INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

[PARAGRAPH 1]

STRUCTURE AND OPERATION OF POST-ENTRY QUARANTINE FACILITIES

(200-)

[Work programme topic: Post-entry quarantine facilities]
[Specification No. 24]

[2]

CONTENTS

[3] # INTRODUCTION

[4] ## SCOPE

[5] This standard describes general guidelines for the design and operation of post-entry quarantine (PEQ) facilities for holding consignments of plants in containment. Four containment levels are specified.

[6] ## REFERENCES

[7] *Glossary of phytosanitary terms*, 2008. ISPM No. 5, FAO, Rome.

[8] *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004. ISPM No. 11, FAO, Rome.

[9] *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006. ISPM No. 1, FAO, Rome.

[10] ## DEFINITIONS

[11] Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

[12] ## OUTLINE OF REQUIREMENTS

[13] The pest risk associated with importation of consignments of plants into a country may be managed by the use of post-entry quarantine (PEQ) facilities that provide the appropriate containment for the risk that has been identified with the consignments being imported. Pest risk assessment is required to determine the level of PEQ for a specified consignment of plants. Pest risk management requirements determine the design and operation of the PEQ facility. The PEQ facility may consist of a field site, screen house, glasshouse and/or laboratory.

[14] Four levels of PEQ containment (PEQ1 to PEQ4) are described. For all PEQ containment levels, an operating procedures manual should show how the PEQ facility meets the containment requirements.

[15] Field sites provide the lowest containment level, PEQ1, and are suitable for consignments of plants that may be infested with quarantine pests that are unlikely to escape and where the consequences of escape are low to moderate. A screen house may provide PEQ1 or PEQ2 containment level. For PEQ2 containment level, a facility should meet certain structural requirements (e.g. relating to openings) and operational requirements (e.g. decontamination of equipment before removal). A glasshouse may be capable not only of providing PEQ1 or PEQ2 containment but also of meeting PEQ3 requirements. PEQ3 introduces requirements relating to air pressure control and air filtration, as well as more physical security for the structure. A specialized quarantine laboratory is the only type of PEQ facility capable of providing PEQ4 containment level. PEQ4 imposes stringent conditions on all physical and operating requirements.

[16] **BACKGROUND**

[17] Imported consignments of plants can present a risk to plant health because they have the potential to introduce quarantine pests. When considering phytosanitary measures for such consignments, National Plant Protection Organizations (NPPOs) should apply measures based on the policy of managed risk (ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*). In order to assess the pest risks and identify appropriate measures for particular pathways, pest risk analysis (PRA) is used. For many commodities that are traded internationally, importing NPPOs identify risk management measures that mitigate pest risk without requirements after entry. For some commodities, NPPOs may decide that certain consignments should be held after entry into the country within a facility providing a known level of containment in order to reduce the risk to an acceptable level. This allows for comprehensive testing for the presence of pests, time for the expression of symptoms, and appropriate treatment if necessary.

[18] Containment facilities may also be required to conduct research with quarantine pests and other imported organisms, but this is outside of the scope of this standard.

[19] Post-entry quarantine (PEQ) may be required for the following reasons:

- containment of imported plant material that needs to be screened for quarantine pests that cannot be detected by inspection at the point of entry
- containment of plant material suspected on import of being infested with quarantine pests for further investigation and possible confirmation of the identity of the pest
- following detection of pests, mitigation of risk by application of appropriate phytosanitary measures.

[20] The purpose of PEQ is to contain both the plant and any quarantine pest potentially associated with it so that neither can escape the facility before the required inspection, testing, treatment and verification activities have been completed, and the consignment is released.

[21] **GENERAL REQUIREMENTS**

[22] **1. PEQ Containment**

[23] The containment levels of PEQ facilities are based on the principles of pest risk analysis as described in ISPM No. 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms). The pest risk assessment determines the level of PEQ containment that is required. Pest risk management requirements determine the corresponding physical characteristics and operating procedures of the PEQ facility.

[24] The NPPO should determine the containment level required for a specific consignment of plants entering PEQ facilities based on a pest risk assessment for the potential pests that may be associated with imported plant material or for the imported organism itself. The assignment of the appropriate containment conditions, and if appropriate the relevant PEQ levels, should also take into account relevant circumstances in the country and the biology of the pest.

[25] Annex 1 contains information on methods for determining PEQ levels and describes four levels of PEQ containment, which range from low, PEQ1 (where the PEQ facility may be an open field), to high, PEQ4 (where the PEQ facility is a specialized quarantine laboratory). The containment levels differ in the number and type of requirements that are recommended (see Appendix 1). The requirements described below may need to be adjusted according to the specific pest risk management circumstances.

[26] Once the required level of containment has been determined for a specific consignment entering quarantine, the NPPO determines whether that containment level can be provided by:

- an existing PEQ facility
- a modification of its structural or operating conditions
- quarantine in a different area
- a new facility designed and constructed to meet requirements.

[27] **2. PEQ Facilities**

[28] These requirements apply to all PEQ containment levels.

[29] PEQ facilities should provide the appropriate level of containment for the level of risk associated with the import of consignments. PEQ facilities may consist of a field site, screen house, glasshouse and/or laboratory.

[30] **2.1 Location**

[31] PEQ facilities should be located in areas that provide some isolation, if possible, stability (e.g. not earthquake-prone areas), a minimum of severe climatic events, and some separation from areas where related plant species are abundant (agricultural or horticultural production, forests or areas of high biodiversity).

[32] **2.2 Physical requirements**

[33] The physical design of the PEQ facility should take into consideration the biology of the pests, the operational procedures, the work flow in the facility and specific emergency requirements (e.g. in the event of loss of electricity). Office facilities and supporting service infrastructure should be available as required and have suitable separation from the PEQ facilities as appropriate.

[34] Physical requirements relate to:

- delimitation of the facility, external structural materials (for walls, floors, roof and windows)
- design of openings (for doors, windows, air vents, drains and other conduits)
- treatment systems (for air, water, solid waste)
- equipment (e.g. specialized safety cabinets, back-up generators).

[35] **2.3 Operational requirements**

[36] PEQ facilities should either be operated by or be authorized by the NPPO.

[37] Operational requirements to meet a specified level of containment involve appropriate policies and procedures relating to management, personnel, general operation of the PEQ facility, record keeping, contingency planning, health and safety, and other aspects of the facility, as well as audit and review of the management system.

[38] Specific procedures are required in the operation of the facility to manage the particular risks relating to containment of the consignments of plants in the quarantine facility. A procedural manual should show how the facility will meet the containment requirements. Where a quarantine pest is known or suspected to be present in the consignment, the operating procedures for PEQ facilities should take into account the biology of the pest, including how the pest is spread and its requirements for establishment in the environment.

[39] The system should include, as appropriate:

- a qualified officer-in-charge (OIC) who has overall responsibility for maintaining PEQ and for all PEQ activities, plus necessary staff
- a list of staff authorized to enter the facility
- a training programme to ensure that all staff are adequately trained
- staff responsibilities clearly defined
- a site plan of the PEQ facility showing the location of the PEQ facility on the site and all facility entrances and access points
- criteria for what constitutes a breach of quarantine containment, and a reporting system to ensure that any breaches are reported to the NPPO
- provision for maintenance and calibration of critical equipment
- effective contingency plans for fires, accidental release of consignments from the facility and other emergencies
- a schedule for internal audits, if relevant, to check that the facility meets the PEQ requirements (e.g. structural integrity and hygiene requirements) and to review the components of the quality system
- a procedure for dealing with non-compliances
- a procedure for identifying consignments in quarantine by suitable means (e.g. labelling of plants) to enable traceability of the consignments through PEQ
- registry of visitors
- a register of all consignments in the facility
- a record of all PEQ activities conducted in the facility (e.g. experiments, treatments and disposal of consignments in quarantine)

- provision for the number of consignments in a PEQ facility not to exceed the capacity of the facility in a way that could impede inspection or compromise containment
- appropriate handling and sanitation procedures to prevent cross-contamination between different plants, lots and consignments
- adequate spatial separation of different consignments or lots within the facility as appropriate.

[40] **2.4 Release from containment**

[41] Consignments should be released from quarantine facilities on completion of the required inspection, testing, treatment and verification. NPPOs may implement systems to monitor or trace consignments once they have left the PEQ containment facility.

[42] **3. Specific Requirements for PEQ Facilities by Containment Level**

[43] In addition to the general requirements for all levels of containment, each level has specific requirements.

[44] Each PEQ containment level incorporates the requirements of the previous levels; for example, a PEQ facility providing PEQ3 containment would include all applicable requirements of PEQ1 and PEQ2.

[45] Appendix 1 provides a summary of the major requirements for PEQ facilities at all containment levels.

[46] **3.1 PEQ containment level 1**

[47] **3.1.1 Type of facility and use, PEQ1**

[48] For PEQ1, the lowest containment level, the PEQ facility may consist of a field site or a structure such as a screen house or open glasshouse or laboratory. PEQ1 facilities are appropriate for consignments of plants that may be infested with quarantine pests that are highly unlikely to disperse naturally or to be spread by air, water, insects or other vectors (e.g. exclusively graft-transmitted viruses) and where the consequences of escape are low to moderate.

[49] **3.1.2 Physical requirements, PEQ1**

[50] For open sites or structures operating as PEQ1 facilities, appropriate separation from potential hosts should be maintained to prevent spread and establishment of quarantine pests that may be associated with the imported consignments of plants. PEQ1 sites should have appropriate signage. The PEQ area should be clearly delineated. A means and system for destruction of waste should be established.

[51] **3.1.3 Operational requirements, PEQ1**

[52] Access to the site should be restricted. It is recommended that sites provide conditions that are conducive for development of signs and symptoms of pests to be exhibited.

[53] **3.2 PEQ containment level 2**

[54] **3.2.1 Type of facility and use, PEQ2**

[55] PEQ2 containment requires no special design features for the PEQ facility beyond those suitable for a well-designed and functional screen house, glasshouse or laboratory. PEQ2 facilities are suited for consignments of plants that may be infested with quarantine pests that are likely to disperse naturally or be spread by air, water, insects or other vectors (e.g. nematode-transmitted viruses). There may be a moderate to high risk of escape of the pest, but the corresponding consequences of escape are moderate to low, respectively.

[56] **3.2.2 Physical requirements, PEQ2**

[57] The glasshouse should be constructed of regular glass or twin-skin plastic. Glasshouses, screen houses and laboratories should have appropriately sized mesh covering vents, drains or other openings. Local pests (e.g. rodents, white flies) should be controlled and excluded from the facility by sealing all the points of penetration, including electrical and plumbing conduits.

[58] Entry into PEQ2 facilities should be through two doors separated by a vestibule or anteroom to reduce the risk of pests escaping or coming in. The doors should be self-closing and tight fitting, with appropriate seals and sweeps. Insect monitoring devices such as sticky traps or light traps should be installed as appropriate. A sink with hands-free operation should be provided in the anteroom.

[59] The facility should have a concrete floor. All surfaces in the facility should be accessible for cleaning and constructed of smooth and impervious material to allow effective decontamination.

[60] **3.2.3 Operational requirements, PEQ2**

[61] All plants should be grown in pest-free growing medium (e.g. pasteurized potting mix).

[62] All staff and visitors should wear protective clothing (e.g. a laboratory coat and dedicated footwear or shoe covers). Waste and equipment (e.g. cutting implements) should be sterilized or decontaminated before removal from the facility.

[63] **3.3 PEQ containment level 3**

[64] **3.3.1 Type of facility and use, PEQ3**

[65] The physical and operational requirements for PEQ3 containment are substantially more stringent than those for lower levels. PEQ3 facilities may consist of a contained and secure glasshouse or laboratory. They are suited for containment of consignments of plants where there is a moderate to high probability of escape and where the consequences of an escape would be serious (e.g. aphid-transmitted viruses).

[66] **3.3.2 Physical requirements, PEQ3**

[67] Glasshouses and laboratory windows should be constructed of breakage-resistant material (e.g. laminated safety glass). Windows in laboratories should be sealed and locked shut.

[68] Doors opening to the anteroom of the PEQ facility should be self-closing. Security measures should be in place surrounding the facility. A security alarm should also be installed in the PEQ facility.

[69] The heating, ventilation and air-conditioning system (HVAC) should be capable of the containment of small aerially dispersed organisms. High-efficiency particulate air (HEPA) filtration and negative air pressure are required for this containment level.

[70] Air pressure in the PEQ facilities should be lower than in adjacent areas so that a negative pressure differential is maintained to prevent passive egress of airborne organisms from containment. Egress of airborne organisms is also prevented by filtration of outgoing air through HEPA filters, which remove particles greater than 0.3 microns with 99.97% efficiency. Containment of some mite species may also require HEPA filtration.

[71] **3.3.3 Operational requirements, PEQ3**

[72] A shower may be required for staff members on leaving the facility. This requirement does not apply to facilities containing non-airborne plant pathogens and arthropods.

[73] The opening doorways of the PEQ should be compatible with the pressure differential in the facility to maintain containment.

[74] Appropriate processes should be implemented to ensure decontamination of equipment (including filters) before it is removed from the facility. If consignments are removed from the PEQ facility they should be free of quarantine pests.

[75] **3.4 PEQ containment level 4**

[76] **3.4.1 Type of facility and use, PEQ4**

[77] PEQ4 facilities provide the highest containment level. These facilities are designed and operated specifically to contain consignments of plants in quarantine (whether deliberately imported or associated pests) where both the risk of escape and the consequences of escape are high (e.g. airborne plant pathogenic fungi).

[78] **3.4.2 Physical requirements, PEQ4**

[79] For a PEQ4 facility, there should be no direct access from the outside of the building. The laboratory should be physically separated from other areas, including offices used by laboratory personnel.

[80] For added security the entry doors should be self-locking. To maintain containment, the vestibule doors should be interlocked so that only one door at a time can be open.

[81] A ventilation system that establishes an inward flow of air into the laboratory should be provided so that there is a directional airflow into the working area. Where laboratories have supply air systems, the supply air and exhaust air systems should be interlocked to ensure inward flow at all times. All fume hoods that discharge to the outside atmosphere should be fitted with HEPA filters.

[82] Tandem filters, parallel filters or other configurations should be installed that allow one filter to be replaced while another supplies air. Negative air pressure should progressively increase from the lowest risk areas to higher risk areas. Backup electricity is required to maintain negative air pressure gradients. Shower-out vestibule facilities should be installed if appropriate.

[83] With high-risk consignments, procedures that could cause the release of pests should be conducted in a biological safety cabinet that contains a HEPA filter. Only preparations in which the organism is killed or contained (e.g. slides, sealed tubes) should be handled in the open laboratory.

[84] 3.4.3 Operational requirements, PEQ4

[85] Operational processes required to maintain PEQ, such as pressure differentials and waste water treatment, should be monitored to prevent failure of essential systems.

[86] A register of staff and visitors should be maintained providing a record of entries and exits of the laboratory. The facility should not be accessible to the general public. Disposable coverall suits should be worn in the facility.

[87] Equipment used in a PEQ4 facility (e.g. autoclaves and biological safety cabinets) should be well maintained and calibrated. All surfaces within the cabinet should be cleaned with a suitable disinfectant as appropriate.

[88] **ANNEX 1**

[89] **METHODS FOR ASSIGNMENT OF PEQ CONTAINMENT LEVELS**

[90] Several approaches can be used to assign containment levels of PEQ facilities. The PEQ containment requirements will depend on the specific organism and other circumstances in the country e.g. climatic, environmental.

[91] The containment levels are described in a matrix that combines the likelihood of pest introduction and establishment with the consequence of their establishment (see Table 1). The risk of pest introduction is a function of the size of the organism, dispersal method, reproductive potential, potential for establishment etc., while the consequences of pest establishment relate to impact on the environment, trade implications, economic factors etc. ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*) provides guidelines for pest risk assessment.

[92] **Table 1**: Assignment of PEQ containment levels based on a matrix of pest risk factors

	Risk of escape and establishment	**Consequence of escape and establishment**		
[row1]		Low	Moderate	High
[row2]	High	PEQ2	PEQ3	PEQ4
[row3]	Moderate	PEQ1	PEQ2	PEQ3
[row4]	Low	PEQ1	PEQ1	PEQ2

[93] Other approaches may be used to designate containment levels that are more directly based on specific biological characteristics of the organism likely to be present in the consignment.

[94]

APPENDIX 1

[95]

SUMMARY OF MAJOR REQUIREMENTS FOR PEQ FACILITIES BY CONTAINMENT LEVEL

[96]

Requirements	PEQ containment level and type of facility				
	PEQ1		PEQ2	PEQ3	PEQ4
	field site	screen house glasshouse laboratory	screen house glasshouse laboratory	glasshouse laboratory	laboratory
Physical requirements					
delineation of facility	**R**	**R**	**R**	**R**	**R**
breakage-resistant window/glasshouse materials	na	O	O	**R**	**R**
concrete floor	na	O	**R**	**R**	**R**
vestibule entrance	na	O	**R**	**R**	**R**
self-closing doors	na	O	O	**R**	**R**
self-locking doors	na	O	O	O	**R**
screen on openings such as air vents, drains	na	O	**R**	**R**	na
sealed windows	na	O	**R***	**R**	**R**
all penetrations sealed	na	na	**R***	**R**	**R**
negative air pressure	na	na	na	**R***	**R**
air pressure gradient	na	na	na	O	**R**
HEPA filtration	na	na	na	**R***	**R**
biological safety cabinet	na	na	O	O	**R***
waste water treatment	O	O	**R**	**R***	**R**
solid waste treatment	**R**	**R**	**R**	**R**	**R**
backup source of electricity	na	O	O	**R***	**R**
Operational requirements					
good management practices	**R**	**R**	**R**	**R**	**R**
under NPPO or responsible authority	**R**	**R**	**R**	**R**	**R**
restricted access	**R**	**R**	**R**	**R**	**R**
protective clothing	O	O	**R**	**R**	**R**
decontamination of equipment upon egress	O	O	**R**	**R**	**R**
decontamination of implements upon egress	O	O	**R**	**R**	**R**
hand washing upon egress	O	O	**R**	**R**	**R**
shower out	na	na	na	O	**R**

na = not applicable; O = optional; **R** = required; **R*** = required, but exceptions exist.