New Zealand Blood Service
Statement of Intent

1 July 2012 – 30 June 2015

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PART 1

1 INTRODUCTION

Purpose

This Statement of Intent (SOI) has been prepared in accordance with part 4 of the Crown Entities Act 2004. It sets out how the New Zealand Blood Service (NZBS) will organise itself and prudently deploy resources (in line with the 22 December 2008 Enduring Letter of Expectations from the Ministers of Health and Finance) to ensure value for money in the support of New Zealand's healthcare sector. It informs Parliament and the New Zealand public about the organisation, the issues it faces and its response to those issues, specifying the objectives and performance measures for the period 1 July 2012 to 30 June 2013 and, in general terms, for the subsequent two years.

Overview

NZBS is a Crown entity established under the New Zealand Public Health and Disability Act 2000. Its primary purpose and core activity is the safe, timely, high quality and efficient provision of blood and blood products and services to clinicians for the people of New Zealand. In addition to this, NZBS provides services for matching of patients and donors prior to organ/tissue transplantation and the provision of tissue banking (skin and bone) and stem cell services. These activities contribute to achievement of the organisation's single enduring Outcome:

Health needs of people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services.

Blood is a special kind of medical resource. The altruistic nature and unique attributes of the "gift" of blood is unlike most other therapeutic modalities. This requires that NZBS as a trusted partner in New Zealand's healthcare system has in place a comprehensive donor recruitment programme and an integrated risk and safety management framework. Safety is at the heart of everything that NZBS does.

Refreshed Strategic Direction

The NZBS Board and Executive reviewed its strategic direction in 2011, looking forward to 2016. This resulted in seven refreshed strategic goals which describe:

- our core activity,
- our quality and safety focus,
- the importance of blood donors to our activities,
- our important relationship with the District Health Boards (DHBs),
- our focus on our people,
- the need for on-going development and
- financial sustainability.

These refreshed strategic goals which are in alignment with the Minister's expectations inform this SOI and will guide NZBS over the next five years as we make the step changes necessary to ensure the organisation is appropriately positioned to meet the on-going needs of the New Zealand health and disability sector.

The review also resulted in minor changes to the way that we describe our enduring outcome statement, which although not changing what NZBS exists to achieve; reflects feedback received in 2011 on last year's SOI.

Government Expectations

NZBS is a Crown agent for the purposes of the Crown Entities Act 2004. Pursuant to section 7 of the Act, NZBS is required to give effect to Government policy when directed by the Responsible Minister, the Minister of Health.

This SOI has been prepared taking into account the Minister's 21 March 2012 Letter of Expectations including:

- Prudent financial management ensuring that NZBS operates in a financially responsible manner;
- Keeping price increases to the DHBs in 2012/13 to an absolute minimum;
- Partnering with the DHBs to promote the wise use of blood and blood products';
- Recognition of the need for an effective, integrated and innovative sector and helping the DHBs to achieve their goals;
- Setting tight, realistic budgets, managing carefully within those budgets, and having financial sustainability as a critical part of NZBS strategy;
- Demonstrating a strong understanding of our business (e.g. price, quantity and standards of service, and cost drivers and how they will be managed);
- Realistic pay and employment conditions, in line with the Government's expectations for pay and employment conditions in the State Sector;
- Continuing to review how services can be delivered better and more cost effectively to ensure they are both effective and represent good value for money and are delivered in a timely manner.

It should be noted that in order to minimise the price increase to DHBs in 2012/13 NZBS is budgeting a $2.2m deficit. NZBS acknowledges the Minister's on-going expectation of ending the financial year at a breakeven position. The Minister further clarified that expectation as:

> "The requirement to end the financial year at a break-even position does not necessarily mean NZBS should not plan for a deficit or surplus. Rather, it reflects the board's collective duty to ensure that NZBS operates in a financially responsible manner."
>
> (letter from Minister to NZBS Chairman 30 April 2012)

NZBS is budgeting to deliver a $2.17m deficit in 2012/13, with a smaller deficit in 2013/14 before returning to a modest surplus in 2014/15.

Financial and Management Constraints

The NZBS receives payment for its products and services on a fee-for-service basis from the DHBs who are our principle customers. The financial plan has been prepared in line with the Minister's expectations, which although delivering deficits in two of the three year reporting period will enable:

- Management of safety requirements;
- Mitigation of risks related to the biological nature of blood products and variable product demand;

- The ability to address key infrastructure requirements including facility issues in Auckland and Christchurch;
- A reduced price increase to the DHBs as a consequence of planned deficits;
- Adherence to existing banking credit facility and covenant obligations;
- Maintenance of medium term financial sustainability.

Business improvement activities

Collections and Facilities

Established in 1998, NZBS is in the process of managing a step change in our business, progressively implementing recommendations from the 2009 NZBS conducted Collections and Facilities Review during the period of this SOI. We are expanding the two major hub-site facilities (which are leased) in Christchurch and Auckland to meet regulatory requirements as a result of:

- technology changes and
- increasing requirements for plasma collection to meet the growing demand for intravenous immunoglobulin.

Planning has commenced for the Christchurch hub-site to move into a purpose built new facility and we will develop a plan to future-proof the Auckland hub-site facility in partnership with the existing landlord.

We will also extend the collection of plasma by apheresis to other NZBS sites which are currently only supported to collect whole blood.

NZBS Costs

As a demand driven service within the public health and disability sector, NZBS has an on-going focus on improving its performance, increasing efficiencies and containing costs. However NZBS is entering a period where key infrastructure assets are either requiring replacement or upgrade. Infrastructure investment introduces additional costs to the business not all of which can be offset by savings initiatives. Consequently over the period NZBS is expecting to apply price increases greater than the sector's contribution to price (CCP) setting but has committed to minimising those increases to an absolute minimum by absorbing some of those additional costs as indicated by planned deficits.

Over the period NZBS is applying a compound price increase of 6.9% as compared to a Sector compound CCP% of 4.3% and a forecast CPI compound movement of 6.1%.

DHB Charging for 2012/13

NZBS is applying a 2.5% increase to the DHBs in 2012/13 after electing to not pass on all costs to the sector as evidenced by a planned deficit in 2012/13 of $2.2m. NZBS has endeavoured to balance the competing expectation of DHBs to minimise price increase to within the sector CCP setting with the obligation of maintaining its own financial wellbeing having regard to the infrastructure issues that are required to be addressed in the short to and medium term.

Rebates

NZBS will provide a rebate to the DHBs if there is an unplanned surplus which is not required by NZBS to meet and discharge its own financial obligations and

responsibilities. NZBS may generate additional revenue or make savings by such events as:

- changes in demand for products and services;
- improved fractionation yields;
- exchange rate gains; and/or
- internal cost efficiencies.

Although NZBS delivered a surplus in 2011/12 no rebate was made to the DHBs, in order to fund the next two financial years.

Financial Plan

A deficit position is forecast over the three year SOI period noting FY 2015 sees NZBS returning to a small surplus position.

	FY 2013 $'000	FY 2014 $'000	FY 2015 $'000	Total $'000
Price increase	2.5%	2.5%	1.75%	6.90%
Net surplus/(deficit)	(2,170)	(339)	455	(2,054)
Net cash flow	(3,082)	(1,448)	292	(4,238)
Cash at year end	4,616	3,168	3,460	3,460
Term borrowings at year end	3,570	3,300	3,300	3,300

NOTE: The Financial Plan has made no allowance for the financial impact of any loss caused by blood component contamination or major manufacturing problems. In the unlikely event that such a situation should occur, NZBS will follow the process outlined in 2005 by the Ministry of Health[1].

Key Project and Sector Changes

In Quarter 1 of the 2012/13 year NZBS will complete a major upgrade of its Blood Management System to e-Progesa. This business improvement initiative will impact both NZBS and the DHBs, and will provide opportunities to enhance the use of technology to improve blood banking services across the sector.

The organisation will continue to participate in opportunities for joint procurement and to share services (including back office functions) as these are identified and developed by the National Health Board and Health Benefits Ltd.

SOI Structure

This SOI is structured in two parts:

- Part I provides:
    - a high-level overview of the context and structure of NZBS;

[1] See Assumption 25 on pg 44

- the Forecast Statement of Service Performance (SSP) which NZBS will report on in its Annual Report for 2012/13;
- Capability and Input Measures (CIM) relating to internal NZBS activities;
- the linkage of performance measures to NZBS's seven new strategic goals[2] and
- organisational capability and issue management.

- Part II presents:
  - the Forecast Financial Statements and supporting assumptions.

As the organisation has now matured to a point where organisational structure and context are consistent year-on-year, this information is once again contained in Appendix 1.

David Chamberlain	David Wright	Fiona Ritsma
Chairman	**Deputy Chairperson**	**Chief Executive**

18 June 2012

[2] See Section 6 from pg 18 for detail of NZBS' Strategic Goals

2 ORGANISATION OVERVIEW

2.1 New Zealand Blood Service Outcome Statement

Health needs of people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services

2.2 NZBS in the context of the New Zealand health and disability sector

NZBS is the only provider of blood and blood products and tissue typing services in New Zealand.

A collaborative relationship with both the prescribing clinicians in the DHBs and more than 120,000 loyal donors is at the heart of the organisations success. Strong relationships also exist with DHB management; the Ministry of Health; CSL Biotherapies based in Melbourne, Australia; recipient organisations (in particular the Leukaemia and Blood Foundation, Immune Deficiencies Foundation of New Zealand and the Haemophilia Foundation of New Zealand); and international partners in the blood sector. Collectively our shared aim is to ensure that New Zealand continues to enjoy a safe and secure supply of blood and blood products and related services now and into the future.

2.3 NZBS Organisation Structure and Locations

NZBS was established in 1998 to integrate the formerly fragmented hospital based blood services into a single national organisation.

Current locations

NZBS facilities are structured in a “hub and spoke” model (see Figure 1, below), with four major collections and manufacturing hubs in Auckland, Hamilton, Wellington and Christchurch; supported by two collection co-ordinating centres in Palmerston North and Dunedin. Regional static collection sites are located in Manukau, Takapuna, Tauranga, Napier and Nelson. Regular mobile collections are also made in a number of cities and towns across New Zealand.

The national Tissue Typing and Red Cell Reference Laboratories and the administrative National Office are located in Auckland. NZBS also runs the hospital blood banks in Auckland, Hamilton, Palmerston North, Wellington, Christchurch and Dunedin Hospitals. All other hospital blood banks are staffed and operated by local DHB staff; however NZBS maintains overall responsibility for blood banking services across the country and has an active DHB oversight programme in place to achieve this.

Changes to locations

NZBS has embarked upon a relocation project for its Christchurch hub-site facility in partnership with Ngāi Tahu Property Limited, which will see us moving into a new purpose built leased facility in 2014. Planning is also underway in partnership with the Auckland hub-site landlord, the Dilworth School Trust Board to future proof this facility; ensuring it is fit for purpose for the next 20 years as technologies change and the requirement for additional donors (to meet the growing demand for fractionated product) can be accommodated in a GMP compliant environment.

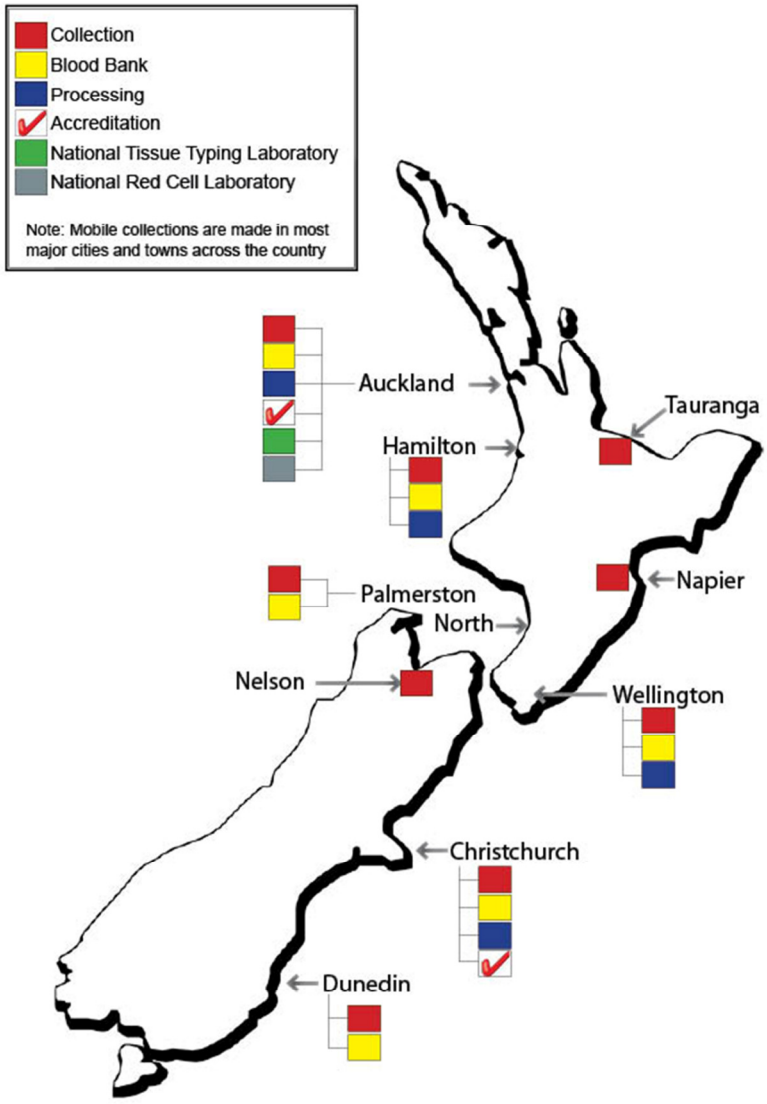

Figure 1: Distribution of NZBS activities across New Zealand

More information about NZBS's established governance and management structure, including the strong focus on quality, organisational values and identification of key external relationships and statutory obligations can be found in Appendix 1.

3 OUTCOMES FRAMEWORK

NZBS activities contribute to achievement of the government and health and disability system's goals as detailed in Figure 2.

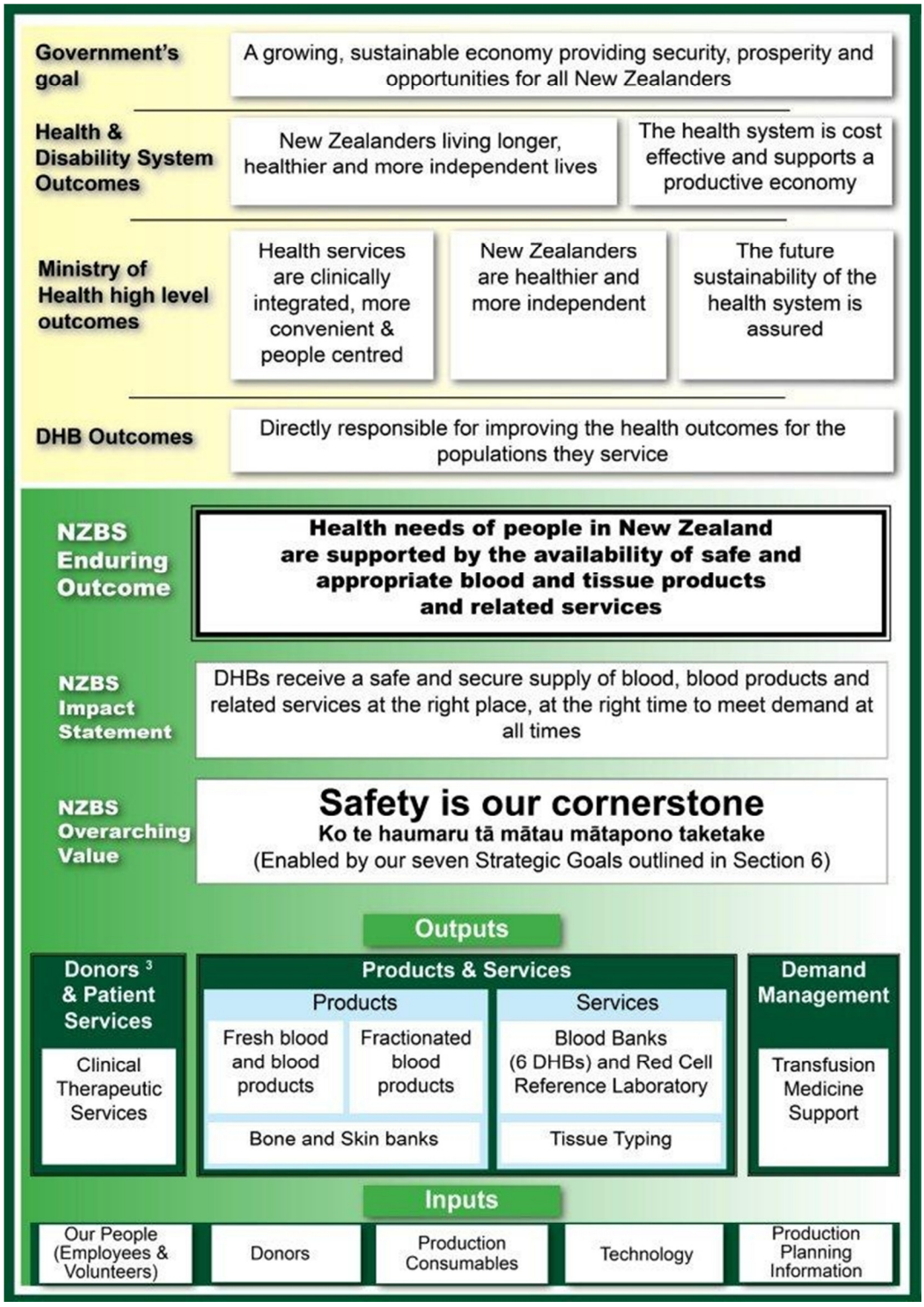

Figure 2: NZBS Outcomes Framework

[3] These services refer to stem cell collections for transplantation and people with Haemochromatosis – in some situations their blood can be used for transfusion, hence referring to them as donors

4 FORECAST STATEMENT OF SERVICE PERFORMANCE 1 JULY 2012 TO 30 JUNE 2013

NZBS has one overall Output Class, comprising three interrelated outputs related to:

- Donors (and patients)
- Products and Services
- Demand Management

each of which collectively contributes to the achievement of the outcome below:

New Zealand Blood Service Outcome

Health needs of people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services

OUTPUT	**Value 2012/13 $ (excl GST)**
Provision of a safe and effective blood service for all New Zealanders through supply and delivery of: • Fresh Blood Components • Fractionated Blood Products • Other products and related services	Revenue of $109.5 M Expenses of $111.7 M

IMPACT STATEMENT
District Health Boards receive a safe and secure supply of blood, blood products and related services at the right place, at the right time to meet demand at ALL times.

The following table details the external service output performance measures for 2012/13 that will be reported against in the NZBS Annual Report. These output performance measures are linked to NZBS's enduring outcome and following two externally focussed strategic goals:

Strategic Goal 1 – NZBS builds on core capabilities to provide a range of products and services which are appropriate to New Zealand health needs and priorities.

and

Strategic Goal 4 – NZBS relationships with other health sector entities are mutually supportive and productive.

The outputs outlined below demonstrate the size and scope of the NZBS operation and will apply for the three years of this SOI.

Performance Measures	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
NOTE: Changing clinical demand may result in the need to adjust output activity, causing variations from forecast levels. Should this occur, an explanation will be provided in the Annual Report.								
1. External output measures related to Key Products and Services which contribute to achievement of NZBS Enduring Outcome and Strategic Goal 1.	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**	**Target**	**Target**
KEY OUTPUT MEASURE 1 **Product and Service availability** 1.1 Key products and services are available at all times (24 x 7). Measure is instances when this is not achieved.	0	0	0	0	0	0	0	0
1.2. Key Fresh Blood Component Outputs	**Actual Demand**	**Actual Demand**	**Actual Demand**	**Actual Demand**	**Forecast Demand[4]**	**Forecast Demand**	**Forecast Demand**	**Forecast Demand**
1.2.1 Total Red Cells (units) issued - used to treat people with cancer, kidney failure & acute blood loss due to trauma or surgery.	140,874	141,519	141,347	138,093	137,500	137,100	137,800	138,200
1.2.2 Total Platelets (units) issued - used to support treatment for cancer, some blood diseases & to control bleeding following cardiac surgery or trauma.	16,804	19,061	19,392	20,981	22,400	22,100	22,550	22,900
1.2.3 Total plasma (units) issued - used in patients following trauma or transplantation.	20,271	20,211	20,889	19,890	20,215	20,650	20,850	21,150
1.2.4 Total Cryoprecipitate (units) issued - contains clotting factors used to treat trauma and during cardiac/transplant surgery.	2,118	2,725	3,120	3,358	4,000	4,000	4,100	4,200
1.2.5 Total plasma for fractionation (kgs) - sent to CSL in Australia to be manufactured into products and returned for use in NZ.	50,908	49,942	44,612	49,546	55,000	56,800	61,250	65,050
Comment: These measures relate to the provision of the main "fresh" blood products (manufactured from either whole blood or apheresis blood donations) to the New Zealand health and disability sector AND fresh frozen plasma to CSL for manufacture into fractionated products.								

[4] Forecast Demand in this context refers to NZBSs best estimate of DHB demand each year; noting this this will be adjusted up OR down throughout the year to best match actual demand and minimise expiry.

Performance Measures	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
1.3 Key Fractionation Product Outputs	**Actual Demand**	**Actual Demand**	**Actual Demand**	**Actual Demand**	**Forecast Demand**	**Forecast Demand**	**Forecast Demand**	**Forecast Demand**
1.3.1 IntragamP (200ml 12gm equivalent vials) issued – Immunoglobulin product used to treat people with immune deficiencies or diseases which compromise patients' immune system.	19,566	19,328	20,199	21,648	23,000	24,525	26,125	27,825
1.3.2 Biostate (250IU equivalent) issued – used to manage the inherited bleeding disorder haemophilia A.	26,777	20,652	13,358	14,186	15,000	14,500	14,500	14,500
Comment: These measures relate to the provision of the main "fractionated" products to the New Zealand health and disability sector. Fractionated products are manufactured by CSL Biotherapies in Australia from plasma collected in New Zealand.								
1.4 Other Key Products /Services Outputs								
1.4.1 Tissue Typings associated with transplant patients/donors and disease studies.	5,570	6,309	6,949	7,230	6,600	7,050	7,450	7,850
1.4.2 Antibody screens for patients awaiting transplant.	6,538	6,843	6,655	7,260	7,450	7,750	8,100	8,450
1.4.3 Femoral head issues.	508	533	613	604	730	765	780	800
1.4.4 Blood groupings.	137,749	144,284	146,611	146,644	148,000	149,500	151,000	152,500
1.4.5 Antibody Screens.	134,033	140,249	142,770	142,399	144,000	145,800	147,600	149,450
Comment: These measures relate to the provision of the key tissue product (femoral heads) and key services that NZBS provides to the New Zealand health and disability sector.								
1.5 Key Therapeutic Service Outputs								
1.5.1 Plasma Exchanges - used to remove antibodies & toxins in patients with a range of haematological and neurological diseases.	425	359	404	446	450	485	520	555
1.5.2 Stem Cell Harvests – used for cancer patients undergoing chemotherapy and bone marrow transplantation.	250	265	312	290	310	345	380	420
1.5.3 Therapeutic venesections – predominantly used to treat haemochromatosis or polycythaemia.	4,379	4,939	5,003	5,460	5,250	5,380	5,530	5,685
Comment: These measures relate to the key therapeutic services (in addition to collecting voluntary blood donations) conducted by NZBS donor services. NZBS provides these services as they require the same equipment and similar nursing skills as our core activity collecting blood donations from voluntary blood donors.								

Performance Measures	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
2. External output measures related to Demand Management and the relationship with DHBs which contribute to achievement of Strategic Goal 4.	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**	**Target**	**Target**
2.1 Planning and Communication with District Health Boards (DHBs) NZBS will demonstrate a productive and supportive relationship with the DHBs, including proactively engaging with them through the Lead DHB CEO to agree pricing for the next financial year, ensuring that this information is provided in sufficient time to inform preparation of DHB Annual Plans. NOTE: Exact measure has changed over recent years.	NZBS worked successfully with MOH and Lead DHB CEO to ensure price engagement process was effective and provision of information to DHBs met requirements. As agreed with DHBs formal confirmation of FFT price increase for 2008/09 was delayed until May 2008.	DHBs through Lead DHB CEO agreed to a price increase in 2009/10 equivalent to FFT and returned amendments to the Supply Agreements signed by 21 DHB CEOs prior to the end of the financial year.	The price increase for the 2010/11 year was held to the level of the MOH announced CCP increase. The DHBs signed off the NZBS FY11 price list in time to inform their annual budget and planning documents.	Proactive engagement with Lead DHB CEO resulted in a price increase for 2010/11 of 0.65% (i.e. less than the 1.72% CCP level). Sector communication has commenced regarding implementation of NZBS rebalanced prices in FY12, following a comprehensive costing review.	Favourable feedback on the timely and relevant provision of information, including issue resolution provided by the Lead DHB CEO.	Favourable feedback on the timely and relevant provision of information, including issue resolution provided by the Lead DHB CEO.	Favourable feedback on the timely and relevant provision of information, including issue resolution provided by the Lead DHB CEO.	Favourable feedback on the timely and relevant provision of information, including issue resolution provided by the Lead DHB CEO.
2.2 NZBS Reports for DHBs Monthly demand management reports outlining purchase volumes by key product line are provided to DHBs to assist them to manage local usage and costs.	Monthly reports detailing product use and expiry information provided to all 21 DHBs throughout 2007/08.	Monthly reports detailing product use and expiry information provided to all 21 DHBs throughout 2008/09.	Monthly reports detailing product use and expiry information provided to all DHBs throughout 2009/10.	Monthly reports detailing product use and expiry information provided to all DHBs throughout 2010/11.	Reports are provided to each DHB by the 12th working day of the following month.	Reports are provided to each DHB by the 12th working day of the following month.	Reports are provided to each DHB by the 12th working day of the following month.	Reports are provided to each DHB by the 12th working day of the following month.

Performance Measures	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
2.3 Clinical Oversight Programme	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**	**Target**	**Target**
All Blood Banks located in main DHB hospitals (other than the 6 DHBs where NZBS is responsible for Blood Bank provision) will receive at least 1 NZBS Clinical Oversight visit (and audit report) per year in order to enable them to meet the requirements of ISO15189 for IANZ Accreditation.	100%	100%	100%	100%	100%	100%	100%	100%
2.4 Haemovigilance Reporting								
2.4.1 To promote risk awareness and best practice in transfusion, NZBS will publish an annual Haemovigilance Report for each calendar year and will share this information with all DHBs to assist them to reduce the incidence of adverse transfusion related events.	Annual Haemovigilance Report distributed to DHBs in December 2007 and available on NZBS web-site.	Annual Haemovigilance Report distributed to DHBs in September 2008 and available on NZBS web-site.	Annual Haemovigilance Report distributed to DHBs in November 2009 and available on NZBS web-site.	Annual Haemovigilance Report distributed to DHBs in November 2010 and available on NZBS web-site.	Haemovigilance Report for the previous calendar year provided to all DHBs by Quarter 2.	Haemovigilance Report for the previous calendar year provided to all DHBs by Quarter 2.	Haemovigilance Report for the previous calendar year provided to all DHBs by Quarter 2.	Haemovigilance Report for the previous calendar year provided to all DHBs by Quarter 2.
2.4.2.1 Number of transfusion related incidents reported to the National Haemovigilance Programme, with a severity score greater than 1 and imputability score classified as likely/probable or certain.[5]	Severity grading's were not yet implemented	40	42	The National Haemovigilance Programme is a surveillance and early warning system that aims to identify emerging problems and trends in areas known to be associated with adverse reactions in recipients. It is therefore not appropriate to set targets for this measure				

[5] As part of the National Haemovigilance programme DHBs report adverse or unexpected transfusion related events or reactions in blood product recipients to NZBS. Internationally recognised Haemovigilance classification systems are used to determine severity and imputability (definitions included in glossary). More information on the NZBS Haemovigilance Programme can be found on the NZBS website at: http://www.nzblood.co.nz/Clinical-information/Haemovigilance-programme

Performance Measures	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
KEY OUTPUT MEASURE 2 **Haemovigilance - Patient safety**								
2.4.2.2 Number of transfusion related incidents occurring as a result of an NZBS "system failure" reported to the National Haemovigilance Programme, with a severity score greater than 1 and imputability score classified as likely/probable or certain.[6]	Severity grading's were not yet implemented	0	0	0	0	0	0	0
Comment: Haemovigilance reporting is a voluntary programme of reporting transfusion related events and is a key tool used internationally by blood services to help prescribers, treating clinicians and the blood service track trend changes and together ensure appropriate, clinically safe and efficacious product utilisation.								

[6] This measure is a sub-set of 2.4.2.1 and reports incidents that have occurred as a result of "system failures" and therefore excludes incidents resulting from a physiological reaction to the transfusion of a biological product.

5 CAPABILITY AND INPUT MEASURES

The following capability and input measures relate to achievement of NZBS's five internally focused strategic goals. They could be considered "proxy output measures" in the context of NZBS activities and are key contributors to NZBS success in achieving its enduring outcome and the external output measures identified in Section 4 and will therefore be reported separately as Capability and Input Measures in the NZBS Annual Report.

Performance Measures continued	**2007/08**	**2008/09**	**2009/10**	**2010/11**	**2011/12**	**2012/13**	**2013/14**	**2014/15**
NOTE: Changing clinical demand may result in the need to adjust collection activity, causing variations from forecast levels.								
1. Internal measures related to Products and Service Quality which contribute to achievement of Strategic Goal 2	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**	**Target**	**Target**
1.1 Donation Testing Each donation will be tested prior to use in accordance with the NZBS Manufacturing Standards (as approved by Medsafe). • No product is released for issue to a patient until it has passed all safety tests and associated records are maintained.	100% tested	100% tested	100% tested	100% tested	100% tested	100% tested	100% tested	100% tested
1.2 Regulatory Compliance - Medsafe NZBS will ensure it is GMP (Good Manufacturing Practice) compliant 100% of the time by maintaining current Medsafe licences for its 6 hub sites.	100%	100%	100%	100%	100%	100%	100%	100%
1.3 Regulatory Compliance – IANZ (International Accreditation New Zealand) NZBS will ensure it maintains IANZ accreditation 100% of the time at all of its diagnostic laboratories.	100%	100%	100%	100%	100%	100%	100%	100%
1.4 Regulatory Compliance – ASHI (American Society of Histocompatibility and Immunogenetics) NZBS will maintain ASHI accreditation 100% of the time at the national Tissue Typing laboratory.				100% First formal on-site audit	100%	100% Biennial on-site audit	100%	100% Biennial on-site audit

Performance Measures continued	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
2. Internal measures related to Donors which contribute to achievement of Strategic Goal 3	**Actual**	**Actual**	**Actual**	**Actual**	**Target**	**Target**	**Target**	**Target**
2.1 Donor Population NZBS maintains a donor population capable of meeting the on-going demand for blood and blood products. • Active whole blood & apheresis donor panel.	125,234	130,243	128,347	128,417 (minimum Whole Blood donor panel of 120,000 donors)	127,300	125,800	126,800	127,500
2.2 Donor Satisfaction Measure of Overall Satisfaction with the Quality of Service using the Common Measurement Tool questionnaire. • Greater than 90% of donors surveyed state that they are either "Satisfied" or "Very Satisfied" with the overall quality of service.	New measure in 2011/12				>90% rating	Equal to or better than baseline year	Equal to or better than baseline year	Equal to or better than baseline year
2.3 Targeted donor recruitment strategies								
2.3.1 Increase percentage of Māori donors on the active donor panel from the 2010/11 level of 6% of all donors.	New measures in 2011/12 based off snapshot in 2010/11			6%	> 6%	Equal to or better than prior year	Equal to or better than prior year	Equal to or better than prior year
2.3.2 Increase the percentage of youth donors between the ages of 19 – 25 years on the active donor panel from the 2010/11 level of 18.8% of all donors.[7]				18.8%	>18.8%	Equal to or better than prior year	Equal to or better than prior year	Equal to or better than prior year
2.4 Raw Material (Collections) Inputs	**Actual Supply**	**Actual Supply**	**Actual Supply**	**Actual Supply**	**Forecast Supply**	**Forecast Supply**	**Forecast Supply**	**Forecast Supply**
2.4.1 Total Whole Blood donations.	149,410	150,756	149,711	149,915	148,000	144,000	144,000	144,500
2.4.2 Total Plateletpheresis donations.	5,583	6,313	6,534	6,546	7,100	7,900	7,600	7,700
2.4.3 Total Plasmapheresis donations.	27,292	22,772	15,222	24,194	31,800	30,100	37,500	42,900
2.4.4 Total donations.	182,285	179,841	171,467	180,655	186,900	182,000	189,100	195,100

[7] Attraction of youth donors assists in future proofing the service – encouraging new donors to replace those who are retiring.

Performance Measures continued	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15
3. Internal measures related to People which contribute to achievement of Strategic Goal 5	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**	**Target**	**Target**
3.1 Annual turnover.	16.6%	9.7%	10.9%	10.7%	10.0%	11.0%	11.0%	11.0%
3.2 Employee Engagement Index Score from biennial Staff Engagement Survey using the JRA and Associates Survey Tool.	No survey	72.7%	No survey	74.4%	No survey	76%	No survey	78%
4. Internal measure related to Development which contributes to achievement of Strategic Goal 6	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**		
4.1 e-Progesa implementation Successful completion of the upgrade of the Progesa Blood Management System to e-Progesa.	Project not formally launched until 2010/11.			Key Project milestones to 31 June 2011 achieved as per Board approved Project Plan.	Key Project milestones to 31 June 2012 achieved as per Board approved Project Plan.	Quarter 1 – Successful e-Progesa go-live.	No measure project complete	N/A
5. Internal measures related to Financial Sustainability which contribute to achievement of Strategic Goal 7	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Target**	**Target**	**Target**
5.1 Revenue per Full Time Equivalent (FTEs) - $000's								
Monitor NZBS total revenue per Full Time Equivalent employee.	$198.54	$205.80	$213.31	$212.12	$210.38	$218.87	$230.87	$241.75
5.2 Financial Management Assure cost efficiency and value for money management through maintenance of financial sustainability in an environment which is demand driven (i.e. changes in product demand - mix and volume by the DHBs, impacts on the NZBS financial result).	Achievement of budget Actual - $7.0m surplus	Achievement of budget Actual - $3.3m surplus with a $2.4M rebate paid to DHBs	Achievement of budget Actual - $1.6M surplus with a $2.0M rebate paid to DHBs	Achievement of budget $9.8m surplus No Rebate paid	Achievement of budget Budget - $920k surplus No Rebate Planned	Achievement of budget Budget – ($2.17m) deficit No Rebate Planned	Achievement of budget Budget – ($339k) Deficit No Rebate Planned	Achievement of budget Budget - $455k Surplus No Rebate Planned

6 ALIGNMENT OF OPERATING INTENTIONS AND MEASURES WITH NZBS STRATEGIC GOALS

The following section presents how NZBS intends to perform its functions and conduct its operations in order to achieve its key outputs and Strategic Goals.

NZBS STRATEGIC GOALS

The NZBS Board and Executive reviewed its strategic direction in 2011 looking forward to 2016. The following seven refreshed strategic goals describe our core activity, our quality and safety focus, the importance of blood donors to our activities, our important relationship with the DHBs, our focus on our people, the need for on-going development and financial sustainability.

	Strategic Goal	Focus
1.	NZBS builds on core capabilities to provide a range of products and services which are appropriate to New Zealand health needs and priorities.	External
2.	NZBS achieves the highest possible Safety and Quality standards in all that it does.	Internal
3.	NZBS manages a sustainable donor population capable of supporting on-going product demand in New Zealand.	Internal
4.	NZBS relationships with other health sector entities are mutually supportive and productive.	External
5.	NZBS has a sustainable, competent and engaged workforce.	Internal
6.	NZBS uses international best practices and internal Research & Development capabilities to improve and develop products and services for the New Zealand health and disability sector.	Internal
7.	NZBS is a financially sustainable organisation operating effectively and efficiently.	Internal

Outputs from the two externally focused strategic goals will be reported in the Statement of Service Performance (SSP)[8].

Outputs from the internally focused strategic goals primarily enhance internal capability - maintaining and/or building capacity and capability. They deliver internal business improvements within NZBS, to enable the organisation to achieve key deliverables (products and services) to the DHBs as safely, efficiently and cost-effectively as possible. Key measures related to achievement of these internally focused strategic goals will be reported in the NZBS Annual report as Capability and Input Measures (CIM)[9].

The seven NZBS strategic goals generate inter-related internal and external outputs which collectively relate to three key areas:

[8] See Statement of Service Performance Measures on pg 10
[9] See Capability and Input Measures on pg 15

1. **Donors (and patients)**

   Collecting blood from donors, ensuring maintenance of their good health and that there are sufficient donors to support product demand, plus a small range of clinical therapeutic services.

2. **Products and Services**

   Testing/manufacturing and supplying blood and tissue products together with related services.

3. **Demand Management**

   Maintaining an excellent relationship with the DHBs as the primary NZBS customers; providing information to assist their management of product demand and informing NZBS production schedules to ensure 100% product availability at all times.

6.1 HOW STRATEGIC GOALS INFORM OPERATING INTENTIONS AND MEASURES

The following section describes the activities related to each of the seven strategic goals and the outlines the key measures reported in either the SSP or CIM to demonstrate progressive achievement of the goals.

STRATEGIC GOAL 1

NZBS builds on core capabilities to provide a range of products and services which are appropriate to New Zealand health needs and priorities.

This strategic goal outlines NZBS's core activity as the only provider of blood and blood products and related services to the New Zealand health and disability sector. NZBS will utilise its core capabilities of specialist transfusion medicine knowledge and expertise to support the sector with a safe and appropriate range of products and services to meet New Zealand's changing health needs and priorities.

Leveraging off our unique competencies and capabilities, NZBS has a focus on:

- Ensuring the safety of the nation's blood supply;
- Respecting the gift status of every voluntary donation through minimising product expiry and maximising efficient utilisation;
- Ensuring safety and certainty of supply of blood and tissue products and services to the healthcare community;
- Meeting 100% of demand, 24 hours per day, 7 days per week, every year.

Achievement of Strategic Goal 1 will be measured in the SSP by;

1. Achievement of the NZBS Impact Statement – ensuring that DHBs receive a *safe* and *secure supply* of the *right blood*, *blood products* and *related services* at the *right place* at the *right time* to meet *demand at all times*.[10]

   NOTE: this is the first of NZBSs two key Output Measures.

2. Achievement of specific key product and service output targets.[11]

[10] See SSP Performance Measure 1.1 on pg 10
[11] See detailed SSP Performance Measures 1.2, 1.3, 1.4 and 1.5 on pgs 10 - 11

NOTE: Targets are set based on forecast demand. Therefore unlike conventional outputs, comparative data should not be used to judge current performance with a view to demonstrating improvement trends, as targets will be flexed up or down throughout the year (and between years) in response to changing demand patterns, in order to always meet demand and at the same time minimise product expiry.

STRATEGIC GOAL 2

NZBS achieves the highest possible Safety and Quality standards in all that it does.

Safety and quality are the over-riding principles of highly regulated blood services across the globe. To assure public confidence in the safety of New Zealand's blood supply, NZBS will ensure that regulatory accreditation and compliance requirements are maintained at all times in each of the three years of this SOI and beyond.

Facilities that are GMP compliant are an important blood service requirement. NZBS is in the process of upgrading its leased facilities in Christchurch (in partnership with Ngāi Tahu) and in Auckland (in partnership with the Dilworth School Trust Board) to address both space and GMP compliance issues.

In the NZBS setting, in addition to standard public sector legislative requirements the following regulatory compliance is required:

- Annual Manufacturing Licences in the 6 NZBS collection and manufacturing sites - audited by Medsafe against the Code of Good Manufacturing Practice (GMP).
- IANZ accreditation against International Standard ISO 15189 – "Medical Laboratories – particular requirements for quality and competence" in all NZBS diagnostic laboratories, including the six hospital Blood Banks run by NZBS.
- ASHI (American Society for Histocompatibility and Immunogenetics) accreditation in the national Tissue Typing laboratory which requires annual monitored self-assessment and a formal inspection and external audit every two years (next due in 2012).

NZBS also complies with the requirements of FACT (Foundation for the Accreditation of Cellular Therapy) for processing of haemopoietic progenitor cells in order to support the FACT accreditation held by Auckland City Hospital and Starship Stem Cell Transplant Programme. Over the period of this SOI NZBS will be working with Christchurch Hospital transplant teams who are also seeking to achieve FACT accreditation. Because NZBS does not hold the accreditation this is not listed as a measure below.

In 2011 the Prime Minister announced that the Australia New Zealand Therapeutic Products Agency (ANZTPA) will be established over the next 5 years. This will replace existing Medsafe regulation of blood and blood products. However as no information has been received about the implications of this change, additional requirements have not been factored into this SOI.

Achievement of Strategic Goal 2 is closely linked to Strategic Goal 1 and assures public confidence. It is in alignment with the Minister's Letter of Expectations of high quality services, the Ministry of Health's outcomes and is a fundamental requirement for any blood service; therefore as an internal strategic goal, maintenance of the following safety and quality requirements will be measured in the CIM as achievement of:

1. Medsafe licences[12]
2. IANZ accreditation[13]
3. ASHI accreditation in 2012[14]
4. Testing of every donation prior to use[15]
5. Reporting of transfusion related incidents as part of the NZBS National Haemovigilance Programme[16]

NOTE: this is the second of NZBSs two key Output Measures.

STRATEGIC GOAL 3

NZBS manages a sustainable donor population capable of supporting on-going product demand in New Zealand.

New Zealand is primarily self-sufficient for blood and blood products however; this does not preclude the procurement of imported product if clinically necessary and/or in exceptional circumstances. The active donor population is the source of the raw product that NZBS requires to manufacture its range of blood and blood products for transfusion; therefore maintenance of good donor health is an essential requirement. To achieve this strategic goal NZBS will:

- Maintain a sustainable number of active donors (people who have donated whole blood and/or apheresis plasma/platelets at least once in the last 24 months) at the level of at least 120,000 whole blood donors and 5,800 apheresis donors in 2012/13, growing to 7,500 over the three years of this SOI in response to the forecast increasing demand for Intragam P product.
- Continue to develop donor recruitment and retention strategies to maintain sufficient voluntary donors to replace retiring or deferred donors including:
  - Maximising use of the electronic Donor Relationship Management system for communicating with donors;
  - Monitoring and implementing strategies to maintain good donor health;
  - Targeting initiatives contained in the NZBS Māori Responsiveness Strategy (MRS) to improve engagement with Māori, with the aim of increasing the number of Māori who donate blood; and
  - Targeting initiatives to recruit and retain youth donors (in particular between the ages of 19-25 years) to ensure sustainable donor support into the future.

Figure 3 shows the current age profile of active donors (i.e. donors who have donated at least once in the last 24 months). Note: the decline in donors less than 20 years old is the result of a deliberate strategy to reduce school based collections to only one annual visit per school.

[12] See CIM Performance Measure 1.2 on pg 15
[13] See CIM Performance Measure 1.3 on pg 15
[14] See CIM Performance Measure 1.4 on pg 15
[15] See CIM Performance Measure 1.1 on pg 15
[16] See SSP Performance Measures 2.4.2.1 and 2.4.2.2 on pgs 13-14

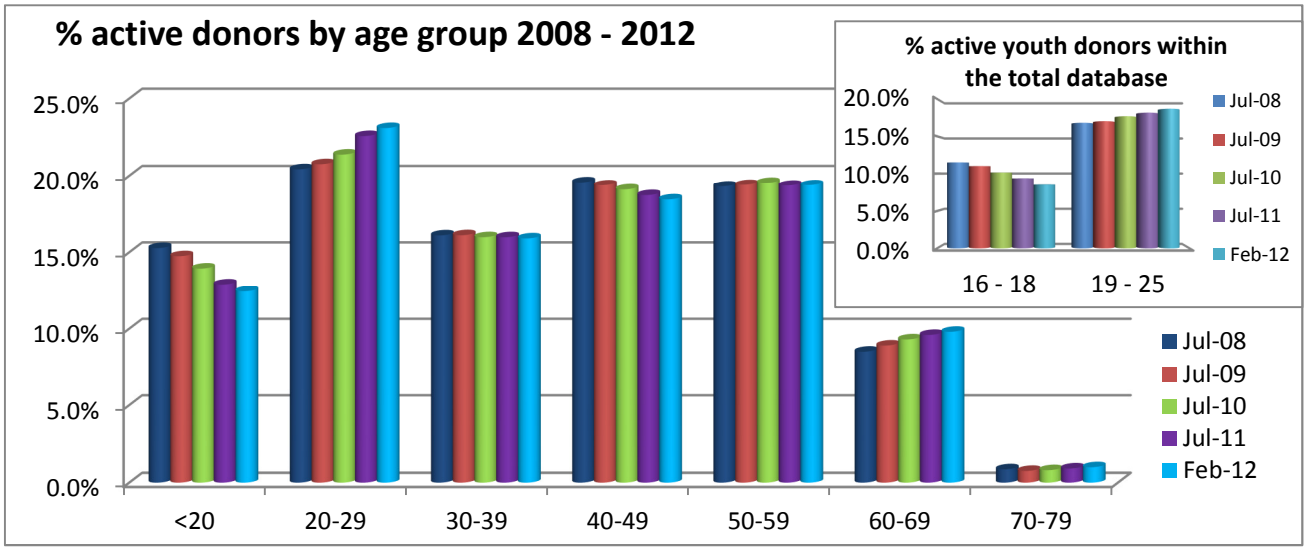

Figure 3: Active Donors by Year and Age Group for 2006- 2011

Achievement of Strategic Goal 3 will be measured in the CIM by:

1. Meeting targeted whole blood and apheresis collection volumes[17]
2. Achieving annual donor population target numbers[18]
3. Achieving target plasma for fractionation targets[19]
4. Meeting youth and Māori donor growth targets[20]
5. Meeting donor satisfaction targets[21]

STRATEGIC GOAL 4

NZBS relationships with other health sector entities are mutually supportive and productive

NZBS is funded on a fee for service basis by its customers, primarily the DHBs. Note: the provision of blood and blood products to private hospitals and other users is coordinated and paid for by the DHBs.

As the only supplier of blood and blood products to the New Zealand health and disability sector, the fiscal and operating environments within the DHBs have a direct impact on NZBS. To successfully support the sector NZBS needs to work in partnership with the DHBs and ensure on-going efficient and effective management of its internal operations.

Activities related to NZBS' achievement of this Strategic Goal also contribute directly to supporting:

a) The government's policy focus for "better public services".
b) The Ministry of Health outcome that "Health Services are clinically integrated, more convenient & people centred.".

[17] See CIM Performance Measure 2.4 on pg 16
[18] See CIM Performance Measure 2.1 on pg 16
[19] See SSP Performance Measure 1.2.5 on pg 10
[20] See CIM Performance Measures 2.3.1 and 2.3.2 on pg 16
[21] See CIM Performance Measure 2.2 on pg 16

c) The Minister of Health's expectation as outlined in his 21 March 2011 Letter of Expectations of "an effective, integrated and innovative sector" and "partnering with DHBs to promote wise use of blood – thus reducing wastage and cost to the sector."

NZBS Support to DHBs

NZBS supports the DHBs who are the prescribers and purchasers of blood and tissue products and services (i.e. the DHBs determine demand). This support includes:

1. Provision of reports and analysis
    - Monthly clinical product utilisation data assists DHB clinicians and management to maximise product utilisation, minimise expiry and cost.
    - Ensuring appropriate blood product stock levels (and hence DHB expenditure) to most efficiently support anticipated clinical demand.
    - Two to three clinical audit reports each year, based on work carried out by the NZBS clinical team (Transfusion Medical and Nurse Specialists) working in partnership with DHB clinical staff to assess targeted specific product utilisation.
    - Monitoring with the aim of minimising adverse reactions in donors and in recipients (as identified by DHBs). This is achieved by analysis and publication of an annual Haemovigilance Report (a key tool used internationally by blood services) to help prescribers, treating clinicians and the blood service track trend changes and together ensure appropriate, clinically safe and efficacious product utilisation[22].
    - Representation and reporting to the National Haemophilia Management Group (NHMG) to ensure a managed transition from plasma-derived to recombinant product for the treatment of people with haemophilia.
2. Clinical Oversight of DHB Blood Banks
    - NZBS Transfusion Medicine Specialists visit all DHB Blood Banks not directly managed by NZBS to provide guidance and clinical oversight; ensuring that nationally consistent quality systems and processes are used in the provision of blood components and products to patients.
    - DHB blood bank responsiveness to NZBS clinical oversight visit recommendations enables them to meet the requirements for International Accreditation New Zealand (IANZ) accreditation.
    - NZBS participation in the local DHB Hospital Transfusion Committees.
3. Planning and Communication
    - The Lead DHB CEO continues to be the key sector contact for NZBS to:
        - Agree the annual price engagement process in time for DHBs to budget for price and volume changes in their Annual Plans.
        - Identify and implement reporting change requirements, particularly to facilitate improved product utilisation.
        - Identify business improvement opportunities, efficiencies and areas where working together can deliver savings to both DHBs and NZBS (e.g. in the

[22] More information about the Haemovigilance Report can be found on the NZBS website at: http://www.nzblood.co.nz/Clinical-information/Haemovigilance-programme

management of Bone Banking Services) and any other mutually beneficial activities/projects.

Achievement of Strategic Goal 4 will be measured in the SSP by the following key areas of interaction between the DHBs and NZBS:

1. Monthly distribution of the key product utilisation monitoring reports.[23]
2. Production and circulation of an annual Haemovigilance Report[24] and reporting of transfusion related incidents reported to the National Haemovigilance Programme.
3. A minimum of one clinical oversight visit to each DHB each year, including timely production of a report outlining any corrective actions and/or recommendations for improvement.[25] Note: implementation of recommendations is the responsibility of the DHBs.
4. Feedback on the NZBS : DHB relationship from the Lead DHB CEO.[26]

STRATEGIC GOAL 5

NZBS has a sustainable, competent and engaged workforce.

NZBS people management strategies, policies, programmes and practices contributing to the achievement of this internal goal over the three year period of this SOI will:

- Be consistent with the Government's expectations for pay and employment conditions in the State Sector as required by the Minister's Letter of Expectations;
- Promote the seven key elements of a "Good Employer"[27]
    1. Leadership, accountability and culture;
    2. Recruitment, selection and induction;
    3. Employee development, promotion and exit;
    4. Flexibility and work design;
    5. Remuneration, recognition and conditions;
    6. Harassment and bullying prevention;
    7. Safe and healthy environment.
- Meet good faith and employment contract obligations in line with government expectations;
- Align with NZBS vision and values;
- Ensure sustainability through the development of a more diverse workforce reflective of the communities that we serve, including ethnic diversity;
- Assist in the development of quality leaders (both management and clinical) attracting, optimising and retaining top talent to achieve strategic objectives;

[23] See SSP Performance Measure 2.2 on pg 12
[24] See SSP Performance Measure 2.4 on pg 13
[25] See SSP Performance Measure 2.3 on pg 13
[26] See SSP Performance Measure 2.1 on pg 12
[27] As defined by the Human Rights Commission in the published guidance from the Equal Employment Opportunities Commissioner (June 2006).

- Support staff to achieve high safety and quality standards, including on-going professional development requirements to achieve annual professional registration.

NZBS recognises the importance of listening to staff and understanding what they see as important in order to enhance:

- Engagement
- Participation
- Productivity
- Retention and reduction in staff turnover
- Achievement of strategic and operational objectives

Employee commitment will be measured biennially through a workforce engagement survey, next conducted in 2013, enabling internal benchmarking by identifying the percentage of staff in each of three defined engagement categories - engaged, ambivalent and disengaged over time.

As New Zealand's only blood service, international collaboration at both a clinical and management level ensures that the nation's transfusion service and blood safety standards continue to be contemporary and cost-effective.

Achievement of Strategic Goal 5 will be measured in the CIM by:

1. An improvement in the Employee Engagement Index in FY14 (when the biennial survey will next be conducted). [28]
2. Annual staff turn-over of 12% or less.[29]

STRATEGIC GOAL 6

NZBS uses international "best practices" and internal Research and Development capabilities to improve and develop products and services for the New Zealand health and disability sector.

Activities associated with achievement of this internal goal contribute to the government's policy driver for growth of "support for science, innovation and trade" and are aligned with the health and disability sector's National Health IT Plan and Health Quality and Safety Commission's aspirations. NZBS activities related to the achievement of this goal include:

- Monitoring and, where appropriate, prioritising internal activities/projects to keep abreast of international developments in transfusion medicine practise and deliver business improvements.

  For example:

  - Use of a Platelet Additive Solution (PAS) which delivers both patient safety and efficiency gains;
  - The move to male only plasma for transfusion and screening plateletpheresis donors to reduce the risk of transfusion related acute lung injury (TRALI).

[28] See CIM Performance Measure 3.2 on pg 17
[29] See CIM Performance Measure 3.1 on pg 17

- Adherence to the Council of Europe Guide to the preparation, use and quality assurance of blood components ("The Guide") as NZBS's external reference standard. The Guide is annually reviewed by an expert internationally constituted committee. By undertaking its own regular review of this internationally recognised Guide, NZBS will assure relevance and appropriate alignment of New Zealand blood safety standards with standards applied in European countries and Australia.
- Benchmarking with international blood services. NZBS is a member of the Asia Pacific Blood Network (APBN) and participates in an annual Comparison of Practise benchmarking analysis looking at metrics such as:
  - Issues of components per 1,000 population;
  - Overall population participation rate in blood donation, including analysis in specific age bands;
  - Donor deferral rates, with more analysis being conducted about reasons for deferral;
  - Donor and recipient adverse events;
  - FTE / specific outputs.
- Assessment of potential collaborative activities in the area of cellular therapy with the University of Auckland, Department of Molecular Medicine and Pathology.
- Upgrading the blood management system Progesa to the web-based e-Progesa. With a planned go-live in Quarter 1 2012/13, this major project will impact on both NZBS and the DHB Blood Banks at the time of implementation. The upgrade will ensure on-going vendor support for this critical software package (used to manage the supply chain of product from the donor, through production and warehousing to cross matching and transfusion to a patient) and provide system resilience to meet future needs and opportunities for business improvements and service enhancements consistent with the national health IT strategy (subject to independent business case approval) in the future.

Achievement of internal Strategic Goal 6 will primarily be monitored through internal organisational measures; however achievement of the e-Progesa project which will impact on the entire sector will be reported in the CIM by:

1. Achievement of e-Progesa go-live in Quarter 1.[30]

STRATEGIC GOAL 7

NZBS is a financially sustainable organisation operating effectively and efficiently.

This strategic goal is in accordance with the Minister's expectation that financial sustainability is a critical part of all crown entities strategy. NZBS's "vein-to-vein" business model is the envy of many blood services around the world. In particular the close relationship this model promotes between the DHBs and NZBS, which ensures a good alignment of priorities and on-going focus on cost control. The underlying principles of the business model will continue to be reviewed over the three years of this SOI to ensure that NZBS continues to meet the nation's requirement for a high quality, safe, cost effective and financially sustainable demand driven support service to the New Zealand health and disability sector.

[30] See CIM Performance Measure 4.1 on pg 17

Key principles within the current model include:

- Self Sufficiency where clinically appropriate (to ensure surety of supply) whereby NZBS collects sufficient blood to meet all of New Zealand's requirements for blood and blood products;
- Plasma fractionation contractual arrangements with CSL Biotherapies, Melbourne, Australia which in 2010 was extended to June 2014, with rights of renewal beyond that.

NZBS acknowledges the financial pressures on the country and the health and disability sector in particular and will:

- Ensure prudent financial management, operating in a financially responsible manner and keeping expenditure under review to ensure we are providing value for money; as outlined in the Minister's 21 March 2012 Letter of Expectations;
- Maintain financial sustainability in response to any change in product mix and volumes through a strong focus on cost containment and internal business improvement activities;
- Provide to the DHBs, by way of rebate, the portion of any unbudgeted annual surplus delivered which is not required by NZBS in discharging its own financial obligations and responsibilities, in accordance with the NZBS Financial Guidelines Policy introduced in 2009.

Achievement of Strategic Goal 7 will be measured in the CIM by:

1. Meeting budget each year whilst continuing to implement required internal initiatives to ensure on-going safety and surety of supply.[31]
2. Monitoring and assessing the Revenue per Full Time Equivalent employee ratio each year to demonstrate efficiency of service provision and sustainability of the business model.[32]

[31] See CIM Performance Measure 5.2 on pg 17
[32] See CIM Performance Measure 5.1 on pg 17

7 CAPABILITY AND ISSUE MANAGEMENT

To achieve the outputs and strategic goals outlined in this document NZBS must maintain or enhance its organisational capability and operate effective systems to identify and manage any issues that may arise as external or internal business needs/conditions alter. Current organisational capability and some of the issues presently identified in key business areas are discussed in the table below along with management activities planned or currently active to address them.

Business Area	Current Status	Management Activities
DHB Relationships, Revenue/Funding	NZBS is a provider of essential products and services to the New Zealand health and disability sector and recovers its costs of operation from revenue obtained on a fee for service basis from its customers. An effective relationship with its primary customers, the DHBs, is vital. The DHB CEOs have identified a Lead DHB CEO for the NZBS relationship which simplifies communication. NZBS acknowledges the sector expectation of working within the annual "Contribution to Cost Pressures" (CCP) price increase to fund "business as usual" and NZBS controlled activities. The mechanism also exists to share with the DHBs the portion of any unbudgeted annual surplus that it may achieve due to changed product mix demand, improved fractionation yields and cost efficiencies, and which is not required by NZBS in discharging its own financial obligations and responsibilities in accordance with NZBS policy (established in consultation with DHBs and Ministry of Health representatives).	The relationship that exists between NZBS and the Lead DHB CEO is well maintained despite a change in Lead DHB CEO in 2011 and provides an effective channel for communication, on-going planning and issue resolution for both NZBS and DHBs. NZBS has incorporated its financial policy settings, internal efficiencies and anticipated volume growth for specific products and services; along with a rebalanced pricing framework in FY13, the result of a two year comprehensive review of all NZBS costs and prices. Specific funding requirements under Ministerial directive require the retirement of bank debt by 30 June 2015, and the meeting of all capital expenditure requirements out of operating cash flows, noting the planned level of capital spend in 2012/13 of $5.5m of which the e-Progesa blood management system implementation project is a major component at $1.4m.
National Health Board, Health Benefits Ltd, Health Workforce New Zealand	NZBS is actively linked in to sector wide developments with respect to shared services and is also participating in the All-of-Government procurement activities.	Maintaining active engagement with key government organisations with a view to adopting changes where a meaningful benefit can be achieved through shared services or

Business Area	Current Status	Management Activities
initiatives		other sector wide initiatives.
Blood Collection / Donor Management	A donor panel of at least 120,000 active whole blood donors is sufficient to meet current and projected whole blood collection requirements for 2012/13. However the apheresis donor panels (for Platelets and Plasma) will need to increase from the December 2011 number of 6,635 to 7,500 by 2014/15 to meet the growth in plasma requirement expected as a consequence of the increasing demand for IntragamP. Demand for plasma products in New Zealand continues to increase, consistent with international trends. Analysis demonstrates that plasmapheresis remains the most cost-effective mechanism to collect plasma required, additional to that recovered from whole blood collected to supply red cells. NZBS will therefore focus on effective management of plasmapheresis donors to match donation numbers with plasma requirements. This will include converting one of the existing regional whole-blood only collection sites to also collecting plasma by plasmapheresis.	Donor recruitment and retention will continue to be a focus for NZBS and there are a number of new and on-going initiatives to support optimal utilisation of the donor database and, in particular, recruit youth donors to address the generally aging demographic of New Zealand blood donors. NZBS committed to a defined Māori Responsiveness Strategy in 2010 to improve its engagement with Māori. This compliments targeted initiatives to encourage Māori support for the New Zealand Bone Marrow Donor Registry (NZBMDR) for which NZBS (working in partnership with the Leukaemia and Blood Foundation) carries out both recruitment and tissue typing services for potential donors. Regular use of computer survey and targeted focus groups enables NZBS to ensure donor satisfaction and to assess donor views on selected issues, facilitating service improvement. A Facebook site launched in mid-2009 to communicate with youth donors has more than 8,300 “fans.” In response to donor requests and to reduce postal costs, NZBS has increased the use of text and email to contact donors. We will continue to promote electronic communication as the preferred contact method during the period of this SOI.
Blood and Tissue Processing, Testing and Accreditation	NZBS maintains full capability to process, test and accredit all collected blood in a manner consistent with accepted international standards (Council of Europe). NZBS complies with the Human Tissue Act 2008 and is the predominant supplier of human bone and sole supplier of human	NZBS will continue to manage introduction of new standards and/or technologies to ensure alignment with international best practice, making modifications as necessary to meet the specific requirements in New Zealand. An annual review of international blood safety is carried out to

Business Area	Current Status	Management Activities
	skin to DHBs and private healthcare providers. NOTE: New Zealand is not self-sufficient in the supply of cadaver skin, needing to rely on importation to meet demand. Due to global shortages, this does mean that NZBS does not have the same surety of supply that it has for blood and blood products.	monitor and inform maintenance of testing standards. NZBS has expanded the number of international cadaver skin suppliers and continues to explore opportunities to increase NZ based collection, in an attempt to limit out-of-stock situations. NZBS is implementing platelets suspended in an additive solution (PAS). This reduces the volume of plasma used to store platelet concentrates, liberating additional plasma for fractionation from within current collection levels. PAS also provides additional safety through reducing the risk of adverse reactions in recipients, which can happen following transfusion of blood products containing plasma.
Plasma Fractionation	NZBS contracts with a third party fractionator (CSL Biotherapies) to ensure fractionated products of required specifications, prepared from New Zealand plasma, are available when clinically required. This contract was renegotiated in 2010 as part of the procurement process to deliver value for money and now includes the option for larger (more cost efficient) fractionation pools. The contract extends to 2014. Consistent with international experience, fractionation fees are the single largest contract cost to NZBS. Unlike a standard manufacturing environment, the protein composition of raw plasma entering each fractionation batch is determined by the individual donors contributing to it. This introduces an unknown biological variable into the production model which adds complexity and risk to forecasting exact yield and hence the amount of manufactured product ultimately derived from each pool of plasma fractionated. Variations in product yield can have significant impacts upon per unit costs of production and production	NZBS and its predecessors have had a long standing relationship with Australian based CSL Biotherapies which is responsive to the changing needs of NZBS. Key staff at NZBS and CSL work together to manage production of fractionated products by altering the amount or timing of plasma fractionation pools to most effectively meet product requirements at all times. CSL also keeps NZBS informed of variations in yield due to changes in manufacturing processes or protein composition of plasma.

Business Area	Current Status	Management Activities
	volumes.	
Product Mix and Volume	Like blood services all over the world, NZBS is vulnerable to unexpected or unmanaged changes in the mix or volume of products utilised by its customers throughout the year. Even small changes in mix, volume or fractionation yield have the potential to affect revenue and result in significant over or under recovery of operating costs. <u>Immunoglobulin products</u> Consistent with blood services around the world, immunoglobulin continues to be the primary product driver for plasma collection in New Zealand. NZBS clinical audit data indicates that the prescribing of intravenous immunoglobulin (IVIg) in New Zealand is largely consistent with published international guidelines. Based on utilisation over the last 12 months, NZBS planning assumes that in the next 3-5 years New Zealand's use of IVIg will grow at the rate of 6.5% per annum. This rate of growth is lower than that seen in other countries (for example growth in Australia continues to increase at 11% per annum).	Working in partnership with DHB clinicians, NZBS plays an active role in product management activities to ensure appropriate utilisation of blood and blood products (i.e. demand management). Some issues in respect of key products and brief discussion of their management are presented below: <u>Immunoglobulin products</u> NZBS works closely with DHBs to manage use of IVIg. This SOI is based on plasma collection volumes to support 6.5% annual growth in IVIg prescribing; however this will be adjusted up or down if there is a sustained change in demand. It is important to understand that there is a lead time from any change in donor collection activity (which cannot be easily "turned on and off") to provision of finished product.
	<u>Biostate (a Factor VIII product)</u> Volumes are determined by the National Haemophilia Management Group (NHMG). All people with Haemophilia who elected to, have now changed from plasma derived Biostate to recombinant product.	<u>Biostate</u> Arrangements are in place with CSL Biotherapies for the sale of surplus Biostate, to ensure that the donor's gift is maximised and providing a return for any surplus product no longer required in New Zealand.
	<u>Monofix (a Factor IX product)</u> In 2010 the NHMG made the decision to allow people with	<u>Monofix</u> NZBS will work with the NHMG to manage the Monofix

Business Area	Current Status	Management Activities
	Haemophilia on plasma-derived Monofix who elect to change, to transition to recombinant product in a planned way over a 3 year period. To date very few patients have elected to change product.	transition. Unfortunately, there is no market for surplus Factor IX product.
Facilities	Details about the location of NZBS facilities can be found on page7. Regular internal and external audit of how facilities are meeting current GMP requirements and organisational needs is undertaken. A comprehensive Collections & Facilities Review was completed in 2009 to model future requirements and to ensure continuation of the most cost-effective and efficient methods of collection as New Zealand's blood service requirements change. Recommendations from this review will begin to be implemented during the period of this SOI as GMP compliance, technology changes and increasing plasmapheresis requirements can no longer be met from existing facilities.	GMP Compliance issues identified in Christchurch will be addressed within the period of this SOI through a partnership arrangement with Ngāi Tahu Developments which will result in a new leased, purpose built facility within close proximity to Christchurch Hospital. Planning has also commenced with the Dilworth School Trust Board to future-proof the existing investment in the leased accommodation for the Auckland hub-site during the period of this SOI. As an interim measure the NZBS National Office has been temporarily relocated to a building within 10 minutes' walk of the hub-site.
Labour Costs	Labour costs are the largest single cost in running the blood service. Over recent years clinical staff numbers have increased in response to higher collection, processing and issuing requirements. Operating in the same labour market, NZBS employment terms and conditions need to be consistent with health and disability sector collectives that have been negotiated by the DHBs.	NZBS is required under the NZPHD Act to consult with the Director-General of Health on its bargaining strategy prior to commencing any Collective Agreement negotiations and settlement with staff on Individual Employment Agreements. This bargaining strategy also needs to be consistent with the Government's 20 February 2009 published expectations for pay and employment conditions in the State Sector. Recognising the significant impact that DHB employment relations practices and collective agreement negotiations have on the organisation, NZBS actively participates in sector forums whenever possible and seeks to keep abreast of employment relations matters in the wider DHB health and disability sector. For some employee groups NZBS is directly linked as part of

Business Area	Current Status	Management Activities
		sector wide Multi Employer Collective Agreements.
Being a "Good Employer"	Consistent with government expectations and to achieve its Strategic Goal 5, NZBS needs to be a "Good Employer". It is critical to the organisation that it can attract and retain skilled, committed employees to ensure that the on-going viability and safety of the blood supply are not compromised; therefore training will always be a primary focus. Turnover over the last couple of years has been low. NZBS has reviewed its recruitment policies to ensure they meet best practice and are non-discriminatory. Training is provided to relevant staff on recruitment practices to ensure that the organisation's obligations as an equal opportunity employer are met. There will be an on-going focus in 2012/13 to support our Christchurch based team as they work through the longer-term implications of the 2011 earthquakes. Staff consultation and involvement is being factored in to planning for facility upgrades in Auckland and Christchurch.	To ensure it has a staff sufficient in both number and skill to provide its specialist services, NZBS places considerable emphasis on creating a work environment capable of attracting and retaining skilled employees. Learning and Development initiatives and attention to succession planning also mitigate the risks inherent in loss of key personnel and ensure best utilisation of financial resources in respect of labour costs. The NZBS Recruitment strategy streamlines recruitment process helping to attract and retain key talent. This will continue to be monitored and developed over the period of this SOI. NZBS has an integrated Learning and Development framework informed by a comprehensive Training Needs Analysis to support appropriate development of the skills and talent necessary to maximise employee potential. NZBS Human Resources policies, practices and programmes ensure legislative requirements are met and that there is alignment with the seven key elements of being a "Good Employer".

Business Area	Current Status	Management Activities
Risk and crisis management	A comprehensive organisational risk management framework ensures that all significant NZBS risks are effectively identified, assessed, managed and monitored. NZBS also has a robust emergency management plan which was well tested in 2011 in response to the on-going earthquakes in Christchurch.	Risk identification and escalated incident management are agenda items at each Executive Team meeting. The NZBS Board receives regular reports on major incidents, reviews the Risk Register and Organisational Health and Safety metrics on a quarterly basis and the Risk Management Policy annually. Financial sustainability is reviewed monthly by NZBS management, Executive and the NZBS Board.
Regulatory compliance and Quality Systems management	All NZBS manufacturing sites are GMP compliant and hold licences to manufacture blood components. NZBS diagnostic laboratories, including the 6 hospital Blood Banks, are IANZ accredited. The National Tissue Typing laboratory is also accredited by ASHI. Maintaining registration and appropriate licences is part of "business as usual" with continuous quality improvement fundamental to the organisation at all levels. The 2011 announcement to work towards the establishment of a joint Australia New Zealand Therapeutics Products Agency (ANZTPA) over the next five years is noted. NZBS has been assured by the Ministry that it will be consulted as an important stakeholder in this area.	NZBS works closely and successfully with regulators/ auditors to ensure that all manufacturing centres retain required licences to manufacture blood components, and all diagnostic laboratories hold appropriate accreditation at all times.
Information Service Initiatives and Usage Reporting	NZBS has established IT systems that promote efficiency in business processes and support maintenance of GMP most notably through the national Blood Management System, Progesa. Progesa, which will be upgraded to e-Progesa in FY13 is the key IT system for NZBS and is also utilised in each of the DHBs to support their blood bank activities. Detailed daily inventory reports enable tight management of the national blood inventory, both within NZBS and the DHB blood	The upgrade to e-Progesa in both NZBS and the DHB's will take place in Quarter 1 of FY13. The upgrade will ensure that this essential system (which is the back-bone to all NZBS activities – both clinical and financial) is vendor supported and capable of maintaining safety, primarily through ensuring reliable donation/product information and traceability. The enhanced structure of the new software provides opportunities for future functionality.

Business Area	Current Status	Management Activities
	banks. Monthly product utilisation/demand management reports are generated for DHBs to enable them to better understand and manage their use of blood products and costs. NZBS has a comprehensive Information Services Strategic Plan which was updated in 2011 and extends to 2014	On-going hardware and software upgrades are planned throughout the three years of this SOI to ensure that the electronic systems supporting NZBS operations are robust and effective.

PART II

8 FINANCIAL PLAN

8.1 Overview of Financial Plan

The 2012/13 Financial Plan has been based on the 2011/12 base year forecast, incorporating actual results to 31 January 2012.

NZBS characterises the current planning environment as extremely challenging with a forward outlook of changing demand patterns with the primary fresh products projecting minimal demand growth, on-going input cost pressures and additional costs associated with renewal of key elements of infrastructure.

NZBS acknowledges the importance of ensuring essential service infrastructure is maintained particularly as the entity has now entered its second decade of operation as a national integrated blood service. Key renewal initiatives incorporated over the planning period are:

- Introduction of a new blood management system, eProgesa, in August 2012, at a capital cost of $6.2m, to replace the existing Progesa system purchased in 1998/99,
- Capital expenditure, excluding eProgesa investment, totalling $14.5m with key equipment within the manufacturing functions planned for upgrade or replacement,
- Commencement of planning initiatives at the hub sites in Auckland and Christchurch to address current accommodation issues in order to provide assurance these essential service sites are ‘fit for purpose’ in the medium to longer term.

This renewal phase brings with it additional costs that cannot be fully offset by the operational savings captured within the financial projections. While acknowledging the Minister and sectors expectation of fiscal restraint NZBS has been required to apply a financial tension that sees:

- Use of current financial strength to absorb cost on behalf of the wider sector via planned deficits in FY13 and FY14,
- Application of price increases which while above the sector CCP % settings are well below full cost recovery requirements. The increases planned over the forecast period sees a compound price increase over the planning period of 6.9% compared with a compound CCP% figure of 4.5%.

While this planning period has required price increases greater than sector CCP, NZBS notes it has a policy mechanism in place to effectively return price increases via a rebate should the actual demand levels and operational performance exceed the planned financial position. NZBS has paid a rebate in 2 of the last 5 years.

The NZBS compound price movement, net of rebates paid, over the 8 year period to 30 June 2015 continues to track below the benchmark CCP setting at compound 14.7% compared to a compound CCP setting over the same period of 19.0%

The financial forecast over the planning period reflects an overall 3.0% compound growth assumption in line with a forecast population growth over the same period of 2.7%.

Throughout the planning period NZBS maintains a conservative financial gearing ratio of 91% equity to 9% debt and operates at all times within its banking covenant obligations.

The financial forecast has been prepared as required by the Crown Entities Act 2004 for disclosure in this SOI and may not be appropriate for any other purpose. If NZBS becomes aware that there are changes to the assumptions detailed below, which may materially impact the stated financial position, this SOI will be amended accordingly under section 148 of the Crown Entities Act 2004.

The NZBS Board has agreed the financial forecast at the date of signing of this SOI.

8.2 Key Assumptions

The following assumptions (and risk assessments where appropriate) are key elements underpinning the financial forecasts for 2012/13 through to 2014/15:

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td>1.</td><td>Price Setting - The price movements over the 3 year forecast period are:
2.50 % in 2012/13 (CCP % 1.49%)
2.50% in 2013/14
1.75% in 2014/15</td><td>It is acknowledged that should unbudgeted costs create unforeseen financial risks over the period then NZBS may require a price increase greater than indicated in the two outer years.
Risk Assessment: LOW – Cost increases could exceed indicated price increases causing deterioration in the NZBS financial position, resulting in a requirement for price increases greater than currently indicated in the 2 outer years.</td></tr>
<tr><td>2.</td><td>Revenue Forecasts – revenue growth over the forecast period has been forecast as:
5.5 % in 2012/13
5.6% in 2013/14
4.8% in 2014/15</td><td>Revenue growth is a combination of price and demand (volume) movements. The specific demand assumptions for the revenue categories are detailed in Assumption 3.
Risk Assessment: MEDIUM - With price settings agreed under annual contractual terms, the major risk to revenue growth stems from the uncertainty of demand for any given product or service. The demand assumptions taken within these Forecasts reflect recent trend indications as well as allowance for any known forward demand impact factors.</td></tr>
<tr><td>3.</td><td>Demand (Volume) Assumptions – Demand growth over the forecast period has been assessed on a product by product basis and the outcome of those assessments is detailed below at product category level.
(a) Blood Product Demand Growth<table><tr><th>Product</th><th>2012/13</th><th>2013/14</th><th>2014/15</th></tr><tr><td>Fresh</td><td>1.10%</td><td>0.90%</td><td>0.90%</td></tr><tr><td>Fractionated</td><td>5.20%</td><td>5.50%</td><td>5.50%</td></tr><tr><td>Other</td><td>1.00%</td><td>1.00%</td><td>2.00%</td></tr><tr><td>Total Blood Products</td><td>2.70%</td><td>3.00%</td><td>2.90%</td></tr></table></td><td>Demand volatility is an ever present reality for NZBS, although the health and disability sector demographics indicate demand growth can be reasonably assumed. As a manufacturer NZBS endeavours to maintain flexibility within its production settings in order to minimise product expiry and ensure inventory levels are keep aligned to the current individual product demand profiles.
The two major products - Red Cells and IVIg IntragamP (a fractionated product) are specifically commented upon in Assumptions 6 and Assumption 7 respectively.
Risk Assessment: HIGH - Demand volatility, both upside and downside, is a risk inherent within</td></tr>
</table>

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td></td><td>
<table>
<tr><td>Services</td><td>4.70%</td><td>3.90%</td><td>3.90%</td></tr>
<tr><td>Total NZBS Products & Services</td><td>3.00%</td><td>3.10%</td><td>3.00%</td></tr>
</table>
</td><td>the NZBS business model. Historically NZBS has seen uneven demand growth for all products. This plan forecasts a compound blood product growth over the period of 2.9% in line with New Zealand's forecast population growth of 2.7% over the same period.</td></tr>
<tr><td>4.</td><td><u>Collection volumes</u> - Based on forecast demand patterns for 2012/13 required collection volumes are forecast to be:
<table>
<tr><th>Collection Method</th><th>2012/13</th></tr>
<tr><td>Whole Blood</td><td>144,000</td></tr>
<tr><td>Plasmapheresis</td><td>30,100</td></tr>
<tr><td>Plateletpheresis</td><td>7,900</td></tr>
<tr><td>Total Collections</td><td>182,000</td></tr>
</table>
The forecast for the out years is as follows:
<table>
<tr><th>Collection Method</th><th>2013/14</th><th>2014/15</th></tr>
<tr><td>Whole Blood</td><td>144,000</td><td>144,500</td></tr>
<tr><td>Plasmapheresis</td><td>37,500</td><td>42,900</td></tr>
<tr><td>Plateletpheresis</td><td>7,600</td><td>7,700</td></tr>
<tr><td>Total Collections</td><td>189,100</td><td>195,100</td></tr>
</table>
</td><td>2010/11 target volumes were:
<table>
<tr><th>Collection Method</th><th>2011/12</th></tr>
<tr><td>Whole Blood</td><td>150,000</td></tr>
<tr><td>Plasmapheresis</td><td>30,000</td></tr>
<tr><td>Plateletpheresis</td><td>6,600</td></tr>
<tr><td>Total Collections</td><td>187,100</td></tr>
</table>
<u>Note</u>: The decrease in whole blood collection volumes is demand driven with red cell volumes trending below historic demand levels. The growth in plasmapheresis collections forecast over the period is required to meet the forecast demand for Fractionated Product (also see Assumptions 3 and 7).

Risk Assessment: MEDIUM - collection volumes are very sensitive to product demand assumptions and will be flexed up or down to align with apparent demand patterns. This would be managed with an increase (or decrease) in donor recruitment and encouragement to existing donors to increase (or decrease) their donation frequency.</td></tr>
<tr><td>5.</td><td>Platelet Additive Solution (PAS) will be implemented for platelets recovered from whole blood collections and for apheresis platelets by June 2012.

PAS liberates plasma previously used to suspend platelets, for fractionation, thus reducing plasmapheresis collection requirements.</td><td>Plasmapheresis collection targets have been based on the assumption that fewer collections will be required after the full implementation of PAS.

Risk Assessment: MEDIUM - risk is that PAS will not be fully implemented by 1 July 2012 requiring more plasma to be collected via plasmapheresis collection and incurring the associated costs.</td></tr>
</table>

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td>6.</td><td>Sales volume for Red Cells (RBC's), the major product within the Fresh Product sales category, is assumed to have a small positive growth factor over the three years of this SOI – refer Assumption 3 for Fresh product growth.</td><td>Sales volumes are totally dependent on health sector demand. Several DHBs are working with NZBS to actively manage down their utilisation of RBCs; however the aging population and increased elective surgery may see an offsetting increase in demand. If demand increases or decreases beyond that forecast (refer Assumption 3) whole blood collections (refer Assumption 4) will be increased or decreased, with that change accommodated within the current donor population.

Risk Assessment: HIGH – Demand for RBCs has declined over the last couple of years, as a result of the focus on product utilisation and cost containment within the DHBs – this makes accurate forecasting in a changing environment very difficult.</td></tr>
<tr><td>7.</td><td>IntragamP as the primary fractionated product has a sales volume forecast expected to increase at 6.5% per annum.

IntragamP sales volume assumptions are:

<table><tr><th>Year</th><th>IntragamP Sales Volumes
(200mL 12 gm equivalent)</th></tr><tr><td>2012/13</td><td>24,525</td></tr><tr><td>2013/14</td><td>26,125</td></tr><tr><td>2014/15</td><td>27,825</td></tr></table>
Inventory levels will be managed at a minimum 3 months stock on hand to ensure surety of supply.</td><td>The 2011/12 year has seen the continuing increase in demand for IntragamP albeit at a lower rate than has historically been the case. Since 2002 IntragamP had been consistently increasing at some 8% per annum. In 2008/09 that growth slowed, then picked up again in late 2009/10 and is currently indicating just over 5% growth. Internationally growth in the use of this class of products is approximately 13% per annum.

Should prescribing increase or decrease from the budgeted assumption of 6.5% growth each year, then collection targets will be flexed to ensure demand is met and product expiry is minimised. (Note: IntragamP has a two year shelf-life which enables stock to be managed up and down).

Risk Assessment: MEDIUM - risk of demand being either greater or less than the forecast 6.5% growth which would be mitigated by collection target flexing (refer assumption 4). This could be accommodated financially without significant short term financial impact due to the 2 year shelf-life of IntragamP.</td></tr>
<tr><td>8.</td><td>Biostate sales volumes are based on 14,500 vials (250 IU equivalent) each year inclusive of the volumes agreed with the NHMG.</td><td>Biostate utilisation will continue to be monitored by the NHMG and Haemophilia Treaters.

Risk Assessment: LOW – indications are that usage has stabilised at the agreed 14,500 vials per annum level.</td></tr>
</table>

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td>9.</td><td>Monofix sales volumes are based on the indicated requirements over the 3 year SOI period as agreed with the NHMG and outlined below:
<table><tr><th>Year</th><th>Monofix Sales Volumes
(500 IU equivalent)</th></tr><tr><td>2012/13</td><td>2,400</td></tr><tr><td>2013/14</td><td>2,400</td></tr><tr><td>2014/15</td><td>2,400</td></tr></table></td><td>Prior to the NHMG decision to transition haemophilia patients on plasma derived factor IX (Monofix) to recombinant product; utilisation was some 3,000 x 500 IU equivalent vials.

Monofix utilisation is being carefully managed to the agreed budgeted volumes by the NHMG and Haemophilia Treaters.

Risk Assessment: LOW – as the volumes are based on the NHMG information as provided by the Haemophilia Treaters based on a patient by patient needs assessment basis.</td></tr>
<tr><td>10.</td><td>Only Biostate and Albumex products will have revenue associated with sale of surplus production volumes.

NOTE: there is no market for surplus Monofix</td><td>NZBS has a developed stock management process to minimise product expiry and maximise product utilisation, however; if stocks of other fractionated product exceed demand and there is a limited or no market for sale of surplus product, then the unrecovered production costs will be carried by the higher demand product lines.

Risk Assessment: LOW – with clearly defined contract arrangements for surplus Biostate and Albumin product sales in place with the NZBS fractionated product manufacturer.</td></tr>
<tr><td>11.</td><td>New Zealand will remain self-sufficient for all major blood products including IntragamP.</td><td>The principle of self-sufficiency (including financial viability) is regularly reviewed, based on financial, clinical and surety of supply criteria, as outlined in discussion of NZBS Strategic Goal 3.

There are likely to be financial implications for NZBS and the wider sector if self-sufficiency is not sustained.

Self Sufficiency does not preclude the procurement of imported product if clinically necessary and in exceptional circumstances.

Risk Assessment: LOW - NZBS collects sufficient blood and produces sufficient blood products to maintain self-sufficiency and the most recent financial analysis supports this principle being maintained.</td></tr>
<tr><td>12.</td><td>Current fractionation yields are maintained over the period of the SOI.</td><td>Changes in the yield of fractionated product obtained from a volume of plasma will impact either adversely (in the case of reduced yield) or favourably (in the case of improved yield) on NZBS' forecast financial position.

Risk Assessment: LOW – based on the prior yield performance of the manufacturer.</td></tr>
</table>

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td>13.</td><td>Plasma Fractionation costs in 2012/13 and subsequent years will increase in accordance with the increase as provided for in the confidential CSL Manufacturing Agreement. Note: This agreement includes increasing the sizing of fractionation pools from 7.5 tonne to 10 tonne, which will result in higher inventory levels after each fractionation pool.</td><td>The CSL Manufacturing Agreement is priced in Australian dollars so there is an exposure to movements in the AUD:NZD cross rate.
Risk Assessment: MEDIUM – NZBS endeavours to mitigate this risk via Forward Exchange contracts purchased in accordance with the NZBS Treasury policy. Also refer to the foreign exchange assumption 19 below.</td></tr>
<tr><td>14.</td><td>The stock turn ratios for the total inventory holding over the forecast period is set out below:
<table><tr><th>Stock Turns</th><th>Turns per Annum</th></tr><tr><td>2011/12 Year</td><td>3.9</td></tr><tr><td>2012/13 Year</td><td>4.4</td></tr><tr><td>2013/14 Year</td><td>4.7</td></tr><tr><td>2014/15 Year</td><td>4.8</td></tr></table></td><td>NZBS sets a minimum stock holding of 3 months demand across its non-fresh product range to ensure surety of supply. This sets the minimum benchmark stock turn for all inventory held at 3 times, a benchmark figure NZBS aims to exceed in the context of efficient working capital management.
Risk Assessment: MEDIUM – risk is an unexpected drop in demand increasing the risk of product expiry (fresh product) and higher short term inventory holding (fractionated product). The primary risk stock category is fractionated product (due to 3 month minimum stock holding) however the risk is mitigated in large part by this product category having a 2 year shelf life.</td></tr>
<tr><td>15.</td><td>Establishment level FTEs incorporated in the financial forecasts are:
<table><tr><th>Year</th><th>Establishment Level FTEs</th></tr><tr><td>2011/12</td><td>501</td></tr><tr><td>2012/13</td><td>508</td></tr><tr><td>2013/14</td><td>509</td></tr><tr><td>2014/15</td><td>509</td></tr></table>NOTE: the FTE increases are clinical (front-line) staff)</td><td>As an essential service provider NZBS must adapt quickly to changes in demand and/or safety requirements. Staffing levels are therefore subject to increases or decreases in response to changing business requirements, particularly changes in demand for products.
Risk Assessment: MEDIUM – risk is the inability to source new/replacement appointments with the required skill mix. NZBS is competing with the health and disability sector at large for resources mitigated in part by participating in the same collective agreements as the DHBs.</td></tr>
<tr><td>16.</td><td>The majority of NZBS staff will continue to be employed on collective agreements (either Multi-Employer Collective Agreements (MECAs) or Single-Employer Collective Agreements).
Assumptions regarding employee cost increases have taken into account the Government's Expectations for Pay and Employment Conditions in the State Sector published on 20 February 2009 and direct consultation with the Ministry of Health.</td><td>Staff costs make up approximately 34.8% of NZBS costs. Most collectives have built into them an annual increase and merit step increases which have an impact on NZBS' overall annual cost increases.
Settlements in relation to Collective Agreement negotiations have a flow on effect to costs associated with staff working under Individual Employment Agreements.</td></tr>
</table>

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td></td><td>Best estimates in respect of possible future settlements have been included in financial forecasts, projected out over the next three years.</td><td>Risk Assessment: MEDIUM - risk of settlement outside of budgeted parameters, depending on wider sector settlements. (Assumption 1 also refers.)</td></tr>
<tr><td>17.</td><td>Plasmapheresis, Plateletpheresis and whole blood consumable costs will reflect forecasted collection requirements.

Consumable costs (based on current contracts, or expected CPI increases) and employee costs (FTE’s required) are in turn based on meeting the projected collection volume targets for 2012/13 and subsequent years, as summarised in Assumption 4.</td><td>Forecast collection volumes are subject to change in response to alterations in demand for products, variation in production yields and/or collection / processing methods.
Further staffing and consumable reductions would be considered in the event that collection volume requirements decrease for a sustained period of time.
Likewise, if collection volume levels are required to increase significantly beyond those forecast; an increase in staffing and consumables may be required to collect and process additional volumes.
Note: Many NZBS consumables purchased from international markets are subject to foreign exchange fluctuations. Potential additional costs due to the global economic situation have not been factored into the financial forecast.
Risk Assessment: MEDIUM - risk that input price increases are higher than budgeted allowances. (Assumption 1 also refers.)</td></tr>
<tr><td>18.</td><td>Changes to regulatory costs will only include costs associated with initiatives to achieve compliance with the Public Records Act 2005.</td><td>While the Government has signalled its intention to reactivate the establishment of ANZTPA in the next 4 years, cost implications are not yet known; therefore this SOI is based on existing Medsafe and other NZBS regulatory costs.
Risk Assessment: HIGH – as ANZTPA is part of the Government’s planned intentions and indications from 2007 discussions about the establishment of ANZTPA suggest increases in NZ regulatory costs.</td></tr>
<tr><td>19.</td><td>Foreign exchange rates over the forecast period of this SOI have been assumed as:

<table><tr><th>Year</th><th>AUD$</th><th>Euro</th><th>US$</th></tr><tr><td>2012/13</td><td>0.78</td><td>0.61</td><td>0.77</td></tr><tr><td>2013/14</td><td>0.80</td><td>0.62</td><td>0.75</td></tr><tr><td>2014/15</td><td>0.81</td><td>0.63</td><td>0.75</td></tr></table></td><td>NZBS has exposure to foreign exchange fluctuations, primarily the Australian dollar through its plasma fractionation contract with CSL Biotherapies.
Based on 2012/13 settings a 1 cent movement in the AUD exchange rate increases or reduces fractionation costs by approximately $250k.
NZBS manages this risk via forward exchange contracts in accordance with the NZBS Treasury Management policy settings.</td></tr>
</table>

<table>
<tr><th></th><th>Assumption</th><th>Comment / Risk</th></tr>
<tr><td></td><td>These rates have been based on the latest information available at time of SOI preparation, and represent the combined views of banking industry forecast economic data, underpinned by advice from NZBS treasury advisors.</td><td>Risk Assessment: MEDIUM to HIGH – the on-going volatility in global financial markets will continue to impact New Zealand's economic settings in the short to medium term.</td></tr>
<tr><td>20.</td><td>As a demand-driven service provider to the health and disability sector, NZBS will share with the DHBs any unbudgeted realised net financial gains that it may achieve due to optimal product mix demand, improving yields and cost efficiencies, in accordance with the NZBS Financial Guidelines policy.</td><td>NZBS has a Financial Guidelines policy that clearly sets out the Board's obligations (having regard to NZBS longer term financial viability) to assess on an annual basis, whether any realised net financial gains will be shared with the DHBs.</td></tr>
<tr><td>21.</td><td>The Capital Charge, paid to the MOH, is based on the forecast closing equity position and has been assumed at the current 8% pa over the forecast period.</td><td>This is a Ministry of Health mandated charge over which NZBS has no direct control.</td></tr>
<tr><td>22.</td><td>The quantum of capital expenditure will be tightly managed, but will require flexing year-on-year in response to clinical requirements.

Examples of significant capital expenditure planned in the 2012/13 year are:
e-Progesa Blood Management System - $1.4m
National replacement programme for blood separation equipment - $1.2m
Collection logistics software - $0.25m</td><td>Safety requirements and the capital intensive nature of the blood service operations means that smooth capital spend year-on-year is not realistic.

Risk Assessment: LOW - the capital expenditure plan is a carefully considered and managed document ensuring a low risk of being greater than budget</td></tr>
<tr><td>23.</td><td>Interest rates on the NZBS Funding Facility over the period of this SOI have been based off projected 90 day bill rate and are assumed to be:

<table><tr><th>Year</th><th>Interest Rate</th></tr><tr><td>2012/13</td><td>4.2 %</td></tr><tr><td>2013/14</td><td>5.7%</td></tr><tr><td>2014/15</td><td>6.6%</td></tr></table></td><td>The level of available funds has been set to ensure forecast funding needs can be accommodated without need for facility renegotiation. The term of the facility covers the majority of the forecast period.

The facility is operated in accordance with the approval terms of the Ministers' of Finance and Health.

Risk Assessment: LOW - based on the forecast level of facility debt NZBS exposure to any interest rate movement is minimal in the context of the overall NZBS cost structure.</td></tr>
</table>

	Assumption	Comment / Risk
24.	Timing of product extraction during fractionation of plasma pools will not result in material "pooling gains" or "losses" which straddle balance date.	The exact timing of fractionation and extraction of product from plasma pools by CSL can affect the year end reported result if fractionation of a pool straddles the 30 June balance date. **Risk Assessment:** LOW - unless there is an urgent requirement to bring forward a fractionation pool to meet unexpected increase in demand for fractionated product with such requirements covered under the contract with the manufacturer.
25.	There will be no financial impact on the forecast financial performance as a result of any plasma pool incident (e.g. loss of a pool of plasma through contamination or manufacturing problem).	NZBS would follow the process outlined in 2005 by the MOH to secure additional funding to off-set financial losses that are unable to be managed by NZBS. **Risk Assessment:** LOW – the basis for managing such a situation was established with the MOH in 2005 and would be enacted if required.

8.3 Forecast Financial Statements

Forecast Statement of Financial Performance

	Budget FY 12 $000	Forecast FY 12 $000	%	Forecast FY 13 $000	%	Forecast FY 14 $000	%	Forecast FY 15 $000	%
Income									
Revenue from supplying Blood Products	89,117	87,018	82.58%	91,532	82.33%	96,563	82.18%	101,035	82.12%
Revenue from supplying Services	17,012	16,737	15.88%	17,948	16.14%	19,088	16.25%	20,160	16.39%
Revenue from Overseas Sales	1,524	1,229	1.17%	1,461	1.31%	1,659	1.41%	1,636	1.33%
Interest Income	275	389	0.37%	224	0.20%	181	0.15%	196	0.16%
Other Income	7	7	0.01%	7	0.01%	7	0.01%	7	0.01%
Gross Income	**107,935**	**105,380**	100.00%	**111,172**	100.00%	**117,499**	100.00%	**123,033**	100.00%
Less Distribution of Surplus to DHBs	-	-		-		-		-	
Net Income	**107,935**	**105,380**	100.00%	**111,172**	100.00%	**117,499**	100.00%	**123,033**	100.00%
Expenditure									
Production and Bought-in Costs (excluding Labour costs)	47,224	43,953	41.71%	47,261	42.51%	49,938	42.50%	52,513	42.68%
Changes in Inventory ***	(2,547)	(2,410)	(2.29%)	1,193	1.07%	360	0.31%	(373)	(0.30%)
Employee Benefit Expense	37,468	36,989	35.10%	39,169	35.23%	40,755	34.69%	41,872	34.03%
Depreciation and Amortisation	3,597	3,245	3.08%	3,878	3.49%	4,072	3.47%	4,423	3.60%
Other Operating Expenses	18,107	16,969	16.10%	18,723	16.84%	19,586	16.67%	20,973	17.05%
Finance Costs	255	235	0.22%	234	0.21%	267	0.23%	279	0.23%
Capital Charge	2,910	3,060	2.90%	2,885	2.60%	2,860	2.43%	2,890	2.35%
Revaluation of Derivative Financial Instruments									
Total Expenses	**107,015**	**102,040**	96.83%	**113,342**	101.95%	**117,838**	100.29%	**122,578**	99.63%
Net Surplus / (deficit) for the Year	**920**	**3,340**	**3.17%**	**(2,170)**	**(1.95%)**	**(339)**	**(0.29%)**	**455**	**0.37%**
Other Comprehensive Income	-	-		-		-		-	
Total Comprehensive Income	**920**	**3,340**	**3.17%**	**(2,170)**	**(1.95%)**	**(339)**	**(0.30%)**	**455**	**0.41%**
Surplus Attributable to NZ Blood Service	**920**	**3,340**	**3.17%**	**(2,170)**	**(1.95%)**	**(339)**	**(0.30%)**	**455**	**0.41%**
Total comprehensive Income Attributable to NZ Blood Service	**920**	**3,340**	**3.17%**	**(2,170)**	**(1.95%)**	**(339)**	**(0.30%)**	**455**	**0.41%**

Forecast Statement of Changes in Equity

	Budget FY 12 $000	Forecast FY 12 $000	Forecast FY 13 $000	Forecast FY 14 $000	Forecast FY 15 $000
Opening Equity balance	**35,461**	**34,905**	**38,245**	**36,075**	**35,736**
Total comprehensive Income Attributable to NZBS	920	3,340	(2,170)	(339)	455
Total recognised income / expense for the year ended 30 June	**920**	**3,340**	**(2,170)**	**(339)**	**455**
Contribution from owner	-	-	-	-	-
Closing Equity balance	**36,381**	**38,245**	**36,075**	**35,736**	**36,191**
Forecast changes in Equity over the forecast period					
(a) Crown Equity					
Opening Balance	15,717	15,717	**15,717**	**15,717**	**15,717**
Total Comprehenive Income for year	**-**	**-**	**-**	**-**	**-**
Closing balance	**15,717**	**15,717**	**15,717**	**15,717**	**15,717**
(b) Retained Earnings					
Opening Balance	19,745	19,189	22,529	20,359	20,020
Total Comprehenive Income for year	920	3,340	(2,170)	(339)	455
Closing balance	**20,665**	**22,529**	**20,359**	**20,020**	**20,475**
Closing Equity Balance	**36,381**	**38,245**	**36,075**	**35,736**	**36,191**

***** Note re Changes in Inventory**

For ease of reporting, the 'Changes in Inventory' category is an aggregated reporting category comprising 'cost of goods sold, production recoveries and inventory valuation adjustments' consistent with the application of manufacturing standard costing methodologies and generally accepted inventory valuation principles.

Forecast Statement of Financial Position

	Budget FY 12 $000	Forecast FY 12 $000	Forecast FY 13 $000	Forecast FY 14 $000	Forecast FY 15 $000
Equity					
Crown Equity	15,717	15,717	15,717	15,717	15,717
Retained Earnings/(Losses)	20,665	22,529	20,359	20,020	20,475
Total Equity	**36,381**	**38,245**	**36,075**	**35,736**	**36,191**
Equity %	63.9%	66.8%	65.0%	64.3%	64.1%
Represented by:					
Assets					
Current Assets					
Cash and Cash Equivalents	5,580	7,698	4,616	3,168	3,460
Trade and Other Receivables	11,143	11,352	11,676	11,947	11,712
Inventories	23,887	23,409	22,324	22,066	22,533
Total Current Assets	40,610	42,459	38,617	37,181	37,706
Non Current Assets					
Property, Plant and Equipment	9,697	9,736	10,326	11,503	11,962
Intangible Assets	6,611	5,030	6,595	6,928	6,836
Total Non Current Assets	16,308	14,766	16,921	18,431	18,798
Total Assets	56,918	57,224	55,537	55,612	56,504
Liabilities					
Current Liabilities					
Trade and Other Payables	6,673	4,028	3,943	4,059	4,170
Provisions	4,089	4,745	5,149	5,282	5,155
Employee Entitlements	3,491	4,077	4,316	4,570	4,839
Total Current Liabilities	14,253	12,850	13,408	13,912	14,164
Non Current Liabilities					
Employee Benefit Liabilities	1,329	1,121	1,173	1,228	1,286
Provisions	1,132	1,186	1,311	1,437	1,563
Term Borrowings	3,822	3,822	3,570	3,300	3,300
Total Non Current Liabilities	6,283	6,129	6,054	5,964	6,149
Total Liabilities	20,537	18,979	19,462	19,876	20,313
Net Assets	**36,381**	**38,245**	**36,075**	**35,736**	**36,191**

Forecast Statement of Cash Flows

	Budget FY 12 $000	Forecast FY 12 $000	Forecast FY 13 $000	Forecast FY 14 $000	Forecast FY 15 $000
Cash Flows from Operating Activities					
Cash was provided from:					
Receipts from Blood Products and Services Revenue	121,930	119,002	125,530	132,748	139,595
Interest Received	275	389	224	181	196
Receipts from Other Revenue	1,496	1,236	1,434	1,632	1,641
	123,702	120,627	127,188	134,561	141,431
Cash was disbursed to:					
Payments to Employees	37,173	36,529	38,846	40,408	41,511
Payments to Suppliers	72,441	71,334	76,623	80,696	85,121
Distributions to Primary Stakeholders					
Interest Paid	210	178	185	213	226
Capital Charge Paid	2,874	3,468	2,589	2,848	2,849
Net GST Payable to IRD	7,806	5,272	5,760	6,011	6,373
	120,504	116,781	124,002	130,175	136,078
Net Cash Flow from Operating Activities	**3,197**	**3,847**	**3,186**	**4,386**	**5,353**
Cash Flows from Investing Activities					
Cash was provided from:					
Proceeds from the sale of Property, Plant & Equipment					
Cash was disbursed to:					
Acquisition of Property, Plant & Equipment	(3,666)	(3,849)	(3,641)	(4,398)	(3,893)
Acquisition of Intangible Assets	(3,436)	(2,922)	(2,392)	(1,184)	(898)
	(7,102)	(6,771)	(6,033)	(5,582)	(4,791)
Net Cash Flow from Investing Activities	**(7,102)**	**(6,771)**	**(6,033)**	**(5,582)**	**(4,791)**
Cash Flow from Financing Activities					
Cash was provided from:					
Advances from Term Borrowings					
Cash was disbursed to:					
Repayment of Term Borrowings	(219)	(219)	(235)	(252)	(270)
	(219)	(219)	(235)	(252)	(270)
Net Cash Flow from Financing Activities	**(219)**	**(219)**	**(235)**	**(252)**	**(270)**
Net increase/(Decrease) in Cash and Cash Equivalents	**(4,124)**	**(3,143)**	**(3,082)**	**(1,448)**	**292**
Cash and Cash Equivalents at the beginning of the year	9,704	10,841	7,698	4,616	3,168
Cash and Cash Equivalents at the end of the year	**5,580**	**7,698**	**4,616**	**3,168**	**3,460**

Reconciliation of Surplus / (Deficit) with Net Cash Flow from Operating Activities

	Budget FY 12 $000	Forecast FY 12 $000	Forecast FY 13 $000	Forecast FY 14 $000	Forecast FY 15 $000
Surplus/(Deficit) post Distributions	920	3,340	(2,170)	(339)	455
Add Back Non Cash Items:					
Depreciation & Amortisation	3,597	3,245	3,878	4,072	4,423
Property, Plant & Equipment Write Off Provision	-	-	-	-	-
Changes in Premises Reinstatement Provision	106	125	125	126	127
Movement in Working Capital:					
(Increase)/ Decrease in Trade and Sundry Receivables	(122)	(286)	(374)	(252)	255
(Increase) / Decrease in Prepayments	(21)	(20)	(19)	(19)	(21)
(Increase) / Decrease in Inventories	(2,748)	(2,954)	1,084	258	(467)
Increase / (Decrease) in Trade Creditors & Other Payables	60	13	50	51	53
Increase / (Decrease) in Other Payables	1,043	33	185	73	127
Increase / (Decrease) in General Accruals	67	76	136	106	73
Increase / (Decrease) in Employee Entitlements	295	274	291	309	328
Net Cash Inflow/(Outflow) from Operating Activities	**3,197**	**3,847**	**3,186**	**4,386**	**5,353**

APPENDIX 1
NZBS Organisational Structure and Context

To support achievement of its enduring outcome:

Health needs of people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services

NZBS is organised and supported by an established structure as outlined below.

Governance

NZBS is governed by a board appointed by and responsible to the Minister of Health and forecasts and reports on performance to the Minister through the Ministry of Health.

The NZBS Board performs the roles and responsibilities of a Crown Entity board as defined in the Crown Entities Act 2004.

Management

While responsibility for overall NZBS performance rests with the Board, operational management matters have been delegated to the Chief Executive.

The Chief Executive is supported by an Executive Team as shown below. Reporting to the NZBS Executive Team are key national specialist roles, along with the senior clinical and operational roles. The key national specialist roles include: National Manager Logistics; National Manager Marketing and Communications; National Manager Information Services; National Manager Procurement; regionally based Area Managers and Transfusion Medicine Specialists and Nurses.

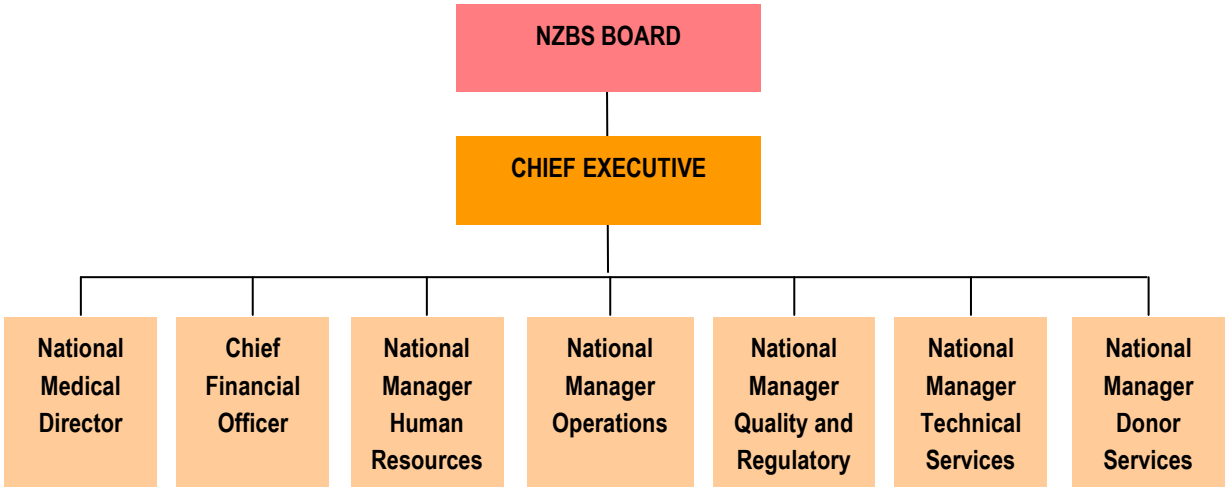

Figure 4: NZBS Board and Executive Management

Details about incumbents can be found on: www.nzbloood.co.nz

NZBS Staff

Teamwork is fundamental to the success of NZBS. Eighty eight percent of NZBS staff are classified as “front-line” (i.e. staff whose role is directly related to the provision of NZBS products and services including maintenance of regulatory and GMP compliance.) Front-line excludes Executive, National and Area Managers and staff employed in functions such as: Finance; Human Resources; Payroll; Information Services and Marketing.

Staff by Operational Area

Figure 5 below provides an overview of NZBS staff groupings by operational area.

"National" refers to the following national roles:

- National Management
- Finance and Procurement
- Information Services
- Marketing and Communications
- Human Resources and Payroll
- Operational Support Officers
- Training and Development Co-ordinators

This centralised national structure is the most efficient management model and facilitates effective control and co-ordination of the national blood service.

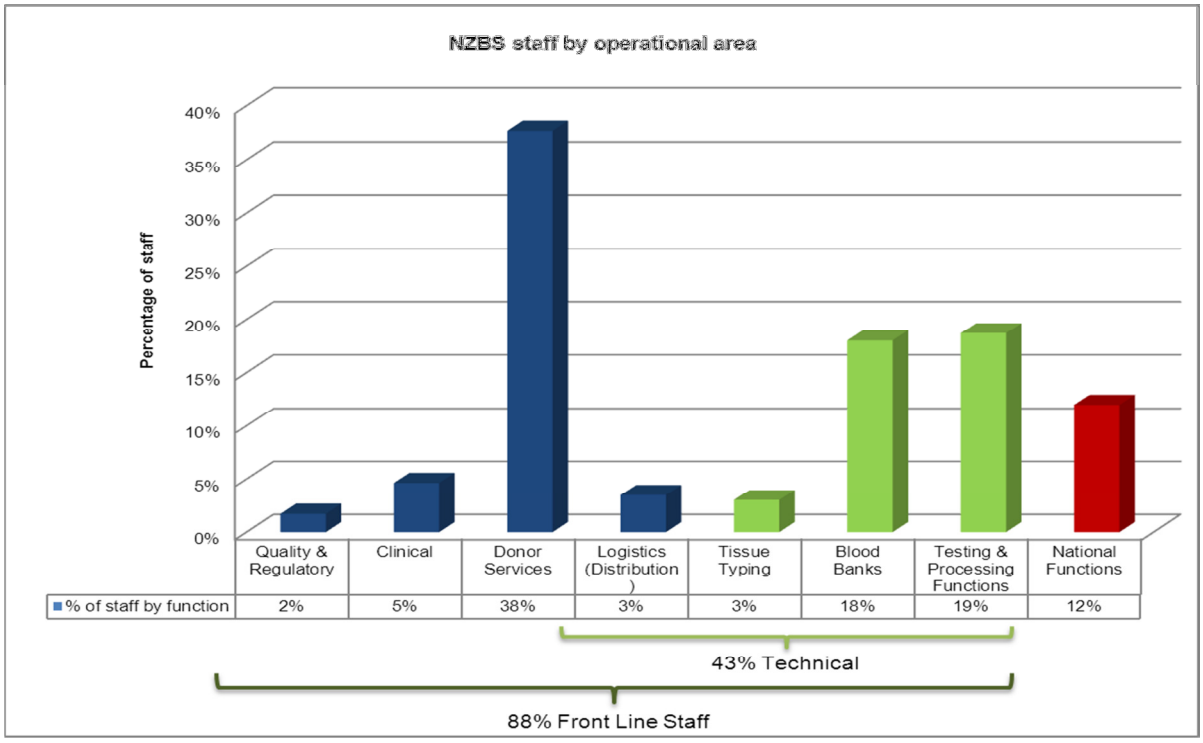

Figure 5: Composition of NZBS staff by operational area

NOTE:

Staff in Donor Services are predominantly Registered Nurses, but also include Enrolled Nurses, Donor Technicians, Donor and Apheresis Recruiters, Drivers, Reception and Front-line Administration staff.

Staff in Technical Services are predominantly Medical Laboratory Scientists, but also include Medical Laboratory Technicians and Assistants and Clinical Scientists

Principle front-line activities can be described as being either clinical, donor or technically related as outlined in Figure 6.

	Key Activities	Responsible for	Location
Donor Services	Donor Recruitment	Maintaining a sustainable donor population - recruiting new donors and retaining existing donors through relationship development & scheduling appointments to achieve collection targets	All NZBS sites
	Collections	Collecting whole blood and apheresis plasma & platelets whilst ensuring maintenance of good donor health	All NZBS sites
Technical Services	Testing	Testing every blood donation for: HIV, HCV, HBV, syphilis, with selective testing for some donors	Auckland Christchurch
	NZBS Processing	Separating whole blood into: Red Cells, Plasma and Platelets through a range of manufacturing processes	Auckland Waikato Wellington Christchurch
	CSL Processing (Fractionation)	Frozen New Zealand plasma is sent to CSL Biotherapies, fractionated and returned to NZBS for distribution	CSL Biotherapies Melbourne, Australia
	Tissue Bank	The national skin bank in Auckland and bone banks at each of the Processing sites and in the blood banks in Palmerston North and Dunedin	Auckland Waikato Palmerston North Wellington Christchurch Dunedin
	Distribution	The logistics function in the 4 hub sites distributes product to each of the DHB hospital blood banks (NOTE: the DHB blood banks supply all private hospitals) and overseeing inventory management, minimising expiry and ensuring that product is always available to meet demand	Auckland Waikato Wellington Christchurch
	Blood Bank	Cross-matching and antibody screening to ensure compatibility between the donated blood and the patient (recipient) prior to dispatching to the appropriate hospital staff for transfusion	At the following hospitals: Auckland Waikato Palmerston North Wellington Christchurch Dunedin
	National Red Cell Reference Laboratory	Undertakes complex pre-transfusion testing and antibody identification. Runs a national quality assurance programme and inhouse reagent manufacturing	Auckland
	National Tissue Typing Laboratory	Key testing and assessment services to DHBs undertaking organ and haemopoetic stem cell transplantation	Auckland
Clinical Services	Clinical Support	Medical and transfusion nursing support to both DHB and NZBS staff on all transfusion medicine related issues	Auckland Waikato Palmerston North Wellington Christchurch Dunedin
	Clinical Services	Provision of therapeutic services such as plasma exchanges, stemcell harvests and therapeutic venesections	Auckland Waikato Palmerston North Christchurch
	Supported by National functions of: Clinical, Quality & Regulatory Systems, Logistics, Marketing, Information Services, Finance and Human Resources		

Figure 6: Key front-line NZBS activities

A focus on Quality

Clinical Service

The NZBS Clinical Team plays a key role in maintaining clinical quality - ensuring that the right product is provided to the right patient at the right time. The clinical role within NZBS impacts on all areas in the "vein to vein" blood service from selection of donors to provision of advice and support for the management of patients with complex clinical problems and analysis of any reported adverse transfusion events.

A multidisciplinary Clinical Advisory Group, chaired by the National Medical Director oversees NZBS clinical activity; providing advice to the Chief Executive on clinical issues and taking a proactive role in setting clinical policy, standards and encouraging transfusion medicine best practice.

A clinical oversight programme enables NZBS to discharge its statutory responsibility for maintenance of effective blood banking and cross-matching systems in the DHB Blood Banks not operated by NZBS. The programme has been endorsed by International Accreditation New Zealand (IANZ). Active participation in the NZBS Clinical Oversight Programme is a key component to the DHB managed Blood Banks maintaining IANZ Accreditation. A comprehensive twenty four hour national clinical advisory service is available to all hospitals.

A national haemovigilance programme examines and reports annually on the frequency and causes of adverse transfusion related events, to help health professionals understand the risks associated with blood transfusion and assist development of improved systems for the safe delivery of blood products to patients.

Quality, Safety and Compliance – "Safety is our Cornerstone"

The NZBS Quality and Regulatory Systems team has a broad scope which includes ensuring organisational compliance with Good Manufacturing Practice (GMP) and maintenance of all required licences and accreditation through the development of robust quality systems. It maintains systems for document and records management, customer complaints, corrective action management, equipment management, validation management and conducting internal and external audits. The team works very closely with operational teams to ensure regulatory requirements are met.

The key external parties with whom the Quality and Regulatory Systems function interacts are: Medsafe; International Accreditation New Zealand (IANZ); the American Society for Histocompatibility and Immunogenetics (ASHI); the Australian Therapeutic Goods Administration (TGA); CSL Biotherapies; Archives NZ and DHB Blood Banks.

NZBS Values

The NZBS organisational structure works within a values based framework. ***Safety is our Cornerstone (Ko te haumaru tā mātau mātapono taketake)*** is the overarching tenet to everything that NZBS does, cementing the four enduring values of:

- ***Striving for Excellence (Kia tau kite Tihi)***
  Maximising the resources NZBS has to draw on, we strive for excellence in everything we do
- ***Teamwork (Te Mahi Ngātahi)***
  We value working towards and supporting each other to meet our common goal

- ***Integrity and Respect (Te Pono me Te Tika)***
  We value an environment where there is mutual trust and respect
- ***Open Communication (Te Whakawhitiwhiti Whakaaro i runga i te Māharahara)***
  We value sharing information and knowledge, thoughts and ideas, in an appropriate and timely manner

Key External Relationships

NZBS has relationships with a number of different stakeholder groups (other than the Minister of Health). Key relationships exist between NZBS and:

- Donors
- DHBs and their patients
- Private hospitals
- Other users of blood products and services
- Ministry of Health
- CSL Biotherapies, based in Melbourne Australia
- MAK-System (e-Progesa software provider)
- Patient advocate groups (e.g. The Leukaemia and Blood Foundation, Haemophilia Foundation of NZ and Immunodeficiency Foundation of NZ)
- National Haemophilia Management Group (NHMG)
- NZBS employees

The expectations of these stakeholders are assessed by a variety of means including regular contact (through routine service delivery and associated activities), focus group meetings, surveys and documented requests and requirements.

NZBS can be considered the custodian of more than 120,000 voluntary New Zealand blood and apheresis donors' "gift of life". In achieving its organisational goals and objectives, NZBS is mindful of its responsibility to these donors and the requirement to protect their taonga through internal activities and by providing support to the prescribers of blood and blood products to ensure appropriate and cost-effective utilisation.

Process of providing blood products to key NZBS customers – the DHBs

Operationally, blood is collected either as whole blood (which is then separated into its component parts) or as individual components (plasma or platelets) via a process called apheresis. Figure 7 outlines the process for providing fresh and fractionated blood products to the DHBs.

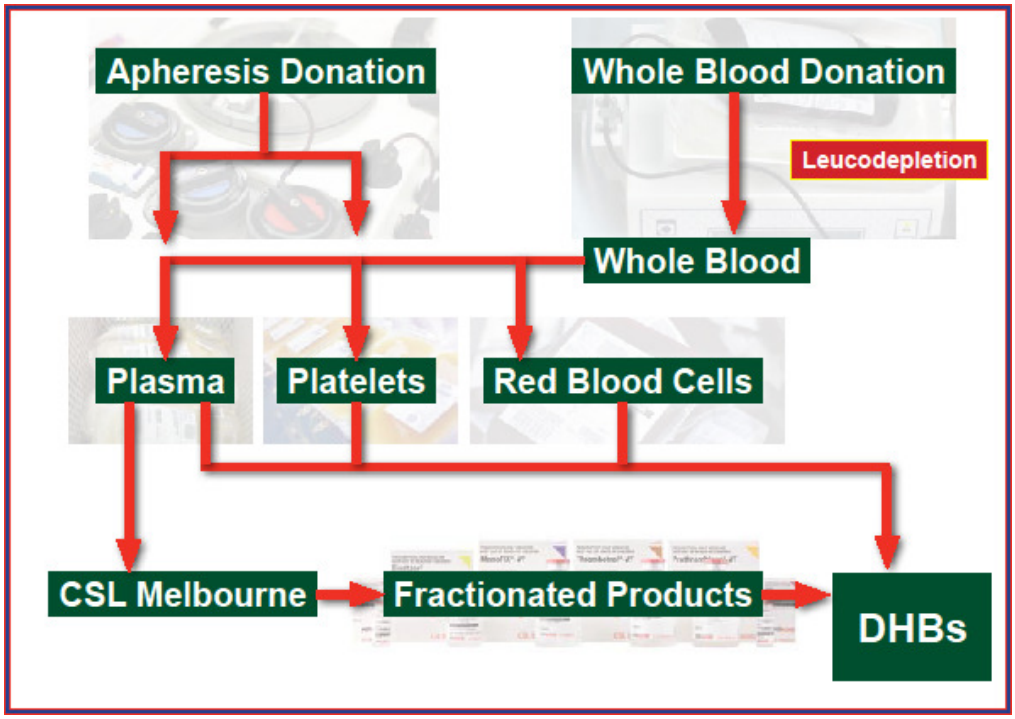

Figure 7: Flow of blood products to DHBs

Statutory Obligations and Minister of Health's Expectations

The core functions of NZBS are specified in section 55 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) and the Gazette Notices to that legislation.

The key function of NZBS identified in the establishment Gazette Notice is:

> *To manage the donation, collection, processing, and supply of blood, controlled human substances, and related or incidental matters, in accordance with its annual plan and any [Ministerial] directions given under section 65 [of the NZPHD Act].*

NZBS adheres to the fundamental principles contained in the New Zealand Health Strategy. In particular:

- NZBS provides blood and blood services to healthcare providers, thus contributing to the good health and well-being of all New Zealanders throughout their lives.
- NZBS delivers timely and equitable access to blood and tissue products and related services to all New Zealanders regardless of ability to pay.
- NZBS maintains a high level of public confidence.
- NZBS involves consumers through liaison with hospitals and recipient groups.
- The special relationship between Māori and the Crown under the Treaty of Waitangi is recognised through the NZBS Māori Responsiveness Strategy.
- As a national entity NZBS seeks community involvement on key issues through consultative processes.

NZBS is committed to on-going organisation awareness of, and where appropriate taking actions to contribute to:

- The New Zealand Health Strategy (December 2000).
- The New Zealand Disability Strategy (April 2001).

- Recognition of the Government's requirements in regard to the Treaty of Waitangi.

This SOI reflects the expectations of its owner, the Crown, as documented in the Minister of Health's 21 March 2012 Letter of Expectations. NZBS will work with the Ministry of Health to ensure that each expectation is appropriately progressed.

APPENDIX 2
Abridged Statement of Accounting Policies

Reporting Entity

The New Zealand Blood Service (NZBS) is an authorised entity pursuant to section 92H of the Health Act 1956, primarily responsible for the performance of functions in relation to blood and controlled human substances in New Zealand.

The entity (New Zealand Blood Service) is a Crown Entity in terms of the Crown Entities Act 2004, and a Statutory Corporation under the New Zealand Public Health & Disability Act 2000.

NZBS is a not for profit organisation and its primary objective is to support the New Zealand healthcare community through managing the collection, processing and supply of blood, controlled human substances and related services. Accordingly, NZBS has designated itself as a public benefit entity for the purposes of New Zealand equivalents to International Financial Reporting Standards (NZ IFRS).

Basis of preparation

The financial statements of NZBS have been prepared in accordance with the requirements of the Crown Entities Act 2004 and the New Zealand Public Health & Disability Act 2000.

These financial statements have been prepared in accordance with NZ GAAP. They comply with NZ IFRS and other applicable Financial Reporting Standards, as appropriate for public benefit entities.

The accounting policies set out below have been applied consistently to all periods presented in these financial statements.

The financial statements have been prepared on a historical cost basis, modified by the revaluation of financial instruments (including derivative instruments).

The financial statements are presented in New Zealand dollars and all values are rounded to the nearest thousand dollars ($'000). The functional currency of NZBS is New Zealand dollars.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions are recognised in the Statement of Financial Performance.

Revenue

Revenue is measured at the fair value of consideration received. Revenue from the provision of products is recognised at the time the risk and effective ownership transfers. Revenue from the rendering of services is recognised as the services are provided. Interest income is recognised using the effective interest method.

Borrowing costs

Borrowing costs are recognised as an expense in the period in which they are incurred.

Capital Charge

The capital charge is recognised as an expense in the financial year to which the charge relates.

Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the Statement of Financial Position.

Trade and other receivables

Trade and other receivables are initially measured at fair value and subsequently measured at amortised cost using the effective interest method, less any provision for impairment.

A provision for impairment of receivables is established when there is objective evidence that NZBS will not be able to collect all amounts due according to the original terms of receivables. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted using the effective interest method.

Inventories

Inventories held for sale on a commercial basis are valued at the lower of cost and net realisable value. The cost of purchased inventory is determined using the FIFO method. The valuation includes allowance for slow moving items. Obsolete inventories are written off.

Inventories held for use in the production of goods and services on a commercial basis are valued at the lower of cost and net realisable value. The cost of purchased inventory is determined using the FIFO method.

The write down from cost to net realisable value is recognised in the Statement of Financial Performance.

Property, Plant and Equipment

Property, plant and equipment consists of operational assets which include plant and equipment, computer hardware, motor vehicles, furniture and fittings / office equipment and leasehold improvements.

Property, plant and equipment is shown at cost less accumulated depreciation and impairment losses.

Depreciation is provided on a combination of straight-line / diminishing value basis on all property, plant and equipment, at rates that will write off the assets at their estimated residual values over their useful lives.

The costs of day-to-day servicing of property, plant and equipment are recognised in the surplus or deficit as they are incurred.

The residual value and useful life of an asset is reviewed, and adjusted if applicable, at each financial year end.

Intangible Assets - Software acquisition

Acquired computer software licenses are capitalised on the basis of the costs incurred to acquire and bring to use the specific software. Costs associated with maintaining computer software are recognised as an expense when incurred.

The carrying value of an intangible asset with a finite life is amortised on a straight-line basis over its useful life. Amortisation begins when the asset is available for use and

ceases at the date that the asset is derecognised. The amortisation charge for each period is recognised in the Statement of Financial Performance.

Equity

Equity is the Crown's interest in NZBS and is measured as the difference between total assets and total liabilities. Equity is disaggregated and classified into a number of reserves.

The components of equity are:

- Crown Equity
- Retained earnings
- Fair value through other comprehensive reserves. This reserve comprises the cumulative net change in the fair value through other comprehensive income financial instruments.

Goods and Services Tax (GST)

All items in the financial statements are stated exclusive of GST, except for receivables and payables, which are stated on a GST inclusive basis. Where GST is not recoverable as input tax then it is recognised as part of the related asset or expense.

The net amount of GST recoverable from, or payable to, the Inland Revenue Department (IRD) is included as part of receivables or payables in the Statement of Financial Position. The net GST paid to, or received from the IRD, including the GST relating to investing and financing activities, is classified as an operating cash flow in the statement of cash flows.

Commitments and contingencies are disclosed exclusive of GST.

Taxation

NZBS is a Statutory Corporation under the New Zealand Public Health & Disability Act 2000 and is exempt from income tax under section CB3 of the Income Tax Act 2007.

Budget Figures

The budget figures are those approved by the Board of NZBS at the beginning of the year as presented in the Statement of Intent. The budget figures have been prepared in accordance with NZ GAAP and comply with NZ IFRS, using accounting policies that are consistent with those adopted by the Board for the preparation of the financial statements.

Cost allocation

Direct costs are those costs directly attributable to the collection and processing of blood products and delivering the associated services. Indirect costs are those costs which are not directly related to the production of its products or services.

Joint and by-product inventory costs arise in situations where the production of a product makes inevitable the production of other products. A key feature of joint and by-products is that they are not identifiable as individual products until a specific point in the production process referred to as a split-off point.

When a group of individual products is simultaneously produced, and each product has a significant value the outputs are usually called and treated as joint products. Those

products which are incidentally produced (not intentional product) are treated as by-products.

Common costs are apportioned to joint products not by-products. Processing costs specifically incurred on further processing of by-products after the split-off point are allocated to those by-products.

Critical accounting estimates and assumptions

In preparing these financial statements NZBS has made estimates and assumptions concerning the future. These estimates and assumptions may differ from the subsequent actual results. Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations or future events that are believed to be reasonable under the circumstances.

NOTE: The above accounting policies are abbreviated. A full set of current accounting policies may be found in the 2010/11 New Zealand Blood Service Annual Report available on the NZBS website www.nzblood.co.nz.

GLOSSARY

TERM	DEFINITION
Accreditation Testing	Testing carried out on all blood donations involving two distinct processes: blood grouping and screening for infectious markers.
ANZTPA	Australian New Zealand Therapeutic Products Authority – a proposed joint agency with Australia to regulate therapeutic products (including blood) the development of which was put on hold in July 2007.
Apheresis	A procedure in which blood is temporarily withdrawn, one or more components are selectively removed, and the remainder of the blood is re-infused into the donor.
ASHI	American Society for Histocompatibility and Immunogenetics. This is an international society of professionals dedicated to advancing the science, education and application of immunogenetics and immunology.
ASHI accreditation	The ASHI accreditation program determines whether laboratory procedures meet documented ASHI standards and requirements.
Biostate	Biostate® is freeze dried, high purity, plasma-derived human Factor VIII concentrate, manufactured by CSL. Manufactured using a process that incorporates two specific viral inactivation steps (solvent detergent treatment and dry heat).
Blood	Consists of cellular components (red cells, white cells and platelets) suspended in plasma.
Blood group	Complex chemical substances found on or in the surface of red cells which distinguish each blood group. The two more important blood group systems in transfusion work are the ABO (blood types A, B O and AB) and Rh D (positive or negative) systems.
CCP	Contribution to Cost Pressures – the annual payment made by the Ministry of Health to DHBs to assist in off-setting the cost pressures of inflation, salary adjustments etc. Prior to 2009 this adjuster was known as the Future Funding Track (FFT).
Code of Good Manufacturing Practice	A set of standards that provide assurance that a manufacturer has a quality system in place that meets the requirements for the product being made.
CSL / CSL Biotherapies	CSL is a company that develops, manufactures and markets pharmaceutical products of biological origin. CSL Biotherapies is based in Australia and manufactures a range of products derived from fractionating human plasma.
Cross-match	A term used when testing the patient's serum against the donor's red cells.
DHB	District Health Boards are responsible for providing, or funding the provision of, health and disability services in their district.
Donor	A person who gives blood or tissues to be used in another person.
FACT Accreditation	The Foundation for the Accreditation of Cellular Therapy (FACT) is a voluntary professional programme involving setting of standards and accreditation of bone marrow transplant facilities. This encompasses collection, processing and clinical transplantation activities.
Factor VIII	Product used to treat certain types of haemophilia that can be either derived from blood plasma or produced synthetically using recombinant DNA technology.
Factor IX	Used to treat haemophilia B (Christmas disease) which is caused by a deficiency in blood clotting factor IX. Treatment product can be derived from blood plasma or produced synthetically using recombinant DNA technology.

TERM	DEFINITION		
Fractionation	Fractionation involves separating substances (e.g. proteins in the case of plasma) by changing the conditions such as temperature or acidity.		
GMP	Good Manufacturing Practice. A prerequisite of licensing.		
Good Employer	As defined by the Human Rights Commission in the published guidance from the Equal Employment Opportunities Commissioner (June 2006).		
Haemophilia	An hereditary deficiency of clotting factors in blood.		
Haemovigilance	Organised surveillance procedures related to serious adverse or unexpected events or reactions in relation to any aspect of transfusion medicine.		
Haemovigilance Imputability Score Definitions	NA	Not assessable	When there is insufficient data for imputability assessment.
	1	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes
	2	Unlikely	When the evidence is clearly in favour of attributing the event to causes other than transfusion
	3	Possible	When the evidence is indeterminate for attributing the event either to the transfusion or alternative causes
	4	Likely, probable	When the evidence is clearly in favour of attributing the event to the transfusion
	5	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the event to the transfusion
Haemovigilance Severity Score Definitions	Grade 1		The recipient may have required treatment but lack of such would not have resulted in permanent damage or impairment of a body function.
	Grade 2 (severe)		The recipient required hospitalization or prolongation of hospitalization directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.
	Grade 3 (life-threatening)		The recipient required major intervention following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.
	Grade 4 (death)		The recipient died following an adverse transfusion reaction. *Grade 4 should only be used if death is probably or definitely related to transfusion. If the patient died of another cause, the severity should be graded as 1, 2 or 3.*
Haematopoietic Stem Cells	Cells found in the bone marrow capable of the formation of all blood cell types.		
HBL	Health Benefits Ltd – formally the Shared Service Establishment Board. Created to help reduce the cost of non-clinical support functions in health and to harness the benefits of bulk purchasing.		
HBV	Hepatitis B is an infectious illness caused by hepatitis B virus (HBV) which infects the liver and causes an inflammation called hepatitis.		
HCV	Hepatitis C is an infectious disease affecting the liver, caused by the hepatitis C virus (HCV). The infection is often asymptomatic, but once established, chronic infection can progress to scarring of the liver (fibrosis), advanced scarring (cirrhosis) or liver failure.		
HIV	Human Immunodeficiency Virus – a virus that causes Acquired Immunodeficiency Syndrome (AIDs) in humans.		

TERM	DEFINITION
HWNZ	Health Workforce New Zealand - set up in 2009 to provide national leadership on the development of the country's health and disability workforce.
IANZ	International Accreditation New Zealand is the national authority for accreditation of testing and calibration laboratories, inspection bodies and radiology services. IANZ promotes the development and maintenance of good practice testing and inspection and maintains a registration scheme for organisations that comply with the practice.
Immunoglobulins	Proteins that combat infection.
Intragam P	An immunoglobulin product manufactured from plasma and used to boost the immune system of patients with immune deficiencies or in the treatment of a range of diseases where the immune system is compromised.
Intravenous	Within or administered into a vein.
IU (International Unit)	In pharmacology an International Unit (abbreviated to IU) is a unit of measurement for the amount of a substance producing a specified effect when tested according to an internationally accepted biological procedure. There is no equivalence among different substances.
MOH	Ministry of Health is the Government's principal advisor on health and disability policy.
MRS	NZBS' Māori Responsiveness Strategy developed in 2010 provides a framework and identifies areas where NZBS can progress its approach to produce benefits for Māori.
NHMG	National Haemophilia Management Group – established in 2007 to take overall responsibility for the management and oversight of the provision of services to people with haemophilia and allied disorders.
NHB	National Health Board - established in November 2009 to improve the quality, safety and sustainability of health care for New Zealanders.
NZBS	New Zealand Blood Service.
NZ GAAP	New Zealand Generally Accepted Accounting Practices.
NZIFRS	New Zealand Equivalents to International Financial Reporting Standards.
Output Agreement	This Agreement is required pursuant to section 170 of the Crown Entities Act 2004 and assists the Minister and NZBS to clarify, align, and manage their respective expectations and responsibilities.
Plasma	Liquid portion of blood that contains proteins.
Plasmapheresis	A procedure where blood is temporarily withdrawn, plasma is selectively removed, and the remainder of the blood is re-infused into the donor.
Platelet Additive Solution (PAS)	PAS is a synthetic additive solution used as a substitute for plasma when storing platelet concentrates.
Recombinant product	Products produced by inserting a human gene into an organism (e.g. bacterium) that produces the required human protein (e.g. Factor VIII).
Self-sufficiency	A fundamental principle in the operation of NZBS, "self-sufficiency" involves collection and manufacturing to meet all blood product demand in New Zealand from blood and plasma collected solely in this country.
Serology	The science of measurement and characterisation of antibodies and other immunological substances in body fluids, particularly serum/plasma.
Serum	The clear, straw coloured fluid portion of the blood that remains after coagulation and removal of cellular blood components by centrifugation.
SSP	Forecast Statement of Service Performance.
TGA	Therapeutic Goods Administration - Australian regulatory body assessing and monitoring activities to ensure therapeutic goods are of acceptable standard.

TERM	DEFINITION
Transfusion Related Acute Lung Injury (TRALI)	Transfusion Related Acute Lung Injury (TRALI) is a complication of blood transfusion characterised by the acute onset of pulmonary oedema (i.e. swelling and/or fluid accumulation in the lungs). This is now recognised to be one of the most frequent severe complications of transfusion.
Vein to Vein Blood Service	The responsibility for the full supply-chain of blood from blood donor selection and collection of blood through management and testing to final administration of blood products to patients and analysis of any reported adverse transfusion events.