

**World Trade Center Health Program Enrollment, Treatment,
Appeals & Reimbursement
Revision**

Supporting Statement A

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Goal of the Study: The WTC Health Program is not a study, but is a limited healthcare program established by the James Zadroga 9/11 Health and Compensation Act of 2010 and administered by the National Institute for Occupational Safety and Health. The goal of the Program is to provide monitoring and treatment to responders of the 9/11 terrorist attacks at the World Trade Center, Pentagon, and Shanksville, PA, as well as survivors in the New York City Area.

Intended Use of the Resulting Data: The data collected in the forms and letters contained within this OMB package are intended solely for determining eligibility and providing treatment in the Program in accordance with the Zadroga Act.

Methods For Collecting Data: This is not a research program. Data collected will be through the use of forms and letters to collect required information on member eligibility, appeals, physician requests for treatment, and pharmacy benefits. Forms and letters will be collected through mail, web, and fax.

Subpopulation to be Studied: This is not a research program. This program is to provide monitoring and treatment to 9/11 responders and survivors.

How Data will be Analyzed: Data will be analyzed to determine eligibility and treatment benefits available to individuals based on the requirements outlined by Congress in the Zadroga Act.

A. **Justification**

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

This is a request for a 3 year revision for OMB clearance from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), promulgated on December 22, 2010, establishes a Federal program to support health monitoring and treatment for emergency responders; recovery and cleanup workers in New York City, the Pentagon and Shanksville, PA; and residents, building occupants, and area workers in New York City who were directly impacted and adversely affected by the terrorist attacks of September 11, 2001.

When this original package was submitted in 2011 the Program was just starting. We now have data since 2011 to estimate the usage of the forms and have readjusted the expected number of respondents where appropriate. This submission will incorporate the World Trade Center Health Program Enrollment, Appeals & Reimbursement (0920–0891), and the World Trade Center Enrollment & Appeals—Pentagon & Shanksville (0920–1001, expiration date 12/31/2016) into one complete package which will be called the World Trade Center Health Program Enrollment, Appeals & Reimbursement. Upon OMB approval, 0920–1001 will be discontinued.

In order to provide medical monitoring and treatment to eligible individuals, the World Trade Center (WTC) Health Program will collect eligibility and appeals data through the application and follow up requests for information as needed through letters to the members. As needed, members may also seek to complete a travel request form for approved travel for medical necessity through the Nationwide Provider Network (NPN). Also required for treatment is for a member to be certified through the WTC Health Program. The certification process is initiated when the WTC physician requests certification using the WTC-3 form. This request is to extend the OMB clearance for the enrollment applications, travel request form, and to add the WTC-3 form and a designated representative form.

Revisions have been made to the enrollment forms to incorporate the World Trade Center Health Program Enrollment, Appeals & Reimbursement (0920–0891, expiration date 12/31/2014), and the World Trade Center Enrollment & Appeals—Pentagon & Shanksville (0920–1001, expiration date 12/31/2016) into one complete package which will be called the World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement. Upon OMB approval, 0920–1001 will be discontinued. Additionally, when the enrollment forms were first created the WTC Health Program was just starting operations. The revised enrollment forms were modified based on feedback from stakeholders and applicants to add, remove, or edit language on the form for clarity and Program usefulness. Lastly, through consultation with our Office of General Counsel, a notices section was added to the end of the application forms.

The Zadroga Act mandates that no individual who is on the terrorist watch list maintained by the Federal government will qualify as an enrolled participant in the Program.

(Appendix A)

All responders and survivors to the New York City attack who will be newly seeking medical monitoring and treatment who were not covered by the Medical Monitoring and Treatment Program (MMTP) or the NYC Health and Hospitals Corporation, WTC Environmental Health Center prior to Zadroga, may apply to obtain coverage under the new WTC Health Program. In order to begin the determination eligibility process, an enrollment form must be completed. If the application is not complete, the member will be sent letters (30 day, 60 day, 90 day, and 180 day) asking for additional information to be submitted. Once enrolled, general responders will also be sent a postcard asking which clinic they would like to join. After an eligibility application is submitted to the Program, an unsuccessful applicant has an opportunity to appeal the decision. Once enrolled, responders will receive monitoring and survivors will receive an initial screening. The member can only receive treatment benefits if they are certified by the Program. The certification process starts when the WTC physician submits a WTC-3 form to request certification of a condition from the Program. Members have further appeal rights if they are denied treatment or certification. Members of the NPN can also request travel reimbursement for medically necessary treatment if a provider cannot be found close to the residence of the member. Members can also request that a designated representative act on their behalf, using the Designated Representative Form, for the enrollment and appeal process.

2. Purpose and Use of Information Collection

This information is being collected in order to determine the eligibility of applicants, allow new general responders to choose their clinic selection, allow for a member to be certified, as well as to provide Program participants with the opportunity to appeal, and allow Program physicians to make requests and seek PA. Finally, information will be collected to reimburse certain enrolled participants for travel.

There are four separate enrollment forms for each population of responders (FDNY responders, general responders, NYC survivors, and Pentagon/Shanksville responders). The following information includes the definition of each population:

- "FDNY responder" is defined as a member of the Fire Department of New York City (whether fire or emergency personnel, active, or retired) who participated at least one day in the rescue and recovery effort at any of the former World Trade Center sites.
- "General Responder" is a worker or volunteer who provided Rescue, Recovery, Demolition, Debris, Removal and related support services in the aftermath of the September 11, 2001 attacks on the World Trade Center but was not affiliated with the Fire Department of New York.
- "Survivor" is a person who was present in the disaster area in the aftermath of the September 11, 2001 attacks on the World Trade Center as a result of their work, residence, or attendance at school, childcare, or adult daycare.
- "Pentagon Responder" is a person who was a member of a fire or police

department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on November 19, 2001.

- “Shanksville Responder” is a person who was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on October 3, 2001.

The eligibility application forms will collect general contact information as well as information regarding the WTC, Pentagon, and Shanksville, PA experiences. Some of the information provided will be shared with the Federal Bureau of Investigation in order to screen an individual against the terrorist watch list maintained by the Federal government. This information will also be shared with the WTC Program Administrator and will be kept in a secure manner. In order to reduce the burden on the respondents and survivors, the WTC Health program will make the form available to be downloaded from the internet or obtained in hard copy and submitted by mail. The enrollment forms will be available for download on the NIOSH website at <http://www.cdc.gov/wtc/apply.html> (Appendices C-F). Paper copies of the applications will be translated (translations will occur after OMB approval and will be submitted as a non-substantive change request once completed). Additionally, the application will be available to complete online through a web-based application system (Appendix G). If the application is not complete, members will receive a letter explaining that more information is needed before a decision can be made. There is an initial decision letter that is mailed (Appendix H) as well as a 30, 60, 90, and 180 day letter (Appendices I-L). These application reminder letters (Appendix H-L) are being provided to OMB as supplemental materials. Once enrolled, responders in the NYC area will receive a postcard to choose which clinic they would like to attend (Appendix M).

Responders will receive monitoring benefits and survivors will receive an initial screening upon enrollment. In order to receive treatment benefits, the WTC physician must submit a certification request, WTC-3, to the Program for approval (Appendix N). Once approved, then the member can receive treatment benefits. Additional medical forms are being provided as supplemental documents, as requested by OMB. This includes the WTC-5, WTC-6, Standard PA form as well as the PA form for Transplants, Dental and member specific Pharmacy requests (Appendices O-T).

WTC Health Program applicants and enrolled participants have opportunities to appeal adverse decisions made by the WTC Program Administrator. The first opportunity to appeal arises after a determination that an applicant does not meet the eligibility requirements (Appendix U). Once enrolled in the Program, participants will also have the opportunity to appeal the Administrator’s decision to deny a certification request (WTC-3) or a determination that treatment will not be authorized as medically necessary. In the notification letter explaining the adverse determination, the applicant will be advised that

an appeal can be requested by submitting in writing their name, contact information, and an explanation for the basis of the appeal (Appendices V-W).

In limited situations, members of the Nationwide Provider Network can request travel reimbursement for medically necessary information. This form includes demographic information and information related to the member's expenses (see Appendix X).

Pharmacies will transmit reimbursement claims to the WTC Health Program. The following data elements will likely be collected for pharmacy reimbursement: pharmacy name, pharmacy address, drug name, prescription number, patient name, patient ID number, and cost (no form available as this is an electronic submission from the pharmacy to the Pharmacy Benefits Manager sub-contractor).

Applications are translated into Spanish, Chinese and Polish. Translation of applications will occur after OMB approval and will be submitted as a non-substantive change request. Letters to applicants requesting more information, as well as enrollment and certification denial letters, are translated on an as-needed basis. Translations are done based on need of each letter and the language the application was submitted. Translations for the current Program letters are attached (Appendices AA – FF).

Lastly, members can also choose to designate a representative to act on their behalf during the enrollment and appeal processes. This request can be made using the Designated Representative Form (Appendix GG).

3. Use of Improved Information Technology and Burden Reduction

The eligibility forms may be collected via online, hard copy mail, or fax. The appeal letter and travel reimbursement and designated representative request must be submitted in writing by mail or fax. Offering alternatives for application submission should reduce the burden for the applicant by allowing them to choose an option easiest for them to apply to the Program. The burden should be similar regardless of the submission method. Treatment forms and WTC-3 requests can be submitted by fax or mail.

4. Efforts to Identify Duplication and Use of Similar Information

This information in its totality is only being collected to determine eligibility, initial treatment approval, appeal reasons, and request travel reimbursement. The information collected in each of these processes is distinct and collected for varying reasons. Additional information may be collected by physicians or medical personal to provide medical care or treatment.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small business.

6. Consequences of Collecting the Information Less Frequently

Without collection of these data, NIOSH will not be able to implement the provisions of the Act, to establish the process for an individual to apply to the WTC Health Program, obtain an initial health evaluation, monitoring, and treatment, and appeal eligibility and treatment decisions.

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

There are no special circumstances.

8. Comments in Response to the Federal Register Notice/Outside Consultation

A. A 60-day Federal Register Notice was published in the Federal Register July 10, 2014 Vol. 79, No. 132, pp. 39399-39400 (Appendix B). Two comments were received (Appendix Y)

B. The WTC Health Program consulted with HHS OGC on the legal requirements needed for data collection. The Program also consulted with Clinical Centers of Excellence (CCEs) and the Steering Committees¹ (both legal entities created by Zadroga) on the availability of data to applicants supporting their 9/11 activities, clarity of instructions, disclosures, reporting format, and data elements requested.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any form of payment or gifts.

10. Assurance of Confidentiality Provided to Respondents

On May 27, 2011, HHS published in the Federal Register (76 Fed. Reg. 31212) a proposal to alter System of Records, 09-20-0147. In order to comply with the tight statutory deadline for implementation of the Zadroga Act, the changes proposed in that notice went into effect 30 days from the publication, "Occupational Health Epidemiological Studies and EEOICPA Program Records, HHS/CDC/NIOSH" (51 Fed. Reg. 42474, May 24, 1986). In accordance with the requirements of the Privacy Act, CDC published the notice of proposal to: add routine uses; amend the categories of individuals covered by the system; amend the categories of records in the system; amend authority for maintenance of the system; and amend the purpose. The purpose of these modifications is to provide notice that NIOSH, in executing its responsibilities under the Zadroga Act, will release personally identifiable information to other Federal agencies and its contractors, as necessary, in order to make eligibility and qualification determinations for purposes of the WTC Health Program and as otherwise required in carrying out Title XXXIII. In addition, NIOSH is also revising the name of the system of records to "Occupational Health Epidemiological Studies, EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH."

A. An overview of the data collection system: The data collection system starts with receipt of the application by either mail, secure fax, or a secure online application system. Once the applications are received, the data will be entered into secure databases at Computer Sciences Corporation (CSC). Hard copies will be saved in a secure location by CSC. Access to data will be limited to authorized NIOSH project staff and authorized CSC contractors. All electronic data will be stored on secure servers accessible only with passwords. CSC will be required to follow equivalent procedures.

¹ Chair of the Responder Steering Committee: Dr. James Melius (melius@nygliuna.org); Chair of the Survivor Steering Committee: Kimberly Flynn (flynnktm@aol.com).

Records are retained and disposed of according to the provisions of the CDC Electronic Records Control Schedule for NIOSH records. Research records are maintained in the agency for three years after the close of the study. Records transferred to the Federal Records Center when no longer needed for evaluation and analysis are destroyed after 75 years for epidemiologic studies, unless needed for further study. WTC Health Program records are transferred to the Federal Records Center 15 years after the case file becomes inactive and are destroyed after 75 years. Any records provided to the Department of Justice for the purpose of screening individuals against the “terrorist watch list” will be destroyed (and not retained by the Department of Justice) once it is determined that an individual is not on the “terrorist watch list.”

- B. A description of the information to be collected: The applications ask for the member’s demographic information (name, address, email, and date of birth) as well as their activities on 9/11. The application also requests supporting documentation to support the activities listed. The follow up letters request information on supporting documentation that was not included in the application. The postcard is for the NY/NJ responder to choose their clinic selection. The WTC-3 certification request form is for the WTC physician to request certification for a WTC-related condition from the Program. This form asks information about the member’s exposure, medical condition, and onset or diagnosis of the condition being submitted for certification. The WTC-5 and 6 as well as the Prior Authorization documents are for the WTC Physician to submit for approval to add treatment outside of the Program’s existing treatment and pharmacy plan. The appeal letters instruct the individual to submit an explanation for why they disagree with the decision to deny enrollment and/or certification or treatment. The travel form requests demographic information and information related to the logistics (cost, type of travel accommodation, etc.) to be reimbursed for travel expenses.
- C. A description of how the information will be shared and for what purpose: See **“Privacy Act Statement and Additional Permitted Disclosures of Personally Identifiable Information and Records”** in the **“Notices Regarding WTC Health Program Requirements”** in Appendices C-F.
- D. A statement detailing the impact the proposed collection will have on the respondent’s privacy: This information is provided in the notices section of all applications.
- E. Whether individuals are informed that providing the information is voluntary or mandatory: Applying to the Program is voluntary. This is also included in the notices section of the application (See Appendices C-F).
- F. Opportunities to consent, if any, to sharing and submission of information:

Information regarding sharing of information is included in the initial application (see Appendices C-F).

- G. How the information will be secured: All information is secured in accordance with HIPAA and the Privacy Act. All information is collected and transmitted through secure channels and materials are stored in secure databases or locations.
- H. Whether a system of records is being created under the Privacy Act: See <http://www.gpo.gov/fdsys/pkg/FR-2011-05-27/pdf/2011-13470.pdf> and its clarification: <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14807.pdf>

11. Justification for Sensitive Questions

No sensitive questions will be asked.

12. Estimates of Annualized Burden Hours

World Trade Center Health Program FDNY Responder Eligibility Application, World Trade Center Health Program Responder Eligibility Application (Other than FDNY), World Trade Center Health Program Pentagon/Shanksville Eligibility Application, and World Trade Center Health Program Survivor Eligibility Application:

Four different eligibility forms were developed to address the different criteria for each group covered by the WTC Health Program: Fire Department of New York responders, general responders, Pentagon/Shanksville responders, and survivors. Based on past enrollment numbers, we expect that to receive approximately 4,500 applications per year. The burden table reflects the annualized total burden broken into the four separate applicant groups: we estimate that 45 Fire Department of New York (FDNY) responders (1% of applicants); 2,475 general responders (55%); 630 Pentagon/Shanksville responders (14%); and 1,350 survivors (30%) will submit applications. The burden estimates for these three different forms are: FDNY = 23 hours; general responders = 1,238 hours; Pentagon/Shanksville responders = 315 hours; survivors = 675 hours.

Clinic Selection Postcard: Of the 4,500 applications we expect to receive per year, we expect that 55% (2,475) of them will be general responder applications from the NY/NJ area and will have to select which clinic they would like to visit. It is expected that it will take the member 15 minutes to complete the postcard. The burden hours are 619 hours.

WTC-3: We expect that WTC physicians will request an estimated 20,000 certification requests a year. These forms will take the physicians 30 minutes to complete for an estimated 10,000 burden hours.

Denial Letter and Appeal Notification -- Eligibility: Of the 4,500 applications we expect to receive per year, we expect that 10% will fail due to ineligibility. We further assume that 10% of those individuals, or 45 respondents, will appeal the decision. The burden

estimate is 23 hours.

Denial Letter and Appeal Notification -- Health Condition: We expect that program participants (enrolled responders and survivors) will request certification for 20,000 health conditions each year. Of those 20,000, we expect that .01% (200) of certification requests will be denied by the WTC Program Administrator. We further expect that 30% of denied certifications, or 60 individuals, will be appealed. The burden estimate is 30 hours.

Denial Letter and Appeal Notification -- Treatment: Of the projected 51,472 enrollees who will receive medical care, it is estimated that .05% (26) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 30 minutes. The burden estimate is 13 hours.

WTC Health Program Medical Travel Refund Request: WTC responders or certified eligible survivors who travel more than 250 miles to a nationwide network provider for medically necessary treatment may be provided necessary and reasonable transportation and other expenses. These individuals may submit a travel refund request form, which should take respondents 10 minutes to complete. HHS expects no more than 10 claims per year. The burden estimate is 2 hours.

Designated Representative Form: Individuals applying to the Program, or members, can designate a representative to act on their behalf. In order for the Program to speak to a third person about a member's application or case, we would need the individual to complete a designated representative form authorizing us to speak with that third person. It is estimated that the Program will receive 30 designated representative forms a year. The forms should take no longer than 15 minutes to complete for a burden estimate of 7.5 burden hours.

Outpatient prescription pharmaceuticals: Pharmacies will electronically transmit reimbursement claims to the WTC Health Program. HHS estimates that 150 pharmacies will submit reimbursement claims for 39,192 prescriptions per year, or 261 per pharmacy; we estimate that each submission will take 1 minute. The burden estimate is 653 hours.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
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FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	45	1	30/60	23
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY)	2,475	1	30/60	1,238
Pentagon/Shanksville Responder	World Trade Center Health Program Pentagon/Shanksville Responder	630	1	30/60	315
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application	1,350	1	30/60	675
Clinic Selection Postcard	Postcard for new general responders in NY/NJ to select a clinic	2,475	1	15/60	619
WTC-3	Physician Request for Certification	20,000	1	30/60	10,000
Responder (FDNY and General Responder)/Survivor	Denial Letter and Appeal Notification - Enrollment	45	1	30/60	23
Responder (FDNY and General Responder)/Survivor	Denial Letter and Appeal Notification -- Health Conditions	60	1	30/60	30
Responder (FDNY and General Responder)/Survivor	Denial Letter and Appeal Notification -- Treatment	26	1	30/60	13
Responder (FDNY and General Responder)/Survivor	WTC Health Program Medical Travel Refund Request	10	1	10/60	2

Designated Rep Form	Form to designate a representative	10	1	15/60	3
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60	653
Total					13,594

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
FDNY Responder (application)	23	\$24.08*	\$554
General Responder (application)	1,238	\$18.20*	\$22,532
Pentagon/Shanksville Responder (application)	315	\$18.20*	\$5,733
Survivor (application)	675	\$12.00	\$8,100
General Responder Clinic Selection Postcard	619	\$18.20	\$11,265.80
WTC-3 Form	10,000	\$100	1,000,000
FDNY Responder (eligibility appeal)	1	\$24.08*	\$24
General Responder (eligibility appeal)	12	\$18.20*	\$218
Pentagon/Shanksville Responder (eligibility appeal)	3	\$18.20*	\$55
Survivor (eligibility appeal)	7	\$12.00	\$84
FDNY Responder (health condition appeal)	1	\$24.08*	\$24
General Responder (health condition appeal)	17	\$18.20*	\$309
Pentagon/Shanksville (health condition appeal)	4	\$18.20*	\$71
Survivor (health condition appeal)	9	\$12.00	\$108
FDNY Responder (treatment appeal)	5	\$24.08*	\$120
General Responder (treatment appeal)	6	\$18.20*	\$109
Pentagon/Shanksville (treatment appeal)	1	\$18.20*	\$18
Survivor (treatment appeal)	2	\$12.00	\$24
Designated Representative Form	7.5	18.20*	\$136.50
General Responder (travel expenses)	1.5	\$18.20*	\$27
Survivor (travel expense)	.5	\$12.00	\$6

Pharmacy technician	653	\$14.10**	\$9,207
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*Data from Bureau of Labor Statistics 2001 State Occupational Employment and Wage Estimates New York

** Data from Bureau of Labor Statistics 2010 Healthcare Practitioners and Technical Occupations

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

There are no additional recordkeeping/capital costs.

14. Annualized Cost to Federal Government

Type of Federal employee support	Total Burden Hours	Hourly Wage Rate	Total Federal Costs
Contractor (review of eligibility forms)	2940	\$25.00	\$73,500
Medical and non-medical staff (review of healthcare requests and eligibility appeals)	10,068	\$100.00	\$1,006,800
Total			\$1,080,300

The total cost to the Federal Government is \$1,080,300

15. Explanation for Program Changes or Adjustments

This is a currently approved ICR being submitted as a revision for OMB clearance from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Revisions have been made to the enrollment forms to incorporate the World Trade Center Health Program Enrollment, Appeals & Reimbursement (0920-0891, expiration date 12/31/2014), and the World Trade Center Enrollment & Appeals—Pentagon & Shanksville (0920-1001, expiration date 12/31/2016) into one complete package which will be called the World Trade Center Health Program Enrollment, Appeals & Reimbursement. Upon OMB approval, 0920-1001 will be discontinued. Additionally, when the enrollment forms were first created the WTC Health Program was just starting operations. The revised enrollment forms were modified based on feedback from stakeholders and applicants to add, remove, or edit language on the form for clarity and Program usefulness. Lastly, through consultation with our Office of General Counsel, a notices section was added to the end of the application forms. Based on OMB guidance, the Program has also added Program letters and WTC-3 forms, as well as a designated representative form. However, these have not been changed but added to the packet.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will continue on approval of this OMB package. The OMB approval will be expected to start September 2015 and last three years until August 2018. The WTC Health Program is funded by Congress through 2016 and there are currently bills in

Congress to reauthorize funding permanently.

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

The OMB expiration date will be displayed on the applications, WTC-3 form, clinic postcard, travel reimbursement form, and designated representative form.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.