**SUPPORTING STATEMENT**
**IRRADIATION PHYTOSANITARY TREATMENT OF**
**IMPORTED FRUITS AND VEGETABLES**
**OMB NO. 0579-0155**

**2016**

**NOTE: This is a reinstatement of a previously approved information collection with changes.**

## A. Justification

### 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The United States Department of Agriculture (USDA) is responsible for preventing plant disease or insect pests from entering the United States, preventing the spread of pests and noxious weeds not widely distributed in the United States, and eradicating those imported pests when eradication is feasible. The Plant Protection Act authorizes the Department to carry out this mission.

Under the Plant Protection Act (7 U.S.C. 7701 – et seq), the Animal and Plant Health Inspection Service (APHIS) is authorized, among other things, to regulate the importation of plants, plant products, and other articles to prevent the introduction of plant pests into the United States.

The regulations in 7 CFR § 319 include specific requirements for the importation of fruits and vegetables. For example, fruits and vegetables from certain regions of the world must be treated for inspect pests in order to be eligible for entry into the United States.

The regulations in 7 CFR § 305 provide for the use of irradiation as a phytosanitary treatment for fruits and vegetables imported into the United States. The irradiation treatment provides protection against all insect pests including fruit flies, the mango seed weevil, and others. It may be used as an alternative to other approved treatments for these pests in fruits and vegetables, such as fumigation, cold treatment, heat treatment, and other techniques.

APHIS is asking the Office of Management and Budget (OMB) to approve, for 3 years, its use of these information collection activities, associated with this program, to employ irradiation as an effective phytosanitary treatment for importing fresh fruit and vegetables into the United States.

### 2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information collection activities associated with this program, to employ irradiation as an effective phytosanitary treatment for importing fresh fruit and vegetables into the United States.

**Compliance Agreement PPQ Form 519 (Business) – 7 CFR 305.9 (c)(ii)**
If irradiation treatment occurs in the United States (as opposed to being performed in a foreign country prior to being exported to the United States), the importer must sign a compliance agreement with APHIS. By signing this document, the importer agrees to comply with additional requirements to prevent the escape of plant pests from the commodities to be irradiated during their transit from the port of first arrival to the irradiation facility, and also during the time the commodities are in the irradiation facility.

**30-Day Notification (Business and Foreign Government) – 7 CFR 305.9 (e)(2)**
Facilities that carry out irradiation operations must notify the Director of Preclearance of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance work plan.

**Labeling/Packaging (Business) – 7 CFR 305.9 (f)**
Pallet loads of treated fruit and vegetables must be marked (either by irradiation facility personnel or by the shipper) with treatment lot numbers, packing and treatment facility identification and locations, and the dates of packing and treatment.

This information will allow APHIS inspectors to identify the treatment lots and, if necessary, trace them back to the packing and treatment facilities from which they originated. Without this information, APHIS would be severely hampered in their efforts to conduct a traceback investigation. It should be noted that packing and treatment facilities already include much of this labeling information on their treatment lots.

**Dosimetry Systems at the Irradiation Facility (Business) – 7 CFR 305.9 (j)**
APHIS will require the owner/operator of an approved irradiation facility to have in place a dosimetry system (the system that is used for determining the dose being absorbed by fruits and vegetables during the irradiation process).

There are requirements for certification of the facilities, treatment monitoring, pallet security, and recordkeeping for irradiation at all facilities, and packaging and labeling requirements for articles irradiated before arrival in the United States. Irradiation facilities must use an approved dosimetry system during treatment and keep records to verify effective irradiation. For irradiation after arrival, compliance agreements will impose requirements on the transit from ports to irradiation facilities, to ensure all shipments requiring irradiation are delivered to the facility and are not rerouted for sale prior to treatment.

This system will consist of dosimeters, measurement instruments, reference standards, and procedures. The information obtained via the dosimetry system must be recorded by facility personnel and maintained on file so that APHIS inspectors can review it.

**Request for Approval of Dosimetry Device (Business) – 7 CFR 305.9 (j)**
The owner/operator of an approved irradiation facility must have the facility's dosimetry devices approved by APHIS. The dosimetry systems is employed during calibration or on a routine bases as part of quality assurance to meet USDA is required entry inspections. The information collected assists APHIS in certifying that the facility has met the desired minimum dose of irradiation treatment.

APHIS will approve these devices after determining that they reliably indicate an absorbed dose in the ranges required, and that they can be read by an inspector under normal working conditions. Requests for approval of these devices must be made to APHIS in writing.

**Recordkeeping (Business) – 7 CFR 305.9 (k)**
Approved irradiation facilities must maintain the treatment records for a period of time that exceeds the shelf life of the irradiated product by 1 year. These records must include (among other things) the lot identification, ionizing energy source, source calibration, dosimetry data, dose distribution in the product, and the date of irradiation. These detailed records area necessary to ensure system integrity for irradiation treatments and for successful enforcement of APHIS regulations.

**Request for Certification and Inspection of Facility (Business) – 7 CFR 305.9 (k)(1)**
Anyone requesting approval of an irradiation treatment facility (and treatment protocol) must submit their request to APHIS in writing.

**Irradiation Treatment Framework Equivalency Work Plan - (Foreign Government) 7 CFR 305.9 (e)(1)**
The plant protection service of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency work plan with APHIS. In this plan, both the foreign plant protection service and APHIS will specify the following items for their respective countries: (i) Citations for any requirements that apply to the importation of irradiated articles; (ii) The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated articles into that country; and (iii) Any other conditions that must be met to allow the importation of irradiated articles into that country.

**Facility Preclearance Work Plan (Foreign Government) – 7 CFR 305.9 (e)(2)(i)**
Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the plant protection service of the country from which articles are to be imported must jointly develop a preclearance work plan that details the activities that APHIS and the foreign plant protection service will carry out in connection with each irradiation facility to verify the facility's compliance with the requirements of this section. Typical activities to be described in this work plan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the requirements for separation of articles, packaging, labeling, and other requirements of this section. This facility preclearance work plan will be reviewed and renewed by APHIS and the foreign plant protection service on an annual basis.

**Trust Fund Agreement (Foreign Government) – 7 CFR 305.9 (e)(2)(ii)**
Irradiated articles may be imported into the United States in accordance with this section only if the plant protection service of the country in which the irradiation facility is located has entered into a trust fund agreement with APHIS. That agreement requires the plant protection service to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection and treatment monitoring services at the irradiation facility during that shipping season. Those costs include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by APHIS in performing these services. The agreement will describe the general nature and scope of APHIS services provided at irradiation facilities covered by the agreement, such as

whether APHIS inspectors will monitor operations continuously or intermittently, and will generally describe the extent of inspections APHIS will perform on articles prior to and after irradiation. The agreement requires the plant protection service to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the plant protection service to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any more articles irradiated in that country may be imported into the United States. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the plant protection service or held on account until needed, at the option of the plant protection service.

**Phytosanitary Certificate (Business and Foreign Government) – 7 CFR 305.9 (h)**
For each shipment treated in an irradiation facility outside the United States, a phytosanitary certificate, with the treatment section completed and issued by the national plant protection organization, must accompany the shipment.

**Denial and Withdrawal of Certification (Business) – 7 CFR 305.9 (m)**
The Administrator will withdraw the certification of any irradiation treatment facility upon written request from the irradiation processor. The Administrator will deny or withdraw certification of an irradiation treatment facility when any provision of this section is not met. Before withdrawing or denying certification, the Administrator will inform the irradiation processor in writing of the reasons for the proposed action and provide the irradiation processor with an opportunity to respond. The Administrator will give the irradiation processor an opportunity for a hearing regarding any dispute of a material fact, in accordance with rules of practice that will be adopted for the proceeding. However, the Administrator will suspend certification pending final determination in the proceeding if he or she determines that suspension is necessary to prevent the spread of any dangerous insect. The suspension will be effective upon oral or written notification, whichever is earlier, to the irradiation processor. In the event of oral notification, written confirmation will be given to the irradiation processor within 10 days of the oral notification. The suspension will continue in effect pending completion of the proceeding and any judicial review of the proceeding.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any considerations of using information technology to reduce burden.**

A database or spreadsheet can be utilized by respondents to maintain records and for APHIS review. Letters for facility approval and 30-day notification may be submitted electronically.

The Compliance Agreement PPQ Form 519 is available electronically on the APHIS website https://www.aphis.usda.gov/library/forms/pdf/ppq519.pdf.

**4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use of the purpose described in item 2 above.**

The information APHIS collects is exclusive to its mission to prevent the introduction of plant pests and plant diseases into the United States. The information is not available from any other source.

**5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.**

The information collected is the absolute minimum needed to ensure that fruits and vegetables have been properly irradiated and thus pose no threat of introducing destructive insect pests into the United States. APHIS has determined that 80 percent of the business respondents are small entities.

**6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

If the information was collected less frequently or not collected at all, APHIS would have no practical way of determining that any given commodity had actually been irradiated. Irradiation leaves no residue and usually causes no discernible change to the commodity's color or texture.

**7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.**

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

Facilities that carry out irradiation operations must notify the Director of Preclearance of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance work plan.

- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no other special circumstances associated with this information collection. This information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

**8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.**

APHIS held productive consultations with the following individuals concerning this information collection activities:

Mr. Dan Carestio
Isomedix, Incorporated
5960 Heisley Road
Mentor, OH 44060
440-354-2600

Ms. Dorther Zadig
California Dept of Food & Agriculture
Plant Health and Pest Prevention Services
Pest Exclusion Branch
1220 N Street, Room A372
Sacramento, California 95814
Telephone: 916-653-1440

Dr. Lyle Wong, Director
Division of Plant Industry
Hawaii Department of Agriculture
1428 South King Street
Honolulu, HI 96814-2512
Phone: 808-973-9560

On Friday, July 1, 2016, pages 43182 - 43183, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. During that time, APHIS received no comments.

**9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.**

This information collection activity involves no payments or gifts to respondents.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.**

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and others that are considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

This information collection activity asks no questions of a personal or sensitive nature.

**12. Provide estimates of hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated**.

**. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

See APHIS Form 71. Burden estimates were developed by using historical data through discussions with Program Specialist.

**. Provide estimates of annualized cost to respondents for the hour of burden for collections of information, identifying and using appropriate wage rate categories.**

APHIS estimated the total annualized cost to these respondents to be $8,935.25. APHIS arrived at this figure by multiplying the total burden hours (347 hours) by the estimated average hourly wage of the above respondents ($25.75). This hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2015 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/pdf/ocwage.pdf

347 X $ 25.75 = $8,935.255.

**13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.**

APHIS does not believe that complying with the dosimetry requirements will cause irradiation facilities to incur any significant additional capital investment costs. Dosimetry systems are a basic and unavoidable business cost for irradiation facilities, for two reasons. First, they are the essential process-monitoring and quality control tool for irradiation; they are the means by which facilities ensure that they are delivering their product (a specified radiation dose). Second, dosimetry at irradiation facilities are required by a wide range of national and international regulations quite apart from the APHIS rule, so facilities would have to invest in these systems even `if the APHIS rule did not exist. The APHIS dosimetry requirements merely require that the dosimetry systems the facility must have in any event be used to document that the doses required by the APHIS rule are delivered.

APHIS decided not to require use of radiation sensitive indicators (RSI's) (which included replacing dosimeters in each box irradiated, which will minimize any impact or burden that the industry would have.

**14. Provide estimates of annualized cost the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.**

The estimated cost for the Federal Government is $491.00. (See APHIS Form 79).

**15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-1.**

ICR Summary of Burden:

| N Requested | Program Change Due to New Statute | Program Change Due to Agency Discretion | Change Due to Adjustment in Agency Estimate | Change Due to Potential Violation of the PRA | Previously Approved |
|---|---|---|---|---|---|
| Annual Number of Responses | 40,434 | 0 | 40,434 | 0 | 0 | 0 |
| Annual Time Burden (Hr) | 347 | 0 | 347 | 0 | 0 | 0 |
| Annual Cost Burden ($) | 0 | 0 | 0 | 0 | 0 | 0 |

The reinstatement of this information collection resulted in a program change increase of +63 respondents and an increase of +40,434 total annual responses, resulting in an increase of +347 total burden hours.

APHIS is now accounting for the Phytosanitary Certificates for Foreign Government respondents which were not included in the previous information collection.

**16. For collections of information whose results are planned to be published, outline plans for tabulation and publication**.

APHIS has no plans to publish the information collected in connection with this program.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

The PPQ 519 is used in 15 collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on this form.

**18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."**

APHIS is able to certify compliance with all the provisions identified in the Act.

**B. Collections of Information Employing Statistical Methods.**

Statistical methods are not used in this information collection.