



Certifying Facilities

Certifying Irradiation Treatment Facilities

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Introduction

In order to receive authorization to conduct approved phytosanitary irradiation treatments, an irradiation facility must obtain a PPQ Form 482, Certificate of Approval from the USDA-APHIS-PPQ Treatment Quality Assurance Unit (TQAU).

The purpose of this chapter is to provide basic guidelines for facility certification, recertification and audits. Approved facilities must be able to demonstrate that their equipment and personnel are able to safely, accurately, and consistently administer the minimum dose (Dmin) to all components of the commodity over the range of conditions expected for commodities treated.

Certification Requirements

The facility must be certified by the national nuclear regulatory authority of the country where the facility is located prior to involvement from USDA.

In order to receive a Certificate of Approval for treating commodities to mitigate regulated pests, a facility must complete the following in numerical order:

- 1. Operational Workplan (OWP)**

An Operational Workplan (OWP) must be established prior to a Cooperative Agreement. The OWP provides general guidelines for safeguarding procedures.

- 2. Addenda to the Workplan**

The addenda to the OWP identifies specific information not covered in the OWP, such as the commodity(ies) and pest(s) that will be irradiated and details pertinent to facility operation.

3. Cooperative Agreement

The Cooperative Agreement establishes a trust fund between the importing and exporting countries.

4. Plan Approval Application

The Plan Approval Application must be completed in its entirety and submitted to:

USDA-APHIS-PPQ-CPHST
Treatment Quality Assurance Unit
1730 Varsity Drive
Raleigh, NC 27606-5202
Phone: 919-855-7450

Refer to [Figure 6-1-1](#) through [Figure 6-1-15](#) for examples of the checklists and worksheets necessary to complete the Application. To receive electronic, fillable copies of these worksheets, contact CPHST-TQAU at the address above.

5. On-site certification

When all documents have been approved, an official on-site visit will be scheduled. During this visit, the certifying official will verify the accuracy of the information submitted in the Plan Approval Application, review the Standard Operating Procedures (SOP), inspect the dosimetry equipment and verify that the personnel are proficient in its use. The on-site certification will also include inspection of the segregation structures to ensure misidentification or cross-contamination of treated and untreated commodities does not occur. Phytosanitary measures must be in place to guard against pest infestation from the perimeter of the facility. The certifying official will also review the dose mapping procedures and records and verify that data management procedures are acceptable.

6. Compliance Agreement

The Compliance Agreement serves as the legal notice to the treatment facility to follow the OWP. The Compliance Agreement defines what the facility must do before, during and after receipt of the fruit (i.e. segregation, inspection, safeguarding, record keeping, and labelling) and any additional requirements specific to the facility.

Recertification

Recertification will be conducted when at least one of the major non-compliances described below have been detected:

- ◆ A problem with the treatment process has been identified by APHIS or the NPPO (i.e. unmitigated pest interception)
- ◆ Change in management which substantially affects any aspect of the treatment process
- ◆ Operational or structural changes of the facility
- ◆ Replenishment, rearrangement or change of the radiation-producing source



Important

Annual recertification is NOT necessary.

Audits

Audits will be performed at the discretion of the Director of APHIS-PPQ-CPHST-TQAU. On-site audits will include review of the dosimetry, dose mapping, safeguarding measures, record keeping, and the treatment process and system integrity as a whole.

Electronic audits will also be performed by TQAU to review routine dosimetry data and dose mapping data.

Certificate of Approval

Upon facility approval, the USDA will issue a PPQ Form 482, Certificate of Approval, outlining the terms, conditions, and restrictions of the approval. The USDA approval status of all irradiation treatment facilities, both domestic and foreign, treating commodities to mitigate regulated agricultural pests will be tracked by USDA-APHIS-PPQ-CPHST-TQAU.

The Certificate of Approval can be revoked if major non-compliances are detected.

Plan Approval Application—Checklists



Plan Approval Application for Irradiation Facilities Checklist Worksheet #1

This document is an application for approval of plans for facilities that wish to irradiate articles for export to the United States. This application and supporting materials will be reviewed by the USDA APHIS PPQ CPHST TQAU to determine if the facility meets USDA requirements for irradiation treatments. Certification of facilities requires onsite inspections and will follow plan approval.

General Instructions:

1. All applications for irradiation facility plan approval must include all the information requested in this document.
2. No facilities will be approved if the application is incomplete.
3. All responses and supporting materials in this application must be written in Standard English.
4. These worksheets were created with Adobe Acrobat. Use Acrobat Reader to view and fill the worksheets.
5. Fill all the fields except those under the heading "TQAU Approved". Fields under this heading are for use by USDA only.
6. If you find that information requested in a field is not applicable to your facility, use worksheet #10 to explain the situation.
 Number each copy of worksheet #10 with a unique, serial page number. Enter "NA" and the number assigned to the corresponding worksheet #10 in each field that is not applicable.
7. If you find that information critical to treatment at your facility has not been otherwise requested, you must include this information. Each item must be described on a separate page with a descriptive title and unique serial page number.
8. Completed applications should be sent to the APHIS/PPQ/CPHST Treatment Quality Assurance Unit via the NPPO and APHIS International Services. Applications should include paper copies of all worksheets and supporting materials as well as electronic copies of the completed worksheets in portable document format (Adobe Acrobat PDF files) on compact disc.
9. Approval of this application may take as long as sixty days.
10. Questions regarding the application should be routed through the NPPO and APHIS International Services to APHIS/PPQ/CPHST Treatment Quality Assurance Unit.

Worksheet # and Name	Description	Total Pages:	TQAU Approved? (TQAU use only)
Worksheet #1: Checklist	Include this page (worksheet #1) with the signature of the facility manager indicating that all materials are submitted in a single application.		

FIGURE 6-1-1 Plan Approval Application Checklist, page 1 of 15



**Plan Approval Application for Irradiation Facilities
Checklist Worksheet #1**

Worksheet # and Name	Description	Total Pages:	TQAU Approved? (TQAU use only)
Worksheet #2: Facility Location Information	Collects information that describes the location of the facility.		
Worksheet #3: License Information	Collects information about the license granted to the facility by the national nuclear regulatory agency.		
Worksheet #4 Irradiator Information	Collects information about the device that emits, controls, and delivers the radiation and the computer hardware and software that control it.		
Worksheet #5 Safety Information	Collects information about safety equipment.		
Worksheet #6: SOP Outline	Describes standard operating procedures (SOP) requirements.		
Worksheet #7: Personnel	Outlines personnel descriptions.		
Worksheet #8: Dosimetry Information	Collects information about the standards and equipment used for dosimetry.		
Worksheet #9: Facility Schematic Requirements	Outlines minimum requirements for a facility plan.		
Worksheet #9a: Facility Schematic Item Key	Provides for additional facility plan information.		
Worksheet #10: Explanation of missing information.	Provides space for explanations of why information is left out of other worksheets.		

Facility Representative Signature: _____

NPPO Reviewer Signature: _____

Print name:
Title:
Date:

Print name:
Title:
Date:

FIGURE 6-1-2 Plan Approval Application Checklist, page 2 of 15



**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:		

Completed By:
 Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-3 Plan Approval Application Checklist, page 3 of 15



**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:		

Attach a color photocopy of the front and back of the license and any supporting addenda, appendices, etc...

Completed By:
Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-4 Plan Approval Application Checklist, page 4 of 15



**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:		

Completed By:
 Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-5 Plan Approval Application Checklist, page 5 of 15



**Safety Information
Irradiation Plan Approval Worksheet # 5**

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

Completed By: _____

Date: _____

Print Name: _____

FIGURE 6-1-6 Plan Approval Application Checklist, page 6 of 15



**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.			

FIGURE 6-1-7 Plan Approval Application Checklist, page 7 of 15



**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.

Completed By:
Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-8 Plan Approval Application Checklist, page 8 of 15



**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).

Completed By:

Signature:

Date:

Print Name:

FIGURE 6-1-9 Plan Approval Application Checklist, page 9 of 15



**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:		

Attach a color photocopy of both sides of the calibration certificate for the spectrophotometer and any supporting documents.

Completed By:
Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-10 Plan Approval Application Checklist, page 10 of 15



**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.	

FIGURE 6-1-11 Plan Approval Application Checklist, page 11 of 15

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.	

Completed By: _____
Signature: _____

Date: _____
Print Name: _____

FIGURE 6-1-12 Plan Approval Application Checklist, page 12 of 15



**Facility Schematic Item Key
 Irradiation Plan Approval Worksheet # 9A**

A detailed floor plan of the irradiation facility must be provided. Use the blank worksheet below to reference items not covered in worksheet #9. Each item must have a consecutive reference number. Do not duplicate numbers. Use additional copies of this worksheet as necessary.

Reference Number	Item	TQAU Approved?

Page ____ of ____

Completed By:
 Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-13 Plan Approval Application Checklist, page 13 of 15



**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:		

Page ____ of ____

Completed By:
Signature: _____

Date: _____

Print Name: _____

FIGURE 6-1-14 Plan Approval Application Checklist, page 14 of 15



**Facility Schematic Item Key
 Irradiation Plan Approval Worksheet # 9A**

A detailed floor plan of the irradiation facility must be provided. Use the blank worksheet below to reference items not covered in worksheet #9. Each item must have a consecutive reference number. Do not duplicate numbers. Use additional copies of this worksheet as necessary.

Reference Number	Item	TQAU Approved?

Completed By: _____
 Signature: _____
 Date: _____
 Print Name: _____

Page ____ of ____

FIGURE 6-1-15 Plan Approval Application Checklist, page 15 of 15

