

Joint Accreditation System of Australia and New Zealand

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**GENERAL REQUIREMENTS FOR BODIES OPERATING
ASSESSMENT AND ACCREDITATION
OF GENERAL PRACTICES FOR RECOGNITION UNDER THE
PRACTICE INCENTIVES PROGRAM (PIP)**

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TABLE OF CONTENTS

0. INTRODUCTION	4
1. OBJECT AND FIELD OF APPLICATION.....	5
2. REFERENCES.....	5
3. DEFINITIONS.....	5
4. GENERAL REQUIREMENTS	7
5. REQUIREMENTS FOR ACCREDITATION BODIES.....	8
5.1. Accreditation body.....	8
5.1.1. <i>General provisions</i>	8
5.1.2. <i>Organization</i>	9
5.1.3. <i>Subcontracting</i>	15
5.1.4. <i>Quality system</i>	15
5.1.5. <i>Conditions for granting, maintaining, extending, reducing, suspending, and withdrawing accreditation</i>	17
5.1.6. <i>Internal audits and management reviews</i>	18
5.1.7. <i>Documentation</i>	20
5.1.8. <i>Records</i>	20
5.1.9. <i>Confidentiality</i>	21
5.2. Accreditation body personnel	21
5.2.1. <i>General</i>	21
5.2.2. <i>Qualification criteria for surveyors and technical experts</i>	22
5.2.3. <i>Selection procedure</i>	25
5.2.4. <i>Contracting of assessment personnel</i>	28
5.2.5. <i>Assessment personnel records</i>	28
5.2.6. <i>Procedures for assessment teams</i>	28
5.3. Changes in the accreditation requirements	29
5.4. Appeals, complaints and disputes.....	29
6. REQUIREMENTS FOR ACCREDITATION OF A GENERAL PRACTICE	29
6.1. Application for accreditation.....	30
6.1.1. <i>Information on the procedure</i>	30
6.1.2. <i>The application</i>	30
6.2. Preparation for assessment	31
6.3. Assessment	32
6.4. Assessment report.....	32
6.5. Decision on accreditation.....	33
6.6. Surveillance and reassessment procedures.....	34
6.7. Use of certificates and logos	36

0. INTRODUCTION

0.1. The authorisation and distribution of this Joint Accreditation System of Australia and New Zealand (JAS-ANZ) procedure is the culmination of a developmental process that included the drafting of criteria by a JAS-ANZ General Practice Technical Committee that was representative of interested parties.

0.2. The General Practice Technical Committee was formed in response to a request from the Australian Department of Health and Aged Care to establish criteria to be met by bodies accrediting general practices to the Royal Australian College of General Practitioners (RACGP) *Standards for General Practices, 2nd edition* (RACGP Entry Standards). This process was itself in response to a decision by Australian Government to require accreditation of general practices as a pre-requisite to funding through the Practice Incentives Program (PIP).

0.3. In order to ensure that accreditation bodies are competent to undertake assessments to the RACGP Entry Standards, it was requested that JAS-ANZ develop an appropriate accreditation program. The internationally recognised standard *ISO/IEC Guide 62 – General requirements for bodies operating assessment and certification of quality systems*, and the IAF¹ interpretation of this document, have been used as the basis for the JAS-ANZ accreditation criteria.

0.4. The clauses in BOLD numbering reflect the requirements of ISO/IEC Guide 62 as modified by the General Practice Accreditation Technical Committee (GPATC) to reflect the requirements of this program and the Guidance clauses are based on IAF Guidance.

0.5. Accreditation of a general practice is a statement as to compliance of the general practice with the requirements of the accreditation standard. It is important that accreditation bodies and stakeholders appreciate that accreditation of a general practice is not a statement by the accreditation body guaranteeing the quality or acceptability of the service provided by the general practice or practitioner or that all legislative requirements are being or will be met at all times.

0.6. It is for the general practice being accredited to develop its own management systems, and, other than where relevant legislative requirements specify to the contrary, it is for the general practice to decide how the various components of these shall be arranged. The degree of integration between the various management system components will vary from organisation to organisation. JAS-ANZ therefore requires that accreditation bodies take into account the culture and practices of their clients in respect of the integration of management systems within the wider organisation.

¹ IAF: International Accreditation Forum

1. OBJECT AND FIELD OF APPLICATION

1.1. This procedure specifies general requirements for a body operating general practice accreditation to meet if it is to be accredited by JAS-ANZ. This procedure does not cover bodies accrediting general practice personnel.

- In the event of conflict between the requirements of this document and that of referenced normative documents, the requirements of these criteria will take precedence.

- The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC Guide 62, are mandatory. The term “should” is used to indicate those provisions which, although they constitute guidance for the application of the requirements, are expected to be adopted by an accreditation body. Any variation from the guidance by an accreditation body shall be an exception. Such variations will only be permitted on a case by case basis after the accreditation body has demonstrated to JAS-ANZ that the exception meets the relevant requirements clause of ISO/IEC Guide 62 and the intent of this Guidance in some equivalent way.

2. REFERENCES

- A. RACGP 1996 Entry Standards for General Practice (referred to in this document as the RACGP Entry Standards).
- B. ISO/IEC Guide 62:1996, General requirements for bodies operating assessment and certification of quality systems.
- C. IAF Guidance on the application of ISO/IEC Guide 62, Issue 1: 1996.
- D. JAS-ANZ Procedure 03 - Rules of procedure governing the use of the accreditation mark.
- E. JAS-ANZ Policy 2/99 - Recognition by JAS-ANZ of standards as being appropriate for accredited certification
- F. ISO 10011-1:1990 – Guidelines for auditing quality systems Part 1: Auditing

3. DEFINITIONS

As a general rule, definitions of ISO/IEC Guide 2 and ISO 8402 are applicable. The following definitions either vary or supplement those definitions to cater for this programme. In particular, definitions 3.1., 3.2., 3.3., 3.4. and 3.5. refer to ‘accreditation’ where ISO would use the term ‘certification’. The term accreditation has been used for this program because of its historical and regulatory use in respect of the Department of Health and Aged Care’s Practice Incentive Program.

3.1. Accreditation body: A third party that assesses and accredits the management system of general practices with respect to published accreditation standards and any supplementary documentation required under the system.

3.2. Accreditation document: Document indicating that a general practice conforms to the accreditation standard.

3.3. Accreditation standard: A document, approved by a recognised body, that provides rules, guidelines or characteristics for activities or their results.

3.4. Accreditation system: System having its own rules of procedure and management for carrying out the assessment leading to the issuance of an accreditation document and its subsequent maintenance.

3.5. Assessment: All activities related to the accreditation of a general practice to determine whether the organisation meets all the requirements of the relevant clauses of the accreditation standard necessary for granting accreditation, and whether they are effectively implemented, including documentation review, practice visit, preparation and consideration of the practice visit report and other relevant activities necessary to provide sufficient information to allow a decision to be made as to whether accreditation shall be granted.

3.6. General practice: General Practice “is that component of the health care system which provides initial, continuing, comprehensive and coordinated medical care for all individuals, families and communities and which integrates biomedical, psychological, social and environmental understandings of health”.²

3.7. Logo: A symbol used by a body as a form of identification, usually stylised. A logo may also be a mark.

3.8. Mark: A legally registered trade mark or otherwise protected symbol which is issued under the rules of JAS-ANZ or of an accreditation body indicating that adequate confidence in the systems operated by a body has been demonstrated or that relevant products or individuals conform to the requirements of a specified standard.

JAS-ANZ Note 1: *The legal registration shall provide sufficient protection to enable the accreditation body to control the use of certificates and logos.*

3.9. Nonconformity: The absence of, or the failure to implement and maintain, one or more mandatory elements of the standard, or a situation which would, on the basis of available objective evidence raise significant doubt as to the compliance of the general practice.

The accreditation body is free to define different grades of deficiency and areas for improvement (e.g. Major and Minor Nonconformities, Observations, etc.) unless the accreditation standard specifies to the contrary. However all deficiencies which equate to the above definition of nonconformity should be dealt with as laid down in G.6.5.2. and G.6.6.1.

² RACGP definition of General Practice approved 26/27 July 1997 Appendix 4 – 29/10 Council Minutes.

3.10. Practice Visit: Systematic and independent examination to determine whether the general practice's system complies with the accreditation standard, and whether the system is implemented effectively and is suitable to achieve objectives.

3.11. RACGP Entry Standards: The Royal Australian College of General Practitioners (RACGP) *Standards for General Practices, 2nd edition*, as published from time to time by the RACGP.

3.12. Surveyor: A person qualified, as defined in clause 5.2 of this procedure, to perform practice visits.

Guidance to clause 3. (G.3.1. - G.3.2.)

G.3.1. The Commonwealth currently recognises the RACGP Entry Standards for as the appropriate standard for the purpose of the accrediting of general practices for direct entry to the Practice Incentive Program (PIP).

G.3.2. JAS-ANZ may apply other limitations to the accreditation, for example a restriction to certain offices or locations if it is not satisfied all such offices or locations meet requirements.

4. GENERAL REQUIREMENTS

4.1. Bodies seeking accreditation by JAS-ANZ for the operation of a general practice accreditation scheme shall establish and maintain a quality system in accordance with this procedure.

4.2. The guidance provided in this document has been based on guidance developed by the International Accreditation Forum (IAF) to enable bodies such as JAS-ANZ to harmonise their application of the standards against which they are bound to assess accreditation bodies.

4.3. As ISO/IEC Guide 62 and the IAF Guidance were developed in the context of quality management systems, they have been modified to be relevant to the assessment and accreditation of general practices.

4.4. An accreditation body may seek advice from JAS-ANZ on any matter which may affect its own accreditation by JAS-ANZ.

5. REQUIREMENTS FOR ACCREDITATION BODIES

5.1. Accreditation body

5.1.1. General provisions

5.1.1.1. The policies and procedures under which the accreditation body operates shall be nondiscriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants other than as specified in this procedure.

5.1.1.2. The accreditation body shall make its services accessible to all applicants. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the general practice or membership of any association or group, nor shall accreditation be conditional upon the number of general practices already accredited.

5.1.1.3. The criteria against which an applicant is assessed shall be those outlined in the accreditation standard. If an explanation is required as to the application of this document, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the accreditation body.

5.1.1.4. The accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

Guidance to clause 5.1.1. (G.5.1.1. – G.5.1.4.)

G.5.1.1. The provision “if an explanation is required” in clause 5.1.1.3. shall be applied by limiting such documents to those recognised by JAS-ANZ. The term “and any supplementary documentation required under the system” used in clauses 3.1. shall mean documentation recognised by JAS-ANZ which provides additional or supplementary guidance as to the application of the accreditation standard. See also guidance G.5.1.4. In exceptional cases the accreditation body itself may issue supplementary documentation, subject to the requirements of clause 5.1.1.3.

G.5.1.2. Accreditation of a general practice shall give adequate confidence that the general practice meets specified requirements. An accreditation of conformity of a general practice to the accreditation standard shall demonstrate that a general practice has addressed the requirements of that standard.

G.5.1.3. Accreditation bodies shall not practice any form of discrimination such as hidden discrimination by speeding up or delaying applications for accreditation.

G.5.1.4. Where an accreditation body accredits a general practice (within the scope of its JAS-ANZ accreditation) against a standard or other normative document the document shall comply with JAS-ANZ policy 2/99.

5.1.2. Organization

The structure of the accreditation body shall be such as to give confidence in its accreditations. In particular, the accreditation body shall:

- a) be impartial;
- b) be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation;
- c) identify the management (committee, group or person) which will have overall responsibility for all of the following:
 - 1) performance of assessment and accreditation as defined in this procedure,
 - 2) the formulation of policy matters relating to the operation of the accreditation body,
 - 3) decisions on accreditation,
 - 4) supervision of the implementation of its policies,
 - 5) supervision of the finances of the accreditation body,
 - 6) delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;
- d) have documents which demonstrate that it is a legal entity;
- e) have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the accreditation body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system;
- f) ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;
- g) have rights and responsibilities relevant to its accreditation activities;
- h) have adequate arrangements to cover liabilities arising from its operations and/or activities;
- i) have the financial stability and resources required for the operation of an accreditation system;
- j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing accreditation functions relating to the type, range and volume of work performed, under a responsible senior executive;
- k) have a quality system, as outlined in 5.1.4, giving confidence in its ability to operate an accreditation system for general practice;
- l) have policies and procedures that distinguish between general practice accreditation and any other activities in which the body is engaged;

- m) together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;**
- n) have formal rules and structures for the appointment and operation of any committees which are involved in the accreditation process; such committees shall be free from any commercial, financial and other pressure that might influence decisions (see note 1);**
- o) ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditations and shall not offer or provide**
 - 1) those services that it accredits others to perform,**
 - 2) consulting services to obtain or maintain accreditation,**
 - 3) services to design, implement or maintain quality systems (see note 2);**
- p) have policies and procedures for the resolution of complaints, appeals and disputes received from general practices or other parties about the handling of accreditation or any other related matters;**
- q) obtain a declaration for quality assurance activities under Part VC of the Health Insurance Act 1973 unless advised otherwise in writing by the Department of Health and Aged Care.**

NOTES

- 1 A structure where members are chosen to provide a balance of interests, where no single interest predominates, will be deemed to satisfy this provision.**
- 2 Other products, processes or services may be offered, directly or indirectly, provided they do not compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.**

Guidance to clause 5.1.2. (G.5.1.5. – G5.1.30.)

G.5.1.5. JAS-ANZ accreditation shall only be granted to a body which is a legal entity as referenced in clause 5.1.2.d) and will be confined to declared scopes, and possibly, activities and locations. If the accreditation activities are carried out by a legal entity that is part of a larger organisation, the links with other parts of the larger organisation shall be clearly defined and shall demonstrate that no conflict of interest exists as defined in guidance G.5.1.17. and G.5.1.18. Relevant information on activities performed by the other parts of the larger organisation shall be given by the accreditation body to JAS-ANZ.

G.5.1.6. Demonstration that an accreditation body is a legal entity, as required under clause 5.1.2.d) means that if an applicant accreditation body is part of a larger legal entity, JAS-ANZ accreditation shall only be granted to the entire legal entity. In such a situation, the structure of the entire legal entity may be subject to audit by JAS-ANZ, in order to pursue specific audit trails and/or review records relating to the accreditation body. The part of the legal entity that forms the actual accreditation body may trade under a distinctive name, which shall appear on the JAS-ANZ accreditation certificate.

For the purposes of clause 5.1.2.d) accreditation bodies which are part of government, or are government departments, will be deemed to be legal entities on the basis of their governmental status. Such bodies' status and structure shall be formally documented and the body shall comply with all the requirements of this procedure.

G.5.1.7. Impartiality and independence of the accreditation body shall be assured at three levels

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- a) Strategic and Policy;
- b) Decisions on Accreditation;
- c) Assessment.

The guidance to clause 5.1.2. is intended to provide for impartiality and independence at all three levels.

G.5.1.8. Impartiality, as required by clause 5.1.2.a) can only be safeguarded by a structure, as required by clause 5.1.2.e) that enables "the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system".

G.5.1.9. The management established to meet the requirements of clause 5.1.2.c) does not have to be the same as the structure required under clause 5.1.2.e).

G.5.1.10. Conformance with clause 5.1.2.e) has the effect of counteracting any tendency on the part of the owners of an accreditation body to allow commercial or other considerations to prevent the consistent technically objective provision of its service. This is particularly necessary when the finance to set up an accreditation body has been provided by a particular interest which predominates in the shareholding and/or the board of directors.

G.5.1.11. Clause 5.1.2.e) therefore requires that the documented structure of the accreditation body has built into it provision for the participation of all the significantly concerned parties. This shall normally be through some kind of committee. The structure established shall be prescribed in the accreditation body's written constitution and shall not be subject to change without notification to JAS-ANZ. The term "written constitution" shall mean a legal document i.e. Constitution, Articles of Association, By Laws etc.

JAS-ANZ Note 2: *The term "written constitution" shall mean a legal document i.e. Articles of Association, By Laws etc.*

G.5.1.12. It is always a question of judgement whether all parties significantly concerned in the system are able to participate. What is essential is that all identifiable major interests shall be given the opportunity to participate, and that a balance of interests, where no single interest predominates is achieved. Consumers shall be regarded as a significantly concerned party.

G.5.1.13. The management responsible for the various functions described in clause 5.1.2.c) shall provide all the necessary information, including the reasons for all significant decisions and actions, and the selection of persons responsible for particular activities, in respect of accreditation, to the committee or equivalent referred to in clause 5.1.2.e), to enable it to ensure proper and impartial accreditation. If the advice of this committee or equivalent is not respected in any matter by the management, the committee or equivalent shall take appropriate measures, which may include informing JAS-ANZ.

G.5.1.14. If the accreditation body and an applicant or accredited general practice are both part of government, the two bodies shall not directly report to a person or group having operational responsibility for both. The accreditation body shall, in view of the impartiality requirement, be able to demonstrate how it deals with such a case.

G.5.1.15. If the decision to issue or withdraw accreditation in accordance with clause 5.1.2.n) is taken by a committee comprising, among others, representatives from one or more accredited general practices, the operational procedures of the accreditation body shall ensure that these representatives do not have a significant influence on decision making. This can e.g. be assured by the distribution of voting rights or some other equivalent means.

G.5.1.16. Clause 5.1.2.o) addresses two separate requirements. Firstly, the accreditation body shall not under any circumstances provide the services identified in sub-paras 1), 2) and 3) of that clause. Secondly, although there is no specific restriction on the services or activities a related body may provide, these shall not affect the confidentiality, objectivity or impartiality of the accreditation body.

G.5.1.17. Consultancy is considered to be participation in an active creative manner in the development of the management system to be assessed by, for example:

- a) preparing or producing manuals, handbooks or procedures;
- b) participating in the decision making process regarding management system matters;
- c) giving specific advice towards the development and implementation of management systems for eventual accreditation.

Note: Management systems as referred to in guidance G.5.1.17. include all aspects of such systems, including financial.

G.5.1.18. Accreditation bodies can carry out the following duties without them being considered as consultancy or having a potential conflict of interest

- a) accreditation including information meetings, planning meetings, examination of documents, practice visits and follow up of non-compliances;

- b) arranging and participating as a lecturer in training courses, provided that where these courses relate to the accreditation standard, management systems or assessment they shall confine themselves to the provision of generic information and advice which is freely available in the public domain, i.e. they shall not provide company specific advice which contravenes the requirements of G.5.1.17.c);
- c) making available or publishing on request information on the basis for the accreditation body's interpretation of the requirements of the assessment standards;
- d) activities prior to practice visits aimed solely at determining readiness for assessment; but such activities shall not result in the provision of recommendations or advice that would contravene the requirements of G.5.1.17 and the accreditation body shall be able to confirm that such activities do not contravene these requirements and that they are not used to justify a reduction in the eventual assessment duration;
- e) performing second and third party assessments or audits according to other standards or regulations than those being part of the scope of accreditation;
- f) adding value during assessments and surveillance visits, e.g., by identifying opportunities for improvement, as they become evident, during the practice visit without recommending specific solutions.

G.5.1.19. Consultancy by a related body and accreditation shall never be marketed together and nothing shall be stated in marketing material or presentation, written or oral, to give the impression that the two activities are linked. It is the duty of the accreditation body to ensure that none of its clients is given the impression that the use of both services (accreditation and consultancy), would bring any business advantage to the client so that the accreditation remains, and is seen to remain, impartial.

G.5.1.20. Nothing shall be said by an accreditation body that would suggest that accreditation would be simpler, easier or less expensive if any specified consultancy or training services were used.

G.5.1.21. A related body, as referred to in clause 5.1.2.o), is one which is linked to the accreditation body by common ownership or directors, contractual arrangement, a common name, informal understanding or other means such that the related body has a vested interest in the outcome of an assessment or has a potential ability to influence the outcome of an assessment.

G.5.1.22. The accreditation body shall analyse and document the relationship with such related bodies to determine the possibilities for conflict of interest with provision of accreditation and identify those bodies and activities that could, if not subject to appropriate controls, affect confidentiality, objectivity or impartiality.

G.5.1.23. Accreditation bodies shall demonstrate how they manage their accreditation business and any other activities so as to eliminate actual conflict of interest and minimise any identified risk to impartiality. The demonstration shall cover all potential sources of conflict of interest, whether they arise from within the accreditation body or from the activities of related bodies. JAS-ANZ will

expect accreditation bodies to open up these processes for audit. This may include, to the extent practicable and justified, pursuit of audit trails to review records of both the accreditation body and its related body for the activity under consideration. In considering the extent of such audit trails account shall be taken of the accreditation body's history of impartial accreditation. If evidence of failure to maintain impartiality is found there may be a need to extend the audit trail back into the related bodies to provide assurance that control over potential conflicts of interest has been re-established.

G.5.1.24. The requirements of clause 5.1. and clause 5.2.3. mean that people who have provided consultancy, including those acting in a managerial capacity, shall not be employed to conduct a practice visit as part of the accreditation process if they have been involved in any consultancy activities towards the general practice in question, (or any company related to that general practice), within the last two years. Situations such as an employer's involvement or previous involvement with the general practice being assessed may present individuals involved in any part of the accreditation process with a conflict of interest. The accreditation body has a responsibility to identify and evaluate such situations and to assign responsibilities and tasks so as to ensure that impartiality is not compromised.

G.5.1.25. The senior executive, staff and/or personnel mentioned in clause 5.1.2. need not necessarily be full-time personnel, but their other employment shall not be such as to compromise their impartiality.

G.5.1.26. The accreditation body shall require all assessment sub-contractors or external surveyors to give undertakings regarding the marketing of any consultancy services equivalent to those required by guidance G.5.1.19. and G.5.1.20.

G.5.1.27. The accreditation body shall be responsible for ensuring that neither related bodies, nor sub-contractors, nor external surveyors operate in breach of the undertakings that they have given. It shall also be responsible for implementing appropriate corrective action in the event such a breach is identified.

G.5.1.28. The accreditation body shall be independent from the body or bodies (including any individuals) that provide any internal audit of the general practice's management system subject to accreditation.

G.5.1.29. A surveyor shall explain the practice visit findings and/or clarify the requirements of the accreditation standard during the practice visit and /or at the closing meeting but shall not give prescriptive advice or consultancy as part of an assessment.

G.5.1.30. The policies and procedures referred to in 5.1.2. p) shall ensure that all disputes and complaints are dealt with in a constructive and timely manner. Where operation of such procedures has not resulted in the acceptable resolution of the matter or where the proposed procedure is unacceptable to the complainant or other parties involved, the accreditation body's procedures shall provide for an appeals process. This appeals procedure shall include provision for the following

- the opportunity for the appellant to formally present its case;

- provision of an independent element or other means to ensure the impartiality of the appeals process;
- provision to the appellant of a written statement of the appeal findings including the reasons for the decisions reached.

The accreditation body shall ensure that all interested parties are made aware, as and when appropriate, of the existence of the appeals process and the procedures to be followed.

5.1.3. Subcontracting

When an accreditation body decides to subcontract work related to accreditation (e.g. practice visits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflict of interests, shall be drawn up. The accreditation body shall

- a) **take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending or withdrawing accreditation;**
- b) **ensure that the subcontracted body or person is competent and complies with the applicable provisions of these criteria and is not involved, either directly or through its employer, with the design, implementation or maintenance of a quality system in such a way that impartiality could be compromised;**
- c) **obtain the consent of the applicant or accredited general practice.**

NOTE 3. Requirements a) and b) are also relevant, by extension, when an accreditation body uses, for granting its own accreditation, work provided by another accreditation body with which it has signed an agreement.

Guidance to clause 5.1.3. (G.5.1.31. – G.5.1.32.)

G.5.1.31. An accreditation body may issue certificates on the basis of an assessment carried out by another body provided that the agreement with the subcontracted body requires it to comply with all the relevant requirements and, in particular, the requirements of clause 5.2. Assessments carried out by subcontracted bodies shall give the same confidence as assessments carried out by the accreditation body itself. Evaluation of the practice visit report and the decision on accreditation shall be made only by the accreditation body itself, and not by any other accreditation body. Where joint assessments are undertaken, each accreditation body shall satisfy itself that the whole of the assessment has been satisfactorily undertaken by competent surveyors.

G.5.1.32. Where an accreditation body issues certificates in accordance with guidance G.5.1.31. it shall have procedures that ensure conformity with all relevant clauses of this document by subcontracted bodies.

5.1.4. Quality system

5.1.4.1. The management of the accreditation body with executive responsibility for

quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

5.1.4.2. The accreditation body shall operate a quality system in accordance with the relevant elements of this Guide and appropriate to the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the accreditation body. The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to

- a) ensure that a quality system is established, implemented and maintained in accordance with these criteria;
- b) report on the performance of the quality system to the management of the accreditation body for review and as a basis for improvement of the quality system.

5.1.4.3. The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

- a) a quality policy statement;
- b) a brief description of the legal status of the accreditation body, including the names of its owners, if applicable, and, if different, the names of the persons who control it;
- c) the names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel influencing the quality of the accreditation function;
- d) an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those taking decisions regarding accreditation;
- e) a description of the organization of the accreditation body, including details of the management (committee, group or person) identified in 5.1.2.c), its constitution, terms of reference and rules of procedure;
- f) the policy and procedures for conducting management reviews;
- g) administrative procedures including document control;
- h) the operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;
- i) the policy and procedures for the recruitment and training of accreditation body personnel (including surveyors) and monitoring their performance;
- j) a list of its subcontractors and details of the procedure for assessing, recording and monitoring their competence;

- k) its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;**
- l) the policy and procedures for implementing the accreditation process, including**
 - 1) the conditions for issue, retention and withdrawal of accreditation documents,**
 - 2) checks of the use and application of documents used in the accreditation of management systems,**
 - 3) the procedures for assessing and accrediting general practices' management systems,**
 - 4) the procedures for surveillance and reassessment of accredited general practices;**
- m) the policy and procedure for dealing with appeals, complaints and disputes;**
- n) the procedures for conducting internal audits based on the provisions of ISO 10011-1.**

Guidance to clause 5.1.4. (G.5.1.33.)

G.5.1.33. The description required by clause 5.1.4.3.e) shall specify which party or parties each member of a Board or a committee is representing.

5.1.5. Conditions for granting, maintaining, extending, reducing, suspending, and withdrawing accreditation

5.1.5.1. The accreditation body shall specify the conditions for granting, maintaining, reducing and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total, for all or part of the general practice's scope of accreditation. In particular, the accreditation body shall require the general practice to notify it promptly of any intended changes to the management system or other changes that may affect conformity.

5.1.5.2. The accreditation body shall require the general practice to have a documented management system which conforms to applicable accreditation standards or other normative documents to the extent that it is required by the accreditation standard and clause G.5.1.34.

5.1.5.3. The accreditation body shall have procedures to

- a) grant, maintain, withdraw and, if applicable, suspend accreditation;**
- b) extend or reduce the scope of accreditation;**
- c) conduct reassessment in the event of changes significantly affecting the activity and operation of the general practice (such as change of ownership or changes in key personnel), or if analysis of a complaint or any other information indicates that the accredited general practice no longer complies with the requirements of the**

accreditation body.

5.1.5.4. The accreditation body shall have documented procedures which shall be made available on request for

- a) **the initial assessment of a general practice's management system, in accordance with the provisions of ISO 10011-1;**
- b) **surveillance and reassessment of general practices' management systems in accordance with ISO 10011-1 on a periodic basis for continuing conformity with relevant requirements and for verifying and recording that a general practice takes corrective action on a timely basis to correct all nonconformities;**
- c) **identifying and recording nonconformities and the need for corrective action by general practices on a timely basis for such items as incorrect references to the accreditation or misleading use of accreditation information.**

Guidance to clause 5.1.5. (G.5.1.34. – G.5.1.36.)

G.5.1.34. An accreditation body shall require the general practice to have a system that is documented to the extent that it conforms to the accreditation standard and demonstrates that the general practice is capable of and demonstrates intent to meet requirements on an ongoing basis.

G.5.1.35. Where they are required by the accreditation standard, measures shall be established by the accreditation body to ensure the ongoing effectiveness of the general practice's management review and internal audit processes.

G.5.1.36. Accreditation of a general practice shall not be granted until there is sufficient evidence to demonstrate that the arrangements for management review and internal audit (where required by the accreditation standards) have been implemented, are effective and will be maintained.

5.1.6. Internal audits and management reviews

5.1.6.1. The accreditation body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is implemented and is effective. The accreditation body shall ensure that:

- a) **personnel responsible for the area audited are informed of the outcome of the audit;**
- b) **corrective action is taken in a timely and appropriate manner;**
- c) **the results of the audit are recorded.**

5.1.6.2. The accreditation body's management with executive responsibility shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of these criteria and the stated quality policy and objectives. Records of such reviews shall be maintained.

Guidance to clause 5.1.6. (G.5.1.37. – G.5.1.38.)

**Procedure No. 16 - GENERAL REQUIREMENTS FOR BODIES OPERATING ASSESSMENT AND
ACCREDITATION OF GENERAL PRACTICES FOR RECOGNITION UNDER THE
PRACTICE INCENTIVES PROGRAM (PIP)**

G.5.1.37. Clause 5.1.6. does not mention a specific period in which at least one complete internal audit of the accreditation body's management system and one management review of the accreditation body's management system shall take place. Complete internal audits followed by management reviews of the body's management system shall be carried out at least once each year. JAS-ANZ may specify a shorter period, depending on the degree of conformity with the requirements, as found in internal audits and reviews as well as in reports to JAS-ANZ

G.5.1.38. The records of internal audits and management reviews shall be made available to JAS-ANZ on request.

5.1.7. Documentation

5.1.7.1. The accreditation body shall document, update at regular intervals, and make available (through publications, electronic media or other means), on request,

- a) information about the authority under which the accreditation body operates;**
- b) a documented statement of its accreditation system including its rules and procedures for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;**
- c) information about the assessment and accreditation process;**
- d) a description of the means by which the accreditation body obtains financial support, and general information on the fees charged to applicants and accredited general practices;**
- e) a description of the rights and duties of applicants and accredited general practices, including requirements, restrictions or limitations on the use of the accreditation body's logo and on the ways of referring to the accreditation granted;**
- f) information on procedures for handling complaints, appeals and disputes;**
- g) a directory of accredited general practices, including their locations, describing the scope of accreditation granted to each;**
- h) information on the training and competencies of surveyors.**

5.1.7.2. The accreditation body shall establish and maintain procedures to control all documents and data that relate to its accreditation functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the accreditation body or general practice, when required to perform any function relating to the activities of an applicant or accredited general practice.

Guidance to clause 5.1.7. (G.5.1.39.)

G.5.1.39. The description of the means by which the accreditation body obtains financial support referred to in clause 5.1.7.1.d) shall be sufficient to show whether or not the accreditation body can retain its impartiality. The description shall also demonstrate that the accreditation body will have sufficient resources to continue its operations at least until the next re-assessment is due.

5.1.8. Records

5.1.8.1. The accreditation body shall maintain a record system to suit its particular

circumstances and to comply with existing regulations. The records shall demonstrate that the accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and other documents relating to granting, maintaining, extending, reducing, suspending or withdrawing accreditation. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and confidentiality of the information. The records shall be kept for a period of time so that continued confidence may be demonstrated for at least one full accreditation cycle, or as required by law.

5.1.8.2. The accreditation body shall have a policy and procedures for retaining records for a period consistent with its contractual, legal or other obligations. The accreditation body shall have a policy and procedures concerning access to these records consistent with clause 5.1.9.

5.1.9. Confidentiality

5.1.9.1. The accreditation body shall have adequate arrangements, consistent with applicable laws, to safeguard confidentiality of the information obtained in the course of its accreditation activities at all levels of its organization, including committees and external bodies or individuals acting on its behalf.

5.1.9.2. Except as required in this procedure, information about a particular patient or general practice shall not be disclosed to a third party without the written consent of the patient or the accredited general practice, as the case may be. Where the law requires information to be disclosed to a third party, the general practice shall be informed of the information provided, as permitted by the law.

Guidance to clause 5.1.9. (G.5.1.40. – G.5.1.41.)

G.5.1.40. The requirement as to confidentiality includes anyone who might gain access to information that the accreditation body shall keep confidential. Subcontracted personnel shall be required to keep all such information confidential, particularly from fellow employees and from their other employers.

G.5.1.41. The "written consent" mentioned in clause 5.1.9.2 only applies to confidential information.

5.2. Accreditation body personnel

5.2.1. General

5.2.1.1. The personnel of the accreditation body involved in accreditation shall be competent for the functions they perform.

5.2.1.2. Information on the relevant qualifications, training and experience of each member of the personnel involved in the accreditation process shall be maintained by the accreditation body. Records of training and experience shall be kept up to date.

5.2.1.3. Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.

Guidance to clause 5.2.1. (G.5.2.1. – G.5.2.4.)

G.5.2.1. Clause 5.1.2.j) means that across the whole of its accredited scope (or that part in which it operates) the accreditation body shall be able to conduct assessments using resources under its own control.

G.5.2.2. The term "resources under its own control" can include individual surveyors who work for the accreditation body on a contract basis, or other external resources. The accreditation body shall be in a position to manage, control and be responsible for the performance of all its resources and maintain comprehensive records controlling the suitability of all the staff it uses in particular areas, whether they are employees, employed on contract or provided by external bodies.

G.5.2.3. The management of the accreditation body shall have the resources to enable it to determine whether or not, and procedures to ensure that, individual surveyors are competent for the tasks they are required to perform within the scope of accreditation in which they are operating. The competence of surveyors may be established by verified background experience, specific training or briefing. The accreditation body shall be able to communicate effectively with all those whose services it uses, in particular it will take into account cultural and locational differences.

G.5.2.4. Accreditation bodies shall have personnel competent to:

- a) select and verify the competence of surveyors,
- b) brief surveyors and arrange any necessary training,
- c) decide on the granting, maintaining, withdrawing, suspending, extending, or reducing of accreditations, and
- d) set up and operate an appeals, complaints and disputes procedure.

5.2.2. Qualification criteria for surveyors and technical experts

5.2.2.1. In order to ensure that assessments are carried out effectively and uniformly, the accreditation body shall define the minimum relevant criteria for competence of surveyors and technical experts.

5.2.2.2. Technical experts are not required to comply with the requirements for surveyors. Guidance on their personal attributes may be obtained from ISO 10011-2:1991, clause 7.

Guidance to clause 5.2.2. (G.5.2.5. - G.5.2.12.)

G.5.2.5 General practitioner surveyors, at a minimum, shall satisfy the following criteria. They must be:

- a) Vocationally registered;
- b) Actively working in general practice during the last two (2) years;
- c) An experienced general practitioner, which means a general practitioner who has been actively in general practice as a vocationally registered general practitioner for four (4) years full time or equivalent pro-rata years.
- d) Trained in survey techniques. Training in the following areas should be regarded as particularly relevant:
 - Knowledge and understanding of the standards against which practice visits may be performed,
 - Assessment techniques of examining, questioning, evaluating, and reporting,
 - Additional skills required for managing an assessment or practice visit, such as planning, organising, communicating and directing.

G.5.2.6. Surveyors, who are not general practitioners and are people employed in general practice, at a minimum, shall satisfy the following criteria. They must be:

- a) Actively working in general practice;
- b) Must be experienced general practice staff, which means that the surveyor has a minimum of four (4) years experience (or the equivalent pro rata) in general practice of which the last two (2) years (pro-rata) are current experience,
- c) Must be trained in survey techniques (see G.5.2.5 d)).

G.5.2.7. Education. Surveyors will have completed at least secondary education, and have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in their officially recognised language.

G.5.2.8. Experience. Surveyor experience will be gained by participating in a minimum of five (5) audits within the first twelve (12) months as a general practice surveyor, supervised by an experienced surveyor. This experience shall include all stages of the assessment process, including documentation review, practice visit and reporting.

G.5.2.9. Personal Attributes. Surveyors should be open-minded and mature; possess sound

judgement, analytical skills and tenacity; have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within the overall organisation. The surveyor should be able to apply these attributes in order to:

- obtain and assess objective evidence fairly;
- remain true to the purpose of the practice visit without fear or favour;
- evaluate constantly the effects of audit observations and personal interactions during the practice visit;
- treat concerned personnel in a way that will best achieve the practice visit purpose;
- react with sensitivity to the national conventions of the country in which the practice visit is performed;
- perform the practice visit process without deviating due to distractions;
- commit full attention and support to the practice visit process;
- react effectively in stressful situations;
- arrive at generally acceptable conclusions based on observations;
- remain true to a conclusion despite pressure to change that is not based on evidence.

G.5.2.10. Maintenance of competence. Surveyors should maintain their competence by:

- ensuring that their knowledge of accreditation standards and requirements is current;
- ensuring that their knowledge of assessment procedures and methods is current,
- participating in refresher training where necessary;
- participating in a minimum of five audits in each year;
- having their performance reviewed at least every three years by an evaluation panel.

G.5.2.11. Where the accreditation standard requires peer evaluation or indicates a need for peer evaluation to ensure effective assessment³, the accreditation body shall demonstrate at both the system and operational levels, how it is addressed.

G.5.2.12. In determining whether a surveyor is a peer, consideration should be given to:

- a) Vocational registration under section 3F of the Health Insurance Act; or
- b) A fellowship of the Royal Australian College of General Practitioners (FRACGP) who participates in, and meets the requirements for, quality assurance and continuing medical education as defined in the RACGP Quality Assurance and Continuing Education Program.

³ An example is the *RACGP Entry Standards*, page 7.

5.2.3. Selection procedure

5.2.3.1. Selection of surveyors and technical experts, in general

The accreditation body shall have a procedure for

- a) selecting surveyors and, if applicable, technical experts, on the basis of their competence, training, qualifications and experience;**
- b) initially assessing the conduct of surveyors and technical experts during assessments, and subsequently monitoring the performance of surveyors and technical experts.**

Guidance to clause 5.2.3. (G.5.2.13.)

G.5.2.13. Clause 5.2.3.1.b) requires the accreditation body to assess and monitor the conduct and performance of surveyors and technical experts. Such assessment and monitoring shall include witnessing the activities of the surveyors and technical experts on-site.

5.2.3.2 Assignment for a specific assessment

When selecting the assessment team to be appointed for a specific assessment, the accreditation body shall ensure that the skills brought to each assignment are appropriate. The team shall

- a) be familiar with the applicable legal regulations, accreditation procedures and accreditation requirements;**
- b) have a thorough knowledge of the relevant assessment method and assessment documents;**
- c) have appropriate technical knowledge of the specific activities for which accreditation is sought and, where relevant, with associated procedures and their potential for failure (technical experts who are not surveyors may fulfil this function);**
- d) have a degree of understanding sufficient to make a reliable assessment of the competence of the general practice to provide products, processes or services in its accredited scope;**
- e) be able to communicate effectively, both in writing and orally, in the required languages;**
- f) be free from any interest that might cause assessment team members to act in other than an impartial or nondiscriminatory manner, for example,
 - 1) assessment team members or their organization shall not have provided consulting services to the applicant or accredited general practice which compromise the accreditation process and decision,**
 - 2) in accordance with the directives of the accreditation body, the assessment****

**Procedure No. 16 - GENERAL REQUIREMENTS FOR BODIES OPERATING ASSESSMENT AND
ACCREDITATION OF GENERAL PRACTICES FOR RECOGNITION UNDER THE
PRACTICE INCENTIVES PROGRAM (PIP)**

team members shall inform the accreditation body, prior to the assessment, about any existing, former or envisaged link between themselves or their organization and the general practice to be assessed.

Guidance to clause 5.2.3.2. (G.5.2.14. – G.5.2.22.)

G.5.2.14. It is a condition of JAS-ANZ accreditation that JAS-ANZ accredited certificates are not issued until adequate resources can be deployed to conduct practice visits meeting the requirements of this document. The accreditation body's procedures shall ensure that staff employed to assess general practices are competent in the field in which they are operating. Staff responsible for managing practice visits shall be identified and their competencies documented.

G.5.2.15. Surveyor teams for practice visits shall consist of not less than two surveyors. At least one surveyor will be a general practitioner. The second surveyor may be a general practitioner or a person who is not a general practitioner and is a person employed in general practice. This requirement is based on the principle that accreditation is a peer review process.⁴

G.5.2.16. Selection of lead surveyor. The lead surveyor for a specific practice visit should be selected by assessment management from qualified surveyors by reviewing such factors as:

- a) the size and composition of the team;
- b) the need for skill in managing the team;
- c) the ability to make effective use of the skills of various assessment team members;
- d) the personal skills needed to deal with a particular general practice; and
- e) the required language skills.

G.5.2.17. Language. No surveyors should participate in unsupported practice visits where they are not fluent in the agreed language of the audit. Support in these terms means the surveyors have at all times available to them a person with the necessary technical language skills, who is not subject to pressures that would affect the performance of the practice visit.

G.5.2.18. The term “directives” in clause 5.2.3.2.f).2) means the same as the term “the mandate” in clause 6.2.5.

G.5.2.19. The assessment team needs a background to ensure that the members understand the requirements relating to the management system they are assessing. Each assessment team shall have a general understanding and background in each sector in which it operates. It shall be able to determine whether the design and implementation of the management system is such that the general practice has the capability of systematically meeting the requirements of the accreditation standard.

G.5.2.20. The above requires that the assessment team, deployed in each case by an accreditation body to conduct a practice visit of a general practice's management system, needs to know what elements, having regard to the activities of that general practice, are essential to ensure compliance. An element is essential if failure of a management system to deal with it in a correct manner presents an unacceptable risk that the general practice will not meet specified requirements. The assessment team shall have the necessary competence, including if necessary specific credentials, to determine

⁴ As practice visits have historically been undertaken by two surveyor teams this requirement has been included in this procedure.

whether the management system covers these essential elements in a manner that gives adequate confidence of compliance.

G.5.2.21. In certain instances, particularly where there are critical requirements and special procedures, the background knowledge of the assessment team may be supplemented by briefing, specific training or experts in attendance. The accreditation body may attach non-surveyor experts to their assessment teams. If an accreditation body does use technical experts, its systems shall include details of how technical experts are selected and how their technical knowledge is assured on a continuing basis. The accreditation body may rely on outside help, for example, from professional institutions.

G.5.2.22. The requirements of clause 5.1 and clause 5.2.3.2. have a bearing on the employment of people who have provided consultancy. See guidance G.5.1.24.

5.2.4. Contracting of assessment personnel

The accreditation body shall require the personnel involved in the assessment to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior and/or present link with the general practices to be assessed. The accreditation body shall ensure that, and document how, any subcontracted assessment personnel satisfy all the requirements for assessment personnel outlined in these criteria.

5.2.5. Assessment personnel records

5.2.5. The accreditation body shall possess and maintain up-to-date records on assessment personnel, consisting of

- a) name and address;**
- b) affiliation and position held in the organization;**
- c) educational qualifications and professional status;**
- d) experience and training in each field of competence of the accreditation body;**
- e) date of most recent updating of records;**
- f) performance appraisal.**

5.2.5.2. The accreditation body shall ensure, and verify, that any subcontracted body maintains records, which satisfy the requirements of this procedure, of assessment personnel who are subcontracted to the accreditation body.

5.2.6. Procedures for assessment teams

Assessment teams shall be provided with up-to-date assessment instructions and all

relevant information on accreditation arrangements and procedures by the accreditation body.

5.3. Changes in the accreditation requirements

The accreditation body shall give due notice of any changes it intends to make in its requirements for accreditation. It shall take account of views expressed by the interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited general practice carries out any necessary adjustments to its system within such time as, in the opinion of the accreditation body, is reasonable.

Guidance to Clause 5.3 (G.5.3.1)

G.5.3.1. Any changes to accreditation requirements shall also be made known to JAS-ANZ.

5.4. Appeals, complaints and disputes

5.4.1. Appeals, complaints and disputes brought before the accreditation body by general practices or other parties shall be subject to the procedures of the accreditation body.

5.4.2. The accreditation body shall

- a) **keep a record of all appeals, complaints and disputes, and remedial actions relative to accreditation;**
- b) **take appropriate corrective and preventive action;**
- c) **document the actions taken and assess their effectiveness.**

Guidance to clause 5.4. (G.5.4.1. – G.5.4.2.)

G.5.4.1. Complaints represent a source of information as to possible nonconformity. On receipt of a complaint the accreditation body shall establish, and where appropriate take action on, the cause of the nonconformity, including any predetermining (or predisposing) factors within the accreditation body's management system.

G.5.4.2. The accreditation body shall use such investigation to develop corrective action, which shall include measures for:

- restoring accreditation as quickly as practicable;
- preventing recurrence;
- assessing the effectiveness of the remedial / corrective measures adopted.

6. REQUIREMENTS FOR ACCREDITATION OF A GENERAL PRACTICE

6.1. Application for accreditation

6.1.1. Information on the procedure

6.1.1.1. A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited general practices, shall be maintained up to date as specified in 5.1.7.1 and shall be provided to applicants and accredited general practices.

6.1.1.2. The accreditation body shall require that a general practice

- a)** always complies with the relevant provisions of the accreditation program;
- b)** makes all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, records (including internal audit reports, where required by the accreditation standard, and medical records) and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;
- c)** only claims that it is accredited with respect to those activities for which it has been granted accreditation;
- d)** does not use its accreditation in such a manner as to bring the accreditation body into disrepute, and does not make any statement regarding its accreditation which the accreditation body may consider misleading or unauthorized;
- e)** upon suspension or withdrawal of its accreditation (however determined), discontinues use of all advertising matter that contains any reference thereto and returns any accreditation documents as required by the accreditation body;
- f)** uses accreditation only to indicate that the system is in conformity with specified standards, and does not use its accreditation to imply that a particular service is approved by the accreditation body;
- g)** ensures that no accreditation document, mark or report, or any part thereof, is used in a misleading manner;
- h)** in making reference to its accreditation in communication media such as documents, brochures or advertising, complies with the requirements of the accreditation body.

6.1.1.3. When the desired scope of accreditation is related to a specific programme, any necessary explanation shall be provided to the applicant. [i.e. accreditation body shall explain implication of having a particular scope]

6.1.1.4. If requested, additional application information shall be provided to the applicant.

6.1.2. The application

6.1.2.1. The accreditation body shall require an official application form, duly completed and signed by a duly authorized representative of the applicant, in which or attached to which is:

- a) the scope of the desired accreditation is defined;**
- b) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for its evaluation.**

6.1.2.2. At least the following information shall be provided by the applicant prior to the on-site assessment:

- a) the general features of the applicant, such as corporate entity, name, addresses, legal status and, where relevant, human and technical resources;**
- b) general information concerning the management system and the activities it covers;**
- c) a description of the systems to be accredited and the standards or other normative documents applicable to each;**
- d) a copy of the quality manual, where required, and associated documentation.**

The information gathered from the application documentation and documentation review may be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality.

6.2. Preparation for assessment

6.2.1. Before proceeding with the assessment, the accreditation body shall conduct, and maintain records of, a review of the request for accreditation to ensure that

- a) the requirements for accreditation are clearly defined, documented and understood;**
- b) any difference in understanding between the accreditation body and the applicant is resolved;**
- c) the accreditation body has the capability to perform the accreditation service with respect to the scope of the accreditation sought, the location of the applicant's operations, and any special requirements such as the language used by the applicant.**

6.2.2. The accreditation body shall prepare a plan for its assessment activities to allow for the necessary arrangements to be made.

6.2.3. The accreditation body shall nominate a qualified assessment team to evaluate all material collected from the applicant and to conduct the practice visit on its behalf. Experts in the areas to be assessed may be attached to the accreditation body's team as advisers.

6.2.4. The general practice shall be informed of the names of the members of the assessment team who will carry out the assessment, with sufficient notice to appeal against the appointment of any particular surveyors or experts.

6.2.5. The assessment team shall be formally appointed and provided with the appropriate working documents. The plan for and the date of the practice visit shall be agreed with the general practice. The mandate given to the assessment team shall be clearly defined and made known to the general practice, and shall require the assessment team to examine the structure, policies and procedures of the general practice, and confirm that these meet all the requirements relevant to the scope of accreditation, and that the system is implemented and give confidence in the services of the general practice.

6.3. Assessment

The assessment team shall assess the general practice's system covered by the defined scope against all applicable accreditation requirements.

Guidance to clause 6.3. (G.6.3.1.)

G.6.3.1. Accreditation bodies shall allow surveyors sufficient time to undertake all activities relating to an assessment or re-assessment. The time allocated shall be based on such factors as the size of the organisation, number of locations and the standards that apply to the accreditation. The accreditation body shall be prepared to substantiate or justify the amount of time used in any assessment, surveillance or re-assessment.

6.4. Assessment report

6.4.1. The accreditation body may adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that

- a) a meeting takes place between the assessment team and the general practice's management prior to leaving the premises, at which the assessment team provides a written or oral indication regarding the conformity of the general practice's management system with the particular accreditation requirements and provides an opportunity for the general practice's management to ask questions about the findings and their basis;
- b) the audit team provides the accreditation body with a report of its findings as to the conformity of the general practice's system with all of the accreditation requirements;
- c) a report on the outcome of the assessment is promptly brought to the general practice's attention by the accreditation body, identifying any nonconformity to be discharged in order to comply with all of the accreditation requirements;
- d) the accreditation body shall invite the general practice to comment on the report and

to describe the specific actions taken, or planned to be taken within a defined time, to remedy any nonconformity with the accreditation requirements identified during the assessment, and shall inform the general practice of the need for full or partial reassessment or whether a written declaration to be confirmed during surveillance will be considered adequate;

- e) the report shall contain as a minimum
- 1) the date(s) of the practice visit(s),
 - 2) the name(s) of the person(s) responsible for the report,
 - 3) the names and addresses of all sites assessed,
 - 4) the assessed scope of accreditation or reference thereto, including reference to the standard applied e.g. the *RACGP Entry Standards*,
 - 5) comments on the conformity of the general practice's system with the accreditation requirements, with a clear statement of nonconformity and, where applicable, any useful comparison with the results of previous assessments of the general practice,
 - 6) an explanation of any differences from the information presented to the general practice at the closing meeting.

6.4.2. If the report authorized by the accreditation body differs from the report referred to in clause 6.4.1 c) and e), it shall be submitted to the general practice with an explanation of any differences from the previous report. The report shall take into consideration

- a) the qualification, experience and authority of the staff encountered;
- b) the adequacy of the internal organization and procedures adopted by the applicant body to give confidence in the general practice's management system;
- c) the actions taken to correct identified nonconformities including, where applicable, those identified at previous assessments.

Guidance to clause 6.4. (G.6.4.1.)

G.6.4.1. In a practice visit that combines audits of more than one management system, the report shall clearly identify all elements important to each management system standard.

6.5. Decision on accreditation

6.5.1. The decision whether or not to accredit a general practice shall be taken by the accreditation body on the basis of the information gathered during the accreditation process and any other relevant information. Those who make the accreditation decision shall not have participated in the practice visit.

6.5.2. The accreditation body shall not delegate authority for granting, maintaining, extending, reducing, suspending or withdrawing accreditation to an outside person or body.

6.5.3. The accreditation body shall provide to each of its accredited general practices accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These documents shall identify, for the general practice and each of its sites covered by the accreditation,

- a) **the name and address;**
- b) **the scope of the accreditation granted, including**
 - 1) **the standards to which the general practice's management system is accredited,**
 - 2) **the type of general practice and, if appropriate,**
 - 3) **any relevant regulatory requirements [or other normative documents against which services are provided];**
- c) **the effective date of accreditation and the term for which the accreditation is valid.**

6.5.4. The accreditation body shall process any application for amendment to the scope of an accreditation that has already been granted. The accreditation body shall decide what, if any, assessment procedure is appropriate to determine whether or not the amendment should be granted and shall act accordingly.

Guidance to clause 6.5. (G.6.5.1. – G.6.5.2.)

G.6.5.1. The information gathered during the accreditation process shall be sufficient

1. for the accreditation body to be able to make an informed decision on accreditation;
2. for traceability to be available in the event, for example, of an appeal or for planning for the next practice visit (possibly by a different team);
3. to ensure continuity.

In addition to the requirements for reporting in clause 6.4.1.e), this information shall cover

- the degree of reliance that can be placed on the internal audit (where required by the accreditation standard);
- a summary of the most important observations, positive as well as negative, regarding the implementation and effectiveness of the general practice's system;
- the conclusions reached by the assessment team.

G.6.5.2. Accreditation shall not be granted until all nonconformities as defined in Clause 3.9. have been corrected and the correction verified by the accreditation body (by practice visit or other appropriate forms of verification).

6.6. Surveillance and reassessment procedures

6.6.1. The accreditation body shall carry out periodic surveillance and reassessment

**Procedure No. 16 - GENERAL REQUIREMENTS FOR BODIES OPERATING ASSESSMENT AND
ACCREDITATION OF GENERAL PRACTICES FOR RECOGNITION UNDER THE
PRACTICE INCENTIVES PROGRAM (PIP)**

at sufficiently close intervals to verify that general practices that are accredited continue to comply with the accreditation requirements.

6.6.2. Surveillance and reassessment procedures shall be consistent with those concerning the initial assessment.

Guidance to clause 6.6.1. (G.6.6.1. – G.6.6.3.)

G.6.6.1. Accreditation bodies shall have clear procedures laying down the circumstances and conditions in which accreditations will be maintained. If nonconformities, as defined in G.3.9., are found to exist after accreditation is granted, such nonconformities shall be effectively corrected within a time agreed by the accreditation body. If correction is not made within the time agreed accreditation shall be reduced, suspended or withdrawn. The time allowed to implement corrective action shall be consistent with the severity of the nonconformity and the risk to the assurance of the product meeting specified requirements.

G.6.6.2. Surveillance activities shall be considered if a general practice with an accredited management system makes major modifications to its system or if other changes take place which could affect the basis of its accreditation.

G.6.6.3. The purpose of re-assessment is to verify overall continuing effectiveness of the general practice's management system in its entirety. It is unlikely that a period greater than three years for periodic re-assessment of the general practice's management system would satisfy this requirement⁵. The re-assessment shall provide for a review of past performance of the general practice's system over the period of accreditation. The re-assessment program shall take into consideration the results of the above review and shall at least include a review of the system documentation and a practice visit (which may replace or extend a regular surveillance practice visit). It shall at least ensure

- the effective inter-action between all elements of the general practice's system;
- the overall effectiveness of the system in its entirety in the light of changes in operations;
- demonstrated commitment to maintain the effectiveness of the system.

6.7. Use of certificates and logos

6.7.1. The accreditation body shall exercise proper control over ownership, use and display of its accreditation mark and logos.

6.7.2. If the accreditation body confers the right to use a symbol or logo to indicate accreditation of a general practice, the general practice may use the specified symbol or logo only as authorized in writing by the accreditation body. This symbol or logo shall not be used on a product, or in a way that may be interpreted as denoting product conformity.

⁵ It is anticipated that there will be a study of the performance of general practices' on-going compliance with the RACGP Entry Standards in 2001 and that the policy of triennial reassessment will be reviewed at that time by JAS-ANZ in consultation with significantly interested parties.

6.7.3. The accreditation body shall take suitable action to deal with incorrect references to the accreditation system or misleading use of certificates and logos found in advertisements, catalogues, etc.

NOTE 4. Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

Guidance to clause 6.7. (G.6.7.1. – G.6.7.8.)

G.6.7.1. A JAS-ANZ accredited certificate shall state the standard(s) or other normative document(s) against which accreditation is granted, the name of the accreditation body that issued it, and JAS-ANZ. It shall be made clear that the certificate is issued within the JAS-ANZ accredited scope of the accreditation body.

G.6.7.2. All certificates issued by an accredited accreditation body which are within its scope of JAS-ANZ accreditation, shall bear the JAS-ANZ mark. In the case of a general practice requesting a certificate to be issued without a JAS-ANZ accreditation mark, for the certificate to be regarded as an accredited certificate it shall include JAS-ANZ's name and the registration number.

G.6.7.3. The accreditation body shall have documented procedures for the use of its mark, and for the procedures it is to follow in case of misuse, including false claims as to accreditation and false use of accreditation body marks.

G.6.7.4. If an accreditation body incorrectly claims accredited status for certificates issued before appropriate JAS-ANZ accreditation has been granted JAS-ANZ may require it subsequently to withdraw them. Where, for reasons that shall be stated to the accreditation body, JAS-ANZ restricts the scope of its accreditation to part only of one of the standard scope headings, this fact may be made public by JAS-ANZ.

G.6.7.5. The provisions in clause 6.7.1. referring to “accreditation mark and logos” and that in clause 6.7.2. referring to a “symbol or logo” are both applicable to marks, logos and symbols.

G.6.7.6. The legal registration of accreditation marks shall provide sufficient protection to enable the accreditation body to control the use of certificates and logos.

G.6.7.7. The accreditation body shall allow neither the JAS-ANZ accreditation mark nor their own accreditation mark to be used on products. Use of the mark on products implies product certification and is not covered by this guidance. Nevertheless the accreditation body shall avoid use of the same mark or a similar mark to indicate different systems of conformity accreditation/certification (for example product certification and general practice accreditation) and shall avoid confusion between the meanings of its own marks if there are more than one.

G.6.7.8. An accreditation body shall have procedures to ensure that accredited general practices do not allow its marks to be used in a way which may be likely to confuse patients.