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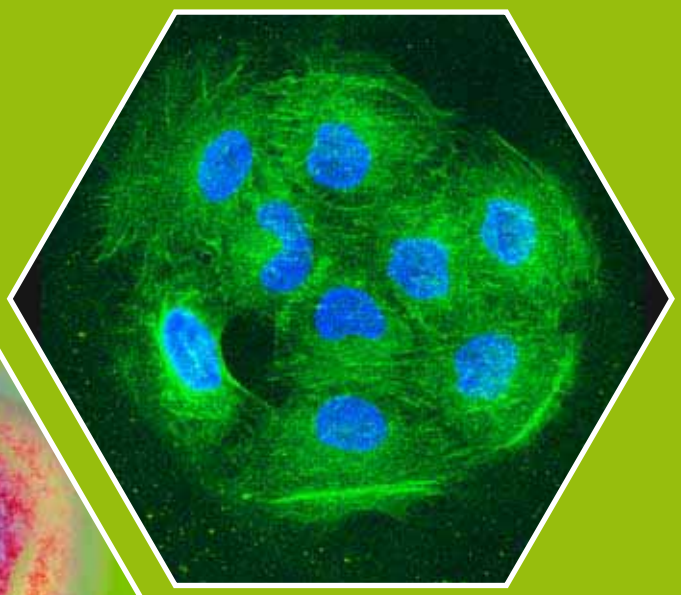

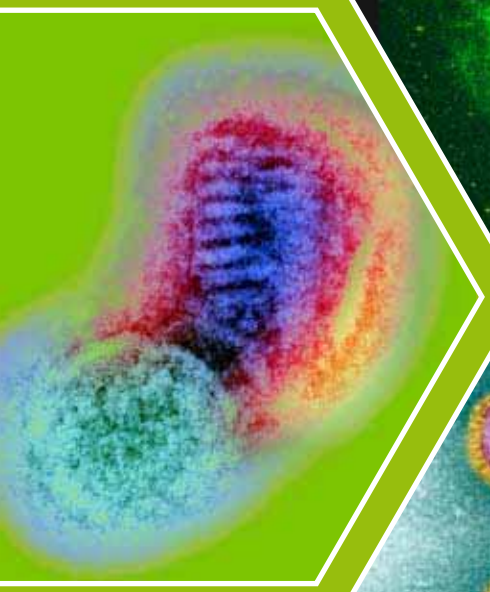

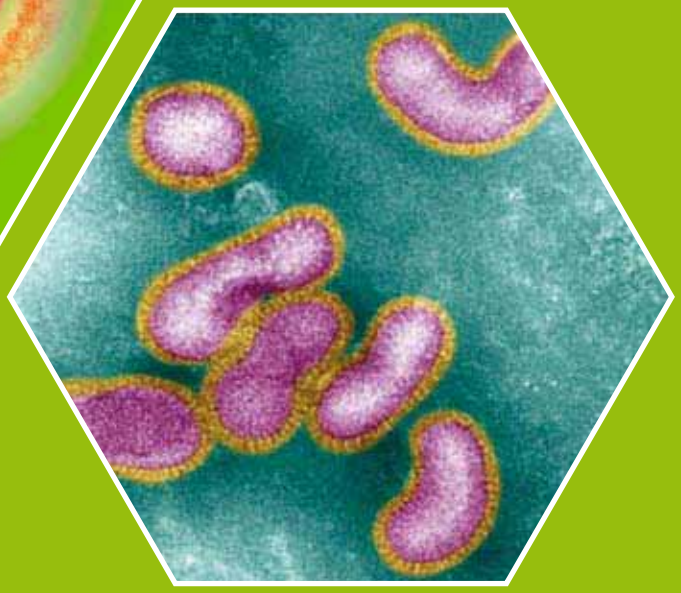

NBSB

Annual Report & Accounts

Annual Report & Accounts
1st April 2006 to 31st March 2007

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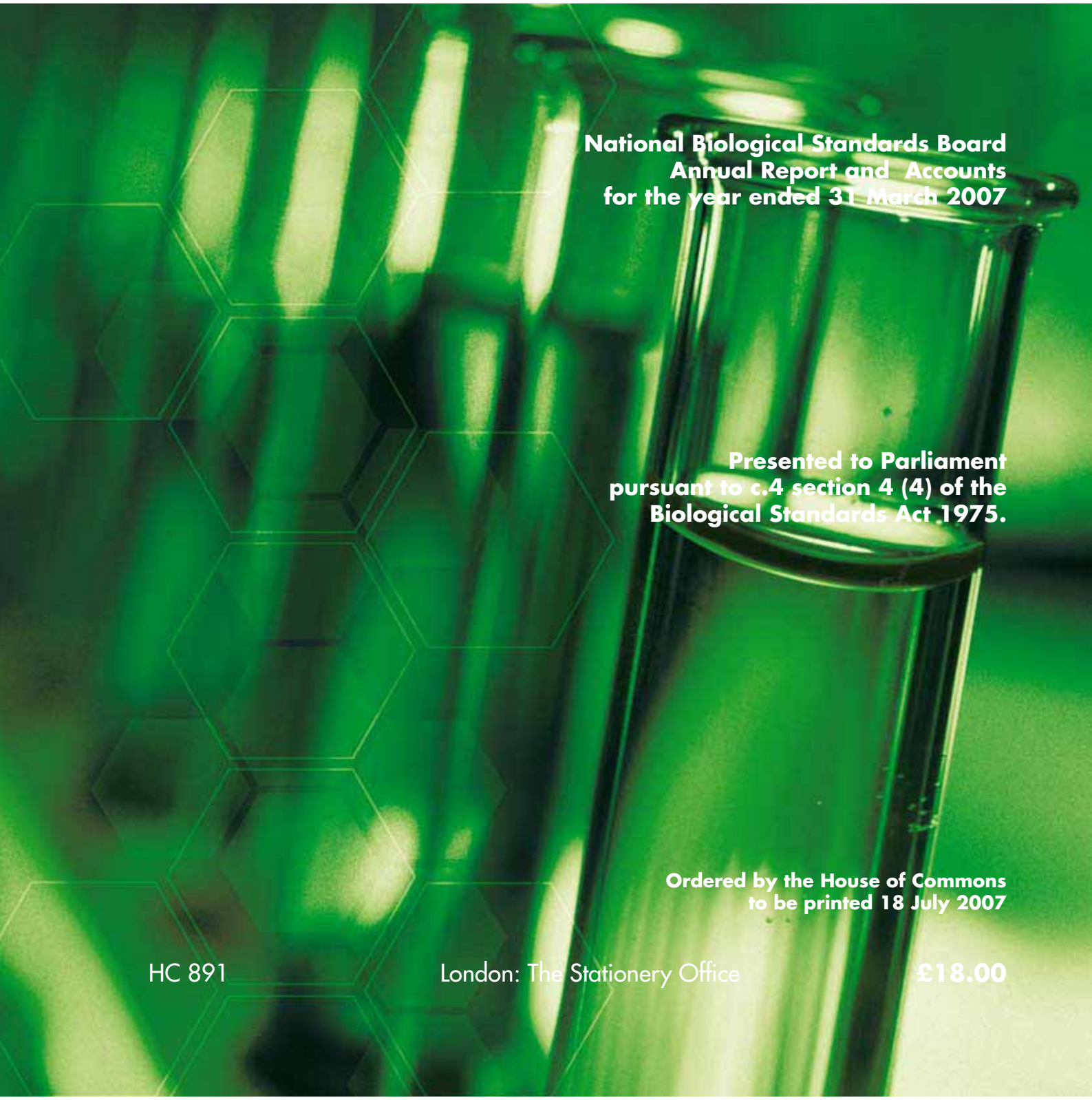
NIBSC's control testing of biological medicines operates under a formal quality system independently accredited by the UK Accreditation Service (UKAS). Accredited test methods are indicated on the UKAS Shedule of Accreditation.

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 2007

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Contents

Chairman's Report

It is a great pleasure to introduce the 2006/07 Annual Report on behalf of the National Biological Standards Board. The work of NIBSC over the last year, and in particular the superb response to the Northwick Park clinical trial disaster, once again illustrated the key role that the Institute plays in assuring the quality of biological medicines, and its importance on the national and international stage. NIBSC is a unique scientific organization, and as the world leader in developing standards for biological medicines it provides a vital pillar to support both UK and global public health needs.

Each year innovative new biological products and technologies are coming on stream, offering exciting new clinical benefits, but also requir-

ing more and more sophisticated expertise and methodologies to ensure safety and efficacy. It is essential that the Institute looks ahead to these challenges as well as maintaining existing capabilities. I am therefore particularly pleased to highlight the many new developments going on at the Institute, such as the provision of new laboratories to house expansion of the influenza vaccine work, the establishment of a permanent building for the UK Stem Cell Bank, the expansion of the Institute's work on monoclonal antibody products, and the growing involvement with biosimilar medicines.

Tackling these new areas is of course a major challenge, since the existing work of the Institute is no less important and resources are limited, but the Institute is finding ways to build sensibly on a now solid platform of funding from the Department of Health to make such new developments possible and sustainable.

Maintaining the Institute's capability is not, however, just about finance. The expertise that NIBSC can draw upon across a very broad range of scientific disciplines has taken many years to build up and is based on the excellence of individuals. It cannot easily be reproduced and succession planning is therefore vital for the future. With this in mind, several key appointments have been made during the past year and a new post-graduate training programme to be initiated in conjunction with Imperial College in the coming year but maintaining and developing multidisciplinary expertise will remain an important priority for the Institute.

The Institute has continued to develop its relationship with the Health Protection Agency in advance of the planned merger between the two bodies, with many of the anticipated benefits already secured through close working. The merger requires primary legislation, however, which has not yet been enacted. It is therefore important to ensure that the strength of the Board and its governance functions is maintained for at least two further years until the merger is finally completed.

Finally, no institution with as wide and important a remit as NIBSC can ever hope to operate successfully without the sustained effort and professional commitment of its people. As in previous years, the NBSB feels particularly fortunate in this respect. All of the staff of NIBSC, and the management team, richly deserve the Board's gratitude.

Professor Sir Gordon Duff
Chairman, National Biological Standards Board

Director's Report

I am delighted to report that during the past year, NIBSC has made excellent progress and has further enhanced its reputation as a world leader in its field. Our scientists have continued to make valuable scientific contributions in many areas crucial to public health, both nationally and internationally, in addition to fulfilling their day to day responsibilities in standardisation and control of biological medicines.

The Phase I clinical trial at Northwick Park Hospital in March 2006, in which eight young male volunteers experienced dramatic and very serious side effects following administration of an experimental antibody, TGN1412, developed as an anti cancer drug, set in train a major programme of work at the Institute that underlined the value of the unique expertise that has been built up at NIBSC over many years. I am very proud of the way our scientific team responded superbly to support the subsequent investigation, first to analyse samples of the product used in the trial and subsequently to develop important insights into why it caused such serious consequences as well as new approaches to product testing that should help prevent similar occurrences in future. This totally unexpected event highlighted both the uncertainties that inevitably go hand in hand with the exciting opportunities offered by innovative biological medicines, and also the importance of maintaining a cadre of world class scientific experts with the knowledge and understanding to deal with such eventualities.

The TGN1412 work was by no means the only highlight. Once again influenza vaccine work was high on the agenda, with further progress towards reducing the response time required to develop new vaccines in a pandemic, and also new developments at the Institute to support more efficient and rapid production of seasonal influenza vaccines. This work will be considerably aided by our plans for a new Influenza Resource Centre that we hope will be completed within the next two years. Important work was also carried out to assess new tests for variant CJD. This is essential to underpin studies on human blood and tissues that aim to investigate prevalence of the disease. The UK Stem Cell Bank hosted by the Institute began to distribute its first cell lines, 14 new International Standards and reference materials were established through the World Health Organisation and we began to carry out batch release work on several new products, including new vaccines against human papillomavirus, rotavirus and pneumococcal infection.

This extensive programme of work, of course, requires appropri-

ate resource and, building on a solid platform of funding from the Department of Health, we have continued to develop our income streams in order to ensure as far as possible that the vital work of the Institute remains sustainable over the long term. Integration with the Health Protection Agency, where appropriate, has continued smoothly in advance of the merger now scheduled for completion in April 2009, and I am confident that the Institute will join the Agency in excellent shape.

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

NBSB and NIBSC

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

NIBSC provides independent testing of biological medicines for the UK market, in particular with vaccines for the UK children's vaccination programme, and operates as an Official Medicines Control Laboratory (OMCL) of the European Union for release of medicines onto the EU market. NIBSC testing of products already released onto the EU market may also be carried out when particular problems arise such as failure of storage conditions or following adverse reactions in patients.

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

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

NIBSC strategic aims:

- To respond to and advise on public health problems involving biologicals;
- To provide a national scientific capacity in the field of biological medicine, and to maintain the flexibility, expertise and facilities needed to address new developments in science and medicine;
- To operate, and be recognised, as a leading international authority on methods of assay such as those to quantify biological activity and to characterise and assess the safety of biologicals;
- To maintain a central role in the development of the scientific basis for control and standardisation of biologicals within Europe;
- To assist in the development of international consensus on scientific aspects of the regulation of biological medicines and, in this respect, work closely with the World Health Organisation (WHO);
- To achieve and maintain Quality Accreditation/Certification in key areas of control work and standardisation.

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 but they are extremely complex products and because of this batches of vaccines and blood products need to be 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 OMCL for the batch release of medicines in the UK. Manufacturers are actively choosing to propose NIBSC as the batch release laboratory for new and innovative products with a high public health impact even though the European OMCL network is expanding significantly with the new accession countries, underlining NIBSC's recognised expertise in the field of biological medicine testing.

Testing of products continued at a high level during 2006/07 and, following the grant of European and US product licences, we received the first batches of the new vaccines against HPV and rotavirus. These are important developments and demand is expected to increase rapidly in 2007/08. NIBSC continued to make a major contribution to the European CAP testing scheme, carrying out post market analysis on four cytokine and growth factor-based products.

Through NIBSC's testing and evaluation activities, our scientists not only ensure the safety and efficacy of biological products but also help minimise the time required to bring new products into clinical use. New products require novel approaches for their control and our research and development activities have continued to focus on innovative approaches to analysis of complex new product classes, such as gene and cell therapeutics.

Batch Release Activity 2006

Product groups	No of batch release certificates in 2006 (2005)
Bacterial vaccines, toxins, antitoxins	316 (285)
Viral vaccines	118 (119)
Blood products: Albumin, coagulation factor concentrates, virus inactivated plasma and fibrin sealants	470 (431)
Immunoglobulins	227 (264)
Total batch release certificates	1131 (1099)
Plasma pools tested (virus testing)	1458 (1665)

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 World Health Organization (WHO) International Standards provides a set of "gold standards" from which countries and manufacturers can calibrate their own standards for biological testing.

4,897 shipments of 188,146 ampoules/vials (46% increase on previous year).

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. NIBSC is the leader amongst only three international laboratories involved in this field. The importance of this role was highlighted specifically at the annual WHO Expert Committee for Biological Standardisation (ECBS) meeting in November 2006, with members expressing strong support for the Institute and deep appreciation of its contribution.

5,563 shipments including dispatch of other non standard biologicals & collaborative studies

Standards distribution increased dramatically once again with an increase of 46% in reference materials shipped to customers compared with 2005. This was largely driven by a very large increase in demand for influenza standards, reflecting greatly increased activity in this area by manufacturers.

94 fills of 254,286 ampoules/vials plus validation fills. Overall increase for general production of 59% for number of fills and 69% for the number of ampoules and vials on previous year.

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 16 important International Standards and Reference Materials were established through ECBS, well ahead of our target for the year of 10.

New & Replacement Standards Established 2006

1st IS for alpha-1 anti-trypsin, 05/162
1st IS for factor XIII, plasma, human, 02/206
2nd IS for Protein C, plasma, human, 02/342
2nd IS for Protein S, plasma, human, 03/228
1st IS for anti-human platelet antigen 3a, 03/190
2nd IS for HBV DNA for NAT assays, 97/750
1st IS for plasmodium falciparum DNA, NAT assays, 04/176
1st International Reference panel for anti HIV, 02/210
4th IS for pertussis vaccine, 94/532
2nd IS for Smallpox vaccine, 06/166
Poliovirus neuro-virulence test titration reference, 05/146
3rd IS for anti-polio antisera, 82/585
3rd IS for anti-measles serum, 97/648
1st IS for thyroid stimulating hormone, recombinant for bioassay
WHO reference reagent for IL-17, 01/420
WHO reference reagent for IL-18, 03/200

Northwick Park clinical trial incident: TGN1412

In late March 2006 NIBSC was called on, at very short notice, to assist the Medicines & Healthcare products Regulatory Agency (MHRA) with an investigation into the very serious consequences that followed a 'first-in-man' clinical trial of an experimental antibody treatment at Northwick Park Hospital. All six healthy volunteers who received the drug suffered very rapid and extremely severe adverse effects.

Over the subsequent 9 months a team of up to 20 NIBSC scientists, drawn from many different groups within the Institute carried out a major project which proved not only crucial to the investigation, but which revealed important scientific information that may help to prevent such events occurring in the future.

An outline of the work was published as part of the Duff Report in December 2006 (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063117) and a fuller report has been submitted for peer-review publication.

The initial work focused on the quality of the product, where our scientific experts were quickly able to provide reassurance that there was no evidence of any contamination or other quality issues that might have explained the adverse events.

On this basis it was evident that the symptoms suffered by the trial participants were almost certainly caused directly by the antibody through binding to its target in the body, a molecule involved in triggering immune responses. This interaction appeared to lead to a massive over-stimulation of the immune system and uncontrolled release of cytokines (a 'cytokine storm'), in the volunteers which in turn resulted in extensive tissue damage throughout the body and organ failure. This had not been predicted by the safety tests carried out before the product was trialed in humans.

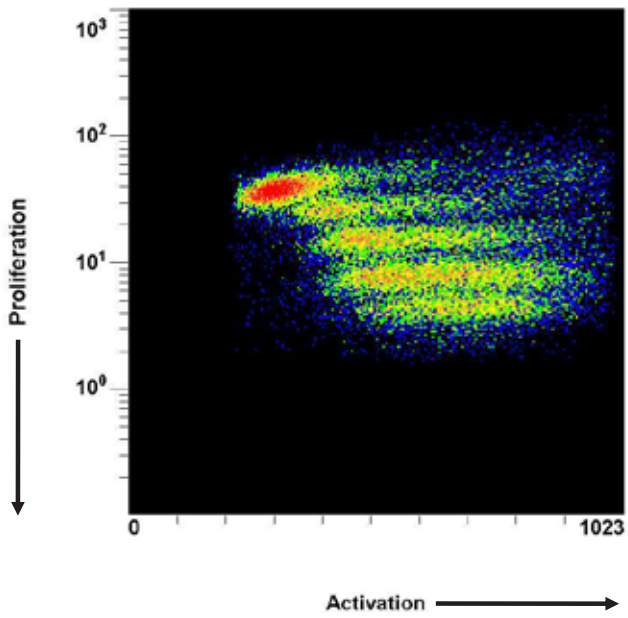
Following the incident an Expert Group was established by the Secretary of State for Health under the chairmanship of Sir Gordon Duff to make recommendations into the conduct of future Phase 1 trials. The committee requested a second phase of work at the Institute aimed at learning more about the effects of the antibody on the human immune system and looking for ways of reducing risk from future clinical trials of this kind. This led to two important findings:

- an innovative laboratory test system was developed that could mimick the *in vivo* effects of the antibody on the human immune system. This new approach may be useful for future preclinical safety testing of experimental

medicines of this kind and is already attracting considerable international interest.

- primate immune cells did not respond in the same way as human immune cells, explaining why preclinical tests in primates did not predict the adverse events in humans. This also has long term implications for preclinical safety testing of those biological medicines which act by stimulating parts of the immune system.

The work by NIBSC scientists received very high praise from the Expert Group for its rigorous quality and international recognition for the important new insights it revealed. The incident also emphasized strongly the value and importance of maintaining NIBSC's breadth and depth of scientific expertise in the field of biological medicines in case of need.



Investigation into the adverse effects caused by the therapeutic antibody TGN1412 in a phase 1 clinical trial: In vitro stimulation with 1µg of TGN1412 induces profound proliferation of human lymphocytes.

Supporting Pandemic and Seasonal Influenza Vaccine Production

There was a substantially increased demand for work to support the development of vaccines against seasonal and pandemic influenza.

H5N1 'bird' flu continues to circulate in poultry worldwide, and a recent outbreak in a turkey farm in the UK underlined the ongoing threat from this highly pathogenic virus. The virus changes as it circulates and new strains continue to emerge. NIBSC's task is to keep pace with these changes by creating new vaccine candidates as required by WHO, and supplying them to vaccine manufacturers in case of need. During the year we constructed a new vaccine strain. NIBRG-23, is based on an H5N1 virus isolated in 2005 from Turkey, and was developed and supplied to several manufacturers for preparation of experimental vaccines.

In a pandemic emergency the time taken to manufacture vaccines will be crucial. We have made major progress in reducing the time needed to generate and supply new pandemic vaccine strains to manufacturers by several weeks to just under a month, and have been instrumental in securing international agreement to allow more rapid distribution of vaccine strains under emergency conditions.

Work also began on an EU-funded project established in conjunction with the Health Protection Agency (HPA) to generate a library of potential pandemic vaccine candidates and associated reference reagents that may reduce the vaccine response time even further.

Our routine work to prepare reference materials and potency assessment reagents to underpin the annual seasonal vaccine production campaign was even more demanding than usual as a number of manufacturers switched to use a different virus strain late in the campaign following poor vaccine yields from the initial strain, requiring production of an additional set of standards for potency assessment at very short notice.

The resulting difficulties with vaccine supply highlighted the need for a more robust global system for generation of vaccine seed strains and more

thorough characterization of their properties before annual decisions are made on vaccine composition for the coming season.

NIBSC agreed to assist with this, and a new purpose-built temporary laboratory was designed, built, installed and commissioned between October 2006 and February 2007. Over the medium to long term, additional permanent facilities are urgently needed and so we were delighted to to hear in August 2006 that an outline proposal for a new Influenza Resource Centre had been accepted by the Department of Health, subject to final approval of an appropriate business case, which is now well advanced.

Standardising vCJD Diagnostic Testing

There is considerable commercial interest in development of diagnostic tests for prion-based diseases that could be used to enhance the safety of donated blood and tissues.

With a number of tests claiming to be able to detect abnormal prions, which are thought to be a marker for disease, now nearing the market, it is essential that they are carefully validated and this in turn requires well characterised reference materials. The NIBSC team has developed a range of such materials and over the year has co-ordinated a number of collaborative studies aimed at providing an authoritative assessment the merits of different tests.

These studies have been highly successful and have provided a platform for the initiation of important studies to assess the prevalence of abnormal prions in human tissues.

Cell-based Medicines

The highlight of the year was the availability of the first cell lines from the UK Stem Cell Bank in September 2006. This was an important milestone, representing the culmination of a long period of period of intense systems development, together with a major scientific effort to establish the first cell banks along with a comprehensive data package describing their characteristics.

By the end of the year, 20 stem cell lines had been accessioned, 16 lines had been banked and testing completed, and 8 were available for distribution. As well as providing quality-assured ethically-sourced cell lines, the Bank aims to provide a range of other useful materials to support stem cell research as well as a source of authoritative information to assist those active in the field. Some 27 non-stem cell banks were prepared and the Bank's scientists acted as the central hub for a major international project (ISCI-1) to develop and distribute and materials for characterisation of stem cells.

These materials and the accompanying information now represent a unique resource to assist in development of stem cell therapies, and we expect the range of materials available to grow rapidly from now on.

UK StemCellBank

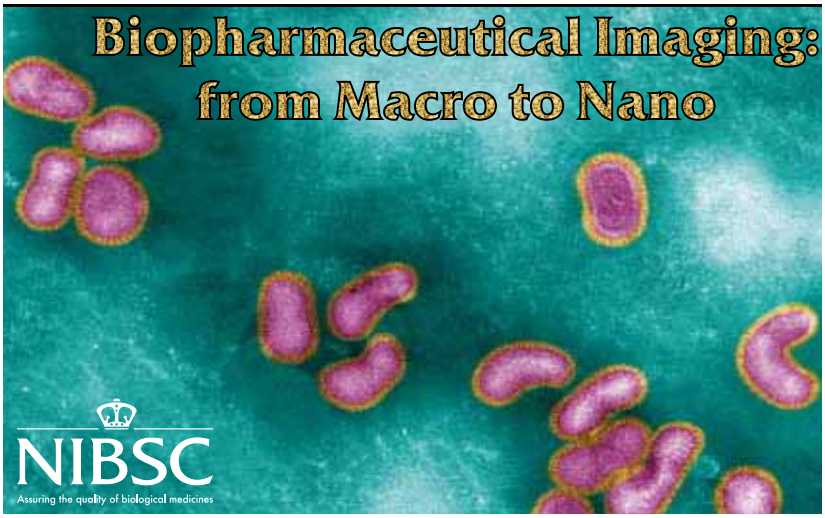
Scientific Communications and Training Activities

One of the Institute's five key strategic objectives is to promote science-led policy making in the field of biological medicines. Consistent with this aim, our scientists have continued to play a major contributory role to a very wide range of policy-making and regulatory bodies both nationally and internationally.

We continued to initiate discussion on topics of importance with a view to informing policy development and improving public health by organizing international workshops, discussion fora and scientific meetings. During the year we organized 14 meetings of this kind covering a diverse range of important topics, including clinical virology standards, influenza vaccine development, and 'next-generation' analytical methods for product development.

Certain aspects of the Institute's work are of considerable public interest, and so in recent years we have become more proactive in communication with the public, through development of an improved website, but also through direct interaction with the media. In the past year we have strengthened our public profile significantly through positive print, radio and television coverage of our work, particularly on pandemic influenza preparation, follow-up to the Northwick Park clinical trial incident, and release of the first cell lines from the UK Stem Cell Bank.

In addition we took the opportunity afforded by completion of our Category 4 facility refurbishment project to invite selected science journalists as well as members of the local community to view the facility and hear about our influenza work before the facility was finally commissioned and resealed.



Stakeholder Links

NIBSC's merger with HPA was delayed due to lack of time for legislative changes in the current Parliamentary year but we have continued to build close relationships throughout the two organisations.

Our Finance team and functions have been integrated with those of HPA and the new, Oracle-based, financial accounting system has been successfully implemented. In addition there has been excellent co-operation in many areas, notably Information Technology, and Human Resources, where shared experience has been beneficial to both organisations.

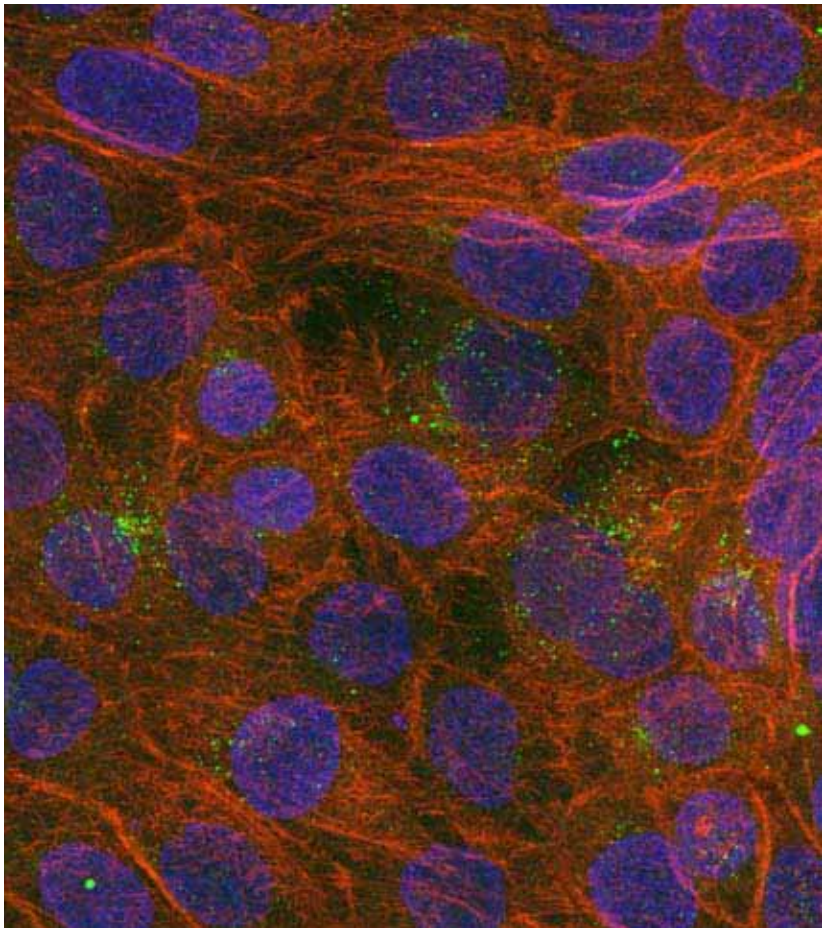
At a strategic level, the NIBSC Director now attends the HPA Executive Group on a regular basis, cross representation at Board level was increased, and a framework for NIBSC's governance within the HPA has been proposed, taking account of our specialist regulatory functions.

Facilities and Technology Infrastructure

Once again it has been an extremely active and productive year with respect to facilities development fuelled by continued very welcome capital investment by DH. Several major projects begun in the previous year were completed, notably the refurbishment of our Category 4 high containment facility and commissioning of our new equipment for scanning and transmission electron microscopy.

In addition we made substantial progress on a number of important new projects, including

- the design, procurement and installation of a temporary laboratory facility to house additional influenza work,
- the design of a new permanent facility for the UK Stem Cell Bank
- the design and submission of a full business case for a new Influenza Resource Centre.



Centre for Biological Reference Materials

NIBSC is home to a world-leading centre for filling and lyophilising biological reference materials, the Centre for Biological Reference Materials (CBRM).

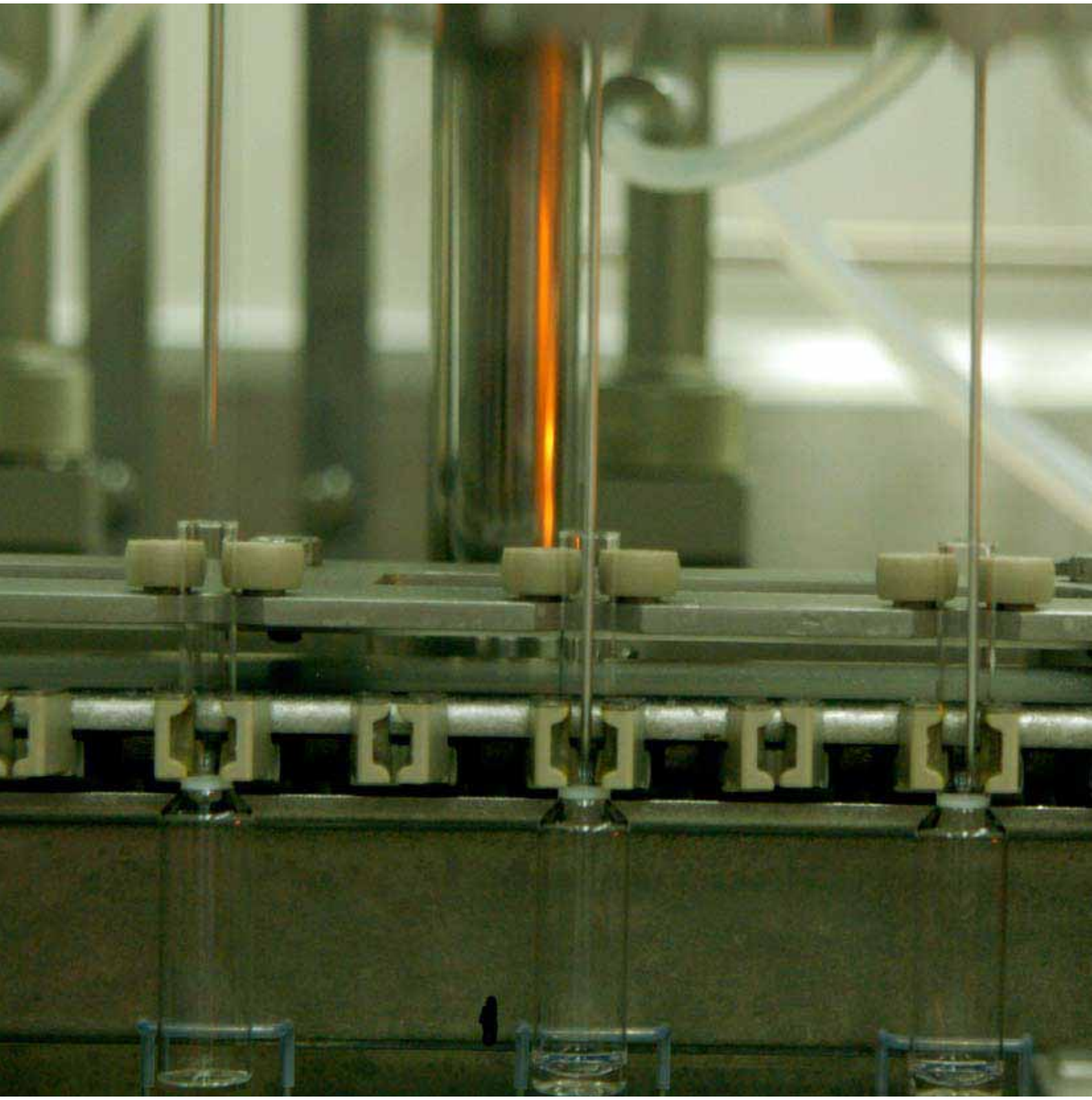
As the world's major producer and distributor of World Health Authority (WHO) International Standards and reference preparations, supplying over 90% of such standards worldwide, the Institute has specialist expertise in developing, producing, filling, freeze-drying and storing biological reference materials over extended periods of time. Biological standards can be highly complex and unstable in aqueous formulation, yet require storage for decades prior to dispatch to users. Many visitors to NIBSC are taken aback to learn that the Institute's oldest catalogue item was produced in 1954.

CBRM possesses specialist expertise in extending the shelf-life of biological materials by filling and freeze-drying them into sealed glass ampoules. This capability is exceptional, requiring a special modification to the automated production equipment that is unique to CBRM. Further, the Centre houses a development suite where Institute scientists develop freeze-dry formulations and processes tailored to each biological material, based on an understanding of their thermal properties.

CBRM's key activities operate in a low bioburden environment which is environmentally monitored and controlled, and its operational processes are quality assured to ISO 9001. In addition to freeze-drying into ampoules, the Centre processes liquid fill and freeze-dry batches into a range of ampoules, vials and tubes.

Three key indicators of the quality of a reference material are accuracy of fill volume, the material's stability and its homogeneity throughout the batch. CBRM operates to a particularly tight variability of fill – typically less than 1% - and the formulation expertise throughout the Institute helps ensure both batch homogeneity and stability. Advanced degradation stability studies are run where appropriate to assess a filled material's stability.

In addition to meeting the Institute's own requirement for reference materials, NIBSC uses its experience in this field to develop customised bioassays and standards for external organizations. This activity fulfils the Institute's public health role, and generates some revenue to help fund NIBSC's ongoing biological standardisation work.



National and International Advisory Activities

The broad nature of NIBSC's role requires that we maintain strong links and constructive relationships with key stakeholders nationally and internationally. Within the UK we have improved significantly our relationship with MHRA over the year, with regular contacts maintained at a senior level, increased involvement in regulatory discussions and decisions, and re-initiation of a joint discussion forum for assessors in the Biologicals group and NIBSC experts.

Within Europe we have actively sought to increase NIBSC's involvement in development of regulatory strategy and have identified key objectives for the future, including working towards improvement of the CAP testing scheme currently used to monitor, post marketing, the quality of biological products not subject to OCABR.

Globally we have maintained very good relationships with WHO and with other collaborating centres involved in standardization, such as FDA and the Paul Ehrlich Institute, while continuing to build contacts with emerging regulatory agencies and biologics manufacturers in the Far East. In May 2006 we hosted an extremely successful visit by the Director and Deputy Director of the National Institute for Control of Pharmaceuticals and Biological Products in China, resulting in a Memorandum of Understanding and initiation of a number of important collaborative projects.

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 and NIBSC also maintains close technical links with the pharmaceutical industry, especially through industrial associations and professional bodies.

During 2006/07, Institute scientists have contributed to many advisory groups and committees, including the following:

United Kingdom

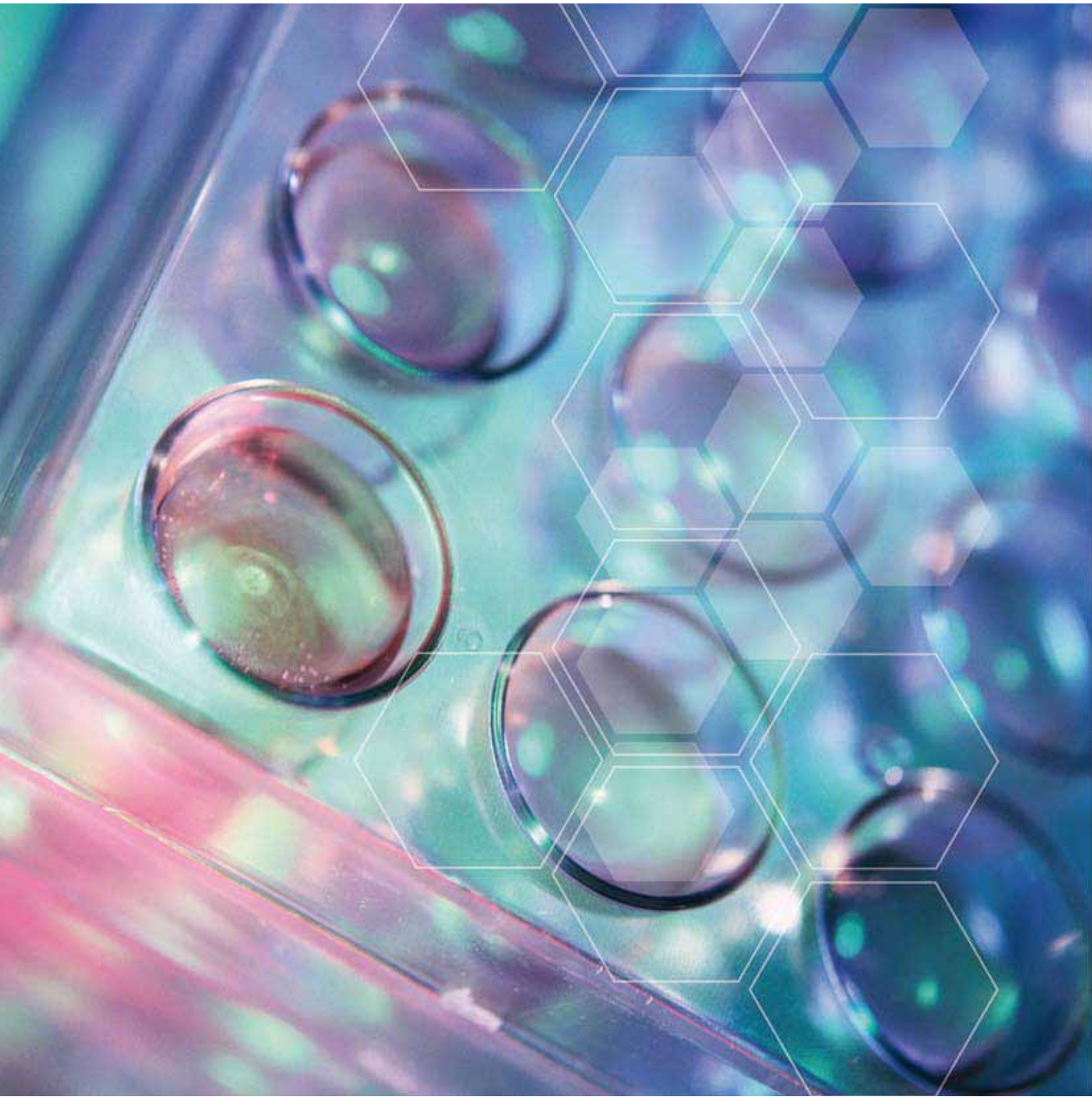
- Academy of Medical Sciences Gene Therapy group
- Advisory Committee on Dangerous Pathogens
- Advisory Committee on the Contained Release of genetically manipulated organisms
- Biosciences Federation Steering Group on Infection
- Brighton Collaboration on Vaccine Safety
- British Blood Transfusion Society Special Interest Group on Transfusion Microbiology
- British Pharmacopoeia
- British Standards Institute
- Commission for Human Medicines
  - Biologicals and Vaccines Expert Advisory Group 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
- Joint Committee on Vaccination and Immunisation-
- Sub-Committees on BCG vaccines, pertussis, anthrax and influenza
- Joint Professional Advisory committee to the Blood Services
- 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 Committee

Europe

- European Department for the Quality of Medicines (EDQM)
  - Biological Standardisation Programme Steering Committee
  - Working party on in vitro pyrogen testing
- European Medicines Agency
  - 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
- EU FP6 AIDS Vaccine Integrated Project (AVIP) Steering Committee
- ECVAM Collaborative Programme
- European Task Force on Haemophilia
- OMCL Laboratory network

International

- WHO Consultation Group on Cytokine Standardisation
- WHO Working Groups on
  - Pertussis vaccines;
  - Diphtheria and Tetanus vaccines;
  - Cholera vaccines;
  - Stability of reference materials;
  - Influenza vaccines;
  - Measles
  - Expert Committee on Biological Standardisation
  - Polio eradication
  - Live viral-vectored vaccines
  - Gene Therapy Products
- TB Vaccine Task Force
- ICH Gene Therapy Expert Group (EU representative)
- International Society for Interferon and Cytokine Research (ISICR): Standards Committee
- International Cytokine Society: Standardisation and Nomenclature Committee
- International Society of Thrombosis and Haemostasis Standardisation Committees tissue factor; fibrinolysis



MANAGEMENT COMMENTARY

In 2006 HM Treasury 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. This is the second such annual review published by the Board.

The development and performance of the Institute during the financial year 2006/07

The National Institute for Biological Standards and Control (NIBSC or The Institute) is the operational unit of the National Biological Standards Board (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 public 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 standardisation work at NIBSC modulates accordingly.

National Biological Standards Board

The year 2006/07 saw development in many scientific areas as outlined in this Annual Report, including establishment of the UK Stem Cell Bank, strengthened support for seasonal and pandemic influenza vaccine production, validation of vCJD testing and improved clinical trial safety following the TGN1412 incident. These activities illustrate well the diversity of funding sources from which the Institute benefits - including core funding from the UK Government, fees for standards handling and control testing, academic grants from UK research councils, the European Commission, the World Health Organisation and charitable foundations.

The previous financial year had been a period of uncertainty for the Institute as the UK Department of Health's review of its 'Arms Length Bodies', such as NBSB, reached its conclusions. However by the end of that year there was a clear forward plan for three years' core funding from the Department of Health as well as an improving outlook for income from other sources. The settlement included a modest increase in the Institute's revenue grant from the Department, following a long period without increases to keep up with inflation. Also the recurrent annual capital grant was increased substantially so that it exceeded the annual depreciation charge and opened the way to replacing capital assets faster than they are consumed.

2006/07 therefore started on a strong footing and financial balance was maintained throughout the year. The new tariff introduced for control testing work at the start of the financial year was accepted by manufacturing customers so that the cost of this aspect of the Institute's services is now broadly covered by the income it generates from customers. There was a further growth in handling charges earned from the distribution of biological standards and reference materials to industrial and academic customers, defraying the cost of making WHO international standards which are issued freely to National Control Laboratories around the world. Underlying research activity and the infrastructure of the Institute was financed by the core funding from the Department of Health and a portfolio of academic research grants from other bodies.

The combined effect of these developments was that the Institute was in a relatively strong position to meet new challenges and improve its physical and intellectual infrastructure.

Financial Results for the year 2006/07

In common with other government funded public bodies in the United Kingdom the Board has adopted a new form of accounts presentation for the year and has restated the previous year's figures on a consistent basis. The changes do not alter the net assets of the Board as a whole. The financial results are presented in an 'operating cost statement' which excludes funding received from the Depart-

National Biological Standards Board

ment of Health, which is now treated as a funding contribution from the Board's controlling body rather than as income.

The net operating cost for the year, including depreciation, financing charges and after crediting operating income, was £17,688k (2005/06: £15,600k). This cost was charged to the general reserve and offset by the Department of Health's funding contributions for the year of £12,742k towards revenue costs, £3,743 towards capital costs and a credit of £2,548k in respect of the notional cost to the Department of financing its investment in the Institute's capital.

The general reserve increased by £2,161k during the year, while the revaluation reserve increased by £2,928k, primarily due to the indexation of fixed asset values for inflation.

The gross operating costs were higher by £3,498k (17%). Of this £595k was the increase in the depreciation charge on a growing capital base, indexed annually for inflation. In the previous year, 2005/06, if an operating cost statement had been prepared it would have included a credit of £1,357k for the increase in the value of standards stocks: the corresponding increase in 2006/07 was much lower at £35k. Staff costs were up by £410k (3.6%) and numbers remained carefully controlled. Of the residual increase in gross operating costs, increases in fuel and energy costs accounted for £242k.

The valuation of stocks of biological standards is based on a financial model which reflects their cost of production, storage and distribution and their current level of demand. During 2006/07 there was a change in the underlying trends of standards activity with increases in the number of standards produced, in the number distributed, and in the proportion of distribution to production. These changes reflect the greater production capacity of the recently completed Centre for Biological Reference Materials, which replaces the previous facility built in 1987, and very strong demand for influenza standards. The impact on the year end stock valuation was modest in 2006/07 while the income from standards handling fees has continued to grow. The biological materials contained in the standards are not valued in the Board's balance sheet as they are donated without charge.

The Board continued its capital investment programme aided by the improved funding from the Department of Health. A detailed capital programme was developed during the early months of the financial year to cover a three year period and new projects then commenced. The rate of capital investment is dependent primarily on the level of design, procurement and project management resources and the interactions of projects on a relatively small site.

The value of goods and services invoiced to customers outside the United Kingdom was £5.03 million (2005/06: £4.5 million) which was well over half of total income from operations.

National Biological Standards Board

The Institute's position at the end of the year (31 March 2007)

The year ended with an increase in the general reserve and a sound working capital position. A number of capital projects were underway as part of the current three year programme with capital commitments at the end of the year of just over £1 million.

Progress was made during the year to transfer the Board's small closed pension scheme to a larger scheme. This affects only 11 of the Board's current employees and a larger number of past employees. By the end of the year plans were in place, subject to necessary legal and parliamentary processes, for a transfer to the NHS Pension Scheme, which is the pension scheme open to all the Board's other employees. The transfer value of the scheme calculated by the Government Actuary's Department at the end of the previous year (31 March 2006), less net payments made to members during 2006/07, is shown as a provision in the balance sheet at 31 March 2007. An offsetting amount receivable from the Department of Health to fund the transfer of the scheme is shown as a current debtor in the balance sheet. The Board expects the transfer of the scheme to be completed during the financial year 2007/08, without significant financial impact on the Board, resulting in the transfer of the related provision and debtor from its balance sheet.

Designs for a permanent building to house the UK Stem Cell Bank and a dedicated influenza facility were developed during the year. Construction is expected to commence during 2007. The combined building will be funded by a grant from the Medical Research Council and funds earmarked by the Department of Health.

Starting in April 2006, NIBSC adopted the accounting system and methods used by the Health Protection Agency. By the end of the financial year transaction processing responsibility had been transferred to the Agency under a service level agreement. Financial systems were therefore in an advanced state of preparedness for the merger of NIBSC's functions into the Health Protection Agency (expected in 2009).

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

The Institute ended the financial year 2006/07 having set a balanced budget for the following year, and with strong balance sheet and well financed capital programme underway. Overall financial stability is enhanced by the diversified nature of NIBSC's products and expertise and by the wide geographical dispersion of its customer base. The recurrent funding of some two thirds of the Institute's operating costs by the UK Government provides a strong core infrastructure. Nonetheless the Institute operates in the complex and sometimes hazardous field of biological medicines and is exposed to financial risks, which could impair its future position, as well as to opportunities for expansion. These risks and opportunities are thoroughly managed as part of the Board's governance arrangements.

The level of funding from the UK Government is determined by Parliament and is therefore outside the control of the Board. By April 2009 NIBSC is expected to become part of the Health Protection Agency, another public body largely funded by the Department of Health. This will introduce an additional factor into the determination of NIBSC's funding.

Research grants are awarded for fixed periods and must be replaced regularly. The success rate of grant applications depends on the reputation of the Institute and the relevance of its work in particular fields. These factors introduce a level of uncertainty in the proportion of NIBSC income from this source. Grants do not contribute significantly to the fixed costs of running the Institute and the employment of staff funded by fixed term grants risks the loss of their expertise when funding ends. However NIBSC and its staff value the scientific benefits of grant funded projects and they are expected to continue as part of the financial profile of the Institute.

The tariff for control testing of batch released biological medicines was changed from April 2006. This has increased income from this activity to a level commensurate with the cost of providing the service. Future income depends on demand for the particular products which manufacturers choose to have tested at NIBSC, rather than at other National Control Laboratories, and on the future scale of biological subject to batch release medicines (notably vaccines and natural blood products). NIBSC does not expect substantial financial growth in this area.

National Biological Standards Board

The income from standards handling fees has grown strongly for many years, despite the proportion of international standards which are provided free of charge to National Control Laboratories. In 2006/07 over half of the total value of such handling fees related to influenza standards. This component of NIBSC's income reflects current intense interest in influenza vaccines and may be affected by expected changes in influenza vaccine production away from traditional egg-based approaches to new technologies, such as cultured cell-based production.

On the cost side, NIBSC maintains careful control of its headcount – both for permanent, core funded staff and for fixed term grant funded staff – as staffing is the largest single element of its costs. After the transfer of NIBSC's activities to the Health Protection Agency it is anticipated that staff will adopt the 'Agenda for Change' terms which apply in the Agency and in the UK National Health Service generally. The impact of this change on NIBSC's future staff costs is currently unknown. The process of evaluating all staff posts in the Institute against the new terms is underway with a completion target during 2007.

NIBSC has a significant income on which UK Value Added Tax is levied and accordingly recovers a proportion of this tax on its purchases. NIBSC is also exempted from income and corporation taxes under its founding statute. The applicable tax regimes are expected to change on merger with the Health Protection Agency, but are not expected to become more favourable than at present.

As a modestly sized organisation based on a single site and with most of its intellectual capital invested in scientific expertise, the Board does not expect NISBC to undergo radical change in the scale or nature of its activities or its financial outlook.

National Biological Standards Board

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 2006/07 Key Targets is shown below.

Objective	Progress
Meet requirements for batch release of existing biological medicines according to defined targets for quality assurance and timeliness.	Agreed (EU) timelines for batch release fully met.
Maintain effective distribution of existing biological standards and develop replacements as required to ensure continuity of supply.	>93% of all requests met within 7 days (agreed internal target). Continuity of supply was maintained
Establish 10 new or replacement who International Standards and reference materials.	16 new standards established by ECBS in November 2006.
Publish at least 100 scientific papers. Identify at least 2 new opportunities for generating significant intellectual property.	101 papers published in calendar year 2006. 2 new patents filed.
Quality: Maintain existing quality certification for supply of standards, batch release and stem cell bank work (ISO13485, ISO 17025, ISO9001). Meet new requirements of WHO guidelines for International Standards.	All existing certification maintained. Compliance with WHO guidelines now in place and new comprehensive quality manual in preparation for standards and reference materials.

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Pandemic Influenza: Improve response time between receipt of outbreak isolates and supply of pandemic influenza vaccine seeds to manufacturers to <1 month. Supply and calibrate H7 and H5 avian influenza vaccine strains for clinical trial as required; begin development using reverse genetics of a library of vaccine candidates and QC reagents.	Successful lobbying of WHO and OIE to endorse distribution of partly-characterised vaccine seeds under Phase 4 and above conditions. This should cut down the response time by 3 weeks. Library development now underway.
Prepare and receive approval for a full business case to develop an Influenza Resource Centre. Complete design brief and tender process.	Business case submitted at beginning of January 2007. Revisions in progress following feedback from DH.
CJD: Design and complete collaborative study to compare blood based diagnostics.	Achieved. Study has provided basis for vCJD prevalence analysis of National Tonsil Archive with HPA, and blood screening evaluation with NBS.
Stem Cell Bank: Complete banking of 20 lines approved for deposit and make available to customers.	14 lines expected to be banked by year end. Shortfall against target due to uncertain growth rates for individual cell lines.
Cell Banking: Complete safety testing and final release of 3T3 cell bank for skin grafting and MRC5 cell bank for vaccine production.	Safety testing complete for 3T3 cell bank and final release certificates signed off. New expanded MRC5 cell bank ready for distribution.
HPA Merger: Develop an integrated financial accounting system and an agreed approach to annual accounts preparation.	Achieved.
Obtain Project Initiation approval for the new Training / Seminar hall project and identify sources of funding.	Funding identified and budgeted, but project initiation put on hold in favour of Influenza Centre/Stem Cell Bank projects because of resource constraints. Business case expected to be completed during 2007.

Funding Sources

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

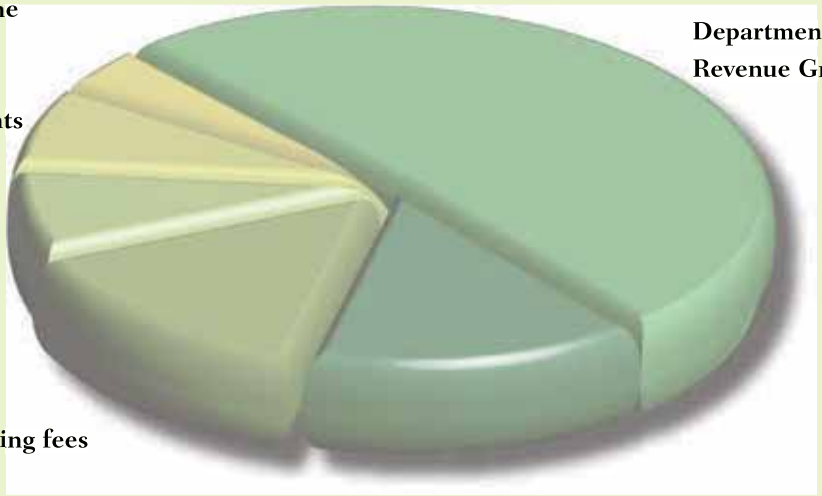
Additional funding includes:

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 2006/07 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 Sir 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 2005/06 to 2006/07 was 3.0 per cent.

A merit pay scheme for staff of the Board below the level of Director was in place during the year which allocated 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 65 (previously 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 Sir Gordon Duff, for the year ended 31 March 2007 amount to £16,191. In 2005/06 the Chairman received a total of £15,420.

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

	2006/07	2005/06
	£	£
M Beaumont	290	-
Professor D Calam	580	725
Professor J Darbyshire	580	580
M Hindle	1,160	1,015
Professor D Latchman	580	290
Professor C Lee	870	580
Professor K Nicholson	290	-
G Noble	1,305	2,030
Dr J Petricciani	580	372
A Robertson	1,305	1,595
Professor Patrick Sissons	-	145
Professor Sir J Skehel	290	145
Dr L Tsang	290	290
	8,120	**7,767**

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 2006/07 was £149,415. In 2005/06 his remuneration was £145,320. 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 2007, classified into bands of £5,000, were as follows:

	Salary 2007	**Salary 2006**
	£'000	£'000
Dr S Inglis Director	145-150	145-150
V Knight Head of Finance/ Board Secretary	60-65	60-65
S Murray Head of Operations	60-65	60-65
A Jowett Head of Human Resources	50-55	45-50

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

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

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 as follows:

	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 2007 (bands of £5, 000)	Lump Sum Value as at 31 March 2007 (bands of £5, 000)	Cash Equivalent Transfer Value as at 31 March 2007	Cash Equivalent Transfer Value as at 31 March 2006	Real Annual Increase in Cash Equivalent Transfer Value
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Dr S Inglis* Director	0.0-2.5	2.5-5.0	20-25	65-70	366	329	29
V Knight Head of Finance/ Board Secretary	0.0-2.5	2.5-5.0	10-15	35-40	208	176	28
S Murray Head of Operations	0.0-2.5	2.5-5.0	0-5	10-15	64	47	16
A Jowett Head of Human Resources	0.0-2.5	0.0-2.5	0-5	10-15	75	60	14

* Restated figures from NHS Pensions Agency in 2007

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.

Certain of the disclosures in the Remuneration Report are subject to audit. These include

- Salary and allowances, bonuses, expenses allowance, compensation for loss of office, and non-cash benefits for each senior manager (this includes advisory and non-executive Board members) who served during the year;
- Pensions for each senior manager who served during the year;
- Compensation payments to former senior managers; and
- Amounts payable to third parties for services of a senior manager.

The disclosures summarised above have been audited.

Further details are found in notes 1, accounting policies, and 2, staff costs, to the accounts.

Dr Stephen Inglis **9 July 2007**
Chief Executive

Additional Corporate Information

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 or before April 2009.

Activities

The Board's prime function is to assure the potency, purity and related efficacy and safety of biological substances used in human medicine. These substances include bacterial and viral vaccines such as those used for immunisation against diphtheria, poliomyelitis, measles and influenza, blood products such as Factor VIII and immunoglobulins and therapeutics such as cytokines and growth factors. Standard preparations, against which the potency of biological substances is measured, are prepared, held and distributed to other national control laboratories and to manufacturers and researchers throughout the world. Control testing of batches of biological medicinal products supplied by holders of licences under the Medicines Act 1968 and/or EC Directive 2001/83 (as amended) is carried out to ensure that requirements relating to potency, purity and associated efficacy and safety have been met. The Board collaborates with the World Health Organization, the European Pharmacopoeia Commission and other international organisations and bodies in relation to the establishment of standards for, the provision of standard preparations of, and the testing of biological substances.

Research and development

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

Form of Account

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

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 disqualifi-

cation. 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.

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 2006/2007, the Board paid 79% (2005/06: 79%) of invoices within 30 days, representing 60% (2005/06: 67%) 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 3 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 necessary steps to ensure that he is aware of relevant audit information and to establish that the Board's auditors are aware of all such 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 2007, except for the audit of one cost report in relation to a grant from the European Commission for which a fee of £940 was paid.

Board members

Board members Board membership during the financial year was:

Professor Sir Gordon W Duff PhD FRCP FMedSci (Chairman)
Mr Michael Beaumont CBE FCA
Professor Derek H Calam OBE MA DPhil CChem FRSC FRSA Hon MRPharmS Hon MBIRA Hon DSc
Professor Janet H Darbyshire OBE FRCP FFPHM
Mr Alan Heath MA MSc CStat
Mr Martin Hindle MSc BPharm MRPharmS
Dr Stephen C Inglis PhD (Director of NIBSC)
Professor David S Latchman PhD DSc FRCPath
Professor Christine Lee MA MD DSc(Med) FRCP FRCPath
Professor Karl Nicholson MD FRCP FRCPath
Ms Gill M Noble CB MA MSc
Dr John C Petricianni MD
Mr Allan J Robertson CA
Dr Nicola Rose PhD
Professor Sir John Skehel FRS
Dr Lincoln Tsang LLB PhD FRSC FIBiol FRSA MRPharmS Barrister

S C Inglis
Accounting Officer
National Biological Standards Board
9 July 2007


CCTV
National
Institute for
Biological
Standards &
Control
National Biological Standards Board

National Biological Standards Board

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 operating costs 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".

National Biological Standards Board

Statement on Internal Control for the year ended 31 March 2007

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 an 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 2007 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

Capacity to handle risk

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

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 assurance systems covering key parts of the Institute'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 endorsed by independent risk management experts and is subject to periodic review and development. It is linked with NIBSC's key targets and Divisional work programmes as set out in the annual Business Plan and provides the basis for the Institute's internal audit plan.

During 2006/07 the corporate governance structure continued to adapt so that the Institute as a whole responded to its strategic targets and best aligned itself for future incorporation into an enlarged Health Protection Agency.

The Board also revised the various quality systems which it uses to meet customer expectations in its different fields of operation. NIBSC is working towards implementation of a quality framework across the organisation from which compliance with recognised quality standards may be readily derived.

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.

I have been advised in my review of the effectiveness of the system of internal control by the Audit Committee. This review provided substantial assurance in some areas . A plan to address weaknesses and ensure continuous improvement of the system is in place where appropriate.

Control issues during the year

From the start of the financial year 2006/07 the Board operated a new finance and resource management system based closely on that used by the Health Protection Agency to replace existing systems and related processes at NIBSC. In the final quarter of the financial year a number of financial services were transferred to the Health Protection Agency under a Service Level Agreement. No impairment of controls or records was experienced during the year under review and the operation of the new financial arrangements since the balance sheet date has given no subsequent cause for concern.

S C Inglis
Accounting Officer, National Biological Standards Board
9 July 2007

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 (the Board) for the year ended 31 March 2007 under the Biological Standards Act 1975. These comprise the Operating Cost Statement, the Balance Sheet, the Cashflow Statement and Statement of Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Board, Accounting Officer and auditor

The National Biological Standards Board and Director as Accounting Officer 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 Treasury and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of the National Biological Standards Board's and Director's Responsibilities.

My responsibility is to audit the financial statements and the part of the remuneration report to be audited 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 National Biological Standards Act 1975 and directions made thereunder by the Secretary of State with the approval of Treasury. I report to you whether, in my opinion, certain information given in the Annual Report, which includes the "Chairman's Report", "Director's Report" and the Management Commentary, is consistent with the financial statements. 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.

In addition, I report to you 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 HM Treasury regarding remuneration and other transactions is not disclosed.

I review whether the Statement on Internal control reflects the Board's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement covers 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. 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 Auditing 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 Accounting Officer 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

Audit Opinion

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 Treasury, of the state of the Board's affairs as at 31 March 2007 and of its net operating cost 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 Treasury; and
- information given within the Annual Report, which includes the "Chairman's Report", "Director's Report" and the Management Commentary, is consistent with the financial statements.

Audit Opinion on Regularity

In my opinion, 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.

Report

I have no observations to make on these financial statements.

John Bourn
Comptroller and Auditor General

11 July 2007

National Audit Office
157-197 Buckingham Palace Road
Victoria
London SWIW 9SP

National Biological Standards Board

Operating Cost Statement for the year ended 31 March 2007

	Note	2006/07 £000	2005/06 (restated) £000
Staff costs	2	11,711	11,301
Other operating charges	3	8,637	6,124
Depreciation	4	3,392	2,817
Gross operating cost		**23,740**	**20,242**
Less: Income from operations	5	8,503	7,001
Net operating cost before interest		**15,237**	**13,241**
Interest receivable		97	94
Cost of capital charge	4	2,548	2,453
Net operating cost for the financial year		**17,688**	**15,600**

All results arose from continuing operations.

Statement of Recognised Gains and Losses for the year ended 31 March 2007

	Note	2006/07 £000	2005/06 £000
Unrealised surplus on revaluation of fixed assets	7, 16	3,710	2,225
Net surplus (deficit) on foreign currency translation	3	4	(2)
Recognised gains and losses		**3, 714**	**2, 223**

The notes on pages 57 to 72 form part of this account.

National Biological Standards Board

Balance sheet as at 31 March 2007

	Note	2007 £000	2006 (Restated) £000
Fixed assets			
Tangible fixed assets	7	61,750	59,903
Intangible fixed assets	7	387	269
		62,137	**60,172**
Debtors due after more than one year	8	-	11,000
Current assets			
Stock	9	8,608	8,509
Debtors	8	14,198	3,082
Cash at bank and in hand	10	6,513	3,752
		29,319	**15,343**
Creditors			
Amounts falling due within one year	11	3,263	3,030
Net current assets		**26,056**	**12,313**
Provisions for liabilities and charges	12, 13	11,057	11,382
Net assets		**77,136**	**72, 103**
Capital and reserves			
General reserve	16	43, 116	40,955
Revaluation reserve	16	32, 789	29,861
Donated asset reserve	16	1,231	1,287
		77, 136	**72, 103**

S C Inglis, Accounting Officer

National Biological Standards Board

9 July 2007

The notes on pages 57 to 72 form part of this account

Cash Flow Statement for the year ended 31 March 2007

	Note	2006/07 £000	2005/06 (restated) £000
Net cash outflow from operating activities	17(i)	(11, 073)	(7,730)
Returns on investments and servicing of finance			
- Interest received		97	94
Capital expenditure		(2, 748)	(3,092)
Receipts from disposal of fixed assets		-	-
Net cash outflow before financing		**(13,724)**	**(10,728)**
Management of liquid resources			
Financing:			
- Government funding for revenue		12,742	12,060
- Government funding for general capital		3,743	1,362
- Grant equipment funds		-	476
Increase in cash	17(ii)	**2,761**	**3,170**

The notes on pages 57 to 72 form part of this account

National Biological Standards Board

Notes to the Account for the year ended 31 March 2007

1 Statement of accounting policies

These accounts have been prepared in accordance with the 2006/07 Government Financial Reporting Manual (FReM) issued by the Department of Health. The accounting policies contained in the FReM follow UK generally accepted accounting practice for companies (UK GAAP) to the extent that they are appropriate to the public sector.

(a) Accounting convention

These accounts have been prepared under the historical cost convention, modified to include the revaluation of fixed assets and stocks.

(b) Change of Accounting Policy

With effect from the 2006/07 reporting period the FReM requires non-departmental public bodies (NDPBs) to account for grants and grant-in-aid received for revenue purposes as financing because they are regarded as contributions from a controlling party which gives rise to a financial interest in the residual income of NDPBs. This is a change of accounting policy from earlier periods when such items were recorded as income. The effect of this change on the audited 2005/06 balances is shown in Note 16 to the accounts

(c) Fixed assets

Tangible fixed assets are shown at current value (cost or valuation) less depreciation. The threshold for capitalising assets is £5,000. Below this value purchased assets are written off to operating costs as incurred.

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 2007.

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

Intangible fixed assets comprise software licences purchased from third parties with a life of more than one year.

(d) 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.

(e) Government grants

Government grants receivable for general capital expenditure are credited to a General Reserve (Note 16). Government grants receivable for specific capital expenditure would be credited to a Capital Reserve and released to revenue over the expected useful lives of the relevant assets by equal annual amounts. Non-government grants for capital items are treated in a similar way through the Donated Assets Reserve. Grants for revenue are set against operating costs in the year to which they relate (Note 6).

(f) 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.

(g) Research and development

Research and development costs are written off as incurred.

(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 2006/07, 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 from a 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 in the Operating Cost Statement in arriving at the net operating cost and is offset by a corresponding credit to the General Reserve as the charge 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, excluding funding received from the Department of Health.

(l) 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 Operating Cost Statement.

(m) 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.

(n) Operating leases

Operating lease costs are charged to operating costs on a straight line basis over the lease term.

2 Staff Costs

(a) All staff	Note	2006/07 £000	2005/06 £000
Salaries and wages		9,537	8,948
Social Security costs		792	753
Employers contributions to the NBSB Pension Scheme	13	57	57
NHS Superannuation contributions		1,108	1,108
Consultancy and agency staff		217	435
		11,711	**11,301**

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

		2006/07 Number	2005/06 Number
Scientific divisions		207	205
Support and operations		67	73
Administration		24	24
		298	**302**

3 Other Operating Charges

(a) Other operating charges

	Note	2006/07 £000	2005/06 (Restated) £000
Consumable laboratory supplies		3,193	3,325
Central services, net of production recovery		2,055	(163)
Premises		2,677	1,955
Equipment		372	374
Travel, subsistence and hospitality:			
Chairman and other Board members		3	5
Employees		208	200
Audit fee		40	50
Increase in provision for early retirements	12	-	225
Bad debts provided for or written off		10	(8)
Loss (profit) on disposal of assets		83	159
Foreign exchange (gain) / loss		(4)	2
		8,637	**6,124**

Comparative figures for 2005/06 have been restated for improved consistency with the revised chart of accounts used in common with the Health Protection Agency since April 2006.

The audit fee relates to the audit of the Board's annual accounts. In addition a fee of £1k has been incurred for the audit of cost statements submitted to a third party grant donor.

(b) Foreign currency translation

Net exchange gains of £4k on foreign currency balances have been credited to other operating charges.

(c) VAT refund

During the year 2006/07 VAT returns were submitted quarterly and the partial recovery of VAT of £1,378k (2005/06: £1,109k) on purchases has been reflected in the accounts as a reduction in the cost of capital additions or revenue expenditure as appropriate.

4 Capital charges

	2006/07 £000	2005/06 £000
(a) Depreciation		
Depreciation charge for the year based on historical cost of fixed assets	3,076	2,621
Additional charge based on current cost of fixed assets	316	176
	3,392	**2,797**
Of which the amount relating to donated assets:	56	70

(b) Cost of capital

Notional interest at 3.5% of the average value of net government funded assets during the year, which is £2,548 k (2005/06 £2,453k) is matched by a notional credit for the same amount in the General Reserve.

5 Income from operations

	2006/07 £000	2005/06 £000
Research grants		
Research Councils etc	547	1,348
World Health Organization	61	160
European Commission	299	443
Other Bodies	1,077	421
Total research grants	**1, 984**	**2, 372**
Contracts	1,068	854
Standards distribution handling charges	3,570	2,690
Control testing fees	1,881	1,085
Total income from operations	**8,503**	**7,001**

6 UK Government Grants

		2006/07 £000	2005/06 £000
Received from the Department of Health		12,867	12,399
Less: Contributions to the NBSB Pension Scheme included in Department of Health grant		(125)	(339)
Department of Health financing of operating costs		**12,742**	**12,060**

The funding received from the Department of Health includes contributions from all the Devolved Administrations of the United Kingdom.

Reconciliation of Net Operating Cost for the year to financing received from the UK Government

	Note	2006/07 £000	2005/06 £000
The Board's performance against financing from the UK Government for the financial year ended 31 March 2007 is as follows:			
Net operating cost for the financial year		**17,688**	**15,600**
Less: Depreciation on assets funded by capital grant in aid from the Department of Health	4(a)	3,336	2,747
Less: Charge for cost of capital	4(b)	2,548	2,453
Less: Losses on disposal of assets funded by the Depatment of Health	3(a)	83	159
		11,721	**10,241**
Financing received from the UK Government:			
Department of Health financing of operating costs		12,742	12,060
Underspending against financing received from the UK Government		**1, 021**	**1,819**

7 Fixed Assets

	Freehold land	Freehold buildings	Equipment & computers	Production equipment	Assets under construction	Total tangible assets	Software	Total fixed assets
	£000	£000	£000	£000	£000	£000	£000	£000
Balances at 1 April 2006	5,303	51,936	11,228	1,543	2,848	72, 858	418	73,276
Additions	-		325	137	1,127	1, 589	222	1,811
Transfers	-	3,832	-	(47)	(3,832)	(47)	-	(47)
Disposals	-	-	(19)	(225)	-	(244)	-	(244)
Diminution	-	-	(31)	-	-	(31)	(31)	(62)
Revaluation / indexation	1,004	11,654	32	(35)	-	12, 655	-	12,655
Cost or valuation at 31 March 2007	**6,307**	**67,422**	**11, 535**	**1,373**	**143**	**86, 780**	**609**	**87,389**
Accumulated depreciation at 1 April 2006	-	4,877	7,476	602	-	12, 955	149	13,104
Charge for the year	-	2,343	903	63	-	3, 309	84	3,393
Disposals	-	-	(19)	(142)	-	(161)	-	(161)
Diminution	-	-	(18)	-	-	(18)	(11)	(29)
Backlog depreciation / indexation	-	8,924	21	-	-	8, 945	-	8,945
Accumulated depreciation at 31 March 2007	**-**	**16,144**	**8,363**	**523**	**-**	**25, 030**	**222**	**25,252**
Net book value								
At 31 March 2006	5,303	47,059	3, 752	941	2,848	59, 903	269	60,172
At 31 March 2007	**6,307**	**51,278**	**3, 172**	**850**	**143**	**61, 750**	**387**	**62,137**

The total of fixed assets is divided between tangible and intangible assets (Note 1(c)). Intangible assets comprise software as above.

Two motor vehicles with a net book value of £nil (2006: £nil) are included in equipment and computers.

8 Debtors

	31 March 2007 £000	31 March 2006 £000
(a) Debtors due more than one year from balance sheet date		
Department of Health	-	**11,000**
(b) Debtors due within one year		
Department of Health	10,875	-
Trade debtors	779	1,308
Grant income receivable	1,308	982
Other debtors	400	368
Prepayments	836	424
	14,198	**3,082**

The debtor due from the Department of Health represents the Department's obligation to fund the future liabilities of the NBSB Pension Scheme (Notes 12 and 13).

Intra-governmental balances:			
Balances with Central Government bodies		11,502	11,367
Balances with NHS Trusts		7	5
Balances with Local Authorities		-	-
Balances with Public Corporations		-	87
Balances with bodies external to Government		2,689	2,623
Total		**14,198**	**14,082**

9 Stock

		31 March 2007 £000	31 March 2006 £000
Standards		7,799	7,764
Raw materials		57	70
Others		752	675
		8,608	**8,509**

National Biological Standards Board

The Board holds stocks of biological reference materials ('standards') which are used in regulatory control, diagnosis and research. At 31 March 2007 2.2 million standards were held of which 1.0 million were publicised for distribution in NBSB's reagent catalogue. The Board estimates their economic value at 31 March 2007 to be £7,799k (2006: £7,764k) at the lower of cost and net realisable value.

As stated in Note 1(f) 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.

10 Cash at Bank and In Hand

	31 March 2007	31 March 2006
	£000	£000
Paymaster account	3, 334	126
Other Department of Health cash at bank and in hand	2, 879	3,326
External cash funding received in advance	300	300
	6,513	**3,752**

11 Creditors: Amounts falling due within one year

	31 March 2007	31 March 2006
	£000	£000
Taxation and social security costs	568	-
Trade creditors	677	1,628
Accruals	483	215
Deferred grant income	1, 535	1, 187
	3, 263	**3, 030**

Intra-governmental balances:		
Balances with Central Government bodies	1, 037	582
Balances with NHS Trusts	-	-
Balances with Local Authorities	-	-
Balances with Public Corporations	-	-
Balances with bodies external to Government	2, 226	2, 448
Total	**3, 263**	**3, 030**

12 Provisions

	NBSB Pension Scheme	Early Retirements	Other Provisions	Total
	£000	£000	£000	£000
Balance at 1 April 2006	11,000	374	8	11,382
Utilised during the year	352	15	-	367
New provisions during the year	-	-	42	42
Balance at 31 March 2007	**10,648**	**359**	**50**	**11,057**

(a) The Board is arranging the transfer of the NBSB Pension Scheme during 2007/08 as part of its preparations for the merger of NIBSC with the Health Protection Agency. The Government Actuary previously calculated the cost of transferring the scheme to other existing schemes would be £11.0 million (at 31 March 2006). The provision for the scheme in the Board's accounts at 31 March 2007 is based on this transfer cost, which is expected to be met by the Department of Health (Note 8).

(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.

13 NBSB Pension Scheme

The NBSB Pension Scheme is overseen by a five member Committee of Administration appointed by the Board, including two staff members of the scheme. Of the 64 members at 31 March 2007, 11 are contributing, 44 are receiving pensions and the other 9 have preserved pension rights. Details of the net cost to the Board are shown below:

	2006/07 £000	2005/06 £000
Lump sum payments	47	46
Transfers to other schemes	-	-
Benefits paid	390	375
Total payments	**437**	**421**
Less:		
Employers Contributions	57	57
Employees Contributions	28	28
Total Contributions	**85**	**85**
Net cost of pension scheme	**352**	**336**

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

14 Government grants for general capital purchases

		2006/07 £000	2005/06 £000
Received from the Department of Health		3,743	1,362

The funding received from the Department of Health includes contributions from all the Devolved Administrations of the United Kingdom.

Government grants for general capital purposes are credited to the General Reserve. All the fixed assets belonging to the Board are funded by government or other grants included in reserves (see Note 16).

15 Capital commitments

	2006/07	2005/06
	£000	£000
Contracted capital commitments as at 31 March 2007 for which no provision has been made	1,040	1,237

16 Capital and Reserves

	General Reserve £000	Deferred Government Grant £000	Revaluation Reserve £000	Donated Asset Reserve £000	Income and Expenditure Account £000	Total £000
Balance at 1 April 2006	-	32,759	29,861	1,287	8,196	72,103
Change of Accounting Policy (Note 1(b)): Transfer of Income and Expenditure Account and Deferred Government Grant to General Reserve	40,955	(32,759)	-	-	(8,196)	-
Restated balance at 1 April 2006	**40,955**	**-**	**29,861**	**1,287**	**-**	**72,103**
Correction of opening reserves	(22)					(22)
Net operating cost for the year	(17,688)					(17,688)
Financing received from the UK Government:						
- For operating costs	12,742					12,742
- For general capital	3,743					3,743
Reversal of charge for cost of capital	2,548		-	-		2,548
Gain (loss) on revaluation – fixed assets			3,710	-		3,710
Current cost element of depreciation charge	316		(316)			
Depreciation transfer from donated assets	56		-	(56)		-
Realised gains on standards stock transferred to General Reserve	466		(466)	-		-
Balance at 31 March 2007	**43, 116**	**-**	**32, 789**	**1,231**	**-**	**77,136**

17 (i) Notes to the Cash Flow Statement

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

		2006/07 £000	2005/06 (Restated) £000
Net operating cost for the year		(17,688)	(15,600)
Interest received		(97)	(94)
Cost of capital charge		2,548	2,453
Depreciation		3,392	2,817
Opening adjustment to reserves		(22)	-
Release from revaluation reserve		-	(575)
Loss on disposal of fixed assets		83	218
Fixed assets transfered to stock		47	-
Diminution in value of computers and software		33	14
Increase in stock		(99)	(1,328)
Decrease in long term debtors		11,000	(2,308)
Increase in short term revenue debtors		(11,116)	4,160
Increase in revenue creditors		1,171	(203)
Decrease in provisions		(325)	2,716
Net cash outflow from operating activities		**(11, 073)**	**(7,730)**

(ii) Reconciliation of Net Cash Flow to Movement in Net Funds	2006/07 £000
Increase in cash in the period	2,761
Increase in liquid resources	-
Change in net funds	2,761
Net funds at 31 March 2006	3,752
Net funds at 31 March 2007	6,513

18 Losses and special payments

There were no losses or special payments during the year.

19 Operating leases

The Board had no commitments under operating leases at the 31 March 2007 (2006: £96,747).

20 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 0.5% 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.

21 Post balance sheet events

There were no post balance sheet events. These accounts were authorised and issued by the Board on 18 July 2007.

22 Contingent liabilities

There were no contingent liabilities not otherwise provided for in the accounts (2006: £nil).

23 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 6 and 14.

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

Health Protection Agency
Home Office
Medical Research Council
Department of Trade and Industry
DSTL

All transactions were carried out on 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 2006/07				
Member	**Organisation**	**Nature of Interest**	**Organisation**	**Nature of Interest**
Mr Michael Beaumont	Health Protection Agency East Midlands Strategic Health Authority	Non-executive Director Non-executive Director, Vice Chairman	Nottingham Healthcare NHS Trust Newark Housing Association Ltd	Mental Health Act Manager Chairman
Professor Derek H Calam	NBSB	Pension		
Professor Janet Darbyshire	Wide range of national and international pharmaceuti-cal companies	Director of MRC Clinical Trials Unit where some of the research is supported in part by industry.		
Professor Sir Gordon Duff	Interleukin Genetics	Scientific Advisory Board, Shareholder		
Mr Alan Heath	None	None		
Mr Martin Hindle	Peterborough and Stamford Hospitals NHS Foundation Trust National Probation Service- Leicestershire and Rutland University Hospitals of Leicester NHS Trust	Non Executive Director Director Chairman	Sanofi Aventis Pension Fund Cable and Wireless Pension Fund	Member Member
Dr Stephen Inglis	Partnerships UK	Associate advisor		

National Biological Standards Board

Declared Interests of NBSB Members relating to 2006/07				
Member	**Organisation**	**Nature of Interest**	**Organisation**	**Nature of Interest**
Professor David Latchman	Biovex Ltd (interest ceased during year) Therakind Ltd London Development Agency Board	Chairman Scientific Advisory Board, Non Executive Director, Consultant, Shareholder Board Member Observer	Health Protection Agency London Higher (Umbrella organization which represents all London Universities)	Board Member 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) Clinical trial NN1731-1084 recombinant human Factor VIII analogue (Novo Nordisk)	DSMB Member DSMB Member DSMB Chair
Professor Karl Nicholson	Health Protection Agency	Board Member		
Miss Gillian Noble	Various Pharmaceutical Companies (Managed by HSBC Trust Company)	Shareholder	Meningitis Trust MRC	Director Audit Committee Member

National Biological Standards Board

Declared Interests of NBSB Members relating to 2006/07				
Member	**Organisation**	**Nature of Interest**	**Organisation**	**Nature of Interest**
Dr John Petricciani	World Health Organisation National Institutes of Health International AIDS Vaccine Initiative	 Occasional Consultancy	International Association for Biologicals InB	Board Member Scientific Advisory Committee
Mr Allan Robertson	MRC	Audit Committee Member		
Dr Nicola Rose	Big Lottery Fund	External Assessor, Research Grants programme		
Prof Sir John Skehel	Animal Health Trust Life Science Ventures Institute of Molecular Medicine	Member of Scientific Advisory Board and Executive Committee Member Consultant Member of Scientific Advisory Committee	Academy of Medical Sciences Medimmune MRC Technology Novartis Foundation	Vice President of Forum and Member of Council Consultant Board Member Science Adviser, Chairman of the Executive Council
Dr Lincoln Tsang	Arnold & Porter LLP BioIndustry Association	Partner specialising in life sciences Chairman of Regulatory Affairs Advisory Committee	The School of Pharmacy, University of London Various pharmaceutical and biotechnology companies	Member of the Governing Council External legal counsel

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