



NBSB
Annual Report & Accounts





Annual Report & Accounts

1st April 2004 to 31st March 2005

National Biological Standards Board
c/o National Institute for Biological
Standards and Control (NIBSC)
Blanche Lane
South Mimms
Potters Bar
EN6 3QG
United Kingdom

Tel: +44 (0) 1707 641000

Fax: +44 (0) 1797 641050

Email: enquiries@nibsc.ac.uk

www: www.nibsc.ac.uk

NIBSC's control testing of biological medicines operates under a formal quality system independently accredited by the UK Accreditation Service (UKAS). Accredited test methods are indicated on the UKAS Schedule of Accreditation.

The Institute's facilities for the formulation and processing, and also the storage and dispatch of biological preparations operates under a formal quality system independently certified by Lloyd's Register Quality Assurance (LRQA).





Contents

Chairman's Overview	04
Director's Overview	05
NBSB and NIBSC	06
Protecting public health	08
Standardisation	09
Highlights of 2004/2005	10
A New Combination Vaccine	11
Avian Influenza	12
New Standards for Genetic Diagnosis	14
UK Stem Cell Bank	16
Innovation	18
Resources & Facilities	19
Advisory and Training Activities	21
Stakeholder links	23
Organisational Development	24
NBSB	25
Progress against Key Targets 2004/2005	26
Funding Sources and Allocations	30
Accounts	32

Chairman's Report

I am delighted to be able to introduce an Annual Report from NIBSC that once again highlights the crucial work the Institute carries out on the national and international stage. Through the year NIBSC has made many important contributions to public health and consolidated its enviable reputation as a world leading scientific Institute concerned with assuring the quality of biological medicines.

As a result of the wide-ranging review of Arms Length Bodies (ALBs) conducted by the Department of Health, Ministers announced in July 2004 that NIBSC would be merged with the Health Protection Agency, itself a result of consolidation between the Public Health Laboratory Service, the National Radiological Protection Board and the Centre for Applied Microbiological Research. This move, which is aimed particularly at reducing administrative 'back-office' costs, is scheduled for completion during 2007, following the necessary Parliamentary legislation. It

will be a significant change for the Institute. Our functions will however be preserved formally through the merger and I am confident that we shall be able to maintain our outputs and service to the many important stakeholders who rely on our materials, work and expertise.

I am proud to say that NIBSC continues to lead the world in biological standardisation and I fully expect this to continue within the expanded framework of the Health Protection Agency

Professor Gordon Duff
Chairman, National Biological Standards Board



Director's Report

The past year has been one in which NIBSC continued to make major scientific contributions, both nationally and internationally. Our core activities of control and standardisation of biological medicines were once again in high demand by regulators, manufacturers and public health authorities, and our scientists made many important technical advances, as well as providing evidence-based expert advice on a wide range of high profile health issues. Three achievements stand out, however.

We consolidated our role as one of only three international laboratories with the remit and capability to generate safe 'seed' viruses for supply to manufacturers in the event of an influenza pandemic. This involves both developing and refining the process and also responding to potential threats in close conjunction with the World Health Organisation. During the year we completed safety testing of a vaccine seed based on the highly pathogenic Vietnamese H5N1 avian influenza virus strain isolated in early 2004. This was supplied to over 20 different manufacturers in 16 countries and has provided the basis for a great deal of subsequent clinical development work to test and optimise the efficacy of pandemic vaccines.

Genetic testing is a rapidly expanding field with important potential clinical benefits. However it is crucial that proper regulation and quality assurance should accompany the development of diagnostic tests, since the consequence of misdiagnosis may be very serious indeed. We were therefore delighted to announce through WHO the establishment of the world's first panel of International Reference Materials for a genetic test in November 2004. This panel, relating to diagnosis of an important genetic risk factor for thrombosis, is the first of many that will be needed to underpin an extremely important new element of clinical medicine.

Finally, following the official opening of the UK Stem Cell Bank in May 2004 by Lord Warner, we began work in earnest to bring in and build up stocks of quality-assured stem cell lines from leading laboratories around the world. These stocks will be made available to other research groups to support translation of laboratory stem cell research into real clinical benefits over the next decade. This major initiative is a world first and consolidates our global expertise in the new and rapidly expanding field of stem cell medicine.

Note on the Auditor's responsibilities in respect of the Annual Report.

The financial statements on pages 42 to 62, together with the Foreword and other statements including the Chief Executive's statement on internal control on pages 38 to 39, and the Certificate and Report of the Comptroller and Auditor General on pages 40 to 41, reproduce in full those included in the Accounts for the National Biological Standards Board for 2004/05 laid before Parliament on 20 July 2005 under reference HC430. Pages 1 to 31 of this Annual Report provide additional information, for which I am responsible, that is not included with those accounts. The auditor is required by auditing standards to read other information in documents containing audited financial statements and to consider the implications for his audit opinion. A supplementary statement has accordingly been provided by the Comptroller and Auditor General at page 41 in respect of his reading of the additional information.

Dr Stephen Inglis, Director,
National Institute for
Biological Standards and Control
13 April 2006

NBSB and NIBSC

The National Biological Standards Board (NBSB) is a non-departmental public body (NDPB) of the UK government, established, in 1975, as a Statutory Body by Act of Parliament. The Board is responsible for safeguarding and advancing public health by assuring the quality and safety of biologicals, through its management of the National Institute for Biological Standards and Control (NIBSC).

NIBSC is the UK's Official Medicines Control Laboratory for biological medicines

may also be carried out when particular problems arise such as failure of storage conditions or following adverse reactions in patients.

NBSB considers it essential to maintain a well balanced and clearly prioritised programme of work on the core functions of NIBSC's work:

Our mission is underpinned by five primary objectives:

To fulfil national and international needs for independent product testing in order to safeguard public health

What this means in practice:

- Carrying out statutory quality testing of many products for release onto the UK and EU market
- In collaboration with WHO, carrying out quality assurance testing of vaccines for use in developing countries
- Providing services for biopharmaceutical companies developing new medicines

*Centralised Facility for AIDS Reagents dispatched
3,136 reagents to 353 recipients in the HIV
research community during 2004/05.*

NIBSC provides independent testing of biological medicines for the UK market, in particular with vaccines for the UK children's vaccination programme, and operates as an Official Medicines Control Laboratory (OMCL) of the European Union for release of medicines onto the EU market. NIBSC testing of products already released onto the EU market

- Control and evaluation of biological medicines.
- Development and provision of key biological standards and other reference materials.
- Mission-orientated research and development.

To maintain world leadership in standardisation of biological medicines

What this means in practice:

- Preparing and distributing international standards for biological medicines.
- Developing improved and standardized methodologies for quality assurance

To facilitate the provision of novel biological medicines

What this means in practice:

- Establishing expertise in new classes of biological medicine
- Helping biopharmaceutical companies develop safe and effective products

NIBSC is the leading WHO International Laboratory for Standards

To anticipate and respond to emerging quality and safety issues associated with existing and future biological medicines

What this means in practice:

- Testing medicines ad hoc in response to emerging issues relating to safety and efficacy
- Helping to develop new tests for product quality assurance

To promote science-led policy making in the field of biological medicines

What this means in practice:

- Contributing expert advice nationally and internationally



Protecting public health – quality and safety testing of biological medicines

Biological substances used in medicines include viral and bacterial vaccines, products derived from human blood, hormones and other therapeutic medicines such as cytokines and growth factors. They have made a major and increasingly important contribution to medicine and public health and have been responsible for radical improvements in the prevention, diagnosis and treatment of disease throughout the world.

Biological medicines are extremely complex products and because of this, batches of vaccines and blood products are independently tested before they are released for use. Assuring the safety of vaccines is particularly critical because they given to healthy individuals and are the basis of national immunisation programmes.

In the UK and Europe biologicals are submitted to one of the EU's Official Medicines Control Laboratories (OMCLs) before being released for use, and NIBSC is the UK's designated OMCL for batch release of biological medicines. During 2004

our overall product testing workload remained at a similar high level with respect to previous years, with some 1200 batch release certificates issued. Testing of plasma pools for the presence of unwanted viruses continued to show a year-on year increase.

New products often require novel approaches for their control, and development of appropriate testing methods to prepare for the introduction of potential new products is an important task for us. Our scientists continued to work on a broad range of new approaches, many of which aim to reduce the requirement for use of animals, but of particular importance was preparation for the possible introduction of vaccines against rotavirus-induced diarrheal disease and against human papilloma virus-induced cervical cancer.

Product testing work is carried within a formally accredited quality system (ISO17025) and we were pleased to maintain accreditation to this standard during the year and to extend its scope to cover a number of new testing areas



Standardisation

The complex assays used to assure the potency of biologicals require the use of a reference standard for biological activity (a batch of a substance that has been designated to contain a defined quantity of units of activity and is used as a comparative “benchmark”). The system of World Health Organization (WHO) International Standards aims to provide a universally accessible primary ‘gold standard’ reference material to ensure that quality testing results carried out in different laboratories around the world are comparable. Using the International Standards, countries and manufacturers can generate and calibrate their own ‘secondary standards’ for biological testing to provide a common basis for measurement.

NIBSC is currently the world’s major producer and distributor of WHO International Standards and reference materials (supplying over 95% of Standards) and our work in both maintaining supply of existing standards and introducing new standards is regarded as crucial

internationally. We were very pleased therefore to have our status as one of only three WHO International Laboratories for Standards reconfirmed early in 2005 following a review of our activities over the previous 5 years.

Demand for our standards continued to increase during the

year, reflected by a 10% increase in the number of Reference Materials dispatched to customers. In addition we established a further 8 new or replacement standards through WHO’s Expert Committee for Biological Standardisation in November 2004 as follows:

WHO 1st International Genetic Reference Panel, Factor V Leiden

WHO 2nd International Standard, Poliomyelitis vaccine oral

WHO 1st Reference Reagent, B Pertussis serotype 2, typing serum

WHO 1st Reference Reagent, B Pertussis serotype 3, typing serum

WHO 1st International Standard, anti-D blood grouping reagents

WHO 1st International Standard, Factor XIII plasma, human

WHO International Reference Reagent, IVIG anti-D positive control

WHO International Reference Reagent, IVIG anti-D negative control

During 2004/05, 1,193 batches of manufactured, commercial biological products were evaluated and released

Highlights of 2004/2005

NIBSC has continued to play a crucial role in maintaining public health in the UK by assuring the quality and safety of vaccines, blood products and other biological medicines, during 2004/2005, in spite of the potentially de-stabilising effect of the Arm's Length Body (ALB) review which led to the announcement in July that the Board is to be abolished and the Institute merged with the Health Protection Agency (HPA).

There have been many successes throughout the year, but the following achievements stand out:

- Completed testing of NIBSC candidate avian influenza vaccine strain based on Vietnamese avian influenza outbreak of January
- Established the world's first International Standard for a genetic test
- Provided essential support for the introduction of a new 5-compo-

During 2004/05, 1,785 plasma pools were tested for freedom from viral contamination.

2004 and supplied it to manufacturers for clinical trial

- Completed, commissioned and achieved MHRA accreditation for the UK Stem Cell Bank on time and on budget

nent combination vaccine as the central component of the UK childhood vaccination programme



A New Combination Vaccine for UK Children

As infection with polio becomes confined to certain areas of the developing world, public health authorities in the developed world have turned their attention to ending the use of live virus oral polio vaccines (OPV) and switching to the alternative, inactivated polio vaccine (IPV). The UK Government decided to switch to a pentavalent combination vaccine incorporating IPV, and the new combined vaccine, featuring IPV was brought into the children's vaccination programme in September 04.

NIBSC has been responsible for batch release of the new vaccine, and the introduction of this complex product has required a major effort from expert scientists across the Institute.

Testing for the continued presence of live polio vaccine strains in the community is a vital part of health surveillance in the UK. As the use of OPV is discontinued in the UK, we have initiated a programme with the Health Protection Agency on environmental monitoring for

these viral strains. In addition, plans have been laid to maintain expertise in OPV testing to support development of an OPV stockpile against future emergencies, and to support the WHO plan for global eradication of polio.



Avian influenza - the path to a pandemic vaccine

The perceived threat of a global influenza pandemic increased significantly during 2004/05 and our work in support of preparation for a potential influenza pandemic continued to grow in international importance.

the provision of high-quality scientific advice and the development of crucial materials to support vaccine development. This builds directly on our routine work providing virus reference strains and quality control reagents to manufacturers of seasonal influenza vaccines.

proposal to prepare, in advance, a 'library' of potential vaccine strains and quality control reagents, one or more of which might be used to launch an initial campaign while a vaccine candidate is prepared from the new outbreak strain. This could save months of response time in the event of a pandemic starting and hence millions of lives.

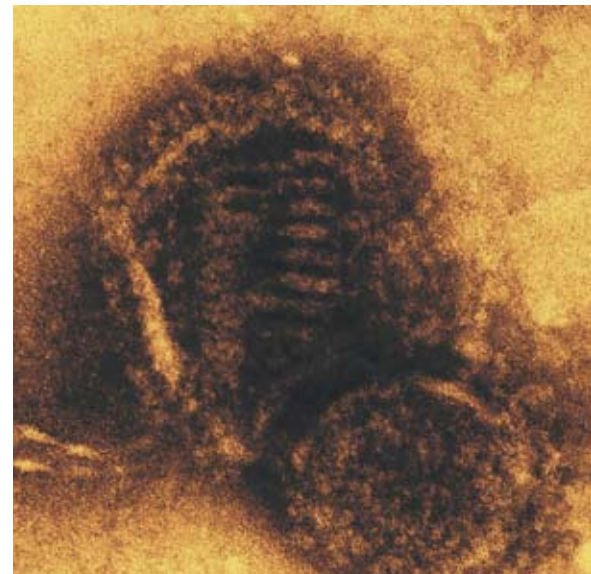
NIBSC: creating vaccine viruses to help prevent a potential global influenza pandemic

The massive outbreak of virulent H5N1 strain, bird "flu" which has killed over 50 million domestic poultry continued to rage through the Far East, with recent findings from China & Russia suggesting that the strain is now affecting migratory birds as well as domestic poultry. There have been a number of human fatalities, and in a few cases, the suggestion of human to human transmission.

NIBSC makes a major contribution to national and international preparation for a potential influenza pandemic vaccine through both

As part of this preparation our scientists developed a potential vaccine strain against an H5N1 virus isolated in early 2004 from Vietnam. During the year we completed its characterisation, and provided it to 25 manufacturers on request. Clinical trials are now underway with this candidate, a crucial step in preparation for a potential outbreak.

Influenza poses a particular threat to public health because of the range of possible strains that might actually cause a pandemic and so our scientists have begun developing a



How could “bird flu” cause a human health disaster?

Pandemic influenza outbreaks arise when influenza viruses from animal species, often from birds, become able to infect and spread in the human population. Usually influenza viruses that infect birds cannot infect man and vice versa. However, sometimes the viruses have the opportunity to meet and re-combine in intermediate hosts, such as pigs, or close contact with sick birds allows humans to become directly infected with bird flu viruses. In this case a natural exchange of genetic material between bird and human viruses could generate a virus similar to the bird strain but with the power to transmit easily from person to person.

In some parts of the world poultry is sold live and there is close and prolonged contact between humans and poultry, in markets and in the home. Crowded conditions and lack of basic hygiene give an ideal opportunity for cross-infection.

An influenza virus similar to H5N1 flu can potentially attack every cell in the human body, whereas “normal” human influenzas are confined to the lungs. This is why mortality rates when humans have been infected with H5N1 are so high. During 1997-2005, avian flu outbreaks (H5N1) have had a 30-60% mortality rate in humans compared with the 1918 “Spanish influenza” where the overall mortality rate was only 1%.

New Standards for Genetic Diagnosis

Genetic tests offer the potential for substantial improvements in health-care, through identification of at risk populations but also as a means to guide effective treatment. Since patient treatment regimes may depend on the result, accuracy is crucial, but until recently, though many tests had been established, quality assurance was not well developed. Recognizing this, in 2002 our scientists initiated

a programme focused on some of the most pressing needs.

In November 2004, working in collaboration with several other groups, we established the world's first International Standard for a genetic test through the WHO Expert Committee for Biological Standardisation (ECBS). The standard was aimed at quality assurance in testing for Factor V Leiden, a genetic muta-

tion known to predispose to thrombosis. The achievement attracted considerable media attention around the world, which has in turn led to immediate demand for the standard.

A number of other standards for commonly-performed genetic tests are also now in development in the Institute.

What is Factor V Leiden?

Discovered in 1994, the genetic mutation known as Factor V Leiden induces a defect in the body's natural anti-coagulation system. This mutation is one of the most common genetic risk factors for venous thrombosis (e.g. deep vein thrombosis, DVT), being involved in 20-40% of all cases.

The test for Factor V Leiden is one of the most frequent genetic tests carried out in clinical laboratories. It determines the presence or absence of the mutation, which has been shown to result in a seven-fold to 80-fold higher risk of thrombosis depending on whether the individual carries one or two copies of the gene respectively.



UK Stem Cell Bank – banking on the future

This year saw the culmination of the MRC and BBSRC-funded project to establish the UK Stem Cell Bank. This was a complex project, involving construction of a suite of pharmaceutical industry (GMP)-grade laboratories and the establishment of a very large number of new quality-assured procedures for stem cell handling.

Stem cells are, potentially, one of the most important emerging biotherapeutic medicines and their use holds out hope for a treatment for a range of health problems including spinal trauma, diabetes, Alzheimer's

a potential for misuse of these new medicines. A dedicated and independent cell bank is essential if stem cells are to achieve their potential as a biological medicine of the future.

The Bank was completed within 15 months, on time and on budget, and was officially opened in May 2004 by Lord Warner, Parliamentary Under-Secretary for Health.

Accreditation for the GMP facilities, by the MHRA, was achieved within the target and work is well underway to bank the first 10 stem cell lines. The Bank is working

International Stem Cell Initiative to characterise all of the embryonic stem cell lines available around the world.

Stem cells are immature cells that have the capacity to be transformed into many different types of cell, such as nerve cells or insulin-producing cells. Stem cell lines can multiply indefinitely, each generation being the same as the preceding one. Stem cell lines are being generated by researchers in universities, both in the UK and abroad. The UKSCB will store these cell lines and provide them to other research teams who will use them to generate therapeutic cells by altering the conditions in which they are grown.

“This bank is the first of its kind in the world and confirms the UK’s position as a leader in stem cell research.” Lord Warner

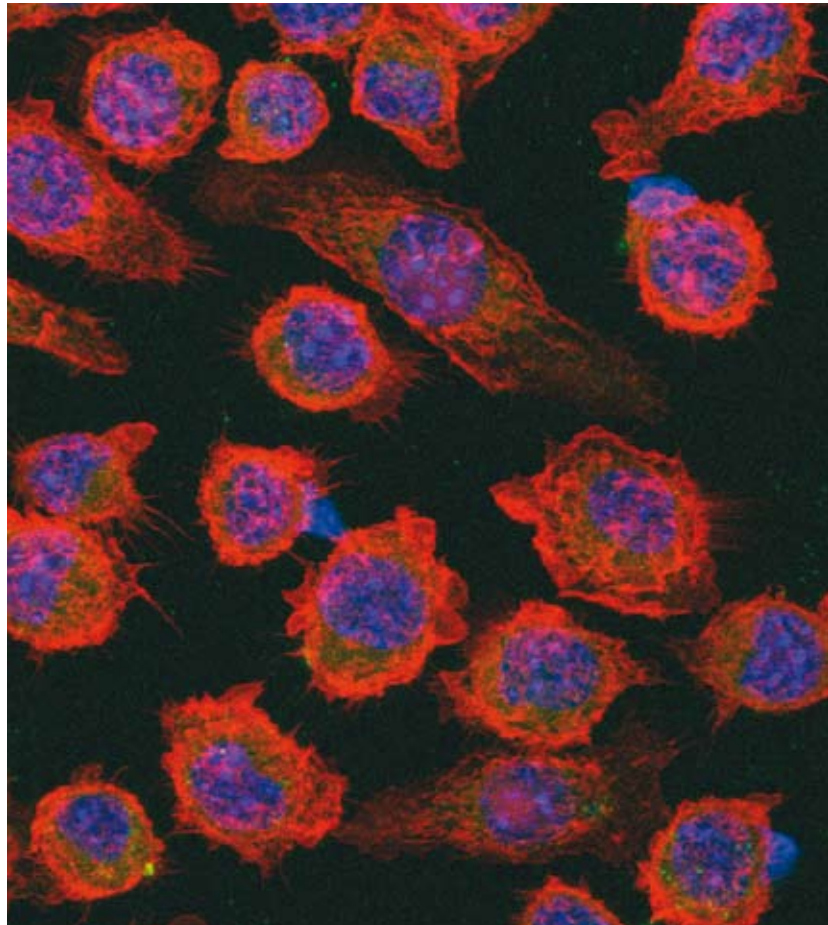
and Parkinson's disease. The key to the success of this new technology is that consistent, quality-assured and defined cell lines can be provided to accredited researchers. This is especially important as there is a considerable potential for profit and thus

actively with scientists in the UK and over 10 other countries to obtain further international cell lines including those of adult stem cell origin. The project has been expanded by securing additional funding from MRC to engage as the technical hub in a new



Innovation

Innovative research has always been an important element of the Institute's work and over the past year work within the Institute has led to a number of patented inventions. These include a novel approach to HIV vaccination, a possible third generation product for treatment of haemophilia, and a novel technology for inactivating bacterial toxins that could have utility in vaccine development. The latter is particularly exciting as it has very clear practical benefits for vaccine manufacture in a wide range of different settings, from paediatric vaccines through to biodefence applications.



Resources & Facilities

The Institute completed several major resource upgrades during this year resulting in both increased standards production capacity and new technologies for scientific research.

Centre for Biological Reference Materials

International standard materials are filled and freeze-dried to exacting specifications and must be of proven stability over many years of storage, with potential “shelf-lives” that far exceed those in normal biological

production situations such as vaccine batches. Continuing improvements to this important facility allow us to consolidate our position as the world’s foremost producer and supplier of biological standard materials.

We have also introduced new project planning techniques to ensure that maximum advantage is obtained from our upgraded facilities. These major improvements have all been achieved while the Institute continued to meet production and dispatch demands and targets for both internal and external customers.

Installation of a custom-designed ampoule filling machine has doubled the capacity of the Institute to make freeze-dried materials and will greatly increase the capacity to produce liquid reference materials.



Information Technology

During 2004 we successfully completed a major project to upgrade and harmonise our IT systems across the Institute, resulting in a greatly improved IT infrastructure and support. This has led to a substantial reduction in requirement for 'trouble shooting' and allowed development and implementation of several important new applications to support scientific projects, risk and safety management, business planning and standards stock control. New main servers have allowed major improvements to email and data handling throughout the Institute and NIBSC has developed new databases.

Communications

Our library has been expanded and transformed into an Information and Communications Centre, offering a complete range of scientific information and imaging resources for Institute staff. We also began a major overhaul of our internal and external websites aimed at enabling on-line ordering of standard materials as well as giving access to information about NIBSC in a clear, accessible and modern format. This project is expected to be complete in 2005.

Our new Mass Spectroscopy facilities will enable us to identify possible protein impurities in some complex vaccines as part of their quality control (QC). It is currently being used in 10 major collaborative projects to identify potential markers for improved QC of biologicals.



Advisory and Training Activities

Advisory work

During 2004-5, Institute staff continued to make a substantial contribution nationally and internationally to over 80 different advisory committees, regulatory bodies and professional societies.

In the UK, participation in the following groups have been particularly important:

- British Pharmacopoeia
- British Standards Institute
- Joint Committee on Vaccination and Immunisation
- National Vaccine Evaluation
- Consortium Steering Group
- Joint Professional Advisory
- Committee to the Blood Services
- Veterinary and Public Health Standardisation Committee
- Advisory Committee on Dangerous Pathogens
- Advisory Committee on the Contained Release of Genetically Manipulated Organisms
- Committee for the Safety of Medicines subcommittee

We have also continued to play a major role within the European regulatory framework through:

- The European Medicines Agency (EMA)
- The Official Medicines Control Laboratory network
- European Pharmacopoeia Commission
- The Joint Committee for Traceability in Laboratory Medicine

Our relationship with WHO has remained extremely strong through our central role in the work of the Expert Committee on Biological Standardisation, together with contributions to a large number of working groups developing policy and drafting guidelines for development and use of biological medicines.



Training Services

NIBSC has an important role in providing high quality, laboratory-based training for visiting staff from regulatory and scientific institutes in other countries. Based on the Institute's worldwide reputation for expertise in biological medicines, demand for such support has continued at a high level and exceeds capacity by a considerable margin. The centre piece of our activity in 2004/05 was the provision, through WHO's Global Training Network, of an intensive 4 week course on Laboratory Quality Systems. We also began developing a new training programme in the theory and practice of developing biological reference materials which we anticipate will be an important element in maintenance of our world leading position in standardisation.



About Us
Products
Services
Spot Light
Partners
Contact

-  **Order Products**
-  **R&D**
-  **Current Influenza Reagents 2005/06**
-  **Recruitment**

Announcements

Please note, our fax numbers have changed.

For orders:
+44 (0) 1707 641064

For general enquiries:
+44 (0) 1707 641050

Assuring the Quality of Biological Medicines

Our mission is to safeguard and enhance public health through standardisation and control of biological products used in medicine.

NIBSC is uniquely placed to fulfil this role, operating at the interface between leading edge scientific research, product development, regulation and policy.

At the heart of our work is the preparation, storage and distribution of WHO International Standards and Reference Materials to provide benchmarks for product quality. In addition we provide product testing services to ensure compliance with product specifications. These activities are underpinned by leading edge scientific research and development expertise covering a wide range of scientific disciplines.



CJD Resource Centre

This project was set up to obtain characterised materials for studying and developing diagnostic tests for Creutzfeldt-Jakob Disease (CJD).



Influenza Pandemic

This project is directed towards improved preparation for an influenza pandemic.



UK Stem Cell Bank

The Bank works with and for the scientific and clinical community to assure the quality of human stem cell lines used in research and therapy.



Centre for AIDS reagents

Originally established in 1989 the facility has grown steadily and the repository now houses over 1900 reagents.








[Freedom of information](#) | [Accessibility](#) | [Terms & Conditions](#)

Stakeholder Links

It is essential that we work closely with a wide range of partners in order to ensure that our programmes and activities are fully responsive to public health needs.

We have continued to maintain particularly close working relationships with the Department of Health (on both policy and technical issues), the Medicines Control Agency, the World Health Organization, the European Medicines Evaluation Agency (EMA) and the European Department for the Quality of Medicines (EDQM). Licensing of new biological medicines is increasingly channelled through the European regulatory route and so we consider our European activities are becoming increasingly important.

We have also sought to strengthen links with other Government bodies within the UK, and in particular the Department for Trade Industry (DTI), reflecting the Institute's crucial role in facilitating the development of new medicines and technologies. We have been very pleased in

particular to participate in the DTI's Measurement for Biotechnology (MfB) initiative which recognises that development of new approaches to characterisation and measurement of biotechnology products will be crucial for their ultimate economic success.

As ever, our work requires close co-operation with the pharmaceutical industry and we have maintained good and productive relationships with a large number of companies. We actively encourage interactions with biopharmaceutical product manufacturers, within the constraints of our regulatory role, in order that our expertise can be made as widely available as possible and so that we have a thorough understanding of new developments in the pipeline.



Organisational Development

Our programme of modernisation and streamlining of the organisational structure and processes has continued throughout the year.

Scientific Groups

Through the development of co-operative working practices and merger of six smaller scientific Divisions, we created three scientific groups, with the aim of maximising efficiency of administration and cross

disciplinary teamwork

- Vaccines
- Biotherapeutics
- Technology Development & Infrastructure (TDI)

The Vaccines and Biotherapeutics groups have a clear product-focused remit, while TDI has a dual role of providing support to product-specific projects while developing and maintain a world leading capability in technological areas crucial to the

Institute's work through internal and external collaborative work.

Administrative Development

Work initiated in the previous year to strengthen the Institute's administrative infrastructure resulted in a greatly strengthened Finance function and HR team, with a considerably greater emphasis on performance monitoring together with internal training and staff development

National Biological Standards Board

National Institute for Biological Standards and Control

Director of NIBSC

Vaccines

Quality Assurance of Bacterial and Viral vaccines

Biotherapeutics

Quality Assurance of Hormones, Cytokines, Blood products

Technology Development and Infrastructure

Leading edge technology development

Operations

(including health, safety & environment, standards production, maintenance, engineering projects, supplies, security, grounds)

Human Resources

Finance & Commercial

Planning & Quality

NBSB

National Biological Standards Board members are appointed directly by the Secretary of State for Health. In accordance with Nolan Committee recommendations, available Board positions are openly advertised and filled on a competitive basis; members serve a four year term of office. Two positions are reserved

In addition to setting overall strategy for the Institute and ensuring appropriate financial controls and corporate governance mechanisms were in place, Board discussions during the year particularly focused on the consequences to the Institute of the proposed merger with HPA, strengthening the Institute's risk

scientific divisions and departments of the Institute, and for making recommendations on future strategic directions and levels of funding for scientific programme areas. During the year, the committee reviewed the work plans of each scientific Division for the coming year and conducted, with external input, an in-depth

NBSB - established by Act of Parliament in 1975

for NIBSC staff members, and these members are nominated on the basis of internal elections. The Board meets quarterly and receives regular reports from its sub-committees and others as required.

The composition of the Board during 2004/5 is described on p50 of this report.

management framework and budgetary issues resulting from the steady erosion over a 13 year period, in the Institute's Grant-in Aid allocation from the Department.

The Board's Scientific Policy Advisory Committee (SPAC) is responsible for advising on NIBSC scientific policy, reviewing work in all the

review of the Biological Services Section as part of a rolling programme of quinquennial assessment for each area of the Institute's scientific work.

Progress against Key Targets

NIBSC addresses a series of key annual performance targets that are agreed between the Minister of State for Public Health and the NBSB. The main purpose of the targets is to provide the Department of Health with a measure of how well NIBSC has carried out its key activities. They also help to focus the work of the Board, NIBSC Management and staff on the core function of assuring the quality of biological medicines. Performance against the 2004/05 Key Targets is shown below.

Objective	Progress
Scientific	
Support DH as necessary in ensuring safety of transfer to new combination vaccines including inactivated polio vaccine (IPV); provide continued testing support for oral poliovaccine (OPV) as 'back-up'	The move to the new combination vaccine was successfully achieved, though it required considerable effort from Institute scientists involved in batch release of the new products and close co-operation with regulators and manufacturers. Standardisation of one element of the safety testing remains an issue that still needs to be resolved. OPV testing capability has been maintained
Re-evaluate old Hib batches for stability and immunogenicity as requested by DoH	Analysis was completed and results provided to DoH.
Complete preclinical physico-chemical evaluation of new staphylococcus aureus and meningococcus ACWY conjugate vaccine in preparation for clinical trial	Evaluation of trial batches was successfully completed.

Initiate environmental studies in collaboration with HPA for detection of vaccine-related poliovirus in sewage	The HPA collaboration has been initiated. Sewage has obtained from two Water Companies to evaluate alternative isolation methods and an appropriate method has been selected for detection of OPV-related virus.
Establish all remaining operational and QA procedures for accession and distribution of UK Stem Cell Bank cell lines	Achieved. All deposit procedures have been agreed with the Stem Cell Bank Steering Committee and are now in practical use. Accreditation by the MHRA according to DH tissue banking guidelines was achieved in June 2004
Establish first International Standard for genetic typing (Factor V Leiden)	Achieved (November 04). The event attracted significant worldwide public interest.
Establish new internal programme on immunogenicity of monoclonal antibody products	A new programme has now been initiated. Collaborations are in place with manufacturers to take this forward. Resource limitations for the future may limit the scope of this programme.
Develop plan to extend the existing AIDS reagent repository to encompass emerging infectious diseases in general	Plans have been developed but implementation will be dependent on obtaining external funding. Applications for funding are being considered through the EU and WHO
Service and Quality	
Maintain accreditation: under ISO17025 for control testing activities; under ISO 9000:2000 in the processing, storage and supply of reference materials	UKAS accreditation for 17025 compliance was successfully maintained in November 2004. Certification of CBRM under ISO 9001:2000 was maintained following an external surveillance visit in June 2004.
Maintain CE marking for new reference materials already established under the in vitro Diagnostics Medical Devices Directive, and extend to cover relevant existing stock items	The required certification to ISO 13485:2003 was maintained following an external surveillance visit in June 2004. A work programme is well advanced to meet the December 05 deadline for other Institute materials covered by the Directive.

Achieve MHRA Tissue Bank accreditation for UK Stem Cell Bank	Achieved in June 04.
Complete batch release testing of all products within 60 days of receipt of samples & protocols; blood products within 30 days; 80% of influenza products within 10 days (over the year)	Target was met
Respond to >93% of requests for Standards/Reference materials within 6 working days	Target was met
Administrative	
Manage Category 4 facility refurbishment programme through to completion	A business case was developed and budget identified, but the HPA merger announcement and the need to ensure that planning consistent with HPA's strategy resulted in a substantial delay. The business case was finally approved Dec 04.
Procure, install and commission new ampoule filling and sealing machine for CBRM; ensure all new facilities are fully operational	Vial filling/freeze drying machines are now functional and going through biological validation. A new custom-designed ampoule filling machine was procured, installed and fully operational. Full validation is ongoing.
Complete replacement of all desktop computers and implement standardized systems for operation, maintenance and upgrade	Completed. A highly successful project which has transformed desktop capability for users and is allowing much more efficient use of resources and initiation of numerous IT projects to underpin Institute's scientific objectives.
Complete restructuring of Finance Division, revise financial processes to meet project plan and submit timely annual accounts	Restructuring complete with new processes and staff in place. 2004/05 accounts submitted for audit in June 2005 and signed off in July 2005.

In liaison with all appropriate parties, complete review of NIBSC pay system and produce a recommendation for implementation in 2005.	This objective withdrawn as a result of ALB review decision to merge NIBSC with HPA
Strategic	
Continue to enhance NIBSC influence in Europe; promote need for adoption of formally recognized quality systems to ensure maintenance of product quality standards	This is an ongoing objective. Institute scientists have been proactive in establishing relationships with release laboratories from accession countries to promote common quality standards
Take a lead in development of structured plans for dealing with the impact of emerging diseases on biological products (with NBAs, MHRA, international agencies)	Ongoing. Discussion with the National Blood Services is being taken forward through the Joint Professional Advisory Committee (JPAC)
Develop an appropriate external communication strategy to raise Institute's public, scientific and political profile	On hold as a result of ALB review decision to merge with HPA. Upgrade to the Institute's website is proceeding after consultation with the HPA. Institute scientists have contributed to several media events, particularly relating to avian influenza, through the Science Media Centre.
Further develop academic connections, to harness expertise and widen influence/provide recognition for NIBSC staff	More formal links with Imperial College explored. First year of post graduate course in cryobiology initiated.
Secure appropriate funding levels from 2006 onwards; implement agreed commercial strategy to maximise additional revenue generation	Future funding levels remain under discussion with Arms Length Body review team. Commercial strategy beginning to generate additional revenue though constraints from avoiding conflicts of interest seriously limits the opportunities available.

Funding Sources and Allocations

NBSB is funded principally through central UK Government funding (from the Department of Health, including contributions from Northern Ireland, Scotland and Wales). This funding is intended to support NIBSC's capability to undertake cover control testing and evaluation of biologicals, standardisation activities, transfusion medicine work, research and development and

provide general support and advice to the UK Government and associated bodies.

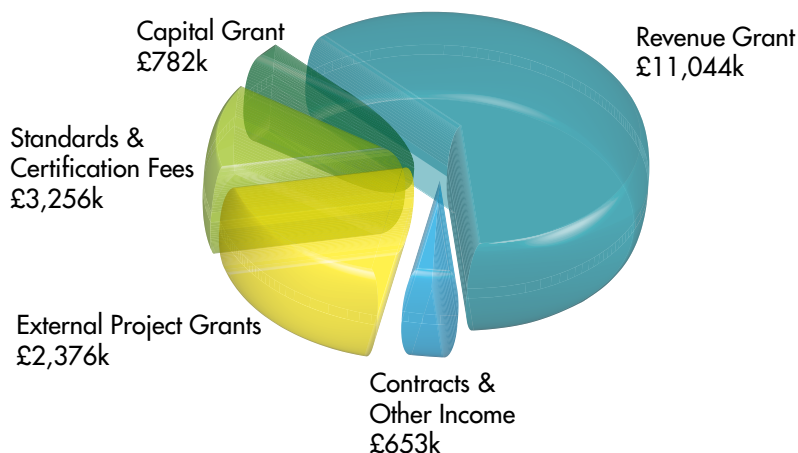
Additional funding includes:

External project grants and contracts (grant awarders include the Medical Research Council, WHO, the European Commission, the Department of Trade and Industry and the Home Office).

Handling fees for the distribution of biological standards and other reference materials.

Certification fees for the issue of batch release certificates to manufacturers (these were increased during this year).

Total funding/income in 2004/05 was as follows:

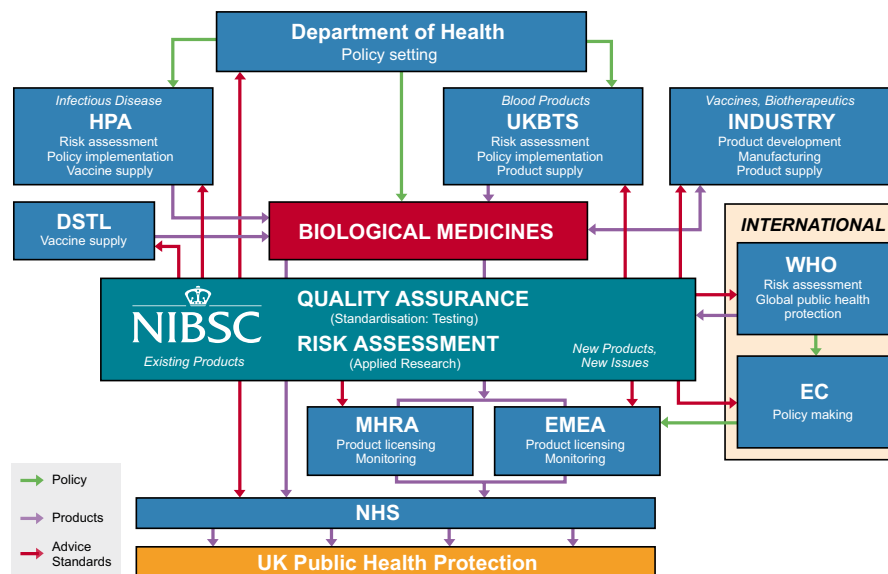


NIBSC's programme activities are reviewed and updated on an annual basis within the context of the Corporate Plan, and submitted to the Department of Health as part of an 'Accountability Review' process held at the beginning of each year. The allocation of resources based on the agreed scientific priorities is proposed

by management, reviewed by the Scientific Policy Advisory Committee (SPAC) and the Finance and General Purposes Committee (F&GP) and approved by the Board.

The Board, advised by its Finance and General Purposes Committee, is responsible for approving NIBSC an-

nual budgets, and monitors expenditure at regular intervals throughout the year. The Board and its committees have access to NIBSC financial management information which allows expenditure to be monitored by expense heading, organisational unit, programme area and by external grant and contract.



Accounts

National Biological Standards Board

Accounts for the year ended March 2005



National Biological Standards Board

Foreword

Background information

The Board's responsibilities are set out in the National Biological Standards Board (Functions) Order 1976. The Board took over the management of the National Institute for Biological Standards and Control (NIBSC) from the Medical Research Council on 1 July 1976. The Institute moved into its new laboratories at South Mimms in July 1987. In July 2004 the government announced that the Board would be abolished and its functions transferred to the Health Protection Agency once the necessary legislation had been passed. This is expected to be in 2007.

Activities

The Board's prime function is to assure the potency, purity and related efficacy and safety of biological substances used in human medicine. These substances include bacterial and viral vaccines such as those used for immunisation against diphtheria, poliomyelitis, measles and influenza, blood products such as Factor VIII and immunoglobulins and therapeutics such as cytokines and growth factors.

Standard preparations, against which the potency of biological substances is measured, are prepared, held and distributed to other national control laboratories and to manufacturers and researchers throughout the world. Control testing of batches of biological medicinal products supplied by holders of licences under the Medicines Act 1968 and/or EC Directive 2001/83 (as amended) is carried out to ensure that requirements relating to potency, purity and associated efficacy and safety have been met.

The Board collaborates with the World Health Organization, the European Pharmacopoeia Commission and other international organisations and bodies in relation to the establishment of standards for, the provision of standard preparations of, and the testing of biological substances.

Research and development

Standardisation and control work is supported by research and development work directed towards designing and improving assay, test and standardisation methods, including in vitro studies, not only for existing biological medicinal products but also for new products arising from scientific developments including those in the field of biotechnology.

Form of Account

The Account has been prepared in a form directed by the Secretary of State with the approval of the Treasury in pursuance of Section 4 (3) of the Biological Standards Act 1975.

National Biological Standards Board

The Board carried out its functions through the National Institute for Biological Standards and Control (NIBSC) as described above. The revenue contribution from UK government through the Department of Health covers over half of the costs of the Institute, but has declined annually as a proportion of total operating costs. The remaining costs are covered by charges for services.

The loss for the year amounted to £410k which when added to the opening balance on the Income and Expenditure Account gave an accumulated surplus of £6,466k. Movements in reserves are shown in Note 12 to the accounts.

Results for the year

The loss compares with a surplus in the previous year of £3,593k which benefited from the anticipated recovery of VAT for earlier periods of £2,073k. Significant financial changes in the year included the increase in employers' contributions to the NHS Pension Scheme from 7% to 14% of pensionable pay from 1 April 2004 resulting in additional payroll costs of £530k, towards which the Department of Health made an earmarked contribution of £486k. Turnover from third party contracts fell in the year by £919k reflecting primarily the decline in polio vaccine testing activity with the replacement of the oral polio vaccine used in the UK by an inactivated vaccine. Income from two of the Institute's core activities – the distribution of biological reference materials and the independent testing of batch released biological medicines – increased by 9% or £268k.

Cash and investment balances decreased by £2,203k to £582k of which £283k (31 March 2004 £2,542k) were Government funds. This movement reflects the unusually high balance of funds earmarked for capital projects for which purchase commitments had been made at 1 April 2004 which were spent in the first part of the year as equipment was delivered.

Capital spending in the year was £3.1 million (2003/04 £3.9 million) and has significantly enhanced the scientific facilities and equipment of the Institute.

The change in financial position between 2003/04 and 2004/05 showed an increasing imbalance between income and expenditure resulting from the ever growing demand on the Institute's resources and the field of biological medicines. This has been addressed by the Board in setting a balanced budget for 2005/06.

The significant additions to fixed assets during the year were:

Fixed assets

- (a) Completion of UK Stem Cell Bank laboratories
- (b) Automated ampoule filling machinery
- (c) Extensive refurbishments to laboratories and plant

The Institute also replaced all its desktop personal computers with uniform equipment and identical operating systems.

National Biological Standards Board

Review of activities and future developments

Purpose-built laboratories for the UK Stem Cell Bank were completed ready to acquire quality-assured stem cell lines for research and, eventually, therapeutic use.

The Board has continued to use advanced genetic techniques to develop vaccine strains for influenza. The resulting vaccine viruses will be used to combat a potential outbreak of pandemic human influenza if avian strains acquire the ability to infect the human population.

Rapid progress in medical science and the application of new biotechnology is leading to an increased rate of development of new biological medicinal products for use in the prevention, therapy and diagnosis of human disease. Among such substances are new and improved vaccines, cytokines and growth factors, cell lines and new types of treatment for blood coagulation disorders. A consequence of the expansion in the range and number of biological medicines is the need for corresponding development of control testing procedures by the NBSB to ensure the safety and efficacy of the new products and reference standards. Safety considerations, particularly microbiological (e.g. of blood and blood products), also require the development and application of increasingly complex tests for infectious agents. The Institute also needs to keep pace with the rapid technological developments in analytical equipment to ensure that its scientists maintain their leading position in biological standardisation and control worldwide. The Institute holds independent accreditation for its control testing work (ISO 17025) and for the production of standards (ISO 9001).

Disabled persons

All those responsible for recruitment to the Board's staff whenever practicable give full and fair consideration of candidates who are disabled. Within the limitations imposed by the nature of the work undertaken by the Board, disabled staff are provided with the same opportunities for training, re-training and promotion as other employees. Whenever possible, staff who become disabled whilst in the Board's employment are re-trained. Currently the Board employs no staff who are registered as disabled.

Employee involvement

It is the Board's policy to be open and fair in its dealings with Staff and recognised unions.

The Board endorses the principle of collective consultation on all matters that concern their staff, and negotiation on matters concerned with the terms and conditions of service of staff. A Joint Negotiating and Consultative Committee has been established, consisting of a 'Staff Side', representing the trade unions that have been formally recognised by the Board, and representatives of the Board and its officers, to provide the machinery for consultation and negotiation.

Two members are elected from the staff of the NBSB for appointment by the Minister to the Board. These staff Board members also serve on Board Committees including the Finance and General Purposes Committee.

Staff are provided with information through staff briefings, seminars and newsletters. The annual accounts are made available to staff through the Annual Report.

National Biological Standards Board

Invoice payment policy	<p>In accordance with the CBI's "Better Payment Practice Code", the Board aims to pay suppliers' invoices within thirty days of receiving an invoice in accordance with its standard terms and conditions. Any departure from these terms is agreed with individual suppliers. In 2004/2005, the Board paid 49% (2003/04 53%) of invoices within 30 days, representing 50% (52%) of the total value of invoices paid. It is the Board's policy to comply with these terms of payment as far as is practical within the constraints of the organisation.</p>
Board members	<p>Board membership during the financial year was: Professor GW Duff PhD FRCP FMedSci (Chairman) Professor D H Calam OBE MA DPhil CChem FRSC FRSA Hon MRPharmS Hon MBIRA DSc Professor J H Darbyshire OBE FRCP FFPH Mr A Heath MA MSc CStat Mr Martin Hindle MSc BPharm MRPharmS Professor J P Hughes FRS Dr S C Inglis PhD (Director) Professor D S Latchman PhD MRCPATH FRCPATH Professor Christine Lee MA MD DSc(Med) FRCP FRCPATH Ms G M Noble CB MA MSc Dr J C Petricianni MD Mr A J Robertson CA Professor J G P Sissons MB BS MD FRCP MRCPATH Professor Sir John Skehel FRS Dr S Thomas PhD Dr Lincoln Tsang LLB PhD FRSC FIBiol FRSA MRPharmS Barrister & Solicitor</p>
Audit	<p>The Board's auditor is the Comptroller and Auditor General. Details of the audit fee for the year are disclosed in Note 4 to the financial statements. Other than the statutory audit of the financial statements, the Comptroller and Auditor General has not provided any other services to the Board during the year ended 31 March 2004.</p> <p>S C Inglis Accounting Officer, National Biological Standards Board 4 July 2005</p>

National Biological Standards Board

Statement of the Board's and Director's responsibilities

Under Section 4(3) of the Biological Standards Act 1975 the National Biological Standards Board is required to prepare a statement of accounts for each financial year in the form and on the basis determined by the Secretary of State, with the consent of the Treasury. The accounts are prepared on an accruals basis and must show a true and fair view of the Board's state of affairs at the year-end and of its income and expenditure and cash flow for the financial year.

In preparing the accounts the Board is required to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed, and disclose and explain any material departures in the financial statements; and
- prepare the financial statements on the going concern basis, unless it is inappropriate to presume that the Board will continue in operation.

The Accounting Officer of the Department of Health has designated the Director of the National Institute for Biological Standards and Control as the Accounting Officer for the Board. His relevant responsibilities as Accounting Officer, including his responsibility for the propriety and regularity of the public finances for which he is answerable and for the keeping of proper records, are set out in the Non-Departmental Public Bodies' Accounting Officer's Memorandum, issued by the Treasury and published in "Government Accounting".

National Biological Standards Board

Statement on Internal Control for the year ended 31 March 2005

Scope of responsibility

The Board is accountable for internal control. As Accounting Officer, I have responsibility for maintaining a sound system of internal control which supports the achievement of the statutory duties of the National Biological Standards Board and its policies, aims and objectives, whilst safeguarding the Board's funds and assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Government Accounting. The policies, aims and objectives of the Board are reviewed by the Minister for Public Health as part of its annual Accountability process, while the authority delegated to the Board by the Department of Health is set out in its Management Statement.

The purpose of the system of internal control

The system of internal control is designed to manage risk to a reasonable level rather than to eliminate the risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness.

The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of boards policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically.

The system of internal control has been in place in the NBSB throughout the year ended 31 March 2005 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

Capacity to handle risk

The Board has established, with help from external experts and the Audit Committee, a continuous risk assessment process covering the activities of the NBSB and the environment within which it operates. Output from the risk management system is reviewed by the Board periodically and its operation is monitored by the Audit Committee. Risks identified within NBSB's scientific divisions and administration are recorded in a risk register to which all staff have access through trained risk champions. Risks are assigned to specific NBSB staff at divisional and organisational level who have responsibility for their management.

National Biological Standards Board

The risk and control framework

The framework which provides evidence to support this statement on internal control includes:

- an Audit Committee which reviews the risk management process regularly, and receives the reports of the internal auditors;
- an internal audit function which sets its work programme based on an analysis of risks and which reports on the risk management system;
- a system of staff responsibility, internal regulations and guidelines to allow staff to conduct the Board's business safely and legally with the minimum of risk to its staff, customers and the public.

Where issues and concerns have been expressed they are considered and actioned as appropriate.

The Board operates a system of risk management in accordance with Treasury guidance. This system has been reviewed and endorsed by independent risk management experts and provides the basis for the Institute's internal audit plan.

During the year 2005/06 the Board will continue to develop its risk management procedures and in particular seek to link departmental and operating risks with Board level strategy and issues. Priority will be given to areas which exhibit higher than average risk.

During 2005/06 the Board expects to complete a review of the corporate governance structure and practice so that the Institute as a whole responds to its strategic targets and best coordinates efforts throughout the Institute in achieving its objectives and in aligning itself for future incorporation into an enlarged Health Protection Agency.

Review of effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. This review is informed by the work of the internal auditors, by comments made by the external auditors in their management letter and by the Audit Committee. I also place reliance on the executive managers within the organisation, who have responsibility for the development and maintenance of the system of internal control and the assurance framework.

S C Inglis

Accounting Officer, National Biological Standards Board
4 July 2005

National Biological Standards Board

The Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements on pages 42 to 61 under the Biological Standards Board Act 1975. These financial statements have been prepared under the historical cost convention as modified by the revaluation of certain fixed assets and the accounting policies set out on pages 45 to 48.

Respective responsibilities of the Board, Director and Auditor

As described on page 37, the Board and Accounting Officer are responsible for the preparation of the financial statements in accordance with the National Biological Standards Board Act 1975 and directions made thereunder by the Secretary of State with the approval of HM Treasury and for ensuring the regularity of financial transactions. The Board and Accounting Officer are also responsible for the preparation of the Foreword. My responsibilities, as independent auditor, are established by statute and I have regard to the standards and guidance issued by the Auditing Practices Board and the ethical guidance applicable to the auditing profession.

I report my opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with the National Biological Standards Act 1975 and directions made thereunder by the Secretary of State with the approval of the Treasury, and whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. I also report if, in my opinion, the Foreword is not consistent with the financial statements, if the Board has not kept proper accounting records, or if I have not received all the information and explanations I require for my audit.

I review whether the statement on pages 38 and 39 reflects the Board's compliance with Treasury's guidance on the Statement of Internal Control. I report if it does not meet the requirements specified by Treasury, or if the statement is misleading or inconsistent with other information I am aware of from my audit of the financial statements. I am not required to consider, nor have I considered whether the Director's Statement on Internal Control covers all risks and controls. I am also not required to form an opinion on the effectiveness of the Board's corporate governance procedures or its risk and control procedures.

Basis of audit opinion

I conducted my audit in accordance with United Kingdom Auditing Standards issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Board and the Director in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Board's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements are free from

National Biological Standards Board

material misstatement, whether caused by error, or by fraud or other irregularity and that, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I have also evaluated the overall adequacy of the presentation of information in the financial statements.

Opinion

In my opinion:

- the financial statements give a true and fair view of the state of affairs of the National Biological Standards Board at 31 March 2005 and of the deficit, total recognised gains and losses and cash flows for the year then ended and have been properly prepared in accordance with the National Biological Standards Board Act 1975 and directions made thereunder by the Secretary of State with the approval of the Treasury; and
- in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

I have no observations to make on these financial statements.

John Bourn
Comptroller and Auditor General
Date: 14 July 2005

National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON SW1W 9SP

Supplementary statement by the Comptroller and Auditor General in respect of material included at pages 1 to 31 of this Annual Report, not included with the financial statements to which the audit opinion above relates.

In respect alone of my responsibility under United Kingdom auditing standards to read the other information included with financial statements on which I express an audit opinion, I have read the additional information on pages 4 to 31 which was not included with the financial statements on which I reached the audit opinion set out in my Certificate above and considered whether it is consistent with the audited financial statements. I have considered the implications for my audit opinion if I have thereby become aware of any apparent mis-statement or material inconsistencies with the financial statements. I have not considered the effects of any events since the date of my Certificate.

In this regard, my audit opinion on the financial statements is unchanged.

Comptroller and Auditor General
Date: 13 April 2006

National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON SW1W 9SP

National Biological Standards Board

Income and Expenditure Account for the year ended 31 March 2005

	Notes	2004/05 £000	2003/04 £000
Income			
Government grants	2a	11,044	10,628
Other grants	2b	3,029	3,970
Income from activities	2c	3,256	2,988
Contributions to depreciation	2d	2,662	2,502
		19,991	20,088
Expenditure			
Staff costs	3a	11,236	9,724
Other operating charges	4a	6,456	6,343
VAT recoverable	4c	47	(2,073)
Depreciation	5	2,662	2,502
Cost of capital charge	2e	2,351	2,230
		22,752	18,726
Operating (deficit)/surplus		(2,761)	1,362
Interest receivable		-	1
Cost of capital reversal	2e	2,351	2,230
(deficit)/Surplus for the year		(410)	3,593

All results arose from continuing operations.

Statement of Total Recognised Gains and Losses for the year ended 31 March 2005

	Notes	2004/05 £000	2003/04 £000
Deficit for the year		(410)	3,593
Unrealised deficit on revaluation of stocks		-	(1,262)
Unrealised surplus on revaluation of fixed assets	12	2,847	2,674
Net deficit on foreign currency translation		(13)	(39)
Total recognised gains and losses		2,424	4,966

National Biological Standards Board

Balance Sheet as at 31 March 2005

	Notes	2005 £000	2004 £000
Fixed assets			
Tangible assets	5	56,932	53,519
Debtors due after more than one year	7	8,692	9,031
Current assets			
Stock	6	7,181	6,795
Debtors	7	7,242	9,497
Cash at bank and in hand	8	582	2,785
		15,005	19,077
Creditors			
Amounts falling due within one year	9	1,197	2,160
Deferred income	14	807	935
		2,004	3,095
Net current assets		13,001	15,982
Total assets less current liabilities		78,625	78,532
Provisions for liabilities and charges	10	8,666	9,018
Capital and reserves			
Deferred government grant	12	33,968	35,802
Revaluation reserve	12	28,387	25,831
Donated asset reserve	12	1,138	1,005
Income and expenditure account	12	6,466	6,876
		78,625	78,532

The notes on pages 45 to 61 form part of this account.

S C Inglis
Accounting Officer
National Biological Standards Board
4 July 2005

National Biological Standards Board

The notes on pages 45 to 61 form part of this account.

Cash Flow statement for the year ended 31 March 2005			
	Note	2004/2005 £000	2003/2004 £000
Net cash inflow/(outflow) from operating activities	16(i)	38	508
Returns on investments and servicing of finance			
- Interest received		-	1
Capital expenditure		(3,156)	(3,925)
Receipts from disposal of fixed assets		-	-
Net cash outflow before financing		(3,118)	(3,416)
Management of liquid resources			
Financing:			
- Capital grants received		782	3,282
- Grant equipment funds		133	861
Decrease in cash	16(ii)	(2,203)	727

The notes on pages 45 to 61 form part of this account.

National Biological Standards Board

Notes to the Account for the year ended 31 March 2005

1 Accounting policies

(a) Accounting convention

The accounts have been prepared in accordance with applicable accounting standards under the historical cost convention, modified to include the revaluation of fixed assets. Without limiting the information given, the accounts meet the accounting and disclosure requirements of the Companies Acts and accounting standards issued or adopted by the Accounting Standards Board so far as those requirements are appropriate. The accounts are also consistent where appropriate with generally accepted accounting practice in the United Kingdom (UK GAAP).

(b) Tangible fixed assets

Tangible fixed assets are shown at current value (cost or valuation) less depreciation.

Buildings are shown at depreciated replacement cost based on the most recent valuation by the District Valuer at 31 March 2004, indexed for movements in building costs since the last valuation. Land is owned by the Treasury, but its value is included in the Board's accounts at 31 March 2005.

Other assets are valued at modified historic cost, being historic cost indexed to depreciated current replacement cost.

(c) Depreciation

Depreciation is provided on all tangible fixed assets except assets under construction, at rates calculated to write off the cost of each asset evenly over its expected economic life as follows:

Buildings	Based on components depreciated between 15 and 80 years
Plant	15 years
Equipment	7 years
Computers	5 years
Software	5 years
Vehicles	5 years
No depreciation is charged in the year of disposal.	

National Biological Standards Board

(d) Government grants

Government Grants receivable for capital expenditure are credited to a Deferred Government Grant account (Note 14) and are released to revenue over the expected useful life of the relevant asset by equal annual amounts.

Grants for revenue are credited to income in the year to which they relate (Note 2a)). Deferred grant income comprises grant funds received in advance of work being undertaken (Note 14 Other grant income is shown in note 2b).

(e) Stocks

Stocks are stated at the lower of cost and net realisable value. The materials incorporated in stocks of biological standards are provided to the Board without charge and are distributed onwards without any charge for the biological materials contained. However, costs are incurred in the production, storage and distribution of standards, including the scientific work undertaken to establish them and a handling charge is levied for their distribution. The value of standards calculated individually at the lower of cost and net realisable value is included in stocks.

(f) Research and development

Research and Development costs are written off as incurred.

(g) Foreign currencies

Assets and liabilities denominated in foreign currency are translated at rates of exchange at the balance sheet date. Transactions in foreign currencies are recorded at the rate ruling at the time of the transaction. Exchange gains and losses are dealt with in accordance with Statement of Standard Accounting Practice 20 and are taken to the Income and Expenditure account.

(h) Pension costs

The majority of the Board's employees are members of the NHS Pension Scheme. This is a statutory scheme the provisions for which are contained in the NHS Pension Scheme Regulations (SI 1995 No 300). Under these regulations the Board is required to pay an employer's contribution, being 14% of pensionable pay for 2004/05, as specified by the Secretary of State for Health. These contributions are charged to operating expenses as they become due.

The scheme provides benefits on a "final salary" basis at a normal retirement age of 60. Benefits accrue at the rate of 1/80th of pensionable salary for each year of service. In addition a lump sum equivalent to 3 years pension is payable on retirement. Members pay contributions of 5% or 6% of pensionable earnings. Pension payments rise in line with the Retail Prices Index. On death, pensions are payable to the surviving spouse at a rate of half the member's pension. On

National Biological Standards Board

death in service, the scheme pays a lump sum of twice the pensionable pay. Medical retirement is possible in the event of serious ill health. In this case, pensions are brought into payment immediately based on an enhanced period of membership.

The NHS Pension Scheme is an unfunded multi-employer defined benefit scheme, and the Board is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out as at 31 March 1999 and details can be found on the NHS Pensions Agency website at www.nhs.gov.uk Copies can also be obtained from the Stationery Office.

The Board also operates a "by-analogy" scheme. This offers benefits similar to the Medical Research Council pension scheme but was set up by the Board and is now closed to new members. It is given legal status by section 51(3) of the Social Security Act 1973. The Government of the day has an obligation to provide pension benefits to members of the schemes in accordance with their respective rules. The liability will be met from the annual grants from the Department of Health.

By-analogy schemes are unfunded in accordance with the Social Security Pensions Act 1975. Payments to the Paymaster General in respect of retired members are funded by employer and employee contributions in respect of active members with any shortfall being made up by an additional contribution by the Board.

The future liability of the by-analogy scheme calculated by the Government Actuary's Department is recognised as a liability in the balance sheet and the corresponding amount receivable from the Department of Health is included in long term debtors.

(i) Donated assets

Fixed assets purchased from donated funds are capitalised, valued and depreciated in the same way as government funded fixed assets. The net book value of the donated assets shown in the balance sheet is matched by the Donated Assets Reserve.

(j) Cost of capital charge

Notional interest for financing the Board's net assets has been calculated on the average book value of net assets funded by the Government at the rate prescribed by the Treasury (3.5% per annum). This interest is charged to the income and expenditure account in arriving at the operating result and is then reversed as it is not actually paid.

National Biological Standards Board

(k) Income

Income comprises the amounts invoiced, excluding Value Added Tax, for goods and services supplied in the normal course of business and funding received from the Department of Health.

(l) Derivatives and other financial instruments

The Board's financial instruments consist of cash balances, trade debtors and trade creditors. It treats term deposits which are repayable at fixed dates within one year of the balance sheet date as investments. Current accounts and demand deposits are treated as cash. The Board has no borrowings or derivatives. Its policy is not to hold foreign currency in excess of known liabilities.

2 Income

(a) Government Grants		2004/05 £000	2003/04 £000
Department of Health		9,791	9,315
Scottish Executive		861	861
National Assembly for Wales		470	470
Northern Ireland Assembly		261	261
		11,383	10,907
Less: Contributions to the NBSB Pension Scheme Included in Department of Health grant		(339)	(279)
Total Government Grants		11,044	10,628

(b) Other Grants		2004/05 £000	2003/04 £000
Research Councils etc		1,341	1,444
World Health Organization		87	198
European Commission		250	455
Other Bodies		698	301
Contracts		653	1,572
		3,029	3,970

National Biological Standards Board

(c) Other Income			
		2004/05 £000	2003/04 £000
Standards distribution handling charges		2,118	1,918
Certification fees		1,138	1,070
		3,256	2,988

(d) Contributions to depreciation			
All the fixed assets belonging to the Board are funded by Government or other grants included in reserves (see Note 12). The cost of depreciation is matched by transfers from reserves as follows :			
		2004/05 £000	2003/04 £000
Historical cost depreciation on other assets transferred from Deferred Government Grant		2,616	2,150
Current cost depreciation adjustment transferred from Revaluation Reserve		46	282
Current cost depreciation on donated assets transferred from Donated Asset Reserve		-	70
		2,662	2,502

(e) Cost of capital charges

Notional interest at 3.5% of the average value of net government funded assets during the year, which is £2,351k (2003/04 £2,230k) is matched by a notional credit for the same amount, shown below the operating deficit.

3 Staff Costs

(a) All staff			
		2004/05 £000	2003/04 £000
Salaries and wages		8,804	7,983
Social Security costs		729	653
Employers contributions to the NBSB Pension Scheme		57	57
NHS Superannuation contributions		1,065	482
Consultancy and agency staff		581	549

National Biological Standards Board

		11,236	9,724
(b) Board members' emoluments		2004/05 £000	2003/04 £000
The emoluments of the Chairman were:		15	15
The emoluments of the Chief Executive were:		164	122

Emoluments exclude pension and National Insurance contributions, but include arrears of salary paid during the year of £25k (2003/04: Nil) to the Chief Executive.

(c) The part-time members of the Board received attendance fees for their services as Board members as follows:

	2004/05	2003/04
	£	£
Professor D Calam	435	568
Professor J Cash	-	423
Professor D Davies	-	284
Professor J Darbyshire	435	426
M Hindle	505	-
Professor J Hughes	435	139
Professor D Latchman	870	710
Professor C Lee	580	-
J Metcalf	-	1,136
G Noble	1,022	852
Dr J Petricciani	580	710
A Robertson	1,012	1,136
Professor J Sissons	435	568
Professor Sir J Skehel	145	568
Dr L Tsang	435	-
	6,889	7,520

National Biological Standards Board

The salary (excluding employer's costs) and pension entitlements of the non-executive Board members were as follows :

	Salary, including performance pay	Accrued pension at age 60 at 31.3.05	Related lump sum at 60	Real increase in pension at 60	Real increase in lump sum at 60	CETV at 31.3.05	CETV at 31.3.04	Real increase in CETV
	£000 p.a.	£000 p.a.	£000	£000 p.a.	£000	£000	£000	£000
Professor G Duff Chairman	15-20	Nil	Nil	Nil	Nil	Nil	Nil	Nil

(d) Senior employees

The salary and pension entitlements of the senior management of the NBSB were as follows:

	Salary, including performance pay	Accrued pension at age 60 at 31.3.05	Related lump sum at 60	Real increase in pension at 60	Real increase in lump sum at 60	CETV at 31.3.05	CETV at 31.3.04	Real increase in CETV
	£000 p.a.	£000 p.a.	£000	£000 p.a.	£000	£000	£000	£000
Dr S Inglis Director	160-165	20-25	70-75	2.5-5	10-15	389	305	76
V Knight Head of Finance/ Board Secretary	60-65	5-10	25-30	0-2.5	0-5	138	108	27
S Murray Head of Operations	55-60	0-5	5-10	0-2.5	0-5	33	17	15
A Jowett Head of Human Resources	40-45	0-5	5-10	0-2.5	0-5	46	25	19

“Salary” includes gross salary, performance pay or bonuses and other allowances. The estimated monetary value of benefits in kind do not form part of “salaries” for disclosure purposes under resource accounting, however there were no benefits in kind to any Board members or staff.

Full details in respect of the pension arrangements in place for NBSB staff are provided in note 1(h) to these Accounts.

Columns 6 & 7 of the above table show the member's cash equivalent transfer value (CETV) accrued at the beginning and the end of the re-

National Biological Standards Board

porting period. Column 8 reflects the increase in CETV effectively funded by the employer. It takes account of the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

A CETV is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The CETV figures, and from 2003/04 the other pension details, include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the NHS Pension Scheme and for which the Scheme has received a transfer payment commensurate to the additional pension liabilities being assumed. They also include any additional pension benefit accrued to the member as a result of their purchasing additional years of pension service in the scheme at their own cost. CETVs are calculated within the guidelines and framework prescribed by the Institute of Actuaries.

(f) The average number of employees during the year was:			
		2004 /05 No	2003/ 04 No
Scientific divisions		203	201
Support and operations		73	75
Administration		25	29
		301	305

4 Other Operating Charges

(a) Other operating charges

		2004/05 £000	2003/04 £000
Consumable laboratory supplies		3,411	2,695
Central services		1,498	1,895
Estate management		755	1,006
Equipment		437	379
Travel, subsistence and hospitality:			
Chairman and other Board members		5	11
Employees		185	151
Audit fee		42	40
Provision for bad debts		2	11
Loss on disposal of assets		108	92
Diminution in value of computers and software		-	24

National Biological Standards Board

Foreign exchange (gain)/loss		13	39
		6,456	6,343

(b) Foreign currency translation

Net exchange losses of £13k on deposits have been debited to the Income and Expenditure account.

(c) VAT refund

The Board has negotiated with HM Customs and Excise a basis of recovery of VAT under the partial exemption rules and submitted claims for partial recovery of some £8.0 million of input VAT, for the period from October 1996 to March 2004. This included £1.4 million of VAT paid on the construction of the new Centre for Biological Reference Materials (CBRM). Of the claims an amount of £2.9 million has been repaid and £5,112k is included in debtors at 31 March 2005 (2004: £6,510k).

During the year 2004/05 VAT returns have been submitted quarterly and the partial recovery of VAT of £1,049k on purchases has been received.

5 Tangible Fixed Assets

	Freehold Land	Freehold Buildings	Software computers & equipment	Motor Vehicles	Production equipment	Assets Under construction	Total
	£000	£000	£000	£000	£000	£000	£000
Balances at 1 April 2004	5,303	36,506	10,642	29	1,788	7,050	61,318
Additions	-	102	31		165	3,037	3,335
Transfers	-	1,175	843			(2,018)	-
Disposals	-	-	(202)		(165)		(367)
Diminution	-	-	(61)				(61)
Revaluation / indexation		3,433	278	1	(19)		3693
Cost or valuation at 31 March 2005	5,303	41,216	11,531	30	1,769	8,069	67,918
Accumulated depreciation at 1 April 2004	-	-	7,264	29	504	-	7,797
Charge for the year	-	1,746	810		106		2662
Disposals	-		(181)		(78)		(259)
Diminution	-	621	(29)				592
Backlog depreciation / indexation	-		193	1			194
Accumulated depreciation at 31 March 2005	-	2,367	8,057	30	532	-	10,986
Net book value							

National Biological Standards Board

At 31 March 2004	5,303	36,506	3,378	-	1,283	7,050	53,520
At 31 March 2005	5,303	38,849	3,474	-	1,237	8,069	56,932

National Biological Standards Board

6 Stock

		31 March 2005 £000	31 March 2004 £000
Standards		6,407	6,029
Raw materials		83	98
Others		691	668
		7,181	6,795

The Board holds stocks of biological reference materials ('standards') which are used in regulatory control, diagnosis and research. At 31 March 2005 2.1 million standards were held of which 0.9 million were publicised for distribution in NBSB's reagent catalogue. The Board estimates their economic value at 31 March 2005 to be £6,407k (2004: £6,029k) at the lower of cost and net realisable value.

As stated in Note 1(e) the biological material contained in the standards is usually obtained without charge to the Board and no charge is levied in respect of the material contained in the standards distributed, although handling charges are made.

7 Debtors

		31 March 2005 £000	31 March 2004 £000
Debtors due more than one year from balance sheet date :			
Department of Health		8,692	9,031
Debtors due within one year :			
Trade debtors		765	1,042
Grant income receivable		994	1,695
Other debtors		5,267	6,542
Prepayments		216	218
		7,242	9,497

The long term debt due from the Department of Health represents the Department's obligation to fund the future liabilities of the NBSB Pension Scheme.

Other debtors at 31 March 2005 includes £5,112k (2004: £6,510k) of VAT recoverable (Note 4(c)).

Intra-governmental balances:

National Biological Standards Board

Balances with Central Government bodies	29	4
Balances with NHS Trusts	14	12
Balances with Public Corporations	93	2
Balances with bodies external to Government	7,106	9,479
Total	7,242	9,497

8 Cash at Bank and In Hand

	31 March 2005 £000	31 March 2004 £000
Paymaster account	151	2,024
Other Department of Health cash at bank and in hand	132	518
External cash funding received in advance	299	243
	582	2,785

9 Creditors: Amounts falling due within one year

	31 March 2005 £000	31 March 2004 £000
Taxation and social security costs	243	337

National Biological Standards Board

Trade creditors	636	1,515
Accruals	318	308
	1,197	2,160

Intra-governmental balances:		
Balances with Central Government bodies	-	-
Balances with NHS Trusts	-	-
Balances with Public Corporations	2	1
Balances with bodies external to Government	1,195	2,159
Total	1,197	2,160

10 Provisions

	NBSB Pension Scheme £000	Early Retirements £000	Other Provisions £000	Total £000
Balance at 1 April 2004	8,800	210	8	9,018
Utilised during the year	(324)	(28)	-	(352)
Balance at 31 March 2005	8,476	182	8	8,666

The Government Actuary last calculated the capitalised value of the Board's future liability for pensions payable to members of the NBSB Pension Scheme as at 31 March 2002 as £7,256k. This was based on the assumption of a 3.5% return in excess of price inflation and members' pensionable pay increasing at a rate 1.5% faster than prices at that time. He also calculated that the cost of transferring the scheme to other existing schemes would be £9.7 million. The provision for the scheme at 31 March 2005 uses the latter basis, as it is expected that responsibility for the scheme will be transferred to the Department of Health.

The early retirements provision is in respect of early retirement of staff where the Board has a continuing liability to meet the costs involved up to and beyond the standard retirement date. This provision covers only those staff where the Board did not elect to meet the costs involved by a commuted payment to the pension scheme in the year of early retirement. Following the valuation by the Government Actuary at 31 March 2002 the provision has been reduced to reflect the remaining liability in respect of those staff.

Other provisions represent the best estimate of the cost to settle legal claims outstanding against the Board at the balance sheet date.

National Biological Standards Board

11 NBSB Pension Scheme

The NBSB Pension Scheme is overseen by a five member Committee of Administration appointed by the Board. Of the 69 members, 13 are contributing, 46 are receiving pensions and the other 10 have preserved pension rights. Details of the net cost to the Board are shown below:

	2004/05 £000	2003/04 £000
Lump sum payments	-	100
Transfers to other schemes	-	-
Benefits paid	409	371
Total payments	409	471
Less:		
Employers Contributions	57	57
Employees Contributions	28	29
Total Contributions	85	86
Provisions utilised	324	385

The scheme first went into deficit in 1988 and since financial year 1990/91 an addition has been made to the Board's cash limit towards the net cost to the Board of funding it. It is assumed that similar arrangements will continue for the foreseeable future.

12 Capital and Reserves

	Deferred Government Grant £000	Revaluation Reserve £000	Donated Asset Reserve £000	Income and Expenditure Account £000	Total £000

National Biological Standards Board

Balance at 1 April 2004	35,802	25,831	1,005	6,876	69,514
Capital grant received (Note 13)	782	-	-	-	782
Donated additions	-	-	133	-	133
Surplus for the year	-	-	-	(410)	(410)
Gains on revaluation – fixed assets	-	2,847	-	-	2,847
Depreciation transfer to Income & Expenditure Account	(2,616)	(46)	-	-	(2,662)
Realised gains on standards stock transfer to Income and Expenditure Account	-	(245)	-	-	(245)
Balance at 31 March 2005	33,968	28,387	1,138	6,466	69,959

13 Government grants for capital

	2004/05 £000	2003/04 £000
Department of Health	688	3,188
Scottish Executive	51	51
National Assembly for Wales	28	28
Northern Ireland Assembly	15	15
	782	3,282

14 Deferred grant income

	2004/05 £000	2003/04 £000
Balance at 31 March 2003	935	1,049
Net transfers to income & expenditure account	(128)	(114)
Balance at 31 March 2004	807	935

15 Capital commitments

National Biological Standards Board

	2004/05 £000	2003/04 £000
Contracted capital commitments as at 31 March 2005 for which no provision has been made	949	2,142

16 (i) Notes to the Cash Flow Statement

Reconciliation of operating surplus to net cash inflow from operating activities.

	2004/05 £000	2003/04 £000
Operating surplus/(deficit)	(2,761)	1,362
Cost of capital charge	2,351	2,230
Depreciation	2,662	2,502
Release from deferred government grant	(2,616)	(2,150)
Release from revaluation reserve	(46)	(283)
Release from donated asset reserve	-	(70)
Revaluation from production assets	-	(8)
Release from stock revaluation reserve	(245)	-
Loss on disposal of fixed assets	108	322
Diminution in value of computers and software	-	24
Increase in stock	(386)	(95)
Decrease in long term debtors	339	279
Decrease in short term revenue debtors	2,255	(3,255)
Decrease in revenue creditors	(1,143)	177
Decrease in deferred grant income	(128)	(114)
Decrease in provisions	(352)	(413)

National Biological Standards Board

Net cash outflow from operating activities	38	508
---	-----------	------------

(ii) Reconciliation of Net Cash Flow to Movement in Net Funds

	2004/05 £000
Decrease in cash in the period	(2,203)
Decrease in liquid resources	-
Change in net funds	(2,203)
Net funds at 31 March 2004	2,785
Net funds at 31 March 2005	582

17 Losses and special payments

During the year the Board wrote off 64 invoices due from customers, and deemed uncollectible, with a value of £ 21,192. This value was offset by unallocated credits of £16,989.

18 Financial instruments

Financial Reporting Standard 13 (FRS 13), "Derivatives and Other Financial Instruments: Disclosures" requires the disclosure of the role which financial instruments have had during the year in creating or changing the risks an entity faces in undertaking its activities. Because of the nature of its activities and the way in which Non Departmental Public Bodies are funded, the Board is not exposed to the degree of risk faced by business entities. Moreover financial instruments play a much more limited role in creating and changing risk than would be typical of the listed companies to which FRS 13 mainly applies.

As permitted by FRS 13, debtors and creditors which mature or become payable within 12 months from the balance sheet date have been omitted from the currency profile.

Liquidity risk

The NBSB's main funding source for both revenue and capital expenditure is the Department of Health through resources voted annually by Parliament and drawn monthly as need arises. The NBSB is therefore only exposed to liquidity risk if it exceeds its voted expenditure or provides services for third parties - primarily donors of academic grants and customers for contract testing – for which funding lags behind expenditure. The Board manages its financial affairs to minimise such risks.

Interest rate risk

The NBSB has no powers to borrow and its Exchequer cash balances are held in non-interest bearing accounts. These do not give rise to interest rate risk. Funds from third parties, primarily donors for academic grants, are held on deposit at prevailing rates of short term interest. The income from this source comprised less than 0.01% of annual income and variations in interest rates do not represent a material risk to the

National Biological Standards Board

Board's financial position.

Foreign currency risk

The Board conducts its business in the United Kingdom and most of its transactions and the major part of its funding are denominated in sterling. Its policy is to hold cash balances in sterling unless a matching obligation exists in another currency. Some funding for academic grants is received in foreign currency to cover sterling expenditure over a number of years, however any effect of exchange rate changes is borne primarily by the donor. The Board is not therefore exposed to any significant currency risk.

19 Related party transactions

(i) The National Biological Standards Board (NBSB) is a Non-Departmental Public Body of the Department of Health.

The Department of Health is regarded as a related party within the definition of Financial Reporting Standard (FRS) 8. During the year, the NBSB has had various material transactions with the Department of Health and with other entities for which the Department of Health is regarded as the parent Department.

The amount of funding received from the Department is disclosed in Notes 2(a) and 13.

In addition, the NBSB has had a significant number of material transactions with other central Government bodies including :

Medical Research Council	£1,528k
Home Office	£40k

All transactions were carried out in an arm's length basis.

(ii) During the year none of the Board Members, members of key management staff or other related parties has undertaken any material transactions with the National Biological Standards Board.

20 Post Balance Sheet Event

Since 31 March 2005, the Board has received a claim for damages arising from an asbestos related injury in respect of a retired former employee. No provision for any costs of settling the claim have been made in these Accounts due to uncertainty over the amounts involved, the likelihood of success of the claim and the timing of any payments that may arise.

National Biological Standards Board

Accounts Determination

The Secretary of State, with the approval of the Treasury, in pursuance of Section 4(3) of the Biological Standards Act 1975, hereby gives the following determination:

- 1 In this determination, 'the Board' means the National Biological Standards Board.
- 2 The Board shall prepare accounts for the financial year ended 31 March 1997 and subsequent financial years comprising:
 - a) a foreword;
 - b) an income and expenditure account;
 - c) a balance sheet;
 - d) a cash flow statement; and
 - e) a statement of total recognised gains and losses;

including such notes as may be necessary for the purposes referred to in the following paragraphs.

- 3 The accounts shall give a true and fair view of the income and expenditure and cash flows for the financial year, and the state of affairs as at the end of the financial year.
- 4 Subject to this requirement, the accounts shall be prepared in accordance with:
 - a) generally accepted accounting practice in the United Kingdom (UK GAAP);
 - b) the disclosure and accounting requirements contained in 'The Fees and Charges Guide' (in particular those relating to the need for appropriate segmental information for services or forms of service provided) and in other guidance which the Treasury or the Secretary of State may issue from time to time in respect of accounts which are required to give a true and fair view;
 - c) the accounting and disclosure requirements given in 'Government Accounting' and in 'Executive NDPBs: Annual Reports and Accounts guidance', as amended or augmented from time to time;

insofar as these are appropriate to the Board and are in force for the financial year for which the statement of accounts is to be prepared.

- 5 Clarification of the application of the accounting and disclosure requirements of the Companies Act and accounting standards is given in Schedule 1 attached. Additional disclosure requirements are set out in Schedule 2 attached.
- 6 The income and expenditure account and balance sheet shall be prepared under the historical cost convention modified by the inclusion of:
 - a) fixed assets at their value to the business by reference to current costs; and
 - b) stocks valued at the lower of net current replacement cost (or historical cost if this is not materially different) and net realisable value.
- 7 This accounts determination supersedes that dated 24 April 1996 and shall be reproduced as an appendix to the accounts.

Dated 6 May 1997

Signed by the authority of the Secretary of State for Health
P Kendall

National Biological Standards Board

Branch Head (RMF-EAC Division)
Department of Health

Schedule 1

APPLICATION OF THE ACCOUNTING AND DISCLOSURE REQUIREMENT OF THE COMPANIES ACT AND ACCOUNTING STANDARDS

Companies Act

- 1 The disclosure exemptions permitted by the Companies Act shall not apply to the Board unless specifically authorised by the Secretary of State with the approval of the Treasury.
- 2 The Companies Act requires certain information to be disclosed in the Director's Report. To the extent that it is appropriate, the information relating to the Board shall be contained in the foreword.
- 3 When preparing its income and expenditure account, the Board shall have regard to the profit and loss format 2 prescribed in Schedule 4 to the Companies Act 1985 (as amended).
- 4 When preparing its balance sheet, the Board shall have regard to the balance sheet format 1 prescribed in Schedule 4 to the Companies Act 1985 (as amended). The balance sheet totals shall be struck at 'Total assets less current liabilities'.
- 5 The Board is not required to provide the additional information required by paragraph 33(3) of Schedule 4 to the Companies Act 1985.
- 6 The foreword and balance sheet shall be signed by the Director of the Board and dated.

Accounting standards

- 7 The Board is not required to include a note showing historical cost profits and losses as described in FRS3.

National Biological Standards Board

Declared Interests of NBSB Members relating to 2004/2005				
Member	Personal Interest		Non-Personal Interest	
	Organisation	Nature of Interest	Organisation	Nature of Interest
Prof DH Calam	NBSB	Pension	None	None
Prof J Darbyshire	None	None	Wide range of national and international pharmaceutical companies	Director of MRC Clinical Trials Unit where some of the research is supported in part by industry.
Prof G Duff	Interleukin Genetics Inc.	Scientific Advisory Board, Shareholder		
Mr Alan Heath	None	None	None	None

National Biological Standards Board

Mr Martin Hindle	National Blood Authority	Non Executive Director	Greater Peterborough Citizens Advice	Trustee
	Peterborough and Stamford Hospitals NHS Foundation Trust	Non Executive Director		
	National Probation Service- Leicestershire and Rutland	Director		
	Aventis Pension Fund	Member		
	Cable and Wireless Pension Fund	Member		
Prof JP Hughes				
Dr Stephen Inglis	Xenova plc	Shareholder	None	None
	Partnerships UK	Associate advisor		
Prof D Latchman	Biovex Ltd	Non Executive Director, Consultant, Shareholder	Health Protection Agency	Board Member
Prof C Lee	Haemophilia Foundation	Board Member		

National Biological Standards Board

Ms Gillian Noble	Various Pharmaceutical Companies (Managed by HSBC Trust Company)	Shareholder		
	Meningitis Trust	Director		
	MRC	Audit Committee Member		
Dr J Petricciani	World Health Organisation	Occasional Consultancy	International Association for Biologicals	President
	Cancervax	Senior VP		
	International AIDS Vaccine Initiative	Occasional Consultancy		
Mr Allan Robertson	MRC	Audit Committee Member	None	None
Prof JGP Sissons	Cantab Pharmaceuticals	Advisor	Smithkline Beecham	Research Support

National Biological Standards Board

Prof Sir John Skehel	MedImmune Inc Life Sciences Ventures	Consultant	MRC Technology	Board Member
		Consultant	Novartis Foundation	Scientific Advisor, Chairman of the Executive Council
			Animal Health Trust	Member of Scientific Advisory Board and Executive Committee Member
			Institute of Molecular Medicine, Oxford	Member of Scientific Advisory Committee
			Academy of Medical Sciences	Vice President of Forum and Member of Council
Dr Steven Thomas	None	None	None	None
Dr Lincoln Tsang	BioIndustry Association	Chairman of Regulatory Affairs Advisory Committee	Arnold and Porter	Barrister specialising in life sciences
	Various pharmaceutical and biotechnology companies	External legal counsel		

National Biological Standards Board



National Biological Standards Board

**c/o National Institute for Biological
Standards and Control**

Blanche Lane
South Mimms
Potters Bar
EN6 3QH
United Kingdom

Tel: +44 (0) 1707 641000
Fax: +44 (0) 1707 641050
Email: enquiries@nibsc.ac.uk