Revised Oct 2006

SUPPORTING STATEMENT
IRRADIATION PHYTOSANITARY TREATMENT FOR
FRESH FRUITS AND VEGETABLES
OMB NO. 0579-0155

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 diseases 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 – 7772), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of injurious plant pests.

APHIS' regulations contained in Part 319 of Title 7, Code of Federal Regulations (CFR), accomplish this by placing specific requirements on the importation into the United States of fruits and vegetables. For example, fruits and vegetables from certain regions of the world must undergo insect-killing treatments before they can be imported into the United States.

APHIS is asking OMB to approve, for 3 more years, its use of this information collection, in connection 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.

Compliance Agreement

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 us. 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

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

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 our 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, we would be severely hampered in our 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 Recording

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 our inspectors can review it.

Recordkeeping

Approved irradiation facilities must maintain the above 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 our regulations.

Request for Approval of Dosimetry Device

The owner/operator of an approved irradiation facility must have the facility's dosimetry devices approved by APHIS. The dosimetry system is employed during calibration or on a routine bases as part of quality assurance to meet USDA entry required inspections. The information collected assists us 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 us in writing.

Request for Facility Approval

Anyone requesting approval of an irradiation treatment facility (and treatment protocol) must submit their request to us in writing.

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 review by APHIS. Letters for facility approval and 30-day notification 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 thus pose no threat of introducing destructive insect pests into the United States.

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.

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.

The following individuals were consulted during 2006:

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

Dr. Lyle Wong, Director
Division of Plant Industry
Hawaii Department of Agriculture
1428 South King Street
Honolulu, Hawaii 96814
(808)973-9535

Dr. Harry Farrar
18 Flintrock Lane
Bell Canyon, California 91307
(818)340-1227

On Thursday, June 8, 2006, 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. However, the confidentiality of information is protected under 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 from discussions with U.S. importers of fresh fruits and vegetables, packers, shippers, and irradiation facility personnel.

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

760 X $20.00 = $15,200.

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: (1) 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); and (2) dosimetry at irradiation facilities is 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 to the Federal Government is $13,887.77.

(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.

There is an adjustment in the burden hours for labeling due to a decrease in the number of respondents. The number of respondents recorded in 2003 was 120 (this was an erroneous amount). The current number of respondents has been reduced to 25, which caused a large decrease in the total burden hours for this collection of information.

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.

There are no USDA forms associated with this collection of information.

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.