



# Certifying Facilities

## *Certifying Irradiation Treatment Facilities*

---

### Contents

Introduction	<a href="#">page-6-8-1</a>
Certification Requirements	<a href="#">page-6-8-1</a>
Recertification	<a href="#">page-6-8-2</a>
Audits	<a href="#">page-6-8-3</a>
Certificate of Approval	<a href="#">page-6-8-3</a>

---

### 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

**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



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.

