SUPPORTING STATEMENT
Location of Irradiation Treatment Facilities in the United States
OMB No. 0579-0383

March 2016

NOTE: This is a Reinstatement of a previously approved information collection with changes. In addition, please note the title of the collection changed slightly from Irradiation Treatment; Location of Facilities in the United States to the above title.

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 into the United States, and eradicating those imported pests when eradication is feasible. The Plant Protection Act (7 U.S.C. 7701 – et seq.) authorizes USDA to carry out this mission.

Under the Plant Protection Act, 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 phytosanitary treatment regulations contained in 7 CFR, Part 305 thru 305.9 (referred to below as the regulations), set out the general requirements for performing treatments and certifying or approving treatment facilities for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or throughout the United States.

The regulations provide generic criteria for new irradiation treatment facilities in the United States to be located anywhere in the United States, subject to approval. This action facilitates the importation of commodities requiring irradiation treatment while continuing to provide protection against the introduction of pests of concern into the United States.

APHIS is asking OMB to approve the use of this information collection activity for 3 years, associated with its efforts to prevent the spread of plant pests and plant diseases in 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 will use the following information collection activities to provide generic criteria for irradiation treatment facilities in an effort to prevent the spread of plant pests and plant diseases in the United States.

Request for Initial Certification and Inspection of Facility (business) (7 CFR 305.9(l))

Persons requesting initial certification of an irradiation treatment facility must submit the request for approval in writing to APHIS, Plant Protection and Quarantine (PPQ), Center for Plant Health Inspection and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606-5202. The initial request must identify the owner, location, and radiation source of the facility. The applicant must supply additional information about the facility construction, treatment protocols, and operations upon request by APHIS if APHIS requires additional information to evaluate the request. Before the Administrator determines whether an irradiation facility is eligible for certification, an inspector will make a personal inspection of the facility to determine whether it complies with the standards of this section.

Certification and Recertification of Facility (business) (7 CFR 305.9(d))

The irradiation treatment facility must be certified by APHIS. Recertification is required in the event of an increase in the amount of radioisotope, a decrease in the amount of radioisotope for a reason other than natural decay, a major modification to equipment that affects the delivered dose, or a change in the owner or managing entity of the facility. Recertification also may be required in cases where a significant variance in dose delivery has been measured by the dosimetry system. In order to be certified, a facility must be capable of administering the minimum absorbed ionizing radiation doses specified in the PPQ Treatment Manual or in another treatment schedule approved in accordance with §305.2 to the regulated articles; the maximum absorbed ionizing radiation dose and the irradiation of food is regulated by the Food and Drug Administration under 21 CFR part 179. Be constructed so as to provide physically separate locations for treated and untreated articles, except that articles traveling by conveyor directly into the irradiation chamber may pass through an area that would otherwise be separated. The locations must be separated by a permanent physical barrier such as a wall or chain link fence 6 or more feet high to prevent transfer of cartons, or some other means approved during certification to prevent re-infestation of articles and spread of pests. If the facility is to be used to treat imported articles and is located in the United States, the facility will only be certified if APHIS determines that regulated articles will be safely transported to the facility from the port of arrival without significant risk that plant pests will escape in transit or while the regulated articles are at the facility.

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 to be in effect pending completion of the proceeding and any judicial review of the proceeding.

PPQ 519 - Compliance Agreements (business-facility) (business-importer) (7 CFR 305.9(c))
Irradiation facilities treating imported articles should have a compliance agreement with importers and facility operators for irradiation in the United States. If irradiation of imported articles is conducted in the United States, both the importer and the operator of the irradiation facility must sign compliance agreements with APHIS. In the facility compliance agreement, the facility operator must agree to comply with any additional requirements found necessary by APHIS to prevent the escape, prior to irradiation, of any pests of concern that may be associated with the articles to be irradiated. In the importer's compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be irradiated during their transit from the port of first arrival to the irradiation facility in the United States.

Irradiation Facilities Treating Imported Articles; Irradiation Treatment Framework Equivalency Workplan (foreign government) (7 CFR 305.9(e)(1))
Facilities will be located within an area over which the U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force. The National Plant Protection Organization (NPPO) of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency workplan with APHIS. In this plan, both the NPPO and APHIS will specify the following items for their respective countries: (1) citations for any requirements that apply to the importation of irradiated fruits and vegetables; (2) the type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables into that country; and (3) any other conditions that must be met to allow the importation of irradiated fruits and vegetables into that country.

Irradiation Facilities Notification (business) (7 CFR 305.9(e)(3))
Facilities located within the United States must notify an inspector at least 24 hours before scheduled operations (excluding Saturday, Sunday, and Federal holidays). If the facility will be used to treat imported articles, the NPPO of the country from which the articles are to be imported into the United States must also sign the irradiation treatment framework equivalency workplan. Inspectors are assigned to APHIS local offices which are listed in telephone directories.

Records (business) (7 CFR 305.9(k))
An irradiation processor must maintain records of each treated lot for 1 year following the treatment date, and must make these records available for inspection by an inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except for holidays). These records must include the lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

Facility to Maintain and Provide Updated Map Identifying Place Horticultural/Crops Are Grown (business)(7 CFR 305.9(a)(1)(viii))
The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are gown within a 4-mile radius of the facility. Proximity of host

material to the facility will necessitate trapping or other pest monitoring activities to help prevent establishment of any escaped pests of concern, as approved by APHIS.

Facility Contingency Plan (business) (7 CFR 305.9(a)(1)(vi))
The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles.

Letter of Concurrence or Non-Agreement (state) (7 CFR 305.9(a)(1)(ii))
The government of the State in which the facility is to be located must concur in writing with the establishment of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, APHIS and the State will agree on a strategy to resolve the pest risk concerns prior to APHIS approval.

Treatment Arrangements (business) (7 CFR 305.9(a)(1)(vi))
Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility.

Pest Management Plan (business) (7 CFR 305.9(a)(1)(viii))
The treatment facility must have a pest management plan within the facility. The plan is established in order to minimize risk of pests and for handling potential outbreaks of pests.

Facility Map - Detailed Layout of Facility (business) (7 CFR 305.9(a)(1)(i))
Prospective facility operators must submit to APHIS a detailed layout of the facility site and its location. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from ports of entry or points of origin in the United States.

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 management plans and treatment arrangements for review by APHIS. Letters of concurrence for the state facility approval may be submitted electronically.

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 therefore pose no threat of introducing destructive insect pests into the United States. APHIS has determined 90 percent of the 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;**
- **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 special circumstances associated with this information collection that would require it to be conducted in a manner inconsistent with the general information collection guidelines 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.

The following individuals were consulted during 2015:

Michael Adams
Assistant Plant Manager and Operator
Sadex Corporation
2650 Murray Street
Sioux City, IA 51111
712-252-3505

Kristen Jones
The Americas Regional Southern Representative
Sterigenics
2015 Spring Road, Suite 650
Oak Brook, IL 60523
1-630-928-1700

Gray Star
Alec Keith, Director
200 Valley Road, Suite 103
Mount Arlington, NJ 07856
973-398-3331

On Friday, October 9, 2015, pages 61155-61156, 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. No comments from the public were received.

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 for burden hour estimates.

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

$36.45 (estimated hourly rate) x 285 (burden hours) = $10,388.25 (estimate of annualized cost)

The hourly rate of $36.45 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/ocwage.t03.htm.

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.

There is zero annual cost burden associated with capital and start-up costs, maintenance costs, and purchase of services in connection with this program.

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 $5,070.73 (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	277	0	277	0	0	0
Annual Time Burden (Hr)	285	0	285	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

There is a program change of +29 respondents, +277 responses and +285 total burden hours for this collection due to its reinstatement.

APHIS is including the following additional burden in this reinstatement as a result of extensive re-examination of the regulations: (1) Request for Initial Certification and Inspection of Facility, (2) Certification and Recertification of Facility, (3) Denial and Withdrawal of Certification, (4) PPQ 519 - Compliance Agreements (completed by the Facility and the Importer), (5) Irradiation Facilities Treating Imported Articles; Irradiation Treatment Framework Equivalency Workplan, (6) Irradiation Facilities Notification, (7) Records, (8) Written Letter of Concurrence or Non-agreement, (9) Treatment Arrangements, and (10) Pest Management Plan (11) Facility Map – Detailed Layout of Facility.

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

APHIS has no plans to publish 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 Form 519 is used in 13 information 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.