Government of Western Australia
Department of Health

Advisory AS24/01: National Safety and Quality Health Service Standards requirements for reprocessing of reusable medical devices in health service organisations

Frequently Asked Questions – Public Health Service Providers

QUESTION	RESPONSE
1. When was Advisory AS24/01 released?	• The Australian Commission on Safety and Quality in Healthcare (the ACSQHC) released two new advisories on 11 November 2024 relating to reprocessing of reusable medical devices (RMDs). - Advisory NSQHS AS24/01 Reprocessing of reusable medical devices in health service organisations. November 2024. - Advisory PCHS24/01 Reprocessing of reusable medical devices in primary and community healthcare services. November 2024. ***Note***: Advisory AS18/07 has been rescinded.
2. When was AS 5369:2023 released?	• AS 5369:2023 was released by Standards Australia in December 2023 and supersedes both AS/NZS 4187:2014 and AS/NZS 4815:2006.
3. What is the intent of Advisory AS24/01?	• AS24/01 describes the minimum compliance requirements within Action 3.17 regarding reprocessing of RMDs in line with the requirements of AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

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4. Who does Advisory AS24/01 apply to?	• AS24/01 is applicable to Private and Public Healthcare Services. • **Public Health Service Providers** (HSPs) are overseen by the following legislation and Policy: - Health Services Act 2016 - Australian Health Service Safety and Quality Accreditation Scheme (the AHSSQA Scheme) - MP 0134/20 - National Safety and Quality Standards Accreditation Policy • This includes facilities who provide health services, where reusable equipment and devices are used, such as: - hospitals - day procedure units - dental facilities
5. Is Advisory AS24/01 (and AS 5369:2023) a mandatory requirement?	• It is mandatory for HSPs to comply with requirements of AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities. • It is mandatory for HSPs to comply with Advisory AS24/01 in accordance with: - Health Services Act 2016 - Australian Health Service Safety and Quality Accreditation Scheme (the AHSSQA Scheme) - MP 0134/20 - National Safety and Quality Standards Accreditation Policy
6. What are the requirements of Advisory AS24/01	• HSPs are expected to continue to work towards compliance with AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities. • HSPs must undertake a gap analysis against AS 5369:2023 to identify risks related to the reprocessing of RMDs by **30 June 2025.** • Where risks are identified, HSPs must ensure that there is evidence that these risks are monitored, and mitigation strategies are in place until the organisation is fully compliant with AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.
7. What are the major changes?	• AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities was issued by Standards Australia in December 2023, replacing both AS/NZS 4187:2014: Reprocessing of reusable medical devices in health service organisations, and AS/NZS 4815:2006 Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment. • Submissions of extension to comply with AS 5369:2023 are not a mandatory requirement. ***Note:*** Although timeframes for submission of extensions are not a mandatory requirement, HSPs can submit an extension request for projects that are anticipated to take more than three years, which aligns with an assessment cycle.

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8. What are the expectations from the ACSQHC regarding compliance with Advisory AS24/01?	• HSPs are expected to continue to work towards compliance with AS 5369:2023, in line with NSQHS Standards accreditation requirements. • Where a HSP does not submit a request for extension or a request for extension is not approved by the Commission, the HSP is expected to progress toward compliance with Advisory AS24/01 and AS 5369:2023 in line with their next accreditation assessment cycle and will be rated accordingly i.e.: - **Met** – *if fully compliant with advisory AS24/01 and AS 5369:2023* - **Met with recommendation** – *if compliant with advisory AS24/01 and demonstrated progress toward compliance with AS 5369:2023* - **Not met** – *if not fully compliant with advisory AS24/01 or AS 5369:2023* • HSPs are at risk of failing accreditation if they receive two consecutive 'met with recommendation' related to Action 3.17 and are not compliant with AS24/01, so each HSP must demonstrate progress towards compliance in time for their second assessment (noting that the timeframe for assessment will not be known with certainty, given accreditation assessments are now carried out at short notice at any time within the three yearly cycle).
9. What happens if a HSP does not demonstrate compliance with Advisory AS24/01 (and AS 5369:2023)?	• At the Accreditation assessment, assessors will review evidence that replaced infrastructure and reprocessing equipment complies with AS24/01 and AS 5369:2023. • If a HSP is rated 'Met with Recommendation' following two consecutive assessments where: a) An extension is approved – the HSP will be able to continue to receive 'Met with Recommendation' without impact on their accreditation status for the **period the extension is approved.** b) An extension is not requested or not approved – the HSP will receive a 'Not Met' for the action as they are unable to have a 'Met with Recommendation' for the same action over two consecutive accreditation cycles.
10. How do HSPs submit a request for extension?	• Applications for extensions to Advisory AS24/01: Reprocessing of reusable medical devices in health service organisations can be submitted to the ACSQHC where timelines for implementation exceed 3 years. • An extension supports Action 3.17 to be rated 'Met with Recommendations' across assessment cycles. • The key steps can be found here. • LARU (regulator) input will be sought (by the ACSQHC) on all submissions.

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11. How will the timeframe for extension be assessed and approved?	• All applications for extension submitted to the ACSQHC must include copies of the gap analysis, risk remediation plan and a summary of the project plan indicating executive approval and allocated funding. • Applications will be reviewed against criteria to determine compliance. Applicants will be notified if the application is not complete. • Submissions cannot proceed for formal approval until all documentation is provided. • Advice on applications will be sought by the ACSQHC from LARU as the regulator of the AHSSQA scheme. • Successful applications will be notified via a letter from the ACSQHC Chief Operating Officer to the HSP, LARU and accrediting agency.
12. Will requests for extensions be categorised by level of risk?	• The gap analysis should identify the level of risk for the HSP.
13. Is there a determined (acceptable) timeframe established that guides the duration of an extension timeframe (risk tolerance)?	• The ACSQHC will consider extensions on a case-by-case basis but generally will be for a period of three years (to align with an accreditation cycle). Further extensions can be sought.
14. How many extensions can be granted before there is impact on the HSPs accreditation status?	• The number of extensions provided will be dependent upon the timeframes of the project plan e.g. where capital works have phased approaches that are anticipated to take up to 10 years. • Provided the criteria of AS24/01 are met, a HSPs accreditation status will not be impacted.
15. Will a source of intelligence data including approved extension timeframes be made available to regulators to assist with implementation of AS24/01 at a system level?	• LARU (regulator) input is sought by the ACSQHC and will be provided with copies of the HSP's gap analysis, risk remediation plan and a summary of the project plan indicating executive approval and allocated funding.
16. What are the expectations from the LARU regarding Advisory AS24/01?	• LARU will employ a risk-proportionate approach in applying regulatory compliance and enforcement functions in order to progress compliance with Advisory AS24/01 as indicated in: - MP 0134/20 - National Safety and Quality Standards Accreditation Policy and outlined in the - National Safety and Quality Standards Accreditation Procedure

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17. How will LARU assess compliance with Advisory AS24/01 (and AS 5369:2023)?	• Through the application of the MP 0134/20 - National Safety and Quality Standards Accreditation Policy and outlined in the National Safety and Quality Standards Accreditation Procedure. • Specifically: LARU will ensure HSPs align with the NSQHS Standards and comply with AS24/01 through articulation of the HSP's identified risks to determine how and to what extent the standard is implemented when full compliance is not feasible. This will be reviewed against: a) Compliance with the Act: I. Health Services Act 2016 b) Compliance with the AHSSQA Scheme, NSQHS Standards and Advisory AS24/01 including: I. Gap analysis against AS 5369:2023 II. Risk assessment and risk mitigation plan III. Progress of the implementation plan IV. Application for extension (if applicable) – details of approval and extension timeframe V. Accreditation outcomes against NSQHS Standard 3 - Action 3.17 c) Compliance with: I. MP 0134/20 - National Safety and Quality Standards Accreditation Policy II. National Safety and Quality Standards Accreditation Procedure
18. Is Advisory AS24/01 (and AS 5369:2023) applicable to the public sector for the design of public hospitals and healthcare facilities?	• Yes, this a mandatory requirement. Consideration must be given to the impact of reprocessing of reusable medical devices and compliance with AS 5369:2023.
19. Are there any resources available to assist HSPs to comply with Advisory AS24/01?	• A suite of resources is available to assist health service organisations to implement AS 5369:2023:2023: - Transitioning from AS/NZS 4187:2014 to AS 5369:2023 - Transitioning from AS/NZS 4815:2006 to AS 5369:2023 - Access detailed information about Action 3.17 here - More information about Reprocessing of reusable medical devices can be accessed here
20. Where can I locate more information about Advisory AS24/01 (and AS 5369:2023)?	• Further information can be accessed on the Australian Commission on Safety and Quality in Healthcare website: - AS24/01: National Safety and Quality Health Service Standards requirements for reprocessing of reusable medical devices in health service organisations | Australian Commission on Safety and Quality in Health Care • Alternatively, contact LARU with any queries. - **Building** related matters: LARUBuilding@health.wa.gov.au - **Licensing** related matters: LARULicensing@health.wa.gov.au - **Compliance** related matters: LARUCompliance@health.wa.gov.au - **Accreditation** related matters: LARUAccreditation@health.wa.gov.au

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