Summary of MPI expectations for PEQ operating manuals
March 2017

KEY POINTS

- All facility operators are expected to read and understand the PEQ facility standard.
- The operating manual should clearly show MPI that the operator knows and understands the requirements of the PEQ standard.
- The MPI example operating manual does not describe the regulatory requirements for operating a PEQ facility.
- You should not rely on the example operating manual to tell you what to do. The requirement is for you to describe what you will do.

PURPOSE OF THE OPERATING MANUAL

The operating manual should be seen as a reference point for all things regulatory and operational. It should be appropriate for the type of PEQ facility and should describe what is required structurally, what to do, how to do it, how you know it's worked and what you do when something goes wrong.

The operating manual can be seen as both a statutory requirement for approval as a facility, and as a core operational document that describes and demonstrates the following:

- the purpose of the facility including the goals of quarantine;
- the physical and operational aspects of the facility and how it will be technically and financially resourced and maintained;
- the facility management structure and the roles, responsibilities, delegations and expectations of key personnel and any other staff working in the facility and associated with its operations;
- how the operator will ensure that the facility will meet the specific requirements of the PEQ standard; specifically, the policies, procedures and processes that will be employed;
- how those requirements will be measured, monitored and assessed to determine that they remain effective (i.e. internal audit); and
- how the operating manual will be reviewed and updated to ensure it remains current and applicable for its purpose.

The manual is central to the day to day operation of the facility and should be used as a reference document by the operator and other staff for training and operational purposes to ensure ongoing compliance with the standard. In MPI's experience, a common failure of operating manual's is that they are written solely to tell MPI what will be done to meet the regulatory requirements. Although it is important that the manual clearly shows MPI that the operator knows and understands the requirements of the standard, it is also critical that the manual clearly tells facility users what they must do to meet the requirements:

Who needs to know it:	✓	All people who have reason to be involved with the PEQ facility (or plants in the facility).
What they need to know:	✓	Where the manual is stored and how to access it; and What parts of the manual are relevant to their role, and what is required.
What they need to do:	✓	Follow the operating procedures documented in the manual; or If the operating procedures change, or need to be updated, notify the operator so that the manual can be updated and approval obtained from the MPI inspector before any operational changes are implemented.
What needs to be checked:	✓	The operator needs to make sure the operating procedures described in the manual are up to date, are followed, and achieve the requirements of the standard.

THINGS TO THINK ABOUT WHEN PREPARING THE OPERATING MANUAL

The example operating manual is intended to be a guide to operators when they are preparing their own manual. However, it is important that a facility operating manual does not just copy exactly what it says in the example operating manual. Instead, your manual should describe the actual processes and procedures you will use to meet the requirements of the PEQ standard.

Keep in mind that when approving an operating manual, MPI will assess the content of the operating manual against the requirements set out in the PEQ standard. As such, when preparing the manual each facility operator should ask the question 'what does the standard require?'. The operator should then accurately describe all relevant procedures used to meet the particular requirement of the standard. As an example, part 3.10.2 of the facility standard states that the operator must do an internal audit of the facility once every six months, and sets various requirements around this. The main requirements around internal audits (as described in the standard) are summarised as follows:

i) records must be kept;
ii) the operating manual must be updated if improvements are identified;
iii) audit reports must be sent to the MPI inspector within two weeks;
iv) audit procedures must be documented in the operating manual;
v) if non-compliances are identified, these must be dealt with as described in the facility standard.

The operating manual should describe how each of the above requirements will be achieved. For example, to meet requirement (iii), the operating manual needs to state that audit reports will be sent to the MPI inspector for review within two weeks of the audit being completed. This will show to MPI that the operator has read this part of the standard and is aware of this particular requirement. Likewise, the manual should note that records of audits will be retained by the operator (to meet requirement (i), above). Note that these requirements are not sufficiently addressed in the example operating manual.

As well as making sure that all relevant information is included in the manual, the operator should also make sure that procedures that are not relevant or will not be used at the facility are not included in the manual. This is particularly important because failure to do what is set out in the operating manual will be regarded as a non-compliance against the standard. For example, if the operating manual says that the operator will inspect all plants twice per week, this is what the MPI inspector will evaluate when a facility is audited. Failing to inspect plants twice per week would be

seen as a non-compliance, even though (for a level 2 PEQ greenhouse) the standard only requires plants to be inspected once per week.

There is considerable variation in the size and complexity of different PEQ facilities across the country. The example operating manual will not be appropriate for all facilities (e.g. where the operator is responsible for all PEQ-related activities, or where many different people have a role in running the facility). This is why the manual should be seen as an example only, and may need a lot of revision in order to adapt the contents to a particular facility.

WHY IS THE OPERATING MANUAL IMPORTANT?

- To ensure that all biosecurity risk is appropriately managed

Plant material imported for propagation is one of the most high risk pathways for the inadvertent introduction of pests and diseases to new areas. This is why it is important for the manual to clearly describe all steps that will be taken to manage biosecurity risk.

- As part of the operator approval process

A critical part of becoming approved as a PEQ facility operator (under section 40 of the Biosecurity Act) is that the person to be approved should demonstrate they understand and that are able to comply with the operating standards for the facility. If the operating manual does not demonstrate clear knowledge of the requirements of the standard, this will call into question whether the operator can comply with the operating standards.

- For audit purposes

The operating manual describes the steps that will be taken to manage biosecurity risk and ensure compliance with the facility standard. Therefore, when auditing a facility the MPI inspector will assess whether procedures are being done as described in the operating manual. If all activities are being done as described in the manual, this will give MPI confidence that all biosecurity risk is being appropriately managed, and requirements of the standard are being followed. If procedures are not being followed, this may be seen as a major or critical non-compliance against the standard because it indicates that risk is not understood or being managed appropriately. This may have significant repercussions for the ongoing operation of the facility including potential suspension or cancellation of the operator and/or facility approval.