

EPA Guidelines— program requirements for compliance testing of diagnostic X-ray apparatus



Environment Protection Authority



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Disclaimer

This publication is a guide only and does not necessarily provide adequate information in relation to every situation. This publication seeks to explain your possible obligations in a helpful and accessible way. In doing so, however, some detail may not be captured. It is important, therefore, that you seek information from the EPA itself regarding your possible obligations and, where appropriate, that you seek your own legal advice.

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Definitions

For purposes of this document the following definitions apply.

Accredited tester: a person who has been accredited by the EPA to perform compliance tests of diagnostic X-ray apparatus.

ALARA: section 23 of the Radiation Protection and Control Act 1982 requires that persons carrying on an activity related to radioactive substances or ionising radiation apparatus, endeavour to ensure that exposure of persons to ionising radiation is kept as low as reasonably achievable, social and economic factors being taken into account.

Audit: the systematic and functional examination of a product, process and establishment.

Compliance testing: performance of quality assurance testing for a determination of compliance with the Regulations and Section 23 of the RPC Act.

Diagnostic X-ray apparatus: a machine used to generate X-rays for diagnostic purposes associated with dental, medical, chiropractic or veterinary applications. It does not include radiotherapy machines.

EPA Protocols: a technical document detailing the procedures for performing tests that are specific to the type of diagnostic X-ray apparatus.

Legal Owner: a person or business that has ownership of a diagnostic X-ray apparatus.

Minister: Minister for the Environment and Conservation.

Regulations: Radiation Protection and Control (Ionising Radiation) Regulations 2000.

RPC Act: Radiation Protection and Control Act 1982.

Test Report: a technical document detailing the results of compliance tests performed by accredited testers.

Third party: an individual not acting under the direct authority of the Minister or the legal owner of the apparatus under test.

Abbreviations and acronyms

ALARA as low as reasonably achievable

EPA Environment Protection Authority

TPC Third Party Certification

1 Introduction

1.1 Purpose

This document discusses the requirements of the Third Party Certification (TPC) program administered by the Environment Protection Authority (EPA) for compliance testing of diagnostic X-ray apparatus. It should be read by persons wishing to become accredited testers, persons already accredited, and owners of diagnostic X-ray apparatus.

1.2 Scope

Determination of compliance of diagnostic X-ray apparatus can only be performed by persons authorised by the EPA. Such persons consist of Authorised Officers under *Radiation Protection and Control Act 1982* (the RPC Act) [1] and persons accredited under the TPC program.

While this document does provide information relevant to testers and owners of diagnostic X-ray apparatus, it does not detail what tests must be performed or how to perform them. This information is documented separately in a series of EPA Protocols. Contact the EPA for availability of EPA protocol documents.

1.3 Background

The TPC program was established by the EPA in June 2009 to enable industry based testing by independent third parties for the purposes of ascertaining compliance of diagnostic X-ray apparatus with the *Radiation Protection and Control (Ionising Radiation) Regulations 2000* (the Regulations) [3] and the RPC Act.

2 The accreditation process

2.1 Who can be accredited

To become an accredited tester in South Australia, a predefined process must be followed to ensure the required standards are achieved by all applicants. These steps are summarised in the flow chart of Figure 1 in Annex B.

A compliance tester must have knowledge in areas of radiation physics, radiation safety, quality assurance methodologies, test instrumentation, and skills in the operation of diagnostic X-ray and/or radiotherapy X-ray apparatus.

Typically, but not necessarily exclusively, a compliance tester would be a qualified professional in one or more of the following areas:

- engineering (including technicians)
- science
- medical physics
- radiography
- radiotherapy.

Any person who has an appropriate professional qualification (ie degree, certificate, diploma, etc.) in a relevant field can be considered for accreditation as a compliance tester and will be assessed by the EPA on a case-by-case basis. While there are no requirement on the number of years of experience, applicants are expected to adequately demonstrate they have the appropriate experience, expertise, and knowledge suitable for the type of apparatus to be tested.

2.2 Applying

Persons wishing to become accredited must complete an application form [1] and send it, together with the required supporting documentation, to the EPA.

Currently, there are no application or ongoing EPA imposed fees that are directly associated with the TPC program. However all compliance testers must have a licence to operate an ionising radiation apparatus and there is an application fee and annual renewal fee associated with the licence.

2.2.1 Licence to operate an ionising radiation apparatus

Current licence holders

To maintain accreditation, testers must have a licence to operate an ionising radiation apparatus. Persons applying for accreditation who already have such a licence need not submit another licence application (for a licence to operate an ionising radiation apparatus) but will still need to submit an application for accreditation. Once accredited their current licence will have an additional condition placed on it that is appropriate to the apparatus they are accredited to test. Any existing licence conditions will be unaffected.

New licence applicants

Persons applying for accreditation who are not current holders of a South Australian licence (to operate an ionising radiation apparatus), will need to apply for a licence concurrently with the application for accreditation. If their accreditation is approved and they fulfill all other requirements, they will also be granted a licence to operate an ionising radiation apparatus carrying a condition that is appropriate to the apparatus they are accredited to test.

Application forms for a licence to operate an ionising radiation apparatus are available from the EPA website at www.epa.sa.gov.au/licensees/radiation_licences.

2.2.2 Mutual recognition

Compliance testers who have been accredited, in another state or territory of Australia, in the last five years, are eligible to apply for mutual recognition. An application form [1] will still need to be submitted; but in the first instance applicants will not be required to demonstrate the competencies (as specified in section 2.2.4) or provide training and employment details. Please refer to the application form for further information.

During the initial assessment of the application, a determination of the suitability of the interstate or inter-territory accreditation to the South Australian program will be made. In some instances, the EPA may still require statements of competency, training and employment details as per the application form.

Note that proof of accreditation in the form of a certificate, licence, or equivalent will need to be provided with the application form.

2.2.3 Prior recognition

Compliance testers who have been accredited in South Australia at any time in the last five years, but no longer hold valid accreditation, are eligible to apply on the basis of prior accreditation. An application form [1] will still need to be submitted but applicants will not be required to demonstrate the competencies (as specified in section 2.2.4) or provide training and employment details. Please refer to the application form for further information.

2.2.4 Competencies

In addition to the professional qualifications, as discussed in section 2.1, testers are expected to have attained an adequate level of competency in several areas as described in the following sections and specified in the application form (ie competencies A, B, C, D, and E).

This expertise could be gained from direct experience, specific training, or a combination of both. The level of expertise required will depend on the type of accreditation sought. For example a higher level of expertise would be required to obtain accreditation to compliance test Computed Tomography apparatus than to test Plain Dental apparatus.

Note: if applying for mutual recognition (as discussed in section 2.2.2) or prior recognition (as discussed in section 2.2.3), applicants need not provide the information specified in this section unless otherwise indicated by the EPA.

Radiation physics (Competency A)

Quality assurance testing requires knowledge of radiation physics which is implicit in the Regulations and the EPA Protocols. The following areas of knowledge, applying to X-rays, are relevant:

- absorbed dose, equivalent dose and effective dose
- dose rate
- tube voltage, tube current, and exposure time
- half value layer
- inverse square law
- collimation
- radiation output, consistency, and linearity
- radiation transmission through barriers.

Radiation safety (Competency B)

Quality assurance testing requires knowledge of radiation safety, which is implicit in the Regulations and the EPA Protocols. The following areas of knowledge, applying to X-rays, are relevant:

- time, distance, and shielding
- the ALARA principle
- operator protocols
- personal monitoring devices
- warning signs.

Operation of X-ray apparatus (Competency C)

Testers must be experienced in the operation of one or more of the following types of X-ray apparatus:

- Bone Densitometer
- Chiropractic
- Computed Tomography (CT)
- Dental—Cone Beam CT
- Dental—Orthopantomographic/Cephalometric
- Dental—Plain
- Image Intensifier
- Mammography
- Medical—Plain
- Radiotherapy
- Veterinary.

This might be in association with installations, servicing, calibrations, teaching, research, clinical work, or similar.

Quality assurance testing of X-ray apparatus (Competency D)

Quality assurance testing involves the confirmation of functionality and performance to specified standards. It also involves confirmation of shielding effectiveness of the environment (ie wall, doors, and fixed protective screens) in which the apparatus is contained.

For quality assurance testing of diagnostic X-ray apparatus, the standards are the Regulations and section 23 of the RPC Act (ALARA). Relevant testing experience of diagnostic and/or radiotherapy X-ray is therefore a required competency.

Instrumentation (Competency E)

While the use of some type of instrumentation is typically required for any type of quality assurance testing, the nature of compliance testing of X-ray apparatus requires specific types of test parameters to be measured in a non-invasive fashion on both the apparatus and on protective barriers of interest. Consequently a competency in the use of test instruments, applicable to the types of tests detailed in the relevant EPA Protocols, is required.

2.2.5 Sample Test Report

All testers are required to document the test results in the form of a Test Report, the preparation of which is the responsibility of the accredited tester. The form and style of the report is at the discretion of the tester but results must be clear and accurate.

Note: all applicants for accreditation, are required to provide a sample Test Report for at least one of the types of apparatus for which accreditation is sought.

2.3 Assessment

Upon receipt of an application, the EPA will perform an assessment of the applicant's qualifications, experience and expertise. The assessment will be based on information provided in the application form, the statements of competencies (if required), and the sample of the Test Report (refer section 2.2.5). If necessary, the EPA may ask for further information or clarification in relation to the application.

If the outcome of an applicant's assessment is satisfactory, the applicant will be granted probationary accreditation (refer section 2.4) as a compliance tester with an appropriate condition on their current licence (to operate an ionising radiation apparatus). However, if an applicant's level of experience and expertise is not considered adequate, their application for accreditation will not be granted.

Irrespective of the results of the assessment, all applicants will be notified in writing of the outcome.

2.4 Probationary accreditation

The initial status for all accredited applicants is probationary—which will provide the EPA with an opportunity to evaluate each tester until their competencies have been adequately demonstrated. This is done by requiring testers to submit at least their initial three Test Reports, in addition to the mandatory Statement of Compliance.

The EPA will assess each report and where appropriate provide feedback to the tester. Once the EPA is satisfied with the quality of the Test Report and the level of competency, full accreditation will be granted, upon which the relevant condition on the tester's licence (to operate an ionising radiation apparatus) will be changed from probationary to full accreditation.

2.5 Right of review

An applicant who is not satisfied with the outcome of their application for accreditation may seek to have the decision reviewed. A request for a review must be in writing and should be addressed to:

The Director
Regulation and Compliance Division
Environment Protection Authority
GPO Box 2607
Adelaide SA 5001.

In addition, a person aggrieved by the decision of the Minister, in relation to a licence to operate an ionising radiation apparatus (section 41 of the RPC Act), may apply to the Supreme Court for a review of the decision.

3 Responsibilities of testers

Once a tester is accredited there are certain areas of responsibility that must be attended to and a specific process followed for each apparatus that is compliance tested. This process, as summarised in the flow chart of Figure 2 of Annex B, allows the EPA to register an apparatus solely on the basis of information provided by the accredited tester.

3.1 Affiliations and conflicts of interest

There are a number of possible relationships that can exist between accredited testers, owners of apparatus, and employers. In some instances these affiliations may lead to conflicts of interest that could, if not correctly managed, negatively impact on the independence and objectivity of the tester and on the integrity of the TPC program.

In particular, an accredited tester who wishes to make a determination of compliance of an apparatus for which they are the legal owner, would be presented with a significant conflict of interest and is unlikely to remain independent and objective during the assessment. For this reason an accredited tester cannot be the legal owner of the apparatus under test. In this circumstance the owner would need to seek the services of an independent accredited tester.

However it is permissible for testers to be an employee of the legal owner of an apparatus, as long as the conflict of interest can be managed by the tester and the process remains free from the influence of owners or employers.

Irrespective of the affiliations between owners, employers, and accredited testers, it is responsibility of the tester to ensure that conflicts of interest are managed appropriately and all testers must endeavour to remain independent and objective at all times.

Note that the EPA, as part of its audit process, will seek to identify conflicts of interest and ensure they have been managed to its satisfaction.

3.2 Liabilities

Contracts or commitments between accredited testers and owners of diagnostic X-ray apparatus are a commercial arrangement, and any financial impositions and other liabilities resulting from work performed by an accredited tester are solely between tester and owner.

3.3 EPA Protocols

Each apparatus type (eg Plain Dental, Image Intensifier, Mammography, Plain Medical, etc.) require tests to be performed that are specific to that type of apparatus. The nature of the tests are governed by the Regulations applicable to the given apparatus and at least one test is aimed to ensure that exposure of persons to ionising radiation is kept as low as reasonably achievable (ALARA), social and economic factors being taken into account.

Note that ALARA is a legal obligation for all persons, including testers, carrying on an activity related to radioactive substances or ionising radiation apparatus (refer section 23 of the RPC Act).

To ensure that compliance testing is conducted in accordance with the Regulations and the Section 23 of the RPC Act, the EPA has established protocols for each apparatus type.

3.4 Compliance Statement

Under section 32 of the RPC Act ionising radiation apparatus must be registered in the name of the owner of the apparatus, but an apparatus cannot be registered unless it has been constructed, shielded, and installed in accordance with the Regulations.

To confirm compliance with the Regulations and the RPC Act testers must within 14 days of the date of testing, submit to the EPA a signed Compliance Statement for each apparatus tested. A Compliance Statement pro forma for each

apparatus type is available from the EPA. The tester must retain a copy of the signed Compliance Statement for their records and may if they wish (but are not obligated to) provide the owner with a copy.

Once received, the EPA will evaluate each Compliance Statement for correctness and if the statement indicates full compliance, will register the apparatus and issue the owner with a registration certificate. However, if the Compliance Statement indicates one or more non-compliances the EPA will inform the owner of any corrective action they must take and a timeframe in which it must be done.

3.5 Test Report

Testers are required to document their test results in the form of a Test Report. The preparation of the report is the responsibility of the accredited tester, with its form and style at the discretion of the tester. However results must be recorded clearly and accurately. In particular any non-compliance issues must be adequately documented to ensure that any person, that might be engaged by the owner to rectify non-compliances, can do so on the basis of the information contained in the report. Therefore, for each apparatus tested, the tester must, within 14 days of the date of testing, provide a copy of a Test Report to the owner.

Note that the tester need not provide the EPA with a copy of the Test Report unless it is part of the probationary period as discussed in section 2.4 or as requested by the EPA as part of an audit as discussed in section 5.1.

3.6 Record keeping

Accredited testers are required to prepare and retain copies of at least the documents that are mandatory for the TPC program. These mandatory documents are a Compliance Statement and Test Report for each apparatus tested. These records must be kept for a period of no less than five years or unless otherwise informed in writing by the EPA.

3.7 Termination of accreditation

An accredited tester (either probationary or full) who has had their accreditation cancelled, by written notification, or has allowed their licence (to operate a ionising radiation apparatus) to expire, will be considered to have had their accreditation terminated and will no longer be able to offer their services as an accredited tester.

3.8 Code of Conduct

Under the RPC Act, persons have obligations in relation to their licence to operate an ionising radiation apparatus. In addition, the EPA has established a Code of Conduct (the Code), as specified in Annex A, that applies to all probationary and fully accredited testers. Failure to follow the Code may result in the suspension or cancellation of accreditation.

4 Information for owners

4.1 Overview

Owners of an ionising radiation apparatus have significant legal obligations to ensure that the apparatus remains at all times compliant with the Regulations. As such owners may, at any time, seek to engage suitable persons to repair, maintain, and test the apparatus to ensure it is compliant. Such persons need not be accredited testers.

However, under the TPC program, only an accredited tester may make a formal determination of compliance as prerequisite for registration. The accredited tester performs compliance tests in accordance with the EPA Protocols relevant to the type of apparatus under test, and can make a declaration that confirms the apparatus is constructed, shielded, and installed in accordance with the Regulations. This confirmation is by means of a Compliance Statement the tester must provide to the EPA, within 14 days of the date of the test.

On the basis of information provided in the Compliance Statement the EPA will either register the apparatus, in the case of a fully compliant apparatus, or provide the owner with an opportunity to rectify any non compliance issues (refer Section 4.3). A flow chart summarising this process is shown in Figure 2 of Annex B.

4.2 Engaging an accredited tester

Prior to engaging an accredited tester, owners must ensure that they have submitted an application to register an ionising radiation apparatus (available from the EPA website at <www.epa.sa.gov.au/radiation.html>). Normally this should be done before the installation of the apparatus is finalised.

On receiving an application, the EPA will provide the owner with a list of accredited testers and a timeframe in which the owner must have the apparatus compliance tested by an accredited tester. In some circumstances, the EPA may notify the owner, in writing, that the X-ray apparatus must not be used until it has been compliance tested by an authorised person and found to be satisfactory.

An owner may engage the services an accredited tester of their choice. Contracts or commitments between accredited testers and owners are a commercial arrangement and any financial impositions and other liabilities resulting from work performed by an accredited tester are solely between owner and tester.

4.3 Non-compliant apparatus

In some cases, the Compliance Statement may indicate the apparatus, its installation, or shielding are not fully compliant with the Regulations. In response, the EPA will notify the owner, in writing, of the areas where the non-compliances exist and a timeframe for which they must be rectified.

To assist owners the accredited tester must, within 14 days of the date of testing, provide the owner with a copy of the results of the compliance test in the form of a Test Report. The report should provide owners and service personnel all the information required to rectify the non-compliance issues. Once rectified the apparatus need not be compliance tested again, but owners must notify the EPA, in writing, that the compliance issues have been rectified and provide evidence as required by the EPA.

Note that an accredited tester may or may not also install and service X-ray apparatus and vice-versa. It is not a requirement that service personnel be accredited or that owners use an accredited tester to perform installation and service work, including rectification of compliance issues.

Note also that the EPA may, as part of the audit process and in relation to an owner's application for registration of an ionising radiation apparatus, confirm the validity of compliance with the Compliance Statement. This may involve a site visit by EPA Officers, a statutory declaration from the owner, or similar.

4.4 Affiliations and conflicts of interest

An owner of a diagnostic X-ray apparatus must use the services of an accredited tester who is sufficiently independent so that the tester can perform the compliance tests and make a determination of compliance in an objective manner and without influence from the owner. Hence, a person is not permitted to make a declaration of compliance for an apparatus for which they are the legal owner. They may, however, utilise accredited persons who are in their employ or employed in the same organisation as the owner.

5 The role of the EPA

5.1 Administration

The EPA is responsible for administering the RPC Act and the Regulations and provides an oversight of all activities relating to the TPC program. It does this by ensuring that testers have appropriate qualifications and meet a satisfactory standard of competence before being granted accreditation and that those standards are maintained after accreditation. Each tester is expected to adhere to the Code of Conduct (Annex A).

Through the audit process the EPA will also maintain the integrity of TPC program by ensuring that tests are performed in accordance with the EPA Protocols and that relationships between owners, employers, and testers and any associated conflicts of interest are appropriately managed.

5.2 Audits

The EPA may conduct audits of accredited testers or owners of apparatus. The purpose of an audit is twofold: to ensure that the integrity of the TPC program is maintained and to provide owners and testers with appropriate advice and feedback on any matters relating to compliance or the TPC program.

Notification for an audit will be in writing. Owners and/or accredited testers will have 30 days from the date of written notification to provide the requested information, which may include, but not necessarily be limited to, the following:

- prior to the registration of the apparatus, owners are to demonstrate that potential conflicts of interest have been identified and appropriately managed
- prior to the registration of the apparatus, owners are to demonstrate that any non-compliances have been rectified
- accredited testers must provide one or more Test Reports from compliance tests they have performed at any time in the last five years
- accredited testers must provide evidence that they have retained a copy of Compliance Statements from compliance tests they have performed at any time in the last five years
- accredited testers must provide evidence that all test instruments used are appropriately calibrated.

5.3 Correspondence

From time to time the EPA may need to provide testers with information, such as changes to the TPC program, points of clarification, or additional material; or request information from testers such as during an audit. Correspondence may be by telephone, letter, fax, or by email. All accredited testers must have a valid email address.

6 References

- [1] Application Form—Accreditation as a compliance tester of diagnostic X-ray apparatus,
<www.epa.sa.gov.au/environmental_info/radiation/regulation_of_x-ray_machines/third_party_acceditation>
- [2] Radiation Protection and Control Act 1982,
<www.legislation.sa.gov.au/LZ/C/A/RADIATION%20PROTECTION%20AND%20CONTROL%20ACT%201982.aspx>
- [3] Radiation Protection and Control (Ionising Radiation) Regulations 2000,
<www.legislation.sa.gov.au/LZ/C/R/RADIATION%20PROTECTION%20AND%20CONTROL%20%28IONISING%20RADIATION%29%20REGULATIONS%202000.aspx>

Annex A Code of Conduct

The following Code of Conduct applies to all accredited testers authorised under the Third Party Certification program in South Australia.

- A person cannot be the accredited tester of an apparatus for which they are the legal owner.
- An accredited tester may perform compliance testing of an apparatus for which their employer is the legal owner, as long as conflicts of interest are managed to the satisfaction of the EPA.
- An accredited tester must endeavour to identify and manage potential conflicts of interests at all times when acting in their capacity as an accredited tester.
- A person must at all times, when acting in their capacity as an accredited tester, behave in a legal and ethical manner and must not engage in any activity that may adversely affect the integrity of the Third Party Certification program.
- An accredited tester must maintain a valid licence to operate an ionising radiation apparatus.
- An accredited tester must maintain a valid email address.
- An accredited tester must, within 14 days of the date of any change to their valid email address, inform the EPA in writing of such a change.
- An accredited tester must, within 14 days of the date of compliance testing an apparatus, provide to the EPA, a signed, original Compliance Statement for the apparatus tested.
- An accredited tester must, within 14 days of the date of compliance testing, provide the owner of the apparatus, a copy of the Test Report. It may be a hard or soft copy, as agreed earlier with the owner.
- An accredited tester must retain a copy of a Compliance Statement for each apparatus tested for a period of no less than five years.
- An accredited tester must retain a copy of a Test Report for each apparatus tested for a period of no less than five years.
- An accredited tester must make available to the EPA, within 30 days of the date of written notification, any information requested that relates to the Third Party Certification program for the purposes of an EPA audit.

Annex B Flow charts

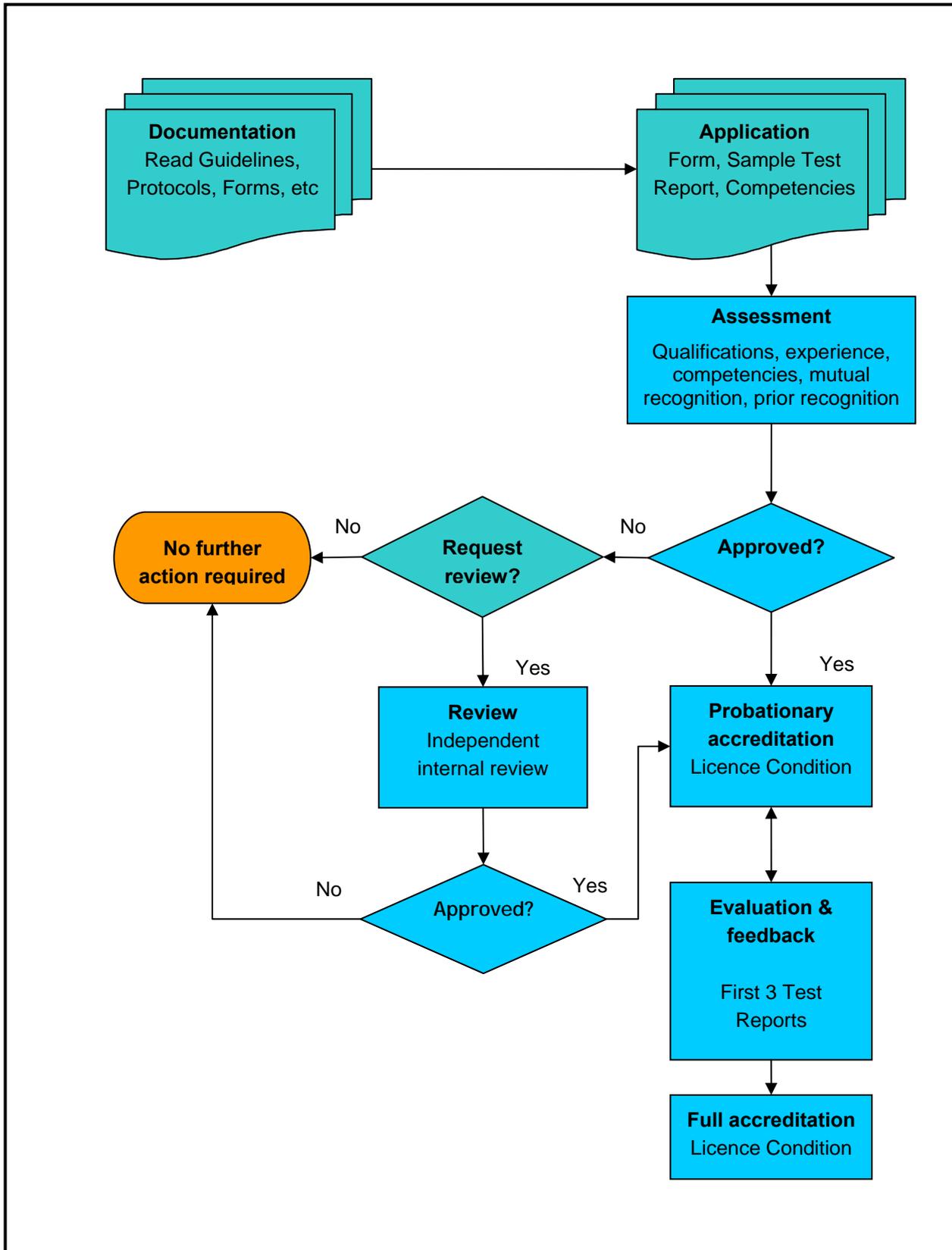


Figure 1 Application for accreditation

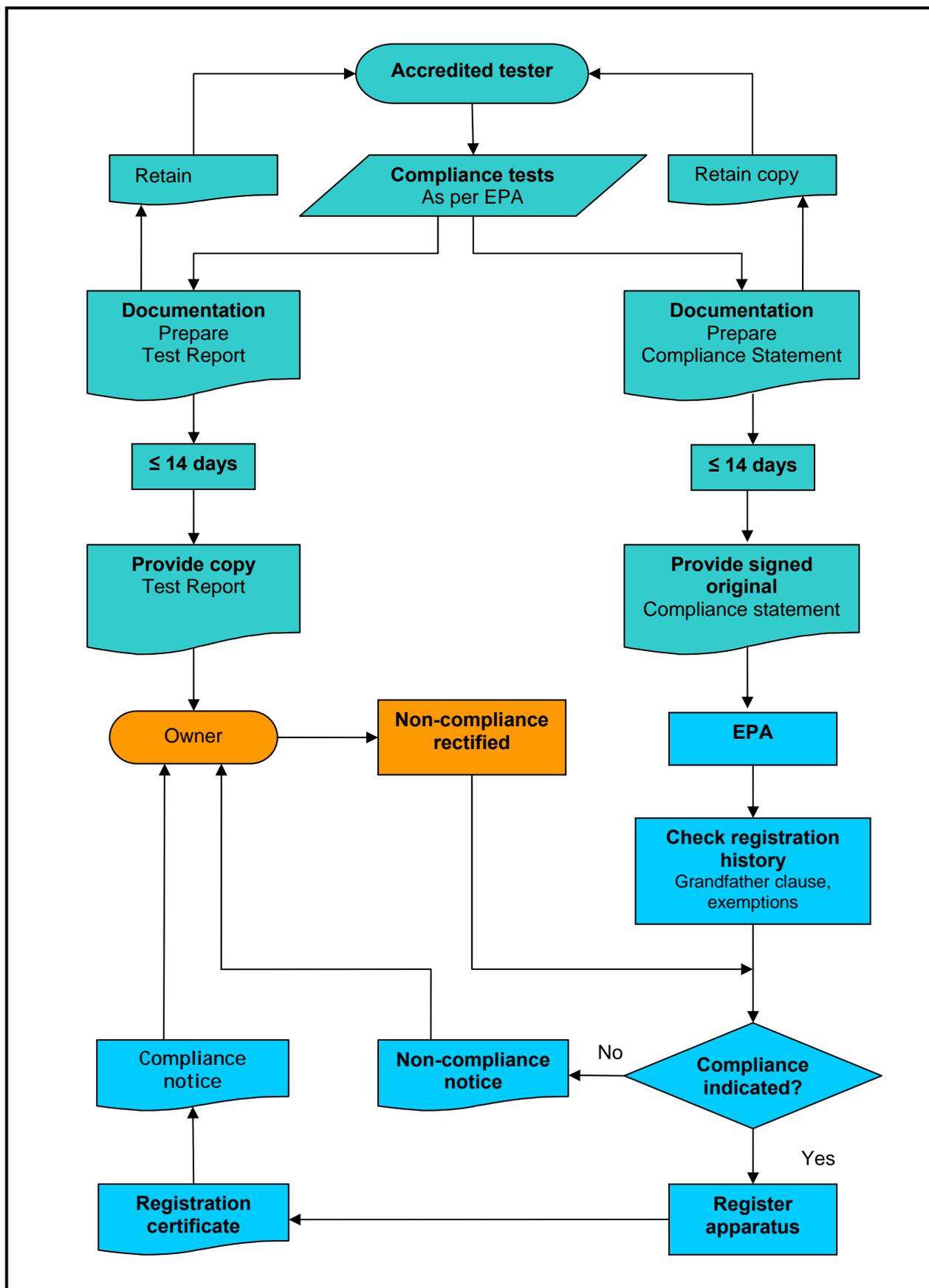


Figure 2 Compliance and registration process