



Section: Continuum of Care

Procedure No. 01603/v2/06/2008

Procedure Title: Acquittal of Prosthesis (Artificial Limb) – QALS

Review Officer: QALS Manager

Review Summary: [2nd Version Review Summary](#)

Applicable To: All Staff and PSPs

Last Review Date: 06 2008

Next Review Date: 06 2010

Authority: QALS Advisory Committee

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Signature of Authorised Officer

Replaces: 01603v1

Key Words: Prosthesis, Prosthetic Service Providers, Amputee Clinics

References:

Acquittal and Quality Control Form
Client Responsibilities Procedure
Therapeutics and Goods Act 2002

Purpose:

To ensure the fit and functionality of the prosthesis is correct and suitable for the client's purpose and needs.

To ensure the quality and manufacturer of the artificial limb is consistent with best practice and prosthetic manufacturing standards AS/NZS 9001:2000.

To ensure the prosthesis is manufactured according to the Therapeutics and Goods Act 2002 for custom made medical devices by the Queensland Health contracted Prosthetic Service Provider (PSP).

Procedure:

As a vital part of assuring a quality product to meet the client's need, QALS requires that a new or replacement prostheses, or major repairs to a prosthesis effecting the fit and function of a prosthesis, is acquitted at a recognised amputee clinic or via QALS.

Acquittal Form:

QALS provides a 'Prosthesis Acquittal and Quality Control Form' which must be completed for all prostheses and major repairs as directed by QALS. The form must be completed in its entirety and

distributed as identified. Please note and complete all areas marked as compulsory as any acquittal submitted without these areas completed may be rejected.

The form incorporates a 'Warning and Compulsory Direction' section regarding the disposal of a replaced prosthesis. This disclosure must be directed to the client as part of the acquittal process. Payment of services may be jeopardised, if QALS is not satisfied that the acquittal process has been pursued adequately by the prosthetic manufacturer or amputee clinic.

Client Responsibility:

All clients are required to participate in the acquittal of services as a condition of their receiving services. It is therefore mandatory for the acquittal form to be duly signed by the client. Only under exceptional circumstances will QALS acquit a service without a client's signature.

If a client refuses, or does not attend, a clinic appointment made on his/her behalf for acquittal, the manufacturer will advise QALS. QALS will advise the client in writing of his/her responsibility in the acquittal process and the consequences of refusal. If the client subsequently chooses not to attend an amputee clinic for a third appointment made for this purpose, then QALS, upon notification by the manufacturer, may consider suspending the client from further services.

Evaluation Method:

1. Client satisfaction survey.
2. Feedback from amputee clinic staff and Prosthetic Service Providers.

Section: Continuum of Care

Procedure No. 01125/v2/08/2008

Procedure Title: Child Amputee Limb Replacement

Review Officer: QALS Manager

Review Summary: 2nd Version
Review Summary

Applicable To: All Staff & PSPs

Date Last Reviewed: 08 2008

Next Review Date: 08 2010

Authority: QALS Advisory
Committee

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**Signature of Authorised
Officer**

Replaces: 01125 v1

Key Words: Child, Amputee

References:

Purpose:

To create an equitable system for meeting the Prosthetic needs of limb deficient children. Due to the rapid growth factors in children a more realistic time frame for replacement of artificial limbs is required rather than the standard adult time frame of three years. Children's prosthesis will have a life expectancy of one (1) year from date of acquittal, noted on the QALS Acquittal Form, funding permitting.

Procedure:

For the purpose of QALS and this procedure "child" means any child or adolescent aged 0 to 16 years inclusive.

All children seeking QALS funding for a prosthesis, whether amputees or congenitally limb deficient, will have successfully completed an interim or rehabilitation program during which the child will be mobilised using a prosthesis of appropriate design. Review of prosthetic needs is available at any time by a multi-disciplinary team at a QALS recognised amputee clinic. A specialist paediatric clinic is available at the Royal Children's Hospital in Brisbane. The multi-disciplinary team (MDT) assessment will consider all

factors including growth rate, activity level and weight, bearing in mind component limitations. While MDT assessment is available at any time, replacement of a prosthesis is on an average, provided each 12 month period – measured from the date of acquittal. Replacement is based on a need basis and is not automatic when the prosthesis is 12 months old. QALS does NOT fund recreational, research or trial prostheses. QALS will not repair or replace a prosthesis that has been neglected or abused.

Socket Replacements:

As is it recognised that children have rapid and irregular growth patterns, a socket replacement may be requested during the expected 12 months life of a prosthesis. Requests for a socket replacement will be considered in relation to the acquittal date of the replacement limb and the expected life of the prosthesis.

Pylons:

Where ever possible, an older child's prosthesis should be of modular construction to allow for growth related lengthening where deemed appropriate by the Prosthetic Service Provider (PSP) manufacturing the artificial limb.

Knee Components:

Knee components are expected to last the life of the prosthesis and will often continue to be serviceable for the replacement prosthesis as well. If there is any doubt about the condition of a prosthetic knee joint, it should be noted on the MDT Form requesting the knee joint be checked and serviced at time of assessing a replacement limb. The PSP is to check and assess if the current knee joint component is still in good working order and likely to last for the life of the replacement prosthesis in question. If in doubt the PSP is to discuss the matter with QALS and seek an approval to replace.

Prosthetic Feet:

Prosthetic feet are expected to last the full twelve months of the prosthesis. Undue care and misuse of feet is common and not taken lightly by QALS. Prosthetic feet will not be automatically replaced within the life expectancy of an artificial limb.

Cosmetic Covers:

A maximum of one cosmetic cover per limb is permitted in any twelve month period. Additional cosmetic covers will require supporting evidence of the need from an amputee clinic or at the client's own expense. Repairs to a prosthesis will not automatically require a replacement cosmetic cover.

Client responsibility:

The child and parents/guardians are responsible for ensuring the prosthesis is maintained in a clean condition. PSPs are happy to provide details on how to maintain and care for your artificial limb. QALS will not repair or replace a prosthesis that has been mistreated, water damaged or used incorrectly. The prosthesis must be used only in the manner and circumstances for which it was designed.

Evaluation Method:

- Monitor child amputee costs and service provision through the QALS database.
- Compare costings and service provision to historical data already collected in the database.
- Provide relevant reports to the Royal Children's Hospital Paediatric Rehabilitation Service and RCH Amputee Clinic on child amputee service provision.
- Monitor complaints both verbal and written and report back to the QALS Advisory Committee.

HYPERLINK TO: [All QALS Procedures](#)



Section: Leadership and Management

Procedure No. 42080/v2/06/2008

Procedure Title: Completion of Multi Disciplinary Team (MDT) Form

Review Officer: QALS Manager

Review Summary: 2nd Version
Review Summary

Applicable To: All Staff & PSPs

Date Last Reviewed: 06 2008

Next Review Date: 06 2010

Authority: QALS Advisory
Committee

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Signature of Authorised Officer

Replaces: 42080v1

Key Words: Prosthetic Services,
Component Limitations,
Compensation, PSP

References:

Purpose:

The procedure was developed to ensure consistent practice was followed by the amputee clinic staff when filling in a prosthetic "**Multi Disciplinary Team Form**".

Procedure:

The following procedure provides information and guidance for Amputee Clinic staff when completing the Multi Disciplinary Team (MDT) Form. The information requested on the form is necessary for QALS approval and if this form is incomplete or lacks adequate information, QALS will be obliged to return the form to the originating Clinic.

The provided information is compared to other data on file when considering approval. If there are unexplained inconsistencies, then approval may be delayed.

The QALS's **File Number** is optional but may be of value to the Clinic when making queries. If known, this number can be placed on the MDT form by the clinic otherwise it will be placed on the form once it is received by QALS.

Patient Information

Amputee clinic staff are asked to confirm with the client their **address and phone numbers are current**, as QALS will be communicating with the client directly.

The '**Date of Birth**' is a key identifier for QALS as we do have on file a number of clients with the same Given names and Surnames.

Basic eligibility to the service is for Australian citizens, and thus a **Medicare Card Number is a requirement**. Clients who normally hold a Medicare card but being held in the custody of the Department of Corrective Services are exempt from producing their Medicare card while in prison.

QALS must also determine whether clients are eligible for extended services (as in the case of DVA Gold card holders), or are involved a compensation case.

Please also indicate, by ticking the box, if the patient wishes to change Prosthetic Service Provider (PSP). QALS will contact them about their choice.

Information about Amputation

Diabetes is a major cause of amputation. It is important that we can identify trends affecting rates of amputation and underlying causes. The data collected previously by QALS was incomplete and unclear. The present form allows us to more accurately identify causes and trends. Please complete the check boxes detailing the diabetes status of the patient.

Information regarding the amputation itself is **mandatory for all primary limbs**. Please include the side (left/right) and type of amputation on all prescriptions (eg. Lt TT, R TH, L TK).

In order to meet our obligations under the Therapeutic Goods Act (TGA) it is necessary to ensure the close matching of the components supplied to an amputee with their **weight** and **activity level**. QALS has adopted the K-Level Classification test called the '*Amputee Mobility Predictor Assessment Tool (AMPAT) Form*'.

Every amputee progressing from interim to definitive service should be classified by assessment of a suitably trained Physiotherapist. Please enter the **AMPAT** score in the relevant check box. Please also enter height (cm) and weight (kg) information for the same reasons. It is preferred that the weight should be taken consistently either with or without the prosthesis to facilitate comparisons from visit to visit.

Relevant Medical Considerations / Co-Morbidities

To be completed by the medical officer only. Any medical condition the medical officer considers significant to the ongoing rehabilitation of the patient and that will affect the ability to wear and use a prosthesis should be noted here. This will help the prosthetist in designing a suitable prosthesis. Examples would include: a colostomy, blindness, stroke/hemiparesis, insensitivity or congestive heart disease.

Prosthetic Rehabilitation Aims

It is important for all MDT members to understand the aims of the rehabilitation program for each individual patient. This allows everyone to work towards the same goal and gives common ground for communication between MDT members and the prosthetic service providers (PSP). This field should be used to note the aims for rehabilitation which are deemed appropriate, realistic and achievable for the patient in question. This allows the prosthetist to understand the goals of the amputee clinic staff and so design an appropriate limb. Examples of aims which might be noted here would include: return to work or transfers only etc.

Reason for Requested Service

Please note here the reasons for the requested service. Examples of entries in this field might include: wear & tear; stump volume change, or medical reasons.

History of Interims

This field should be used to include a brief history of the treatment during the interim phase for those clients progressing onto a definitive limb. Numbers and frequency of socket provision would be useful information. It should also be used to record any interim prostheses provided for someone who has returned to the interim program e.g. following revision surgery.

Generic Limb Description

This area can be used to indicate the suggestion of the Multi Disciplinary Team for limb design considering any special requirements of the patient. A generic description such as 'suction socket' or 'SACH foot' is all that is required. QALS requires the PSP to supply specific details of the components they wish to use to be submitted to QALS prior to approval.

Signature Block

The recognised amputee clinic will have health practitioners from the following designations, a medical officer, a prosthetist and a physiotherapist as the core members of the multi disciplinary team. There may also be health practitioners from other areas of service such as social worker, occupational therapist and nurse involved in the client's rehabilitation program. In ideal circumstances all of the core members would be present at all clinics. QALS recognises that this is not always possible, particularly in non-metropolitan clinics. For this reason there is provision on this form for a variety of members to sign requesting service with limitations as noted below.

This area has provision for the indication of whether social work / grief counselling was offered to the patient. Please indicate by use of the check boxes whether the offer was made or the service has been requested, either by or on behalf of the patient.

For progression from interim to definitive service it is necessary that a medical officer is satisfied that the patient is suitable for prosthetic treatment. If a client is already receiving definitive prosthetic treatment, the assumption is made that they continue to be suitable until a medical officer signs to say this is no longer the case. In either circumstance the medical officer should tick the relevant check box to let QALS know of the decision. Under no circumstances can a client be accepted as a QALS client without the necessary confirmation of their suitability for prosthetic treatment from a medical officer.

However, when no medical officer is available and the patient is already receiving services from QALS then the MDT form may be submitted with all details completed other than Relevant Medical Considerations and the Confirmation of Medical Suitability. In this case QALS will consider the request as ongoing provision.

With the exception of transition from interim to definitive services it is acceptable for the MDT form to be signed by a member of the Multi Disciplinary Team other than the medical officer. In this case the MDT member should note their designation (e.g. physiotherapist, prosthetist) on the relevant line. If the script is unsigned or signed by a non-recognised MDT member, the script will be returned to the originating Clinic.

The contracted Prosthetic Service Provider (PSP) can NOT sign the MDT form under any circumstances, even if they are the prosthetist in attendance at the amputee clinic.

MDT Form Expiry

An MDT Form is valid for up to six months after approval, but may be cancelled earlier if QALS required responses are not forthcoming.

Evaluation Method:

- Indicator monitors on time frames for processing of prescriptions
- Monitoring the number of uncompleted forms returned to amputee clinics per annum
- Monitoring of complaints by staff, PSPs or patients in relation to the understanding and completion of the form.

HYPERLINK TO: To all other QALS procedures.



Section: Leadership and Management

Procedure No. 42202/v1/08/2008

Procedure Title: Completion of PSP Assessment of Prosthetic Needs Form

Review Officer: QALS Manager

Review Summary: 1st Version
Review Summary

Applicable To: All Staff & PSPs

Date Last Reviewed: 08 2008

Next Review Date: 08 2010

Authority: QALS Advisory
Committee

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Signature of Authorised Officer

Replaces: New procedure

Key Words: Prosthetic Services,
Component Limitations,
Compensation, PSP

References:

Purpose:

The procedure was developed to ensure consistent practice was followed by the prosthetist when filling in a 'PSP Assessment of Prosthetic Needs Form'.

Procedure:

The following procedure provides information and guidance for prosthetist when completing the PSP Assessment of Prosthetic Needs Form. The information requested on the form is necessary for QALS approval and if this form is incomplete or lacks adequate information, QALS will be obliged to return the form to the originating PSP.

The provided information is compared to other data on file when considering approval. If there are unexplained inconsistencies, then approval may be delayed.

The QALS **File Number** is optional but may be of value to the PSP when making queries. This number can be placed on the PSP Assessment of Prosthetic Needs Form by the PSP otherwise it will be placed on the form once it is received by QALS.

Patient Information

PSPs are asked to confirm with the client that their **address and phone numbers are current**, as QALS will be communicating with the client directly.

The '**Date of Birth**' is a key identifier for QALS as we have a number of clients with the same Given names and Surnames on file.

Basic eligibility to the service is for Australian citizens, and thus a **Medicare Card Number is a requirement**. Clients who normally hold a Medicare card but are being held in the custody of the Department of Corrective Services are exempt from producing their Medicare card while in prison.

QALS must also determine whether clients are eligible for extended services (as in the case of DVA Gold card holders).

Services Required

Tick the box which best describes the service being requested. One PSP Assessment of Prosthetic Needs Form should be completed for each service being requested. So, a bi-lateral amputee requesting 2 prostheses would require 2 forms.

Prosthetic Requirement

Use this area to describe the prosthesis requested. Be as specific as possible as to the components to be used for the fabrication of the prosthesis. Use the "\$" area to indicate the price of the component. The price stated should be the price on the QALS Component Management System database as this is the price that would be paid by QALS.

Assessed Activity Level

This is the activity level as stated on the MDT form completed at the transition from interim to definitive programs. For clients who have not been assessed by the amputee clinic a nominal level of K2 will be assumed until advised otherwise. If the PSP feels a reassessment is necessary to establish a more

appropriate activity level designation, an appointment should be made at an amputee clinic for a mobility assessment for the client. Assessment by the PSP is not accepted by QALS.

Weight and Height

At any assessment appointment a current weight should be recorded to establish the most appropriate components for the client. The height should also be recorded as this will be used to calculate a Body Mass Index for the client on the patient record on the ALS database. Specify whether the weight was measured with a prosthesis or without by ticking the appropriate box.

Amputation Level

Record the level of amputation using ISO approved abbreviations – e.g. TT for trans-tibial etc. The side should also be recorded by ticking the appropriate box.

Signature Block

PSP: The name of the prosthetic manufacturing company at which the treating prosthetist is employed.

Prosthetist Name: The printed name of the treating prosthetist

Prosthetist Signature: The signature of the treating prosthetist

Date: The date on which the assessment was carried out.

Presented Prosthesis ID

The prosthesis that may need replacement or repairs should be scanned using the QALS supplied scanner. The ID (transponder) number of the prosthesis should then be recorded in this box. Failure to complete this box will result in delays in any approval of the services being sought. If the ID number is not apparent by scanning or visual inspection then “no number apparent” should be entered in this box. QALS will then investigate the lack of identification prior to any approval being given. At the very least the allocated limb number on associated paper work is to be provided when the scanner does not detect or read a transponder.

Reason for replacement

A short description of the reasons for the service being sought should be entered here. This is a mandatory field. Failure to complete this field will result in delays as QALS will seek further information.

How old is the item being replaced?

The time, to the nearest month, since the socket or prosthesis was last replaced.

Special considerations:

This provides an opportunity to explain any extenuating circumstances leading to this request for service. If there is insufficient space available on the form then an additional sheet should accompany the form.

MDT reference number

Enter here the number printed in red on the lower right corner of the MDT form if applicable.

QALS Approval Number

This is entered in the QALS office once approval is given by the QALS manager.

Client Signature Block

When the client is present when the PSP Assessment of Prosthetic Needs Form is completed, they should complete this section. They should indicate their preference for a PSP in the area indicated, and then complete the form by signing where indicated.

Completion

Once all relevant fields of the form are completed it should be forwarded to QALS for approval. QALS will then consider the service being requested and the service history of the client. Once a decision has been made the QALS manager will approve or decline the request for service and inform all parties. Only once approval has been given in writing by the QALS manager, or delegate, should the PSP commit to any work on behalf of the client and QALS. Any work undertaken prior to written approval is at the risk of the PSP.

Evaluation Method:

- Indicator monitors on time frames for processing of prescriptions
- Monitoring the number of uncompleted forms returned to amputee clinics per annum
- Monitoring of complaints by staff, PSPs or patients in relation to the understanding and completion of the form.



Section: Leadership and Management
Procedure Title: Completion Time – QALS

Procedure No. 42081/v2/08/2008

Review Officer: QALS Manager

Review Summary: [2nd Version](#)
[Review Summary](#)

Applicable To: All Staff and
PSPs

Last Review Date: 08 2008

Next Review Date: 08 2010

Authority: QALS Advisory
Committee

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**Signature of Authorised
Officer**

Replaces: 42081 v1

Key Words: QALS database,
Performance targets

References

Purpose:

To ensure standard routines are implemented and followed by staff and Prosthetic Service Providers (PSP) thereby providing a consistent practice of service delivery to all clients in the State.

Procedure:

The length of time which elapses between the writing of a request for service and the acquittal of the prosthesis is a measure of the effectiveness of the Service from the client perspective. QALS will support and encourage methods to establish norms for the various parts of the process and will monitor performance.

Elements of the Process

All of the following events will be recorded in the client's record on the QALS database for all primary limbs, replacement limbs and major repairs.

Request for Service date - is the date recorded on the Multi Disciplinary Team Form by the Multi Disciplinary Team leader or on the PSP Assessment of Needs Form by the prosthetist - whichever is the earlier.

Client notification date - is the date on which the notification letter informing the client of approval of services is mailed. If the client has not already notified QALS of their choice of PSP then they are requested to

advise QALS by phone or by letter.

Manufacturer notification - is the date that QALS is informed of the client's choice of manufacturer and this is entered on the ALS database.

Cast date - is the date that the PSP takes a cast when required or otherwise initiates work with the client. This date is provided to QALS by the PSP by a notation on the reverse of the PSP Assessment of Prosthetic Needs Form when this is submitted for payment.

Trial Date - is the date upon which the prosthesis is taken for trial by the client. This date is provided by the PSP by a notation on the reverse of the PSP Assessment of Prosthetic Needs Form when this is submitted for payment.

Acquittal Date - is the date recorded on the Acquittal and Quality Control Form when completed.

Measurements:

The process will examine a number of periods:

Total completion time: that period for the whole process to be completed, that includes all the above elements. The time period is measured in days from the date of the initial request for service to the date of acquittal.

Office time: the period, measured in days, from the prescription date to the date of the client notification letter. It encompasses the time required for the script to reach the QALS office, time for review of the client's file, assessment of the request and approval or refusal. It also includes any time required for further information to be gathered etc.

Waiting time: that period between notification of an approval for services to manufacturer and cast date.

Manufacturing time: that period between the cast date and the trial date. Breakdown of the elements may be completed if required.

Acceptance period: that period between the trial of the prosthesis and acquittal.

Ad hoc reports: various periods of time in the process may be analysed in a number of combinations as required.

Performance targets

The target for any element shall be established through mutual agreement with the parties involved. The client's perspective shall be provided by the Advisory Committee. Wherein mutual agreement cannot be reached, comparison to other jurisdictions or industry norms shall be made and considered.

It is recognised that different services and indeed differing prostheses may well have different performance targets. These may be extracted from the database as required.

Regular reports will initially address a "macro" view of the outcomes. If warranted, more detailed analysis can be performed. The date of acquittal shall be the date considered for data inclusion in a reporting period.

Although comparative outcome reports by manufacturer may be prepared, they will be considered confidential and for internal use only. Identification of the particular manufacturer will not be divulged except wherein some corrective action is being contemplated as a result of the reports generated.

Quality Improvement Activity

Periodic reports will be prepared on the major outcomes sought and submitted as appropriate. These will reflect data accumulated since July 1, 1998. Current levels (that is, quarterly blocks of activity) shall be prepared for comparison against historic patterns.

It is recognised that data limitations will preclude a number of detailed reports until data gathering is fully implemented.

The results of the analysis shall be used as the basis to evaluate overall performance of the service and its different components. Remedial action, including interaction and evaluation of a provider may arise from this analysis.

Outcome targets may be altered through this review.

Evaluation Method:

- Entering of the time periods onto the QALS data base.
- Annual report and monthly report to Director of Division of Rehabilitation on indicator measures.
- Review and assessment of business and operational practices of both PSPs and QALS staff for improvement suggestions.
- Performance targets are set in writing in contracts with PSPs.



Section: Leadership and Management
Procedure Title: Components

Procedure No. 42082/v2/08/2008

Review Officer: QALS Manager

Review Summary: [2nd Version Review Summary](#)

Applicable To: All Staff and PSPs

Last Review Date: 08 2008

Next Review Date: 08 2010

Authority: QALS Advisory Committee

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Signature of Authorised Officer

Replaces: 42082 v1

Key Words: standard and Non standard components

References

Purpose:

Patient safety is paramount when providing prostheses to amputee clients. This procedure aims to support practices which ensure a fair and equal service delivery to all amputees in the State.

Procedure:

QALS maintains a database of prosthetic components available in Queensland. This database, the QALS Component Management System (QCMS), allows QALS to designate any component as pre-approved for use on QALS clients. QALS will ensure that components are approved on this database to meet all weight and activity levels within industry norms. In addition, QALS will establish processes for the ad-hoc approval of components, not pre-approved on a needs basis. QALS may seek professional assistance in determining the approved components as appropriate. All QALS contracted Prosthetic Service Providers (PSPs) will use the QCMS to identify available and appropriate components when completing the PSP Assessment of Prosthetic Needs Form prior to forwarding the form to QALS for approval.

Minimum Standard for Component

Unless a component is specifically exempted from the requirements of the Therapeutic Goods Act 2002, all prosthetic components included and pre-approved for use in QALS funded prostheses will be included in the Australian Register of Therapeutic Goods (ARTG) which is maintained by

the Therapeutic Goods Administration. The supplier of these components declares this inclusion by checking the appropriate field in the QCMS. This will be taken by QALS as a declaration that the components included on the ARTG meet all relevant national and international standards required for sale and use in Australia.

Acceptance as "Pre-Approved" on the QCMS

QALS's mission is to provide essential prosthetic devices and will seek to do this within the funding availability of Queensland Health. QALS will endeavour to seek pre-approve components in all categories to suit all weight and activity levels within industry norms while operating within their funding limits.

At all times the criteria for inclusion will include: appropriateness for purpose, value for money and patient safety. As an example where 2, functionally identical, components are available in both Steel and Titanium the less expensive Steel component would be preferred for pre-approval.

Non QCMS Pre-Approved Components

QALS recognises that there are circumstances when the client's essential prosthetic needs cannot be fully met by the items pre-approved on the QCMS (refer to Procedure 42086/v2/07/2008). As these components are typically outside the normal level of QALS funding, approval for use in one instance does not mean automatic approval will be given again in the future. Any subsequent requirement for replacement of such a component will require further consideration and approval by the QALS manager.

Client Funded Improvements

In circumstances where the component requested cannot be approved by QALS due to funding or any other issues, QALS may permit such a component to be incorporated into a QALS supplied prosthesis at the client's expense. The addition of such components, improvements or enhancements must be compatible with the prosthesis as approved by QALS and not incur any extra expense for QALS. The client remains responsible for all costs associated with the addition of such components and QALS will not fund the

servicing, maintenance or repair of any such component, improvement or enhancement incorporated in a prosthesis in this manner.

Where QALS permits an upgrade of components at the client's expense, QALS will in general fund to the value of a pre-approved component, leaving the difference in cost for the client to pay directly to the PSP. In all such cases the client assumes full responsibility for the service and repair of such component.

For post market surveillance purposes in all cases and at all times QALS must be aware of all components incorporated in a QALS funded prosthesis. The PSP must inform QALS by annotation on the reverse of the PSP Assessment of Prosthetic Needs Form of any client funded changes to the prosthesis specification. Both the client funded component and the QALS funded component should be listed and the actual serial/batch numbers of the components used noted on the client's record on the ALS database.

Evaluation Method:

- Prescriptions are monitored for QCMS pre-approved and non QCMS pre-approved items.
- Entry of non QCMS pre-approved components entered on the QALS data base.
- Annual report on component usage.
- Review of new components by the QALS staff prosthetist and QALS manager.

HYPERLINK TO: Hyperlink to relevant procedures



Section: Continuum of Care

Procedure No: 01620/v3/08/2008

Procedure Title: Home Visits by Prosthetic Service Providers

Review Officer: QALS Manager

Review Summary: [2nd Version Review Summary](#)

Applicable To: All Staff and PSPs

Last Review Date: 08 2008

Next Review Date: 08 2010

Authority: QALS Advisory Committee

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Signature of Authorised Officer

Replaces: 42089 v1

Key Words: Home visits, client's Request, minor services.

References: Department of Industrial Relations.

Purpose:

To identify the guidelines Prosthetic Service Providers (PSPs) must follow when home visiting recognised QALS clients, to ensure patient safety, PSPs staff safety and consistency of service is maintained.

Procedure:

Clients may at times request that a PSP visit them at home or in another place of residence due to restrictive mobility such as a nursing home, corrective services or refugee accommodation. The PSP may undertake ad hoc home visit at their discretion. QALS does not expect PSPs to make home visits nor will QALS pay for travel time or expenses to do so. Home visits to the client's private residence should be due to extenuating circumstances such as illness, lack of mobility or restricted movement.

A home visit should only be undertaken at a client's explicit request. It is the responsibility of the PSP to ensure that only appropriately qualified staff are involved in home visit services. Only tasks appropriate to a home environment should be undertaken in a client's home. In all circumstances the PSP will leave the client's premises in a clean and tidy condition regardless of the complexity of the task being undertaken. Any damage or injury caused during the home visit is the responsibility of the PSP.

Risks and Precautions:

The contracted PSP must ensure that they and their staff are familiar with the Department of Industrial Relations, Health and Community Services Workers guidelines and requirements associated with the safety and security.

The PSP is responsible for the appropriate insurance coverage involved with a home visit. Insurance should include cover for employee related risks, industrial regulations and damage caused to a client's property or person arising from the home visit.

As a trained professional Prosthetist, the PSP should assess the need for a home visit and whether the client's residence is suitable for the service the client is requesting. QALS does not support home visits as a regular form of service delivery. Rather, the PSP makes a judgement and sees the need for a home visit as essential and is willing to take the risk associated with it. The client should always be encouraged to visit the PSP's registered place of service delivery in the first instance.

Evaluation Method:

- Feedback for QALS clients
- Client satisfaction survey

HYPERLINK TO:



Section: Leadership and Management

Procedure No. 42085/v2/08/2008

Procedure Title: Identification of Limbs

Review Officer: QALS Manager

Review Summary: [2nd Version](#)
[Review Summary](#)

Applicable To: All Staff and
PSPs

Last Review Date: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory
Committee

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**Signature of Authorised
Officer**

Replaces: 42085 v1

Key Words: transponder,
Limb number,

References

Purpose:

The purpose of this procedure is to allow proper identification of prostheses in order to enhance patient safety and tracking of prosthetic services funded by Queensland Health.

Procedure:

It is essential that all prostheses which are provided or maintained by QALS be permanently and individually identified to meet client safety, legal, ethical and operational needs. QALS requires compliance with the Therapeutic Goods Act 2002 (TGA) in the production of all QALS funded prostheses. The Essential Principles of the TGA stipulate the labelling requirements that a manufacturer must meet. However due to privacy issues and practical limitations on the application of a label to prostheses an alternative, approved by TGA, is used. All prostheses are to be supplied with a label (not attached to the prosthesis) which, in addition to all other TGA requirements, carries a microchip transponder number. The corresponding microchip transponder is to be implanted/attached to the socket of the prosthesis. When this is not possible, the Prosthetic Service Supplier (PSP) is to engrave a serial number on the socket and append this number on the label supplied with the prosthesis.

QALS Role

QALS will provide the transponder microchips for incorporation into all new or replacement prostheses or socket replacements as required. Each

unique transponder number will be recorded in the appropriate field of the Prosthesis Details Form in the ALS database. This field will be updated each time a new microchip is included in a replacement socket or prosthesis. QALS will provide the transponder readers as appropriate to amputee clinics and PSP.

Amputee Clinic Role

QALS will not honour any invoice for work done on a prosthesis that cannot be identified using the means described in this procedure. In practice, this means that any prosthesis presented at an amputee clinic for acquittal must bear either a microchip transponder or an identifying number engraved on it. QALS requests that PSP and/or amputee clinic staff record the identifying number either by reading the engraving or scanning the embedded microchip, on the Acquittal and Quality Control Form. QALS will use the number recorded on the Acquittal and Quality Control Form as certification that that ID number or transponder is present on the prosthesis.

If a Multi Disciplinary Team (MDT) Form is completed requesting service from QALS, it is requested that the ID number or transponder number of the limb to be serviced is recorded on the form if possible. It is **mandatory** for the PSP to record the ID number or transponder number on the Prosthetic Assessment Form for any service requests to be considered. If there is no number visible, then an appropriate notation should be made on the form indicating the reason the prosthesis can not be identified. QALS will accept this entry as certification that that number is on the prosthesis. In those instances where it is recorded that the number cannot be found, QALS will review its records and enter the most likely limb number and only repairs or replacement to that limb will be authorised.

Prosthetic Service Provider (PSP) role in identifying prostheses.

Identification of Prostheses

QALS will continue the issue of a four digit sequential number preceded by a "Qxxxx" (the approval number) for any approved new prosthesis. However, with the introduction of the implanted transponders, there will no longer be a requirement to visibly identify the prosthesis with this number. Any instance where a microchip transponder cannot be incorporated requires that the approval number should be engraved somewhere accessible but inconspicuous.

In any new / replacement prosthesis or socket replacement, the supplied transponder will be functionally tested and implanted in a safe location.

Repairs

The PSP will positively identify all prostheses **prior** to commencement of any work on behalf of QALS. Only prostheses identified as "current" on the ALS database may be serviced on QALS behalf. QALS will not fund any work on an "expired" or unidentified prosthesis. The PSP should use the supplied scanner to identify the prosthesis presented for servicing and record the number on the Prosthetic Assessment Form and/or Repair Voucher. This annotation is the PSP's certification that the prostheses which was serviced was in fact so identified by the number quoted and that the service was provided to that prosthesis and no other.

If the prosthesis presented for service cannot be identified by normal means the PSP should seek advice from QALS prior to commencing any work on the prosthesis. When it is necessary to engrave the prosthesis with the appropriate limb number, it should be as unobtrusive as possible. The PSP must be satisfied when affixing identification that the prosthesis which is being identified is in fact the prosthesis referred to in the QALS database.

Replacement or Major Repairs

The PSP is only authorised to replace or provide major repairs to properly identified prostheses. Any approved request for service will have the identification number of the relevant prosthesis recorded on it. Only the stipulated prosthesis, and no other, is to be repaired on that approval. The PSP may obtain information from QALS, or the ALS database as to the identification number of a client's current prosthesis, as well as its acquittal date.

If the prosthesis presented for service cannot be identified by normal means the PSP should seek advice from QALS or use the ALS database for the identification of the prosthesis and, prior to commencing any work on the prosthesis, should engrave the prosthesis with the appropriate limb number. This must be carried out regardless of whether it is a prosthetic repair or replacement. Where the repair is a socket replacement, QALS will provide a transponder, which is to be implanted.

Verification

QALS intends to carry out audit activities as appropriate to ensure that all prostheses which are being provided, repaired, maintained or supplied with consumables are properly identified.

QALS will consider a breach of this procedure by a PSP as a serious occurrence which is inconsistent with the spirit of the Prosthetic Provider Service Agreement.

Evaluation Method:

- Annual Report on the number of limbs presented that have expired requesting repairs & replacement.
- Check transponder number is written on all invoices and prescriptions.

HYPERLINK TO: [Hyperlink to relevant procedures](#)



Section: Leadership and Management

Procedure No. 42084/v2/08/2008

Procedure Title: Interim to Definitive Prosthesis

Review Officer: QALS Manager

Review Summary: [2nd Version
Review Summary](#)

Applicable To: All Staff and
PSPs

Last Review Date: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory
Committee

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**Signature of Authorised
Officer**

Replaces: 42084 v1

Key Words: interim limb,
Definitive limb, component
Weight limitations,
Safety checks.

References

Purpose:

To ensure patient safety by requiring consistent practices when scripting prosthetic needs. Prosthetist check and ensure components are safe and within the listed component limitations schedule.

Procedure:

It is recognised that circumstances will arise where the client's immediate prosthetic needs are best met by the conversion of their interim artificial limb (prosthesis) to definitive status. This procedure identifies the issues involved and related conditions.

Client Status

Before any conversion can occur, it must be clearly recognised and indicated to QALS that the client has completed an appropriate rehabilitation program and that the client is ready for a definitive (permanent) prosthesis.

In order to identify the appropriate artificial limb type for a client transitioning to a definitive prosthesis QALS requires that all clients (other than bi-laterals and upper limb amputees) undertake a test to establish their mobility level. At present QALS recognises the AMPRO test resulting in the allocation of a "K-Level" of 0 - 4. No client with a K-Level of "0" will be considered for QALS services. Testing must be carried out by a suitably trained physiotherapist prior to any request for service to QALS.

Prosthesis Construction

QALS requires that components used in QALS funded prostheses are included on the Australian Register of Therapeutic Goods (ARTG). In general, prosthetic components included on the ARTG are stipulated as single person / multiple use. This allows the same component to be used multiple times **on the same client**. For any interim prosthesis to be accepted for conversion to a definitive prosthesis it must be composed of components that were new when used in the interim limb manufacturing.

Where only a new socket is produced during conversion to definitive status, the prosthesis will be given a new limb number, not a major repair number as is the normal process just for socket replacements. This allows QALS to track the number of interim limbs separate to number of definitive limbs otherwise the actual numbers reported will be less than what is actually supplied and funded.

In some unique circumstances the socket may remain the same and only the components are replaced in particular the foot. The same rules apply as above, a new limb number will be allocated to indicate the upgrade from interim to definitive status, all components parts will be recorded as per QALS procedure Identification of Limbs 42085/v2/08/2008.

Required Changes

Where the above conditions are met, QALS is prepared to fund for the provision of a new socket and/or a foam cover where clearly required and requested. These services will be obtained from a QALS recognised Prosthetic Service Provider.

Payment for Existing Components

Where the conversion of the interim to definitive meets the above conditions and is approved by QALS, or in the case of a client with DVA entitlements also by DVA, the manufacturer of the prosthesis will only be paid for the costs incurred for the changed/new components used in the definitive prosthesis. No payment whatsoever will be made for any other previously incurred costs associated with the production of the interim limb.

Database

QALS will enter the limb identification information in the database as a Primary Definitive and will assign a Limb Number in the form "Qxxxx" to the prosthesis and the prosthesis is to be so identified.

Warranty

Any services which are normally considered as subject to warranty will remain the responsibility of the party who provided the service involved.

Evaluation Method:

- Checking request for service forms have a clearly written indication of the changes required and the interim components that do not require replacement.
- PSPs identify such limbs clearly on their invoices and charge only for the replacement components.
- Annual report on numbers and types of conversion prostheses.
- Amputee clinic staff support for such a conversion is to the benefit of the client.

HYPERLINK TO: Hyperlink to relevant procedures



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**PRINCESS ALEXANDRA HOSPITAL
HEALTH SERVICE DISTRICT**

PROCEDURE MANUAL

Section: Leadership and Management

Procedure No. 42086/v2/07/2008

Procedure Title: Processing Non Standard Prosthetic Requests

Review Officer: QALS Manager

Review Summary: 2nd Version
Review Summary

Applicable To: All Staff & PSPs

Date Last Reviewed: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory
Committee

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Signature of Authorised Officer

Replaces: 42086 v1

Key Words: Non Standard
Components, Medical Justification

References:

Purpose:

This procedure sets a standard method for the processing of a request for a prosthesis incorporating components not pre-approved on the QALS Component Management System database.

The procedure ensures that a set routine is followed in the processing of any request for prosthetic service, even when non QCMS pre-approved components are involved. It also helps to confirm that consistent business practices are used when assessing and approving a request, thereby, supporting a fair and equitable service provision to all QALS clients.

Procedure:

QALS recognises that there will be clients where pre-approved prosthetic components from the QALS Component Management System database (QCMS) will not meet their special needs. Due to the high costs of certain prosthetic components it is necessary that there be clarity in communications between all parties involved in any request for special service. To this end, all and any verbal communications will be committed to writing after the fact. No

approval will be given for the use of non pre-approved components without QALS first receiving a signed '**Prosthetic Assessment Form**' from the Prosthetic Service Provider (PSP) stipulating the components requested and all costs involved. This PSP prosthetic assessment form shall be binding and, if approved, no additional costs to QALS will be considered.

QALS reserves the right to obtain competitive quotes from other suppliers for any job outside the normal scope of services or costs. QALS has a responsibility to obtain services in the most cost-effective manner.

Process

In the course of justifying the need for using components not pre-approved on the QCMS, additional supporting information may be required from the PSP, clarifying the purpose or reason for the type of component requested. If the request is based on a medical or clinical basis, it must be substantiated in writing by the treating medical officer. This supporting information will be requested in addition to the PSP Assessment of Prosthetic Needs Form already submitted. Technical advice from the QALS Staff Prosthetist may also be sought in the process of the decision making.

If appropriate and affordable, approval and funding for such a component may be given. Approval is likely to be given on a case by case basis, as a 'once off' only condition. At all times the QALS manager has discretion to approve or not approve any such application on financial or other grounds.

In the event that QALS funding is declined to meet such a request (generally an enhancement), then QALS will indicate on the prosthetic assessment form or in written response, that the item is "not QALS funded" or "at the Client's own expense".

Client Funded Improvements

Under some circumstances, QALS may partially fund towards the upgrade of components not normally supplied or pre approved on the QCMS. When this occurs, QALS will indicate in writing to the PSP the funding limit QALS will provide and is usually based on a QCMS pre-approved component used for a similar function. All such components will be noted on the back of the PSP Assessment Form, when this cost sharing exercise occurs.

Where the component requested cannot be approved or partially funded by QALS due to funding or any other issues, QALS may permit such a component to be incorporated into a QALS supplied prosthesis at the client's own expense. The addition of such components, improvements or enhancements must be compatible with the prosthesis as approved by QALS and not incur any extra expense for QALS. The client remains responsible for all costs associated with the addition of such components and QALS will not fund the servicing, maintenance or repair of any such component, improvement or enhancement incorporated in a prosthesis in this manner.

For post market surveillance purposes in all cases and at all times QALS must be aware of all components incorporated in a QALS funded prosthesis. The PSP must inform QALS by annotation on the reverse of the PSP Assessment of Prosthetic Needs Form of any client funded components incorporated in the prosthesis specification. Both the client funded components and the QALS funded components should be listed and the actual serial/batch numbers of the components used recorded on the client's record on the ALS database.

Evaluation Method:

- Checking components on prescriptions against the QALS Component Management System database.
- Monthly report on non QALS Component Management System pre-approved components approved.
- Ensuring justification is provided with all prescriptions before processing script.



Section: Leadership and Management

Procedure No. 42200/v1/07/2008

Procedure Title: Prosthesis Disposal Procedure - QALS

Review Officer: QALS Manager

Review Summary: [1st Version Review Summary](#)

Applicable To: All Staff and PSPs

Last Review Date: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory Committee

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Signature of Authorised Officer

Replaces: New procedure

Key Words: Prosthesis, disposal

References:

Purpose:

To ensure safe and reliable disposal of expired prostheses and the prostheses of deceased clients.

Procedure:

A prosthesis is made of a variety of materials which, in normal use, are benign. However, incorrect disposal methods such as burning can cause the release of materials into the environment which are potentially harmful.

When a prosthesis has reached the end of its useful life, or the client to whom it was supplied has no further use for it, the original supplier is required to accept it back for disposal.

The Prosthetic Service Provider (PSP) should dispose of the unwanted prosthesis according to their normal procedures as laid out in their quality manual while following normal Health and Safety requirements and guidelines.

Conditions:

This policy is applicable to expired prostheses. A prosthesis will be expired when it has been superseded/replaced for fitting or safety reasons.

Process:

It is the clients' responsibility to return an expired prosthesis to the PSP for disposal. This can be done at collection of a replacement or by posting the prosthesis to the PSP. QALS is not responsible for any postage charges involved in limb disposal.

Evaluation Method:

- Annual inspections at premises of prosthetic manufacturers by QALS manager.
- Review of Quality Assurance Certification incorporating Workplace Health & Safety practices.



Section: Leadership and Management

Procedure No. 42199/v1/07/2008

Procedure Title: Prosthetic Service Providers (PSP) Referral to Clinic - QALS

Review Officer: QALS Manager

Review Summary: [1st Version Review Summary](#)

Applicable To: All Staff and PSPs

Last Review Date: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory Committee

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Signature of Authorised Officer

Replaces: New procedure

Key Words: Referral, prosthesis

References:

Purpose:

This procedure provides a documented method for Prosthetic Service Providers (PSP) to refer clients to an amputee clinic.

Procedure:

QALS recognises the value of the amputee clinics and the multidisciplinary input available there. When a QALS client has a non-prosthetic issue identified by the PSP they should be referred to an amputee clinic for further investigation.

Conditions:

Completing the "PSP Referral to Clinic" form provides a method for referral from the PSP to the amputee clinic with the relevant information noted and documented. This is especially useful when the PSP cannot be present at the clinic appointment.

Process:

The Clinic referral form should be completed including the following information where appropriate:

- Patient information – Enter all information required to identify, contact and make an appointment for the client.
- ID Number on Presented Prosthesis – The PSP should scan the presented limb and note the number here. This is useful to confirm the prosthesis the client presents to clinic with is the one the prosthetist last saw the client with.
- Reason for provision – Note here the service being considered. This may include a change in prosthesis type, renewal of components or any other type of service the prosthetist wishes to be considered.
- Reason for referral – Note here the concerns that prompted the referral. This might include unidentified skin conditions, variation in socket fit or a change in the general wellbeing of the client affecting prosthesis use.
- Prosthetist request / suggestion / concern – Use this space to express ideas or suggestions to address the issue at hand or to expand on the reason for referral to the multidisciplinary team.
- Signature block – Enter information enabling identification of the referring prosthetist and when the referral was made.

Evaluation Method:

- Client is given an appointment for review by the multidisciplinary team
- Clinics receive clear and useful information as to the reason for referral.
- A clear path from PSP to clinic is documented and recorded in the client's files.

QALS PSP Information on QALS
Procedures

2008 Edition



Section: Leadership and Management

Procedure No. 42089/v2/07/2008

Procedure Title: Replacement of a Prosthesis – QALS

Review Officer: QALS Manager

Review Summary: 2nd Version
Review Summary

Applicable To: All Staff & PSPs

Date Last Reviewed: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory
Committee

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Signature of Authorised Officer

Replaces: 42089 v1

Key Words: Prosthesis, Medical
Justification, 3 year life expectancy

References:

Purpose:

To ensure, as far as practicable, client safety by the establishment of sound clinical and business practices leading to appropriate provision of services.

Procedure:

Where a current prosthesis is identified as ill-fitting or unsafe to use, by either a Prosthetic Service Provider (PSP) or the Multi-Disciplinary Team (MDT) at an amputee clinic, the Queensland Amputee Limb Service (QALS) will provide a replacement artificial limb if eligibility and funding permits. QALS shall strive to ensure that replaced, inappropriate or unsafe artificial limbs are not utilised by its clients.

Request for a replacement Prosthesis

The client seeking a replacement prosthesis must attend a QALS recognised amputee clinic or a QALS contracted PSP for assessment. The assessment will consider if any of the following apply:

- The prosthesis is no longer appropriate for the needs of the client.
- The continuing use of the prosthesis may present a danger to the client.
- The prosthesis is at, or near, the end of its useful life.

The request on the Multi-Disciplinary Team Form or the PSP Assessment of Prosthetic Needs Form must indicate these findings. If no justification is provided or does not address these issues, the form shall be returned for clarification.

QALS expects a prosthesis to last an average of 3 years. However, the age of a prosthesis is not in itself justification for replacement.

Multi-Disciplinary Team Oversight

QALS recognises that amputees are never cured but that neither are they in a perpetual state of rehabilitation. QALS considers that once the interim program is completed and the client has progressed beyond their primary definitive prosthesis that the rehabilitation phase is generally complete. However, QALS also recognises that some amputees have a variety of co-morbidities which may make oversight by a Multi-Disciplinary Team experienced in the treatment of amputees desirable. QALS requires all clients to attend an amputee clinic for assessment/review by an MDT for the first 3 years post amputation and at every second request for socket/prosthesis replacement or every 6 years, whichever occurs sooner. This does not apply to minor repairs or provision of supplies.

Any significant change in prosthesis design would also require assessment by a Multi-Disciplinary Team. This would include, but not be limited to, a change in suspension type e.g. from suction to liner & shuttle-lock, change in component type e.g. from a locked knee to safety knee or any other change which significantly effects the manner in which the limb functions or the user utilises the prosthesis. If the PSP is in any doubt about the requirement to have a MDT assessment QALS should be consulted for a ruling.

PSPs should check the ALS database prior to any request for service being sent to QALS to ensure the client is referred to an amputee clinic as appropriate. Only in exceptional circumstances would the QALS manager consider approving services if this condition is not met.

QALS Approval

When a request for a replacement prosthesis is received by QALS, the client's record is retrieved and reviewed. If there are queries arising from the client's records, QALS will contact the amputee clinic for clarification.

If it is the first request for service for a new client, QALS will send the necessary paperwork to the client for registration and to assess if the client is eligible for prosthetic services funded by Queensland Health. At this stage the client will also be asked to indicate which Prosthetic Service Provider (PSP) they prefer to attend, if there is a choice available. Once the client has returned the necessary Registration Form and any other necessary paperwork, QALS will forward the approval for work to commence to the appropriate PSP.

Replaced Prosthesis

QALS shall take measures which actively discourage any use of an expired prosthesis which are, by definition, no longer appropriate or safe for use by the client. When the prosthesis is replaced, a **Warning and Compulsory Direction** to the client regarding replaced limbs will be made on the Acquittal and Quality Control Form. An option to return the limb to either an amputee clinic (in the case of an interim prosthesis) or PSP shall be included.

If the client returns the limb, the clinic or prosthetic service provider who receives the replaced limb shall dispose of the prosthesis according to QALS Procedure No. 42200/v1/07/2008.

The following text has been placed on the Acquittal and Quality Control Form for signature acknowledgement by the client.

' Warning and Compulsory Direction to Patient'

The Queensland Amputee Limb Service requires you to discontinue the use of any replaced artificial limb. Please ensure that your replaced (expired) artificial Limb is destroyed and then disposed of in a responsible manner. Alternatively, the expired limb may be returned to your amputee clinic or limb manufacturer (PSP) for disposal on your behalf free-of-charge.

Evaluation Method:

- Monthly activity reports based on clinical indicators and set performance measures.
- Checking forms are completed accurately by the appropriate qualified staff.
- Ensuring patient's needs are met via annual Patient Satisfaction Survey.

HYPERLINK TO: [Prosthesis Disposal Procedure.](#)



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**PRINCESS ALEXANDRA HOSPITAL
HEALTH SERVICE DISTRICT**

PROCEDURE MANUAL

Section: Leadership and Management

Procedure No. 42099/v2/07/2008

Procedure Title: Weight and Prosthetic Components Limitations – QALS

Review Officer: QALS Manager

Review Summary: 2nd Version
Review Summary

Applicable To: All Staff & PSPs

Date Last Reviewed: 07 2008

Next Review Date: 07 2010

Authority: QALS Advisory
Committee

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Signature of Authorised Officer

Replaces: 42099 v1

Key Words: Prosthesis,
Components Weight Limitations
Prosthetic Service Providers

References:

Purpose:

This procedure aims to ensure patient safety by advising and informing clients of any limitation of their prosthesis and the components used in the making of the prosthesis.

Procedure:

QALS recognises that the components used in the manufacture of a prosthesis have weight and activity limitations stipulated by the manufacturer of the components. QALS requires that all clients be informed of any, and all, limitations placed on the prosthesis with which they are supplied, either by the component manufacturers or the Prosthetic Service Provider (PSP). The Therapeutic Goods Act 2002 places responsibilities on the PSP as regards to prosthesis design, risk analysis and labelling of prostheses. All PSPs contracted to QALS are required to fully comply with the requirements of the relevant sections of the Therapeutic Goods Act 2002 in the design and supply of any prosthesis to a QALS's client and to stipulate this compliance by signing the "**Prosthesis Issue Document**" when the client takes the prosthesis for trial

Role of the Amputee Clinic

All requests for service must record the current weight of the client on the Multi-Disciplinary Team (MDT) form. The leader of the MDT shall advise the client to discuss any limitation of their prosthesis and/or components with their PSP.

Role of the Manufacturer

When the client attends the PSP, the prosthetist will review the requirements of the client in the context of the MDT form from an amputee clinic. The Prosthetist will explain to the client the prosthesis weight and activity limitations both verbally and in writing and have the client acknowledge their understanding and acceptance of these limitations by signing the Prosthesis Issue Document prior to taking the prosthesis on trial. The copies of the form are distributed as identified.

Role of QALS

QALS will not process an invoice for payment of services unless the client has been informed of the issues relating to the use of the prosthesis. QALS requires that the original copy of the Prosthesis Issue Document be submitted with the invoice for services provided. The Prosthesis Issue Document shall be placed on the QALS client's file.

Evaluation Method:

- Verify MDT Form and/or PSP Assessment Form correctly completed before approval of requested services.
- Ensure Prosthetic Service Providers return the signed Prosthesis Issue Document with invoices before payment is processed.
- Response by clients on the annual client survey on PSP service provision.

HYPERLINK TO: