**MANAGEMENT INFORMATION SYSTEM FOR COMPREHENSIVE CANCER CONTROL PROGRAMS**

**OMB # 0920-0841**

**Revision**

**SECTION A: JUSTIFICATION**

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**ABSTRACT**

In January 2010, CDC received OMB approval to collect information from 65 cooperative agreement awardees that receive funding for participation in the National Comprehensive Cancer Control Program (NCCCP). Each awardee’s progress and activity information has been reported to CDC semi-annually (“Management Information System for Comprehensive Cancer Control Programs,” OMB No. 0920-0841, exp. 1/31/2013). The electronic MIS provides CDC with the capacity to respond in a timely manner to requests for information about the NCCCP from the Department of Health and Human Services (HHS), Congress, and other sources. Advantages of the electronic MIS include: reducing respondent reporting burden; improving real-time CDC-awardee communications; and strengthening CDC’s ability to monitor awardee progress and provide data-driven technical assistance. In 2012, CDC entered into new five-year cooperative agreements with these awardees.

In this Revision request, CDC seeks OMB approval to continue using MIS-based reporting for the National Comprehensive Cancer Control Program. Minor changes to the existing core MIS data elements will be implemented for all 65 NCCCP awardees. The changes reflect the new cooperative agreements’ increased emphasis on policy and environmental approaches to improving health outcomes.

Thirteen of the 65 awardees received additional cooperative agreements for a demonstration program aimed at accelerating the development of their policy and environmental approaches to cancer control. CDC will request separate semi-annual reports on the activities conducted under the demonstration program cooperative agreement.

This Revision request also presents a revised method for estimating respondent burden. The revised method distinguishes between (i) the initial burden of populating the MIS, and (ii) routine MIS maintenance and report generation. This method provides a more accurate depiction of burden per response in comparison to the method presented in the initial request for OMB approval. The previous method was based on a long-term average burden per response. Separate burden estimates are provided for reporting of a) core cancer prevention and control program activities and b) detailed reporting of policy and environmental activities under the demonstration program.

**A. JUSTIFICATION**

 **1. Circumstances Making the Collection of Information Necessary**

*Background*

This statement supports the request for clearance of electronic collection of information by the National Comprehensive Cancer Control Program (NCCCP), funded by the Comprehensive Cancer Control Branch (CCCB) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS). OMB approval is requested for three years.

The CCCB manages the NCCCP, which provides funding to state, tribal, territorial, and U.S. Affilated Pacific Island health departments to design, implement, and evaluate comprehensive cancer control (CCC) plans to reduce the burden of cancer locally. Support for these programs is a cornerstone of CDC efforts to reduce the burden of cancer throughout the nation.

In 1994, the CDC, the American Cancer Society, the National Cancer Institute, the American College of Surgeons, the North American Association of Central Cancer Registries, and other public health leaders at the state and national levels began promoting a comprehensive approach to cancer control that would coordinate and integrate cancer prevention and control programs across specific cancer funding boundaries. In 1998, the CDC provided funding to Colorado, Massachusetts, Michigan, North Carolina, Texas, and the Northwest Portland Area Indian Health Board as a pilot to assist with implementation of their existing CCC plans. This pilot provided a foundation for the NCCCP, which currently supports CCC programs in all 50 states, the District of Columbia, seven tribes/tribal organizations, and seven territories/U.S. Pacific Island jurisdictions. Awards to individual applicants are made for a five-year budget period. Continuation awards for subsequent budget periods are made on the basis of satisfactory progress in achieving both national and program-specific goals and objectives, as well as availability of funds.

Since the inception of the NCCCP in 1998, the CDC has requested submission of twice yearly progress reports from each CCC program. The information collected is used to identify training and technical assistance needs, monitor compliance with cooperative agreement requirements, and evaluate progress made in achieving program-specific goals. CDC uses a variety of sources to collect program information including the initial cooperative agreement application, continuing applications for each yearly budget period, twice yearly progress reports, and financial status reports. A database-driven Management Information System (MIS) for the collection of this information was developed and implemented in 2010 (Management Information System for Comprehensive Cancer Control Programs, OMB No. 0920-0841, exp. 1/31/2013). CCC programs funded under the five-year Funding Opportunity Announcement (FOA) DP07-703 (National Cancer Prevention and Control Program) have used the MIS to enter program data, progress reports, and work plans. The submission of this information has been coordinated by each awardee’s Program Director, and CDC has used the information to monitor each awardee’s progress. The information collection is authorized by the Public Health Service Act, Section 301, 241(a) (see **Appendix 1**).

Activities under FOA DP07-703 activities were concluded in June 2012. All NCCCP awardees (see **Appendix 3**) successfully competed for funding under a new FOA (DP12-1205, “Cancer Prevention and Control Program for State, Territorial, and Tribal Organizations”) to implement cancer prevention and control programs to reduce morbidity, mortality, and related health disparities. Although core activities for cancer control programs will be maintained, the new funding announcement includes new performance measures that relate to policy and environmental approaches to improve health outcomes. Therefore, the MIS data elements for all NCCCP awardees will be enhanced to provide information on these performance measures. Screen shots of the revised MIS data elements are included as **Appendix 4**. A summary of the enhancements is included as **Appendix 4A**.

In 2010, CDC announced a competitive funding opportunity entitled “Demonstrating the Capacity of Comprehensive Cancer Control Programs to Implement Policy and Environmental Cancer Control Interventions” (DP10-1017). The purpose of this funding opportunity is to support a demonstration program for CCC programs “to use policy, systems, and environmental change approaches to advance NCCCP cancer control efforts through decreased tobacco use, increased physical activity, healthier diets, increased access to screening tests, improved screening for cancer survivors to reduce the risk of recurrent or new cancers, and improved delivery of high quality cancer care services.” New staff and program activities funded under the demonstration program FOA are distinct from staff and activities funded under the NCCCP cooperative agreement, but should be “aligned with the existing comprehensive cancer control program in a manner that minimizes duplication, capitalizes on existing activities, and fosters rapid implementation.” Thirteen of the 65 NCCCP awardees received funding as part of the demonstration program and each awardee has identified a Policy Task Force Coordinator. Recipient activities include demonstrating organizational capacity to implement activities to advance policy or environmental changes to improve cancer control, building and maintaining collaborative working partnerships that support the planning and implementation of policy and environmental change, and developing a policy agenda. Demonstration program awardees will submit separate progress reports to CDC to allow for focused oversight of the related - but distinct – objectives of this cooperative agreement. **Appendix 3** provides a list of awardees funded under each cancer control cooperative agreement.

In order to facilitate the alignment of activities and to ensure that measurable outcomes are consistent with performance goals for the National Center for Chronic Disease Prevention and Health Promotion, a similar reporting, monitoring, and evaluation framework will be used for NCCCP cooperative agreements and for demonstration program cooperative agreements.

*Privacy Impact Assessment*

A) Overview of the Data Collection System

The MIS has been used for collecting information from CDC-funded CCC programs since June 2010. Electronic reporting of core NCCCP data elements will continue with minor changes in content. Information will be collected semi-annually from all 65 NCCCP awardees (**Appendix 4**). The 13 NCCCP awardees that receive separate funding for demonstration program activities will submit separate semi-annual reports on those activities (**Appendix 5**). The data elements for both reports are based on a common program monitoring and evaluation framework, but allow for custom content that reflects different objectives, work plans, etc., as outlined in the performance requirements for each cooperative agreement.

B) Items of Information to be Collected

The MIS will be used to collect information about the financial and staffing resources dedicated to cancer control by each awardee, the types of cancer addressed by each awardee, and their work plan objectives, activities, and partnerships. Awardees will provide the information for resources and activities related to each cooperative agreement. The MIS collects a limited amount of information in identifiable form (IIF) for key program staff (e.g., Program Director, Coalition Chairperson). Awardees will provide this information for key program staff hired or retained to help implement the award (e.g., Policy Taskforce Coordinator). The contact person will only provide information about the new program, not personal information.

C) Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The MIS is a Web-based application. Access to the MIS is controlled by a password-protected login for authorized users. There is no Website content directed at children less than 13 years of age.

**2. Purpose and Use of the Information Collection**

The MIS is designed to improve the capacity of the CDC, as well as each CCC program, to efficiently report information needed to monitor program progress, report performance measures, track changes in work plans, and document and report information required as a condition of cooperative agreement funding. The standardized and automated information collection enables CDC to sort the collected information to compare the effectiveness of different programs and intervention strategies in preventing and controlling cancer. In addition, the MIS design allows both NCCCP and CCC program staff to access the data entry pages for data entry, data review, and collaboration on technical assistance. CCC program staff are able to review the completeness of data necessary to submit required reports, enter basic summary data for reports, and finalize and save required reports for upload into Grants.gov. Information collected through the MIS also allows CDC to respond to inquiries about cancer prevention and control program activities.

**A. Privacy Impact Assessment Information**

The MIS is a centralized, Web-based system that supports the collection and reporting of information that is used by CDC to help assess the impact of each CCC program, as well as the overall effectiveness of the NCCCP, in reducing the burden of cancer. CDC uses the information to make performance-based funding decisions.

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

The MIS is based on well-defined information components and processes that foster consistency in data collection and reporting. The MIS takes advantage of technology to improve information quality by minimizing errors and redundancy.

Special attention has been given to ensuring the system is easy to use and collects information that can later be queried and summarized through its reporting capabilities. The MIS is intended to accomplish the following functions:

* Reduce both CCC program and CDC burden of program planning, reporting, and overall cooperative agreement administration.
* Standardize the CCC program reporting process to facilitate development of evaluation methods.
* Enable reporting information to be sorted and aggregated to assess the overall effectiveness of NCCCP and respond to stakeholder inquiries.
* Support a common monitoring and evaluation framework for core cancer prevention and control program activities as well as activities associated with accelerated implementation of policy, systems and environmental strategies for cancer control.

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

The collection of progress report information is part of a federal reporting requirement for cooperative agreement awardees. The MIS consolidates information necessary for both continuation applications and progress reports so that information entered once can be used to generate two types of reports without having to duplicate efforts. The MIS does not cause duplication and, in fact, eliminates duplicative efforts under paper-based reporting systems. The information collected from NCCCP awardees and demonstration program awardees is not available from other sources.

Each cooperative agreement has related but distinct performance requirements. As a result, separate progress reports will be collected for activities conducted under the NCCCP (which are coordinated by the state or territory’s program director) and for activities conducted as part of the capacity building demonstration program (which are coordinated by a policy task force coordinator). The program director and task force coordinator will work together to ensure that demonstration program activities are aligned with the existing comprehensive cancer control program in a manner that minimizes duplication, capitalizes on existing activities, and fosters rapid implementation. However, demonstration program awardees are required to define specific work plans for these activities and to identify the resources that are specific to demonstration program objectives. As a result, CDC will require separate semi-annual reports for each cooperative agreement.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will participate in the MIS data collection.

**6. Consequences of Collecting the Information Less Frequently**

Currently, NCCCP reports are collected semi-annually. The same reporting schedule will be maintained during the next three-year OMB approval period for all 65 NCCCP awardees. Less frequent reporting would negatively impact monitoring progress of national, state, tribal, and territorial efforts to prevent and control cancer, and undermine accountability efforts at all levels. The twice-yearly reporting allows CDC to respond to inquiries from Congress and other stakeholders in a timely manner and with up-to-date information.

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

There are no special circumstances related to the modification of the MIS, and the request fully complies with the regulation.

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

**A. Federal Register Notice**

A 60-day Notice was published in the Federal Register on November 6, 2012 (Volume 77, Number 215, pages 66617-66619) (**Appendix 2**). No public comments were received in response to the Notice.

**B. Other Consultations**

The MIS was designed collaboratively by CDC staff and the data collection contractor. Consultation will continue throughout the system modification process.

**9. Explanation of Any Payment or Gift to Respondents**

Respondents do not receive payments or gifts for providing information.

**10. Assurance of Confidentiality Provided to Respondents**

1. **Privacy Act Assessment**. Staff in the National Center for Chronic Disease Prevention and Health Promotion have reviewed this Information Collection Request and have determined that the Privacy Act is not applicable. The data collection does not involve collection of sensitive and/or personally identifiable information. Respondents are state- and tribal-based comprehensive cancer control programs. Although contact information is obtained for each program, the contact person provides information about the state or tribal program, not personal information.
2. **Security**. Access to the MIS is controlled by a password-protected login. The same log-in will be required to enter data for activities conducted through the National Comprehensive Cancer Control Program (DP12-1205) and data for activities conducted as part of the capacity building demonstration program (DP10-1017). Access levels vary from read-only to read-write, based on the user’s role and needs. Each CCC awardee has access to its own information and decides the level of access for each user. Recipients of funding for both FOAs will decide whether the Program Director for DP12-1205 and the Policy Task Force Coordinator for DP10-1017 will have access to information for both programs. The extent to which local partners may access a CCC awardee’s information is decided by that awardee. Aggregated information is stored on an internal CDC SQL server subject to CDC’s information security guidelines. The MIS is hosted on NCCDPHP’s Intranet and Internet Application platforms, which undergo security certification and accreditation through CDC’s Office of the Chief Information Security Officer.
3. **Consent**. The MIS data collection is not research. The information collection does not require consent from individuals, or IRB approval.
4. **Requirement to Respond**. Awardees are required to respond as a condition of cooperative agreement funding.

**11. Justification for Sensitive Questions**

The MIS instrument does not collect sensitive information. No personal information is requested. The MIS collects a limited amount of information in identifiable form (IIF) for key program staff (e.g., Program Director, Coalition Chairperson). This information will also be collected for staff hired or retained to help implement DP10-1017, including Policy Taskforce Coordinators. Awardees provide the names of these individuals as well as their professional contact information. The contact person only provides information about the CCC program, not personal information.

**12. Estimates of Annualized Burden Hours and Costs**

**A. Estimated Annualized Burden Hours**

CDC will collect information twice per year. CDC anticipates that burden to respondents will vary substantially over the award period. The time commitments for data entry and training are greatest during the initial population of the MIS, typically in the first six to twelve months of funding. The efficiencies of the electronic MIS are realized in subsequent reporting periods. After initial population of the MIS has been completed, ongoing maintenance of the system is limited to entering changes, progress information, and new activities.

All 65 NCCCP awardees (funding announcement DP12-1205) will submit Data Elements for All CCC Programs (**Appendix 4**). The estimated burden for initial population of the MIS is four hours per response. The estimated burden is relatively modest, because some of the information was entered during the previous FOA period (coinciding with the previous OMB approval period), and does not need to be re-loaded. Distributed over the three years of this clearance request, the total annualized estimate for this information collection is 88 burden hours (22 respondents/year x 1 response/year x 4 hours/response). Due to rounding of the number of respondents (65/3 ~ 22), total annualized respondent burden is slightly over-estimated for this information collection.

After initial population of the MIS, NCCCP awardees will be responsible for entering updates, entering changes, and producing semi-annual reports (**Appendix 4**). The estimated burden per response is three hours. The total annualized estimate for this information collection is 390 hours (65 respondents x 2 responses/year x 3 hours/response).

Initial population of MIS data elements is estimated at six hours per response for the subset of 13 awardees participating in the demonstration program (funding announcement DP10-1017) (see **Appendix 5,** Data Elements for CCC Programs with Enhanced Policy, Systems, and Environmental Activities). Distributed over the three years of this clearance request, the total annualized estimate for this information collection is 30 hours (15 respondents/year x 1 response/year x 6 hours/response). Due to rounding of the number of respondents (13/3 ~ 5), total annualized respondent burden is slightly over-estimated for this information collection.

After initial population of their MIS data elements, demonstration program awardees will be responsible for entering updates, entering changes, and producing semi-annual reports (**Appendix 5**). The estimated burden per response is three hours. The total annualized estimate for this information collection is 78 hours (13 respondents x 2 responses/year x 3 hours/response).

For all data collection and reporting for cancer prevention and control programs, the total estimated annualized burden to respondents is 586 hours, as summarized in Table A.12-1.

**Table A.12-1. Estimated Annualized Burden to Respondents**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of respondents | Form Name | Number ofrespondents | Number ofresponses perrespondent | Burden perresponse (in hours) | Totalburden(in hours) |
| Program Director for State- or Territory-Based Cancer Prevention and Control Program | Data Elements for All CPC Programs: Initial MIS Population | 22 | 1 | 4 | 88 |
| Data Elements for All CPC Programs: Semi-annual Reporting | 65 | 2 | 3 | 390 |
| State- or Territory-Based Policy Task Force Coordinator | Data Elements for CPC Demonstration Program: Initial MIS Population | 5 | 1 | 6 | 30 |
| Data Elements for CPC Demonstration Program: Semi-annual Reporting | 13 | 2 | 3 | 78 |
|  |  | Total | 586 |

**B. Estimated Annualized Cost to Respondents**

Table B.12-1 displays the estimated annualized cost to respondents for reporting program progress information. The hourly wage rates for program managers are based on wages for similar mid-to-high level positions in the public sector. The total estimated annualized cost to respondents is $20,732.

**Table B.12-1. Estimated Annualized Cost to Respondents**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of respondents | Form Name | Number of respondents | Total Burden (in hours) | Median hourly wage\* | Total cost |
| Program Director for State- or Territory-Based Cancer Prevention and Control Program | Data Elements for All CPC Programs: Initial MIS Population | 22 | 88 | $35.38 | $3,113 |
| Data Elements for All CPC Programs: Semi-annual Reporting | 65 | 390 | $35.38 | $13,798 |
| State- or Territory-Based Policy Task Force Coordinator | Data Elements for CPC Demonstration Program: Initial MIS Population | 5 | 30 | $35.38 | $1,061 |
| Data Elements for CPC Demonstration Program: Initial MIS Population | 13 | 78 | $35.38 | $2,760 |
|  | Total | $20,732 |

\*Hourly wage information is from the U.S. Department of Labor, Bureau of Labor Statistics Web site (www.bls.gov/ncs/ocs/sp/nctb1479.pdf).

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

The MIS is designed to use existing hardware within funded sites, and all respondents currently have access to the Internet to use the information system. No capital or maintenance costs have been required. Additionally, there have been no start-up, hardware or software costs.

**14. Estimates of Annualized Cost to the Federal Government**

**A. Development, Implementation, and Maintenance**

The MIS developer and data collection contractor is Northrup-Grumman. Major cost factors related to deploying the MIS include development and testing costs, system maintenance costs, and the cost of oversight by CDC program staff. The total estimated annualized cost of the MIS is $171,319.

The total estimated annualized cost includes $71,792 for cancer prevention and control programs funded through the NCCCP (DP12-1205) and $99,527 for demonstration program awardees (DP10-1017).

Tables A.14.1 and A.14.2 provide detailed breakdowns of the estimated annualized cost for each program component.

**Table A.14.1**

Estimated Annualized Cost for Collection of MIS-based NCCCP (DP12-1205) Data

|  |  |
| --- | --- |
| Annualized cost of system development and implementation\* | $30,044 |
| Annual system maintenance contract | $31,000 |
| CDC personnel – 15% FTE for one GS-12 | $10,748 |
|  |  |
| **Total annualized cost to the government** | **$71,792** |

\* The annualized cost of system development and implementation is based on a three-year estimated total of $90,132 ($1,800 for initiation and concept development; $200 for planning; $8,765 for requirements analysis; $11,585 for design; $40,645 for development; $24,945 for testing; and $2,192 for implementation). Some development costs were reported in the previous OMB clearance period and are not included in the estimate for the upcoming three-year clearance period.

**Table A.14.2**

Estimated Annualized Cost for MIS-based Collection of Demonstration program (DP10-1017) Data

|  |  |
| --- | --- |
| Annualized cost of system development and implementation\*\* | $52,779 |
| Annual system maintenance contract | $36,000 |
| CDC personnel – 15% FTE for one GS-12 | $10,748 |
|  |  |
| **Total annualized cost to the government** | **$99,527** |

**\*\*** The annualized cost of system development and implementation is based on a three-year estimated total of $158,336 ($2,536 for initiation and concept development; $197 for planning; $4,849 for requirements analysis; $11,237 for design; $88,343 for development; $42,393 for testing; and $8,781 for implementation). These costs have not previously reported.

**15. Explanation for Program Changes or Adjustments**

In the previous clearance period, total annualized burden was estimated at 780 hours, based on 65 respondents (awardees), a semi-annual reporting schedule, and an estimated burden of six hours per response (65 x 2 x 6 = 780).

Changes proposed at this time include 1) adjustments to the burden estimate for all 65 awardees, and 2) additional burden associated with new reporting requirements for a subset of 13 awardees.

1. For core NCCCP information collection for all 65 awardees, the total estimated annualized burden is being reduced from 780 hours to 478 hours, based on experience with the MIS over the last three years and a more refined approach to the method for estimating burden per response. The new approach provides separate estimates for a) burden associated with semi-annual reporting and b) burden associated with initial loading of the MIS.
	1. For semi-annual reporting for all 65 awardees, the revised estimated burden per response is 3 hours. The total annualized burden is 390 hours (65 awardees x 2 responses per year x 3 hours per response = 390).
	2. To estimate burden for initial population of the MIS, we allocate one-third of the 65 awardees to each year in the 3-year clearance period (22 awardees per year). The estimated burden per response is 4 hours and the total annualized burden is 88 hours (22 awardees x 1 response per year x 4 hours per response = 88 hours). Because some information collected during the previous clearance period can be re-used, the initial burden for populating the MIS is modest.

For the 65 awardees that are participating in core NCCCP information collection, the revised estimated annualized burden is 478 hours (390 + 88 = 478). Compared to the previous clearance period, the new estimate represents a reduction of 302 hours per year (780 – 478 = 302).

1. Separate reporting is required for the 13 awardees that are funded under the new demonstration program. This is a new information collection.
	1. For semi-annual reporting, the estimated burden per response is 3 hours and the total estimated annualized burden is 78 hours (13 awardees x 2 responses per year x 3 hours per response = 78).
	2. To estimate burden for initial population of the MIS, we allocate one-third of the 13 awardees to each year in the 3-year clearance period (5 awardees per year; resulting in a slight over-estimate). The estimated burden per response is 6 hours and the total annualized burden is 30 hours (5 awardees x 1 response per year x 6 hours per response = 30 hours).

For the 13 awardees that are participating in the new demonstration program, the total estimated annualized burden is 108 hours.

The total estimated annualized burden for all information collection is 586 hours. This is a net reduction of 194 hours compared to the previous clearance period (780 – 586 = 194).

**16. Plans for Tabulation and Publication and Project Time Schedule**

**A. Time schedule for the entire project**

The cooperative agreement cycles for DP12-1205 and DP 10-1017 are 5 years each. OMB approvalis being requested for the initial 3 years for each FOA and will be extended for the duration of the cooperative agreement.Actual data collection for each FOA will begin immediately after OMB approval. Tables including beginning and ending dates for the collection of information for each FOA and other actions are provided below.

| Table 16-1 Project Time Schedule for DP12-1205 |
| --- |
| **Activity** | **Time Schedule** |
|  Notify respondents |  Within 2 weeks after OMB approval |
|  Training |  1 month after OMB approval |
|  Ongoing support (as required) |  1 month after OMB approval |
|  Analyses and Validation |  2 months after OMB approval |

| Table 16-2 Project Time Schedule for DP10-1017 |
| --- |
| **Activity** | **Time Schedule** |
|  Notify respondents |  Within 2 weeks after OMB approval |
|  Training |  1 month after OMB approval |
|  Ongoing support (as required) |  1 month after OMB approval |
|  Analyses and Validation |  2 months after OMB approval |

**B. Publication plan**

DP12-1205- and DP10-1017-related information collected through the MIS will be reported in internal CDC documents and shared with CCC programs.

**C. Analysis plan**

CDC will not use complex statistical methods for analyzing progress report related information. All information will be aggregated and reported with no program identifiers present in external documents. Most statistical analyses will be descriptive. Statistical modeling may be included to examine predictors of specified outcomes.

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

The CCC MIS program will display the expiration date for OMB approval of the policy-related information system data collection on its Internet home page.

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

There are no exceptions to the certification statement.