Bariatric Solutions Australia
A division of Sphere Surgical Pty Ltd

Bariatric Solutions Australia Quality Manual

for ISO 9001:2015 Quality Management System

Definitions

Customer/Client – either an internal or external recipient of a product or service provided by Bariatric Solutions Australia.

Corrective Action Request – a CAR is a document, which identified a non conformance and outlines preventative and corrective actions taken to correct the non conformance and minimise a recurrence.

Controlled Document – any document (hard copy or electronic) for which a record of revisions and record of recipients is maintained (e.g. Regulations, Australian Standards, Quality Manual).

Infrastructure – infrastructure needed to produce a product that conforms to the specified requirements. May include buildings and related utility services, workspace, plant and equipment, hardware and software, supporting services.

Non Conformance – Non-fulfillment of specified requirements and may cover any area of the Company's operations (e.g. product damage).

Product Notification - means the issue of precautionary information about a therapeutic good, in a situation that is unlikely to involve significant adverse health consequences.

Quality Management System - is a set of policies and procedures required for planning and execution of a product or service in the core business area of an organisation. (i.e. areas that can impact the organization's ability to meet customer requirements.)

Safety Alert - means advice regarding a specific situation with respect to a therapeutic good which, whilst performing to meet all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions in regard to its use are not observed.

Sponsor - person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.

The sponsor is responsible for applying to the TGA to have their therapeutic good included on the Australian Register of Therapeutic Goods (ARTG).

Contents

1. Purpose and Scope

This Quality Manual provides an overview of the quality elements of the Quality Management System and the quality policy implemented by The Company for its business operations.

2. Company

2.1. Background

Bariatric Solutions Australia (BSA) is the trading name of Sphere Surgical Pty Ltd, ABN: 22 129 200 022. BSA head office is located at Level 1, Unit 2b West, 1030 Dandenong Rd, Carnegie VIC 3163.

BSA supplies medical devices and products to service the bariatric and general surgical needs of its clients. BSA specialise in offering the highest quality training and support along with innovative quality products. Our focus is our clients, and how they can help their patients achieve successful surgical outcomes.

Bariatric Solutions Australia's products are sourced from Bariatric Solutions GmBH, Boehringer Laboratories LLC and Qingdao Medical Technology Co Ltd. In order to ensure that all Bariatric Solutions products are made to the highest quality standards, all products are produced, sterilised and packaged by a certified manufacturer in Europe, USA or China.

BSA has representation in each Australian major city. All BSA sales representatives are highly trained with a wealth of industry experience.

2.2. Organisation Structure

BSA is a sponsor of medical devices and supplies medical devices and products to the health industry across Australia. The management team has over 40 years cumulative experience within the medical industry at major multi-national companies both in Australia and abroad. The organisation chart is included in Figure 1.

Head Office and warehouse facility is located at Carnegie in Melbourne, Victoria.

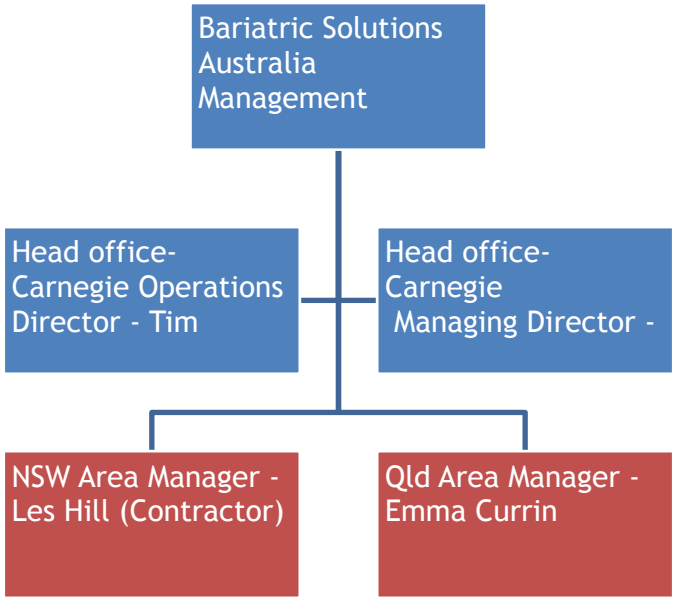


Figure 1 Organisational Chart

3. Company Objectives

3.1. Vision

We are a leading supplier of high quality medical devices into the Australian medical industry ensuring provision of quality technical support to our end users.

3.2. Mission

To provide products and services that lead to healthy outcomes for our clients bariatric and other surgical needs.

3.3. Values

- Zero harm or injury to people
- Strong stakeholder relationships
- System and Product Compliance
- Leadership based on accountability, vision and innovation
- Honesty, integrity, stewardship and excellence

3.4. Goals

- To effectively manage product delivery sustainably and efficiently
- To engage and build relationships with key stakeholders
- To foster a positive and supportive workplace culture
- To provide technical support to end users

4. Quality Management System

4.1. Quality Policy

Bariatric Solutions Australia aims to provide high quality products and services that lead to healthy outcomes for our clients bariatric and other surgical needs.

Our Quality Management System is based on the International Quality Management Standard AS/NZS ISO 9001:2015. Our activities include:

- Sponsoring, supply and distribution of quality medical devices and solutions via the Australian Therapeutic Goods Administration to the bariatric and general surgery industry
- Industry and market research into bariatric and general surgery products
- Provision of technical Information and support to our customers

Commitment:

- Comply with relevant statutory requirements
- Establish and maintain objectives and targets with the aim of improving inefficiencies
- Define roles and responsibilities of personnel
- Comply with ISO 9001:2015
- Make available all operating instructions and directions to ensure consistency in delivery of product and services
- Ensure that purchased products and materials meet required standards
- Ensure that providers of contract services are appropriately qualified and competent
- Monitor, inspect, measure and report the effectiveness of our quality management goals and system.

Strategies and Objectives:

- Availability of relevant and current information and resources necessary to support our operations
- Selection and training of employees and contractors to maintain required standards
- Compliance with relevant regulations
- Commitment to health and safety management
- Waste minimisation and regard for our environment
- Monitoring our clients' level of satisfaction
- Ensuring that our clients and stakeholders are satisfied with our services
- Improving our business through project planning, goal setting and performance measurement
- Maintaining the suitability and effectiveness of our management system through continual improvement.

This statement is issued to indicate our commitment to our clients and our standards of service. The full support of our staff, suppliers and contractors is sought in meeting our commitment.

4.2. Scope

The provision and supply of sterile and unsterile medical devices for medical and related applications.

This Quality Manual describes how Bariatric Solutions complies with ISO9001:2015 Quality System Requirements – General. The Company has implemented a stand-alone Manual for Quality to describe its management system.

How the Company is structured is detailed in Figure 1. The Company's organisation and job descriptions, detailing key responsibilities and authorities for Quality are included in Section 7.1 below.

The processes described and referenced in this Manual provide detailed instructions for performing business processes in a manner that ensures The Company's objectives are met. An integrated business model (refer to IBM-01) has been mapped that references the internal and external processes and stakeholders included in BSA's activities.

The organisation operates nationally with staff located in the head office in Melbourne, Victoria and mobile offices in Queensland and New South Wales. The organisation has offices at;

Australia	
Head Office - Melbourne	Unit 2b West, 1030 Princes Highway Carnegie 3163
New South Wales	Mobile Office
Queensland	Mobile Office

4.3. Dispensations

Exclusion (ISO9001:2015 Items 7.1.5 and 8.3)

Monitoring and measuring resources

BSA is not responsible for controlling the accuracy or reliability of any equipment (including software) used in monitoring, measuring, testing or validating our products or services, to determine product or process conformity.

Design and Development of products and services

Design processes in relation to product development and realisation into the Australian market are included in the management system, however product design is managed at international warehouse and manufacturing locations. Thus, workshop manufacturing procedures are not included in the management system as the organisation does not presently perform manufacturing works.

If at a later stage, design and manufacturing is introduced to The Company's business operations, accreditation of procedures and forms will be sought during a planned third party surveillance audit.

5. Legislation and Other Obligations

The organisation has compiled a list of legal and other obligations into a separate register. Management attends regular industry events and conferences where legislative changes and updates are discussed and also receives updates to legislation through email.

Also, as a sponsor and distributor of medical devices in Australia, BSA acknowledges its responsibilities and regulatory requirements under the Australian Regulatory Guidelines for Medical Devices (ARGMD). BSA holds Australian Register of Therapeutic Goods (ARTG) certificates for each product it supplies approved by the Department of Health.

BSA's suppliers and manufacturers also hold relevant certifications and comply with international standards (e.g. ISO 13485) to manufacture and supply medical devices.

6. Planning

6.1. General

The organisation undertakes the following planning activities:

- Business planning
- Current product supply and demand
- New and Emerging product supply
- Tender and Contract Submissions
- Sales and Marketing
- Financial and Budgeting

6.2. Quality Objectives

The organisation has developed detailed measurable quality objectives to aim for continual improvement across all business activities. These measurable quality objectives include:

- Achieve 95% customer satisfaction & timely action the feedback received- 48 hrs.
- Achieve double digit revenue growth year on year
- On time deliveries in full achieved to a 90% standard
- Backorders not to exceed 2% of total orders
- Zero non-conformances of services and products- including complaints, etc.

6.3. Product Development and Design

BSA are a leading supplier of medical devices and products and a critical part of business planning processes includes identifying client and customer needs and demands for its

products. Management attend conferences to keep up to date with industry best practice and determine if there are other feasible bariatric products and solutions suitable for the Australian market.

BSA conducts a planning and feasibility process for each medical product or device prior to an approved release to the Australian market. The product planning and feasibility process involves input from both internal and external stakeholders to ensure viability and compliance requirements of the product are met to ensure government approval.

External stakeholders can include:

- Suppliers and manufacturers,
- distribution agencies,
- customers and their organisations and
- Therapeutic Goods Administration (TGA) within the Department of Health.

The product planning process is described in Attachment A. At each stage, from Stages 1 through to Stage 6 in the product planning process risks are identified and assessed to highlight any issues before moving onto the next stage in the planning process. The risk management process is detailed in section 7 below. BSA will also provide input into risk assessments conducted by its product manufacturers and suppliers.

As part of product planning, the organisation conducts desktop research activities and supports industry research into the effectiveness of various bariatric solutions approved in Australia. The organisation conducts extensive research into customer needs for the appropriate and successful bariatric solutions to meet the demands of the medical industry.

6.4. Product Realisation Processes

Once the products have been approved for release by the TGA, a certificate is issued and all products are registered on the Australian Register of Therapeutic Goods (ARTG). The certificates are referenced in the Legal and other obligations register.

Prior to full release to the market, clinical testing and trials are conducted (refer Stage 5 in Attachment A). BSA are involved with this process and seek product reviews, assessment and feedback from customers to gather information. Stakeholders involved in the product review phase are requested to sign and submit a Non-disclosure agreement to protect the organisation.

As stated in Section 12.6, a customer evaluation form for each product (refer to FRM-09 and FRM-10) is sent to its customers (i.e. surgeons and nurses) to obtain feedback and reviews of the product's use. Any feedback is collated and changes are implemented before fully supplying and distributing their product.

The products approved for supply by BSA as detailed on the Company website include:

- MiniMizer Gastric Ring
- MiniMizer Extra Gastric Band
- The Tube
- ViSiGi3D
- Pinky Trigger
- Laparoscopic Cholangiography Forceps

Products supplied include relevant specifications and product codes on the company website. There is also supportive information on relevant process and procedures for use with the supplied products available for customers on the Company website, (http://bariatricsolutions.com.au/). Further reading and references to procedure videos include:

- Gastric Banding
- Banded Sleeve Gastrectomy
- Banded Gastric Bypass

6.5. Sales and Marketing

Sales and promotion activities to market the medical products are conducted by all staff and include regular networking events and conferences and meetings with other professionals in the bariatric and medical industry. Area managers are responsible for the sales processes in their allocated locations across Australia.

Product specification documents and marketing materials are supplied to potential customers at organised marketing events including trade shows, conferences and face-face meetings. These documents are also available on request.

7. Organisational Risk Management

7.1. Risk Management Strategy

The organisation is committed to the concept and operational framework ensuring tangible and measurable risk management procedures as part of decision making processes. This is achieved by identifying, implementing and continually improving measures for the management of risks in order to control, minimise or eliminate potential loss.

Risk is identified and managed throughout all activities conducted by the organisation from product development into the Australian market through to end user (refer to Integrated Business Model - IBM-01)

Any changes in the organisation due to external or internal factors will trigger an assessment of the risk that this may introduce into the business and relevant actions will be identified to

minimise any risks associated with the change. Actions identified can be tracked and monitored through the corrective action process as per Section 5.3 below.

The risk management strategy aims to address all risks that may undermine the organisation's ability to achieve its goals. Risk management is an organisational responsibility with all staff having responsibility for managing risk. Refer to Figure 2 for an illustration of the Risk Management Process.

BSA conducts risk assessment activities in all areas of the business and is committed to effective risk management. The risk assessment template (FRM-01) is utilised for identifying and analysing risks. Additionally, the organisation provides input and utilises risk assessment tools provided by product manufacturers, particularly in the product planning process.

An organisational risk register has been developed to manage operational and continuity risk and is reviewed annually. Refer to the Company Risk Register.

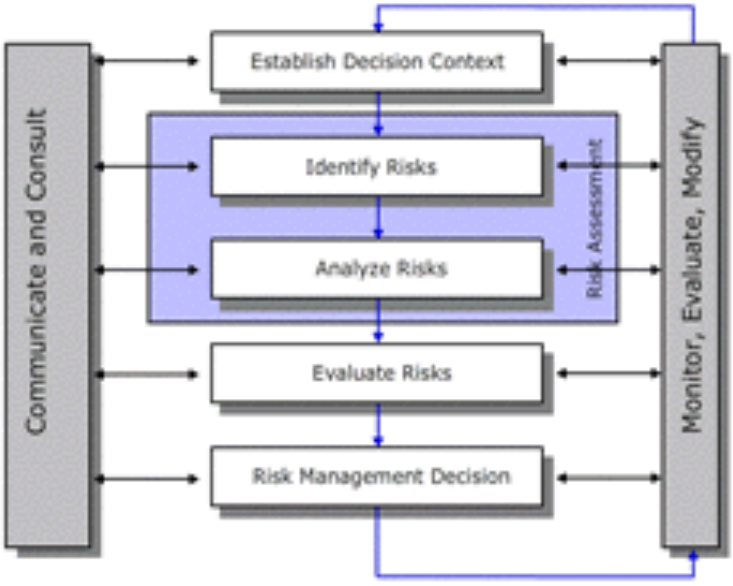


Figure 2 Risk Management Process

7.2. Risk Management Process

Step 1 - Identifying Risk

Risks are identified by drawing on the knowledge and experience of Directors and Staff to identify actual or potential problems that may arise across a range of business activities including:

- Financial

- Legal
- Human Resources
- Technological
- Health and Safety
- Security

The organisation will identify risk through:

- Brainstorming exercises
- Consultation with staff and other stakeholders
- Root cause analysis processes
- Documenting unanticipated risks as they become apparent

Step 2 - Analysing Risk

The aim of risk analysis is to separate minor, acceptable risks from major risks. This process allows priorities for action to be identified and provides data to assist with the identification and evaluation of possible treatment options.

The assessed severity of risk is a product of:

- The consequence or impact if the event was to occur
- The likelihood of that event occurring
- The effectiveness of existing control measures

The following qualitative measures of likelihood (Table 3) and consequences (Table 4) are used to inform the analysis of risk:

Table 3: Risk Likelihood Rating Table

A	**Almost certain**	Expected in most circumstances
B	**Likely**	Will probably occur in most circumstances
C	**Possible**	Could occur at some time
D	**Unlikely**	Not expected to occur
E	**Rare**	Exceptional circumstances only

Table 4: Risk Consequence Rating Table

1	**Severe**	Would threaten the survival of BSA, causing major problems for clients, the administration of the entire organisation and for customers and associated organisations
2	**Major**	Would threaten at least one aspect of BSA operations and have major ramifications, including financial, reputational and political
3	**Moderate**	Would not threaten BSA but would have some financial/ reputational/political ramifications and would require significant adjustment to achieve objective(s)
4	**Minor**	Would threaten the efficiency or effectiveness of some aspects of BSA operations. Would require some adjustment to achieve objective(s) and would be dealt with internally
5	**Insignificant**	Very little consequence to achievement of the objective(s). The consequences are dealt with by routine operations

Once the likelihood of a risk occurring has been identified, along with the consequences of that event, it is plotted in a qualitative risk analysis matrix (Table 5), which will assist to identify the overall risk rating.

Likelihood	**Consequences**				
	Insignificant 1	**Minor 2**	**Medium 3**	**Major 4**	**Severe 5**
A (almost certain)	M	H	H	E	E
B (likely)	M	M	H	H	E
C (possible)	L	M	M	H	H
D (unlikely)	L	M	M	M	H
E (rare)	L	L	L	M	H

Legend:		
E	Extreme risk	Immediate action required
H	High risk	Management attention needed
M	Medium risk	Management responsibility must be specified
L	Low risk	Manage by Routine procedures

Once the level of risk has been established, it is necessary to decide whether there are currently adequate measures in place to control the risk. The assessment of likelihood, consequences and adequacy of controls for each identified risk are to be recorded in the risk register.

Step 3 – Evaluate Risk

If the existing control measures for an identified risk are considered to be extreme and unable to be managed utilising existing control measures, then an action plan is to be developed.

Step 4 – Risk Management Decision

Risk management options for controlling risks include:

- Avoidance: don't proceed with the activity likely to generate the risk
- Reduction: develop actions and strategies to reduce either the likelihood of a risk occurring, the impact of the risk if it did occur, or both
- Transference: look at mechanisms to shift the risk to other parties or share the risk, for example, through contractual arrangements, insurance etc

An action plan should be completed for each risk requiring treatment, detailing the proposed actions ('treatment') to manage the risk, resource implications, responsible persons, timing and reporting and monitoring requirements. In deciding which treatment option to adopt careful consideration needs to be given to the level of risk and the cost of the treatment versus the benefit. The costs may outweigh the benefits.

Where large reductions in risk may be obtained with relatively low expenditure (dollars and resources) such options should be implemented. Further options for reducing risk may be uneconomical or impractical and judgement needs to be made on whether to proceed. In general, the adverse impact of risks should be made as low as possible within the available resources.

After risks have been reduced or transferred there may still be some residual risk. Strategies to manage the consequences of these residual risks should be established if not cost prohibitive.

Step 5 - Monitoring and Review

Strategies and timelines for monitoring risks are specified on individual action plans. Additionally, when a change in the system, product or process is identified, this shall also initiate a risk review.

A general review of the organisation's risks and risk management strategy will be conducted annually to assess the effectiveness of control measures and identify emerging risks or changes to existing risks.

7.3. Emergency Planning and Response

As part of business planning, risks to continuing business operations from adverse events including emergencies have been identified and assessed. These have been included in the Organisation's Risk Register and are risks such as fire, flood, threats and loss of data and security.

Actions in case of an emergency (e.g. fire) within the head office premises include contacting the head office building representative and emergency services where required. Insurance policies have been obtained to cover emergency or adverse events and are referenced in the Legal and Obligations Register.

A list of emergency contacts and their corresponding contact details have been detailed in a separate Emergency Response register.

8. Human Resources

This section provides information about the human resources system and how recruitment and selection is undertaken.

The organisation has developed a human resources policy (HRE-01) and health and safety policy (HSE-01) that details its expectations of and commitment to its employees.

8.1. Roles and Responsibilities

The organisation chart indicates the various roles within the Company and is included in Figure 1. The following section details the responsibilities and accountabilities for each role.

The Managing Directors are responsible for:

- review, currency and approval of this Quality Manual and the related QMS documentation.
- Ongoing reviews of risk relating to the organisations activities
- Monitoring the effectiveness and overall performance of the Quality Management System and ensuring continual improvement.
- Undertaking training sessions to communicate its requirements to all staff
- Ensuring resources are made available for the development, updating and implementation of all management systems procedures

All staff including contractors are responsible for:

- Complying with and implementing the QMS policies and manual for all product and service delivery
- Checking the effectiveness of the QMS through ongoing training, reviews and verifications

- Identify and report product or service related incidents, non conformances and corrective actions
- Closing out corrective actions
- Monitoring continuous improvements.

In such cases where modifications are required, the Managing Director (or delegate) is responsible for executing and approving the required changes through the change management process.

8.2. Infrastructure

The organisation operates from the head office located in Carnegie, Melbourne as well as mobile locations in NSW and Qld.

All staff are provided with access to quality IT software resources and data security protection, to ensure high quality work performance. All staff also have access to the internal Company drives to locate QMS documents.

Data backup and recovery is managed in head office. IT hardware and software is checked internally and annually by an external IT consultant to prevent any functioning, security or loss issues.

Staff utilise own vehicles and it is the responsibility of each individual to manage the safe operation and performance of their vehicles.

8.3. Recruitment, Training and Competency

The organisation is a small business with staff being selected and recruited to work with the organisation based on their experience and understanding of the medical industry, devices and products and the medical procedures associated with the products supplied.

Internal training is conducted with staff regularly. This consists of sales and educational training and is conducted face to face as well as over the phone at regularly throughout the year. International suppliers also visit head office and conduct specific product training annually.

In house, BSA conducts a yearly sales conference where all staff are invited to discuss and learn about new procedures and products. BSA use this time to have a debrief on the current product range and any industry changes.

All BSA staff are highly trained health care representatives with vast industry and clinical knowledge.

8.4. Employee and Contractor Management

Contractors are engaged on a rolling 12 month contract agreement which is reviewed annually. An example BSA employee contract is included in QMS.

Performance management is conducted regularly. An internal weekly report template is completed by staff to monitor and track performance and to discuss opportunities for improvement and identify potential opportunities.

9. Purchasing, Procurement and Delivery

9.1. Supplier selection

This section describes the process associated with supplier selection prior to procurement.

The Directors of the organisation hold a good relationship with its international suppliers and manufacturers and regularly discuss business and product requirements. Suppliers are selected based on their reliability of product performance and supply, certification with international and local regulatory requirements, reputation and market knowledge.

Suppliers and manufacturers once approved through the TGA process are then registered into the organisation's accounting software, Xero, which captures all relevant details.

9.2. Purchasing

BSA purchases approved medical devices, approved by the Australian Therapeutic Goods Administration, from certified compliant international manufacturers. The international suppliers and manufacturers comply with international standards for medical products and all products need to be listed as an approved medical product on the ARTG register before it is allowed to be supplied to the Australian medical industry.

This section provides information on how a purchase requisition is raised and how a purchase order is generated following a requisition request.

Once the product has been approved by the government, BSA can receive purchasing requisitions from its customers. Purchasing requests are lodged via the company email purchasing@bariatricsolutions.com.au or facsimile transmission. New account applications are then set up with new customers using the New Account Application Form (FRM-06).

Once the order has been submitted to the supplier, BSA coordinates and manages its delivery to its Australian warehouse at the head office in Melbourne. Once the products are received BSA supplies and distributes these products to its customers to various locations across Australia.

BSA holds only a small amount of product on consignment, however most purchasing of product is conducted once stock supplies have reached a predetermined number. Stock is monitored through inventory registers.

9.3. Financial and Procurement Management

All current suppliers and contractor details, shipments and product orders are kept up to date in the Xerox system. Purchase requisitions are processed and filed on the internal drive system at head office.

Purchase orders and invoices are then created and tracked in the Xerox system. Any issues, queries or changes to orders can be managed through this system. Additionally, any non conformances that are identified during the procurement process can be raised via the corrective action request (CAR) form (FRM-05). Further detail is included in Section 11.3 below.

Sales, stock, distribution and purchasing figures are monitored, tracked and reported to Management monthly.

9.4. Product Inward Verification

This section describes the process of receipting and verifying purchased products against the purchase order to ensure compliance.

All product shipments are checked on receival for any damage or faulty goods. Following inspection and acceptance of the product by an authorized representative, a receipt is collected and filed in a locked filing cabinet to track the product.

To ensure traceability of product, all “Lot Numbers” are recorded against the deliveries and the business accounting software, Xero, keeps a record of distribution.

The organization prides itself on being able to locate, monitor and track all deliveries and is able to assist its customers when items are misplaced at the delivery location due to the accuracy of records kept. This is due to thorough identification and traceability of all products shipped and then delivered to its customers.

Additionally, as a supplier of implantable prostheses BSA is required by law to maintain a stringent check of stock received and distributed to each customer. For example, BSA can triple check and recall a single serial/ lot number and isolate when it was received, when it was delivered to a hospital and , in some situations, when it was used (refer to Recall process in Section 12.8 below).

Stock is received into the head office and stored in segregated, labelled shelving according to the type of stock. Stock is distributed and used according to the use by dates as indicated by the product labels. Stock is rotated to ensure that the older product is used first.

On the rare occasion where stock has expired its use by date, it is segregated and stored separately. Any out of date stock is then used for training and sample demonstrations for customers.

9.5. Identification and Traceability

BSA have developed and implemented a unique identification system that ensures adequate product traceability from delivery to end user. A label is applied to each product and includes:

- Company contact details
- Product name
- Product order code

- Rebate code
- Contents including number of units
- Bar codes (for prostheses)

9.6. Product Storage and Distribution

BSA distributes the TGA certified medical devices to various locations across Australia. BSA utilise TNT Express for all local deliveries and as a backup for international deliveries. DHL has been selected for backup of local deliveries. UPS has been selected for all international deliveries.

Management takes responsibility for the day to day running of all warehousing and distribution. The office and warehouse premises are in a private lockable space and the area is completely temperature controlled.

9.7. Product delivery verification

BSA supplies and distributes its products to customers and clients across Australia.

Sent with products are a BSA packing slip (FRM-04) and a BSA stock delivery receipt (FRM-07) including the organisations contact details and the customers order details so that customers can verify receipt of product at delivery location and notify the organisation if there are any issues that are identified upon delivery receipt.

Product specifications and codes specific to each product is included on the company website and easily located for customer download.

The delivery couriers also require a signatory from the customer following receipt of the product to verify the goods have been received and meet their requirements.

10.Technical product support

Once products have been ordered, technical support is offered to BSA clients and customers of its products. Education based training can be conducted by staff as part of product development, design and product realisation.

The education program offered to clients and customers (e.g. Surgeons, nursing staff) using the products is extensive. Various programs are offered and delivered on a needs basis including:

- onsite training,
- proctorship courses,
- nurse in-servicing,
- ongoing clinical support in theatre,

- educational assistance at specialist courses,
- procedural videos and clinical papers.

Upon enquiry, BSA can offer each site the following:

- Product brochures
- Nurse in-services
- Clinical in theatre support for customers
- Demo product to show the customers and end user

11.Document and Record Control

11.1. Document control

The BSA document control system adheres to the AS/NZS ISO9001:2015 Quality Management Systems - Requirements. Any changes to documents are approved by Management.

Documents and templates included in the QMS are listed in the Document Control Register. New procedures or manual documents to be created are to include the Company logo in the header and use the following fonts:

- Arial Font size 11
- First level heading: Bold Arial font size 16
- Second level heading: Bold Arial font size 13

QMS forms include a form number (FRM-XX) in either the header or footer as well as the Company logo in the header.

Manuals and procedures are uncontrolled when printed, thus the following is to be included on the bottom of QMS procedures or the manual (note: Bold, Font size Arial 9):

"This document is uncontrolled in hard copy"

11.2. Record Control

Accurate hard copy records and organisation documents are filed in lockable, secure filing cabinets in head office.

Record retention requirements as per the ARTG Certificates includes distribution records are to be retained for a minimum period of 10 years for Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device.

Records relating to any other medical device including distribution records must be retained for a minimum period of 7 years.

Company documents shall be archived and held in the head office in a clean, dry, secure and clearly defined storage location.

12.Quality Control and Assurance

12.1. Quality Control

The purpose of quality control process is to inspect, identify and verify all incoming products supplied are in compliance with TGA, other regulatory and client requirements. It is also conducted to identify any non conformances in the products or processes as a basis for taking corrective action.

The organisation carries out regular inspection and verification processes to ensure integrity of products and that they conform to specifications and/or client requirements on delivery receipt and are checked again prior to distribution.

The inspection process includes inspection of the product and the delivery documentation to ensure it matches the set detailed product specifications and requirements. Inspection points include:

- At delivery of the product to head office;
- prior to packing and shipping to a customer; and
- Customer check prior to signing and accepting at delivery of product.

An important part of quality control involves regular communication with both internal and external stakeholders. This includes suppliers and manufacturers, customers, nurses and distribution agencies.

All records and reports of inspections become part of the quality records and are retained at head office until filed into archiving.

12.2. Non conformance

Non conforming product or process can occur at the input and/or output stages of all business activities. Inputs are any items, purchased or supplied from external suppliers, for sale and distribution to the Australian market.

Management within the head office carry out the necessary inspections and verifications, authorise and endorse acceptance of product and record and report any non conformances. It is important to check that items delivered conform to the details listed on the delivery docket. Proof of delivery shall be by signing the delivery docket.

Should the purchased product or service be found to be nonconforming, the product or item is to be segregated and/or marked and labelled to prevent use. The supplier is to be notified immediately upon identifying a non conforming product and a corrective action request (FRM-05) completed and entered into the corrective action request register.

Non-conforming product includes:

- Damage to interior or exterior packaging
- Damage to interior product
- Evidence of tampering
- Evidence of water or pest infestation or damage
- No packing or delivery docket slips
- Product supplied not matching purchase order request

12.3. Raising a CAR

A non conformance may be identified in any aspect of the Quality Management System for various reasons including:

- Failure to follow documented procedures and processes
- Incident or complaint investigations
- Management reviews
- Product verification checks
- System failures
- Regulatory inspections
- Internal audits
- Supply or delivery issues or delays
- Faulty product or
- Poor product performance

A CAR shall be raised as a means of recording the non conformance, providing a record of actions taken and to verify that these actions were completed. Where non conformances are identified, corrective actions can then be assigned to prevent reoccurrence.

Any non conformances identified during routine inspections or observations are documented via the CAR Form (FRM-05). The person raising the CAR shall:

- Take action to clearly mark and segregate the non conforming product where possible
- Enter the details of the non conformance into the CAR register relating to the specification, procedure, regulation or policy in the 'Details of Non conformance' section
- Insert a realistic 'Date action required by', taking into account the risks involved.

12.4. Corrective and Preventive Action

Where non conformances against the QMS and associated processes or customer complaints are raised, relevant corrective and/or preventive actions are identified to prevent re-occurrence. The corrective action implemented shall:

- Aim to eliminate the root cause of the nonconformity,
- Provide an acceptable product to the client, and
- Ensure the effective and timely resolution of non conformance.

When the corrective action has been completed, management shall enter the date completed and by whom in the 'Corrective Action' section of the CAR as well as close out the issue in the corrective action register.

12.5. Internal Audits

Internal audits are conducted on operational activities twice per year. Internal audits will also identify any non conformances within the QMS.

Improvements, non conformances or corrective actions will be identified within a documented internal audit report and followed up through the corrective action register.

12.6. Customer Satisfaction

BSA is focused on customer satisfaction at all levels within its operations. BSA communicates with its clients and requests customer feedback is requested following supply and use of its products and services utilising the customer feedback form (FRM-08).

During product feasibility and design process, a customer evaluation form for each product (refer to FRM-09 and FRM-10) is sent to its customers (i.e. surgeons and nurses) to obtain feedback and reviews of the product's use.

Positive feedback is collated and any improvements or actions that can be integrated into the organisation are entered and followed up in the Feedback register. Refer to Flowchart 1 below for the feedback review process.

Whether a complaint or feedback is reported by any of its customers, a customer feedback form is completed. Details of the feedback and any actions required to be completed are entered directly onto the feedback register and any actions requiring follow up are monitored and closed out.

12.7. Reporting

As a supplier of medical devices, including Class 1, IIA and IIB devices, BSA has reporting requirements to maintain inclusion on the ARTG register. As per the ARTG Certificate for each medical device, the following reporting requirements are noted:

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the TGA regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years.

The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. This is completed by the manufacturer directly with the TGA and may/ not be seen by BSA as it may contain manufacturer personal information.

12.8. Product recall incidents

Where a BSA medical device has been used and an adverse event occurs, the organisation is notified immediately.

An adverse event is then reported directly to the TGA via an online Users Medical Device Incident Report. The details of the adverse event are documented and completed (refer to link here https://apps.tga.gov.au/prod/mdir/udir03.aspx). The adverse event is then documented on the Database of Adverse Events Notifications managed by the Department of Health.

The Therapeutic Goods Administration (TGA) will assess and determine what further actions are to be taken in regards to ensuring the safe use of the medical device or product. In some instances, an official recall action is required to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

The recall is either:

- Permanent removal of deficient goods from the market or from use; and
- correction, which may involve temporary removal from the market or from use.

Alternatively, a non recall action includes either a safety alert, product notification, withdrawal and recovery all of which are not recall actions.

Further information on the TGA protocols and requirements of sponsors relating to recall and non recall actions can be found by following this link - https://www.tga.gov.au/recalls.

13.Management Review

Management Review Meetings shall be held by the organisation at the end of every quarter. Management consists of the two Directors of the business. If required, additional meetings shall be conducted at the discretion of management.

The Management Meeting Agenda (FRM-02) shall be reviewed and any changes made prior to the meeting.

Minutes shall be taken during the meeting and recorded using Minutes of Meeting (FRM-03) form and the items shall be followed-up at regular intervals until closed-out. The Managing Director shall be the custodian for the action follow ups and close outs.

Minutes will be stored on the internal local storage drive.

The meeting assists top management in ensuring that the requirements of ISO9001:2015 are being met, and that changes to the quality system are planned and implemented in such a way that the integrity of the system remains.

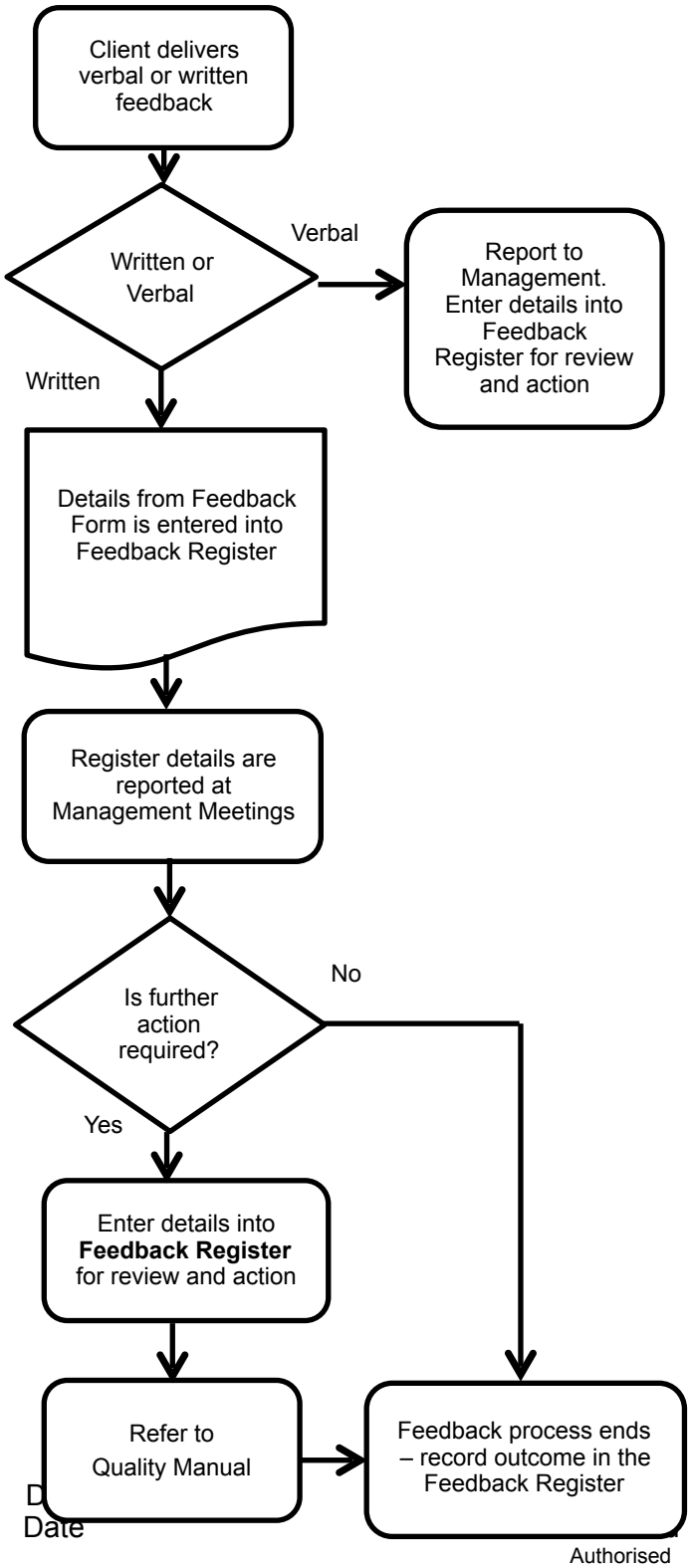
Areas of the quality system that are regularly reviewed may include;

- Follow up actions from previous meetings
- Customer feedback and complaints
- Corrective and preventative action of issues
- Detail of internal and external audits
- Changes to legislation and any resulting impacts to the quality system
- Reports on incidents

- Recommendations for improvement.

Decisions and actions from the quality meeting will be recorded and followed up at future meetings to ensure improvement of the quality system and the organisation in general.

Flowchart 1



When verbal feedback is given, report this to Management. They will determine if any further action is required.

Where written feedback is delivered on the **Feedback Form FRM-08,** enter the details into the **Feedback Register**.

Details from the **Feedback Register** are reported and discussed at the Management Review meeting.

A determination is to be made by the meeting as to whether further action is required.

If no further action is required, the close out details can be added to the **Feedback Register**.

Where further action is deemed necessary, the details are to be entered into the **Corrective Action Register** for further review and action. Following this, the details are closed out in the **Feedback Register** by Management.

Attachment A – Product Feasibility Process