Advice from OGTR on managing certified facilities and licences during COVID-19 restrictions

OGTR acknowledges that we have entered uncertain and challenging times. The health and safety of people and the environment remains our priority. We have received several requests for advice about how organisations can continue to comply with certification guidelines and licence conditions in an environment where key staff are no longer in their physical workplace and common laboratory consumables are in limited supply. We have provided some information below.

IBC functions

If you have concerns regarding IBC functions, you are reminded that:

- IBC meetings do not have to be conducted face-to-face with all participants present in the same room. They can be conducted via videoconferences, teleconferences or email, as long as the participants have the collective technical and scientific expertise, and include at least one independent member.
- You are still required to retain records of assessment, meetings (including those conducted out-of-session) and inspections.

Certified facilities

The OGTR appreciates that there are fewer members of the IBC and support staff present to service facilities.

We encourage you to proactively identify potential issues regarding certified facilities and contact us as soon as possible to discuss them. Please note that while some flexibility regarding time frames may be appropriate, annual facility inspections are considered to be a critical risk-management tool for certified facilities. As such, full exemptions from this requirement are unlikely to be granted.

Please remember that:

- Facility inspections can be conducted by a single person if that person is a 'suitable person' i.e. is experienced or otherwise qualified to assess the facility's compliance with certification conditions.
- You can do things differently, for example, if a key person is in isolation, perhaps they may inspect via a video link.
- If no GM work is currently happening, you can suspend certification until the inspection is carried out.
- You can inspect early whilst staff are available. Another inspection will then not be required for 12 months.

If you have any concerns with the ability to meet certification conditions, please contact OGTR.

Please consider the following options as they may introduce some flexibility at this time of reduced personnel and dwindling resources:

- Prioritise projects and conserve resources to mitigate the risks.
- Limit non-essential work if you anticipate an inability to comply with the relevant guidelines.
- Aggregate GM work to selected facilities and suspend certified facilities where no dealings with GMOs are being conducted. Dealings with non-GMOs may continue in a suspended facility.

Please note that the expiry date of a facility's certification is not changed by a suspension and the facility will expire unless its certification is extended. Once suspended, a facility needs to be inspected by a 'suitable person' prior to lifting the suspension.

To conserve resources whilst maintaining safety, we also encourage a review of work practices and the risks posed by any given situation. The following are some examples.

- Encourage staff to plan their work to reduce the number of times the facility is entered or exited to conserve PPE.
- Revise local practices such as universal use of face masks in animal facilities to a risk-based approach.
- Remind staff that 1 full pump of hand wash is a measured dose and is sufficient to wash up to the wrist.

Shortages of standard decontaminant solutions

Institutions may consider the use of alternative decontaminants. The TGA instructions for disinfectant testing may be helpful and provides guidance on the testing of the effectiveness of decontaminants. Please note that this guidance document uses 'disinfectant' whereas 'decontaminant' is used in guidelines that are issued by the OGTR. AS/NZS 2243.3:2010, Appendix F, is a recommended source of information when selecting and using chemical decontamination agents.

Please be aware that work should not proceed where you cannot provide a decontaminant that is effective against the GMO being used in the lab.

Inability to test/calibrate decontamination or containment equipment

The PC Guidelines stipulate annual maintenance on a set of equipment to ensure it is functioning effectively. If this annual maintenance cannot be achieved, a risk assessment should be conducted and a risk management strategy sent to the OGTR as part of a Certification Variation request. The risk management strategy could include considerations of alternative validation measures such as including spore tests in autoclave runs and storing the waste until it has been demonstrated that the kill was effective, or build in a safety margin by increasing time or temperature in autoclave runs.

Licence conditions

The OGTR appreciates that important work is being conducted under licences and that licence holders wish to continue this work. Licence conditions must be complied with even in these difficult times.

General principles for licences:

- Your priority is to ensure that GMOs or viable GM material are not dispersed and that the work is being conducted safely.
- Consider alternative approaches to your standard work practices that still ensure that you meet licence conditions.
- You may wish to update your contingency plans and SOPs to ensure that licence conditions will continue to be met and risks are managed under a variety of circumstances. These include:
    - effectiveness of current containment requirements
    - impact of reduced workforce availability
    - impact of restrictions on travel/transport of GMOs
    - impact of travel restrictions on conducting inspections
    - complying with reporting obligations.

- Consider stopping or limiting non-essential work.
- Reconsider initiating new work.

Plant DIR licences

The following general suggestions may help your considerations:

- Prepare and update a risk assessment to prioritise sites for inspection (e.g. sites with known or advanced volunteers should have priority over sites with no previous reports of volunteers).
- As part of the assessment, consider that we are currently heading into the cooler months when growth of volunteers such as cotton, is likely to slow down.
- Consider if other people (e.g. farmers) might be trained to inspect the sites on their property.
- Consider other methods for ensuring the GMOs remain contained.
- Consider if current sites might be sprayed out prior to setting seed. This strategy is likely to reduce the number of volunteers.
- Consider destroying part or all of the crop.
- Continue to keep the OGTR updated if disruption to the inspection schedule, or delayed control of volunteers, harvest or cleaning are expected to occur.

Clinical trial licences

OGTR has contacted clinical trial licence holders individually to collect information about any issues they are facing.

General guidance on clinical trials has been issued that reflects the views of state and territory Departments of Health, TGA, NHMRC and the Clinical Trials Project Reference Group.

Whilst we appreciate that some participants do not wish to attend hospital, administration of GMOs to a patient or collection of samples containing GMOs should continue to be conducted in an authorised facility. Licence variations to include these activities in a person's home are unlikely to be approved.

If you have any concerns with your capacity to comply with licence conditions, please contact OGTR as soon as possible, so that we can process these issues on a case-by-case basis.

The OGTR's priority remains the protection of the health and safety of people and the environment. We strongly encourage our stakeholders to acknowledge the risks that will arise with reduced staffing, lack of decontamination options and reduced supplies of PPE. With these risks in mind, IBCs should conduct a realistic appraisal of their ability to continue conducting 'business as usual'. IBCs are reminded that facilities must retain the capacity to conduct dealings safely and to execute a risk management plan in the face of dwindling resources and limited personnel.

Please continue to be proactive in protection of human health and the environment.