

Assessment of STLT Public Health Agencies to Guide the Update of CDC/ATSDR Cancer Cluster Guidelines

CSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Program Official/Project Officer

Alisha Etheredge, MS, MPH
Public Health Advisor
Centers for Disease Control and Prevention
4770 Buford Highway, S106-6, Atlanta, GA 30341
Office: 770-488-7884
Fax: 770-488-0333
aetheredge@cdc.gov

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- **Purpose of the data collection**

The purpose of this proposed data collection is to assess current state, tribal, local, and territorial (STLT) public health agency's current approaches, best practices, and capacity for addressing cancer cluster inquiries that can be used to inform CDC/ATSDR's update of federal cancer cluster guidelines.

- **Intended use of the resulting data**

The information collected will aid in understanding some of the challenges faced and best practices used when STLT public health agencies respond to cancer cluster inquiries in their communities. This information will help inform CDC/ATSDR's update of federal cancer cluster guidelines and assist in understanding STLT public health agency needs for other tools and guidance to assist them in better preparing for and responding to cancer clusters.

- **Methods to be used to collect data**

Data will be collected via an electronic assessment and virtual group interviews.

- **Respondent Universe**

The respondent universe for the electronic assessment includes a total of 3,070 (50 state, 3000 local, 12 tribal epidemiology centers, 5 territorial and 3 freely associated state) health departments. The respondent universe for the virtual group interviews include up to 120 multi-disciplinary STLT public health agency staff involved in assessing and responding to cancer cluster inquiries. The total respondent universe for the electronic assessment and virtual interviews is 3,190. All respondents will be acting in their official capacities.

- **How data will be analyzed**

Both quantitative and qualitative methods will be used to analyze the data. Close-ended questions will be analyzed using quantitative methods, specifically descriptive and inferential statistics. Open ended questions will be analyzed using qualitative methods, specifically thematic analysis to extract themes among participant responses.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using OMB No. 0920-0879 "Information Collections to Advance State, Tribal, Local and Territorial Governmental Agency System Performance, Capacity, and Program Delivery" nicknamed the "CSTLTS Generic." The respondent universe for this information collection aligns with that of the CSTLTS Generic. Data will be collected from a total of 3,190 respondents across 3,070 (50 state, 3000 local, 12

tribal epidemiology centers, 5 territorial, and 3 freely associated state) health departments. All respondents will be acting in their official capacities.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems¹

In 2018, there were approximately 1,735,350 incident cases of cancer and 609,640 deaths caused by cancer in the United States. While 38.4 percent of men and women will be diagnosed with a cancer at some point in their lifetime, communities are often alarmed by suspected cancer clusters. Due to the relatively common nature of cancer and many analytical challenges with confirming a cluster, it is often difficult to conclude if a suspected cluster of cancers is a true cancer cluster, and to further identify a potential cause.

CDC's National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) are at the forefront of providing technical assistance to public health practitioners in STLT public health agencies to investigate suspected cancer clusters. In September 2013, NCEH/ATSDR and the Council of State and Territorial Epidemiologists (CSTE) published guidelines in the Morbidity and Mortality Weekly Report for public health agencies to respond to and investigate suspected cancer clusters in their communities in a systematic way – *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists* (2013 Guidelines). The 2013 Guidelines outline four key steps for evaluating suspected cancer clusters, including: initial contact and response, assessment, determining the feasibility of conducting an epidemiologic study, and conducting an epidemiologic study to assess the association between cancers and environmental causes.

While the 2013 Guidelines have provided many public health agencies with valuable resources for investigating cancer clusters, new technical and scientific innovations in the

field (e.g., cancer genomics, new biological markers for cancer tumors, advances in geographic information system methodologies and spatial statistics, new systems for residential history searches) warrant review and revision of the 2013 CDC/CSTE guidelines. To ensure that STLT public health agencies and stakeholders have access to information about current scientific tools and approaches to assess and respond to potential cancer clusters in communities, NCEH is working with ATSDR to update the 2013 Guidelines.

In the fall of 2018, NCEH/ATSDR began working to update federal guidelines for investigating potential cancer clusters, in accordance with \$1 million FY2019 Congressional appropriation to CDC to implement section 399V-6(c) of the Public Health Service Act, also known as “Trevor’s Law.” Trevor’s Law was passed in 2016 as a provision within the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

To guide the update of the 2013 Guidelines and assist in developing other tools and guidance that can be used by STLT public health agencies, NCEH/ATSDR will collect two types of information:

1. An electronic assessment of 3,070 STLT public health agencies (i.e., 50 state, 3000 local, 12 tribal, 5 territorial and 3 freely associated states) will be conducted to understand the current activities related to cancer cluster inquiries, available and needed resources, and ways to improve how STLT public health agencies address cancer cluster inquiries. One epidemiologist (or their designee) will complete the assessment on behalf of their public health agency (one response per agency).
2. Up to ten focus groups will be conducted with a total of up to 120 STLT public health agency professionals and staff who have a role in responding to cancer clusters in their communities.

NCEH/ATSDR has funded a contract with ICF, a global consulting services company, to assist with the planning, facilitation, and reporting of the focus groups. NCEH/ATSDR will provide oversight of all contractor activities and ensure completion of the data collection. In addition to ICF, eight subject matter experts were consulted on the development of the data collection instruments. These individuals volunteered their support. NCEH/ATSDR will develop and conduct the electronic assessment independently.

The purpose of this NCEH/ATSDR-led information collection is to assess current state, tribal, local, and territorial (STLT) public health agency’s current approaches, best practices, and capacity for addressing cancer cluster inquiries that can be used to inform CDC/ATSDR’s update of federal cancer cluster guidelines. In accordance with the Trevor’s Law provision within the Frank R. Lautenberg Chemical Safety for the 21st Century Act, CDC/ATSDR is updating its federal guidelines for investigating potential cancer clusters.

The information collected will be used by NCEH/ATSDR to inform and improve the current 2013 Guidelines, and to determine the need for additional tools and guidance to assist STLT

public health agencies in assessing and responding to cancer cluster inquiries in their communities.

Overview of the Information Collection System

Electronic Assessment:

Data will be collected from 3,070 (50 state, 3000 local, 12 tribal epidemiology centers, 5 territorial and 3 freely associated state) health department epidemiologists (or their designated representatives) via electronic assessment (see **Attachment A – Assessment: Word Version** and **Attachment B – Assessment: Web Version**) using REDCap, a secure web application for building and managing online surveys and databases. The instrument will be used to gather information from STLT health departments regarding their current activities related to cancer cluster inquiries, available and needed resources, and ways to improve how STLT public health agencies address cancer cluster inquiries.

The information collection instrument for the electronic assessment was pilot tested by five public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the information collection instrument.

Focus Groups:

Data will be collected from up to 120 multi-disciplinary STLT public health agency staff involved in assessing and responding to cancer cluster inquiries across 50 state, five territorial, and two freely associated state health departments, via small discussion groups (see **Attachment C – Focus Group Facilitator’s Guide**). The multi-disciplinary staff will include any staff involved in assessing and responding to cancer cluster inquiries, which could include health communicators, epidemiologists, program coordinators, cancer registry administrators and directors, cancer program managers, or research and statistical analysts. Up to ten focus groups will be conducted. The instrument will be used to gather information from health department staff involved in assessing and responding to cancer cluster inquiries, regarding how public health agencies address cancer cluster inquiries, best practices, and ways to improve how STLT public health agencies address cancer cluster inquiries. The focus groups will serve as an opportunity to collect more detailed information than would be possible with an assessment. Because each jurisdiction and their process for assessing and responding to cancer cluster inquiries is different, some information cannot be gleaned solely from an electronic assessment. Therefore, a focus group will allow more detailed information to be collected regarding current processes and procedures and resources needed to assist each jurisdiction. Additionally, the focus groups will encourage discussion among health department staff, offer an opportunity to seek clarification from responses obtained in the electronic assessment, and provide a deeper

understanding of the true needs and concerns of health department staff. Each focus group will be limited to no more than two participants per health department.

The information collection instrument for the focus group was pilot tested by three public health professionals. Feedback from this group was used to refine questions as needed and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The first primary data collection for this assessment is the electronic assessment instrument (see **Attachment A – Assessment: Word Version** and **Attachment B – Assessment: Web Version**). The data collection instrument consists of 55 main questions of various types, including dichotomous (yes/no), multiple response, interval (rating scales), open-ended text entry.

In order to assess the current processes and practices used when responding to cancer cluster inquiries, and to determine the areas that may need the most attention in the guideline update, the instrument will collect data on the following areas:

- Agency background information (e.g., agency name, jurisdiction type)
- Use of 2013 CDC/CSTE Cancer Cluster Guidelines (e.g., are STLT agency protocols modeled after 2013 Guidelines?)
- Cancer cluster inquiries and response activities (e.g., frequency of cancer cluster concerns from the public, tracking system for inquiries, number of inquiries about excess cancer received in 2019 and source of inquiries)
- Communication with the public (e.g., use of CDC cancer cluster investigation communications toolkit)
- Cancer cluster response staffing (e.g., type of STLT public health agency personnel who are involved with cancer cluster inquiries)
- Barriers, facilitators, and needed resources for addressing cancer cluster inquiries (e.g., what can CDC do to assist STLT public health agencies to more effectively respond to cancer cluster inquiries?)
- Best practices and recommendations for updated Guidelines (e.g., what does your STLT public health agency do to respond to cancer cluster inquiries that you believe is a best practice?)

The final method of primary data collection is the virtual focus group discussion instrument (see **Attachment C – Focus Group Facilitator’s Guide**). This consists of nine main, open-ended questions, along with several sub questions and probes. In order to gather in-depth information on current health department processes and practices when responding to cancer cluster inquiries and how CDC can update the current guidelines to address challenges and opportunities, the focus groups will collect data on the following topics:

- Overall response to inquiries about excess cancer

- o How jurisdiction manages and responds to inquiries about excess cancer (step-by-step process);
- o Information provided to inquirer during the initial communication response;
- o Information elicited from the inquirer during the initial communication;
- o Actions taken by the agency after receiving and responding to the initial inquiry;
- o Who reviews, triages, and addresses inquiries about excess cancer;
- o When and how cancer data is evaluated;
- o When and how environmental data is reviewed;
- o The process for determining when and how inquiries are closed;
- o The process for determining a satisfactory outcome of a cancer cluster inquiry;
- o Approaches that work well for communicating with the public about potential cancer clusters.
- Federal Support and Updated Guidelines
 - o Under what circumstances the agency requested assistance from CDC or ATSDR related to inquiries about excess cancer;
 - o How CDC/ATSDR can best support the agency's response to inquiries;
 - o Aspects of the 2013 CDC/CSTE Guidelines that should be retained or removed or revised;
 - o Aspects of the 2013 CDC/CSTE Guidelines that should be changed or improved upon.

2. Purpose and Use of the Information Collection

The purpose of this NCEH/ATSDR-led information collection is to assess current state, tribal, local, and territorial (STLT) public health agency's current approaches, best practices, and capacity for addressing cancer cluster inquiries that can be used to inform CDC/ATSDR's update of federal cancer cluster guidelines. In accordance with the Trevor's Law provision within the Frank R. Lautenberg Chemical Safety for the 21st Century Act, CDC/ATSDR is updating its federal guidelines for investigating potential cancer clusters. The information collected will be used by NCEH/ATSDR to inform and improve the current 2013 Guidelines, and to determine the need for additional tools and guidance to assist STLT public health agencies in assessing and responding to cancer cluster inquiries in their communities.

3. Use of Improved Information Technology and Burden Reduction

An electronic assessment was deemed the most appropriate method to gather information from a large audience to quantify and prioritize STLT public health agency needs for assessing and responding to cancer cluster inquiries. The electronic assessment will provide the CDC with quantitative information on best practices, and ways to improve how STLT public health agencies address cancer cluster inquiries. The electronic data collection instrument was designed to collect the minimum information necessary for the purposes of the project (i.e., limited to 55 questions).

The focus groups were selected to provide CDC with more insight into the quantitative results, capture in-depth detail regarding how the CDC can best update the current cancer cluster investigation guidelines to meet the needs of STLT public health agencies, as well as uncover information that could not be effectively asked in electronic assessment form. The focus group data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 26 questions).

4. Efforts to Identify Duplication and Use of Similar Information

There are no recent similar data available for this project. A survey of STLT public health agencies was conducted by the Council of State and Territorial Epidemiologists (CSTE) in 2010

(<http://www.cste2.org/webpdfs/ASynopsisofthe2010NationalAssessmentofStateCancerClusterInvestigationsandProtocols.pdf>) and a summary of that data is publicly available.

However, since 2010, there has been an increase in the number of cancer cluster inquiries received by STLT public health agencies and increasing attention surrounding perceived cancer clusters or perception of increased cancer rates in communities. Additionally, new scientific tools and approaches have been developed to assess and respond to potential cancer clusters in communities, including potential cancer clusters among pediatric populations. Understanding current STLT public health agency processes and use of current technologies will help NCEH/ATSDR to update and improve current federal guidelines.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Adequately update the CDC cancer cluster investigation guidelines to meet the needs of STLT public health agencies;

- Identify best practices for STLT public health agencies when assessing and responding to cancer cluster inquiries;
- Identify barriers for STLT public health agencies to effectively assess and respond to cancer cluster inquiries;
- Identify resources needed or other CDC support for STLT public health agencies to effectively assess and respond to cancer cluster inquiries.

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

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the CSTLTS Generic Information Collection Service (CSTLTS Generic) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply to this data collection. STLT governmental staff and / or delegates will be speaking from their official roles.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature. This data collection is not research involving human subjects.

12. Estimates of Annualized Burden Hours and Costs

This collection includes two components: 1) electronic assessment of STLT public health agencies, and 2) virtual focus groups of multi-disciplinary STLT public health agency staff and professionals who are involved in assessing and responding to cancer cluster inquiries in their communities.

The estimate for burden hours of the electronic assessment is based on a pilot test of the data collection instrument by five public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 25 minutes (range: 20 - 30). For the purposes of estimating burden hours, the upper limit of this range (i.e., 30 minutes) is used.

The estimate for burden hours of the focus group virtual interview is based on a subject matter expert review conducted by three public health professionals. In the review, the average time determined to complete the focus group interviews was determined by subject matter experts to be approximately 90 minutes. For the purpose of estimating burden hours, 90 minutes is used.

Electronic Assessment:

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for epidemiologists <https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>. Based on DOL data, an average hourly wage of \$33.49 is estimated for the 3,070 respondents who will complete the electronic assessment.

To account for potential increases due to the COVID-19 response, the hourly wage rate has been doubled to \$66.98 to account for fringe benefits and overhead (<https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>).

Focus Groups:

Focus group participants will encompass a wide range of occupations within STLT public health agencies, including epidemiologists, cancer registry administrators, and communicators. Focus group participants will include staff who are involved in assessing and responding to cancer cluster inquiries in their health departments. The hourly wage rate for focus group participants was calculated by averaging the wage rates for epidemiologists (\$33.49 per hour, <https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>), environmental scientists (\$34.20/hour, <https://www.bls.gov/ooh/life-physical-and-social-science/environmental-scientists-and->

[specialists.htm](#)), statisticians (\$42.40 per hour, <https://www.bls.gov/ooh/math/mathematicians-and-statisticians.htm>), and public relations specialists (\$28.85 per hour, <https://www.bls.gov/ooh/media-and-communication/public-relations-specialists.htm>). By averaging the hourly wage for the four occupations above, an average hourly wage rate of \$34.74 was calculated and used for estimating burden $((\$33.49 + \$34.20 + \$42.40 + \$28.85)/4 = \$34.74)$. To account for potential increases due to the COVID-19 response, the hourly wage rate has been doubled to \$69.48 to account for fringe benefits and overhead (<https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>).

Table A-12 shows estimated burden and cost information.

There will be a total of 3,190 respondents and 3,190 responses.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Data collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Electronic Assessment	STLT Public Health Agencies	3,070	1	30 / 60	1,535	\$66.98	\$102,814
Focus Group Facilitator's Guide	STLT Staff involved in Assessing and Responding to Cancer Cluster Inquiries	120	1	90 / 60	180	\$69.48	\$12,506
	TOTALS	3,190	1		1715		\$115,320

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

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff and contractors to develop the data collection instrument, collect data, and perform data analysis. ICF (contractor) is being used to support the following tasks: reviewing the focus group facilitator’s guide; facilitating the focus groups; transcribing focus group discussions; conducting qualitative analyses to identify common themes and issues. The total estimated cost to the federal government is \$47,019. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Project Manager– GS-14, Step 5 (x2 staff); Responsible for oversight and execution of the data collection activity; developing data collection instruments	40	\$61.68/hour	\$2,467.20
Science Project Coordinator – GS-13, Step 2; Responsible for oversight and execution of the data collection activity; developing data collection instruments; analysis of electronic assessment data	120	\$47.59/hour	\$5,710.80
Policy Project Coordinator– GS-11, Step 5; Responsible for oversight and execution of the data collection activity.	40	\$36.62/hour	\$1,464.80
ORISE Fellow GS-9 Equivalent Project Support;	120	\$26.71/hour	\$3,205.20
Contractors			
ICF Global Consulting Services (x2 staff) – Facilitate focus groups; record and transcribe focus group discussions; conduct qualitative analyses to identify common themes and issues.			Contractor Sub-total: \$34,171.00
Estimated Total Cost of Information Collection			\$47,019.00

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

As resources and respondents may be impacted by the COVID-19 pandemic, we propose that data collection begin in August 2020.

Electronic Assessment

After the data collection period has ended, respondent data will be downloaded and exported to an Excel spreadsheet and subsequently cleaned and coded for analysis. Univariate analysis will be conducted for each question of the electronic assessment. Descriptive statistical analyses (counts and frequencies) will be conducted using Microsoft Excel on responses to dichotomous and multiple-choice questions. Qualitative analyses will be conducted on responses to open-ended questions.

Focus Groups

De-identified data collected from ICF will be stored on the password-protected computers of staff and on secure CDC servers. CDC will analyze the data using qualitative methods and thematic analysis, for open-ended questions.

All information shared with stakeholders will be reported in aggregate form. Formal reports will be written for view and use by CDC. The data will be used to inform NCEH/ATSDR's update of federal cancer cluster guidelines and assist in understanding STLT public health agency needs for other tools/guidance around cancer clusters.

Task	Timeline	Status
Design instruments	8 weeks	COMPLETE ✓
Develop protocol, instructions, and analysis plan	8 weeks	COMPLETE ✓
Pilot test instruments	2 weeks	COMPLETE ✓
Prepare OMB package	16 weeks	COMPLETE ✓
Submit OMB package	4 weeks	TBD --
OMB approval	In process	TBD --
Conduct data collection	Within 4 weeks after OMB approval	TBD --
Code, quality control, and analyze data	Within 4 weeks after data collection	TBD --
Prepare summary reports	Within 8 weeks after	TBD --

Task	Timeline	Status
	data analysis	
Disseminate final results/reports	Within 4 weeks after summary reports prepared	TBD --

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- **Attachment A – Assessment: Word Version**
- **Attachment B – Assessment: Web Version**
- **Attachment C – Focus Group Facilitator’s Guide**

REFERENCE LIST

1. National Cancer Institute. “Cancer Statistics.” Available at <https://www.cancer.gov/about-cancer/understanding/statistics>. Accessed on 1/24/20.
2. Centers for Disease Control and Prevention (CDC). “Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists.” Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6208a1.htm>. Accessed on 1/24/20.
3. Goodman, Michael. “Cancer Clusters in the USA: What do the Last Twenty Years of State and Federal Investigations Tell Us?” *Critical Reviews in Toxicology*, vol. 42, no. 6, 2012, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3408895/>
4. Goodman, Michael. “Cancer Cluster Investigations: Review of the Past and Proposals for the Future.” *International Journal of Environmental Research and Public Health*, vol. 11, no. 2, 2014, <https://jhu.pure.elsevier.com/en/publications/cancer-cluster-investigations-review-of-the-past-and-proposals-fo-4>
5. Centers for Disease Control and Prevention (CDC). “National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services.” Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.