2005/06

NBSB

Annual Report

NBSB

Annual Report
1st April 2005 to 31st March 2006

National Biological Standards Board

National Institute for Biological
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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 Shedule 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).

National Biological Standards Board Annual Report and Accounts for the year ended 31 March 2006

Presented to Parliament pursuant to c.4 section 4 (4) of the Biological Standards Act 1975.

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Contents

Chairman's Report

During the past year, NIBSC, along with many non-departmental public bodies, has been under close scrutiny, as the Department of Health carried out a major review of all of its Arm's Length Bodies to ensure that their objectives are appropriate and that their resources are being used efficiently. This was a challenging exercise and required considerable effort from our senior staff, but I am pleased to report that the outcome was very satisfactory for the Institute, demonstrating a high degree of confidence by the Department in the way we operate, and a strong endorsement of our work in support of public health protection through assuring the quality of biological medicines.

This positive view of the Institute was reinforced by the results of a wide-ranging stakeholder consultation carried out by the Department during the year to seek views on appropriate mechanisms for integration of NIBSC into the Health Protection Agency. NIBSC is clearly held in very high regard by its customers in the UK and abroad, and the consultation delivered a very clear message that our work continues to be vitally important and must be sustained effectively through the merger. The Board was very pleased to note the formal response to the consultation exercise from Ministers which clearly recognized the importance of retaining the NIBSC 'brand', the need to establish a robust mechanism for avoidance of conflict of interest and the importance of ensuring that NIBSC's outputs are preserved over the long term.

While the Arm's Length Body Review and the impending merger with HPA have been high on our agenda over the past year, the most important aspect of our progress has been the Institute's scientific achievements, and once again our staff have made important, science-based contributions to public health in very many areas, as can be seen in the pages of this report. That the scientists, support staff and management team of NIBSC have continued to deliver such excellent outputs through a time of considerable uncertainty about the future is a strong testament to their dedication, skill and commitment, for which the Board is most grateful.

Professor Gordon Duff
Chairman, National Biological Standards Board

Director's Report

A recent report on the pharmaceutical industry predicted that over the next five years more than half of the expected growth in the sector will come from biological medicines. This emphasizes the rapidly increasing importance of a class of medicines that is already at the heart of public health protection and that includes all vaccines, products derived from blood and tissues, and biopharmaceuticals manufactured using recombinant DNA technology. It also highlights the fact that NIBSC's scientific work to support quality assurance of biological medicines has never been more important.

The development and distribution of standards and reference materials lies at the heart of the Institute's day to day work and the past year was once again very productive, with some 15 new international standards added to our catalogue after endorsement by WHO. Testing of products under the EU's Official Control of Batch Release (OCABR) system also continued at its usual high level. During the year NIBSC was asked to carry out batch release for new and innovative products. This reflects considerable confidence in the Institute, and fits with our strategy to focus particularly on innovative medicines with major public health impact.

The Institute's strength lies in the high level of scientific expertise that underpins its statutory role in standardization and control, maintained through a vigorous research and development programme. This means that we are well positioned to respond to new developments and emerging problems associated with biological medicines, and there have been many examples of such work over the past year.

Preparation for pandemic influenza has assumed an even higher profile than last year, with efforts focused particularly on reducing the time required to create and supply safe vaccine strains to manufacturers following isolation of new virus types, as well as creating new vaccine strains in response to changing antigenic characteristics of currently circulating H5N1 strains.

Work towards producing reference materials in support of diagnostic tests for prion-based diseases has also come very much to the fore; promising new tests are currently being developed but these will need very careful validation in order to avoid serious problems with their implementation.

The UK Stem Cell Bank also made good progress, with over 20 cell lines accessioned and 7 almost ready for distribution. We were very pleased to learn from the Medical Research Council (MRC) in December that funding had been approved to operate the bank for a further five years; the next phase of the project will involve construction of a permanent facility and will be a major task for the coming year.

Finally the Institute was asked by Medicines and Healthcare products Regulatory Agency (MHRA) in March 2006 to respond to the incident at Northwick Park hospital in which very serious adverse events followed a Phase 1 clinical trial involving the experimental monoclonal antibody TGN1412. Working against a very tight timetable, Institute scientists carried out a comprehensive series of tests on the product used in the trial, the results of which implied strongly that the adverse effects were due directly to the action of the drug on its target. Incidents such as these serve to underline the vital importance to the Institute and its stakeholders of maintaining broad and high quality scientific expertise in the field of biological medicines. This is a considerable challenge, but it is one which the Institute is well positioned to meet now and in the future.

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

NBSB & NIBSC

The National Biological Standards Board (NBSB) is a non-departmental public body 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 biological medicines, through its management of the National Institute for Biological Standards and Control (NIBSC).

Biological medicines are of huge importance to public health, encompassing vaccines, blood products and other medicines produced from living organisims. They are generally very complex and so analysing them and measuring their action requires highly specialised methods, materials and expertise.

The Institute fulfils its remit through four core activities:

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

Its 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

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 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 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

NBSB - established by Act of Parliament in 1975

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. For many years they have brought radical improvements in the prevention, diagnosis and treatment of disease throughout the world. These are extremely complex products and because of this batches of vaccines and blood products are independently tested before they are released for use. In the UK and Europe biologicals are submitted to one of the EU's Official Medicines Control Laboratories (OMCLs) before being released for use; NIBSC is the UK's OMCL for the batch release of biological medicines.

Through the Institute's testing and evaluation activities, NIBSC's scientists help to ensure the safety and efficacy of biological products while helping to minimise the time taken to bring new products into clinical use. New products require novel approaches for their control and our activities in the development of new testing methods have been detailed in our scientific highlights and key targets. The vast potential increase in the numbers and complexity of biologicals, as a result of the genomics revolution will demand yet more radical control strategies.

Overall our product testing activities grew slightly during the year. The trend towards use of increasingly complex combination vaccines has resulted in greater testing requirements for individual products, albeit spread over fewer product batches.

For the future, it is pleasing to note that NIBSC has been asked to carry out batch release for two important new vaccines, one directed against childhood diarrhoeal disease caused by rotavirus and the other against cervical cancer caused by human papillomavirus. This reflects considerable confidence in the Institute, and fits with our strategy to focus particularly on innovative medicines with major public health impact.

Standardisation

The complex assays used to assure the potency of biologicals require the use of a standard of biological activity (a batch of a substance that has been assigned units of activity and is used as a "benchmark"). The system of WHO International Standards provides a set of "gold standards" from which countries and manufacturers can calibrate their own standards for biological testing. The effective use of vaccines, most therapeutic biotechnology products and many other biologicals depends on the availability of standards supplied by NIBSC, which are essential for quality testing results from different parts of the world to be comparable.

We have continued to see substantial growth in demand for our standards, with an overall **43% increase in numbers of reference materials shipped to customers since 2000**.

Preparation and supply of new standards and reference materials continues to lie at the heart of NIBSC's work, and during the past year a further 15 important International Standards and Reference Materials were established through WHO's Expert Committee for Biological Standardisation.

NIBSC is the world's major producer and distributor of WHO International Standards and reference materials (supplying over 95% of Standards).

Amongst these was a panel of standards for genetic diagnosis, aimed at detection of mutations that represent a risk factor for cardiovascular disease. This project builds on our pioneering work in 2004 to establish the first International Standard for a genetic test and cements NIBSC's position as the world leader in development of quality assurance materials for this vitally important new area of clinical medicine.

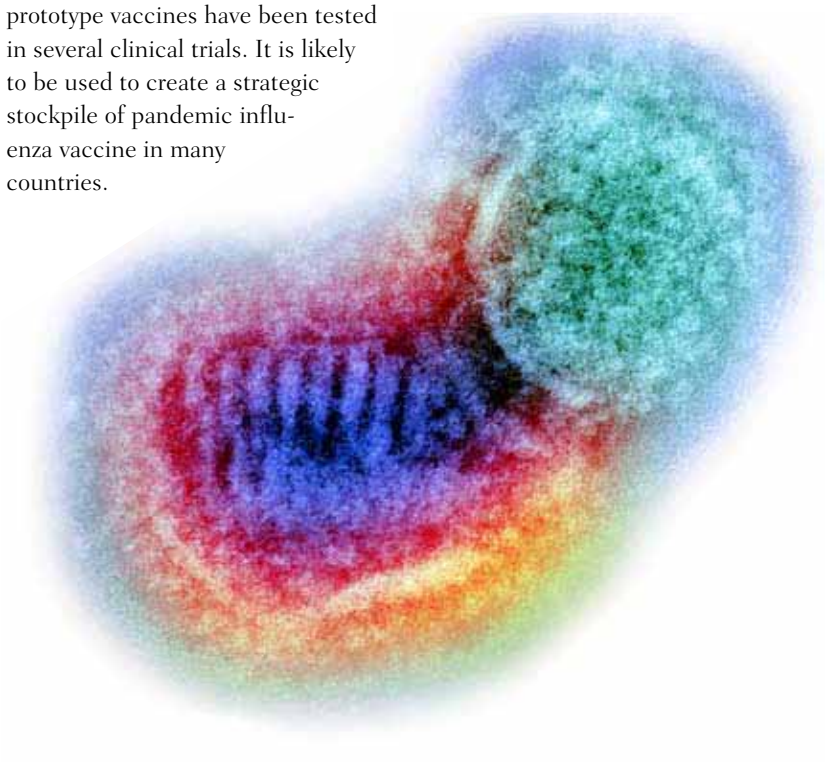
WHO 1st reference reagent for Anti Dengue Serum 1+2+3+4
WHO reference panel for monovalent Anti Dengue 1,2,3 and 4
WHO 1st reference reagent for human VEGF165
WHO 1st reference reagent for human KGF
WHO 1st reference reagent for human KGF (24-163)
WHO 1st International Standard Haemophilus influenzae type b capsular Polysaccharide Polyribosyl ribitol phosphate (PRP)
WHO 1st International Standard for quantitation of Anti-HPA-1a
WHO 1st International Standard for Minimum Potency of Anti-A Blood Grouping Reagents
WHO 1st International Standard for Minimum Potency of Anti-B Blood Grouping Reagents
WHO 1st International Standard for vitamin B12 and serum folate
WHO 1st International genetic reference panel for Prothrombin Mutation G20210A
WHO 1st International Standard for Factor V Plasma
WHO 1st International Standard for Blood Coagulation Factor XI, Plasma, Human
WHO 3rd International Standard for thromboplastin (rabbit, plain)
WHO 2nd International Standard for HIV-1 RNA

Supporting seasonal and pandemic influenza vaccine production

The virulent "bird flu" strain H5N1 has now spread from South East & Central Asia to Europe and Africa and this increased prevalence, together with its particular genetic characteristics, has increased concern about its potential to start a human pandemic. There have been increasing numbers of human cases and fatalities, including the first European cases in Turkey and Azerbaijan in 2006.

Building on its routine work in support of seasonal influenza vaccination, NIBSC has continued to play a central role in planning and preparation for pandemic influenza through the year. NIBSC has advised the Department of Health on appropriate vaccine strategies and worked with regulators and manufacturers to develop new approaches for quality assurance and batch release of vaccines in the event of a pandemic, and for continued provision of reference strains and reagents to support vaccine manufacture.

The original H5N1 vaccine candidate strain prepared by NIBSC in early 2004, NIBRG-14, has now been supplied to 50 manufacturers around the world and the resulting prototype vaccines have been tested in several clinical trials. It is likely to be used to create a strategic stockpile of pandemic influenza vaccine in many countries.



As the H5N1 strain spreads it mutates and changes so that a vaccine reagent created from one outbreak may not be so effective against the virus causing the following one. Therefore, in October 2005, WHO asked NIBSC to construct a new H5N1 vaccine candidate based on the strain associated with an outbreak of avian influenza in Turkey. This has now been completed and is ready for supply to manufacturers (NIBRG-23).

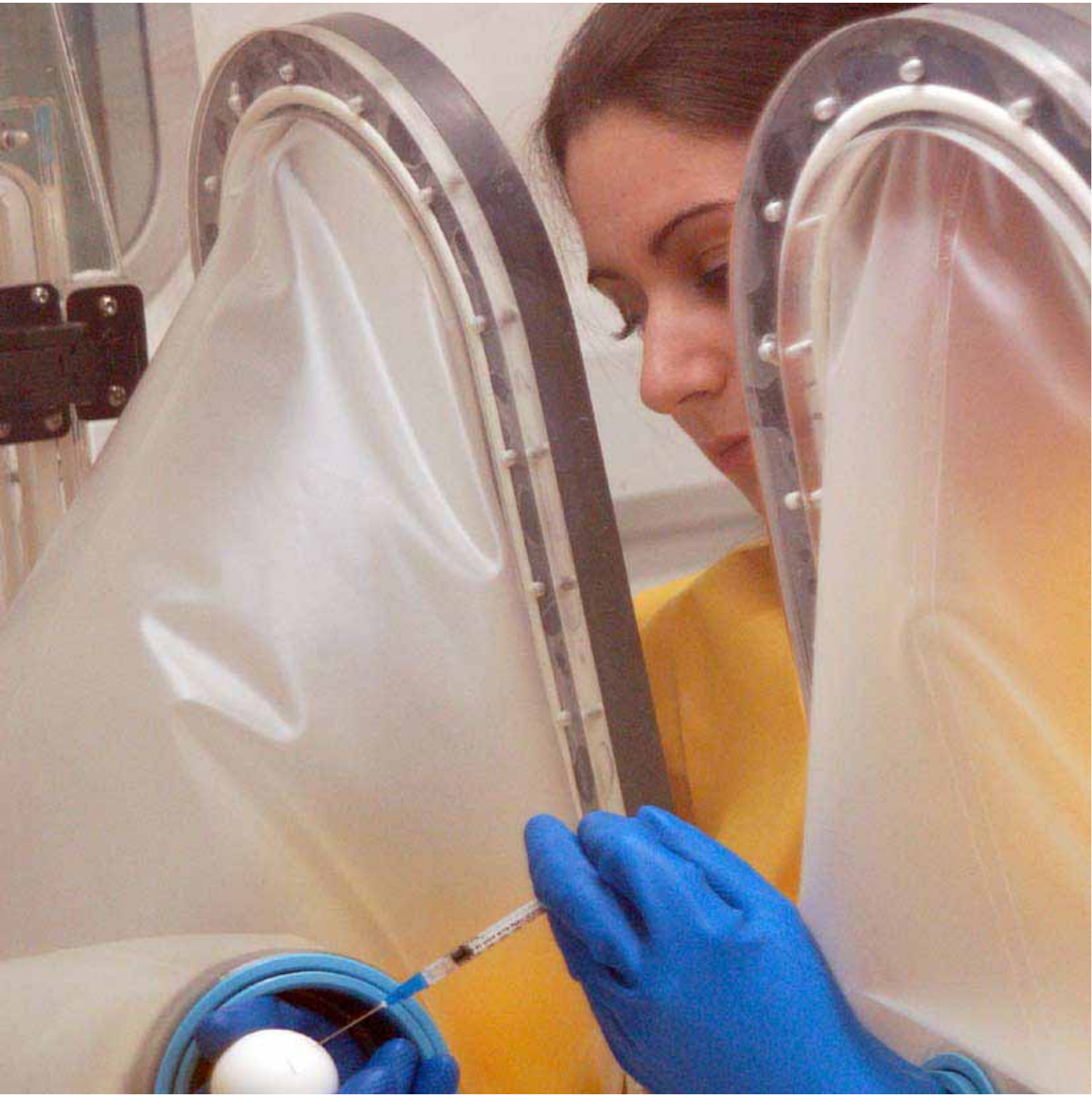
Institute scientists have also been developing a strategy to reduce as much as possible the time needed to create and supply new vaccine strains to manufacturers in the event of an outbreak. Since millions of vaccine doses would be produced each week when full production is underway, every day saved at this stage would have a major impact on public health. Implementation of this strategy will require international co-ordination, and NIBSC is playing a leading role to facilitate the necessary regulatory approvals for this strategy both in the UK and those countries in which major manufacturers are based.

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%.



Trouble-shooting - TGN1412 monoclonal antibody

On 13th March 2006 a group of healthy young volunteers for a Phase 1 clinical trial were injected with TGN1412, a monoclonal antibody-based product designed to activate human T cells and being developed as a treatment for leukaemia. All the participants given the product subsequently developed serious adverse reactions.

As the UK's Official Medicines Control Laboratory (OMCL) for biological medicines, NIBSC received an urgent request from the Medicines and Healthcare products Regulatory Agency (MHRA) to collect and test samples of the product. Over the following two weeks, a team of twelve Institute scientists, working under considerable pressure, carried out a comprehensive series of tests, which showed that the characteristics of the product were as expected from its specification, and hence that the clinical problem was most likely to be an unexpected reaction to the antibody itself. This work made a major contribution to the MHRA's announcement on April 5th of the findings of their preliminary investigation.

This incident provided a very clear demonstration of the value to the UK of NIBSC's broad scientific expertise across a wide range of biological medicines, and of our capacity to bring this to bear rapidly and efficiently in the event of an emergency. It also underlined the potential risks inherent in new product development and, in particular, the need to ensure that the Institute keeps abreast of developments in the field of monoclonal antibodies, one of the fastest growing areas of biological medicine development.

Clinical Trials

Before licensing

Phase I trials	researchers test an experimental drug or treatment in a small group of people (e.g. less than 20) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
Phase II trials	the experimental study drug or treatment is given to a larger group of people (e.g. 100-300) to see if it is effective and to further evaluate its safety.
Phase III trials	the experimental study drug or treatment is given to large groups of people (perhaps several thousand) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

After licensing

Phase IV trials	these studies collect additional information about the drug to assess long term benefits and risks, and to help guide optimal use.

Reagents for standardising CJD diagnostics

Although the incidence of new vCJD (Creutzfeldt-Jacob Disease) cases in humans in the UK has been falling in recent years, the risk that it could be passed on from infected individuals via biological medicines derived from human sources (e.g. blood products) remains and potential diagnostic tests for prion-based diseases are in advanced development. It is vital that any such tests are properly validated before they could be used for screening purposes. NIBSC initiated important collaborative programmes during the year with the Health Protection Agency, the National Blood Services and the Veterinary Laboratory Agency to build up an archive of quality-assured samples that will be crucial for assessing the validity of new testing methods. This complements the existing programme, through the CJD Resource Centre, to generate and supply reference materials to standardize tests for TSE diseases (Transmissible Spongiform Encephalopathies).

Cell Based Medicines and the UK Stem Cell Bank

NIBSC is on course to establish a world-leading position in the emerging field of cell-based medicines. The first phase of the UK Stem Cell Bank (UKSCB) project, funded by MRC and Biotechnology and Biological Sciences Research Council (BBSRC), was completed during the year, with all facilities now up and running, procedures and quality accreditation in place, and over 20 cell lines now accessioned.

The World Technology Network Award for Innovation in Healthcare, a prestigious mark of international recognition, was awarded to the UKSCB, in November 2005, at a special ceremony in San Francisco.

We were also delighted to receive confirmation in early January 2006 that over £9m will be provided by the MRC and BBSRC for Phase II of the Stem Cell Bank project. Over the next five years this will fund support for the existing scientific team and expansion of the bank's capacity through construction of a permanent building on the NIBSC site.

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 (which can multiply indefinitely, each generation being the same as the preceding one) are generated by researchers in universities, both in the UK and abroad.

The UKSCB's job is to amplify each cell line it receives into a bank of identical samples which can be distributed to research teams to help them in their work towards developing stem cell-based therapies for a range of important human diseases.

The tightly-regulated supply of consistent, quality-assured and defined cell lines to accredited researchers from a dedicated and independent cell bank is vital to ensure that the work carried out on these cells is both ethically assured and of the highest quality.

UK StemCellBank

http://www.ukstemcellbank.org

NIBSC has also carried out work on another crucial cell banking project. A quality-assured bank of standardised cells required to support the growth of human skin cells for grafting purposes has been distributed to a number of skin grafting centres for evaluation.

Innovation - New Vaccines

Anticipating the introduction of new vaccines is a key strategic aim for NIBSC. An important element of the strategy is to work in close collaboration with manufacturers and regulators to develop the methodologies needed for batch release of promising new vaccines.

In the last year there have been exciting advances particularly in development of vaccines against Human Papillomavirus (HPV) (the causative agent of both cervical cancer and genital warts) and Rotavirus (a common cause of childhood diarrhoeal illness). Marketing authorization applications were submitted for each of these vaccines in both the US and Europe with licensure possible in 2006. The Institute has developed, in collaboration with the manufacturers, the appropriate methodologies for batch release of these vaccines. In the case of HPV, we have begun to develop a panel of international reference materials to underpin accurate measurement of immune responses to the vaccines and diagnosis of infection, essential to monitor the impact of any vaccination programme.

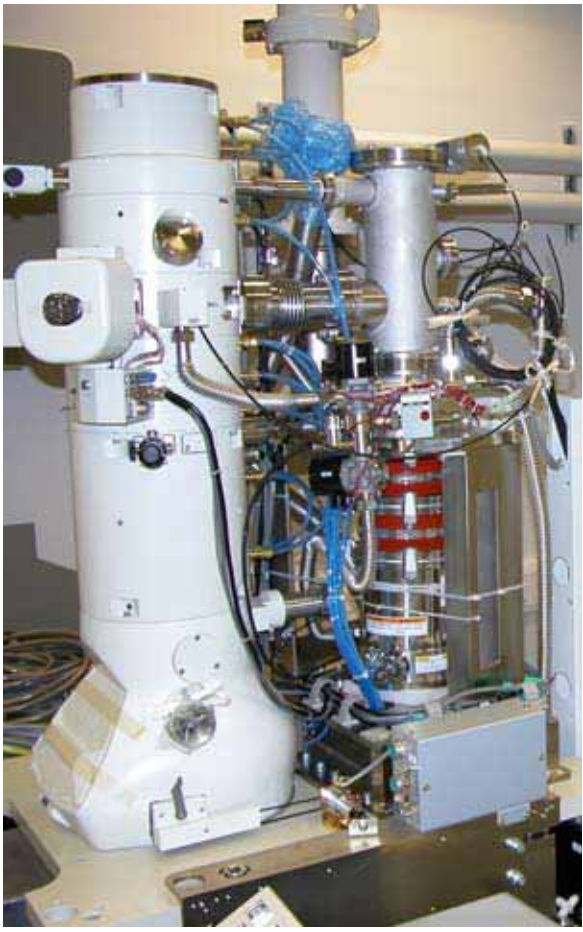
Resources & Infrastructure

During the year a substantial programme of improvements to the fabric and facilities of the Institute was carried out. Amongst the many projects, two in particular stand out:

- Our Category 4 high containment laboratories, originally built in the 1980s, were completely refurbished. This development will enhance significantly the specialist national capabilities for research and development work on potentially lethal infectious disease agents.
- The Institute's facilities for imaging were substantially improved through replacement of 30-year old equipment for transmission and scanning electron microscopy.

NIBSC's management structure was further refined during the year with the creation of a new Biotherapeutics Group through merger of the former Haematology, Immunology and Endocrinology Divisions. This move has allowed more efficient use of support services and has enhanced flexibility in forward planning.

The Institute's Containment Level 4 laboratories underwent a £1M upgrade to enable NIBSC to continue to work with pathogens which require the highest level of biocontainment (e.g. avian influenza isolates). NIBSC is one of a handful of facilities in the UK equipped to deal with such dangerous pathogens.



Stakeholder Links

"WHO knows from long experience that to have the stamp of "NIBSC" on a product, whether this is an international reference preparation, or advice on a scientific issue, or on the content of a training course, attaches a credibility to that product which cannot be obtained elsewhere. "

Extract from Stakeholder Consultation

Preparing for the anticipated merger with Health Protection Agency (HPA) in 2007/8 was a major objective during the year and the Institute has established good working relationships with the HPA in many areas including Finance, Health and Safety, Operations, Human Resources, staff organisations and IT, building on the strong scientific relationships that already existed. A major project to integrate NIBSC's financial system with that of the HPA through implementation of new Oracle-based financial ledger was largely completed by April 2006.

A joint project team and plan has been established to oversee the merger process and high level discussion is underway with Department of Health on appropriate governance mechanisms following the formal consultation process with stakeholders on the merger conducted late 2005. This consultation sought feedback on several important aspects of the proposed merger with HPA, including the validity of the Institute's mission in present day circumstances, the importance of the NIBSC name and appropriate governance mechanisms for the Institute with the HPA to deal with potential conflicts of interest.

The results underlined the esteem in which the Institute is held nationally and internationally, and they strongly endorsed the continuing importance of NIBSC's work in standardisation and control of biological medicines.

Stakeholders also gave strong support to the retention of the NIBSC name, which was felt to be an internationally recognised mark of scientific excellence.

"NIBSC enjoys an international reputation for excellence… It is a National Asset"

Extract from Stakeholder Consultation

National & International Advisory Activities

Advice from NIBSC helps to shape the policies of international bodies including WHO and the European Union as well as those of the UK Government and the Institute has always had a key role in providing scientific advice and expertise to a large number of organisations. Scientists at NIBSC are members of key committees at both European and International level. NIBSC also maintains close technical links with the pharmaceutical industry, especially through industrial associations and professional bodies.

During 2005/06, Institute staff have contributed to the following advisory groups and committees:

United Kingdom

- Academy of Medical Sciences Gene Therapy group,UK
- Advisory Committee on Dangerous Pathogens
- Advisory Committee on the Contained Release of genetically manipulated organisms
- Biosciences Federation Steering Group on Infection
- Brighton Collaboration on Vaccine Safety
- British Blood Transfusion Society Special Interest Group on Transfusion Microbiology
- British Pharmacopoeia
  - Panel of Experts on Immunological Products
  - Panel of Biological and Biotechnological Expert
  - Panel of Experts on Blood Related Products
  - Committees H and N
  - Statistics Working Group
- British Standards Institute
  - CH/194/100 committee, Medical Devices Utilizing Tissues.
  - CH/194 committee, Biological evaluation of medical devices.
  - CH/212 committee (IVDs).
  - Panel SS/6/-/4 Statistical Aspects of Reference Materials
- British Society for Histocompatability and Immunogenetics
- British Blood Transfusion Society
- Committee for the Safety of Medicines Biologicals subcommittee
- COST (European Cooperation in the field of Scientific and Technical Research) Laboratory Animal Science & Welfare Working Group Society for Applied Microbiology Committee
- Fund for the Replacement of Animals in Medical Experiments
- Health Protection Agency
  - Forum on Deliberate Release Agents-Strategy Group
  - Meningococcal Forum.
- Joint Committee on Vaccination and Immunisation-
  - Sub-Committees on BCG vaccines, pertussis, anthrax and influenza
  - Joint Professional Advisory committee to the Blood Services
  - Representation on all standing advisory groups
- London Technology Network
- National Vaccine Evaluation Consortium Steering Group

- NEQAS Specialist Advisory Groups
- Meningitis Trust Scientific Committee
- Meningitis Research Foundation Research Advisory Panel
- MRC College of Experts
- Parenteral Society: Freeze Drying Working Group
- United Kingdom Accreditation Service
  - Biological and Medical Sciences Technical Advisory Committee
  - Reference Materials Project Steering Committee
- UK Pediatrics group
- UK Reference Materials Working Group
- Veterinary and Public Health Standardisation Committe

Europe

- EQQM
  - Biological Standardisation Programme Steering Committee
  - Working party on in vitro pyrogen testing
- EMEA
  - Vaccine Expert group
  - Gene Therapy Expert group
  - Biotech Working Party
  - Ad hoc Influenza group
  - Plasma virus safety group
  - Expert Committee on recombinant and plasma-derived FVIII products and inhibitor development
- JCTLM (Joint Committee for Traceability in Laboratory Medicine): Protein Review Team, Working Group I.
- European Pharmacopoeia Commission
  - EDQM/EP working Party/In vitro pyrogen test
  - Group of Experts No. STA (Statistics)
  - Group of Experts No 15 (Vaccine and Sera)
  - Group of Experts 6B (Human Blood and Blood products)
  - Working Party on Monoclonal Antibodies
  - Working Group on Botulinum toxin
- EU FP6 AIDS Vaccine Integrated Project (AVIP) Steering Committee
- ECVAM Collaborative Programme
- European Task Force on Haemophilia
- OMCL Laboratory network

WHO

- Consultation Group on Cytokine Standardisation
- Working Groups on
  - Pertussis Vaccines;
  - Diphtheria and Tetanus Vaccines;
  - Cholera Vaccines;
  - Stability of reference materials;
  - Influenza vaccines;
  - Measles
  - Expert Committee on Biological Standardisation
- WHO Monitoring Group on Gene Therapy Products
- Ad hoc Advisory Group on polio eradication
- Consultation group on Live Viral Vectored Vaccines

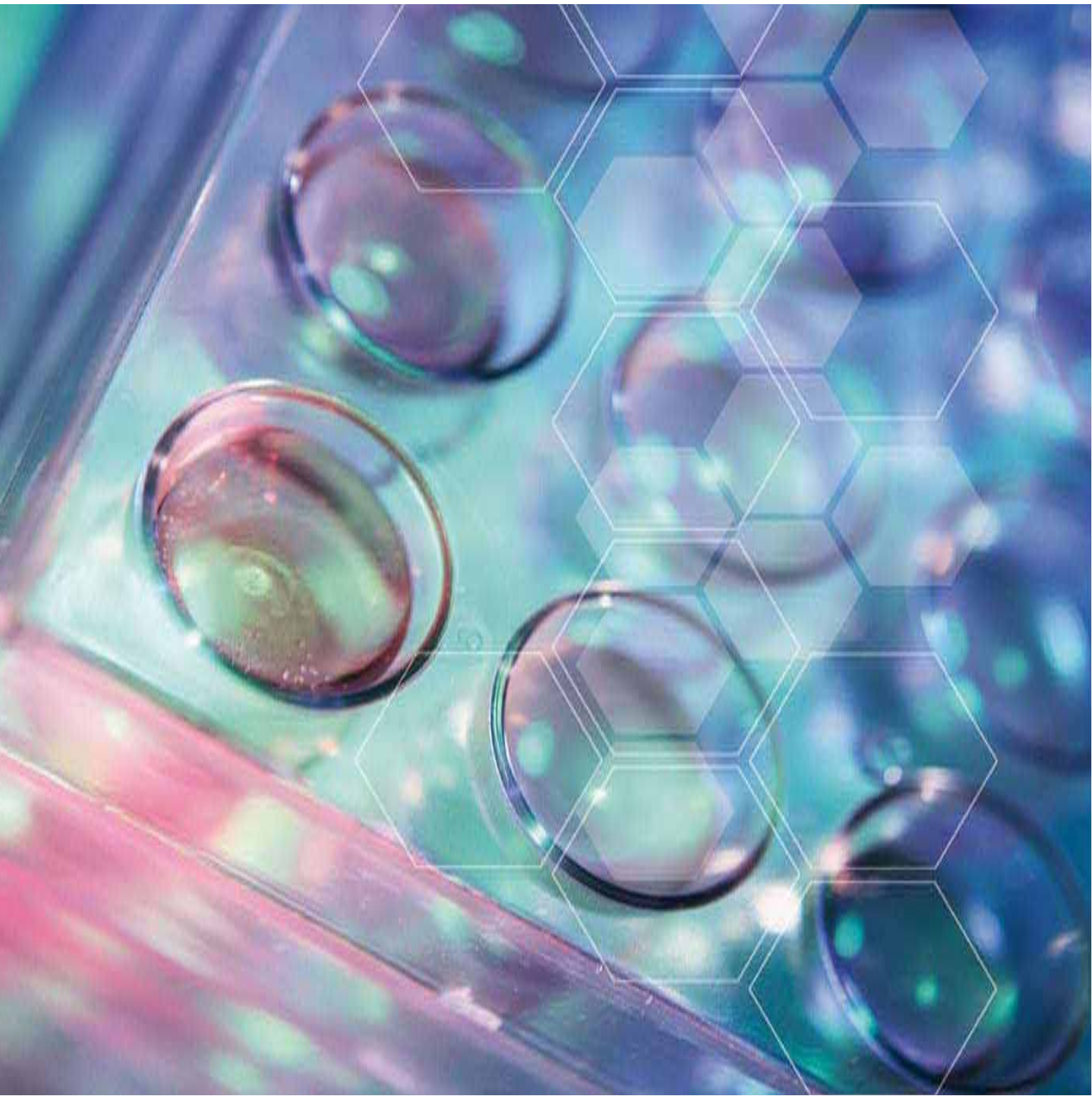
Training Activities

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 continues at a high level. NIBSC is a key part of the WHO Global Training Network, currently providing an intensive, 4-week course in Quality Systems to staff of National Regulatory Authorities in developing countries. This will soon be complemented by a **training course in Biological Standardisation**.

"We feel that NIBSC plays a pivotal role internationally in biological product characterization, standardization, safety and methods development, and in its advisory capacity to stakeholders. …There is a need to maintain this critical expertise in the rapidly expanding and diversifying biologics pharmaceuticals sector"

Extract from Stakeholder Consultation



Management Commentary

HM Treasury has introduced a new requirement for public bodies to provide a Management Commentary in their annual reports in line with the Operating and Financial Review of UK Reporting Standard Number 1 for companies.

The development and performance of the Institute during the financial year

The National Institute for Biological Standards and Control (NIBSC) is the operational unit of the NBSB. It is a government owned, not-for profit, research institute dedicated to the protection of public health in the UK and worldwide through the testing of biological medicines, the development and distribution of biological reference materials and standards and all aspects of scientific research supporting these aims.

NIBSC's activities are determined by the Board and agreed by the Minister for Public Health through an annual planning cycle. The process identifies numerous work programmes including specific key targets which are published in the annual report.

Rapid progress in medical science and the application of biotechnology has led to an increased rate of development of new biological medicinal products for use in the prevention, diagnosis and therapy 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 NIBSC to ensure the safety and efficacy of the new products and reference standards. Safety considerations, particularly microbiological, also require the development and application of increasingly complex tests for infectious agents, for example in blood and blood products). 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.

The Institute's activities cover the whole field of biological medicines. While some are relatively stable in nature, changing incrementally from one year to another, other pubic health demands arise suddenly. The physical size of the Institute and its complement of scientists are largely fixed so that new challenges and targets must be regularly prioritised against existing ones.

Against the background of increasing numbers of biological medicines, individual products come and go and the related research, testing and standardization work at NIBSC modulates accordingly.

The UK Stem Cell Bank acquired its first quality-assured stem cell lines for research and, eventually, therapeutic use.

National Biological Standards Board

Concern about the spread of avian influenza across the globe persists, and the Board has continued to use advanced genetic techniques to develop appropriate human vaccine strains. These will be used to combat a potential outbreak of pandemic human influenza if avian strains acquire the ability to infect the human population.

During 2005/06 other important issues in public health included the introduction of the new 5-component childhood vaccine in the UK, preparation for the introduction of diagnostic tests for variant Creutzfeldt Jakob Disease and the development of further genetic reference standards following production of the first WHO International standard by NIBSC in 2004.

The financial structure of the Institute reflects these features. Over recent years the pricing policy of NIBSC services has moved firmly towards full cost recovery for those activities for which customers should pay: pharmaceutical companies for control testing of batch released products and a wide range of industrial, medical and academic institutions for biological reference materials. A further step towards full cost recovery was taken at the end of the financial year by introducing price bands for control testing work according to the complexity of the product testing required. This leaves the UK government and taxpayer supporting the core infrastructure and research on which these services to the UK and the world are based. From the resources provided by government and customers, NIBSC is able to provide, without charge, international biological standards to the National Control Laboratories of every nation. It also collaborates with a worldwide network of scientists and publishes numerous research papers.

NIBSC has important relationships with academic, government and commercial bodies in the fields of science and healthcare in many countries. These reflect its various roles and services. NIBSC encourages commercial interactions with third parties where these support its core mission and where any potential conflicts of interest can be managed. In accordance with UK government policy, NIBSC exploits intellectual property to maximize the advance of science to the benefit of public health, while protecting the interests of the tax payer funding the research.

This scientific work was conducted against the background of the planned merger of the Institute into the UK's Health Protection Agency by April 2008. A merger plan and project board have been established and cross representation of the Board and staff members of the two organizations on committees has been established to minimise any adverse impact of change. During 2005/06 progress towards integration included the implementation of the HPA's finance and resource management software at NIBSC to operate from April 2006 and arrangements to transfer members of the Board's closed pension scheme to an alternative scheme.

National Biological Standards Board

Financial results

Core government funding made up more than half of the Board's income and comprised "Grant in Aid", the government share of the depreciation charge on fixed assets and the notional financing of the Institute's capital base. The balance, covering 31% of the Board's expenditure, came from third parties including academic grant donors and customers for control testing, contract services and distribution of reference materials.

The financial regime imposed by the Treasury on public bodies such as NBSB is now based on "resource accounting" (technically "accrual accounting") rather than earlier cash based systems. However, there is no capacity to borrow or to hold general surpluses so that any significant imbalance in the income and expenditure account is typically the result of non-cash items. The net surplus of £1.73 million reported for 2005/06 is after crediting gains of £1.93 million in relation to stocks and after charging £225k of increases in the provision for the future costs of previous early retirements and £213k arising from the revaluation to current transfer value of the balance due from the Department of Health for the NBSB Pension Scheme. Before these non-cash items the surplus for the year was approximately £0.2 million.

NIBSC holds a large number of international reference standards in the form of ampoules and vials manufactured from materials normally donated to NIBSC free of charge for the purpose. To this bulk donation NIBSC adds value through scientific evaluation, manufacture and controlled storage of the resulting reference standard. The stock held represents several decades' future supply of materials and the economic value of NIBSC's investment in them is calculated for accounting purposes by a formula which considers the cost of preparing the standards and the handling charges which may be recovered for them. Changes in the value of standards stocks are a significant element in the annual financial result of the Institute. As noted above, the overall reported surplus for 2005/06 of £1.73 million included gains of £1.93 million in the valuation of stocks of biological reference materials. The major part of this gain arose from the impact of the increasing volumes of standards produced in the year and held at the year end to meet the increased demand for them.

The Board has a substantial asset base, reflecting the high level of plant and equipment required to support the complex science carried out at NIBSC. The annual depreciation charge is 12% of annual operating expenditure and additions to fixed assets were over £4 million in 2005/06, including scanning and transmission electron microscopes, refitting the Category 4 containment facility and extensive refurbishments to laboratories.

The value of goods and services invoiced to customers outside the United Kingdom during the year was £4.5million.

National Biological Standards Board

The Institute's position at the end of the year

The Institute's position at 31 March 2006 was stronger than for some time. After several years with no increase in annual core funding and no allowance for inflation an additional award of £985k was received from the Department of Health in March 2006. A further £674k was received to cover specific and non-recurrent costs. The effect of this extra revenue at the end of a year which had seen constraint on staff recruitment was an approximate break even position for income and expenditure (before the non-cash adjustments referred to above). The balance sheet was strong with sufficient liquidity despite temporarily high levels of trade debtors and trade creditors. The future liabilities of the NBSB Pension Scheme are shown as a provision and are offset by the related debt due from the Department of Health to fund them. Both amounts have been increased to reflect the latest transfer value of the scheme calculated by the Government Actuary's Department.

The main trends and factors underlying the development, performance and position of the Institute which are likely to affect it in the future.

Building on its increased award in 2005/06, a three year settlement from the Department of Health covering the years 2006/07 to 2008/09 provides a sound basis for financial balance in the future and includes annual allowances for inflation. Importantly, the annual capital grant has been raised substantially from 2006/07 so that it covers the annual depreciation charge and allows the orderly replacement and enhancement of NIBSC's scientific equipment and infrastructure year by year.

Demand for biological reference materials has grown annually and total income from handling fees has increased in value terms by 93% over the last 5 years allowing the continuing supply of international standards free of charge to National Control Laboratories. The share of standards distributed relating to influenza, 29% of the total distributed in 2005/06, is a significant part of the total income from standardization work and may be vulnerable to future decline if world concern over influenza subsides. The growth and diversity of products and customers in this market is clear evidence of a continuing role for biological standardisation and the work of NIBSC.

Against this strong and optimistic outlook, the Board notes a number of risk factors for its future.

The Board introduced a banded pricing structure for its control testing work from April 2006, replacing the lower fixed charge for a test certificate which had applied to all products previously. This development reflected the increasing number of multiple component vaccines, the wide variation of resources employed to test different products, and the need to recover full costs from customers with a choice of alternative providers in Europe. The change in prices represents some risk to NIBSC's future share of activity in control testing to the extent that customers are price sensitive and

that other Official Medicine Control Laboratories may offer more competitive or subsidised prices. Regardless of service pricing, NIBSC's place in the competitive European control testing field is subject to changes in products and in the preferences of manufacturers and governments, particularly since the last expansion of EU membership. NIBSC however remains confident of the speed and quality of its service and the depth of scientific experience which it offers to manufacturers.

The Health Protection Agency, in common with UK National Health Service organizations, has adopted the employment terms and pay structures known as "Agenda for Change". The new terms are expected to apply to NIBSC staff from the date of its merger into the HPA and experience of other organizations is that this will cause a net increase in staff costs. The Board is assessing the likely impact of Agenda for Change so that sufficient resources are identified to meet the cost and stable operation of NIBSC within the HPA is assured.

Other concerns include the future of particular areas of work and succession planning. Individual projects have been identified and financed to manage the continuity of skilled scientific resources in a number of key areas. NIBSC's contribution will thus be assured in fields where the loss of expertise would be a significant scientific set back for world health programmes.

NIBSC's role in providing international standards is dependent on the continuing free movement of biological materials by mail and specialist air couriers. These specialist suppliers are closely supported.

The Institute will continue to work towards its harmonious and efficient integration into the larger structures of the HPA to the mutual advantage of both organisations. It has completed the adoption of the Oracle Financials software already in use in the HPA and in line with central government initiatives to harmonise financial systems.

It is important that its merger with the Health Protection Agency does not dilute or diminish the research programmes that underpin NIBSC's control testing and standardisation work. Extensive discussions have taken place with representatives of the Health Protection Agency and the Department of Health to ensure that the eventual arrangements for corporate governance do not have an adverse impact on these aspects of the NIBSC mission.

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 2005/06 Key Targets is shown below.

Objective	**Progress**
Meet batch release testing requirements for Pediacel and implement improved, validated methods for assay of residual pertussis toxin and diphtheria potency	Batch release testing performed promptly, but issues with testing still remain. Improved methods still undergoing validation/ awaiting European Pharmacopoeia approval
In collaboration with manufacturing partner, supply and calibrate H7N1 avian influenza vaccine material for completion of clinical trial; initiate development by reverse genetics of a comprehensive panel of vaccine candidates against potentially dangerous avian influenza A virus strains	New quality control reagents prepared and ready for H7N1 vaccine assessment, vaccine still to be supplied by manufacturer. New engineered vaccine strain prepared for H5N1 (Turkey) isolate. New approach proposed to reduce time for generating vaccine seeds from 3 months to 3 weeks based on detailed process mapping
Establish programme for accession of at least 10 new embryonic stem cell lines into UK Stem Cell Bank	23 approved embryonic stem cell lines received into the Bank of which 7 are at distribution stock level
Prepare and test 3T3 mouse feeder cell line bank ready for distribution to skin engraftment centres	3T3 mouse feeder cell line bank ready for distribution – currently under validation by engraftment centres prior to safety testing

National Biological Standards Board

Objective	Progress
Establish appropriate batch release assays for Human Papilloma Virus vaccines	Assays developed with manufacturer; further validation underway
Complete analysis of consistency lots to support NVEC clinical trial of Staphylococcus Aureus vaccine	Completed, but product to be discontinued by manufacturer following disappointing trials
Establish batch release assays for live attenuated rotavirus vaccine	Preliminary assays developed; further validation under way
Complete collaborative study on proposed International Reference Panel for prothrombin 20210 gene mutation	Collaborative study completed, report sent to WHO/Expert Committee on Biological Standardization, International Reference Panel established by WHO October 2005
Preparation and distribution of reference material panels to underpin development of in vitro tests for vCJD	New reference materials prepared internally and in collaboration with Veterinary Laboratory Agency. Collaborative study for developers to assess relative suitability of assays under way
Develop assay for detection and measurement of unwanted antibodies induced by anti-TNF products	Neutralisation and binding assays developed; application of assays for evaluation of clinical patient samples planned
Maintain accreditation status: ISO17025 for control testing activities; ISO 9000:2000 for processing, storage and supply of reference materials; CE marking as appropriate for diagnostic standards	Accreditation/certification status maintained with only minor non-compliances
Meet Institute targets for timeliness of product testing and supply of standards and reference materials	Targets met except for products out of compliance. Supply of standards and reagents on schedule. Evaluation and release of batches of products completed within time frame. Problems with some immunoglobulin batches identified and appropriate action/measures taken.

National Biological Standards Board

Objective	Progress
Complete Category 4 facility refurbishment programme	Business case approved, work tendered and project completed in April 2006
Install and commission new electron microscopy facility: recruit key staff and establish new central imaging service function	Business case approved and tendered, site prepared and equipment delivered. Scanning electron microscope operational and transmission electron microscope under commissioning by April 2006. One staff member appointed
Establish an off-site contingency stock for key biological materials	Supplier identified and specification agreed. Audit work on new equipment/facilities needs to be completed before transfer (2nd Quarter 2006)
With Department of Health, Health Protection Agency, MHRA and other NIBSC stakeholders, establish an appropriate mechanism for integration into HPA that preserves NIBSC's excellence, scientific output and international reputation	Merger workstreams developed and merger project board formed between HPA/NIBSC. DH consultation process completed and proposal prepared for Minister
Establish funding mechanism for a new Training Centre, initiate design/build project and complete pilot training course	Project not committed due to uncertainty about finance/ ALB review. Capital funding recently resolved for three years from 2006/07
Manage the financial response to the Arm's Length Body review process and ensure savings plans are met	2005/06 budgets set and income plans devised to meet ALB Review decisions of early 2005. Timely responses provided to ALB Review Team leading to final settlement which preserved scientific output while reducing back office costs
Enhance income generation and profitability through increased market analysis, refined costing and pricing, and commercial negotiation	Banded price structure for control testing developed and implemented in the last quarter of 2005/06 to help assure financial balance in 2006/07. Permanent Business Development Manager appointed

Funding Sources

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.

Total funding/income in 2005/06 was as follows:

Remuneration Report

Remuneration and Terms of Service Committee

The remuneration of non-executive Board members and the Board Chairman is set by the Department of Health. The remuneration of the Director of NIBSC is managed by a Remuneration Committee comprising:

Professor Gordon Duff,
Non-executive Chairman of the Board
Professor Janet Darbyshire,
Non-executive Deputy Chairman of the Board
Gill Noble,
Non-executive Board member
Tony Jowett,
Head of HR

The remuneration of all other staff is the responsibility of the Board through the Director and Human Resources staff. This function is overseen by the Board and its Finance and General Purposes Committee.

Remuneration Policy

Non-executive board members

Non-executive board members, including the Chairman, are appointed by the Secretary of State for Health as advised by the NHS Appointments Commission, for a defined term, normally four years. They are appointed through a rigorous process of open competition against an agreed specification of the roles and capabilities required. Non-executive Board members are eligible to be considered for reappointment at the end of their term of office.

The Chairman of the Board receives a salary and the remaining non-executive board members receive only attendance fees for their duties on the Board and its committees. The level of the attendance fee is set and reviewed periodically by the Secretary of State for Health.

Non-executive board member remuneration is not pensionable.

The remuneration of non-executive board members is not performance related, but performance is assessed by the Chairman of the Board through a periodic appraisal process.

In addition to remuneration, members of the Board are entitled to reimbursement of travel and accommodation expenses incurred in carrying out their Board duties on terms comparable to staff as set out in the Staff Code.

The Director

The Board's remuneration package for the Director of NIBSC consists of a salary, and pension provisions. In determining the remuneration of the Director, the Remuneration Committee has regard to:

- Pay and employment policies elsewhere in the public sector and scientific institutions especially when determining annual salary increases;
- The Principles of Good Governance relating to senior executives' remuneration appropriate to the Board;

- The need to recruit, retain and motivate suitably able and qualified people to exercise their different responsibilities;

The Director's salary is reviewed annually, in line with guidance from the Department of Health and changes to terms and conditions of employment in the NHS.

Senior staff

The remuneration of all Board staff other than the Director of NIBSC, is determined by the Board's Staff Code. This includes the executive heads of administrative functions and of the scientific divisions. The Board is a member of the pay club of the Biotechnology and Biological Science Research Council which sets the pay scales and negotiates collective pay awards annually on the Board's behalf.

The increase in basic salary from 2004/05 to 2005/06 was 3.0 per cent.

There is a merit pay scheme for staff of the Board below the level of Director which allocates an amount not exceeding 0.5% of the total pay bill on merit between all eligible staff on the basis of objective assessments.

The Director and senior staff are members of the NHS Pension Scheme, details of which are included in the notes to the financial statements. They hold employment contracts with a normal retirement age of 60 or 65. Early termination, other than for misconduct, would result in the individual receiving compensation in accordance with the Board's terms and conditions.

National Biological Standards Board

Remuneration and Pension entitlements

Remuneration of the non-executive Board Members

The total remuneration of the Chairman of the Board, Professor Gordon Duff, for the year ended 31 March 2006 amount to £15,420. In 2005 the Chairman also received a total of £15,420.

The other non-executive Board members received the following amounts (including 2004/05 arrears) in respect of attendance allowances for carrying out their Board duties and responsibilities as follows:

	2005/06 £	2004/05 £
Professor D Calam	725	435
Professor J Hughes	-	435
Professor J Darbyshire	580	435
M Hindle	1,015	505
Professor D Latchman	290	870
Professor C Lee	580	580
G Noble	2,030	1,022
Dr J Petricciani	372	580
A Robertson	1,595	1,012
Professor J Sissons	145	435
Professor Sir J Skehel	145	145
Dr L Tsang	290	435
	7,767	**6,889**

No other benefits were received by any non-executive Board member.

National Biological Standards Board

Remuneration of the Director

The remuneration of the Director of NIBSC, Dr Stephen Inglis, for the year 2005/06 was £145,320. In 2004/05 his remuneration was £164,205 including arrears of salary of £25,000. These figures exclude employer's pension and National Insurance contributions.

Remuneration of senior staff

The salary of the senior management employed by the Board during the year ended 31 March 2006, classified into bands of £5,000, were as follows:

	Salary 2006 £'000	**Salary 2005 £'000**
Dr S Inglis Director	145-150	160-165
V Knight Head of Finance/ Board Secretary	60-65	60-65
S Murray Head of Operations	60-65	55-60
A Jowett Head of Human Resources	45-50	40-45

"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.

No benefits in kind were received by the Director or any member of the senior staff and no amounts were payable to third parties for services of any of them. During the year no awards or compensation payments have been made to former Directors or senior staff.

Pension Entitlements of the non-executive Board members

The remuneration of the non-executive Board members is not pensionable and neither the Board Chairman nor any of the non-executive members of the Board were members of a pension scheme associated with the Board, except for Professor Derek Calam who is a pensioner member of the NBSB Pension Scheme by virtue of his former employment at NIBSC before his retirement and subsequent appointment to the Board.

Pension Entitlements of the Director and senior staff

	Real Annual Increase in Accrued Pension (bands of £2,500)	Real Annual Increase In Lump Sum (bands of £2,500)	Accrued Pension as at 31 March 2006 (bands of £2,500)	Lump Sum Value as at 31 March 2006 (bands of £2,500)	Cash Equivalent Transfer Value as at 31 March 2006 (bands of £1,000)	Real Annual Increase in Cash Equivalent Transfer Value (bands of £1,000)
	£'000	£'000	£'000	£'000	£'000	£'000
Dr S Inglis Director	0.0-2.5	5.0-7.5	2.5-5.0	80.0-82.5	457-458	58-59
V Knight Head of Finance/ Board Secretary	2.5-5.0	5.0-7.5	10.0-12.5	32.5-35.0	175-176	34-35
S Murray Head of Operations	0.0-2.5	0.0-2.5	2.5-5.0	7.5-10.0	47-48	13-14
A Jowett Head of Human Resources	0.0-2.5	0.0-2.5	2.5-5.0	7.5-10.0	59-60	12-13

National Biological Standards Board

The Director, senior staff and staff members of the Board are entitled to membership of the NHS Pension Scheme on the same basis as all Board employees. The pensions entitlements of the members of the Director and senior management are shown above.

The Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a scheme 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 include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the NHS Pension Scheme. 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. Where a member is ineligible to transfer their benefit, the CETV is nil. CETVs are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries.

The real increase in the value of the CETV 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.

S C Inglis
Accounting Officer
National Biological Standards Board
18 July 2006

National Biological Standards Board

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 on or before April 2008.
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.

Additional Corporate Information

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.
Disabled persons	The Board, as a responsible employer, acknowledges its obligation to employ disabled people. It gives full and fair consideration and ensures the equal treatment of disabled applicants for all types of vacancy where their disability is not an absolute occupational disqualification. Any disabled candidates meeting the essential criteria set out in the person specification for the job will be interviewed. Wherever possible, after any necessary rehabilitation training , the Board retains or transfers to more suitable work any otherwise capable employees who become disabled during their employment, and who do not wish to accept ill-health retirement benefits. The Board accepts that disabled employees should have equal opportunities with other employees for training, promotion and career development in order to use their capabilities to the full. The Board has particular regard for the safety of its disabled employees. It expects individuals upon whom safety responsibilities have been placed, to pay attention to the safety of the various workplaces under their care and the means of escape in case of fire in relation to the needs of people with disabilities.

National Biological Standards Board

Employee involvement

The Board is committed to the belief that well informed and properly consulted employees will feel that they are an integral part of the Institute and therefore work more effectively. The Board also believes that all employees have a contribution to make to the running and future planning of the Institute and welcomes suggestions they may make.
Information on all aspects of the Institute's work is given through staff briefings, meetings, workshops, seminars, through e-mail and notices. The process of upwards communications is being developed currently.
The consultation rights of recognised Trades Unions through the Staff Side are established at the Institute and acknowledged in the Staff Code. Other systems of communicating with staff are not intended to infringe or supersede these arrangements.

Two members are elected from the staff of the Institute for appointment to the Board. These staff Board members also serve on the Board Committees including the Finance and General Purposes Committee, Audit Committee and the Scientific Policy Advisory Committee.

Invoice payment policy

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 2005/2006, the Board paid 79% (2004/05: 49%) of invoices within 30 days, representing 67% (2004/05: 50%) 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.

National Biological Standards Board

Audit	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. The Board can confirm that there is no relevant audit information of which the auditors are unaware: the Accounting Officer has taken all the steps he ought to ensure that they are aware of relevant audit information; and the Accounting Officer has taken all the steps he ought to establish that the Board's auditors are aware of the information. 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 2006.
Board members	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 Hon DSc Professor J H Darbyshire OBE FRCP FFPHM 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 Dr N Rose PhD (from November 2005) Professor J G P Sissons MB BS MD FRCP MRCPath Professor Sir John Skehel FRS Dr S Thomas PhD (to November 2005) Dr Lincoln Tsang LLB PhD FRSC FIBiol FRSA MRPharmS Barrister & Solicitor

S C Inglis
Accounting Officer
National Biological Standards Board
18 July 2006


CCTV
National
Institute for
Biological
Standards &
Control
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 comply with the requirements of the Government Financial Reporting Manual and in particular to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements;
- apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards as set out in the Government Financial Reporting Manual 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".

Statement on Internal Control for the year ended 31 March 2006

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 a continuous process designed to identify and prioritise the risks to the achievement of the Board's 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 2006 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 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;
- accreditation to formal quality systems covering parts of the Board's work.

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.
In 2005/06 the Board continued to develop its risk management procedures and in particular to link the risk register with NIBSC's key targets and Divisional work programmes as set out in the annual Business Plan. This has further improved the reporting of risks internally and the management of related action plans.

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. The opinion of the internal auditors for the year ended 31 March 2006 based on the controls they evaluated was that the Board had adequate and effective risk management, control and governance processes to manage the achievement of its objectives.

Control issues during the year

In reaching their overall opinion on the Board's system of internal control the internal auditors made recommendations on the frequency of review of the risk register, on improving the system for inducting and training new Board members and on the process for setting and reporting performance against budgets, all of which have been implemented by the Board.

S C Inglis
Accounting Officer,
National Biological Standards Board
18 July 2006

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

I certify that I have audited the financial statements of the National Biological Standards Board for the year ended 31 March 2006 under the Biological Standards Act 1975. These comprise the Income and Expenditure Account, the Balance Sheet, the Cashflow Statement and Statement of Total Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them.

Respective responsibilities of the Board, Director and Auditor

The Board and Director are responsible for preparing the Annual Report, the Remuneration Report and the financial statements in accordance with the Biological Standards 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. These responsibilities are set out in the Statement of Board and Director's Responsibilities.

My responsibility is to audit the financial statements in accordance with relevant legal and regulatory requirements, and with International Standards on Auditing (UK and Ireland).

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Biological Standards Act 1975 and directions made by thereunder the Secretary of State with the approval of HM Treasury. I also report 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 to you if, in my opinion, the Annual Report is not consistent with the financial statements, if the Board has not kept proper accounting records, if I have not received all the information and explanations I require for my audit, or if information specified by relevant authorities regarding remuneration and other transactions is not disclosed.

I review whether the statement on page 50 reflects the Board's compliance with HM Treasury's guidance on the Statement on Internal Control, and I report if it does not. I am not required to consider whether the statement on internal control cover all risks and controls, or form an opinion on the effectiveness of the Board's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises only the Annual Report and the Management Commentary, excluding the audited part of the Remuneration Report. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of audit opinion

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Audit-

ing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the Remuneration Report to be audited. It also includes an assessment of the significant estimates and judgments made by the Board and Director in the preparation of the financial statements, and of whether the accounting policies are most 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 and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error 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 also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

Opinions

In my opinion:

- the financial statements give a true and fair view, in accordance with the Biological Standards Act 1975 and directions made thereunder by the Secretary of State with the approval of HM Treasury, of the state of the Board's affairs as at 31 March 2006 and of its surplus for the year then ended;
- the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Biological Standards Act 1975 and directions made thereunder by the Secretary of State with the approval of HM 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

19 July 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 2006

	Notes	2005/06 £000	2004/05 £000
Income			
Government grants	2a	12,060	11,044
Other grants	2b	3,226	3,029
Income from activities	2c	3,775	3,256
Contributions to depreciation	2d	2,817	2,662
		21,878	**19,991**
Expenditure			
Staff costs	3a	11,301	11,236
Other operating charges	4a	6,124	6,456
VAT recoverable	4c		47
Depreciation	5	2,817	2,662
Cost of capital charge	2e	2,453	2,351
		22,695	**22,752**
Operating deficit		**(817)**	**(2,761)**
Interest Receivable		94	-
Cost of capital reversal	2e	2,453	2,351
Surplus/(deficit) for the year		**1,730**	**(410)**

All results arose from continuing operations.

Statement of Total Recognised Gains and Losses for the year ended 31 March 2006

	Notes	2005/06 £000	2004/05 £000
Surplus / (Deficit) for the year		1,730	(410)
Unrealised surplus on revaluation of fixed assets	11	2,225	2,847
Net deficit on foreign currency translation	4b	(2)	(13)
Realised Gain on standards stock	11	(575)	-
Total recognised gains and losses		**3,378**	**2,424**

The notes on pages 57 to 70 form part of this account.

National Biological Standards Board

Balance sheet as at 31 March 2006

	Notes	2006 £000	2005 £000
Fixed assets			
Tangible assets	5	60,172	56,932
Debtors due after more than one year	7	11,000	8,692
Current assets			
Stock	6	8,509	7,181
Debtors	7	3,082	7,242
Cash at bank and in hand	8	3,752	582
		15,343	**15,005**
Creditors			
Amounts falling due within one year	9	1,843	1,197
Deferred income	13	1,187	807
		3,030	**2,004**
Net current assets		**12,313**	**13,001**
Total assets less current liabilities		**83,485**	**78,625**
Provisions for liabilities and charges	10	11,382	8,666
Capital and reserves			
Deferred government grant	11	32,759	33,968
Revaluation reserve	11	29,861	28,387
Donated asset reserve	11	1,287	1,138
Income and expenditure account	11	8,196	6,466
		83,485	**78,625**

S C Inglis
Accounting Officer
National Biological Standards Board
18 July 2006

The notes on pages 57 to 70 form part of this account.

Cash Flow Statement for the year ended 31 March 2006

	Note	2005/06 £000	2004/05 £000
Net cash inflow/(outflow) from operating activities	15(i)	4,330	38
Returns on investments and servicing of finance			
- Interest received		94	-
Capital expenditure		(3,092)	(3,156)
Receipts from disposal of fixed assets		-	-
Net cash inflow before financing		**1,332**	**(3,118)**
Management of liquid resources			
Financing:			
- Capital grants received		1,362	782
- Grant equipment funds		476	133
Increase/(decrease) in cash	15(ii)	**3,170**	**(2,203)**

The notes on pages 57 to 70 form part of this account.

Notes to the Account for the year ended 31 March 2006

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 have been prepared in accordance with the Government Financial Reporting Manual (FReM) issued by HM Treasury. 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 2006.

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.	

(d) Government grants

Government Grants receivable for capital expenditure are credited to a Deferred Government Grant account (Note 13) 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 2005/06, 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 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. Further details of the scheme can be found on the NHS Pensions Agency website at www.nhspa.gov.uk.

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.

(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	2005/06 £000	2004/05 £000
Department of Health	10,807	9,791
Scottish Executive	861	861
National Assembly for Wales	455	470
Northern Ireland Assembly	276	261
	12,399	**11,383**
Less: Contributions to the NBSB Pension Scheme included in Department of Health grant	(339)	(339)
Total Government Grants	**12,060**	**11,044**

(b) Other Grants	2005/06 £000	2004/05 £000
Research Councils etc	1,348	1,341
World Health Organization	160	87
European Commission	443	250
Other Bodies	421	698
Contracts	854	653
	3,226	**3,029**

(c) Other Income

	2005/06 £000	2004/05 £000
Standards distribution handling charges	2,690	2,118
Certification fees	1,085	1,138
	3,775	**3,256**

(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 :

	2005/06 £000	2004/05 £000
Historical cost depreciation on other assets transferred from Deferred Government Grant	2,571	2,616
Current cost depreciation adjustment transferred from Revaluation Reserve	176	46
Current cost depreciation on donated assets transferred from Donated Asset Reserve	70	-
	2,817	**2,662**

(e) Cost of capital charges

Notional interest at 3.5% of the average value of net government funded assets during the year, which is £2,453k (2004/05 £2,351k) is matched by a notional credit for the same amount, shown below the operating deficit.

3 Staff Costs

(a) All staff	2005/06 £000	2004/05 £000
Salaries and wages	8,948	8,804
Social Security costs	753	729
Employers contributions to the NBSB Pension Scheme	57	57
NHS Superannuation contributions	1,108	1,065
Consultancy and agency staff	435	581
	11,301	**11,236**

(b) The average number of full time equivalent employees during the year was:

	2005/06 No	2004/ 05 No
Scientific divisions	205	203
Support and operations	73	73
Administration	24	25
	302	**301**

4 Other Operating Charges

(a) Other operating charges

		2005/06 £000	2004/05 £000
Consumable laboratory supplies		3,349	3,411
Central services		956	1,498
Estate management		831	755
Equipment		355	437
Travel, subsistence and hospitality:			
Chairman and other Board members		5	5
Employees		200	185
Audit fee		50	42
Increase in provision for early retirements	Note 10 (b)	225	-
Provision for bad debts		(8)	2
Loss on disposal of assets		159	108
Foreign exchange (gain)/loss		2	13
		6,124	**6,456**

(b) Foreign currency translation

Net exchange losses of £2k on foreign currency deposits have been debited to the Income and Expenditure account.

(c) VAT refund

During the year 2005/06 VAT returns were submitted quarterly and the partial recovery of VAT of £1,109k on purchases has been reflected in the accounts as a reduction in the cost of capital additions or revenue expenditure as appropriate. The balance of VAT of £5,111k due at 31 March 2005 in respect of the remaining amounts recoverable for all previous years was repaid by HM Revenue and Customs in July 2005.

5 Tangible Fixed Assets

	Freehold Land £000	Freehold Buildings £000	Software computers & equipment £000	Motor Vehicles £000	Production equipment £000	Assets Under construction £000	Total £000
Balances at 1 April 2005	5,303	41,216	11,531	30	1,769	8,069	67,918
Additions	-	470	633	-	99	2,848	4,050
Transfers	-	7,374	695	-	-	(8,069)	-
Disposals	-	-	(1,739)	-	(151)	-	(1,890)
Diminution	-	-	(26)	-	-	-	(26)
Revaluation / indexation	-	2,876	522	-	(174)	-	3,224
Cost or valuation at 31 March 2006	5,303	51,936	11,616	30	1,543	2,848	73,276
Accumulated depreciation at 1 April 2005	-	2,367	8,057	30	532	-	10,986
Charge for the year	-	1,897	841	-	79	-	2,817
Disposals	-	-	(1,663)	-	(9)	-	(1,672)
Diminution	-	-	(12)	-	-	-	(12)
Backlog depreciation / indexation	-	613	372	-	-	-	985
Accumulated depreciation at 31 March 2006	**0**	**4,877**	**7,595**	**30**	**602**	**-**	**13,104**
Net book value							
At 31 March 2005	5,303	38,849	3,474	-	1,237	8,069	56,932
At 31 March 2006	**5,303**	**47,059**	**4,021**	**0**	**941**	**2,848**	**60,172**

6 Stock

	31 March 2006 £000	31 March 2005 £000
Standards	7,764	6,407
Raw materials	70	83
Others	675	691
	8,509	**7,181**

The Board holds stocks of biological reference materials ('standards') which are used in regulatory control, diagnosis and research. At 31 March 2006 2.1 million standards were held of which 0.8 million were publicised for distribution in NBSB's reagent catalogue. The Board estimates their economic value at 31 March 2006 to be £7,764k (2005: £6,407k) 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 2006 £000	31 March 2005 £000
Debtors due more than one year from balance sheet date : Department of Health	**11,000**	**8,692**
Debtors due within one year :		
Trade debtors	1,308	765
Grant income receivable	982	994
Other debtors	368	5,267
Prepayments	424	216
	3,082	**7,242**

The debtor due from the Department of Health of £11,000k (2005: £8,692k) represents the Department's obligation to fund the future liabilities of the NBSB Pension Scheme. Plans to transfer the scheme before April 2008 (Note 10) will call for this debt to be realized to fund the receiving scheme. The Department of Health has confirmed its intention to meet the obligation on transfer of the scheme at the current market valuation by the Government Actuary's Department.

Intra-governmental balances:		
Balances with Central Government bodies	367	29
Balances with NHS Trusts	5	14
Balances with Public Corporations	87	93
Balances with bodies external to Government	2,623	7,106
Total	**3,082**	**7,242**

8 Cash at Bank and In Hand

	31 March 2006 £000	**31 March 2005 £000**
Paymaster account	126	151
Other Department of Health cash at bank and in hand	3,326	132
External cash funding received in advance	300	299
	3,752	**582**

9 Creditors: Amounts falling due within one year

	31 March 2006 £000	**31 March 2005 £000**
Taxation and social security costs	-	243
Trade creditors	1,628	636
Accruals	215	318
	1,843	**1,197**

Intra-governmental balances:		
Balances with Central Government bodies	-	-
Balances with NHS Trusts	-	-
Balances with Public Corporations	-	2
Balances with bodies external to Government	1,843	1,195
Total	**1,843**	**1,197**

10 Provisions

	NBSB Pension Scheme £000	Early Retirements £000	Other Provisions £000	Total £000
Balance at 1 April 2005	8,476	182	8	8,666
Utilised during the year	(336)	(33)	-	(369)
New provisions during the year	2,860	225	-	3,085
Balance at 31 March 2006	11,000	374	8	**11,382**

(a) The NBSB Pension Scheme is a closed unfunded scheme backed by the Department of Health (Note 1 (h)). It is overseen by a five member Committee of Administration appointed by the Board, including two staff members of the scheme. Of the 65 members at 31 March 2006, 12 are contributing, 43 are receiving pensions and the other 10 have preserved pension rights. Details of the £336k (2004/05: £324k) net cost to the Board are shown below:

	2005/06 £000	2004/05 £000
Lump sum payments	46	-
Transfers to other schemes	-	-
Benefits paid	375	409
Total payments	421	409
Less:		
Employers Contributions	57	57
Employees Contributions	28	28
Total Contributions	85	85
Provisions utilised during the year	**336**	**324**

The cost of pensions in payment has exceeded the contributions from members and the Board since 1988 and the difference has been funded by the Department of Health. The liability for future pensions, less contributions, is shown as a provision in the Board's accounts. The amount is offset by an amount receivable from the Department of Health shown in debtors.

The Board is arranging the transfer of the NBSB Pension Scheme before April 2008 as part of its preparations for the merger of NIBSC with the Health Protection Agency. The Government Actuary's Department calculated the cost of transferring the scheme at 31 March 2006 to other existing schemes would be £11.0 million. The provision for the scheme in the Board's accounts is based on this transfer cost, which is expected to be met by the Department of Health (Note 7).

(b) 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 NHS Pension Scheme in the year of early retirement.

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

11 Capital and Reserves

	Deferred Government Grant £000	Revaluation Reserve £000	Donated Asset Reserve £000	Income and Expenditure Account £000	Total £000
Balance at 1 April 2005	33,968	28,387	1,138	6,466	69,959
Capital grant received (Note 12)	1,362	-	-	-	1,362
Donated additions	-	-	219	-	219
Surplus for the year	-	-	-	1,730	1,730
Gains on revaluation – fixed assets	-	2,225	-	-	2,225
Depreciation transfer to Income & Expenditure Account	(2,571)	(176)	(70)	-	(2,817)
Realised gains on standards stock transfer to Income and Expenditure Account	-	(575)	-	-	(575)
Balance at 31 March 2006	**32,759**	**29,861**	**1,287**	**8,196**	**72,103**

12 Government grants for capital

	2005/06 £000	2004/05 £000
Department of Health	1,268	688
Scottish Executive	51	51
National Assembly for Wales	28	28
Northern Ireland Assembly	15	15
	1,362	**782**

13 Deferred grant income

	2005/06 £000	2004/05 £000
Balance at 31 March 2005	807	935
Net transfers to income & expenditure account	380	(128)
Balance at 31 March 2006	**1,187**	**807**

14 Capital commitments

	2005/06 £000	2004/05 £000
Contracted capital commitments as at 31 March 2006 for which no provision has been made	1,237	949

15 (i) Notes to the Cash Flow Statement

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

	2005/06 £000	2004/05 £000
Operating surplus/(deficit)	(817)	(2,761)
Cost of capital charge	2,453	2,351
Depreciation	2,817	2,662
Release from deferred government grant	(2,571)	(2,616)
Release from revaluation reserve	(176)	(46)
Release from donated asset reserve	(70)	-
Revaluation from production assets	(174)	-
Release from stock revaluation reserve	(575)	(245)
Loss on disposal of fixed assets	159	108
Diminution in value of computers and software	(26)	-
Increase in stock	(1,328)	(386)
Increase in long term debtors	(2,308)	339
Decrease in short term revenue debtors	4,160	2,255
Decrease in revenue creditors	(305)	(1,143)
Increase in deferred grant income	380	(128)
Increase in provisions	2,711	(352)
Net cash inflow from operating activities	**4,330**	**38**

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

	2005/06 £000
Increase in cash in the period	3,170
Increase in liquid resources	-
Change in net funds	3,170
Net funds at 31 March 2005	582
Net funds at 31 March 2006	**3,752**

16 Losses and special payments

The Board has settled a legal claim in respect of a former employee of the Medical Research Council for which the Board assumed legal responsibility under its founding statute in 1975. During the year the Board wrote off 60 invoices due from customers, and deemed uncollectible, with a value of £ 9,988. This value was offset by unallocated credits of £18,145.

17 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 0.05% of annual income and variations in interest rates do not represent a material risk to the 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.

18 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	£1,567k
Home Office	£21k

All transactions were carried out in an arms 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.

National Biological Standards Board

Declared Interests of NBSB Members relating to 2005/06				
Member	**Personal Interest**		**Non-Personal Interest**	
	Organisation	**Nature of Interest**	**Organisation**	**Nature of Interest**
Professor Derek H Calam	NBSB Pension Scheme	Pension	None	None
Professor Janet Darbyshire	None	None	Wide range of national and international pharmaceutical companies	Director of MRC Clinical Trials Unit where research is both supported and commissioned by industry.
Professor Gordon Duff	Interleukin Genetics Inc	Shareholder, consultancy		
Mr Alan Heath	None	None	None	None
Mr Martin Hindle	National Blood Authority Peterborough and Stamford Hospitals NHS Foundation Trust National Probation Service- Leicestershire and Rutland Aventis Pension Fund Cable and Wireless Pension Fund	Non Executive Director Non Executive Director Director Member Member	Greater Peterborough Citizens Advice	Trustee
Professor John P Hughes	None	None	None	None

National Biological Standards Board

Declared Interests of NBSB Members relating to 2005/06				
Member	**Personal Interest**		**Non-Personal Interest**	
	Organisation	**Nature of Interest**	**Organisation**	**Nature of Interest**
Dr Stephen Inglis	Xenova plc Partnerships UK	Shareholder Associate advisor	None	None
Professor David Latchman	Biovex Ltd Health Protection Agency	Chairman Scientific Advisory Board Non Executive Director, Consultant, Shareholder Board Member	London Higher (umbrella organization which represents all London Universities)	Chairman
Professor Christine Lee	Hemophilia Foundation (supported by Novo Nordisk)	Board Member	Kogenate Liposome Data Safety Monitoring Board (supported by Bayer) Von Willebrand Disease Prophylaxis Network (supported by ZLB Behring)	Data Safety Monitoring Board member Data Safety Monitoring Board member
Miss Gillian Noble	Various Pharmaceutical Companies (Managed by HSBC Trust Company) Meningitis Trust MRC	Shareholder Director Audit Committee Member		

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Declared Interests of NBSB Members relating to 2005/06				
	Personal Interest		Non-Personal Interest	
	Organisation	**Nature of Interest**	**Organisation**	**Nature of Interest**
Dr John Petricciani	World Health Organisation Cancervax International AIDS Vaccine Initiative	Occasional Consultancy Senior VP (to December 2005) Occasional Consultancy	International Association for Biologicals	President
Mr Allan Robertson	MRC	Audit Committee Member	None	None
Dr Nicola Rose	Big Lottery Fund	External Assessor, Research Grants programme		
Professor JG Patrick Sissons	Arthritis Research Campaign British Heart Foundation	Trustee Trustee	GlaxoSmithKline	Research support to the School of Clinical Medicine, Cambridge University

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Declared Interests of NBSB Members relating to 2005/06				
	Personal Interest		**Non-Personal Interest**	
	Organisation	**Nature of Interest**	**Organisation**	**Nature of Interest**
Professor Sir John Skehel	MedImmune Inc Life Sciences Ventures MRC Technology Novartis Foundation Animal Health Trust Institute of Molecuar Medicine, Oxford	Consultant Consultant Board Member Scientific Advisor, Chairman of the Executive Council Member of Scientific Advisory Board and Executive Committee Member Member of Scientific Advosry Committee	Academy of Medical Sciences	Vice President of Forum and Member of Council
Dr Lincoln Tsang	Arnold and Porter LLP BioIndustry Association The School of Pharmacy, University of London Various pharmaceutical and biotechnology companies	Barrister specialising in life sciences Chairman of Regulatory Affairs Advisory Committee Member of the Governing Council External legal counsel		

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