



Irradiation Facility Certification for Phytosanitary Treatments

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Plant Protection and Quarantine
Animal and Plant Health Inspection Service
United States Department of Agriculture

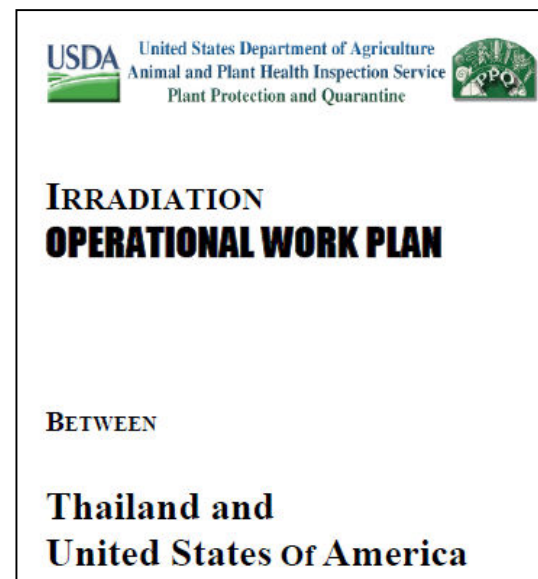
Outline

- Regulatory Summary
- Resources
- Facility Approval
- Certification Preparation
- Facility Certification
- Facility Recertification



Import Regulatory Summary

- Market Access Granted
- Framework Equivalency Work plan Signed
- Trust Fund Established (Preclearance)
- Operational Work Plan Signed
- Commodity-Specific Addendum Signed



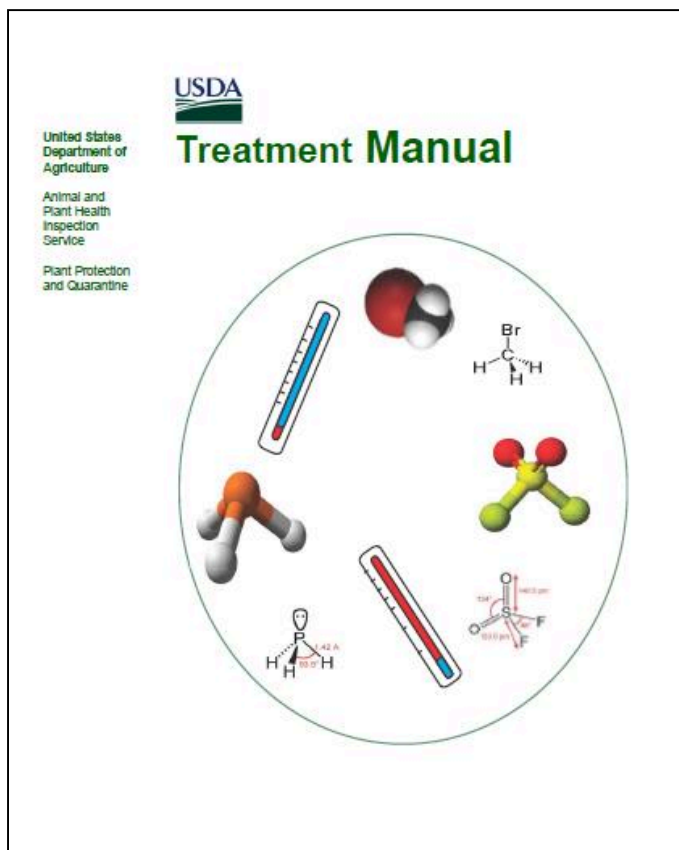
Import Regulatory Summary



- Facility Plan Approved ★
- Facility Certified ★
- Importer Compliance Agreement Signed
- Importer Permit Granted
- Packaging Approved
- Process Configuration Approved

PPQ Treatment Manual

http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf

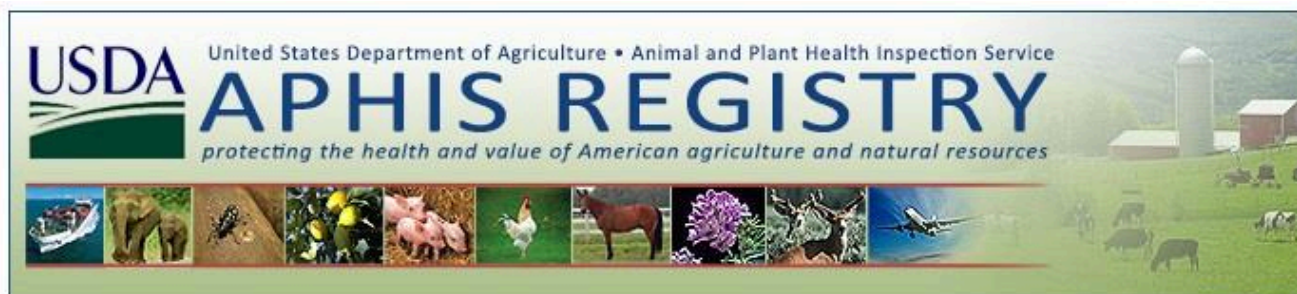


- Import-driven Manual
- Treatment Schedules
- Irradiation Overview
- Pest Specific/Generic Doses
- Facility Certification
- Facility Audits
- Dosimetry
- Dose Mapping



PPQ Stakeholder Registry

<https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new>



Email Updates

To sign up for updates or to access your subscriber preferences, please enter your contact information below.

Subscription Type

*Email Address

Your contact information is used to deliver requested updates or to access your subscriber preferences.



PPQ Stakeholder Registry



Welcome laura.a.jeffers@aphis.usda.gov

Quick Subscribe for laura.a.jeffers@aphis.usda.gov

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- APHIS - Employees
- Animal Care
- Biotechnology Regulatory Services
- International Services
- Legislative and Public Affairs
- Plant Health Information
 - Importation into the US
 - Exportation from the US
 - Plant Health in the US (Domestic)
- Manuals Updates
 - Import Inspection Manuals
 - Agricultural Quarantine Inspection Monitoring (AQIM) Handbook [Y](#) [I](#)
 - Animal Product Manual [Y](#) [I](#)
 - Canadian Border Agricultural Clearance Manual [Y](#) [I](#)
 - CITES I-II-III Timber Species Manual [Y](#) [I](#)
 - Cut Flowers and Greenery Import Manual [Y](#) [I](#)
 - Export Program Manual (XPM) [Y](#) [I](#)
 - Federally Recognized State Managed Phytosanitary (FRSMP) Program Manual [Y](#) [I](#)
 - Fruits and Vegetables Import Requirements (FAVR) database [Y](#) [I](#)
 - Fresh Fruits and Vegetable Manual [Y](#) [I](#)
 - Hawaii Manual [Y](#) [I](#)
 - Japanese Beetle Program Manual for Airports [Y](#) [I](#)
 - Manual for Agricultural Clearance [Y](#) [I](#)
 - Mexican Border Job Aid [Y](#) [I](#)



- Miscellaneous and Processed Product Manual [?](#)
- National Detector Dog Manual [?](#)
- Plants for Planting Manual [?](#)
- Postentry Quarantine Manual for State Inspectors (PEQ) [?](#)
- Puerto Rico Manual [?](#)
- Reviewer's Manual for the Technical Advisory Group for Biological Control Agents of Weeds/Settings [?](#)
- Seeds Not for Planting Manual [?](#)
- Treatment Manual [?](#)

Program Manuals [?](#)

- Aerial Application Manual [?](#)
- Emerald Ash Borer Program Manual (EAB) [?](#)
- Emergency Response Manual [?](#)
- Golden Nematode Program Manual [?](#)
- Grasshopper Guidebook [?](#)
- Gypsy Moth Manual [?](#)
- Imported Fire Ant Program Manual [?](#)
- New Pest Response Guidelines [?](#)
- Panicle Rice Mite Program Manual [?](#)
- Treatment Manual [?](#)
- Federally Recognized State Managed Phytosanitary (FRSMP) Program Manual [?](#)

News and Information

- News and Information (Plant Health) [?](#)
- Federal Register Notices (Plant Health) [?](#)
- Meetings (Plant Health) [?](#)
- Electronic Databases - System Status [?](#)
 - e-permits [?](#)
 - Integrated Plant Health Information System (IPHIS) [?](#)
 - Phytosanitary Certificate Issuance and Tracking (PCIT) [?](#)
 - Fruits and Vegetables Import Requirements (FAMR) [?](#)

Veterinary Services

Wildlife Services

PPQ Stakeholder Registry



PPQ Irradiation Treatment Site

http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_plant_health%2Fsa_import%2Fsa_quarantine_treatments%2Fct_irradiation_treatment

“I am interested in having an irradiation facility certified by APHIS to apply quarantine treatments for fresh fruits and vegetables.

Where can I get more information?”

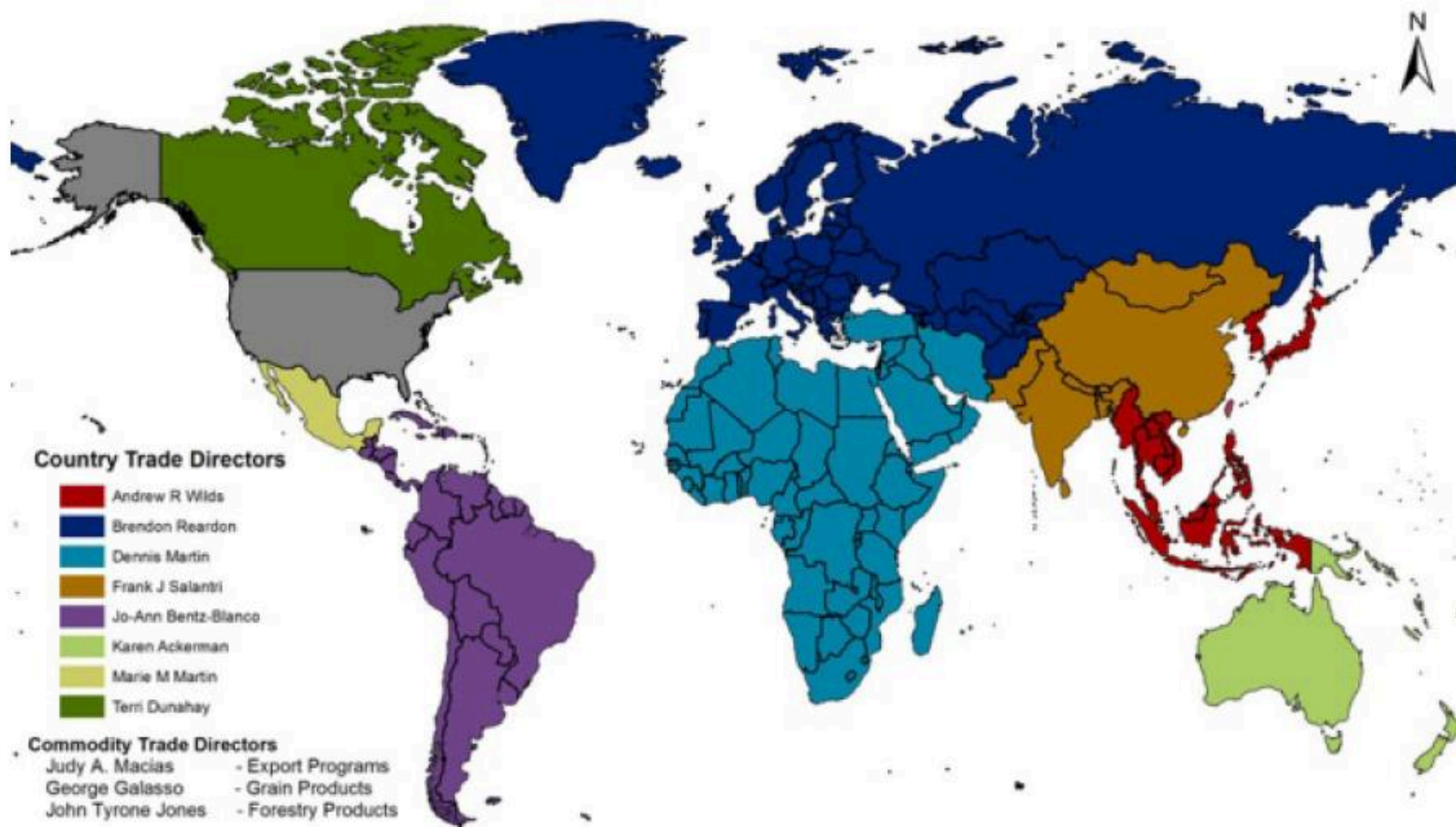
Facility Approval and Certification

Laura Jeffers

(919) 855-7455

laura.a.jeffers@aphis.usda.gov

PPQ Trade Team





PPQ Trade Team

Country Trade Directors

- Karen Ackerman (301) 851-2111, Oceania
- Jo-Ann Bentz-Blanco (301) 851-2091, Central America, South America, Caribbean
- Terri Dunahay (301) 851-2369, Canada
- Dennis Martin (301) 851-2033, Africa, Middle East
- Marie Martin (301) 851-2107, Mexico
- Brendon Reardon (301) 851-2223, Europe
- Vacant, China, India, Pakistan
- Vacant, Japan, Korea, Taiwan, ASEAN

So you want an irradiation facility?

Step 1. In what program type are you interested?
Depending on the program type, your requirements may differ.

- Preclearance
- Port of entry
- Domestic
- Export



FEWP

Countries with signed Framework Equivalency Workplan with the U.S.

- India
- Laos
- Malaysia
- Mexico
- Pakistan
- Peru
- Philippines
- South Africa
- Thailand
- Vietnam

as of 8/29/14



So you want an irradiation facility?

Step 2. If your facility is in the USA, contact CPHST (Laura Jeffers) for a Facility Plan Approval Application. She will tell you who else to keep informed of your progress (State Plant Health Director (SPHD), State Plant Regulatory Official (SPRO), PPQ Trade Directors, etc.).



So you want an irradiation facility?

Step 2 cont. If your facility is outside of the USA, contact Laura Jeffers for a Facility Plan Approval Application. It is **imperative** to contact to the PPQ Country Trade Director to make sure that the appropriate agreements/work plans are in place.

Step 3. Prepare and turn in an electronic copy of your Facility Plan Approval Application to CPHST (Laura Jeffers), ensuring the appropriate people are copied. Please send the signed hard copy directly to CPHST.



So you want an irradiation facility?

Step 4. CPHST reviews application. Depending on condition of application, review can take 1 - 3 months.

Step 5. CPHST schedules call with facility to discuss facility application and collects additional information (if needed). CPHST issues facility approval letter.

Step 6. CPHST schedules call with facility and other PPQ staffs to discuss and schedule certification visit. Depending on identified issues, certification visit usually occurs 2-3 months after approval.



So you want an irradiation facility?

Step 7. During interim, facility prepares for PPQ certification visit.

Step 8. PPQ (CPHST, Field Operations or Preclearance) conducts facility certification. PPQ issues facility certificate (Form 482).

Southern US States only: A letter supporting the establishment of a port of entry irradiation facility signed by the State Plant Regulatory Official (SPRO) must be submitted **before** facility approval.

Facility Approval

- Facility Location
- License Information
- Irradiator Information
- Safety Information
- Standard Operating Procedures (SOP)
- Personnel Information
- Dosimetry Information
- Facility Diagrams



Facility Location

Facility Location Information Irradiation Plan Approval Worksheet # 2

| Item | Response | TQAU Approved? |
|--------------------|----------|-------------------|
| 1. Facility name: | | |
| 2. Street address: | | |
| 3. City: | | |
| 4. State/Province: | | |
| 5. Postal code: | | |
| 6. Latitude: | | |
| 7. Longitude: | | |
| 8. Country: | | |
| 9. Email address: | | |



License Information

License Information Irradiation Plan Approval Worksheet # 3

| Item | Response | TQAU Approved? |
|---------------------------------|----------|-------------------|
| 1. License grantor: | | |
| 2. Grantor street address: | | |
| 3. Grantor city: | | |
| 4. Grantor state/province: | | |
| 5. Grantor postal code: | | |
| 6. Grantor contact person: | | |
| 7. License identification #: | | |
| 8. License effective date: | | |
| 9. License expiration date: | | |
| 10. License conditions: | | |



Irradiator Information

Irradiator Information Irradiation Plan Approval Worksheet #4

| Item | Response | TQAU Approved? |
|---|----------|-------------------|
| 1. Manufacturer name: | | |
| 2. Model: | | |
| 3. Serial number: | | |
| 4. Manufacturer street address: | | |
| 5. Manufacturer state/province: | | |
| 6. Manufacturer postal code: | | |
| 7. Manufacturer country: | | |
| 8. Manufacturer contact person: | | |
| 9. Date installed: | | |
| 10. Radiation source: | | |
| 11. Radiation potential /size of source: | | |
| 12. Projected source replenishment date: | | |



Safety Information

Safety Information Irradiation Plan Approval Worksheet # 5

| Item | Response | TQAU Approved? |
|--------------------------------|----------|-------------------|
| 1. Dose badge manufacturer: | | |
| 2. Dose badge model: | | |



SOP Outlines

Standard Operating Procedures (SOP) Outline Irradiation Plan Approval Worksheet # 6

All tasks that impact treatment performed at the facility must be described with a Standard Operating Procedure (SOP). The procedures listed below represent a minimum requirement and other procedures that impact treatment must be included. All SOPs should be included in 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). Where applicable, SOPs should reference locations in the facility using reference numbers from worksheet #9 and #9a.

| Section | Procedure Name | Start Page Number | End Page Number | TQAU Approved? |
|------------|--|-------------------|-----------------|----------------|
| Section 1 | Article arrival and unloading. | | | |
| Section 2 | Pre-treatment inspection of articles. | | | |
| Section 3 | Storage of packaged articles prior to treatment. | | | |
| Section 4 | Irradiation of articles. | | | |
| Section 5 | Post-treatment storage. | | | |
| Section 6 | Loading and shipping of treated articles. | | | |
| Section 7 | Pest exclusion and trapping. | | | |
| Section 8 | Handling of rejected articles. | | | |
| Section 9 | Facility cleaning and sanitation. | | | |
| Section 10 | Management of treatment documents and data. | | | |
| Section 11 | Dose Mapping. | | | |
| Section 12 | Dosimetry. | | | |
| Section 13 | Calibration of spectrophotometer. | | | |



SOP Outlines (cont.)

Standard Operating Procedures (SOP) Outline Irradiation Plan Approval Worksheet # 6

| Section | Procedure Name | Start Page Number | End Page Number | TQAU Approved? |
|------------|---|-------------------|-----------------|----------------|
| Section 14 | Verification of conveyor speed or exposure times. | | | |
| Section 15 | Staff training. | | | |

Each SOP for the irradiation facility must contain the following sections labeled with the numbers provided here:

1. Name of procedure.
2. Definitions of non-conventional terms.
3. List of specialized equipment used in each SOP.
4. Description of procedure. The procedure must be described in enough detail to allow a person who has not worked at a 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.



Personnel Information

Description of Personal Irradiation Plan Approval Worksheet # 7

A description of the organization of personnel must be included. This description must be organized in a hierarchical fashion and include the following information:

1. Position name.
2. Brief description of duties.
3. Number of employees in this position.
4. Name(s) of employee(s).



Dosimetry Information

Dosimetry Information Irradiation Plan Approval Worksheet # 8

| Item | Response | TQAU Approved? |
|--|----------|-------------------|
| 1. Name of standard used to perform dosimetry: | | |
| 2. Spectrophotometer manufacturer: | | |
| 3. Spectrophotometer model: | | |
| 4. Spectrophotometer serial number: | | |
| 5. Dosimeter manufacturer: | | |
| 6. Dosimeter model: | | |

Dosimetry

6 Dosimetry Systems in Use (all have ASTM standards for practice)

- Alanine (Pellets and Film)
- Ceric-cerous Sulfate
- Radiochromic Film
- Polymethylmethacrylate
- Ethanol-Chlorobenzene
- LiF Photo Fluorescent Film



Dosimetry

All dosimetry systems used in APHIS Programs must be traceable to National Standards Lab (NIST)

- Irradiate NIST dosimeters (transfer) alongside facility dosimeters (adjustment factor is calculated and applied to facility dosimetry system)
- NIST calibration of facility dosimeters (calibration curve is calculated and applied to facility dosimetry system)





Facility Diagrams

Facility Schematic Requirements Irradiation Plan Approval Worksheet # 9

A detailed plan of the irradiation facility must be provided. The items listed below represent the minimum requirements for the plan. The reference number for each item must be placed on the plan for easy identification of that item. Each number may be used multiple times.

| Reference Number | Item | TQAU Approved? |
|------------------|---|----------------|
| 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. | |
| 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. | |
| 16. | Fire extinguishers. | |
| 17. | First aid kits. | |

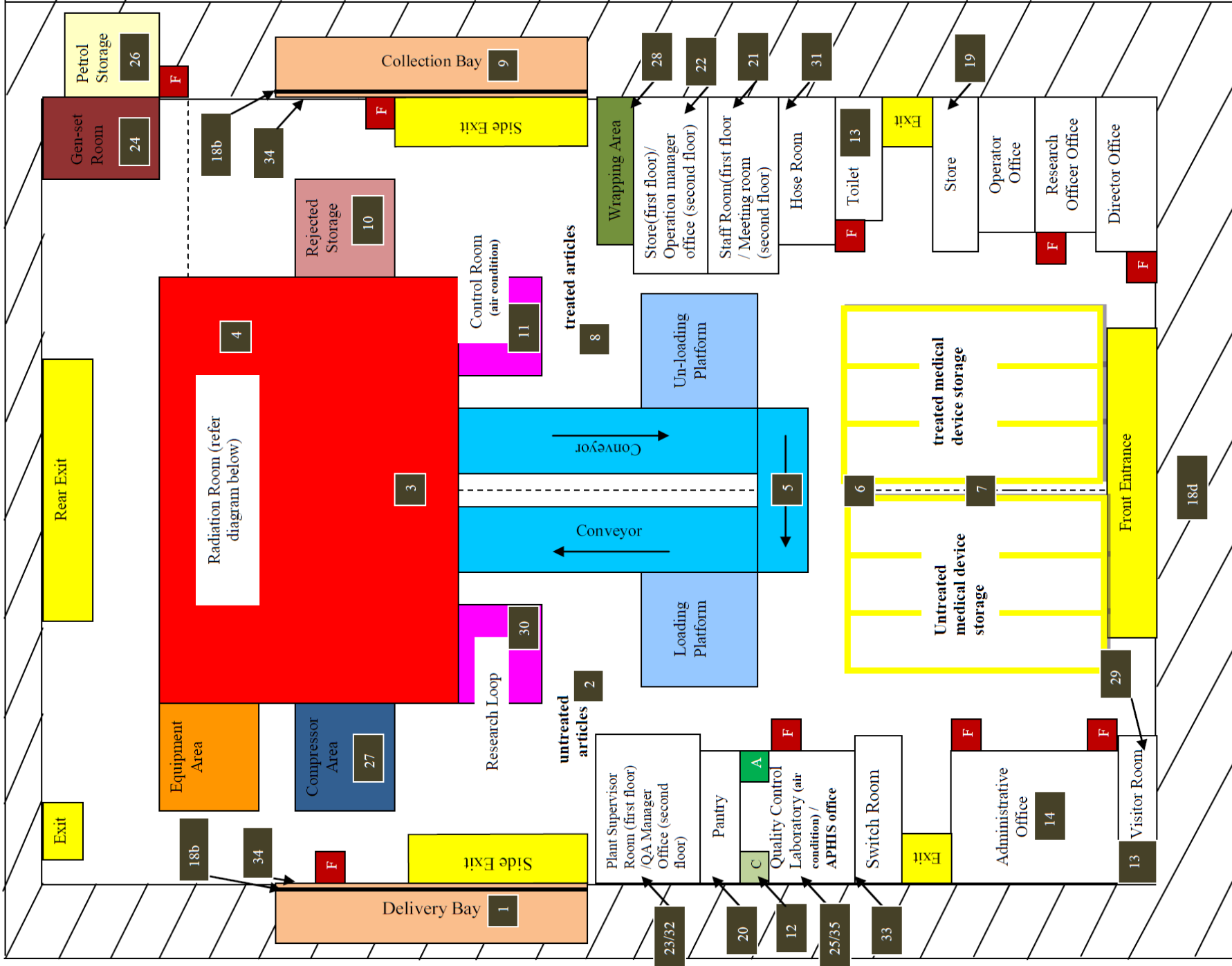


Facility Diagrams (cont.)

**Facility Schematic Requirements
Irradiation Plan Approval Worksheet # 9**

| Reference Number | Item | TQAU Approved? |
|-------------------------|--|-----------------------|
| 18. | Quarantine measures: 18a) Double doors. 18b) Air curtains. 18c) Loading dock boots. 18d) Screens on windows or other openings. | |

WORKSHEET #9



Reference:

- Fire extinguishers
- Climate controlled dosimetry
- First aid kits
- fence



Missing Items

Missing Information Explanation Irradiation Plan Approval Worksheet # 10

Indicate the worksheet number, the item number, and an explanation for each missing item. Use a separate copy of this worksheet for each item.

| Item | Response | TQAU Approved? |
|---------------------------------|----------|-------------------|
| 1. Worksheet number: | | |
| 2. Item number: | | |
| 3. Explanation of missing item: | | |

Just when you thought it was safe to go back in the water....



CPHST is revising the Facility Plan Approval Application

Get ready for us!

What should the facility do to prepare for the certification inspection?

- Test process configurations to be sure they meet the quality and volume goals of the facility, boxing and shipping requirements of the exporters, and APHIS dose requirements.
- Be sure there are enough dosimeters on hand to perform dose mapping work.
- Work with fruit suppliers to be sure fruit in the appropriate boxes is available



Facility Certification

- Tour of the Facility
- SOP Review
- Delivery of Phytosanitary Dose
- Calibration of Dosimetry System
- Process Configuration Approval
- Database Training

Validation of Facility Application Information

Tour of the Facility

- Facility Familiarization
- Follow Commodity Path
- Meet Facility Personnel
- Address Outstanding Issues from Facility Approval
- Identify Additional Safeguarding Issues
- Identify Additional Operational Issues

SOP Review

- Address outstanding issues from facility approval
- Data collection (paperwork)
- Record storage
- Flow of commodity through facility
- Practices for storage of treated, untreated, improperly packaged, and improperly irradiated goods
- Emergency plans
- Are SOPs specific enough for phytosanitary treatments?

Calibration of Dosimetry System

All dosimetry systems used in APHIS programs must be traceable to NIST

- Irradiate NIST dosimeters alongside facility dosimeters (adjustment factor is calculated and used with dosimetry system)
- NIST calibration of facility dosimeters (calibration curve is calculated and applied to dosimetry system)

Process Configuration

Packaging

- Approval of Components
- Configuration Arrangement
- Pest-Proof Packaging

Commodity

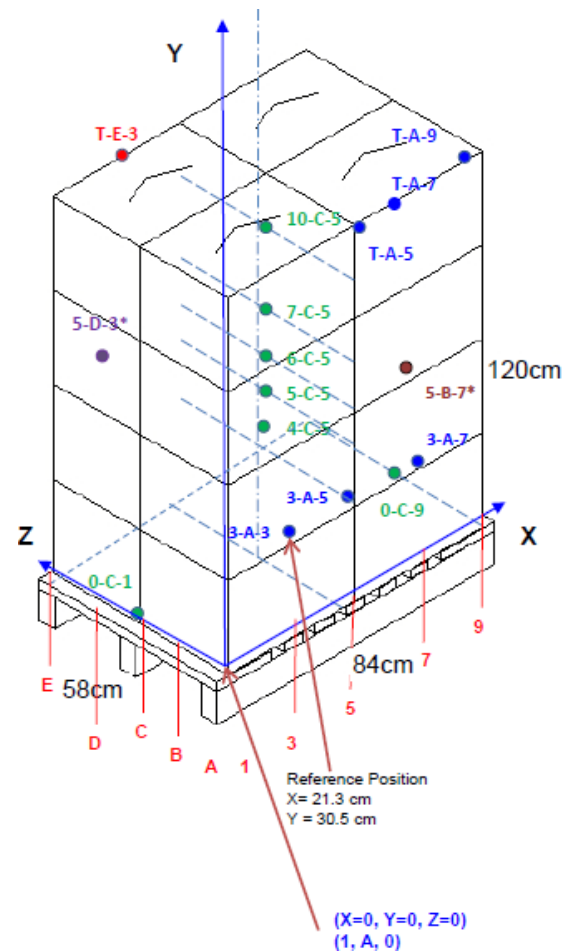
- Article Weights
- Box Weights



Process Configuration

Dose Mapping

- Place dosimeters throughout load
- Focusing on areas expected to receive high and low absorbed doses
- Includes a reference location, R_f



Process Configuration

- Absorbed doses for 3 replicates are entered into workbook
- Determination of R_{\min} and R_{\max} (applied to R_f)
- Configuration details entered into IRADS



Process Configuration Testing

Issues with Current Process

- Time Consuming
- Cost Prohibitive (Destructive)
- Overly Conservative

What Do We Need?

- Non-Destructive Testing
- Immediate Release of Commodity

Alternate Processes

Several facilities approached CPHST with alternative process configuration approval procedures

Port of Entry Program

- Approval upon arrival
- Approval pest proof packaging in advance
- Validation of facility timing methodologies





Process Configuration Approval

To date, no E-beam or X-ray facilities have approached CPHST with a proposal.

CPHST will work with previously-certified Co_{60} facilities to approve alternate methodologies.

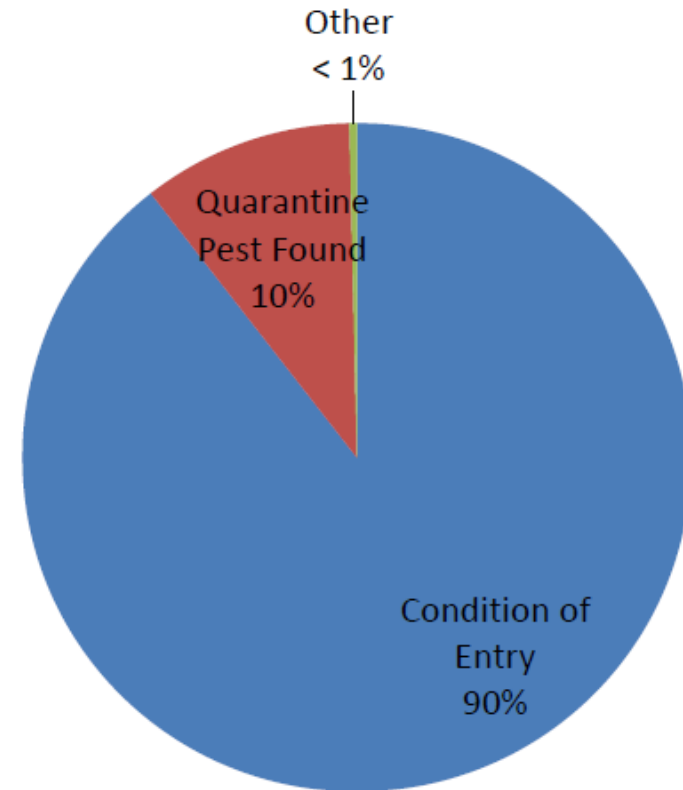
In the future, methods for process configuration testing will be addressed during approval and certification.

Process Configuration Testing

Condition of Entry
Treatment



Emergency
Action at Port of
Entry

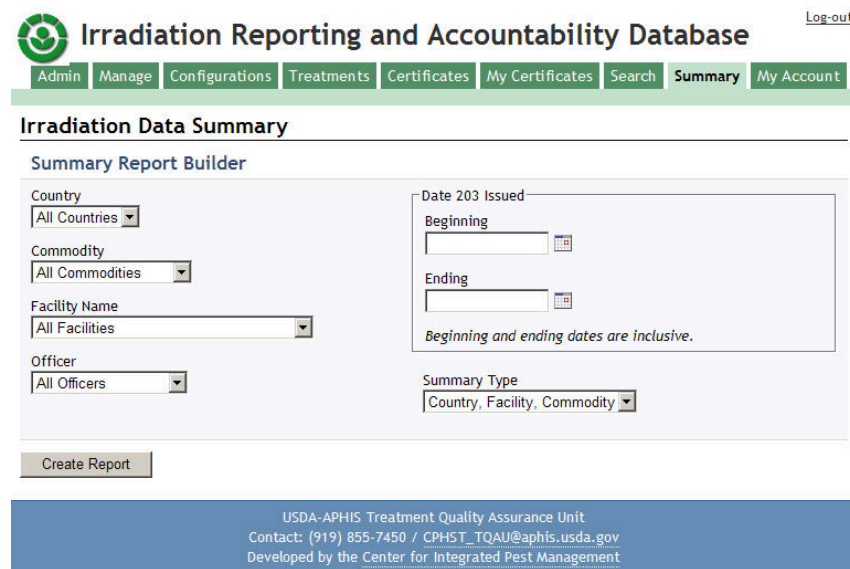


US Imports: 2013 MB Usage

IRADS Training

Irradiation Reporting and Accountability Database

- Tracks irradiation treatment and trace-back data
- Creates treatment certificates
- Modules for import and export treatments



The screenshot shows the IRADS web application interface. At the top, there is a navigation menu with options: Admin, Manage, Configurations, Treatments, Certificates, My Certificates, Search, Summary, and My Account. The main heading is "Irradiation Reporting and Accountability Database" with a "Log-out" link. Below this is the "Irradiation Data Summary" section, which includes a "Summary Report Builder" form. The form contains several dropdown menus: "Country" (set to "All Countries"), "Commodity" (set to "All Commodities"), "Facility Name" (set to "All Facilities"), and "Officer" (set to "All Officers"). To the right, there is a "Date 203 Issued" section with "Beginning" and "Ending" date input fields, each with a calendar icon. Below these fields is the text "Beginning and ending dates are inclusive." and a "Summary Type" dropdown menu set to "Country, Facility, Commodity". A "Create Report" button is located at the bottom of the form. At the very bottom of the page, a blue footer contains the text: "USDA-APHIS Treatment Quality Assurance Unit", "Contact: (919) 855-7450 / CPHST_TQAU@aphis.usda.gov", and "Developed by the Center for Integrated Pest Management".

Treatment Information Systems

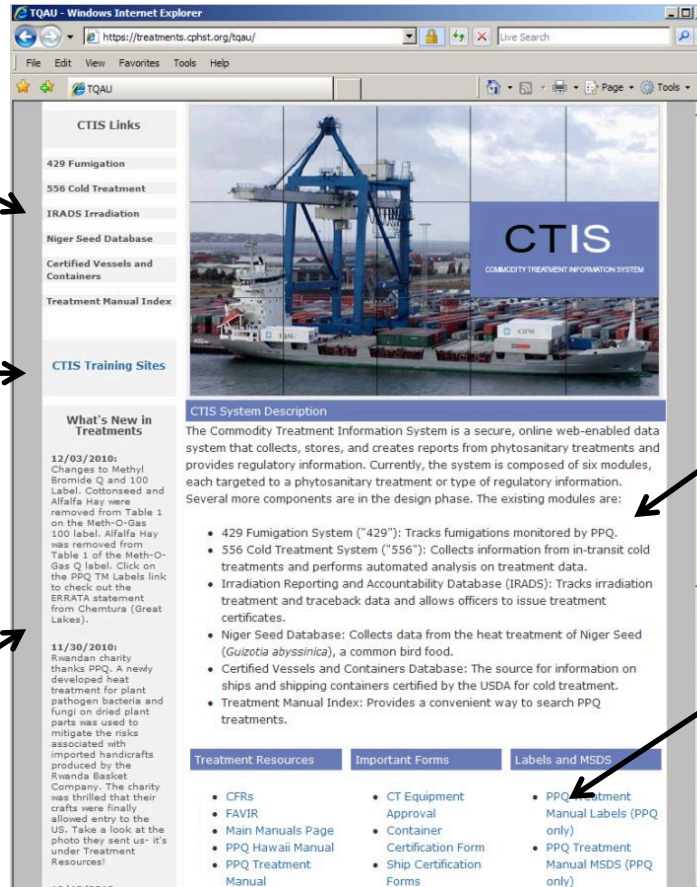
Links to the CTIS treatment databases

Links to the CTIS treatment training sites

CPHST staff enters treatment news

Descriptions of the CTIS treatment databases

Links to helpful treatment sites and documents





Certificate of Approval

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Plant Protection
and Quarantine

For: _____
Type of Facility

This treatment facility and associated equipment have been examined and found acceptable for use in the treatment of articles regulated under the provisions of quarantines and regulations administered by Plant Protection and Quarantine.

Name of Facility

Operator

Location

Conditions of Approval:

Date Approved

Certifying Official

Expiration Date

Title

Recertification

Re-certification of a facility is initiated by the following

- Problems with treatment process identified by APHIS or NPPO (i.e. unmitigated pest interceptions)
- Change in facility management
- Significant operational or structural changes at the facility
- Replenishment, rearrangement or change of the radiation-producing source

Annual recertification is NOT necessary.

Facility Audits

On-Site Audit Review:

- Treatment Processes
- Dosimetry and Dose Mapping
- Safeguarding Measures
- Recordkeeping

Electronic Audit Review:

- Routine Dosimetry Data; checking for significant variation in dose
- Treatment Failures

APHIS Certified Domestic Facilities

- Food Technology Service Inc. (FTSI)
- Sadex
- National Center for Electron Beam Research
- Gateway America
- Hawaii Pride
- Pa'ina Hawaii







APHIS Certified International Facilities

- Krushak, India
- Synergy Health, Thailand
- Thai Irradiation Center, Thailand
- Son Son Corporation, Vietnam
- An Phu Irradiation, Vietnam
- Benebion, Mexico
- Sterigenics, Mexico
- Hepro, South Africa



Final Thoughts & Questions

