



Audit guidance for low-THC hemp

December 2017

Introduction

The audit program for Low-THC Hemp allows the Department to verify that licensees are complying with the *Hemp Industry Act 2008* and *Hemp Industry Regulations 2016*. 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 biosecurity auditors 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 *Hemp Industry Act 2008*, *Hemp Industry Regulations 2016* and the *Hemp Production in 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

Before the auditor leaves the cultivation site, they will ask themselves the question 'Is the licensee managing the production of low-THC hemp crop in a manner that it will not exceed 1.0% THC or contravening their licence conditions'?

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 7. Corrective Action Request 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.

Major 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 authority, 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 1: 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: <ul style="list-style-type: none"> • Name • Address • Proof of I.D 	Identification of employees was not available at time of audit
Security of cultivation site		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).
Annual Report			
Annual Report	Annual report was received before the 1 st of August	No annual report has been submitted	
Annual Planting Notifications (APN)		APN was submitted greater than 7 days after planting	APN was not submitted
Visitor register	Visitor register not current	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
Purchasing of seed	1-2 of the following details are missing from the register: <ul style="list-style-type: none"> • <i>Name of person/ company seed were purchased from</i> 	More than 2 of the following details are missing from the register: <ul style="list-style-type: none"> • <i>Name of person /company seed were purchased from</i> 	No supplier information for seeds available at time of audit

	<ul style="list-style-type: none"> ● <i>Date seed was purchased</i> ● <i>Variety of seed</i> ● <i>Weight of seed</i> 	<ul style="list-style-type: none"> ● <i>Date seed was purchased</i> ● <i>Variety of seed</i> ● <i>Weight of seed</i> 	
Category	Minor	Major	Critical
Sowing of seed	1-2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Location seed was sown</i> ● <i>Date seed was sown</i> ● <i>Variety of seed sown</i> ● <i>Weight of seed sown</i> 	More than 2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Location seed was sown</i> ● <i>Date seed was sown</i> ● <i>Variety of seed sown</i> ● <i>Weight of seed sown</i> 	No seed sowing information available at time of audit
Selling of seed	1-2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Name and contact details of person / company seed was sold to</i> ● <i>Date seed was sold</i> ● <i>Variety of seed</i> ● <i>Weight of seed</i> 	More than 2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Name and contact details of person / company seed was sold to</i> ● <i>Date seed was sold</i> ● <i>Variety of seed</i> ● <i>Weight of seed</i> 	No purchaser information for seeds available at time of audit
Destruction and disposal of seed	1-2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Reasons for disposal or destruction of seed</i> ● <i>Location of seed disposal or destruction</i> ● <i>Date seed was destroyed or disposed of</i> ● <i>Variety of seed</i> ● <i>Weight of seed</i> 	More than 2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Reasons for disposal or destruction of seed</i> ● <i>Location of seed disposal or destruction</i> ● <i>Date seed was destroyed or disposed of</i> ● <i>Variety of seed</i> ● <i>Weight of seed</i> 	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: <ul style="list-style-type: none"> ● <i>Name of person / company plants were purchased from</i> ● <i>Date plants were purchased</i> ● <i>Variety of plants</i> ● <i>Number of plants</i> 	More than 2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Name of person / company plants were purchased from</i> ● <i>Date plants were purchased</i> ● <i>Variety of plants</i> ● <i>Number of plants</i> 	No supplier information for plants available at time of audit
Planting of plants	1-2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Location plants were planted</i> ● <i>Date plants were planted</i> ● <i>Variety plants were planted</i> ● <i>Number of plants were planted</i> 	More than 2 of the following details are missing from the register: <ul style="list-style-type: none"> ● <i>Location plants were planted</i> ● <i>Date plants were planted</i> ● <i>Variety plants were planted</i> ● <i>Number of plants planted</i> 	No planting information available at time of audit

Category	Minor	Major	Critical
Selling plants	<p>1-2 of the following details are missing from the register:</p> <ul style="list-style-type: none"> • <i>Name and contact details of person / company plants were sold to</i> • <i>Date plants were sold</i> • <i>Variety of plants</i> • <i>Quantity of plants</i> 	<p>More than 2 of the following details are missing from the register:</p> <ul style="list-style-type: none"> • <i>Name and contact details of person / company plants were sold to</i> • <i>Date plants were sold</i> • <i>Variety of plants</i> • <i>Quantity of plants</i> 	No purchaser information for plants available at time of audit
Destruction and disposal of plants	<p>1-2 of the following details are missing from the register:</p> <ul style="list-style-type: none"> • <i>Reasons for disposal or destruction of plants</i> • <i>Location of plant disposal or destruction</i> • <i>Date plants were destroyed or disposed of</i> • <i>Variety of plants</i> • <i>Quantity of plants</i> 	<p>More than 2 of the following details are missing from the register:</p> <ul style="list-style-type: none"> • <i>Reasons for disposal or destruction of plants</i> • <i>Location of plant disposal or destruction</i> • <i>Date plants were destroyed or disposed of</i> • <i>Variety of plants</i> • <i>Quantity of plants</i> 	No destruction/disposal information for plants available at time of audit

Harvesting

	<p>1-2 of the following details are missing from the register:</p> <ul style="list-style-type: none"> • <i>Date of harvest</i> • <i>Number of plants/area (e.g. Ha) harvested</i> • <i>Variety of plants harvested</i> • <i>Weight of any seeds obtained from harvested plants and the variety</i> • <i>Location of the harvesting</i> 	<p>More than 2 of the following details are missing from the register:</p> <ul style="list-style-type: none"> • <i>Date of harvest</i> • <i>Number of plants/Area (e.g. Ha) harvested</i> • <i>Variety of plants harvested</i> • <i>Weight of any seeds obtained from harvested plants and the variety</i> • <i>Location of the harvesting</i> 	Harvesting records were not available at the time of audit
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Laboratory testing

			<p>THC laboratory tests were not available at the time of audit</p> <p>THC laboratory tests exceeding 1% THC were not reported to the Department</p>
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Previous Actions

	Licensee has failed to rectify defects identified through self-monitoring.	Licensee has failed to rectify minor CAR's issued at previous audit	<p>Licensee has failed to rectify major or critical CARs issued at previous audits.</p> <p><i>If licensee has not closed out a major or critical CAR, the Department will take</i></p>
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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 (shown in Table 5).

Table 5. 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

Table 6. Unacceptable audit frequency

Rating	Maximum period for follow up audit (s)	Unacceptable follow up audit	Acceptable follow up audit
UNACCEPTABLE	1 month	Remain on 1 monthly audits and additional enforcement action	Return to original audit schedule

Acceptable Audit Frequency

If an audit outcome is acceptable the next audit will be carried out in 12 months.

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-conformances. The audit report will be sent to you, either as hard copy or electronically. If you have any questions regarding the findings contained in the audit report, it is recommended you contact the auditor to discuss, prior to the next audit.

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