Presentation 4

UDI and patient safety from traceability to safer care

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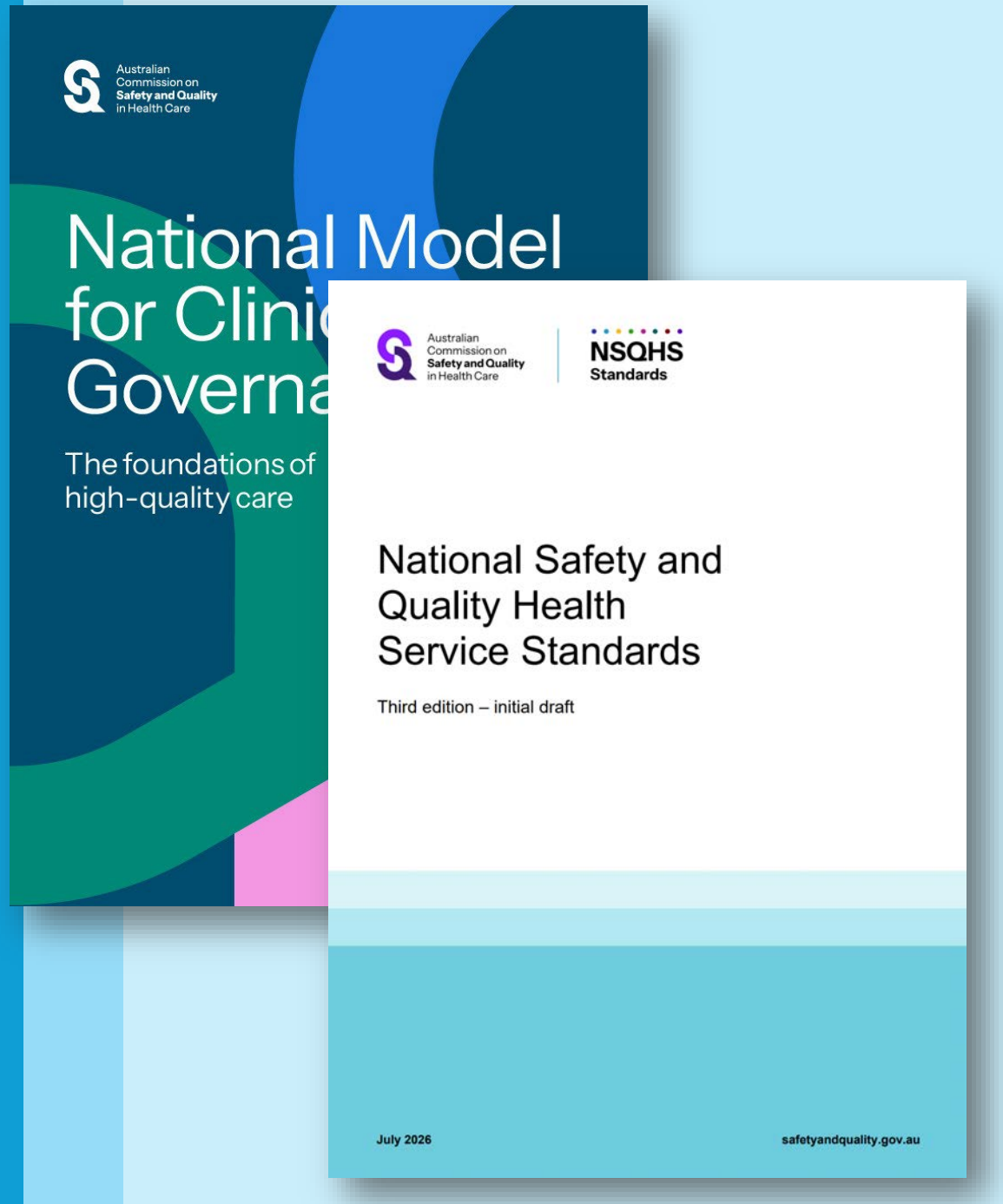
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Australian Commission on **Safety and Quality** in Health Care

UDI and patient safety:
from traceability to safer care

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Organisational culture, systems and structures – the six foundations of clinical governance



What is different this time

The third edition is built on the National Model for Clinical Governance

FROM	TOWARDS
Minimum safety requirements	**High-functioning learning organisations**
Specifying clinical processes	**Prioritising how patients experience care and measuring outcomes**
Complying with accreditation requirements	**Building the culture of the whole organisation**

The aim is high-quality care every day, not evidence gathered before an assessment.

Overview of the standards



Where UDI landed

Standard 3, Safe Clinical Systems, Medical devices

3.18 Purpose

Device traceability
improves patient safety, recall effectiveness and quality improvement.

Related requirements

3.16
Safe, compliant and reliable medical devices are provided

3.17
Medical devices are used as intended

3.21
Medical device incidents are reported

What 3.18 asks of a health service organisation

a

Receive

Capture the device and its location in the service.

Serves entry into the service via procurement and supply

b

Use

Capture the UDI in the healthcare record at the point of use or implantation.

Serves the patient and the next clinician

c

Report

Capture the UDI in the incident management system and report to the TGA for an adverse event.

Serves the regulator and the manufacturer

d

Act

Safety alerts and recalls, post-market surveillance, quality improvement, and clinical registries*.

Serves ongoing quality improvement

If assessment was tomorrow, what evidence would you (or could you) show the assessors?

* *"Recording the unique details about medical devices (i.e. UDIs) to more easily and quickly identify device revisions".*

Australian Framework for National Clinical Quality Registries 2024, page 33

What this means in everyday practice

For the clinician

The device in front of you is identified once, correctly, and stays identified.

No second system.
No transcribing numbers by hand.
No sticker in a paper record.

For the patient

What is inside me, and is it safe?

The UDI is the ‘what’.
The requirements in 3.18 are the ‘how’.

Accreditation is the quality assurance mechanism

Why you do it

To find the right patients quickly when something goes wrong.

What assessment does

Checks that the system works before you need it.

The intention of the NSQHS Standards is to embed systems, processes, and outcome measurement as **business as usual** – with accreditation serving as periodic, external review.

Testing the UDI requirement

3.18 captures the UDI to:

- Inform the regulator
- Embed in clinical quality registries
- Drive quality improvement

Opportunities to extend UDI to:

- the patient
- the next care provider (‘transitions of care’)
- digital health systems

The UDI stays inside the system that captured it. Should it go somewhere else, or how else should it be used?

Implementation resources: a wide view

1. **Guidance, educational resources, progress checklists, exemplars/use cases**
   Built with health services to navigate national regulation to local implementation.

2. **Assessor guidance and training**
   Health services are confident that a ‘met’ rating means the same thing, from every accrediting agency.

3. **Advisories**
   Keeping 3.18 current as the UDI landscape evolves over time (from 2030 and beyond).

What implementation resources would help you prepare for applying the NSQHS Standards (3rd ed.) to everyday practice?

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Thank you

Public consultation is open

Provide your feedback on the initial draft of the NSQHS Standards (third edition)

The consultation is open until Friday 25 September 2026.

