



Australian Government

Department of Health
Office of the Gene Technology Regulator

**PRACTICE NOTE:
UNANNOUNCED SPOT CHECKS**

**In accordance with the
*Gene Technology Act 2000***

February 2015

Monitoring activities are under continual improvement and will evolve as systems are assessed and validated. This document is intended as a guide only. Readers of this document should also familiarise themselves with the gene technology legislation.

1. Policy

Each year, the OGTR routinely conducts monitoring inspections to ensure that Licence and Certification holders are complying with the *Gene Technology Act 2000* (the Act) and its subordinate legislation. The OGTR will inspect both current field trial and past genetically modified organism (GMO) trial sites that are still subject to post harvest monitoring. The OGTR also inspects certified Physical Containment (PC) facilities and dealings conducted in those facilities including; Dealings Not involving Intentional Release (DNIRs) and Notified Low Risk Dealings (NRLDs).

The majority of these monitoring visits are conducted with prior notification given to the Licence or Certification holder. A number of unannounced 'spot' checks will be conducted throughout the year to ensure that compliance is maintained at all times and not just when organisations are informed of an impending OGTR visit.

The 'spot' checks will be conducted randomly to ensure coverage of a range of dealings, locations and organisations. 'Spot' checks may also be conducted as follow-up action from an announced monitoring inspect or as a component of an audit or investigation.

2. Legislation

The 'spot' checks are conducted under the auspices of Section 152 of the Act, which provides powers to inspectors for monitoring compliance with the Act.

For the purpose of determining whether the Act has been complied with, Inspectors may:

- Enter any premises; and
- Exercise the monitoring powers set out in Section 153.

An inspector is authorised to enter the premises if, amongst other reasons, the occupier of the premises is a licence holder, or a person covered by a licence and the entry is at a reasonable time.

The monitoring powers set out under Section 153 includes the powers to:

- Search the premises and any thing on the premises;
- Inspect, examine, take measurements of, conduct tests on, or take samples of, any thing on the premises that relates to a GMO; and
- Take photographs, make video or audio recording or make sketches of the premises or any thing on the premises.

Under the Act it is a condition of all licences that an OGTR authorised person be allowed to enter premises for auditing or monitoring purposes (section 64).

3. Inspection Procedure

All 'spot' checks will be conducted at a 'reasonable' time. The actual timing of the monitoring visit will be determined according to the type of business being inspected.

Upon arriving at the premises the OGTR inspectors will contact the occupier of the premises and:

- Identify themselves (OGTR inspectors are issued with identity cards, carry them at all times and must produce them when requested);
- Explain the reason for the inspection;

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- Confirm that the occupier has been informed of their obligations to the OGTR by the Licence holder;
 - Seek consent to enter the inspection site;
 - Answer any questions regarding the inspection process; and
 - Invite the occupier of the premises to accompany them on the inspection.

OGTR inspectors will make all reasonable attempts to contact the occupier of the premises and or the Licence holder when first arriving at the premises and before conducting the visit.

In the event that contact cannot be made then, OGTR inspectors will consider all circumstances known to them at the time, including, if known:

- The priority given to the inspection;
- Risk to public health and/or the environment;
- History of the site/organisation (including frequency/severity of any previous non compliances); and
- For field trials conducted under DIRs issues of farm hygiene and personal safety.

4. Farm Hygiene

The OGTR inspectors are aware of farm hygiene issues and will undertake all practicable steps to ensure that their routine inspection activities do not increase the risk of transfer of disease, bacteria, pollen or weed seeds around and between properties.

5. Reporting on the monitoring visits and implementing any necessary action

The OGTR will inform the Licence holder of the ‘spot’ inspection and the findings of the inspection in writing as soon as practicable after the inspection is completed.

Where non-compliance with specific licence conditions is identified a risk assessment and compliance assessment will be conducted. This report will assess any risks to human health and safety or the environment presented by the non-compliance and determine what remedial action, if any, is required. The report will also determine what if any compliance action is required. The report may also recommend that investigation action be considered.

A separate report summarising the findings will be provided to the licence holder conducting the GMO dealing for comment on matters of fact.

The findings of all monitoring visits will be included in the Regulator’s Quarterly Reports.