Ministry for Primary Industries Manatū Ahu Matua



PATHWAY ASSURANCE REPORT

VIET NAM DRAGON FRUIT PATHWAY ASSESSMENT & 5 TREATMENT FACILITY REVIEWS

15-19 APRIL 2013

Fresh Produce Imports Plants, Food & Environment Directorate Standards Branch

May 2013

New Zealand Government

Growing and Protecting New Zealand

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ACKNOWLEDGEMENTS

The Ministry for Primary Industries (MPI) acknowledge and thank the officials of the Vietnamese Ministry of Agriculture and Rural Development (MARD) who generously gave their time and co-operation during this observational and verification visit. In particular, thanks are extended to **Sector Content** (Director, Plant Protection Department, Post Entry Quarantine Center No II, MARD, Ho Chi Minh City) for the organisation of the itinerary, co-ordination of meetings and visits to dragon fruit orchards, vapour heat and irradiation treatment facilities. We also thank **Sector Content** Deputy Head of Mission, Ha Noi, Vietnam, for liaison with MARD on MPI's behalf and accommodation arrangements.

EXECUTIVE SUMMARY

The primary purpose of the visit to Viet Nam was:

- To MPI-approve/accredit and review activities at vapour heat treatment and irradiation facilities to meet the importing requirements for mango to New Zealand.
- To assess the production, post-harvest handling and processes involved in the intended export of dragon fruit from Vietnam to New Zealand and to enable the developments of a risk management proposal, draft import health standard and official assurance programme.

Treatment facility review

The review of treatment facilities focussed on general system components and operational processes (i.e. phytosanitary inspections, treatment facility infrastructure, treatment procedures, treatment application, post-treatment security and phytosanitary inspection and certification).

In general, the review of four treatment facilities showed that all were operating quality systems which comply with MPI requirements. A fifth facility was also visited but is only recently built and not currently in operation. Viet Nam is currently exporting pre-cleared dragon fruit to Japan, Korea and the USA from four treatment facilities. The facilities are supervised by these NPPOs from at least May through to August which provides MPI with a high level of assurance that they are consistently operating to an acceptable level to meet phytosanitary requirements of the import health standard for mangoes.

MARD, the Japanese and Korean NPPOs conduct pre-season audits (i.e. x 3 audits) of vapour heat treatment facilities. A recommendation was made for MARD officials to conduct some of the activities conducted by USDA, Japanese and Korean officials before and after treatment. Also, a recommendation is made for MPI to update the OAP for mangoes (or a combined dragon fruit/mango OAP) to clearly detail MPI's expectations regarding the communication of changes to treatment facility practices.

Dragon fruit pathway assessment

The dragon fruit pathway assurance aspect of the visit focused on the production and pest management system in orchards, fruit traceability and pack house practices. The dragon fruit export system is well established and well managed by MARD for the Japanese, Korean and USA markets. A robust system is in place for product traceability and registration of packhouses which has been developed for the USA market. The same export system is proposed by MARD to meet New Zealand's importing requirements when they have been developed.

Documented procedures are under development for the treatment of dragon fruit for export to New Zealand. It is proposed that these can be included as an Appendix to the system that the facilities have already developed for the export of mango to New Zealand. It is suggested that, if appropriate, MPI considers changes to the structure of official assurance programmes so that commodities can be easily added as appendices. This is only likely to be feasible where there are similarities for system components for different commodities.

BACKGROUND

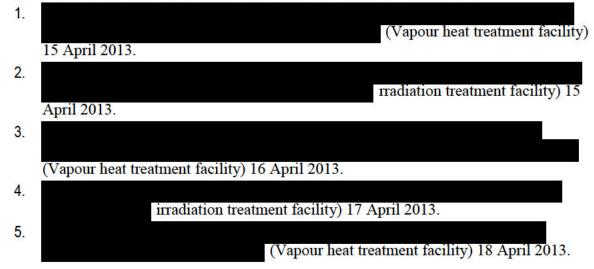
The Government of Vietnam (Plant Quarantine Division, Plant Protection Department, MARD) requested access to the New Zealand market for fresh dragon fruit (*Hylocereus* spp.) for consumption. A draft assessment of dragon fruit was undertaken to determine appropriate mitigation measures for risk organisms associated with the pathway. The aim of the visit is to assist with finalising the risk management proposal and draft import health standard for the commodity by clarifying outstanding questions regarding the production, pest management and post-harvest practices associated with dragon fruit.

New Zealand is currently developing trade in fresh produce with Viet Nam and the first commodity to be approved for market access was mango in December 2011. MPI granted provisional approval to four treatment facilities to export mangoes to New Zealand in February 2013 following a "desk-top" review of facility activities. The purpose of the visit is to review the operational activities at four facilities in order to determine eligibility of a full MPI-approval to the facilities. An additional vapour heat treatment (VHT) facility was included in the itinerary.

Two of the five treatment facilities were visited in 2011 (20110428 Vietnam mango pathway assurance report.doc <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b3807b42f3</u>) and the most pressing issues identified were related to the lack of documentation of the system from orchard through to treatment and export for mangoes. Since the 2011 visit, MARD has worked with treatment facilities to develop standard operating procedures for each facility. MARD, in conjunction with the Japanese and Korean NPPOs have gained expertise in auditing vapour heat treatment facilities and have worked with the USDA irradiation experts and quarantine officers to develop a quality system.

The visit itinerary included:

A review of activities at the following treatment facilities (15-19 April 2013)



- On-site visit to dragon fruit production site at Long An Province specifically looking at production techniques, pest management, harvest, 18 April 2013.
- Visit to primary packhouse to view pre-treatment activities (18 April 2013).
- A discussion with MARD officials on the preliminary outcomes of the visit (19 April 2013).

DEFINITIONS

[Note: terms such as non-compliance and corrective action are not applicable to pathway assurance visits as standards have not been finalised nor a workplan or an official assurance programme developed. Quality systems terms have been replaced with "actions" and "issues". For consistency these terms will also be used for the review of treatment facility activities where appropriate]

Term	Definition
Critical actions	 Actions that must be undertaken before trade can commence because: 1. import of the commodity using current practise(s) would place New Zealand's public health, animal welfare, market access, official assurances, biosecurity, national good or MAF Directors' credibility at risk. Where possible critical actions will be reported to the requesting country during a closing meeting and appropriate action(s) taken before trade can commence/continue. 2. it is requested by the country seeking market access e.g. assessment of equivalent requirements.
Issues	An issue that demonstrates risk to the operation of a specification or set of specifications. It may be a specific issue or a system with multiple issues having a cumulative effect. Resolution of the issue will be required before trade can commence.
Recommendations	 Recommendations are given to highlight areas of a system that require improvement (or clarification) even though an issue has not occurred. Recommendations must be considered by the requesting country when formulating actions for resolution. NB: A recommendation to change existing specifications does not constitute a change. Existing specifications must be complied with until any changes are officially promulgated.

REFERENCES

- Import Health Standard, Commodity Sub-Class: Fresh Fruit/Vegetables, Mango (*Mangifera indica*) from Vietnam;
- Official Assurance Programme for the export of mango (*Mangifera indica*) from Viet Nam to New Zealand;
- Australia New Zealand Food Standards Code Standard 1.5.3 Irradiation of Food;
- Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979);
- Codex General Standard for Irradiated Foods Codex Standard 106-1983, Rev.1-2003;
- International Standard for Phytosanitary Measures Publication No. 18 Guidelines for the Use of Irradiation as a Phytosanitary Treatment;
- MAF Biosecurity Authority Standard 158.03.03: Specification for Fruit Fly Heat Treatment Monitoring. (NB: this standard was not provided to MARD as it is currently under revision and therefore only acts as a guideline);
- Standard operating procedures for the treatment facilities seeking MPI-approval.

[Checklists for treatment facility reviews were composed of the above standards and are attached in appendices]

ENTRY MEETING

An entry meeting was conducted with MARD in-transit to the first treatment facility on 15 April 2013. The following points were clarified:

- Expectations of the pathway assurance visit for dragon fruit
- Purpose, scope and criteria of the treatment facility review
- Confirmation of the review plan and itinerary [this changed from the original itinerary]
- Process of facility approval following MPI verification

SUMMARY OF PATHWAY REVIEW & ASSESSMENT FINDINGS

All treatment facilities had a high level of security which restricted access to non-authorised VHT facility, all standard operating personnel. With the exception of the procedures were provided to MPI in advance of the visits which were reviewed to grant provisional MPI-approval to allow market access. The visits to facilities confirmed that they were operating to the documented procedures and records regarding staff training, facility hygiene, equipment calibration and maintenance and treatment traceback were easily retrievable either by computer or through hard copy. Facility hygiene and pre-treatment and post-treatment activities including product security were observed. With the exception of the observation of ants in the post-treatment area at the facility and additional information VHT facility, only minor recommendations for quality requirements for the improvement are made. In addition, four recommendations were made for MARD PPD to provide the necessary assurance that MPI requirements will be met. It is recommended that and are given full MPI-approval for the export of mango to New Zealand. However, critical actions for need to be resolved before approval can be given.

The visit to dragon fruit production sites gave a good overview of the pre-harvest practises currently in place. Information gathered during this visit will assist with finalising the risk

management proposal under development for the market access request. Once this has been finalised, it will be distributed for New Zealand stakeholder consultation for a period of 60 days.

SUMMARY OF CRITICAL ACTIONS

Critical Action 1: to address the presence of ants in the post-treatment secure area. [One agreed action was that all cut fruit would be disposed of immediately and ant baits will be used]

Critical Action 2: MPI to review the SOP for the VHT facility [completed 10/05/2013]

Critical Action 3: MARD PPD to notify MPI when has gained Japanese/Korean approval [Note approval of the facility is dependent on the SOP review and outcomes and Japanese/Korean approval].

Critical Action 4: to add procedures into SOP for:

- a. Treatment failure and handling of rejected fruit
- b. Fruit traceability (including forms and checklists)
- c. Post-treatment storage

SUMMARY OF OTHER ACTIONS

Action 1: MPI to provide a copy of the facility review to for quality assurance records.

Action 2: to send MPI unpublished field survey information regarding fruit fly infestation of dragonfruit [completed 23 April 2013, ref 1].

Action 3: MPI to provide MARD with a list of fruits approved for irradiation.

SUMMARY OF RECOMMENDATIONS

Recommendation 1: to remove references to irradiation in the standard operating procedures for the export of mangoes to New Zealand. have agreed and will update their SOP's as appropriate]

Recommendation 2: to include a procedure in their SOP regarding how nonconforming product (product for which treatment has failed) is managed.

Recommendation 3: to develop a system that clearly links the phytosanitary certificate with the treatment certificate and treatment record to ensure efficient traceability in the event of an issue. A MARD PPD discussed the solution and presented this to MPI]

Recommendation 4: to display load configurations for mango to New Zealand in the tote loading area to ensure technical staff load totes correctly.

Recommendation 5: to include procedures for treatment failure and rejected fruit into SOP.

Recommendation 6: to retain treatment records for fruit treated for New Zealand for 2 years.

Recommendation 7: make a lamp available to the PPD inspector for phytosanitary inspection have agreed to this and will supply a lamp for phytosanitary inspection]

Recommendation 8: to display load configurations for mango to New Zealand in the tote loading area to ensure technical staff load totes correctly.

Recommendation 9: MARD PPD to work with treatment facilities to address recommendations.

Recommendation 10: MARD PPD officer to sign the beginning of the treatment printout log to verify that all treatment parameters have been correctly entered.

Recommendation 11: MARD PPD officer to verify VHT probe position, by cutting probed fruit, and confirm that treatment has met NZ requirements.

Recommendation 12: MARD PPD officer to check that irradiation totes are loaded as per the approved configurations.

Recommendation 13: MPI considers the structure of the OAP to ensure better understanding by NPPOs as well as including multiple commodities within the same OAP where processes are similar.

MANGO PATHWAY REVIEW FINDINGS

Contacts:

Deputy Director & Factory Manager Deputy General Director

The facility floorplan is presented in Appendix 1.

was a well maintained and clean facility. The staff were well organised and efficient at providing documentation as requested. It was encouraging that no treatment failures had been recorded since the establishment and approval of the facility by Japan in 2009. The only fruit rejected to date have been for quality issues.

Entry hatches

Largest fruit for sensor insertion



Plate 1-3: Pre-treatment, access area to post-treatment area, and post-treatment area at

Standard operating procedures (SOPs) for mangoes (updated) and dragon fruit for export to New Zealand were presented. MARD has assisted with the development of SOP's for all treatment facilities to ensure consistency in actions and presentation. SOP was more simplistic than other facilities, using pictures and few words to describe procedures. Procedures were supported by forms that clearly demonstrated the chain of activities pre- and post-treatment (including cleaning schedules) and the responsible personnel. It was noted that some references were made to irradiation within the SOP documents as they used an irradiation facility SOP as a template. The SOP did not include reference to non-conforming product although actions for such product were verbally discussed.

An examination of phytosanitary certificates and treatment certificates showed that there was no clear link between the documents. At present, it appears the facility is able to traceback all consignments based on treatment date and market only.

It was noted that the Japanese inspector, on-site for pre-clearance activities, verified parameters of the treatment prior to its initiation by signing the treatment printout log. It was proposed and agreed that the onsite MARD PPD inspector undertakes this activity for consignments for New Zealand. In addition, the PPD inspector will verify all temperature and time requirements following treatment, as per the OAP.

The post-treatment secure area was clean and well maintained. The area is cleaned daily and is regularly disinfected with alcohol. All efforts are made to exclude insect pests by a double door access system to the post-treatment area, plastic strip curtains, air curtains at each of the access area, however; the presence of two ants was noted. Ants are of particular concern to New Zealand and there are many regulated species of importance.

The verification checklist for activities at the facility is presented in Appendix 2 and is the basis for determining actions and recommendations for the facility.

CRITICAL ACTION

1. to address the presence of ants in the secure area needs to be addressed.

[One agreed action was that all fruit cut for phytosanitary inspection would be disposed of immediately and ant baits would be used]

RECOMMENDATIONS

to remove references to irradiation in the standard operating procedures for the 1. export of mangoes to New Zealand.

have agreed and will update their SOP's as appropriate]

- to include a procedure regarding how non-conforming product (product for 2. which treatment has failed) is managed.
- 3. to develop a system that clearly links the phytosanitary certificate with the treatment certificate and treatment record to ensure efficient traceability in the event of an issue.

and MARD PPD discussed the solution and presented this to MPI]

Contacts:	Sales Offic	General Director, er, 19 A Preclearance Mitiga	tion Specialist
irradiates fre	esh fruit,		
p	roducts using	irradiation	The facilities treatment

capacity is 120 tons per day. The company was verified and certified in July 2009 by the

Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) to irradiate fresh approved fruits for the US market. The facility operates three production lines, one of which is dedicated to irradiating fresh produce. The facility employs between 5-10 research and development staff, and 11-20 quality control staff as well as many other operational staff.

The facility was clean, secure and is certified by the USDA to undertake irradiation of dragon fruit and rambutan to the USA under a pre-clearance programme. A treatment run was not observed but pre- and post-treatment activities were observed for dragon fruit for export to the USA. Activities included inspection of fruit, sea and air containers. Air containers are loaded inside a coolstore within the facility and are checked and sealed by customs officials. Likewise, sea containers are loaded in a secure area which prevents reinfestation of the consignment.

Dose mapping was discussed with the USDA inspector on-site who has been trained specifically for pre-clearance activities related to irradiation treatments. Initial dose mapping for USA commodities was under the supervision of the USDA APHIS officers. It was noted that the USDA has not detected fruit fly during inspections of dragon fruit since the programme began.

Appendix 3 provides a summary of the review of the facility and corresponding objective evidence. One recommendation was made which was applicable to both irradiation facilities

RECOMMENDATION

4. to display load configurations for mango to New Zealand in the tote loading area to ensure technical staff load totes correctly.

Contacts:

Secretary, General Affairs Department Deputy General Director



Plates 4-6: Pre-treatment operations for dragon fruit at



Plates 7 & 8: Preparation of VHT machine for treatment of dragon fruit. Plate 9: Packaging for mango for export to New Zealand.

have only been operating for a short period of time but have developed a robust quality assurance system. They have dedicated quality assurance and control staff and they are currently working towards gaining ISO 22000 (food safety) accreditation. The facility has highly trained staff, was clean, secure and was able to provide all records relating to equipment calibration, maintenance, training, hygiene etc. Appendix 4 provides a floorplan of the facility and Appendix 5 is a summary of the review of the facility and corresponding objective evidence. Three recommendations are made to provide regarding equipment, procedures and record retention. A copy of MPI's audit report was requested by and this will provided once completed.

RECOMMENDATIONS

- 5. make a lamp available to the PPD inspector for phytosanitary inspection have agreed to this and will supply a lamp for phytosanitary inspection]
 - to include procedures for treatment failure and rejected fruit into SOP.
- 7. to retain treatment records for fruit treated for New Zealand for 2 years.

ACTION

6.

2. MPI to provide a copy of the facility review to for quality assurance records.

IRRADIATION FACILITY

Contact:

Quality Assurance Department,

Co. Ltd

Plate 10: Loading of rambutan and dragonfruit for irradiation for the US market. Plate 11: Loading bays for irradiated fresh produce for sea and air freight.

irradiates fresh fruit and products using x-ray irradiation. Separate posttreatment storage and loading bays are used for seafood and fresh produce. The facility had a dedicated packing house which supplies packed fruit for irradiation at the adjacent irradiation treatment facility. The pre-treatment processing of mangoes for New Zealand was demonstrated at the packing house. These activities include unwrapping, stem cutting, washing, host water dipping (50°C for 5 minutes), drying and packing. The packing house was secure against insect infestation and was clean. Carton loading information (configuration and weights) was available in the packing house for mangoes to New Zealand as well as the tote configuration, although the tote was not loaded in this area.

The post-treatment activities following irradiation treatment of rambutan and dragon fruit for the USA was observed. Staff were interviewed and records retrieved for equipment maintenance, staff qualifications and training. The facility is able to traceback consignment information easily for USA consignments and a system is in place for New Zealand consignments. Appendix 6 provides a summary of the review of the facility and corresponding objective evidence.

RECOMMENDATION

8. to display load configurations for mango to New Zealand in the tote loading area to ensure technical staff load totes correctly.

Appendix 7 shows the flow of fruit for treatment at facility. The plates below provide photos of key areas within the process.

VHT



Plates 12-14: Pre-processing cleaning areas and insect



Plate 15: Pre-treatment areaPlate 16: Interior of the VHT machinePlate 17: Clean water in-take for VHT machine



Plate 18: Computer controls for VHT machine Plate 19: Post-treatment cooling system Plate 20: Phytosanitary inspection area

The **Control** VHT facility has recently received MARD PPD approval and is awaiting approval from the Japanese NPPO before the export of dragon fruit to Japan can commence. The facility has four VHT operations engineers and three dedicated QC supervising staff. The facility was well organised and clean however, no fruit or treatment was observed during the visit. The quality assurance staff had prepared an SOP for the facility and this was reviewed on return to New Zealand. Appendix 8 provides an assessment of the facility SOP and information obtained from the visit.

CRITICAL ACTIONS

- 3. MPI to review the SOP for the
- 4. MARD PPD to notify MPI when

[completed 10/05/13] has gained Japanese approval.

- 5. to add procedures for:
 - a. Treatment failure and handling of rejected fruit
 - b. Fruit traceability (including forms and checklists)
 - c. Post-treatment storage

PHYTOSANITARY ACTIVITIES BY MARD PPD

Contact:

Director, Plant Protection Department, Post Entry Quarantine Center No II, MARD, Ho Chi Minh City

MARD PPD and pre-clearance activities were observed for the export of dragon fruit to the USA, Korea and Japan. A number of activities undertaken by the pre-clearance inspectors were observed that could be undertaken by MARD PPD to provide additional assurance that MPI requirements will be met.

It was evident during the treatment facility review that the official assurance programme (OAP) was not well understood and an additional recommendation is made to MPI regarding communicating MPI's expectations and future considerations for OAP document structure.

RECOMMENDATIONS

- 9. MARD PPD to work with treatment facilities to address recommendations.
- 10. MARD PPD officer to sign the beginning of the treatment printout log to verify that all treatment parameters have been correctly entered.
- 11. MARD PPD officer to verify VHT probe position, by cutting probed fruit, and confirm that treatment has met NZ requirements.

- 12. MARD PPD officer to check that irradiation totes are loaded as per the approved configurations.
- 13. MPI considers the structure of the OAP to ensure better understanding by NPPOs as well as including multiple commodities within the same OAP where processes are similar.

DRAGONFRUIT PATHWAY ASSESSMENT FINDINGS

The visit to dragon fruit production sites gave a good overview of the pre-harvest practises currently in place. Information gathered during this visit will assist with finalising the risk management proposal under development for this market access request. Once this has been finalised, it will be distributed for New Zealand stakeholder consultation for a period of 60 days.

ACTION:

- 2. to send MPI unpublished field survey information regarding fruit fly infestation of dragonfruit [completed 23 April 2013, ref 1].
- 3. MPI to provide MARD with a list of fruits approved for irradiation.

The proposed pathway for the export of fresh dragon fruit from Vietnam to New Zealand (shown below) based on observations and discussions with MARD during the visit.

Dragon fruit produced in exportand GAP-registered orchards in Viet Nam. Specific pests are managed culturally during production and insecticide treatment is minimised.

Fruit harvested & transported to primary pack houses or directly to VHT treatment facility





Fruit sorted, air brushed & cleaned, washed and loaded into crates for vapour heat treatment.





Probes inserted into largest fruit, treatment parameters checked and consignment vapour heat treated







Probes checked post-treatment to ensure they were inserted correctly to measure fruit core temperature. Dragonfruit unloaded from VHT machine, dried and re-packaged in insect-proofed packaging with traceability information in a posttreatment secure area.







Phytosanitary certificate issued when all requirements met (including inspection).



Export to NZ



EXIT MEETING

A meeting was conducted on 19 April in Ho Chi Minh City at MARD offices:

Staff present at the exit meeting were:

MPI

MARD



Senior Adviser, Fresh Produce Imports

Director, Plant Protection Department, Post Entry Quarantine Center No II, MARD, Ho Chi Minh City

The majority of critical actions, actions and recommendations were conveyed to during the exit meeting. However, was informed that additional points may be raised following review of all information. All actions and recommendations will be summarised and sent in a formal letter to was in Ha Noi copied to will be formed in Ho Chi Minh City.

Once again, MPI thanks MARD for openly providing all requested information and for organising the visits to treatment facilities and dragon fruit production sites and packing house facilities. We look forward to working with MARD over the coming months with a view to export of dragon fruit in 2013.

REFERENCES, REPORTS AND INFORMATION

1. Fruit Fly management for Dragon fruit Production in Vietnam – A presentation for New Zealand market (April 22, 2013)

Fruit Fly management for Dragon fruit Production in Vietnam to NZ market.doc <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380b8864f</u>

Appendix 1: Map of

VHT Facility

Key:

3.

1. Weighing and sorting of fruit

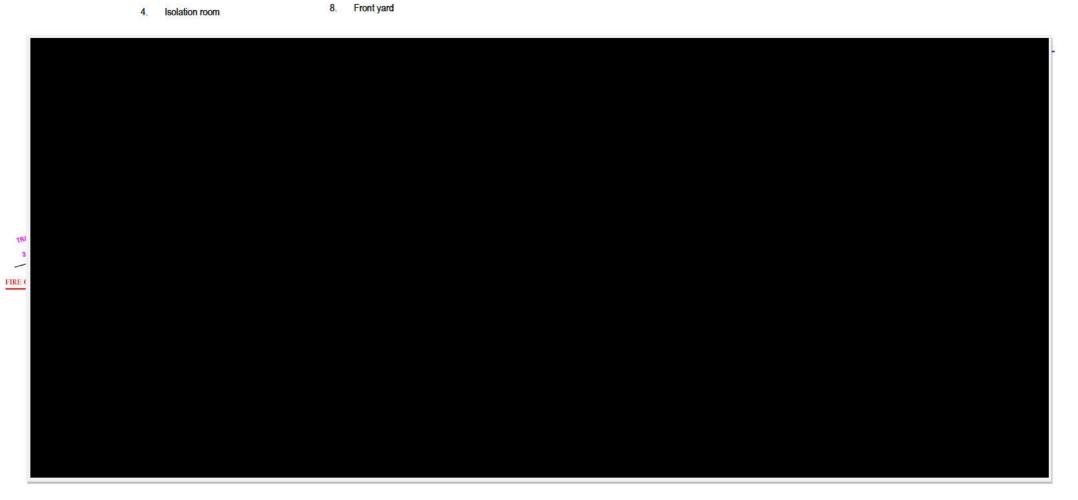
5. Packing area

Storage

7. Loading area

6.

- VHT machine 2.
 - Isolation room &
- 4. Isolation room



Appendix 2: VHT Verification Checklist for

DATE: 15 April 2013

Procedure	Complies	Comments/Corrective Action
FACILITY		
 MARD registration and approval Approvals from other countries? 	✓ ✓	MARD confirmed that the facility is registered and approved by them and undergoes an annual audit prior to audits by Korea and Japan that conduct pre-clearance activities for the export of dragon fruit to these countries. Audit reports were not sighted, however the presence of the Japanese inspector indicated that the facility was compliant and passed the annual audit. Japanese and Korean inspectors are present at the facility all year round.
STAFF COMPETENCY		
Treatment operators	~	Training records (certificates) were observed for specific personnel involved with the operation of the VHT machine. Operator training occurs at two levels. Vietnamese technicians are trained in Japan and a Japanese technician will also conduct training on-site. Experienced operators assist with the training of new staff.
HYGIENE		
 Hygiene log? Harvested fruit arrives at pack house in cleaned lined crates in clean trucks with traceability info Floors and walls clean Surfaces and equipment cleaned 	✓ ✓	The facility maintains a strict hygiene regime which is documented in their SOP. Staff wear clean uniforms and hair nets in the post-treatment area. Shoes are changed between the pre- and post-treatment sections of the facility. Observed for dragonfruit consignment The pre-treatment area is cleaned at regular intervals and regularity is dependent on the area or equipment type. That is, floors are cleaned twice per day with water and every two days with alcohol. The VHT machine is cleaned monthly as are ceiling,

Procedure	Complies	Comments/Corrective Action
 and disinfected Pest control activities in and around facility (e.g. vermin and fruit fly traps) (frequency of insecticide spraying?) 	~	lights, pallets and crates. The post-treatment area has a similar regime and includes the addition of monthly chemical spraying. In addition to chemical sprays, pests were excluded from the post-treatment area by a double door system, plastic strip curtains, an air curtain and electro-insect lights. Despite this, ants were observed in the area around fruit that had been cut for phytosanitary inspection. This issue was raised with MARD and the facility general manager. It was agreed that cut fruit would be disposed of immediately.
 Clean water source and washing water changed regularly Staff hygiene equipment (e.g. coats, hairnets, booties?) 	* *	It was requested by MPI that remedial action such as ant baits were also applied. Clean ground water used for washing. Staff wear hair nets, uniforms and specific post-treatment footwear. Washing facilities are provided in the double door entry area.
VHT UNIT STANDARD		
 VHT unit able to sustain fruit core at 46.5 for 30 minutes Cold spot testing (minimum of nine sensors in treatment chamber?) 	✓ ✓	A treatment record for a recent treated consignment (13/4) was obtained which showed that all sensors were at the required temperature before the treatment time began. Cold spot testing has previously been undertaken by Japanese technicians. Staff demonstrated the selection of the largest fruit and insertion of fruit sensors. All
chamber :)		probed fruit (9) were in top crates within the treatment chamber as per plate 1.
TEMPERATURE RECORDING SY	YSTEM	
• Accuracy of ±0.3°C in 37-52°C range with a resolution of 0.1°C	1	A copy of the most recent sensor calibration record was obtained which demonstrated the accuracy and resolution of the sensors. Each sensor was identifiable on the record.
 Continuous automatic monitoring of time (at least every 2 min for treatments less than 2 hours and 5 mins for over 2 hours) and 	~	A recent copy of a thermograph was obtained that showed that temperature was recorded every 5 minutes. The total of treatment is greater than 2 hours which includes temperature ramping therefore this is acceptable.

Procedure	Complies	Comments/Corrective Action
 temperature for each sensor from ramp up through treatment period. Temp and time correctly loaded into automatic control system + treatment batch #, date and runtime are entered into data acquisition system or printed record. Individual sensors identifiable on records 	~	Observed for dragonfruit treatment. Individual sensors are identifiable on the printout (recent copies viewed) The loading of temperature and time was observed for one treatment run. These parameters are normally checked by the pre-clearance inspectors from Japan and Korea. The officers sign the beginning of the thermograph record to acknowledge this. It is recommended that MARD undertake the same procedure on behalf of MPI
EQUIPMENT CALIBRATION AN	D MAINTE	NANCE
 Sensors correctly calibrated 	~	A copy of the most recent sensor calibration record was obtained. The calibration record was confirmed by both Vietnamese technician and the Japanese official. Each sensor had a unique number. A calibration was not observed. Calibration is performed monthly.
FRUIT CORE SENSORS		
• Numbers and position(s) of fruit sensors correlate with cold spot test	~	Fruit weighing and sensor insertion was observed. Sensor placement was confirmed following treatment by the Japanese inspector removing the probe and cutting fruit to determine the depth of insertion. Mangoes were not observed due to issues with the Japanese NPPO not allowing NZ produce to be treated in the facility. Therefore, only a dragonfruit treatment for export to Japan was observed.

Procedure	Complies	Comments/Corrective Action
 Heaviest fruit selected for probing and weighed Sensors placed next to seed at point of maximum pulp thickness Sensors sealed into fruit with approved sealant or tape 	~	The sensor was not sealed into the fruit as required in Section 3.7 – Treatment supervision; MAF Biosecurity Authority Standard 158.03.03: Specification for Fruit Fly Heat Treatment Monitoring. However, this is not considered necessary for dragonfruit as the anatomy of the fruit is conducive to the secure positioning of the sensor. Sensors are checked for positioning at the time of treatment and post-treatment to determine its correct positioning and security.
TREATMENT		
 Treatment supervised/monitored by NPPO authorized officer? Ensures fruit security maintained throughout Treatment parameters met 	~	MPI stipulates that treatment is monitored and currently MARD are supervising treatments in conjunction with pre-clearance officers from other NPPOs. <i>MARD have agreed to undertake additional responsibilities which ensure that treatment parameters are correctly entered into the VHT machine, checks of probes and position, and verification of the treatment parameters following download of the thermograph record.</i>
 Treatment records complete Treatment sensor plan Non-export bins clearly labelled 		Treatment of mangoes was not observed however a dragonfruit treatment was observed. The staff were methodical at checking fruit volumes, sensor placement and treatment parameters. Pre-, treatment and post-treatment checklists were in place to ensure all requirements are met.
Largest fruit placed at bottom of bins		The facility only treats fruit for export and therefore non-export bins are not present in the facility.
Fruit placed stem downBins filled to same level		Largest fruit are placed in top bins. Cold spots are located in top bins as the airflow of the system is from bottom up.
Temp., times, batch, date and run-time are correctly loaded and meet NZ requirements		Treatment run not observed for fruit for export to NZ

Procedure	Complies	Comments/Corrective Action
Computer off-set readings correspond with probe assignment and verification tables for the month		
Contingency for treatment failure		The facility's documented procedures were basic and did not include a contingency for treatment failure. It was encouraging that no treatment failures had occurred since the facility began operation. However, if more than 30% of fruit are damaged, the treatment is assessed as failed and removed from the facility.
		A verbal description of removal of fruit from the secure area was provided.
		MPI recommends that the facility have a written contingency in place in the event of treatment failure
PRODUCT SECURITY		
 Pre- and post-treatment 	~	Photos were taken of the security of the facility. This included gated entry, insect strip curtains and air curtains on entry and exit points; screens on all windows; double door entry into the post-treatment; electro insect zappers, separate cool storage areas for product for different destinations and strip curtaining and air curtains in the loading area.
PRODUCT TRACEABILITY		
Pre-treatment	~	Documented procedures are in place for the receipt of fruit and traceability of fruit. At present the facility is only sourcing fruit from one orchard cooperative which has a unique PUC (production unit code).
Post-treatment		A hard copy of an example of the traceability system was observed. Records were accessible by computer and are retained for 3 years which meet NZ requirements.

Additional Information & Objective Evidence

Interviews were conducted with the maintenance technician, the on-site facility treatment operator and the MARD (NPPO) official. New Zealand's requirements for inspection as per the agreed OAP for mangoes.

Appendix 3: Review of

Requirement/Criteria:	Complies	Comments/Remarks
Facility		
Irradiation facility is registered with appropriate authorities (NPPO, IAEA recognised body etc) and has been approved (audited) by NPPO to carryout phytosanitary treatments.	~	The facility is registered with the NPPO, however the NPPO relies on the USDA to conduct audits. The facility is registered with the Vietnam Radiation and Nuclear Safety & Control (VARANSAC).
The treatment equipment must be able to perform irradiation treatments to the relevant agreed standard (ISO, IAEA, CODEX, or MPI Standard) and ensure that the exposure rate that the commodity is subjected to is constant throughout the product.	~	irradiates fresh fruit, products using treatment capacity is 120 tons per day. The company was verified and certified in July 2009 by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) to irradiate fresh approved fruits for the US market. The facility operates three production lines, one of which is dedicated to irradiating fresh produce.
Facility buildings are designed and built to be suitable in size, materials, and placement of equipment to facilitate proper maintenance and operations for the lots to be treated.	~	Documentation was provided that equipment had been calibrated in accordance with international standards
The treatment equipment must be regularly maintained and maintenance records kept and presented upon request.	¥	The equipment maintenance log was sighted and was easily accessible.
All buildings and structures should be maintained in a state of good repair and weatherproof.	~	The facility is relatively new (approx. 5 years old) and was clean, well maintained and in a good state of repair.

Buildings, equipment, and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent reinfestation of the consignments and/or lots being treated	√	The facility has a dedicated area for the irradiation of fresh produce which incorporates a pre-processing area (for washing of fruit), packaging and phytosanitary inspection. The facility has plastic strip curtains, air curtains, electro insect zappers and screens to prevent the entry of pests into the pre- and post-treatment areas. The facility was clean when visited and has a hygiene/sanitation schedule in place for all areas of the processing facility. The facility has dedicated areas for pre- and post-treatment segregation of
System in place, preferably integral to the facility design, to ensure segregation of treated and untreated lots	√	treated and untreated lots. Produce enters from one side of the irradiator and exits from a different area. The design of the facility does not allow for treated and untreated lots to be inadvertently mixed.
Effective measures are in place to prevent pests from being introduced into processing areas and to protect against the contamin- ation or infestation of consignments and/or lots being stored or processed (effective pest control programme).	✓	As above, physical exclusion of pests are utilised in the facility, as well as sanitation and trapping. The QA manager also monitors monthly records to look for any trends in pest activity.
Documented procedures are in place to dispose of commodities or consignments that are improperly treated or unsuitable for treatment	✓ ✓	The facility SOP has a documented procedure for the handling of rejected articles. The facility has a dedicated area for rejected articles, a system for marking them as "rejected" and removal from the facility.
Quality System		
A quality system is in place which details key management and personnel and associate responsibilities.	~	The facility has a defined management structure and has QC, operational and research and development staff.
Detailed SOP's are in place covering all aspects of operations (including but not limited to management, process, facility	✓	has provided an SOP which covers all activities involved in the pre- and post-treatment processing of mangoes for export to NZ, pest exclusion, handling of rejected articles, treatment, dose mapping and dosimetry and staff

hygiene, dosimetry, treatment process). System in place for storage and filing of documentation and that these are accessible to NPPO (and other agencies) upon request.	V	training. The SOP does not include the management structure but key personnel and their roles were discussed during the review. The facility had a hard copy and computer retrieval system for all aspects of the treatment process. Copies of templates for forms and reports were provided. These documents were easily retrievable in both electronic and hard copy format. Copies of all forms and reports are retained for 3 years.
A system of internal audit is in place to ensure that all documented procedures are followed and maintained. These audits must be documented and copies of reports available on request.	√	It was not determined whether the facility had an internal audit process in place however; audit was discussed with the USDA pre-clearance inspector during the visit. All activities relating to the pre-, treatment and post-treatment of fresh produce is overseen by USDA pre-clearance inspectors and is closely scrutinised for the duration of their visit. MARD inspectors are also on site throughout the process and have a good understanding of the process for export.
Treatment facilities must maintain a documented and auditable system of procedures that include the following aspects:	√ √	The SOP provided by the facility and approved by MARD covers all aspects of receipt through to loading of the consignment. Additional checks of sea and air freight containers occur under strict security in the post-treatment area of the facility. Air and 40ft sea containers are inspected within the facility by both MARD and Vietnamese customs.
 Produce receipt; Identification of produce; Segregation of treated and untreated produce; Quarantine security for treated produce; Supervision of produce during loading for despatch. 	V	
Staff Company staff conducting treatments must hold appropriate qualifications reflecting government requirements of the country in which the facility is located.	✓	Training records and certificates of training were sighted and were appropriate for the tasks that specific staff undertake.
System of training and approval for staff		Staff showed evidence of completion of external training courses. The manager

must be in place with records available on request.	\checkmark	develops an annual training plan and records the specific training each employee receives as relevant to their job description.
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes and their responsibilities.	√ √	The QC staff and operational staff spoken to (through basis) were able to effectively demonstrate the requirements for correct handling and phytosanitary inspection of produce for processing. Display charts were available at key areas in the pre-treatment area for weighing and inspection of produce.
Dosimetry Capable of recording/measuring the entire range of dosages likely to be received by the product (Dmin & Dmax)	\checkmark	Dosimetry records were provided in advance of MPI's visit. Measures of Dmin and Dmax were clearly in the dose range required by MPI and the facility has been operating these for the export of dragon fruit and rambutan to the USA since 2009.
Calibrated in accordance with international standards or appropriate national standards (ISO/ASTM 51261 "Selection and Calibration of Dosimetry Systems for Radiation Processing", ISO/ASTM 51204 "Dosimetry in Gamma Irradiation Facilities for Food Processing" and ASTM guide - F1355 "Irradiation of Fresh Fruits as a Phytosanitary Treatment", and ISPM 18)	V	The facility SOP documents the calibration of the dosimetry equipment and records of these are saved in ECMS: certification of conformance.PDF <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380b2ecbc</u> calibration Cuver.PDF <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380b2ecbb</u> Calibration NIST- FWT.doc <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380b2ecba</u>
Appropriate for the treatment conditions (ie temperature etc in the treatment chamber) Evaluated for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required	√	These aspects have been previously assessed by the USDA to gain approval.
Consider variations due to density and	✓	

 composition of the material treated, shape and size, orientation of the product, stacking, volume and packaging Dose mapping of the product in each geometric packing configuration, arrangement and product density used during routine treatments must be carried out prior to the approval of the facility. Only approved configurations are used for actual treatments. 	✓ ✓ ✓	Specific load configurations have been provided to MPI and align with dose mapping. Contingencies are in place if an incomplete load is irradiated, involving totes loaded with dummy material with the same density as the target material. Discussion with the USDA pre-clearance inspector showed that partial loads were acceptable with the particular system in place at This has been approved by USDA (pers. comm.). Dose mapping was provided to MPI in advance of the visit and is filed in ECMS: dosemapping.xls http://fcs.maf.govt.nz/webtop/drl/objectld/090101b380994620 dosemapping.xls http://fcs.maf.govt.nz/webtop/drl/objectld/090101b380994623 Mango Load configuration doc http://fcs.maf.govt.nz/webtop/drl/objectld/090101b380994625
All components of the dosimetry system are calibrated according to documented standard operating procedures. An independent	v	MPI was provided with a presentation on the irradiation system undertaken for dragon fruit at the facility during the visit:OOSE MAPPING IN IRRADIATION.ppt <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380b880ae</u>
organisation recognized by MPI should assess performance of the dosimetry system	\checkmark	Calibration of all dosimetry equipment is reported in the facility SOP. The performance of the dosimetry system has been previously assessed by the USDA.
A system in place to ensure that accurate measurement of absorbed dose in a consignment is carried out. The required	~	
number, location and frequency of these measurements are prescribed based on the specific equipment, processes, commodities,	\checkmark	The facility SOP and observation of the set up for irradiation of a consignment of dragonfruit for the USA showed that the required number, location and frequency of dosimetry measurements are as per dose mapping.
relevant standards and phytosanitary requirements.	\checkmark	
Absorbed dose delivered to each type of commodity is verified by proper dosimetric	~	

measurement practices using calibrated dosimetry.		
Dose Mapping Dose mapping is completed and documented for each treatment configuration and available on request.	✓	Records of dosimetric measures were sighted and competency in measurement practices for the facility staff were confirmed by the USDA. USDA has been involved in training.
Dose mapping is used to select the most appropriate location for dosimeters during the treatment of produce.	✓ ✓	Dose maps were received in advance of the visit and indicated the appropriate locations of dosimeters. The USDA confirmed the appropriateness of the dosimetry system for variables.
All aspects of the dosimetry systems are appropriate for the treatment conditions, i.e. temperature, light, humidity, storage time and type of treatment.	✓	dosinietry system for variables.
All components of the dosimetry systems are calibrated according to documented operating procedures.	√ √	Records of calibration of the dosimetry system were obtained.
Calibration of dosimetry systems are calibrated in accordance with the relevant international standards.	\checkmark	
Dose mapping is carried out in accordance with documented (proven) standard operating procedures. The information from the dose mapping studies is documented and used in the selection of locations for dosimeters during routine processing.	✓	A certificate of conformance for dosimeters was presented.
	\checkmark	

Dose mapping for incomplete (partially- filled) as well as first and last process loads is undertaken to determine if the absorbed- dose distribution is significantly different from a routine load and to adjust the treatment accordingly.	✓	Dose mapping documents were provided in advance of the visit for the two varieties of mangoes intended for export. Load configurations and dosimeter locations are available for operational staff.
Dose mapping carried out on "like" density product/s if actual commodity not used (approval sought from MPI prior to mapping being undertaken). Dose mapping has taken into account the Dmax where specified (Dmax 1 KGy on fresh produce).	✓	Procedures for incomplete loads are in place and dummy totes containing same- density material for irradiation are used (p14 SOP). Discussion with the USDA pre-clearance inspector showed that partial loads were acceptable with the particular system in place at the irradiated consignment received in NZ in 2012 (PC 66296/12/0201).
Irradiation treatment		NA as dose mapping undertaken on mangoes.
Where applicable, inspection for non target pests has been undertaken (usually NPPO responsibility). Need to ensure system in place that only product that has been inspected and passed is treated.Inspection is undertaken to ensure suitability for treatment (configuration/density etc).	✓ ✓	Dose mapping did not exceed 1 KGy. This is also specified in the current OAP (P 5) and is understood.
A documented process control system is in place, providing criteria to assess irradiation efficacy, including standard operating procedures Proper process procedures are established for each type of commodity or consignment to	✓	The pre-treatment inspection system was demonstrated on dragonfruit for the US and the same system will be applied for fruit for export to New Zealand. Note, that it was emphasized that NZ requires a 600 fruit inspection etc. as documented in the OAP.

be treated.

Written procedures have been supplied and approved by MPI and are well known to appropriate treatment facility personnel

Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry. System in place to deal with under/over dosed product.

Dosimetry records are kept and made available to the MPI as required.

Specific commodity requirements may be required to be taken into account. Specific (approved) SOP's are in place and followed according to requirements. (additional checksheet maybe required)

Product Security

Systems must exist to ensure that treated produce is segregated from untreated produce and that no cross-contamination can occur.

Following treatment, each treatment lot must be maintained under quarantine security. Quarantine security must be maintained through to the export of the produce.

 \checkmark

 \checkmark

 \checkmark

Weight charts are available in the inspection area for dragon fruit and will be for mangoes to New Zealand to ensure density criteria are met. The MARD inspector samples and weighs fruit during the phytosanitary inspection process.

Written procedures are in place for the irradiation of mangoes and these were supplied to MPI in advance of the visit. The correct dosimetric measurement system is in place and has been verified by the USDA. Contingencies are addressed in the SOP including interrupted loads.

As per SOP

Dosimetry records are kept for 3 years and examples were retrieved and sighted during the visit.

A specific SOP has been developed for mangoes to NZ.

Where produce is not to be loaded directly after treatment, a system must be provided to and approved by MPI that outlines the procedures to ensure product security post treatment to the point of export.

Specific commodity requirements may be required to be taken into account. Specific (approved) SOP's are in place and followed according to requirements. (additional checksheet maybe required)

Packaging and labelling

Commodity is packaged (if necessary) using materials suitable to the product and process.

Treated consignments and/or lots are adequately identified or labelled and adequately documented to allow traceback to individual treatment lots

Each consignments and/or lot carries an unique identification number or other code to distinguish it from all other consignments and/or lots

Labelling or marking on the package clearly identify that the consignment has been treated with irradiation (radura symbol or similar). Check specific commodity requirements for other labelling/packaging requirements (eg pest proof packaging, grower identification etc). The layout of the facility ensures that treated and untreated fruit are unable to be mistakenly mixed or cross-contaminated. The post-treatment area is secure and sea and air freight containers are unable to be infested as they are contained and inspected within the facility before and during loading.



Air containers are inspected and loaded in the secure post-treatment area. This ensures product security. In addition to MARD inspection, Vietnamese customs inspects and seals sea and air containers within the facility.

SOP available and in ECMS

Packaging type has been approved by the USDA and is known to be suitable for irradiation.

A traceability system is in place and is being used for product exported to NZ.

Specific commodity requirements may be required to be taken into account. Specific (approved) SOP's are in place and followed according to requirements. (additional checksheet maybe required)

Record requirements

Treatment facilities must maintain records of phytosanitary treatments for a minimum period of 5 years to ensure traceability of treated lots. These records must include:

- Identification of the treatment facility;
- The purpose of the treatment;
- Identification marks on packages;
- The quantity treated;
- Target absorbed dose; and
- Achieved absorbed dose (Dmin and Dmax)
- Phytosanitary certification number (if applicable)

Records are to be made available to MPI upon request.



Example of dragonfruit labelling for the US market. The same labelling is being used for mangoes exported to NZ.

The example also shows irradiation labelling on the exterior of the box as well as pest proof packing as required in the OAP.

The requirements for mangoes are similar to system for the export of dragonfruit to the USA. These are documented in SOP and were demonstrated with a consignment with the export of dragon fruit to USA.

Records are retained by for 3 years. Records were easily retrievable and this was demonstrated for various consignments for export to the USA. Note that ISPM 18 states that "All NPPO procedures should be appropriately documented and records, including those of monitoring inspections made and phytosanitary certificates issued, should be maintained for <u>at least one year</u>. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available as described in ISPM 13:2001." Therefore it is considered that 3 years is a sufficient record retention time.



Appendix 5: VHT Verification Checklist for

DATE: 15 April 2013

Procedure	Complies	Comments/Corrective Action
FACILITY		
 MARD registration and approval Approvals from other countries? 	~	Documentation was sighted showing facility approval from MARD, Japan and Korean NPPOs.
STAFF COMPETENCY		
Treatment operators	~	A technician list and corresponding training records (certificates) were provided for specific personnel involved with the operation of the VHT machine.
HYGIENE		
 Hygiene log? Harvested fruit arrives at pack house in cleaned lined crates in clean trucks with traceability info Floors and walls clean Surfaces and equipment cleaned and disinfected Pest control activities in and around facility (e.g. vermin and fruit fly traps) (frequency of insecticide spraying?) Clean water source and washing 	✓ ✓ ✓ ✓	The facility maintains a strict hygiene regime which is documented in their SOP. Staff wear clean uniforms and hair nets in the post-treatment area. Shoes are changed between the pre- and post-treatment sections of the facility. The pre-treatment area is cleaned at regular intervals and regularity is dependent on the area or equipment type. That is, floors are cleaned twice per day with water and every two days with alcohol. The VHT machine is cleaned monthly as are ceiling, lights, pallets and crates. The post-treatment area has a similar regime and includes the addition of monthly chemical spraying. In addition to chemical sprays, pests were excluded from the post-treatment area by a double door system, plastic strip curtains, an air curtain and electro-insect lights.

Procedure	Complies	Comments/Corrective Action		
 water changed regularly Staff hygiene equipment (e.g. coats, hairnets, booties?) 	✓ ✓	Clean ground water is used. Hairnets, dedicated footwear and uniforms are required in the post-treatment area.		
VHT UNIT STANDARD				
 VHT unit able to sustain fruit core at 46.5 for 30 minutes Cold spot testing (minimum of nine sensors in treatment chamber?) 	✓ ✓	Chamber test data was provided from a minimum of 10 sensors for half and full loads of mangoes. The VHT test data and unit specification was shown to be able to sustain the MPI required treatment specifications as per the IHS.		
TEMPERATURE RECORDING SYSTEM				
• Accuracy of ±0.3°C in 37-52°C range with a resolution of 0.1°C	~	A copy of a sensor calibration record $(27/11/2012)$ was obtained which demonstrated the accuracy and resolution of the sensors. Each sensor was identifiable on the record.		
Continuous automatic monitoring of time (at least every 5 min for treatment over 2 hours) and temperature for each sensor from ramp up through treatment period.	~	The thermograph showed that temperature was recorded every 5 minutes. The loading of temperature and time was observed for one treatment run for dragon fruit. These parameters are normally checked by the pre-clearance inspectors from Japan and Korea. The officers sign the beginning of the thermograph record to acknowledge this.		
• Temp and time correctly loaded into automatic control system + treatment batch #, date and run- time are entered into data acquisition system or printed record.	~	It is recommended that MARD undertake the same procedure on behalf of MPI as evidence of supervision of the treatment Thermograph records sighted and machine screen confirmed this.		

Procedure		Complies	Comments/Corrective Action
 Individual records 	l sensors identifiable on		
EQUIPMEN	T CALIBRATION AN	D MAINTE	NANCE
 Sensors c 	correctly calibrated	~	A copy of a recent sensor calibration record was obtained (10/4). The calibration record was confirmed by both the Vietnamese technician and the Japanese official. Each sensor had a unique number.
			The sensor calibration process was described and documentation and records provided.
			Calibration is performed monthly and records of the last three calibrations were sighted.
			The maintenance and calibration logs were sighted.
FRUIT COR	RE SENSORS	<u>.</u>	
fruit s	ers and position(s) of ensors correlate with pot test	~	Fruit sensor insertion was observed. Sensor placement was confirmed following treatment by the Japanese inspector removing the probe and cutting fruit to determine the depth of insertion. Mangoes were not observed due to issues with the Japanese NPPO not allowing NZ produce to be treated in the facility. Therefore only a dragonfruit treatment for export to Japan was observed.
	est fruit selected for ng and weighed	~	Fruit selection, weighing and probe insertion was observed for dragon fruit.
	rs placed next to seed at of maximum pulp less		
	rs sealed into fruit with ved sealant or tape		

Procedure	Complies	Comments/Corrective Action
TREATMENT		
 Treatment supervised/monitored by NPPO authorized officer? Ensures fruit security maintained throughout Treatment parameters met Treatment records complete Treatment sensor plan Non-export bins clearly labelled Largest fruit placed at bottom of bins 	~	 MPI stipulates that treatment is monitored and currently MARD are supervising treatments in conjunction with pre-clearance officers from other NPPOs. MARD have agreed to undertake additional responsibilities which ensure that treatment parameters are correctly entered into the VHT machine, checks of probes and position, and verification of the treatment parameters following download of the thermograph record. Treatment of mangoes was not observed however, a dragonfruit treatment was observed. The staff were methodical at checking fruit volumes, sensor placement and treatment parameters. Pre-, treatment and post-treatment checklists were in place to ensure all requirements are met.
 Fruit placed stem down Bins filled to same level Temp., times, batch, date and run-time are correctly loaded and meet NZ requirements Computer off-set readings correspond with probe assignment and verification tables for the month 		All procedures were observed relating to the preparation, loading and treatment of dragon fruit for Japan.
Contingency for treatment failure	~	Treatment failure procedures were discussed and a number of examples presented to me by the facility quality assurance technician. Treatment failures were assessed on a case-by-case basis and the actions for each case recorded in a log book for future

Procedure	Complies	Comments/Corrective Action
		reference.
		It is recommended that document contingencies for treatment failure where possible.
PRODUCT SECURITY		
Pre- and post-treatment	Ý	Photos were taken of the security of the facility. This included gated entry, insect strip curtains and air curtains on entry and exit points; screens on all windows; double entry into the post-treatment; electro insect zappers, three separate cool storage areas for product for different destinations and strip curtaining and air curtains in loading area.
PRODUCT TRACEABILITY		
 Pre-treatment Post-treatment	~	Documented procedures are in place for the receipt of fruit and traceability of fruit. A hard copy of an example of the traceability system was observed. Records were accessible by computer and are retained for 1 year. The facility is less than 1 year old.
		It is recommended that retain treatment records for fruit to New Zealand for two years.

Additional information & Objective Evidence

have only been operating for a short time but have developed a robust quality assurance system. They have dedicated quality assurance and control staff and are working towards gaining ISO 22000 accreditation. The facility meets MPI requirements with respect to treatment, hygiene, training, security etc. Recommendations were made to to provide a lamp for phytosanitary inspection, as well as document contingencies for rejected fruit and treatment failures in their SOP and retain records for NZ treated fruit for 2 years.

Appendix 6: Review of

Irradiation Facility

Requirement/Criteria:	Complies	Comments/Corrective Actions
Facility		
Irradiation facility is registered with appropriate authorities (NPPO, IAEA recognised body etc) and has been approved (audited) by NPPO to carryout phytosanitary treatments.	~	The facility is registered with the NPPO, however the NPPO relies on the USDA to conduct audits. The facility is registered with the Vietnam Radiation and Nuclear Safety & Control (VARANSAC).
The treatment equipment must be able to perform irradiation treatments to the relevant agreed standard (ISO, IAEA, CODEX, or MPI Standard) and ensure that the exposure rate that the commodity is subjected to is constant throughout the product.	~	A copy of the USDA certificate of approval (Sept 2008) was sighted and the USDA pre-clearance inspector was present on site to confirm this. In addition, the facility provided a copy of a service agreement between them and the USDA APHIS.
Facility buildings are designed and built to be suitable in size, materials, and placement of equipment to facilitate proper maintenance and operations for the lots to be treated.	~	The equipment maintenance log was sighted and was easily accessible. The irradiation area and adjoining offices were well maintained and in a good state of repair. The facility had a separate packaging facility associated with the irradiation facility. Access is restricted via a guard house to the packhouse and irradiation facility.
The treatment equipment must be regularly maintained and maintenance records kept and presented upon request.	~	
All buildings and structures should be maintained in a state of good repair and weatherproof.	~	

Requirement/Criteria:	Complies	Comments/Corrective Actions
Buildings, equipment, and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent reinfestation of the consignments and/or lots being treated	~	packhouse associated with the irradiation facility. The equipment maintenance log for the irradiation facility was sighted.
		The packing facility associated with the irradiation was clean and well maintained as was the irradiation facility provided a SOP in advance of the visit which included a facility cleaning, sanitation and personal hygiene procedure.
System in place, preferably integral to the facility design, to ensure segregation of treated and untreated lots	~	A loading and unloading procedure (observed and in SOP) ensures that treated and untreated lots are not mixed.
Effective measures are in place to prevent pests from being introduced into processing areas and to protect against the contamin- ation or infestation of consignments and/or lots being stored or processed (effective pest control programme).	V	The facility has a dedicated area for the irradiation of fresh produce which incorporates a phytosanitary inspection and pre- and post-treatment storage area. The facility has plastic strip curtains, air curtains, electro insect zappers and screens to prevent the entry of pests into the pre- and post-treatment areas. The facility was clean when visited and has a hygiene/sanitation schedule in place for all areas of the processing facility.
Documented procedures are in place to dispose of commodities or consignments that are improperly treated or unsuitable for treatment	~	Procedures are in place that describes the handling of rejected lots and deviation reporting.

Requirement/Criteria:	Complies	Comments/Corrective Actions
Quality System		The facility has a defined management structure and has QC, operational and research and development staff. Certificates of competency were sighted for
A quality system is in place which details	~	key treatment operator personnel.
key management and personnel and associate	~	
responsibilities.		provided an SOP which covers all activities involved in the pre- and
		post-treatment processing of mangoes for export to NZ, pest exclusion,
Detailed SOP's are in place covering all		handling of rejected articles, treatment, dose mapping and dosimetry and staff
aspects of operations (including but not	~	training.
limited to management, process, facility	200.2	N77
hygiene, dosimetry, treatment process).		The facility had a hard copy and computer retrieval system for all aspects of the treatment process (these are defined on p21-22 in the SOP). Copies of
System in place for storage and filing of		templates for forms and reports were provided. These documents were easily
documentation and that these are accessible		retrievable in both electronic and hard copy format. Copies of all forms and
to NPPO (and other agencies) upon request.		reports are retained for 1 year. Some records such as radiation surveys, training and personnel are permanently retained. [the computer storage system was
	~	observed].
A system of internal audit is in place to ensure that all documented procedures are followed and maintained. These audits must		It was not determined whether the facility had an internal audit process in place however; audit was discussed with the USDA pre-clearance inspector during the visit. All activities relating to the pre-, treatment and post-treatment of fresh
be documented and copies of reports available on request.		produce is overseen by USDA pre-clearance inspectors and is closely scrutinised for the duration of their visit. MARD inspectors are also on site throughout the process and have a good understanding of the export process.
Treatment facilities must maintain a		infolghout the process and have a good understanding of the export process.
documented and auditable system of		
procedures that include the following		The SOP provided by the facility covers all aspects of receipt through to
aspects:		loading of the consignment. Additional checks of sea and air freight containers
idad a 🔺 umin u addesin		occur under strict security in the post-treatment area of the facility. Air and 40ft
Produce receipt;		sea containers are inspected within the facility by both the MARD and
• Identification of produce;		Vietnamese customs as they are at the irradiation facility.
 Segregation of treated and untreated 		

Requirement/Criteria:	Complies	Comments/Corrective Actions
produce;Quarantine security for treated produce;Supervision of produce during loading for despatch.	~	
Staff	~	
Company staff conducting treatments must hold appropriate qualifications reflecting government requirements of the country in which the facility is located.	√	Training records and certificates of training for 7 staff were sighted and were appropriate for the tasks that specific staff undertake. Vietnamese science technology department approved the facility and the trained personnel.
System of training and approval for staff must be in place with records available on request.		Staff showed evidence of completion of external training courses. The manager develops an annual re-training plan and records the specific training each employee receives as relevant to their job description. The training system is described in more detail on p46-47 of the SOP.
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes and their responsibilities.	√ °	The QC staff and operational staff spoken to were able to effectively demonstrate the requirements for correct handling and phytosanitary inspection of produce for processing. <i>Display charts were not available at key areas in the</i> <i>pre-treatment area for weighing and inspection of produce for mangoes to New</i>
Dosimetry		Zealand and it is recommended that tote loading configurations were available in the loading area.
Capable of recording/measuring the entire range of dosages likely to be received by the product (Dmin & Dmax)	~	Dosimetry records were provided in advance of MPI's visit. Measures of Dmin and Dmax were clearly in the dose range required by MPI and the facility has been operating these for the export of dragon fruit and rambutan to the USA.
Calibrated in accordance with international standards or appropriate national standards (ISO/ASTM 51261 "Selection and Calibration of Dosimetry Systems for Radiation Processing", ISO/ASTM 51204		The facility SOP documents the calibration of the dosimetry equipment. The methodology conforms with ASTM Standard E 2303-03 "Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities".

Requirement/Criteria:	Complies	Comments/Corrective Actions
"Dosimetry in Gamma Irradiation Facilities for Food Processing" and ASTM guide - F1355 "Irradiation of Fresh Fruits as a Phytosanitary Treatment", and ISPM 18) Appropriate for the treatment conditions (ie temperature etc in the treatment chamber)	✓ ✓	These aspects have been previously assessed by the USDA to gain approval. Alanine pellet or film standards irradiated at the National Institute of standards and Technology, Gaithersburg, MD are used.
Evaluated for stability against the effects of variables such as light, temperature, humidity, storage time, and the type and timing of analyses required	~	Specific load configurations have been provided to MPI and align with dose mapping. Contingencies are in place if an incomplete load is irradiated, involving totes loaded with dummy material with the same density as the target material. However, partial
Consider variations due to density and composition of the material treated, shape and size, orientation of the product, stacking, volume and packaging		loads are not normal protocol and procedures are in place to provide dose maps for changes to configurations. Dose mapping for two varieties of mango was provided to MPI in advance of the visit and is filed in ECMS:
Dose mapping of the product in each geometric packing configuration, arrangement and product density used during routine treatments must be carried out prior to the approval of the facility. Only approved configurations are used for actual treatments.	~	Dose Mapping for CATCHU Mango.pdf <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380977f71</u> Dose Mapping for HOALOC Mango.pdf <u>http://fcs.maf.govt.nz/webtop/drl/objectId/090101b380977f73</u> <u>Since the visit dose mapping information has been provided for the Kensington variety</u> of mango.
	~	The facility SOP and observation of the set up for irradiation of a mixed consignment of rambutans and dragonfruit for the USA showed that the required number, location and frequency of dosimetry measurements were relevant to the system.
All components of the dosimetry system are		It was recommended that the approved configurations for mangoes for export to New Zealand were displayed in the tote loading area to ensure that correct

Requirement/Criteria:	Complies	Comments/Corrective Actions
calibrated according to documented standard operating procedures. An independent organisation recognized by MPI should	~	<i>configurations were loaded.</i> At present these were displayed in the packhouse with weight ranges for packaging.
A system in place to ensure that accurate measurement of absorbed dose in a consignment is carried out. The required	¥	Records of dosimetric measures were sighted and competency in measurement practices for the facility staff were confirmed by the USDA. The dosimetry system was calibrated using the documented SOP approved by the USDA.
number, location and frequency of these measurements are prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.	~	The calculation and verification of dosimetric measurement is documented in the facility SOP. The facility uses alanine pellets of film standards which are read on a Bruker Electron paramagnetic resonance spectrometer instrument. The SOP outlines the appropriate procedure for operation of the equipment and references international standards and certified laboratories.
Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry.	~	
Dose Mapping	~	As above.
Dose mapping is completed and documented for each treatment configuration and available on request.	~	
Dose mapping is used to select the most appropriate location for dosimeters during the treatment of produce.	¥	Dose mapping documents were provided in advance of the visit for the two varieties of mangoes intended for export. MPI received further dose mapping
All aspects of the dosimetry systems are appropriate for the treatment conditions, i.e.	~	results for the Kensington variety of mangoes on 8/5/13. Load configurations and dosimeter locations are available for operational staff, however the

Requirement/Criteria:	Complies	Comments/Corrective Actions
temperature, light, humidity, storage time and type of treatment.	~	appropriate location for these was discussed with the
All components of the dosimetry systems are calibrated according to documented operating procedures.	NA	These were appropriate as per discussions with the USDA preclearance inspector trained in irradiation technology.
Calibration of dosimetry systems are calibrated in accordance with the relevant international standards.		
Dose mapping is carried out in accordance with documented (proven) standard operating procedures. The information from the dose mapping studies is documented and		As per the SOP and configurations provided to MPI in advance of the visit.
used in the selection of locations for dosimeters during routine processing.	~	As per the SOP
Dose mapping for incomplete (partially- filled) as well as first and last process loads is undertaken to determine if the absorbed- dose distribution is significantly different from a routine load and to adjust the treatment accordingly.		
treatment accordingly. Dose mapping carried out on "like" density	\checkmark	
product/s if actual commodity not used (approval sought from MPI prior to mapping being undertaken).		
Dose mapping has taken into account the Dmax where specified (Dmax 1 KGy on	~	As per the SOP. Dose mapping is undertaken for deviations to the approved configurations where the same density products can not be substituted in partial loads.

Requirement/Criteria:	Complies	Comments/Corrective Actions
fresh produce).		
Irradiation treatment	~	
Where applicable, inspection for non target pests has been undertaken (usually NPPO responsibility). Need to ensure system in place that only product that has been inspected and passed is treated.	V	
Inspection is undertaken to ensure suitability for treatment (configuration/density etc).	~	Dose mapping does not exceed 1 KGy. This is also specified in the current OAP (P 5) and is understood.
A documented process control system is in place, providing criteria to assess irradiation efficacy, including standard	~	
operating procedures Proper process procedures are established for each type of commodity or consignment to be treated.	V	The system of pre-treatment inspection was observed for rambutan and dragonfruit to the USA. A separate inspection room was available with lighting for phytosanitary inspection.
Written procedures have been supplied and approved by MPI and are well known to appropriate treatment facility personnel		MARD inspectors check that totes are loaded correctly for the treatment as per the approved load configuration
Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry. System in place to deal with under/over dosed product.	~	As per the SOP, has a robust system in place for assessing Dmin and Dmax for treated consignments.
		At present only mangoes are approved for export to NZ and the procedures

Requirement/Criteria:	Complies	Comments/Corrective Actions
Dosimetry records are kept and made available to the MPI as required.	~	have been developed by with approval from MARD for this commodity.
Specific commodity requirements may be required to be taken into account. Specific (approved) SOP's are in place and followed according to requirements. (additional checksheet maybe required)	~	SOP supplied to MPI in advance of the visit.
enceksneet maybe required)	×	The SOP provides the necessary detail which verifies dosimetric measure and has contingencies for product that deviates from this. Examples of dosimetric measurement records were observed.
Product Security		Dosimetry records are kept for 1 year
Systems must exist to ensure that treated produce is segregated from untreated produce and that no cross-contamination can occur.	~	A specific SOP has been developed for mangoes to NZ.
Following treatment, each treatment lot must be maintained under quarantine security. Quarantine security must be maintained through to the export of the produce.	~	
Where produce is not to be loaded directly after treatment, a system must be provided to and approved by MPI that outlines the procedures to ensure product security post treatment to the point of export.	×	The SOP for the facility ensures that treated and untreated fruit are unable to be mistakenly mixed or cross-contaminated as does the conveyer position for treated and untreated fruit, loading and unloading worksheets and dosimeter checks.
Specific commodity requirements may be		

Requirement/Criteria:	Complies	Comments/Corrective Actions
required to be taken into account. Specific (approved) SOP's are in place and followed according to requirements. (additional checksheet maybe required) Packaging and labelling	~	The post-treatment area is secure and sea and air freight containers are unable to be infested as they are contained and inspected within the facility before and during loading. Consignments are held in the post-treatment area until loading after which they are exported immediately.
Commodity is packaged (if necessary) using materials suitable to the product and process.	~	As above. Packaging type has been approved by the USDA and is suitable for irradiation.
Treated consignments and/or lots are adequately identified or labelled and adequately documented to allow traceback to individual treatment lots		A traceability system is in place and is being used for product exported to NZ. SOP saved in ECMS for all aspects of harvest through to export.
Each consignments and/or lot carries an unique identification number or other code to distinguish it from all other consignments and/or lots		The requirements for mangoes are similar to system for the export of dragonfruit to the USA. These are documented in SOP and were demonstrated for a consignment of dragonfruit and rambutan for export to USA.
Labelling or marking on the package clearly identify that the consignment has been treated with irradiation (radura symbol or similar). Check specific commodity requirements for other labelling/packaging requirements (eg pest proof packaging,	~	The traceability of product was continuous throughout the pre-, treatment and post-treatment system. Product could and was easily traced back to the orchard of origin. Examples were demonstrated for dragonfruit to the US, which is the same system as used for mango to New Zealand.
grower identification etc). Specific commodity requirements may be		Yes, and these were recorded on the accompanying forms. Examples of US dragonfruit were observed.
required to be taken into account. Specific (approved) SOP's are in place and followed		

Requirement/Criteria:	Complies	Comments/Corrective Actions
according to requirements. (additional checksheet maybe required) Record requirements Treatment facilities must maintain records of phytosanitary treatments for a minimum period of 5 years to ensure traceability of	~	Carton vents are covered with insect-proof mesh and each mango is labelled with traceability information. The same was observed for US rambutan and dragonfruit
 treated lots. These records must include: Identification of the treatment facility; The purpose of the treatment; Identification marks on packages; The quantity treated; Target absorbed dose; and Achieved absorbed dose (Dmin and Dmax) 		(including the Radura symbol)
 Phytosanitary certification number (if applicable) Records are to be made available to MPI upon request. 		Most records are relating to treatments are retained by for 1 year which meets the requirements of ISPM 18. Other records such as training are retained into perpetuity. Records were easily retrievable and this was demonstrated for various consignments for export to the USA.
		The quality control department retains one hard copy and one computer record per consignment and has a retrievable system for reporting to MARD PPD as required. Treatment certificates are attached and traceable to the phytosanitary certificate. The system of retrieval allowed requested information to be accessed quickly and staff were obliging.

Appendix 7: Map and VHT Process Flow for

Appendix 8: Review of VH

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Procedure	Complies	Comments/Corrective Action	
FACILITY			
MARD registration and approvalApprovals from other countries?	~	MARD confirmed that the facility was registered and approved by them and is now awaiting approval from Japan and Korea for the export of dragonfruit. Registration and approval included acceptable water testing reports which were provided.	
		It is essential that MPI awaits confirmation of either Japanese or Korean approval. No fruit was being processed during the visit and therefore operational parameters could not be confirmed	
STAFF COMPETENCY			
Treatment operators	1	Four certificates of completion of training for personnel to operate the VHT machine were sighted. Technicians were trained in the Philippines where the VHT equipment was built. The facility also has three registered QC staff. All are university degree qualified.	
HYGIENE	1		
 Hygiene log? Harvested fruit arrives at pack house in cleaned lined crates in clean trucks with traceability info Floors and walls clean Surfaces and equipment cleaned and disinfected 	~	The facility maintains a strict hygiene regime and this was discussed during the site visit. The company as has developed their own internal regulations on labour safety and hygiene. No hygiene log was sighted as the facility was not operational as it is awaiting Japanese and Korean approval. More documentation on this process needed i.e. frequency of cleaning and pest control activities.	
 Pest control activities in and around facility (e.g. vermin and 	~		

Procedure	Complies	Comments/Corrective Action
 fruit fly traps) (frequency of insecticide spraying?) Clean water source and washing water changed regularly Staff hygiene equipment (e.g. coats, hairnets, booties?) 	V	Exclusion structures are in place such as plastic strip curtains, air curtains and electro- insect zappers. See Appendix 7 for other exclusion structures.
VHT UNIT STANDARD		
 VHT unit able to sustain fruit core at 46.5 for 30 minutes Cold spot testing (minimum of nine sensors in treatment chamber?) 	✓ ✓	Temperature mapping, equipment and calibration test results provided Cold spot testing results provided.
TEMPERATURE RECORDING SYSTEM		
 Accuracy of ±0.3°C in 37-52°C range with a resolution of 0.1°C Continuous automatic monitoring 	~	Results sighted showing accuracy range

Procedure	Complies	Comments/Corrective Action
 of time (at least every 5 min if treatment over 2 hours) and temperature for each sensor from ramp up through treatment period. Temp and time correctly loaded into automatic control system + treatment batch #, date and run- time are entered into data acquisition system or printed record. Individual sensors identifiable or records 	~	The thermograph showed that temperature was recorded every 5 minutes. Not sighted as no treatment run was in operation during the visit. However, at other VHT facilities the loading of temperature and time was observed for one treatment run for dragon fruit. These parameters are normally checked by the pre-clearance inspectors from Japan and Korea. The officers sign the beginning of the thermograph record to acknowledge this. <i>It is recommended that MARD undertake the same procedure on behalf of MPI as</i> <i>evidence of supervision of the treatment</i> Thermograph records sighted that confirms this.
EQUIPMENT CALIBRATION A	ND MAINTE	NANCE
 Sensors correctly calibrated 	✓	A copy of a recent sensor calibration record was obtained (4/2/2013). The sensor
		calibration process was described and documentation and records provided.
		Calibration is performed monthly and records of the last three calibrations were sighted.
FRUIT CORE SENSORS	Eic.	
 Numbers and position(s) of fruit sensors correlate with cold spot test 	~	Cold spot testing results were provided.
 Heaviest fruit selected for probing and weighed 		Process described in SOP but not observed

Procedure	Complies	Comments/Corrective Action
 Sensors placed next to seed at point of maximum pulp thickness Sensors sealed into fruit with approved sealant or tape 		
TREATMENT		
Treatment supervised/monitored by NPPO authorized officer?		MPI stipulates that treatment is monitored and currently MARD are supervising treatments in conjunction with pre-clearance officers from other NPPOs for other
Ensures fruit security maintained throughout		facilities. MARD have agreed to undertake additional responsibilities which ensure that
Treatment parameters met		treatment parameters are correctly entered into the VHT machine, checks of probes and position, and verification of the treatment parameters following download of the
Treatment records complete		thermograph record.
Treatment sensor plan		
Non-export bins clearly labelled		
Largest fruit placed at bottom of bins		
Fruit placed stem down		
Bins filled to same level		
• Temp., times, batch, date and run-time are correctly loaded and meet NZ requirements		
 Computer off-set readings correspond with probe 		

Procedure	Complies	Comments/Corrective Action	
assignment and verification tables for the month			
Contingency for treatment failure		Not documented. Recommended that the SOP includes a procedures for rejected consignments and treatment failures	
PRODUCT SECURITY			
Pre- and post-treatment	~	Photos were taken of the security of the facility. This included gated entry, insect strip curtains and air curtains on entry and exit points; screens on all windows; double entry into the post-treatment; electro insect zappers, three separate cool storage areas for product for different destinations and strip curtaining and air curtains in loading area.	
PRODUCT TRACEABILITY			
 Pre-treatment Post-treatment		More documentation on this process needed.	