Health Service Establishments Compliance Audits

Advisory Notice 08 November 2022

The Department of Health (the Department) is the licensing and regulatory authority for all private sector health service establishments in Tasmania under the *Health Service Establishments Act 2006* (the Act) and the *Health Service Establishments Regulations 2021* (the Regulations).

To ensure that services are being provided in accordance with the Act, the Regulations, and the conditions specified in individual licenses, the Regulation, Licensing and Accreditation Unit (RLA Unit) conduct Compliance Audits throughout the calendar year.

Regulatory compliance auditing

Throughout the calendar year, the RLA Unit conduct regular compliance audits to monitor compliance with the Act.

The object of the Act is to ensure the quality and safety of services provided at a Health Service Establishment (HSE) by specifying the standards to be met by the HSE and ensuring that services are provided in accordance with clinical practice guidelines.

Auditing is also a powerful quality improvement tool. It allows HSEs to better understand their responsibilities under the Act, which in turn aids compliance and identifies opportunities for improvement.

Audit topics cover all aspects of the Act and relevant sections of the Regulations. Audits are normally completed in accordance with a three-year audit schedule, however not all elements of the Act and Regulations are assessed at once.

Whilst audit topics are planned over a three-year schedule, additional audits may be scheduled when a need is identified (for example there is a cluster of unexpected critical incidents or deaths within a specialised service). This can mean a more frequent audit schedule.

Requirements under the Act

Section 54 of the Act requires a person who conducts a HSE to provide any information that is required for the purposes of the Act, to ensure:

1. the quality and safety of services provided at the HSEs by specifying the standards to be met by those HSEs; and
2. that services are provided to effectively meet the needs of Tasmanians in accordance with clinical practice guidelines as to the provision of services and standards observed in Tasmania and elsewhere in Australia.

Under Section 46 of the Act, the Secretary can give the power to a person to enter and inspect any establishment licensed under the Act or applying for a licence.

HSEs licensed under the Act are required to comply with the provisions in both the Act and Regulations.

It is an offence to fail to provide to the Secretary the information requested under section 54 of the Act. In addition, a person must not wilfully hinder, obstruct, or delay any person in the performance of any function under section 48 of the Act. Penalties may be applied.

Audit Process

Audits can be conducted in several ways:

- Desk top audit, with information provided in hard copy to inform the topic being audited.
- On site audit. This can be announced or unannounced.
- Telephone / video conference audit. This can be announced or unannounced.
- Any combination of the above.

Licensee responsibilities

It is the responsibility of the Licensee to ensure ongoing compliance with the Act. This requires systems, processes and monitoring that supports continuous safety and quality improvements.

The Licensee must ensure that:

1. all requests for information are provided by the specified due date. If an extension to the timeframe is required, this must be emailed to hselicensing@health.tas.gov.au, with the reason why an extension is requested. The request will be considered, and a response provided by the RLA Unit within 48 hours.
2. during telephone, video or onsite audits staff participating in the audit must have the knowledge and experience to provide the auditors with relevant information.
3. Action Plans are put in place to address any 'not met' requirements within 60 business days.

Medical Advisory Committee (MAC)

The Medical Advisory Committee (MAC) is an important governance body required under the Act and Regulations to ensure clinical standards in safety and quality are met by licensed HSEs.

The MAC plays an important role in ensuring the licensee complies with the MAC's advice. The MAC is responsible for, as soon as is reasonably practicable, reporting to the Secretary any repeated failure by the Licensee of the HSE to act on the advice given under Schedule 1, Part 2 of Regulation 4(3) if the failure is likely to adversely impact on the health or safety of patients and/or staff.

Significant risks and non-compliance reports will be sent to the MAC for monitoring, and to ensure clinical standards for safety and quality are met by HSEs.

Audit Outcomes

HSEs are assessed against compliance to the Act, Regulations, applicable Guiding Principles, College Guidelines, relevant actions with applicable National Standards, and specific conditions for their licence.

The following ratings are used in the assessment:

Rating	Description
Met	All requirements are fully met
Not Met	Part, or all, of the requirements have not been met.
Not Applicable	The requirement is not relevant in the service context being assessed.

Throughout the audit, the RLA Unit may also identify quality improvement opportunities which are outside the scope of the current audit. These will be identified as **Recommendations**. These will not affect the result of the audit.

Preliminary Report:

Within ten business days of the audit completion, the **Preliminary Report** will be provided to the HSE Licensee, Director of Nursing and MAC Chair.

The Licensee has five business days to respond to the Preliminary Report concerning any omissions or incorrect facts. Supporting evidence must be provided.

The RLA Unit will consider any response from the Licensee concerning the Preliminary Report.

Final Report or Interim Report:

Within 20 business days of the audit completion, the RLA Unit will either:

- issue a **Final Report** if all requirements are 'met'. This will be provided to the Licensee, Director of Nursing, MAC Chair and the Department of Health's Chief Medical Officer / Deputy Secretary – Clinical Quality, Regulation and Accreditation, or
- issue an **Interim Report** if any requirements are 'not met'. For any requirements assessed as 'not met' the HSE has 60 business days from receipt of the Interim Report to submit evidence to demonstrate compliance to the requirement. The Final Report will then be issued within 20 business days. This will be provided to the Licensee, Director of Nursing, MAC Chair and the Department of Health's Chief Medical Officer / Deputy Secretary – Clinical Quality, Regulation and Accreditation.

Please see Appendix 1 - Audit Process Flowchart.

If information is not provided by the requested due date, the specific element of the audit that the information relates to will be noted as 'not met'.

Significant risk

If a significant risk is identified during the audit, the RLA Unit will notify in writing the Licensee, the Director of Nursing, the MAC Chair, and the Department of Health's Chief Medical Officer / Deputy Secretary – Clinical Quality, Regulation and Accreditation.

The HSE has 48 hours from receipt of the notification to provide an Action Plan to address the significant risk, with details of immediate corrective actions.

If the Action Plan does not address the issue, the Secretary may give notice to cancel the licence or cancel an element of the licence[1], such as a specialised service or class.

The RLA Unit have adopted the same definition of significant risk as per the Australian Commission on Safety and Quality in Health Care (the Commission):

> *Risk is one where there is a high probability of a substantial and demonstrable adverse impact for patients if the practice is to continue. In each case, a significant risk will be sufficiently serious to warrant an immediate response to reduce the risks to patients. This may include interventions or changes to systems, the clinical care service environment, or clinical practice. While the focus of reporting by assessors will be on significant risks of patient harm, it will not necessarily exclude other significant risks.*[2]

---

[1] *Health Service Establishments Act 2006,* cl 30

[2] NSQHS Standards Advisory AS18/09 Notification of significant risk

Not Met requirements

The licensee must submit an Action Plan to address all 'not met' requirements to the RLA Unit within five business days of receiving the Interim Report in the approved format. Please use the *Corrective and Preventative Action Plan (CAPA)Template,* which can be found at the following location:

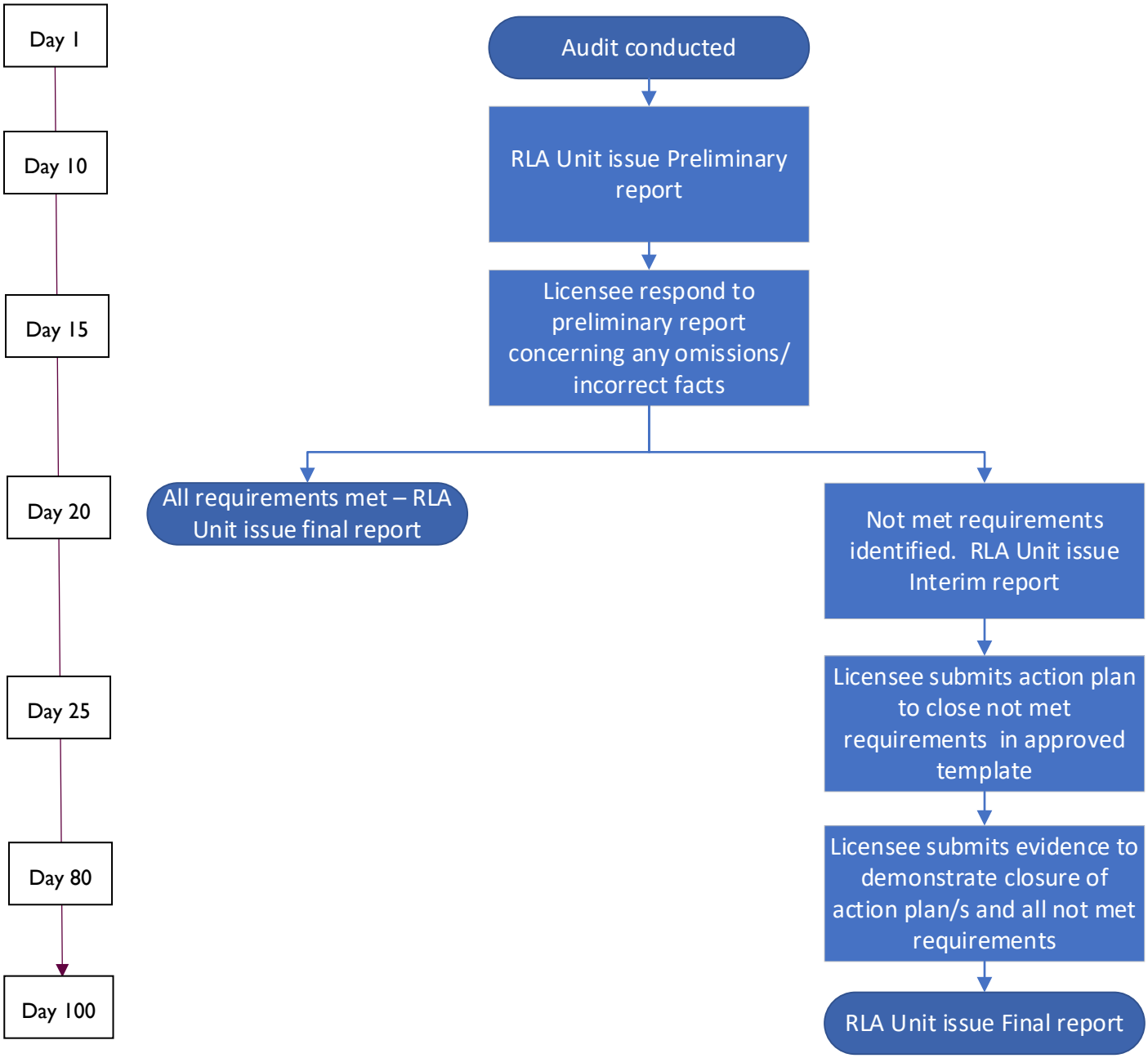
Once the Final Report is issued, if any of the requirements are 'not met', the Secretary may give notice to cancel the licence (or cancel an element of the licence)[3] or apply additional conditions on the HSE's licence.

Questions and further information

For all questions or further information concerning audits, please contact 03 6166 3856 or hselicensing@health.tas.gov.au

[3] *Health Service Establishments Act 2006,* cl 30

Appendix 1- Audit Process Flowchart



A text only version of this flowchart is also available and can be found here: https://www.health.tas.gov.au/publications/advisory-notice-82022-health-service-establishments-compliance-audits-november-2022

Regulation, Licensing and Accreditation Unit
GPO Box 125, HOBART Tasmania 7001
Phone: 03 6166 3856
Email: hselicensing@health.tas.gov.au
Visit: https://www.health.tas.gov.au/about/private-health-regulation-unit

Tasmanian Government