will study two different subpopulations. Respondent refugees from Burma and Bhutan are largely unable to read written materials in their native dialects; therefore, study materials will be formatted in English. Interpreters and verbal translation services from English to ethnic dialect will be used to assure that the intent of the questions are properly conveyed and the translation of the responses from native dialect to English are accurately recorded on the forms. Urban subsistence anglers will be provided materials, instructions, and interviews in English and Spanish. Spanish language translation services will be obtained after OMB approval of the English language documents and forms. Program elements and data collections for the target subpopulations are described below.

RDS will be used both for refugees from Burma and Bhutan and for urban anglers from the low-income neighborhoods of Syracuse. An alternative sampling strategy such as RDS is suitable for reaching hidden populations for which there is no known sampling frame (Salganik & Heckathorn, 2004; Johnston & Sabin, 2010; Sabin, 2011). RDS has been successfully demonstrated in the *2010 Biomonitoring of Great Lakes Populations Program* (OMB Control No: 0923-0044, expiration date 10/31/2015) by the NYSDOH.

- Refugee Community from Burma and Bhutan:
  - o Population: Refugees from Burma and Bhutan, aged 18-69 years, who live in the City of Syracuse and eat fish caught in Onondaga Lake and its tributaries. The Burmese and Bhutanese Community is defined as refugees from Burma (Myanmar) or Bhutan and their descendants. The Burmese claim ancestry from indigenous ethnic groups like Burmese, Karen, Kachin, Chin, and Karenni. The Bhutanese are ethnic Nepalis, referred to as Lhotshampas, who were expelled from Bhutan beginning in 1991. A high proportion of recently admitted Bhutanese refugees lived for several years in refugee camps in Nepal before coming to the U.S. These communities were resettled in the City of Syracuse by the United Nations in 2008 (<http://onondagacitizensleague.org/wp-content/uploads/2013/09/OCL-Refugees-2013-w-final.pdf>).
  - o Organizations with ties to this community, such as Catholic Charities of Onondaga County (<http://www.ccoc.us/>) and Interfaith Works of Central New York Refugee Resettlement Program will help identify five to eight initial recruits (referred to as “seeds”) who are socially well-connected, respected in the community, and interested in participating. These agencies provide many services to the refugees including employment, health, interpretation, family support groups, transportation, and educational and legal consult. NYSDOH will work with such agencies to support outreach and study recruitment, and to maximize response rates.
- Subsistence Anglers:

- o Population: Subsistence anglers aged 18 to 69 years who fish in Onondaga Lake or its tributaries and eat their catch. This urban, poor and subsistence population consumes locally caught fish as a source of food, and resides primarily in the Southwest neighborhood of Syracuse, New York (see Attachment 6).
- o Organizations with ties to this community, such as Jubilee Homes (<http://www.jubilee-homes.com>) and the Syracuse Model Neighborhood, Inc. (<http://smnfwcc.org/>), will help identify two to five initial recruits (referred to as “seeds”) who are socially well-connected, respected in the community, and interested in participating. Social connections are expected to be relatively strong among some residents of low-income areas, via residential proximity, use of neighborhood schools, churches, membership in community organizations, and social service agencies.

The ICR will be implemented in three main phases: eligibility screening and recruitment; informed consent; and the biomonitoring assessment which consists of personal interviews, measurement of height, weight and blood pressure, and collection of blood and urine samples.

- Sequence of RDS Procedures:
  - o NYSDOH will contract with resettlement agencies and community organizations to hire trained interpreters for the interview process, and to help find “seeds” in the target populations. Other than these circumstances, the majority of the data collection will be done by NYSDOH staff with plans to hire full time interviewers and a data analyst.
  - o Information sessions to instruct seeds to administer the RDS coupon to their peers will be held prior to the beginning of recruitment. The sessions will be led by NYSDOH project staff and a key organizational staff member. A project information sheet has been developed to promote the study (Attachment 7). RDS sampling, screening, and recruitment will occur simultaneously.
  - o During the eligibility screening and personal interview, structured questionnaires will be administered. These structured questionnaires will consist of questions adapted from the *2010 ATSDR Biomonitoring of Great Lakes Populations Program* (OMB Control No: 0923-0044, expiration date 10/31/2015). The NYSDOH program will record all responses using paper questionnaires. The previously approved questionnaire items have been tailored to Onondaga Lake and surrounding areas, local fish species and the target subpopulations. Proposed modifications are described in Attachment 8: 8a1 – 8h1. Each line in the annualized burden table in Section A.12 reflects the state’s data collection forms.
  - o All RDS-identified community members will respond to the Eligibility Screening Survey by paper-and-pencil personal interview (Attachment 8a, Bhutanese and Burmese, Attachment 8e, Subsistence anglers). The eligibility screening will assess age, frequency of eating fish caught in Onondaga Lake and its tributaries,

and residence in the City of Syracuse or its surrounding communities for at least one year. Core personal interview questionnaire domains include demographic information, residential history, housing characteristics, job history, lifestyle factors, dietary intake, recreational activities, smoking history, fish consumption patterns with a focus on fish species and locally caught fish, and reproductive history in women.

- Enrollment: Informed consent will be documented on a paper-and-pencil form (Attachment 8b, Bhutanese and Burmese, Attachment 8f, subsistence anglers). The NYSDOH will provide information on each respondent's rights and protections, such as for privacy and informed consent (Attachments 8b & 8f).
  - Interview: Responses to the Interview Questionnaire will be collected by paper-and-pencil personal interview (Attachment 8c, Bhutanese and Burmese, Attachment 8g Subsistence anglers). During this phase blood and urine specimens and body measures will be collected.
  - Enrolled respondents will answer Network Size Questions for RDS by paper-and-pencil personal interview (Attachment 8d, Bhutanese and Burmese, Attachment 8h Subsistence anglers).
- Recruitment: After the interview, each participant will be invited to be a recruiter. If the participant accepts, he/she is trained to recruit other persons like him/herself. Each recruiter is then given three referral coupons and three payment coupons (Attachment 4).

### *Items of Information to be Collected*

NYSDOH will acquire information in identifiable form (IIF) permitting eligibility screening and results reporting to respondents. The categories of directly identifiable information to be collected include: names, date of birth, street address, mailing address, phone numbers, email addresses, and biological specimens. At this point, the IIF will be stored and managed in New York's already established record system by their authorized and trained staff.

Information in identifiable form (IIF) will not be part of the deliverables to ATSDR. ATSDR will not receive identifying information including: name, address, residential history, and household demographics. ATSDR will also not receive information that in 'raw' form may indirectly identify an individual. For example, occupation will be classified into one of 23 major groups according to the 2010 Standard Occupational Classification (SOC) system. Furthermore, data will be collapsed into groups for any cross-tabulation of data that results in a 'cell size' of 5 or less.

The ATSDR program has required a core set of Great Lakes legacy contaminants for biomonitoring which were selected based on established analytical methods and human burden. NYSDOH proposes to analyze the same set of analytes and use the same analytical methods as

the FY2010 biomonitoring of licensed anglers and Burmese refugees living in Great Lakes areas of contamination. NYSDOH will include the core set of chemicals to be analyzed in blood and urine specimens. Optional state-specific chemical analytes of local concern will also be measured. The laboratory analyses will be provided by NYSDOH's Wadsworth Center laboratories (Attachment 9 – Program Laboratory Policies and Procedures; Attachment 9a – Chemical Analytes and Justification). Blood and urine specimens will be labeled by study ID number only. Laboratory personnel will not see or have access to any records with IIF.

- QA/QC and interlaboratory proficiency testing will be implemented in accordance with the program's laboratory procedures policy (Attachment 9b).
- The New York State Department of Health (NYSDOH) laboratory is approved by the Clinical Laboratories Improvement Amendments of 1988 (CLIA). The state laboratory's current CLIA certificates are included (Attachment 9c).
- The NYSDOH laboratory participates in the Arctic Monitoring and Assessment Program (AMAP). AMAP designed and implemented a coordinated external proficiency testing and monitoring program to monitor levels of pollutants and assess the effects of pollution in all compartments of the Arctic environment (atmospheric, terrestrial, freshwater and marine environments, and human populations). The current AMAP external proficiency test reports are included in Attachment 9d).
- Standard operating procedures (SOPs) for each of the laboratory methods are included in Attachment 9e1 through Attachment 9e7.

A secondary purpose of this IC is to obtain demographic factors and lifestyle information that potentially contribute to a higher likelihood of exposures including: ethnicity and race or tribal affiliation, age, sex, education and income level, dietary patterns, hobbies, occupations and employment status, residential history, and household exposures (Attachments 8c & 8g). Some items purely of local interest are collected as a benefit to the community and for the individual respondent. These response items will not be delivered to ATSDR. For example, the NYDOH will ask household information to evaluate potential public health impact of sharing locally caught fish and associated outreach.

Some health-related items will be collected to better understand exposure levels. Since lipophilic compounds like PCBs and pesticides are stored and released from fat tissue, measures of obesity serve as important information to evaluate chemical body burden levels. For example, height and weight will be used to calculate body mass index (BMI) by NYSDOH. Cholesterol and triglycerides are part of the laboratory process to perform lipid adjustment of lipophilic compounds. The NYSDOH program will provide respondent feedback on BMI, blood pressure, cholesterol, and triglycerides as a public health service. The ATSDR will not receive data on cholesterol, triglycerides and blood pressure.

### *How Information will be Shared and for What Purpose*

The NYSDOH has materials and methods to provide the respondent with his or her own biomonitoring results (Attachment 10). As soon as laboratory results become available to the state principal investigator (PI), individual results reporting will begin. The analytical results will be examined and properly routed based on established threshold and alert values. NYSDOH has developed individual results reporting form templates (Attachments 10a and 10b), so that the respondent's own biomonitoring results are disseminated as rapidly as possible.

An overview of the state-required and provisional action levels are provided in Attachment 10:

1. Indicators for analytes of clinical relevancy (i.e. of known health consequence with associated action levels or interpretation), such as for toxic or heavy metals, nutrients, and blood pressure;
2. Laboratory analytes measured in biological matrices;
3. Individual biomonitoring results to be reported or not reported to the respondent;
  - a. The individual analyte results to be reported are those generated from CLIA-approved laboratory methods. For example, NYSDOH is not CLIA-approved for PBDEs, PFCs, and toxaphene; these results will not be included in Attachment 10a. The methods used to analyze the required analytes are all CLIA-approved methods; the required analyte results will be reported back to individual respondents.
4. Consistent with the FY2010 program, national reference values, such as those from the *Fourth National Report on Human Exposure to Environmental Chemicals 2009* or the corresponding *Updated Tables, February 2015* (See <http://www.cdc.gov/exposurereport/>) will be used to make comparisons to the U.S. general population.
  - a. Attachment 10 delineates those analytes with NHANES reference values, and the year of collection.
  - b. Where those data are lacking, or where established clinical guidelines are available, Attachment 10 provides alternative published sources of reference values.
  - c. For some chemicals, no NHANES reference range values are available. These measures will be compared to self-reported dietary fish intake assessed by questionnaire.
5. Rapid toxic metals reporting (See Attachment 10 for action levels).

The New York State Department of Health (NYSDOH) Heavy Metals Registry (HMR) is a tool for the surveillance of adult exposures to lead, mercury, cadmium and arsenic. The HMR was established in 1980 under the State Sanitary Code (10 NYCRR) and authorized by Public Health Law. Reporting to the HMR began in 1982. The NYSDOH receives reports of all blood lead tests performed on New York State residents, along with reportable levels of mercury, arsenic and cadmium. Once reports are received, registry staff conduct interviews to determine the source of exposure, for those heavy metal levels exceeding certain thresholds, which vary by metal and gender. When the threshold is exceeded, information is provided to exposed individuals and employers on reducing hazards and eliminating exposure. Where it appears that family members may be exposed, recommendations are made for reducing exposure and the local health

department is contacted, if applicable  
([http://www.health.ny.gov/environmental/workplace/heavy\\_metals\\_registry/](http://www.health.ny.gov/environmental/workplace/heavy_metals_registry/)).  
Attachment 10b provides a metals report template that can be used in the event an action level is exceeded for heavy metals.

### ***Impact the Proposed Collection will have on Respondent Privacy***

Because the NYSDOH will store, manage, and maintain IIF on their already established record systems, there would be a likely effect on the respondent's privacy if a breach of data security occurred. Therefore, the established state record system has stringent safeguards in place. For ATSDR, de-identified information that might be considered sensitive, such as pregnancy status in the past year among female respondents, will not have associated information that might directly identify these respondents; therefore, after data delivery the proposed data collection will have little or no effect on the respondent's privacy.

### ***Voluntary or Mandatory Nature of the Provision of Information***

All respondents will be informed about the voluntary nature of their responses in program materials and during informed consent.

### ***Opportunities to Consent to Sharing and Submission of Information***

During the informed consent process, all respondents will be told about the measures that will be taken to keep their identity safe from disclosure. Eligible refugees from Burma and Bhutan and urban subsistence anglers will meet with trained study staff in a private setting. After the respondents have had sufficient time to read the consent form and ask questions, written informed consent will be obtained. Any respondent indicating difficulty with reading will have the consent document read to him or her by the interviewer or an interpreter trained in appropriate Burmese or Bhutan dialects or Spanish language.

### ***How Information will be Secured***

At the end of the data collection, the NYSDOH will deliver its de-identified data to ATSDR, through a secure and encrypted file transfer protocol. Data received by ATSDR will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

At CDC/ATSDR, data security is maintained by policies on physical, technical, and administrative controls that comply with the *CDC/ATSDR Protection of Information Resources Policy* and the *CDC/ATSDR IT Security Program Implementation Standards*. These policies apply to all authorized ATSDR employees and contractors.

Physical controls – The CDC/ATSDR issues identity credentials based on the Federal Information Processing Standards (FIPS) Publication 201 for Personal Identity Verification (PIV) authentication of government employee and contractor identities. This credential is referred to as a PIV Card; it employs microprocessor-based smart card technology, and is designed to be counterfeit-resistant, tamper-resistant. Security measures for physical access to



secured facilities include the use of PIV Cards, security guards, and closed circuit TV monitoring.

Technical Controls – CDC/ATSDR policy requires employees to gain authorized logical access to its information systems through the use of PIV Cards and associated PIN. Computer-controlled limits on what can be done by the “User ID” are assigned based on program roles and privilege requirements.

Administrative Controls –Authorized CDC/ATSDR employees and contractors are required to:

- Complete required privacy and information security refresher training.
- Read, acknowledge, sign (if online completion is not available), and comply with the HHS Rules of Behavior, as well as other applicable CDC/ATSDR- and system-specific rules of behavior before gaining access to the CDC/ATSDR’s systems and networks.
- Adhere to the requirements set forth in the *CDC/ATSDR IT Security Program Implementation Standards*, and other security policies and procedures that minimize the risk to CDC systems, networks, and data from malicious software and intrusions.
- Abide by all applicable acceptable use policies and procedures regarding use or abuse of CDC/ATSDR IT resources.

At the completion of the state data collection, ATSDR requires that the program provide data deliverables. ATSDR will serve as the central data repository. Federal programs are encouraged to make data collected with federal funds available to investigators to maximize the public health benefit. ATSDR understands the importance of maintaining individual confidentiality in sharing data. Prior to the transfer of data, ATSDR will establish a Data User Agreement with each state program in consultation with the National Center for Health Statistics (as an independent subject matter expert) to utilize rigorous de-identification/privacy standards. Prior to delivery of de-identified records to the ATSDR, the provision of data security by the NYSDOH is described below.

The State of New York Committee on Open Government has enacted its *Personal Privacy Protection Law* (<http://www.dos.ny.gov/coog/pppl.html>) under the *Public Officers Law, Article 6A*. As defined under Section 92 Paragraph 11, the term "system of records" means any group of records under the actual or constructive control of any state agency pertaining to one or more data subjects from which personal information is retrievable by use of the name or other identifier of a data subject. The remainder of the law describes the agency obligations, and the permitted circumstances for granting or denying access to or disclosure of records.

Pursuant to the *Personal Privacy Protection Law*, any electronic data generated for the project will be stored on a password-protected network in project-specific password-protected folders. If it is necessary for data collected in the field to be stored electronically, the computers will be password protected, hard drives encrypted, and data deleted within a specified timeframe. All data collected electronically in the field will be encrypted, backed up daily on an external hard drive, and comply with NYSDOH security guidelines, with oversight by NYSDOH IT specialists. Alternatively, using an AirCard®, data can be transmitted back to the NYSDOH Center for Environmental Health using the HCS Secure File Transfer Utility. Personal

identifiers will be stored locally in a separate database and will not be transmitted with sample results or interview data.

No websites will be developed to collect information for the *ATSDR Biomonitoring of Great Lakes Populations Program II*. No websites or website information will be directed at children under 13 years of age. Participants will be at least 18 years of age.

#### ***System of Records Requirements under the Privacy Act.***

No ATSDR system of records applies to this ICR. All IIF will be stored and managed in NYSDOH's already established record system. The NYSDOH health department will use the IIF for the purposes reporting of results to respondents.

- Per respondent consent, the NYSDOH will store biological specimens (blood and urine) after completion of the study period. These biological specimens will be used to measure analytes whose laboratory test methods are still under development. Additionally, these stored specimens may be used to test for other environmental contaminants that may be found in the Great Lakes in the future. IIF will be retained for consenting respondents who wish to be notified about future analytical tests (Attachments 6b & 6f). All directly identifiable information for respondents who consent to future contact will remain in the already established NYSDOH record system with a mechanism to relink their IIF for future analytic testing by NYSDOH.
- The NYSDOH will deidentify all records to be delivered to the ATSDR, according to CDC/ATSDR deidentification standards. Examples of such standards include the CDC Public Health Information Network (PHIN) or Biosense models. Deliverables will be in the form of Statistical Analysis Software (SAS; Cary, NC) flat files. Files will be delivered to the ATSDR in an approved manner for secure and reliable transmission. Transmission is not anticipated to occur until the year 2017.

#### **A.11. Justification for Sensitive Questions**

*Pregnant Women.* A history of pregnancy or breastfeeding in the past 12 months will be asked of all women during the interview. Pregnancy and breastfeeding can mobilize and, consequently, alter levels of some contaminants. The NYSDOH will account for potential effect modification from pregnancy and breastfeeding among women during statistical analysis. In support of their biomonitoring efforts among female respondents, NYSDOH is asking additional questions about reproductive history prior to the past 12 months. Women will be asked to list the years in which children were born and the number of months each one was breastfed. As previously described, the number of pregnancies and duration of lactation is needed to help understand the effect of these physiological processes which mobilize some of the analytes from body stores in fat and bone among the female respondents. The state does not report any cultural concerns in asking these questions among their refugee subpopulation.

## A.12. Estimates of Annualized Burden Hours and Costs

The burden estimates published in the 60-day FRN were based on informal testing among state health department program staff. IRB nonresearch determinations and reviews were completed during the 60-day comment period. During this period, the NYSDOH revised its protocol and tested its subpopulation-specific forms among fewer than 10 respondents. NYSDOH tested its full-length questionnaire among a maximum of four respondents per subpopulation. We anticipate that patterns of fish consumption will be the chief contributor to variability in questionnaire time burdens among the selected subpopulations.

With respect to time burdens for the state’s questionnaires, the NYSDOH questionnaire for urban subsistence anglers is estimated to take 30 minutes. The questionnaires for the NYSDOH refugees from Burma and Bhutan are estimated to take approximately 45 minutes. The Burmese, Bhutanese questionnaire will take longer to administer than the angler questionnaire for three primary reasons: 1) NYSDOH has been informed that the Burmese and Bhutanese do not like to be rushed through an activity; 2) the process of administering questionnaires to the Burmese and Bhutanese involves translations, which are expected to add to the required time; and 3) there is additional content in the Burmese/Bhutanese questionnaire due to anticipated higher fish consumption, more varied fish preparation, and more complex fish-eating histories.

A. Estimated annualized burden hours, averaged over the requested two year approval period, are presented for each study population and in total.

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Refugees from Burma and Bhutan	Eligibility Screening Survey	212	1	5/60	18
	Informed Consent	150	1	1/60	3
	Interview Questionnaire	150	1	45/60	113
	Network Size Questions for Respondent Driven Sampling	150	1	5/60	13
	Blood Collection	150	1	15/60	38
	Urine Sample	150	1	10/60	25
Urban subsistence anglers	Eligibility Screening Survey	90	1	5/60	8
	Informed Consent	50	1	1/60	1
	Interview Questionnaire	50	1	30/60	25
	Network Size	50	1	5/60	4

	Questions for Respondent Driven Sampling				
	Blood Collection	50	1	15/60	13
	Urine Sample	50	1	10/60	8
Program Grand Total					269

B. Estimated annualized burden costs are presented for study population and in total. To estimate the cost to the respondent, the median hourly wage was selected for all occupations for the metropolitan statistical areas (MSAs) corresponding to Syracuse, NY.

On an annualized basis, NYSDOH will recruit a total of 150 Burmese and Bhutanese refugees and 50 urban subsistence anglers located in Syracuse, NY each year of the two-year data collection. The 2013 median hourly wage for the MSA that corresponded to Syracuse, NY was applied.

Type of Respondents	Total Burden (in hours)	Hourly Wage Rate	Total Burden Costs
Refugees from Burma or Bhutan	210	\$17.33	\$3,639
Urban Subsistence Anglers	59	\$17.33	\$1,022
Program Grand Total			\$4,662

Source: BLS, 2013. May 2013 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates: Median Hourly Wage for All Occupations. <http://www.bls.gov/oes/current/oesrcma.htm>.

### A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no additional capital and maintenance costs for the *ATSDR Biomonitoring of Great Lakes Populations Program II* for respondents or record keepers.

### A.14. Annualized Cost to the Government

The Environmental Protection Agency has transferred funding and responsibility for executing this program to ATSDR under an interagency agreement (IAA) for the *ATSDR Biomonitoring of Great Lakes Populations Program II*.

The total estimated cost to the government is \$1.26 million, based on the current actual costs for the first year spent in protocol and ICR development and the estimated costs for this program's request to collect information over the next 2 years.

The estimated average annualized cost of the program is \$631,000.

- Personnel: \$37,750 per year. This is based on percentages of time spent on the project by ATSDR staff.
- Travel: \$3,250 per year. This amount is based on the number of site visits conducted following the General Services Administration Schedule for travel and per diem.

- Cooperative Agreements: \$590,000 per year. This amount is based on the approved applications of the current grantee.

### A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

### A.16. Plans for Tabulation and Publication and Project Time Schedule

Upon completion of data collection and laboratory analysis, NYSDOH will tabulate and report individual results of laboratory analysis back to the respondent. In the event that clinically significant laboratory results are detected, such as for toxic metals like mercury and lead, the principal investigator will provide advance notification to the respondents. Summary reports will be tabulated and released to the public.

Six months of the program period was dedicated to planning and protocol development. Upon receiving their first year awards, NYSDOH has been working on outreach, health education, planning activities, piloting instruments for clarity and burden estimation (9 or fewer people), and protocol development and IRB review for data collection. The state also assisted the ATSDR in developing this ICR.

IC procedures will begin upon the date of OMB approval. Therefore, the two years of information collection will require a timely approval of this ICR to complete this federal acquisition.

The schedule for project completion is as follows:

Activity	Time Schedule*
Formative work to learn about characteristics of the social networks in each target community for RDS and identification of 'seeds' (by NYSDOH and 9 or fewer local community leaders)	1-2 months after OMB approval
Recruit and enroll, interview, and blood and urine specimens collection for each subpopulation (by NYSDOH)	2-8 months after OMB approval
Laboratory analysis (by NYSDOH Wadsworth Center)	3-15 months after OMB approval
Data validation, data entry, data analysis complete (by NYSDOH)	12-18 months after OMB approval
Respondent results reporting complete (by NYSDOH)	12-18 months after OMB approval
Summary study reports complete (by NYSDOH)	18 months after OMB approval
Data transfer to ATSDR (by NYSDOH)	18 months after OMB approval

#### **A.17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The *ATSDR Biomonitoring of Great Lakes Population Program II* will display the OMB Control Number and expiration date on all data collection forms as required.

#### **A.18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## LIST OF ATTACHMENTS

### Attachment 1. Authorizing Legislation

Attachment 1a. *Department of Interior, Environment, and Related Agencies Appropriations Act, 2010 (Public Law 111-88)*

Attachment 1b. *Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and Superfund Amendments and Reauthorization Act of 1986 (SARA)*

### Attachment 2. 60-Day Federal Register Notice

### Attachment 3. Program Overview

### Attachment 4. Example RDS Referral Coupon

### Attachment 5. Determination Letters of Non-research Status

Attachment 5a. *ATSDR Determination Letter of Non-research Status*

Attachment 5b. *NYS DOH Determination Letter of Non-research Status*

### Attachment 6. Map of Syracuse census tracts by poverty rate

### Attachment 7. Program Information Sheet

### Attachment 8. New York State Department of Health Data Collection System

Attachment 8a. *Eligibility Screening Survey, Burmese and Bhutanese*

Attachment 8a1. *Changes to form approved OMB No.0923-0044 (Attachment 6h)*

Attachment 8b. *Informed Consent, Burmese and Bhutanese*

Attachment 8b1. *Changes to form approved OMB No.0923-0044 (Attachment 6i)*

Attachment 8c. *Interview Questionnaire, Burmese and Bhutanese*

Attachment 8c1. *Changes to form approved OMB No.0923-0044 (Attachment 6j)*

Attachment 8d. *Network Size Questions for Respondent Driven Sampling, Burmese and Bhutanese*

Attachment 8d1. *Changes to form approved OMB No.0923-0044 (Attachment 6k)*

Attachment 8e. *Eligibility Screening Survey, Urban Subsistence Anglers*

Attachment 8e1. *Changes to form approved OMB No.0923-0044 (Attachment 6h)*

Attachment 8f. *Informed Consent, Urban Subsistence Anglers*

Attachment 8f1. *Changes to form approved OMB No.0923-0044 (Attachment 6f)*

**Attachment 8g. Interview Questionnaire, Urban Subsistence Anglers**

**Attachment 8g1. Changes to form approved OMB No.0923-0044 (Attachment 6g)**

**Attachment 8h. Network Size Questions for Respondent Driven Sampling, Urban Subsistence Anglers**

**Attachment 8h1. Changes to form approved OMB No.0923-0044 (Attachment 6k)**

**Attachment 9. Program Laboratory Policies and Procedures**

**Attachment 9a. New York State Department of Health Chemical Analytes  
Chemical Analytes Justification**

**Attachment 9b. Biomonitoring of Great Lakes Populations Laboratory QA/QC  
Procedures**

**Attachment 9c. Clinical Laboratory Improvement Amendments (CLIA) Certificate**

**Attachment 9d. NY AMAP Proficiency Test Reports**

**Attachment 9e. Laboratory Standard Operating Procedures New York State Public  
Health Laboratory**

**Attachment 9e1. SOP #1 - PCB Analysis**

**Attachment 9e2. SOP #2 - Blood Metals**

**Attachment 9e3. SOP #3 - Mirex**

**Attachment 9e4. SOP #4 - Polycyclic Aromatic Hydrocarbons**

**Attachment 9e5. SOP #5 - Urine Mercury**

**Attachment 9e6. SOP #6 - Perfluorinated Compounds**

**Attachment 9e7. SOP #7 - Serum Cholesterol/Triglycerides and Urine  
Creatinine**

**Attachment 10. New York Results Reporting and Communications**

**Attachment 10a. Sample letter reporting metal results**

**Attachment 10b. Sample letter reporting chemical, cholesterol, and triglyceride results**