Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA quality management system audits and certification

Guidance for manufacturers of medical devices

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Contents

About this guidance

This guidance provides information for medical devices manufacturers on:

- how we conduct quality management system (QMS) audits
- roles and responsibilities for QMS audits
- the QMS auditing aspects of TGA conformity assessment (CA) certification
- post-audit activities.

Appendix 1 lists several audit-related definitions.

Terminology—audit vs inspection

We use 'audit' and 'auditor' when referring to medical device quality management systems.

We use term ‘inspection’ and ‘inspector’ when referring to Good Manufacturing Practice (GMP).

Introduction

We conduct a QMS audit when we:

- receive an application for TGA conformity assessment QMS certification
- identify a signal that indicates non-compliance with:
  - applicable conformity assessment procedures
  - conditions of your certificates
  - the essential principles of safety and performance
- identify safety, performance, or quality issues with the devices you are manufacturing
- receive a report or complaint about potential non-compliance with the Act
- identify a safety concern following a post-market review.

The types of audit we conduct

Onsite QMS audits

We conduct onsite audits when we need to:

- physically view:
  - your facility and its processes
  - the facility of one or more of your suppliers
- observe non-verbal communication.

Remote QMS audits

We conduct remote audits over the internet using video conferencing software. Generally these are only performed if there are travel restrictions.

Our remote audits include:

- interviews
- observation of activities
- review of documentation.

Desktop QMS audits

We conduct desktop QMS audits on documents you send to us:

- as part of your initial application
- in response to specific requests for information.

We often ask for:

- risk assessments
- quality management procedures
- test protocols and records
- validation records and any other relevant documents.

Desk top audits (DTA) can only be performed if evidence of an assessment against requirements that are comparable to the Conformity Assessment procedures is available. For example, MDSAP audit report(s). The outcome of the DTA may be a decision to conduct an on-site audit or partial on-site audit.

Abridgement

We can abridge our audits in some cases.

We may ask you for details of any assessment against requirements that are comparable to the Conformity Assessment Procedures by an overseas regulator. We will use this and other information to decide whether we can abridge your audit.

Onsite and remote audits

Our audit process

Our audit process has 5 stages:

1. Announcing our audit.
2. Preparing for the audit.
3. Conducting the audit.
4. Preparing an audit report.
5. Closing out the audit.

Audit announcement

We will announce most of our audits.

Sometimes we conduct unannounced audits.

We will arrange dates for the audit with you weeks or months before we conduct the audit. We will usually do this by telephone.

We will then send you a formal announcement letter by email. In the letter we will ask you to send us a selection of documents.

Audit preparation

To prepare for your audit, we will:

- draft:
    - an audit plan
    - an audit attendance sheet
- request documents to review and then review the documents and records you have sent us
- review publicly available material on your company and products
- review technical standards or guidance you have used as evidence of compliance
- review conditions of the certificates you have applied for.

At audits of certified manufacturers, we usually also review:

- conformity assessment certification applications submitted to us, such as for:
    - variations to current scope of certification
        - new product category
        - new suppliers
        - new manufacturing sites
        - etc.

- past audit reports and close-out records
- all recalls you have carried out since our last audit
- results of any product testing we have performed
- the details of any regulatory issues we are aware of
- details of your therapeutic goods included in the Australian Register of Therapeutic Goods (ARTG)
- relevant reports in our Medical Device Incident Reporting & Investigation Scheme (IRIS) database.

For onsite audits, you should organise an area for our audit team to work.

You must provide us with site safety and security procedures and equipment. For example:

- information on known health risks, and their controls, relating to manufacturing operations at your site
- personal protective equipment such as:
    - high visibility vests
    - safety shoes
    - clean room garments
    - eye protection
    - hearing protection.

Gifts

Per Australian Government requirements, we cannot give or accept gifts.

Conduct of audits

Audit attendees

Our audit team

Our audit team will have a lead auditor and, where appropriate, one or more:

- auditors
- technical specialists.

At some audits we also have:

- trainee auditors
- trainee technical specialists
- observers.

We will tell you who will be in our audit team before the audit.

You can learn more about the different roles in Appendix 3—Audit member roles.

Our observers

We may organise for observers to attend the audit.

Our observers can include:

- Australian Government officers
- representatives of overseas regulatory bodies.

Our observers:

- will not influence or interfere with the audit
- are subject to confidentiality agreements.

We will tell you about any observers before the audit.

Your observers and consultants

You can invite observers and consultants to the audit. You must identify them, and they must not influence or otherwise interfere with the audit.

Note: We will consider all people named as observers and consultants who influence the audit to be:

- part of your team
- subject to audit findings.

Interpreters

We conduct our audits in English.

You must provide someone to interpret if you have people who do not speak English.

Your interpreters must:

- be able to interpret technical language
- transpose *exactly* what both parties are saying with no additions or subtractions.

Your interpreters **must not** embellish or say what they think our audit team wants to hear.

Translators and translations of written content

You must make documents, records, manufacturing equipment manuals, facility signs, etc. available in English. You can provide us with translations if the source documents are in a different language.

We may ask you to translate certain materials while we are onsite.

You must ensure that your translations are technically accurate and complete.

Your translators **must not** embellish or write what they think our audit team wants to read.

Opening meeting

Our lead auditor will chair an opening meeting with your management team. At this meeting, we will:

- record who attends

- introduce the members of our audit team and outline their roles
- confirm the scope and objectives of our audit with you
- discuss and confirm our audit plan with you
- propose tentative times and dates for:
  - an interim meeting of our audit team and your management team
  - the closing meeting
- propose times and dates for interim meetings with your management team
- outline how we will conduct the audit
- explain that our audits are a sampling exercise
- explain our dispute-handling process
- explain our complaint-handling process.

Our lead auditor will also explain when and how you can respond to potential issues we identify including:

- at the moment we find the issue
- at daily debriefs (when held)
- during the closing meeting
- after the closing meeting.

Collection of objective evidence

Our audits involve us collecting objective evidence of the extent to which requirements relevant to the audit scope have been fulfilled.

The evidence we collect will:

- include information relating to interfaces between functions, activities, and processes
- be a sample of available information.

Our audit team will:

- ask you questions
- interview your personnel (at all levels in the organization)
- observe your manufacturing:
  - environment
  - infrastructure
  - equipment
  - production process
  - activities
- review procedures, records, logs, and databases

- take photocopies or photos where required for recording evidence
- collect samples where required
- review your procedures and how you put them into practice
- review your compliance with the state of the art and relevant technical standards
- ask questions of your staff to test their expertise, knowledge of procedures, etc.
- review scientific and engineering evidence
- observe how your staff do their roles
- review how well your quality system works for *you* and *your* business.

When planning the audit, we will, where possible, seek to accommodate:

- your production schedule
- the availability of staff members.

Our audit approach

We look for compliance not noncompliance with the requirements. This means that we are not trying to catch you out. It is your responsibility to show your compliance with the requirements in the way you choose. We will look at your evidence in an objective way. Note that observed NCs will not be removed at audit if corrections or corrections are implemented during the audit.

Open communication

We design our audits to allow for open communication. You can ask our auditors questions at any time.

We will inform you of the progress, including our findings, while the audit is underway.

We will not surprise you at the end of the audit with more findings.

Our auditors will talk to you throughout the audit. Unless we state otherwise, you should not take these to be potential nonconformities.

You should view audits as an opportunity to improve your quality management system.

We encourage you to ask questions during the audit.

Our auditors

Our auditors are all technical specialists we have trained to be auditors.

Our audits involve a technical review of your systems and medical devices.

Ours auditors and technical specialists differ in both nature and technical specialty. Each of our audit team members will also have a different focus. This is by design. A diverse and changing audit team can better test, over time, the breadth and depth of your QMS.

Testing the integrity and resilience of your QMS

We often review many QMS elements at the same time. For example:

- how different parts of your system interact
- how your system operates over the lifetime of your devices, and
- how your systems and people handle issues.

In part, this is so we can carry out the audit in as short a time as possible. It is also because our audits are process-based audits, not checklist audits.

What might appear to be a review of a maintenance procedure could also cover:

- training
- understanding of a procedure by a worker
- evidence of record keeping
- etc.

Testing in this way helps us test the integrity and resilience of your QMS.

Rotation

We rotate our audit teams over time.

This ensures that over time we:

- audit you with people with different technical expertise
- check different parts of your quality system
- look at your quality system in different ways.

Audit conclusion

The audit conclusion involves us:

- generating audit findings
- holding a closing meeting with you to present our findings.

Audit findings

Our audit team will spend a period of time preparing for the closing meeting. In this time we will:

- review the evidence and any other information we have collected during the audit
- consider the nature and significance of our findings (if applicable)
- prepare for the closing meeting we will hold with you.

Closing meeting

We will hold a closing meeting with you at the end of the audit to present our findings.

In this meeting, we will:

- record who attends
- give you a spoken overview of the audit
- explain our dispute-handling process

- explain our complaint-handling process
- present, explain, and discuss our audit findings with you, including possible nonconformities
- emphasise issues that could lead to action to suspend or revoke your certificate
- give you an opportunity to raise any concerns.

Our audit findings will state either compliance or non-compliance with the audit criteria.

You might not agree with our findings. We will attempt to resolve these with you at the closing meeting. If we cannot agree, we will record both yours and our views. You will have an opportunity to respond when we send you our formal audit report.

Our dispute-handling process

Introduction

We aim to minimise misunderstandings and resolve any disputes:

- in a timely way
- in the most direct way possible.

We design our audits:

- for open communication
- to allow regular opportunities for you to raise any concerns with our lead auditor.

We will explain our dispute-handling process in both our opening and closing meetings.

Dispute-handling

You can discuss issues with our lead auditor at any time before we send you our audit report.

After we issue you with our audit report, you must raise any issues to us in writing.

Audit report

After the audit, we will prepare and send you a report that includes:

- for the processes sampled, a summary of the extent to which the QMS complied with requirements, our audit findings, including any nonconformities we have identified.

We will send you our report in approximately 60 days of the audit closing meeting.

We will peer-review our audit report before we send it to you.

Classification of nonconformities

We classify non-conformities as major or minor.

A major nonconformity is a nonconformity that:

- has led to or could lead to a medical device that does not comply with the essential principles of safety and performance
- indicates a major deviation with the QMS requirements
- indicates a major deviation with the conditions of certification

- indicates that people responsible for QA/QC have not fulfilled their duties
- consists of several other minor nonconformities that together represent a major nonconformity.

A Minor nonconformity is a nonconformity that cannot be classified as Major, but indicates a departure from the applicable standard and/or regulatory requirement.

See *Appendix 2* for some examples.

Provisional compliance ratings

We will decide a provisional compliance rating according to the following criteria.

Rating	Criteria
A1—High compliance	No major nonconformities identified. You have made suitable corrections in response to our audit report. This rating usually has less than 10 minor nonconformities.
A2—Average compliance	1–5 major nonconformities identified. In response to our audit report, you have: • identified causal factors of observed nonconformities • made suitable corrections • taken suitable corrective action. This rating usually has less than 20 minor nonconformities.
A3—Low compliance	6–10 major nonconformities identified. In response to our audit report, you have: • identified causal factors of observed nonconformities • made suitable corrections • taken suitable corrective action. This rating usually has less than 30 minor nonconformities.
A4—Not compliant	• More than 10 major nonconformities identified. • In response to our audit report, you have **not**: • identified causal factors of observed nonconformities • made suitable corrections • taken suitable corrective action. There is the possibility of substandard or unsafe products being supplied. • As otherwise determined by a review panel.

Review panel

We hold review panels for audits that return a provisional compliance rating of unacceptable.

Our review panels:

- are chaired by a director or someone at an equal or higher level
- include auditors with relevant expertise and experience
- include technical experts with relevant expertise and experience.

Our panel chair and members are independent of the team who carried out the audit.

Our review panel members will:

- review the audit report
- do a risk assessment
- recommend future actions (for example a follow up audit)
- prepare recommendations to the Delegate for regulatory actions, as applicable.

Responding to our audit report

To start closing out the audit, with our audit report, we will usually:

- send you a formal request for a response to our report and the identified nonconformities
- ask you to provide an initial response by a certain date (for example, four weeks from the date of our request).

If you do not give us a response in the stated time frame:

- your application for initial TGA certification may lapse
- we may suspend or revoke your conformity assessment certification
- we may impose conditions on your conformity assessment certificates
- your sponsor's ARTG entries may become invalid.

We will give you a close-out record template with our request. You can use this to give your responses to the identified nonconformities.

For each nonconformity raised, your response should include:

- identification of causal factors
- actions you have taken, or propose to take, to correct the specific issue. This must include details of corrections made to the examples identified.
- corrective actions you have taken to prevent recurrence.
- date completed or target date for completing.

You must give us objective evidence for how you have addressed major nonconformities. Examples of objective evidence include:

- copies of amended documentation
- photographs
- copies of records
- samples.

In some cases, we will accept a plan with time frames and regular reporting for when you expect to resolve outstanding nonconformities. Examples of where providing a plan may be acceptable include where you need further time to:

- generate more stability data
- make updates or fixes to facilities or equipment

- conduct verification and validation studies following:
    - corrections to manufacturing equipment
    - commissioning of new equipment, processes, and systems.

Note

You **do not** need to respond to statements we make in the body of our audit reports.

Close-out audits

We will sometimes conduct a close-out audit. For example, where:

- you have a large number of major nonconformities
- we need to review your corrections and corrective actions in person.

If we decide to close out your audit

We will close out the audit where we have accepted all your proposed corrections and corrective actions. We will send you a close-out letter if we decide to close out your audit.

Our letter will include:

- your compliance rating
- the approximate timing for your next audit
- details of approved changes to scope, or conditions, of certification.

We will use your compliance rating with other information to decide when we will next audit you. We audit manufacturers with higher compliance ratings less often.

We will not normally close out our audit until you have:

- made corrections
- put in place corrective actions

for all major nonconformities.

In some limited cases we will close out the audit based on a detailed plan with regular reporting to us of your progress.

If the audit cannot be closed

We will send you a letter if your audit cannot be closed out in a reasonable time frame.

If your audit cannot be closed out in a reasonable time frame:

- your application for, or change to, QMS certification may not be successful
- we might take enforcement actions such as:
    - revoking your conformity assessment certificate

- suspending or cancelling the ARTG entries supported by your certificate.

Timelines for close-out

We usually issue our audit reports within 60 calendar days after our audit.

We usually ask that you provide your response within four weeks of the date of issue of our audit report. This will give you about twelve weeks from the closing meeting to provide your response.

We will usually review your response within four weeks of receipt. This time will vary according to the availability of our auditors.

We may ask you for more information after your first response. We will generally give you at least two weeks to respond.

TGA QMS Conformity Assessment (CA) certification audits

Applications

We audit your quality management system as part of assessing your application for TGA CA certification.

Note

TGA CA certification is one of several regulatory evidence options. TGA CA certification is not mandatory.

Not all manufacturers are required to hold TGA or third-party certification.

You can apply for a TGA QMS certificate at TGA conformity assessment certification.

QMS certification process

QMS certification is an ongoing activity that starts with full certification.

- Full certification audit

  This is the audit we conduct to certify manufacturers for the first time. It is our most comprehensive audit.

- Surveillance audit

  This is an audit to check ongoing compliance. We generally look at only part of your quality management system at a surveillance audit. We conduct two or more surveillance audits before conducting a recertification audit.

- Recertification audit

  This is an audit similar in scope to a full certification audit. We conduct these when your TGA certificate is nearing expiry.

Purpose of the audit

The purpose of our audit is to find out if you are complying with:

- the requirements according to the audit criteria
- any technical standards you are using as evidence.

What the audit will include

Our audit will involve examination of your:

- quality manual
- practices
- documents
- records
- policies
- procedures.

We **will not** review your compliance to other laws in Australia, such as:

- environment
- financial
- labour practices
- occupational health and safety
- building codes.

However, we:

- can refer possible breaches of these laws to the relevant authorities
- do look at any factor that can affect:
    - your quality management system including:
        - the environment of manufacture
        - IT financial systems that hold data relevant to the audit (for example, training records)
    - the safety, performance, and quality of medical devices you manufacture.

Certification decision

We will decide whether to issue you with a certificate or not after we close out our audit and other assessment activities.

Decisions to issue a certificate

If we issue you with a certificate, it will include:

- your name

- site addresses
- scope of products covered by the certificate
- criteria you are certified against.

Decisions to not issue a certificate

We will inform you in writing if we decide to not issue you with a certificate.

Appealing our conformity assessment certification decision

You can appeal our conformity assessment certification decision under Section 60 of the Act.

We will tell you how to make an appeal when we make our decision.

Post-certification activities

Your ongoing obligations

To maintain your certification, you must:

- comply with the conditions of the certificates we issue to you
- continue to comply with the relevant conformity assessment procedures
- ensure your devices comply with the essential principles of safety and performance
- continue to comply with the standards you have used as evidence of compliance
- tell us of significant changes in the structure and operations of your business
- pay fees by the stated dates
- maintain your facilities and manufacturing operations
- give us access to premises, facilities, and records on request
- make personnel available for interview
- rectify any nonconformities found during audits in a time frame accepted by us.

Following certification

Following certification, we will:

- conduct audits of your manufacturing facilities every 1 to 3 years
- tell you, in writing, of any changes to your scope of certification
- tell you, in writing, of any audit findings that you must respond to with corrections or corrective actions.

Conditions of ongoing certification

The Act and MD Regulations contain details on the conditions of Australian conformity assessment certification.

Section	Section/Division number
Granting a conformity assessment certificate	Section 41EE
Refusal of application	Section 41EH
Conditions of the certificate	Division 2 of Part 4-4
Suspension of the certificate	Division 3 of Part 4-4
Revocation of the certificate	Division 4 of Part 4-4

Changes to scope of certification

You can apply to change or add to the products you are certified to manufacture. We will let you know as part of the application whether we will audit you to assess the change in scope.

Confidentiality

We treat application and ongoing certification information as confidential. This includes from applicants who have been authorised by you to request the audit on your behalf.

In some cases, we give audit information to other authorities, for example:

- an authority of the Commonwealth, State, or Territory
- a regulatory authority of another jurisdiction where we hold:
  - a memorandum of understanding
  - mutual recognition agreement
- the World Health Organization.

See section 61 of the Act for more information.

Enforcement actions

We can take regulatory action when you are not meeting the certification conditions. This could include:

- suspending your CA certificates
- revoking your CA certificates.

Feedback and complaints

Refer to the following link: Inspection and audit feedback forms

Contact us

For more information about QMS audits, you can contact us at:
QMS.Certificates@health.gov.au

Appendix 1—Audit-related definitions

We use the following definitions for our audits.

Term	Definition
Audit	Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 19011, Clause 3.1). Note: A joint audit is when two or more auditing organisations cooperate to audit a manufacturer at the same time.
Audit criteria	Set of policies, procedures or requirements (ISO 19011, Clause 3.2) Note: Audit evidence is compared against the audit criteria.
Audit evidence	Records, statements of fact, or other information that are relevant to the audit criteria and that are verifiable (adapted from ISO 19011, Clause 3.3)
Audit findings	Results of the evaluation of the collected audit evidence against audit criteria (ISO 19011, Clause 3.4) Note: Audit findings can indicate either conformity or nonconformity with audit criteria.
Audit conclusion	Outcome of an audit, provided by the audit team after consideration of the audit objectives and all audit findings (ISO 19011, Clause 3.5)
Audit scope	Extent and boundaries of an audit (ISO 19011, Clause 3.13) Examples: locations, organisational units, activities, processes, and the dates and times covered.
Corrective action	Action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000, Clause 3.6.5) Note: Corrective actions are different to corrections. Corrective actions are made against an identified causal factor. A correction can be made in conjunction with a corrective action.

Term	Definition
Correction	Action to eliminate a detected nonconformity (ISO 9000, Clause 3.6.6) Note: • Corrective actions are different to corrections. • Corrections are made against individual examples of a core issue. A correction can be, for example, rework or regrade. • There can be more than one causal factor for a nonconformity. • A correction can be made in conjunction with a corrective action.
Nonconformity	Non-fulfilment of a requirement (ISO 9000, Clause 3.6.2)
Objective evidence	Data supporting the existence or verity of something (ISO 9000, Clause 3.8.1) Note: Objective evidence is collected through observation, measurement, test, and other means.
Preventive action	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation (ISO 9000, Clause 3.6.4)
Recurring nonconformity	A nonconformity: • that was identified at a previous audit, and • for which the corrective and preventive actions taken earlier were inadequate.

Appendix 2—Examples of major nonconformities

Examples of major nonconformities:

- lack of validation of critical processes (for example, sterilisation validation)
- evidence of pest infestation that could affect device safety, performance, or quality
- falsification or misrepresentation of quality test results
- no or inadequate air filtration to minimise airborne contaminants (where appropriate)
- cleaning program not followed and evidence of dirty premises/equipment
- un-validated cleaning procedures where resulting contamination is a safety hazard
- no stability program or equivalent to support the life of a device incorporating a medicine
- damage (holes, cracks, peeling paint) to walls/ceilings in manufacturing areas where product is exposed
- design of manufacturing area that does not permit effective cleaning
- size or design of manufacturing spaces that could lead to manufacturing process mix-ups
- inadequate segregation of sterilised and non-sterilised devices
- sanitary fittings not used on liquid/cream manufacturing equipment
- stored equipment not protected from contamination
- individuals in charge of QC/production not qualified by education, training and experience
- inadequate initial and ongoing training and/or no training records
- cleaning procedures not documented and/or no cleaning records
- production equipment cleaning procedures not validated
- reduced QC testing of raw materials without data to certify suppliers
- incomplete testing of raw materials
- test methods not validated
- unapproved/undocumented changes to master batch documents
- non-approved deviations from instructions
- no or inadequate internal audit program
- no or inadequate release for supply procedure
- product reworked without approval
- no system/procedures for handling complaints or returned goods
- inadequate testing of packaging materials
- insufficient lighting in production or audit areas

Appendix 3—Audit member roles

Role	Description
Lead auditor	Auditor with overall responsibility for the audit.
Senior auditor	Auditor with significant auditing experience.
Trainee auditor	Auditor in training. Traineee auditors conduct parts of an audit or entire audits under senior auditor supervision.
Technical specialist	Person with specialised technical knowledge of: • product • technologies • technical standards • specialist manufacturing activities. Note: Our auditors are all technical specialists in one or more technical disciplines. Not all our technical specialists are auditors.

Appendix 4—Common issues we see with new QMS's

We often see the following issues with manufacturers who have set up a QMS for the first time:

- treating the QMS as a collection of documents and records rather than as a business system
- installing a new and complex QMS software system that doesn't fit the needs of the business
- insufficient documentation and record-keeping to meet requirements
- setting up a QMS based on the structure of ISO 13485 rather than on how the business operates
- setting up a QMS based on what the manufacturer thinks the certifying body wants to see rather than on:
  - meeting the requirements (usually regulatory and of the standard), and
  - ensuring the QMS works for the manufacturer and its specific business.
- putting in place SOPs and WIs based on the imagined idea of how things operate rather than how they do or will in practice.

Version history

Version	Description of change	Effective date
V1.0	Original publication (Guidance on licensing/certification inspections)	29 April 2013
V2.0	Update to: • scope, • title • content to: • make medical device specific (including use of 'audit' rather than 'inspect') • remove content specific to other types of therapeutic goods. Addition of information on: • remote audits and desktop audits • audit attendees • our audit approach • certification decisions • audit member roles • cases where the audit cannot be closed out • examples of minor nonconformities. Update to content, language, and style to: • align with new department name (Health and Aged Care) • updated TGA visual identity • align with Australian Government Style Manual.	19 December 2023

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