UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

APPLICATION FOR USDA IRRADIATION FACILITY APPROVAL

FOR USE IN CONDUCTING PHYTOSANITARY IRRADIATION TREATMENTS UNDER USDA REGULATIONS

INSTRUCTIONS

a. Use one application for each facility.

b. Review the regulatory requirements in Chapters 3 (Nonchemical Treatments) and 6 (Certifying Facilities) of the USDA Treatment Manual. An electronic PDF document of the manual is available at the APHIS website: https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf.

c. Each application must include technical documents that support the information supplied. Please attach the supporting documentation in the form of PDF or Word files. Any large blueprints or facility schematics need to be in a high resolution format so that details can be clearly seen.

d. Fill in each field of the application completely. Review of the application will not begin until all information is received. If a field is not applicable, please put "N/A" in the space provided.

e. All responses and supporting materials in this application must be written in English.

f. After receiving all requested information and required documentation, application approval may take as long as 60 (sixty) days.

g. Once the application has been approved by APHIS-S&T, an onsite certification inspection may be scheduled.

h. Facilities located in the United States should contact USDA-APHIS PPQ Field Operations (PPQ.Ops.Treatments@usda.gov) to discuss the certification process and requirements.

i. Facilities located in countries other than the United States should contact the National Plant Protection Organization (NPPO) in their country to request information and submit their applications. The foreign country NPPO will then forward the application to USDA-APHIS International Services. (Your applicable International Services office can be located at https://www.aphis.usda.gov/aphis/ourfocus/internationalservices/contact_map.) Applications will then be forwarded to PPQ Phytosanitary Issues Management (PIM), and finally Preclearance and Offshore Programs (POP). Foreign facilities should not contact PPQ without first consulting with their NPPO.

j. Questions regarding the application should be routed to:

USDA-APHIS-PPQ-S&T-TMT
Phone: +1-305-278-4877
ppqtmt@usda.gov

SECTION 1. CONTACT INFORMATION

This information will be used by USDA as the official contact information for this facility.

NAME OF FACILITY			
STREET ADDRESS OF FACILITY			
CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
LATITUDE		LONGITUDE	
NAME OF FACILITY CONTACT PERSON		JOB TITLE OF FACILITY CONTACT PERSON	
TELEPHONE		EMAIL	

☐ *(Required)* Attach a map showing the location of the treatment facility (drawing or satellite map).

SECTION 2. TYPE OF REQUEST

What type of request is this? (Check one only)

☐ Request for approval of a new facility. (Facility is fully built and all equipment is in place.)

☐ Request for approval of plans to begin construction of a new facility. (For this type of request, only fill out sections 1 and 2 and attach facility drawings/plans. When the facility is fully built and all equipment is in place, you will need to submit a full application.)

☐ Request for recertification of an approved facility. If this is a request for recertification, please select the reason(s) for recertification:

- ☐ Changes to facility operations or infrastructure
- ☐ Changes to the radiation source (e.g., source replenishment or equipment repairs)
- ☐ Changes to facility management
- ☐ Other reason, describe below:

For recertification, ONLY complete the sections below where changes have been made since the last time the facility was certified. If no changes have been made for a particular section, leave it blank. For recertification due to changes to the radiation source, submit detailed information about the source characterization before and after the change.

SECTION 3. OPERATING PROCEDURES

Which irradiation programs would this facility like to participate in? (Check all that apply.)

☐ US Imports - Preclearance/Offshore (Irradiation facilities located outside the US)

☐ US Imports - Upon Arrival (Irradiation facilities located in the US)

☐ Domestic/Interstate (Movement within Federal U.S. Quarantines)

☐ US Exports

Standard Operating Procedures (SOPs)

☐ *(Required)* Attach Standard Operating Procedures (SOPs) that describe all tasks that impact treatment performed at the facility. Attach these SOPs to the application as a single document with pages numbered consecutively in a manner that shows the current page number and the total number of pages (for example, page 2 of 10). Please make sure that the pages are dated as well. The required SOPs listed below represent a minimum requirement, and other procedures that impact treatment must be included.

For each SOP, include the following details:

1. Name of procedure.
2. Definitions of abbreviations and non-conventional terms.
3. List of specialized equipment used (make and model number).
4. Description of procedure. The procedure must be described in enough detail to allow a person who has not worked at the facility to understand and visualize the work being performed. Procedures should use outline format.
5. Any diagrams, drawings, or figures that are necessary to describe the procedure.

Required SOPs	Procedure Name	Start Page Number	End Page Number
1	Overview of process flow. Briefly describe all steps from start to finish for processing a load of articles. A flow chart may be appropriate.		
2	Article arrival and unloading.		
3	Pre-treatment inspection of articles.		
4	Identification and labelling conventions for treatments (e.g., treatment identification number, TIN).		
5	Storage of packaged articles prior to treatment.		
6	Irradiation of articles.		
7	Post-treatment storage.		
8	Loading and shipping of treated articles.		
9	Pest exclusion and trapping.		
10	Handling of rejected and non-conforming articles. Include destruction methods for rejected articles and destruction methods for debris from conveyances if applicable.		
11	Facility cleaning and sanitation.		
12	Management of treatment documents and data.		
13	Dosimetry. Include methods to establish traceability to a national standards laboratory, procedures for a new dosimeter batch or lot, and routine dosimetry practices.		

Required SOPs, continued	Procedure Name	Start Page Number	End Page Number
14	Calibration and recalibration of all equipment, including spectrophotometers, and procedures for equipment maintenance and servicing.		
15	Dose mapping of new process configurations for phytosanitary treatments.		
16	Requalification procedures after changes to the source or article transport system: Operational Qualification (OQ) and Performance Qualification (PQ).		
17	Methods for keeping USDA-program materials separated from non-USDA-program materials.		
18	Staff training.		
19	Emergency procedures: weather incidents, critical staff shortages, power outages, other emergencies.		
20	Change Control System: Describe how the facility manages and tracks changes to SOPs (e.g., person(s) authorized to change SOPs, tracking of reasons and dates for changes).		

License Information

This section collects information about the license granted to the facility by the national/regional nuclear regulatory agency.

NAME OF NUCLEAR REGULATORY AUTHORITY GRANTING LICENSE (LICENSE GRANTOR)

GRANTOR STREET ADDRESS

GRANTOR CITY	GRANTOR STATE/PROVINCE	GRANTOR POSTAL CODE	GRANTOR COUNTRY

NAME OF CONTACT PERSON AT NUCLEAR REGULATORY AUTHORITY

GRANTOR TELEPHONE	GRANTOR EMAIL

LICENSE IDENTIFICATION NUMBER

LICENSE EFFECTIVE DATE (mm/dd/yyyy)	LICENSE EXPIRATION DATE (mm/dd/yyyy)

LICENSE CONDITIONS (EXPLAIN):

☐ *(Required)* Attach a color copy of the original license (front, back and any supporting addenda). Include an official English translation of the license if not in English.

Description of Personnel

☐ *(Required)* Attach a document that describes the organization of personnel, such as an employee tree. This description must include the following information:

1. Chain of command.
2. Position name.
3. Brief description of duties.
4. Number of employees in this position.
5. Name(s) of employee(s).
6. Whether employees are permanent, temporary or seasonal.
7. The person responsible for Quality Control (QC)/Quality Assurance (QA).

SECTION 4. DESIGN / LAYOUT

Do all windows and vents in the facility have pest-proof screens? ☐ YES ☐ NO

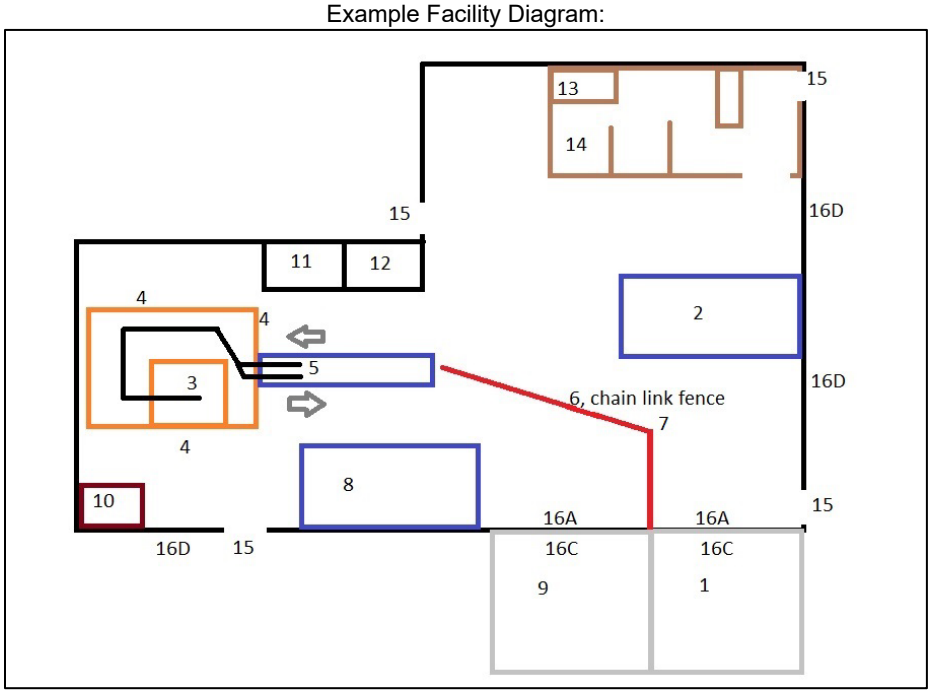
Do all loading docks in the facility have loading dock boots (cushions that tightly seal against the rear doors of the truck)? ☐ YES ☐ NO

Do all exit doors and loading docks in the facility have air curtains (flying insect fans)? ☐ YES ☐ NO

☐ *(Required)* Attach a detailed floor plan of the irradiation facility. Include all items listed below on the diagram. The reference number for each item must be placed on the diagram for easy identification of that item. Each number may be used multiple times. See example below.

Reference Number	Item
1.	Article delivery and unloading area.
2.	Storage of untreated articles.
3.	Irradiator.
4.	Delineation of all areas that may be exposed to radiation above ambient levels.
5.	Conveyor (or similar system) used to move articles through irradiator.
6.	Delineation between areas for storage and processing of untreated and treated articles.
7.	Barrier between untreated and treated areas. ☐ *(Required)* Attach photographs of the barrier.
8.	Storage of treated articles.
9.	Article loading and shipping.
10.	Storage of rejected articles.
11.	Air conditioned control room.
12.	Climate controlled dosimetry area.
13.	Bathrooms.
14.	Offices.
15.	Exit doors.
16a.	Double doors (quarantine measure), if applicable.
16b.	Air curtains (quarantine measure), if applicable.
16c.	Loading dock boots (quarantine measure), if applicable.
16d.	Screens on windows or other openings (quarantine measure), if applicable.

Example Facility Diagram:



SECTION 5. EQUIPMENT

Irradiator Information

MANUFACTURER NAME		
MODEL	SERIAL NUMBER	
MANUFACTURER STREET ADDRESS		
MANUFACTURER STATE/PROVINCE	MANUFACTURER POSTAL CODE	MANUFACTURER COUNTRY
MANUFACTURER CONTACT PERSON		
DATE INSTALLED (mm/dd/yyyy)	RADIATION SOURCE	
RADIATION POTENTIAL OF CURRENT SOURCE	PROJECTED SOURCE REPLENISHMENT DATE, IF APPLICABLE	
What unit is treated in the irradiator? (For example: tote, individual box)	UNIT TYPE	
Describe how units are transported into the irradiator for treatment (for example: conveyor belt, hanging unit transport system)	TRANSPORT SYSTEM	
How long does it take to treat a load at 400 Gray (in minutes)?	MINUTES	

☐ *(Required)* Attach a diagram or photographs of the irradiator, showing product flow during treatment.

Dosimetry System

Provide the following information for the primary and backup dosimetry systems for the facility.

Description	Primary Dosimetry System	Backup Dosimetry System
TYPE OF DOSIMETRY SYSTEM (E.G., ALANINE EPR)		
NAME OF STANDARD USED TO PERFORM DOSIMETRY (E.G., ISO/ASTM 51607)		
SPECTROPHOTOMETER MANUFACTURER		
SPECTROPHOTOMETER MODEL		
SPECTROPHOTOMETER SERIAL NUMBER		
DOSIMETER MANUFACTURER		
DOSIMETER MODEL		
HAS TRACEABILITY TO A NATIONAL STANDARDS LABORATORY BEEN ESTABLISHED IN THE DOSE RANGE OF 100 TO 1000 GRAY FOR THIS SYSTEM?	☐ YES ☐ NO	☐ YES ☐ NO
WHICH NATIONAL STANDARDS LABORATORY DID YOU USE?		
ON WHAT DATE DID YOU WORK WITH THE NATIONAL STANDARDS LABORATORY TO ESTABLISH TRACEABILITY?	DATE (mm/yyyy)	DATE (mm/yyyy)

DESCRIBE HOW TRACEABILITY TO A NATIONAL STANDARDS LABORATORY WAS ESTABLISHED FOR THESE DOSIMETRY SYSTEMS:

☐ *(Required)* Attach a color copy of the calibration certificate for the spectrophotometer(s).

☐ *(Required)* Attach evidence of traceability of the dosimetry system to a national standards laboratory (for example, the National Institute of Standards and Technology, NIST)

SECTION 6. SAFETY

Does the facility have fire extinguishers?	☐ YES ☐ NO
Does the facility have a first aid kit?	☐ YES ☐ NO
Does the facility use radiation monitoring badges to monitor personnel irradiation exposure?	☐ YES ☐ NO

SECTION 7. ATTACHMENTS (supporting documentation)

Are the following technical documents included in the submission attachments?

Map showing the location of the treatment facility.	☐ YES ☐ NO
All facility SOPs in a single document.	☐ YES ☐ NO
A color copy of the original nuclear regulatory license (front, back and any supporting addenda). Include an English translation of the license if not in English.	☐ YES ☐ NO
A document that describes the personnel at the facility.	☐ YES ☐ NO
A detailed facility diagram/floor plan with required items 1 through 16d labeled on the diagram (see Section 4).	☐ YES ☐ NO
Photographs showing a sturdy physical barrier that separates the areas where untreated and treated articles are present.	☐ YES ☐ NO
Diagram or photographs of the irradiator, showing product flow during treatment.	☐ YES ☐ NO
The calibration certificate for the spectrophotometer.	☐ YES ☐ NO
Documents demonstrating dosimetry traceability to a national standards laboratory (e.g., NIST).	☐ YES ☐ NO

SECTION 8. ADDITIONAL INFORMATION

Information critical to treatment at your facility not otherwise captured in this application form. Please describe below:

Missing Information

If you left any fields blank, please identify the section and page numbers and provide reasons for each missing field.

SECTION	REASON FOR MISSING INFORMATION	
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SECTION 9. REQUESTOR SIGNATURE

SIGNATURE	PRINT NAME	DATE *(mm/dd/yyyy)*