# Department of Primary Industries and Regional Development



# Audit guidance for low-THC hemp

September 2024

#### Introduction

The audit program for Low-THC Hemp allows the Department of Primary Industries and Regional Development (Department) to verify that licensees are complying with the *Hemp Industry Act 2008* (Act) and *Hemp Industry Regulation 2016* (Regulation). The audit and compliance program also assures the industry that a robust system is in place to maintain the integrity of the industry, which is consistently applied, and is risk based.

The aim of this document is to provide both Department officers and licensees with a consistent information and understanding of the audit process. This guidance document can also be used by licensees to understand why defects are identified during audits, and the severity of potential defects.

# Cultivation of low-THC hemp

All low-THC hemp licence holders are audited against the Act and Regulation and the Hemp Industry New South Wales Licence Manual.

#### What is in the audit?

An audit is a process where an authorised auditor visits a facility or cultivation site to assess compliance. During the audit the auditor carries out an inspection of the facility/site and reviews documentation (including the licence register and records).

During a licensing or compliance audit, the authorised officer will check that the licensee is:

- Conducting activities permitted on the certificate of licence
- Adhering to the licence conditions and legislative requirements
- Managing the security of the cultivation or processing site
- Accurately and correctly completing the Hemp Licence Register
- Maintaining current and accurate records of employee's details

If the auditor does not have confidence that licence conditions are being met, they will record an unacceptable audit outcome and implement appropriate compliance action, supported by evidence available at the time of the audit.

## Hemp Licence Register

The Hemp Licence Register must be used by all licensees to record the following types of activities:

- Selling and buying of seed or plants
- Movements of all plants and seed on and off the property
- Cultivation activities

- Destruction of all seed and plants
- Identification of any unauthorised activity
- Test results
- Identification of personnel
- other activities related to ensuring the licence conditions and regulations are being managed

# Corrective Action Requests

The auditor has a list of areas that must be checked. If an area is not compliant, the auditor will raise a Corrective Action Request (CAR). A Corrective Action Request identifies the non-compliance, and generally allows the licensee a period of time to take action to address the issue. The Corrective Action Requests (CARs) identified during audits are rated as Minor, Major or Critical, depending on their severity. Each CAR attracts a numerical value, the total of which determines the audit outcome.

Table 1. Corrective Action Request (CAR) Scoring.

CAR category	Numeral value
Minor	2
Major	8
Critical	64

#### Minor CAR

A minor CAR is a non-conformance, which threatens neither the effectiveness nor the assurance provided by the audit program. Minor non-conformances are generally administrative or technical in nature and are low risk to the effective operation of the system.

#### Maior CAR

A major CAR is a non-conformance where there is a significant breakdown in the implementation or documentation of controls, which threatens the effective operation of systems.

## **Critical CAR**

A critical CAR is a non-conformance which, in the opinion of the authorising officer, seriously threatens the effectiveness of the low-THC hemp arrangement and has, or will, mean regulated articles do not comply with the legislation.

The table below is a guideline for audits, based on existing knowledge and data, and are typically the main areas of risk to be aware of. It should be noted however that these are guidelines only and intended to be used in conjunction with other available resources and the professional judgement and knowledge of the auditor.

Table 2. Non-conformance categorisation guidelines.

Category	Minor	Major	Critical
Licence conditions			
Permitted activities			The licensee is conducting activities not permitted under their licenses
Location of cultivation area			Cultivation area was not approved by the Department
Guarantee of low-THC seed		No documentation to show seed used has a concentration of THC less than .05%	Seed used has a concentration of THC greater than .05%
Record of employees	1-2 employees are missing from employee lists	2 + employees are missing from the employee list, OR Details of employees are missing: Name Address Proof of I.D	Identification of employees was not available at time of audit
Security of cultivation site		Ineffective security precautions in place to ensure activities remain under licensees control	No security precautions in place to ensure activities remain under licensees control
Hemp leaving property			Hemp was not substantially stripped of leaf before leaving property on which it was cultivated (not applicable to Research License).

Category	Minor	Major	Critical
Annual report	Annual report was received before the 1st of August	Annual report details incomplete	No annual report has been submitted
Planting notifications (PN)		PN was submitted greater than 7 days after planting	PN was not submitted
Visitor register	Visitor register not current	Visitor register incomplete	Visitor register not available at time of audit
Licence register	Licence Register not current to within 2 working days Entries illegible, incomplete or only partially filled in	Licensee register not current within 5 working days or missing significant entries	Licence Register not available at time of audit
Seeds			
Purchasing of seed	1-2 of the following details are missing from the register: Name of person/ company seed were purchased from Date seed was purchased Variety of seed Weight of seed	More than 2 of the following details are missing from the register: Name of person /company seed were purchased from Date seed was purchased Variety of seed Weight of seed	No supplier information for seeds available at time of audit
Sowing of seed	1-2 of the following details are missing from the register: Location seed was sown Date seed was sown Variety of seed sown Weight of seed sown	More than 2 of the following details are missing from the register: Location seed was sown Date seed was sown Variety of seed sown Weight of seed sown	No seed sowing information available at time of audit
Selling of seed	1-2 of the following details are missing from the register: Name and contact details of person / company seed was sold to Date seed was sold Variety of seed Weight of seed	More than 2 of the following details are missing from the register: Name and contact details of person /company seed was sold to Date seed was sold Variety of seed Weight of seed	No purchaser information for seeds available at time of audit

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Category	Minor	Major	Critical
Destruction and disposal of seed	1-2 of the following details are missing from the register: Reasons for disposal or destruction of seed Location of seed disposal or destruction Date seed was destroyed or disposed of Variety of seed Weight of seed	More than 2 of the following details are missing from the register: Reasons for disposal or destruction of seed Location of seed disposal or destruction Date seed was destroyed or disposed of Variety of seed Weight of seed	No destruction/disposal information for seeds available at time of audit
Plants			
Purchasing of plants	1-2 of the following details are missing from the register: Name of person / company plants were purchased from Date plants were purchased Variety of plants Number of plants	More than 2 of the following details are missing from the register: Name of person /company plants were purchased from Date plants were purchased Variety of plants Number of plants	No supplier information for plants available at time of audit
Planting of plants	1-2 of the following details are missing from the register: Location plants were planted Date plants were planted Variety plants were planted Number of plants were planted	More than 2 of the following details are missing from the register: Location plants were planted Date plants were planted Variety plants were planted Number of plants planted	No planting information available at time of audit

Category	Minor	Major	Critical
Selling plants	1-2 of the following details are missing from the register: Name and contact details of person / company plants were sold to Date plants were sold Variety of plants Quantity of plants	More than 2 of the following details are missing from the register: Name and contact details of person / company plants were sold to Date plants were sold Variety of plants Quantity of plants	No purchaser information for plants available at time of audit
Destruction and disposal of plants	1-2 of the following details are missing from the register: Reasons for disposal or destruction of plants Location of plant disposal or destruction Date plants were destroyed or disposed of Variety of plants Quantity of plants	More than 2 of the following details are missing from the register: Reasons for disposal or destruction of plants Location of plant disposal or destruction Date plants were destroyed or disposed of Variety of plants Quantity of plants	No destruction/disposal information for plants available at time of audit
Harvesting			
	1-2 of the following details are missing from the register: Date of harvest Number of plants/area (e.g. Ha) harvested Variety of plants harvested Weight of any seeds obtained from harvested plants and the variety Location of the harvesting		Harvesting records were not available at the time of audit

Category	Minor	Major	Critical
Laboratory testing			
			THC laboratory tests were not available at the time of audit THC laboratory tests exceeding 1% THC were not reported to the Department
Previous actions			
	Licensee has failed to rectify defects identified through self-monitoring.	Licensee has failed to rectify minor CAR's issued at previous audit	Licensee has failed to rectify major or critical CARs issued at previous audits. If licensee has not closed out a major or critical CAR, the Department will take enforcement action

# **CAR Escalation Policy**

A failure of a licensed business to rectify any CAR or defect identified during an audit by the required timeframe will result in the re-issuing of the original CAR. In addition, a further CAR or defect is to be considered as the business has failed to implement effective corrective actions to rectify the original issue.

#### How is the audit outcome determined?

At the conclusion of the audit, the allocated points are added to give a total rating of ACCEPTABLE or UNACCEPTABLE.

Table 3. Audit score outcome.

Audit Rating	Total number allocated points	Audit results
ACCEPTABLE	0 - 64	ACCEPTABLE
UNACCEPTABLE	64 and above	UNACCEPTABLE

# Unacceptable audit result

In the event an audit results in an unacceptable outcome one or more enforcement actions may occur:

- remedial action may be required
- immediate corrective action may be required with specific timeframes for compliance
- conditions may be imposed that restrict or prohibit certain activities by the licensee or permit holder
- the licence may be suspended, cancelled or not renewed or not granted
- individuals or companies may receive penalty notices or be prosecuted
- Follow up audit or inspection

#### Acceptable Audit Frequency

If an audit outcome is acceptable the next audit will be carried out in accordance with the Compliance Calendar.

#### **Unannounced Audits**

Routine audits will generally be carried out on an announced basis, however unannounced or unscheduled audits may be carried out. These audits can be in response to complaints, sampling or other matters requiring investigation or to monitor compliance.

#### Communication

The auditor will document the audit, all findings and CARs raised in an audit report. This report will generally be completed while the auditor is on site. They will discuss the findings, any non-conformances identified, and expected timeframes to correct the non-

