
2007/08
NBSB
Annual Report & Accounts

NBSB

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1st April 2007 to 31st March 2008

National Biological Standards Board
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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 Schedule of Accreditation.

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

National Biological Standards Board
Annual Report and Accounts
for the year ended 31st March 2008

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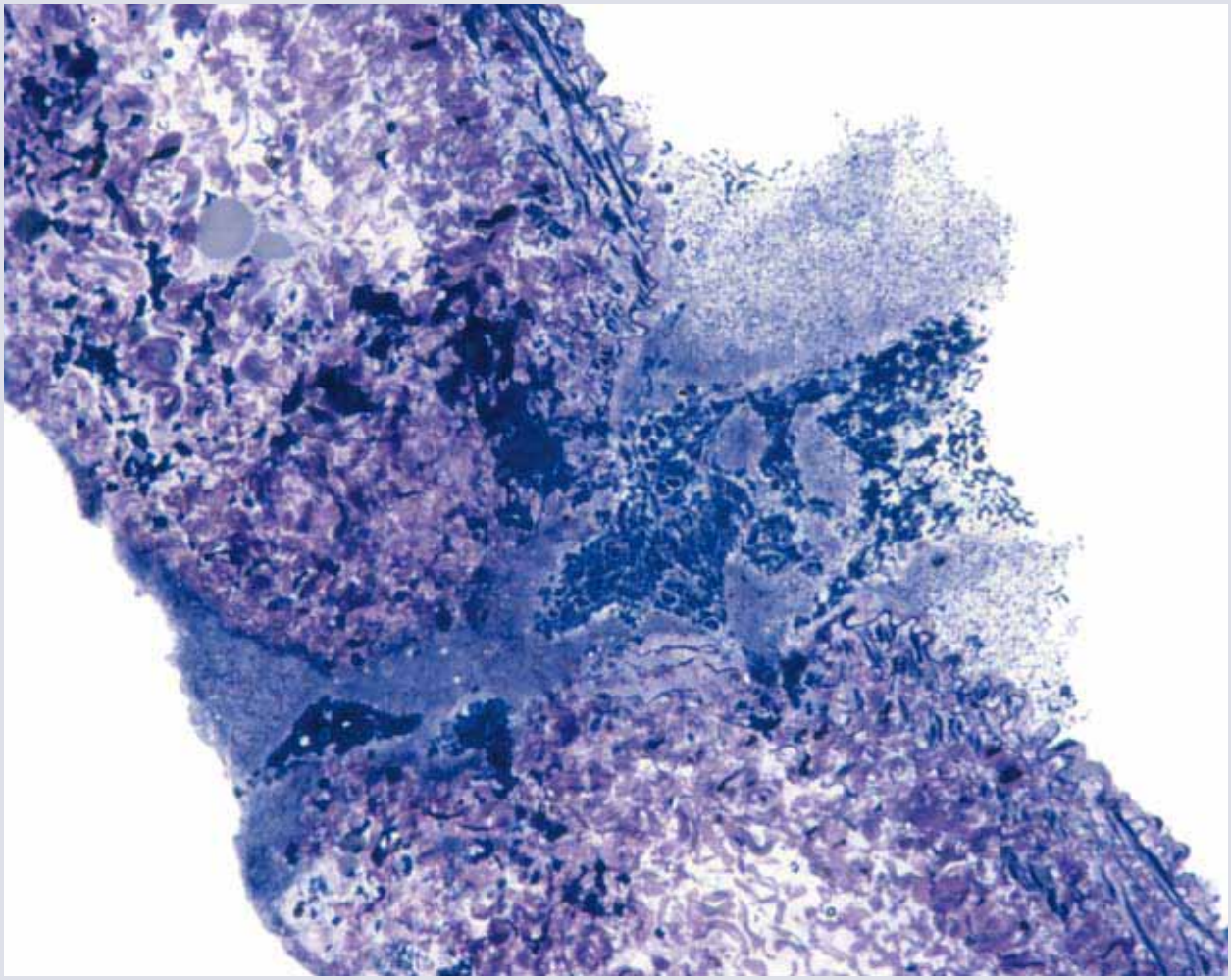

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Chairman's Report

It is a pleasure to introduce the 2007/08 Annual Report for the National Institute of Biological Standards and Control. To fulfill its public health role in the UK and beyond, the Institute must always achieve the highest standards in day to day work, as well as keeping in step with advancing biological and biochemical sciences. I am happy to say that a review of the last year provides clear evidence that these have been achieved.

We read daily of scientific innovations that promise many new treatments for diseases where there is huge clinical need, but the translation of research discoveries into new medicines for human diseases is a demanding process that needs different sets of skills.

As well as assuring the quality and standards of today's biological medicines the Institute has continued to lay the foundations for the development of safe and effective new medicines for the future. Excellent progress has been made in areas such as stem cell technology, pandemic flu preparedness, novel vaccine development, molecular immunology and molecular engineering. This level of sustained achievement can only result from a shared commitment and dedication among the scientists, support staff and management of the Institute.

The National Biological Standards Board will be abolished in the near future and NIBSC will then merge with the Health Protection Agency (HPA). This will be a good grouping of talents, and I am pleased to report that preparations for a smooth transition are well advanced. I am also very pleased that the retention of the NIBSC name has been recognised as important in terms of its international reputation for scientific strength, reliability and quality, built up over many decades.

As always, in 2007/08 it has been a privilege to chair the National Biological Standards Board, and I offer my warm thanks to its members who have worked hard to ensure that the Board's contributions to the merger have been timely and comprehensive. It is never a good idea to name individuals, but I will break with this convention once by recording special thanks to Gillian Noble for her heroic work on the transfer of the NBSB pension scheme prior to the merger.

Finally, I would like to express the Board's warm gratitude to the exceptional staff of NIBSC; the scientists, support staff, managers and Director. It is their sustained efforts and achievements over the year that now enable me to write such a positive annual report.

Sir Gordon Duff FRCP FMedSci FRSE

Chairman, National Biological Standards Board

Director's Report

Wherever I go in the world I am constantly gratified by the high regard in which NIBSC is held for its work on standardisation and control of biological medicines. We are without doubt world leaders in the field, and the practical importance of what we do is recognized by manufacturers, regulators, policy makers and the research community. At the heart of this success is our work on International Standards and once again this year our scientists have been very productive. These are crucial tools for assuring the efficacy and safety of many of our most widely-used and valuable medicines, and it is a remarkable fact that, as the leading WHO International Laboratory for standards, we produce and distribute almost all of the world's 'gold standard' reference materials for biological medicines.

NIBSC's work attracts enormous international credit and gratitude to the Institute, and also to the UK in general. It would be wrong, however, to think that this is an entirely altruistic activity. The unique expertise built up at the Institute over many years around its standardisation and control work and our ability to bring this expertise to bear on rapidly on important national health issues such as MMR safety, pandemic influenza, vCJD, adverse reactions following experimental drug trials, and most recently contamination of heparin, has proved its worth time and time again.

Furthermore the development of new biological medicines, based on existing technologies and also through completely new approaches, offers not only public health benefits but also the opportunity for wealth creation. The Institute's expertise in standardisation and control of such products effectively and its support for innovation, is therefore an important competitive advantage to the UK.

Finally emerging health threats are no respecters of international borders. Infectious agents can spread around the world very rapidly, and the inevitable and growing globalisation of biopharmaceutical production means that problems arriving on our doorstep are often imported from elsewhere. NIBSC's position as the international hub for standardisation and control of biological medicines therefore provides both an 'early warning' system for emerging issues and an opportunity to influence positively international developments to reduce future risk.

These practical contributions must be underpinned by top class scientific research. It has been particularly pleasing to note over the past year an increase in both and outputs, measured by publications, and inputs, in the form of external funding. There is an increased focus nationally on translational research and NIBSC's position at the interface between cutting edge research, product development, policy and regulation, means that it is ideally placed to make a significant contribution to this national agenda.

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 medicines include viral and bacterial vaccines, products derived from human blood, hormones and other biotherapeutic 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. Testing of products continued at a high level during 2007/08. Testing of the newly-licenced HPV and rotavirus vaccines is now well established and we have been pleased to be nominated as OMCL for the batch release of a proposed new pneumococcal conjugate vaccine, indicating continued confidence in both the scientific expertise of the Institute and the quality of its service.

Batch Release Activity 2007

Product groups	No of batch release certificates in 2007 (2006)
Bacterial vaccines, toxins, antitoxins	289 (316)
Viral vaccines	109 (118)
Blood products: Albumin, coagulation factor concentrates, virus inactivated plasma and fibrin sealants	539 (470)
Immunoglobulins	233 (227)
Total batch release certificates	**1170 (1131)**
Plasma pools tested (virus testing)	1428 (1828)

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 Organisation (WHO) International Standards provides a set of "gold standards" from which countries and manufacturers can calibrate their own standards for biological testing. The effective use of vaccines, most therapeutic biotechnology products and many other biologicals depends on the availability of standards supplied by NIBSC, which are essential for quality testing results from different parts of the world to be comparable. NIBSC is one of only three international laboratories involved and is by far the strongest in this field.

A recent study carried out by Institute scientists on standardisation of tests for detection of Human Papilloma Virus (HPV) in clinical specimens serves as a powerful illustration of the need for reference materials. Detection of HPV DNA in clinical specimens is central to the assessment of the effectiveness of HPV vaccines and techniques of this type, while very consistent within individual laboratories, can be highly variable between laboratories.

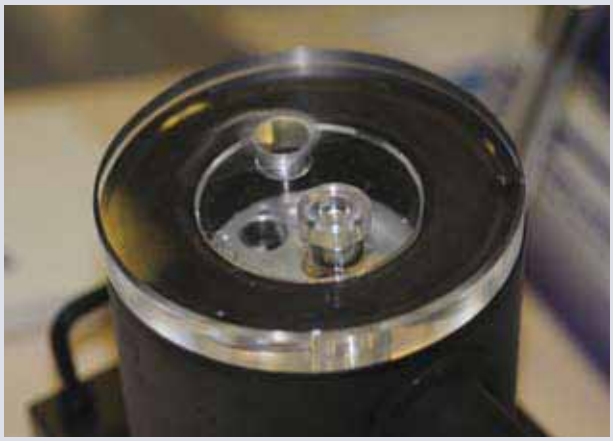
When laboratories attempt to express their results in absolute terms (in this case the number of detectable copies of HPV DNA) the scatter of results between laboratories is very large. However if the same data are presented as a potency measurement relative to an international standard, the results between laboratories are highly consistent and therefore comparable. The value of a reference preparation as a yardstick is therefore clear.

Standards distribution remained comparable with previous years.

Sales & Distribution of Existing Standards
4856 shipments of 132,015 ampoules/vials
5741 shipments including dispatch of other non standard biologicals & collaborative studies
96 fills of 304,436 ampoules/vials plus validation fills (up from 94 fills of 254,286 in 2006).
Overall income from the sale of reference materials during calendar year 2007 was £3,517k (excluding carriage), an increase of £373k (12%) from 2006 (£3,144k).

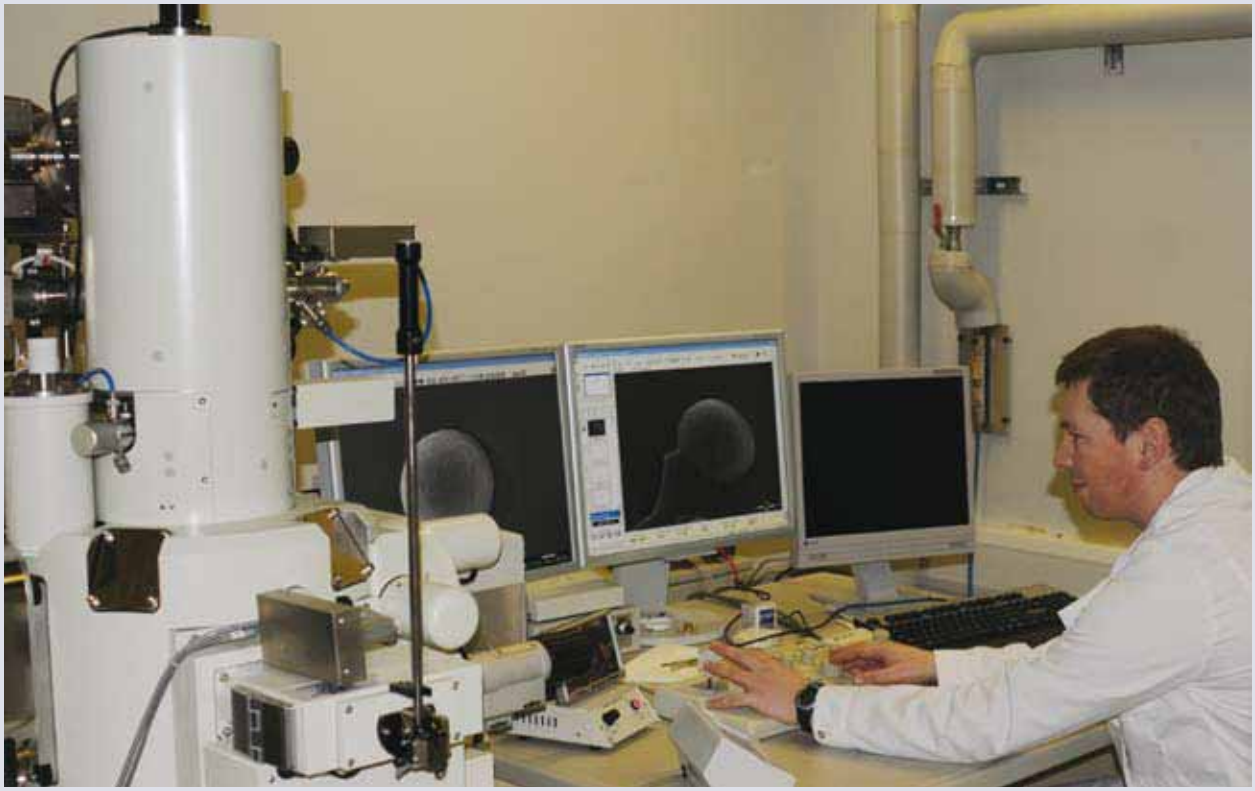
Once again NIBSC established a wide range of new reference materials and International Standards during the year in response to public health need and 13 standards were endorsed at the WHO's Expert Committee for Biological Standards in Geneva in November. Of these, seven were new, relating to areas as diverse as syphilis diagnosis, testing for clotting factors, measurement of parathyroid hormone and assessment of anti HPV vaccine responses.

New & Replacement Standards Established 2007	
Tetanus toxoid for flocculation testing	(2nd International Standard)
Diphtheria toxoid for flocculation testing	(2nd International Standard)
Anti-human papillomavirus type 16 serum	(1st WHO Reference Reagent)
Protein C, Concentrate for chromogenic assays	(1st International Standard)
Heparin, low molecular weight (calibrant for MW distribution)	(2nd International Standard)
Antithrombin concentrate	(3rd International Standard)
Anti-human platelet antigen 1a (minimum potency preparation)	(2nd WHO Reference Reagent)
Tissue plasminogen activator antigen in plasma	(1st International Standard)
Parathyroid Hormone 1-34, recombinant, human	(1st International Standard)
TNF-related Apoptosis Inducing Ligand	(1st WHO Reference reagent)
Anti-syphilitic plasma IgG and IgM (human)	(1st International Standard)
Anti-syphilitic plasma IgG (human)	(1st International Standard)
Hepatitis C virus RNA for Nucleic Acid Amplification test assay	(2nd International Standard)



Mission Orientated Research

The Institute maintains a vigorous research programme to inform its public health functions and also to ensure that its scientists are at the forefront of their fields and so can provide the best scientific advice. NIBSC research output as measured by publications increased significantly over 2006 (129 vs 101), and we have enjoyed a substantial rise in grant income during the year (£2,872k vs £1,984k for 2006/07). This reflects the ability of our scientists to attract funding on a competitive basis.



Supporting Pandemic And Seasonal Influenza Vaccine Production

NIBSC continues to play a key role in this area and has made substantial progress this year in several areas.

NIBSC scientists have extended their library of potential influenza vaccine strains that might be of use in a pandemic influenza emergency and now have 13 such strains, including representatives of the H2, H5, H7, H9 and H10 subtypes as well as reagents and reference materials for standardising the potency of pandemic vaccines.

The business case for new laboratories to house our planned Influenza Resource Centre was approved during the year, the outline design completed, planning permission received and the first phase of the project tendered. Completion is anticipated by the end of 2009.

Our international lead in the strategy to promote more effective co-ordination between public and private sector laboratories involved in development of new vaccine candidate strains has been highly successful and has led to numerous improvements, including a new website specifically for manufacturers providing up to date information on strains and reference materials available and progress on other projects.

Finally the Institute made a substantial contribution to the inter-governmental discussions on influenza virus strain sharing, helping to develop and support UK policy

and working with WHO to ensure that the existing global system for dealing with a potential pandemic is not undermined. One of the most important practical outcomes from these discussions was the development of a new WHO-sponsored mechanism to enable the tracking of virus strains as they are transferred between laboratories in the global network. NIBSC scientists made an important contribution to this work.

Polio – New Vaccines For The Post-Eradication Era

As the prospect of polio virus eradication grows nearer, there is a growing realisation that complete cessation of vaccination against polio is simply not an option. This raises a fundamental problem since the live attenuated vaccine currently being used to eliminate the disease can itself generate disease outbreaks. This means that any post-eradication vaccination strategy will have to be based on the use of inactivated vaccine. This is also problematic since current inactivated vaccines are manufactured from fully virulent poliovirus strains. Continued use of such strains for large scale vaccine manufacture and the potential for an escape, could therefore pose a global health risk. Hence there is considerable interest in the possibility that production could be switched to use of the attenuated strains used for live virus vaccination.

Institute scientists have long been at the forefront of poliovirus research, and have made many important contributions to our understanding of what makes the virus virulent, and how to ensure that vaccines are controlled to maintain their safety and potency, as well as supporting the international effort to eradicate the disease globally.

Building on many years of careful research, Institute scientists have created new genetically-engineered strains that appear to retain the full vaccine capabilities of the vaccine virus but without any risk of reversion to virulence. Provided that they can be grown successfully on an industrial scale, these strains have considerable potential as the platform for vaccine production in a post-eradication era.

Cell-based Medicines

During the last year, the UK Stem Cell Bank matured considerably. Embryonic stem cell lines have now been acquired by the bank of which 20 have been fully banked and 11 are now available for supply to requestors.

The Bank's strategy includes not only the supply of quality assured cell lines, but also more general support for the field of stem cell research. Among many important contributions during the year, the Bank's central role in the International Stem Cell Initiative, establishment of a regular technical forum for sharing of stem cell culture expertise and input to the development of regulatory guidelines for assessment of stem-cell based products stood out.

Finally we made very good progress toward the next Phase of the Bank's development – provision of a permanent set of laboratories to house its expanded work programme. The new laboratories will be built as part of a joint development alongside the Influenza Resource Centre in order to maximise cost effectiveness, and are expected to be available from mid 2009.

Improved Bioassays For Biotherapeutics

The potency of biological medicines often needs to be assessed by bioassay involving measurement of the effect of the product on living cells. Traditionally these assays involve detection and quantification of proteins produced by the cell in response to treatment with the product. This is cumbersome and has several practical limitations, and NIBSC scientists have been developing an alternative approach, based on direct measurement of RNA within cells. This has the potential to be much faster, easier and to give better data and during this year, the approach has been applied successfully to measuring the potency of two biotherapeutic products. The new method will also be very useful for monitoring stability of reference materials.

TGN1412 Antibody

Work has continued to investigate the devastating and unpredicted effect which occurred during a clinical trial at Northwick Park hospital in 2006. We have sought to elucidate the cellular and molecular mechanisms underlying the adverse reactions and to understand why preclinical evaluation of the antibody carried out in vitro and in vivo failed to predict these effects.

This work has generated important new scientific insights that have led to development of a method for reproducing the antibody effect in vitro. This has been published and has attracted considerable international attention from biopharmaceutical manufacturers.

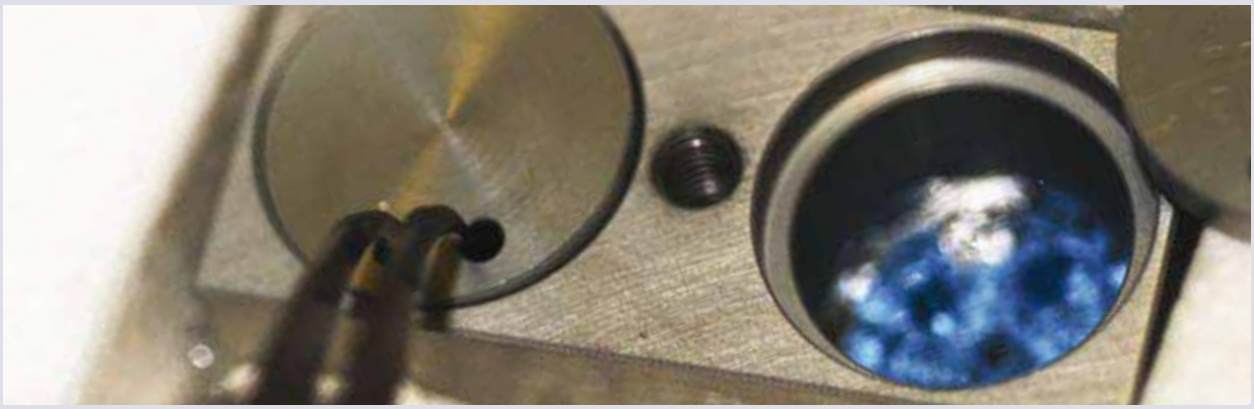
Scientific Communications And Training Activities

Once again this year the work of our scientists led to a substantial output of scientific research papers (129). This continues to be a very important part of the Institute's work, and publication of results is actively promoted.

In addition, we organised several international meetings and workshops focusing on important current issues in biological medicines, such as heparin. We also provided practical training in quality control of vaccines, covering newly licensed rotavirus vaccines, and influenza vaccines. The latter course was aimed at influenza vaccine manufacturers and regulators in developing countries in order to support increased worldwide capacity for pandemic vaccine production, a key strategic public health goal worldwide.

In March 2008, in line with our aim to cement the Institute's position as the global hub of expertise for standardisation of biological medicines, we established a new training course, entitled 'Principles of Biological Standardisation'. The course was oversubscribed and rated very highly by the 40 international delegates from over 19 countries.

We were also pleased to initiate a new PhD training programme in collaboration with Imperial College. Two studentships were established, funded by surpluses on contract revenue, one aimed at a model for hepatitis C virus infection and the other at characterisation of vaccine candidate proteins on the surface of meningococcal bacteria.



Stakeholder Links

NIBSC's merger with the Health Protection Agency (HPA) is scheduled for completion in April 2009 and we have continued to build excellent working relationships throughout the two organisations. Integration of IT systems has been facilitated by a cross appointment between NIBSC and the HPA, a unified security access system has been introduced, and NIBSC is now fully represented on virtually all key HPA management committees including the Executive Group, covering all aspects of administration, such as Finance, Corporate Governance, Human Resources, Property Asset Management, IT Strategy, Quality, Health, Safety and Environment.

In addition NIBSC has played a full part in the HPA's strategic development, contributing significantly to the establishment of its key priorities and assisting with sevelopment of its new 5 year plan. New strategic requirements, such as a Sustainable Development Plan, are being met on a joint basis, and work has continued on policy alignment in as many areas as possible in advance of the merger.

Facilities And Technology Infrastructure

Once again this year we were able to make major improvements to the Institute's facilities and infrastructure, through the generous capital funding provision from Department of Health to cover 2006/07 to 2008/09. The extensive refurbishment of our laboratories is now complete and this year has seen the start of programmes to improve more general facilities and amenities. These have included:

- the final phase of installing an updated and upgraded fire alarm system,
- installation of a site-wide cooling system to replace the current energy-inefficient piecemeal system,
- a major project to refurbish our reception area,
- the completion of the first phase of a crucial project to improve the resilience of Institute's power supply,
- introduction of a new security access system (compatible with the HPA).

Planning the new Influenza Resource Centre/UK Stem Cell Bank building required a great deal of effort but the tender has been placed and construction is expected to begin in 2008.

National And International Advisory Activities

One of the Institute's five key strategic objectives is to promote science-led policy making in the field of biological medicines, and this requires continued proactive contribution to policy discussion and development on a very broad canvas. Consistent with this aim, our scientists play key roles in a very wide range of policy-making and regulatory bodies both nationally and internationally.

During 2007/08, Institute scientists have contributed to over 80 advisory groups and committees:

United Kingdom

- Academy of Medical Sciences Gene Therapy group, UK
- Advisory Committee on Dangerous Pathogens
- Advisory Committee on the Contained Release of genetically manipulated organisms
- Biosciences Federation Steering Group on Infection
- Brighton Collaboration on Vaccine Safety
- British Blood Transfusion Society Special Interest Group on Transfusion Microbiology
- British Pharmacopoeia
  - Panel of Experts on Immunological Products
  - Panel of Biological and Biotechnological Expert
  - Panel of Experts on Blood Related Products
  - Committees H and EAG NOM
  - Statistics Working Group
- British Standards Institute
  - CH/194/100 committee, Medical Devices Utilizing Tissues.
  - CH/194 committee, Biological evaluation of medical devices.
  - CH/212 committee (IVDs).
  - Panel SS/6/-/4 Statistical Aspects of Reference Materials
- British Society for Histocompatability and Immunogenetics
- British Blood Transfusion Society
- Commission for Human Medicines
  - Biologicals and Vaccines Expert Advisory Group
  - Advisory Group on Phase I clinical trials
- COST (European Cooperation in the field of Scientific and Technical Research) Laboratory Animal Science & Welfare Working Group Society for Applied Microbiology Committee
- Fund for the Replacement of Animals in Medical

Experiments

- Health Protection Agency
  - Forum on Deliberate Release Agents-Strategy Group
  - Meningococcal Forum.
- Intergovernmental Working Group on Virus Sharing
- Joint Committee on Vaccination and Immunisation-
  - Sub-Committees on BCG vaccines, pertussis, anthrax, influenza & Varicella
- Joint Professional Advisory committee to the Blood Services
  - Representation on all standing advisory groups
- London Technology Network
- National Vaccine Evaluation Consortium Steering Group

- National Measurement System Steering Group
- National Genetics Reference Laboratory 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

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

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
- WHO Monitoring Group on Gene Therapy Products
- Ad hoc Advisory Group on polio eradication
- Consultation group on Live Viral Vectored Vaccines

- International Non-proprietary Name (INN) Committee
- Chemokines Nomenclature Committee
- Standardisation Committee
- Biometrics Subcommittee
- 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: Committees and Working Parties on standardisation
- TB Vaccine Task Force
- International Atomic Energy Agency (IAEA) consultation group on radiolabelled biological

This year NIBSC cemented our growing relationship with the national and international measurements community in a number of ways, notably through membership of the National Measurement System's Measurement Board, sponsored by the Department of Innovation, Universities and Skills (DIUS). New biotechnologies in which NIBSC has already well established skills, such as stem cell therapy, are increasingly recognized as drivers of economic growth and this is stimulating interest in standardisation from the physical science based measurement community. NIBSC involvement in such developments ensures that the Institute's expertise in the area is fully appreciated, and that such initiatives are carried through with a full understanding of the complexities of biological systems.

We have continued to initiate discussion on topics of importance with a view to informing policy development and improving public health. This is done through organisation of workshops, discussion fora and international meetings. During the year we organised some 15 meetings of this kind covering a diverse range of important topics, influenza vaccine development, yellow fever and rotavirus, vaccine quality, blood safety, imaging as a tool for biopharmaceutical analysis, characterisation of heparin products, clinical virology standards and stem cell culture methods.

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.

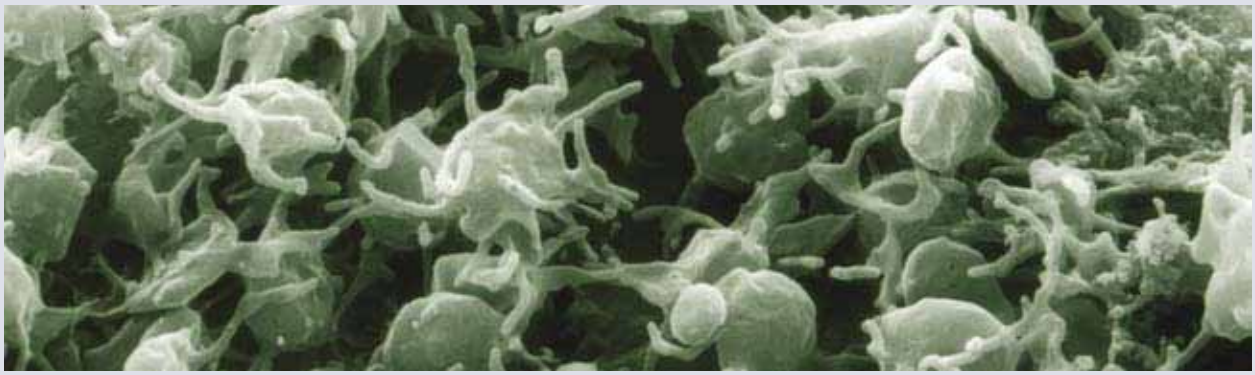
Progress Against Key Targets For 2007/08

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 the Institute 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 2007/08 Key Targets is shown below.

SCIENTIFIC OBJECTIVES

	Ojective	Progress
Control	Meet requirements for batch release of existing biological medicines according to defined targets for quality assurance and timeliness	Achieved
Standardisation	Maintain effective distribution of existing biological standards	Achieved
	Establish 10 new and replacement WHO International Standards and reference materials	Achieved – 13 new standards established
Research & Development	Publish at least 100 scientific papers and utilise in excess of £2.5m in external research funding	Achieved – 129 publications and utilised £2,872k in grant funding
	Initiate internal Ph.D training programme and recruit first two students	Achieved – two students in post in conjunction with Imperial College
Quality	Maintain existing accreditation/certification for batch release, supply of standards and stem cell work (ISO/IEC17025, ISO13485, ISO9001).	Achieved
	Achieve ISO17025 accreditation for all batch release activities	Achieved – all product testing activities covered. Successful inspections by UKAS.
	Complete and authorise quality manual for development of standards and reference materials, taking account of ISO34 principles as appropriate and implement agreed systems.	Achieved – manual officially implemented for all new projects. Training course developed for all staff running reference material projects with >90% uptake. Role definitions developed for all divisional reference material co-ordinators.

	Ojective	Progress
Influenza vaccines – seasonal and pandemic	Construct further five new potential influenza pandemic vaccine strains for 'library'	Achieved – library now consists of 13 strains (H5, H6, H9, H7, H10, H2)
	Test ability to distribute rapidly part-characterised vaccines strains in an emergency	Not achieved. Requires international co-operation which is difficult to organise. Objective will be carried forward.
	Establish capability for constructing high growth reassortant strains for seasonal influenza vaccine production and create strains for Northern and Southern hemispheres	Achieved – some technical difficulties but on track to generate new strains for 08/09 season
Variant CJD	In collaboration with the HPA and NBS evaluate performance of test methods for vCJD on human donor blood.	Human studies now considered premature following discussions with external parties. Panels of "mock-up" animal blood now ready for testing by kit developers. Oversight committee established -will review the inter-pretation of result.
New licensed vaccines	Initiate batch release of licensed rotavirus vaccine	Achieved
	Initiate batch release of licensed HPV vaccine	Achieved
	Develop new international standard for measuring anti-HPV16 antibodies	Achieved – endorsed at ECBS 2007 as International Reference Preparation pending further stability studies



	Ojective	Progress
Childhood Vaccines	Complete evaluation of new assay (combined enzyme and binding) for pertussis toxin in vaccines	Development of the new assay (using fetuin as substrate) has been completed and evaluated as far as possible against a range of products. However, validation against its most important target has not been completed because material has not been available.
Healthcare Associated Infections	Begin evaluation of candidate *C. difficile* vaccine	First batch of toxoids has completed physico-chemical analysis. Immunoassay under development.
Immunostimulatory Medicines	Develop and validate new tests to improve preclinical safety assessment of immunostimulatory human medicines	New improved methods developed and published. Further improvement work is ongoing. Publication has provoked approaches from manufacturers for help in establishing the new tests
Provision of External Training	Develop and agree external training strategy and implementation plan	Strategy in development in conjunction with the HPA. New course in Biological Standardisation developed.
Information Technology	Complete desktop replacement programme	Achieved
	Begin implementation of Institute LIMS system	Project tendered and on track to begin implementation by year end.
Capital Development Programme	Begin Biological Services refurbishment programme	Layouts now finalized and invitation to tender for the design work expected by year end. Design needs to accommodate additional demands resulting from merger with the HPA CFI facility.
	Tender accepted for new Training Centre	Target missed. Insufficient resource at this time but will be rolled forward
	Begin building work on combined Influenza Resource Centre and UK Stem Cell Bank structure	Outline Business case accepted, project tendered, planning permission gained and Phase 1 or project expected to be complete by year end, Building to begin in April
Porton Programme	Complete programme to achieve required colony health status	Achieved
	Agree plan with stakeholders to move colony to new facilities	On track. New strategy developed with HPA Porton and Department of Health

	Ojective	Progress
Stakeholder Satisfaction: working effectively with partners	Second Staff Attitude survey completed	Internal agreement to change focus to project aimed at developing core values for Institute. Project underway.
	Implement process for capturing feedback from key stakeholders on NIBSC performance	Achieved
	Develop joint strategy to promote improved regulatory assessment of biological medicines in Europe	Strategy agreed. Will be pushed forward at annual Official Medicines Control Laboratory (OMCL) meeting in May.
Communications	Implement improved process for updating of NIBSC/ UK Stem Cell Bank (UKSCB) websites	New system in place. Training on content management system complete for main administrators. UKSCB website subjected to major overhaul and new influenza resource website launched.
	Continue programme to raise NIBSC public profile	Ongoing programme. Good relationships established with the HPA communications team. Radio 4 programme highlighting NIBSC's role broadcast in February was well received.
HPA Merger	Agreed Service Level Agreement (SLA) targets (with the HPA) met for integrated finance system	Achieved
	Governance structure for NIBSC within HPA agreed	Achieved
	Identify key policy differences between the HPA and NIBSC and devise plan to achieve successful harmonisation	Ongoing project. Major differences identified and logged for discussion and negotiation during 2008/09.
Maintaining & Extending expertise	Maintain expertise in biostatistics and build capacity for monoclonal antibody analysis	New monoclonal antibody group established. Recruitment of statisticians remains problematic.
	Enhance strength in corporate governance functions	Achieved – new Corporate Affairs Manager in post and trained.
Agenda for change	Agenda for Change preparation completed as far as possible/practical (job descriptions, person specifications completed, job matching completed, project review)	Good progress. 70% of staff have attended Agenda for Change surgeries with about 40% having finalized Agenda for Change job descriptions and person specifications.

	Ojective	Progress
Finance	Maintain permanent staff in post at or below 312	Short term research posts, resulting from success in attracting grant income, have pushed overall headcount above 312, with Department of Health agreement, but core posts remain below the target.
	Achieve break-even against Department of Health revenue budget	General reserve increased £352k, operating costs exceeded Department of Health funding by £196k.
	Increase sales of goods and services to more than £6 million by year end (20% increase on 2006/07 target)	Achieved
	Achieve second year target of 3-year capital programme (commitment of £7.5 million)	Achieved

Management Commentary

The National Institute for Biological Standards and Control (NIBSC) 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 increase and diminish and the related research, testing and standardisation work at NIBSC modulates accordingly.

The development and performance of the Institute during the financial year 2007/08

The Institute made good use of a further year of stable finances with growth in its staff and the quality of its estate. Most significant was the capital expenditure

programme with its cumulative £7.5 million plan to the end of the second year of a three year funding programme. This programme included improvements to laboratories and staff amenities, as well as the new and replacement scientific equipment. Although most of the Institute buildings are now 20 years old they have been brought up to ample specification to serve for the years ahead.

The Institute continues to pursue rational pricing policies for its products and services in international fields notable for non-economic pricing for reasons of history and government policy. In the field of control testing charges are based on price bands according to the complexity of the work and set to recover the economic cost of the service as a whole.

In the field of biological standardisation NIBSC receives the materials which ultimately become international standards without charge. In accordance with its role of holding WHO international standards for many biological medicines, NIBSC provides these free of charge to National Control Laboratories of all other countries. The handling charge levied on commercial and academic customers for NIBSC standards goes some way to covering the costs of the activity which is otherwise funded by the UK government.

The Institute made further progress with its PhD student programme adding two students funded from income on commercial sales contracts so that at the end of the year there were seven studentships. At the other end of the career path, further appointments were made to provide succession planning for key scientific staff approaching retirement.

For many years the staff salary structures and pay awards have followed those of the Biotechnology and Biological Sciences Research Council (BBSRC) which employs comparable scientific staff. This process has involved slow negotiations between the recognised negotiating parties in which NIBSC has only an observer role. The annual pay award due from 1 July 2007 was delayed by a particularly complex revision of the BBSRC structures and NIBSC used its own negotiating process to substitute a local pay and pay it in the last month of the financial year.

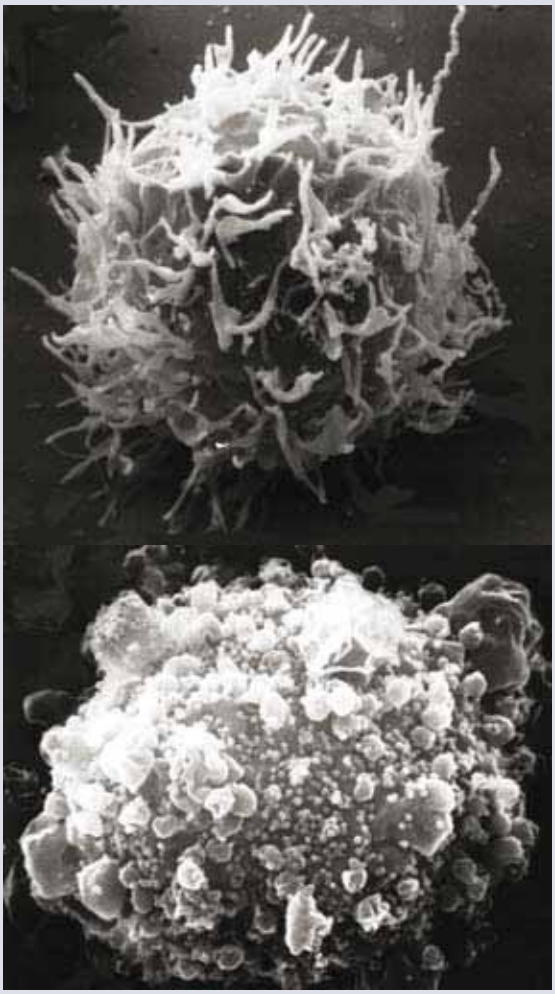
On 1 September 2007 the remaining members of the NBSB Pension Scheme were transferred to the NHS Pension Scheme, which caters for the remaining staff of the Institute, and the NBSB Scheme was then closed. This allowed the Board to extinguish its liability for the future benefits of these members and the related debt from the Department of Health. It also relieved the Board of the specialist administrative responsibility of running a pension scheme and assured secure arrangements for all

staff after the impending abolition of the NBSB and the transfer of its functions to the Health Protection Agency.

Financial Results for the year 2007/08

The financial results for the year are presented in the form of an operating cost statement (page 54), as in the previous year, and in common with other UK government bodies which derive a significant part of their funding in the form of 'grant in aid', rather than income for services provided. The gross operating cost of the Institute for the year was £27,482k (2006/07: £23,740k). After offsetting £10,100k of income from third parties and adjusting for notional interest on the capital provided by the government, the net operating cost of NIBSC to the Department of Health was £20,067k (2006/07: £17,688k). This cost was offset by contributions from the Department of Health of £13,246k for revenue spending, £3,848k for capital and the funding of notional interest of £2,710k. The balance of the general reserve increased by £352k over the year to £43,468k.

The year saw increases in activity funded by academic grants. Funding received for project expenditure rose to £2,872k from £1,984k and the amount received in advance but not yet expended rose by £683k. This follows a wave of successful bids for grant funding in a very competitive environment.



Handling fees for biological reference standards were little changed on the previous year, at £3,579k, reflecting a stabilisation in the demand for influenza reagents after several years of substantial growth. Fee income for control testing rose 8% and other contractual income by 35%.

Capital expenditure was £4.1 million on an accruals basis (£3.9 million cashflow), which brought the cumulative capital spending over two years to £5.9 million (£6.6 million cashflow). This compares to £7.6 million capital funding received from the Department in the same two year period and to a depreciation charge of £7.3 million.

There is a large international component to NIBSC's activities reflecting the nature of public health challenges which it addresses. The value of goods and services invoiced to customers outside the United Kingdom was £6.3 million (2006/07 £5.03 million).

Included in the operating result is a charge for the reduction in standards stock values of £1.5 million. This arose in the year because the increasing production capacity and output of standards reduces their replacement cost. As stocks are valued at the lower cost and net realisable value, their carrying cost has decreased.

The Institute's position at the end of the year (31 March 2008)

The financial position at the end of the year was strong. The budget was broadly balanced, working capital was ample and the capital programme was on target. The substantial asset and liability relating to the NBSB Pension Scheme in earlier years had been transferred from the Board.

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

The financial year 2008/09 is expected to be the final year during which the NBSB operates as an autonomous body if the abolition of the Board and the transfer of its functions to the Health Protection Agency takes place on 1 April 2009. Significant efforts have been made to align the administrative framework of NIBSC with that of the HPA and this will continue to occupy management time during the coming year.

The total activity in grants is not fully predictable as applications have long lead times and success rates vary. However only about one third of projects start or end in any year, and the total fluctuates gently. The total

employment on grants is budgeted at a historic high in 2008/09 as a result of past awards and further growth can only be accommodated as the capital spending on laboratory space is completed. Construction should get underway for the new building to house the permanent UK Stem Cell Bank and the Influenza Resource Centre, funded by the Medical Research Council and the Department of Health respectively, and now fully designed and tendered.

The financial profile of standards production is unusual with a very significant scientific investment in the stages leading to the production and adoption of a particular standard. Costs may amount to hundreds of thousands of pounds before the standard is distributed, even though the biological material is provided free to NIBSC. The handling fees from paying customers may then contribute to the production, storage and distribution costs over many years. This business model would be unsustainable without the very large capital resources and capacity to take risks that the government backing provides. NIBSC has experimented with other patterns of financing standards activity which share risks and benefits, and will continue to do so to assure the future provision of biological reference materials.

The eventual adoption of Agenda for Change terms for staff, and the change in the VAT treatment of NIBSC activities are expected to affect financial balance only in the years after 2008/09 assuming that merger with the HPA takes place in April 2009. NIBSC has provided its capital and revenue expectations for 2008/09 and beyond to the Health Protection Agency so that all concerned become familiar with the financial structure of the combined organisation in advance of the merger. A project has been underway for many months to assess the effect of HPA pay structures on NIBSC staff and salary costs and to optimise the transition to the new organisation.

NIBSC's activities are well diversified across product types and between the public and private sectors and between UK, Europe and the wider world. However the decline in the general economic climate must be expected to affect the level of income from third parties, the creditworthiness of some customers and the level of price inflation.

Funding Sources

NBSB is funded principally through central UK Government grants (through 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, standardisation activities, transfusion medicine work, research and development and provide general support and advice to the UK Government and associated bodies.

Additional funding includes:

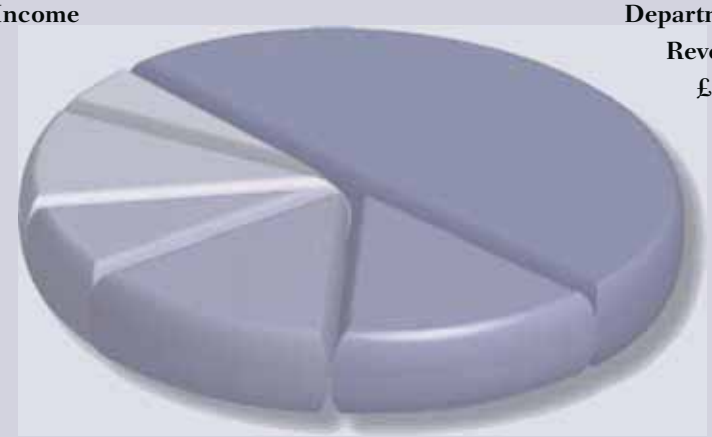
- External project grants and contracts (grant awarders include the Medical Research Council, WHO, the European Commission, the Department of Trade and Industry and the Home Office).
- Handling fees for the distribution of biological standards and other reference materials.
- Certification fees for the issue of batch release certificates to manufacturers.

Total funding/income in 2007/08 was as follows:

Contracts & Other Income
£1,444k

External Project Grants
£2,872k

Certification Fees
£2,038k



Department of Health
Revenue Grant
£13,246k

Standards handling fees
£3,579k

Department of Health
Capital Grant
£3,848k

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 Human Resources

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 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 and other 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. Since 1996 the Board was a member of the pay club of the Biotechnology and Biological Science Research Council (BBSRC) which set the pay scales and negotiated collective pay awards annually on the Board's behalf.

For the pay award due from 1 July 2007, the BBSRC joined with other research councils in negotiation of a three year pay settlement with significant change in the structure of pay scales and the composition of annual awards between consolidated and non-consolidated amounts related to performance. The Board expects its staff to transfer to the Health Protection Agency in 2009, with its pay scales based on the 'Agenda for Change' terms of the National Health Service. It did not consider that an intermediate change to the new BBSRC scales was in the best interests of staff or the organisation and negotiated a simple local pay settlement, with the approval of the Department of Health.

The increase in basic salary from 2006/07 to 2007/08 was 3.0 per cent.

The former 'merit pay' scheme for staff of the Board below the level of Director was ended in the previous year in anticipation of the move to the 'Agenda for Change' terms which have no merit component. The former scheme allocated an amount not exceeding 0.5% of the total pay bill on merit between all eligible staff on the basis of objective assessments. For 2007/08 this 'merit pay pot'

was shared evenly between staff at or above the standard pay point of their scales.

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.

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 2008 amount to £16,191. In 2006/07 the Chairman received a total of £16,191.

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:

	2007/08 £	2006/07 £
M Beaumont	730	290
M Brown	584	-
Professor D Calam	435	580
Professor J Darbyshire	730	580
M Hindle	1,168	1,160
Professor D Latchman	290	580
Professor C Lee	1,022	870
Professor K Nicholson	584	290
G Noble	1,459	1,305
Dr J Petricciani	438	580
A Robertson	580	1,305
Professor Sir J Skehel	290	290
Dr L Tsang	438	290
	8,748	**8,120**

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

Remuneration of the Director

The remuneration of the Director of NIBSC, Dr Stephen Inglis, for the year 2007/08 was £162,489, including arrears of £5,603. In 2006/07 his remuneration was £149,415. 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 2008, classified into bands of £5,000, were as follows:

	Salary 2007/08 £'000	Salary 2006/07 £'000
Dr S Inglis Director	160-165	145-150
V Knight Head of Finance/ Board Secretary	65-70	60-65
S Murray Head of Operations	65-70	60-65
A Jowett Head of Human Resources	50-55	50-55

"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 was a pensioner member of the NBSB Pension Scheme for part of the year by virtue of his former employment at NIBSC before his retirement and subsequent appointment to the Board. Professor Calam and all other members of the NBSB Pension Scheme were transferred to the NHS Pension Scheme on 1 September 2007.

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 2008 (bands of £2,500)	Lump Sum Value as at 31 March 2008 (bands of £2,500)	Cash Equivalent Transfer Value as at 31 March 2008 (bands of £1,000)	Cash Equivalent Transfer Value as at 31 March 2008 (bands of £1,000)	Real Annual Increase in Cash Equivalent Transfer Value (bands of £1,000)
	£'000	**£'000**	**£'000**	**£'000**	**£'000**	**£'000**	**£'000**
Dr S Inglis Director	0.0-2.5	5.0-7.5	22.5-25.0	70.0-72.5	409	366	34
V Knight Head of Finance/ Board Secretary	0.0-2.5	2.5-5.0	12.5-15.0	42.5-45.0	233	208	20
S Murray Head of Operations	0.0-2.5	2.5-5.0	2.5-5.0	12.5-15.0	82	64	16
A Jowett Head of Human Resources	0.0-2.5	2.5-5.0	5.0-7.5	15.0-17.5	0	75	(77)

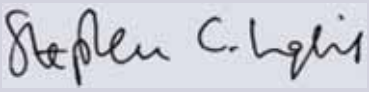
The Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a scheme member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is 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.

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

- Salary and allowances, bonuses, expense allowances, compensation for loss of office and non-cash benefits for each senior manager (including advisory and non-executive Board members) who served during the year;
- Pensions for each senior manager who served during the year; 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 C Inglis
Accounting Officer
9 July 2008

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 on 1 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 disqualification. Any disabled candidates meeting the essential criteria set out in the person specification for the job will be interviewed.

Wherever possible, after any necessary rehabilitation training, the Board retains or transfers to more suitable work any otherwise capable employees who become disabled during their employment, and who do not wish to accept ill-health retirement benefits. The Board accepts that disabled employees should have equal opportunities with other employees for training, promotion and career development in order to use their capabilities to the full. The Board has particular regard for the safety of its disabled employees. It expects individuals upon whom safety responsibilities have been placed, to pay attention to the safety of the various workplaces under their care and the means of escape in case of fire in relation to the needs of people with disabilities. During 2007/08 further structural changes were made to improve access into and around the Institute buildings and its facilities.

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 2007/08, the Board paid 72% (2006/07: 79%) of invoices within 30 days, representing 57% (2006/07: 60%) 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.

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.

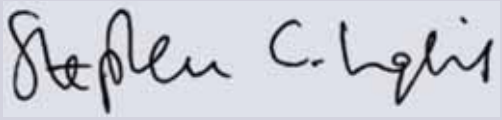
Other than the statutory audit of the financial statements, the Comptroller and Auditor General has not provided any other services to the Board during the year ended 31 March 2008.

Board members

Board members during the financial year were:

Professor Sir Gordon W Duff PhD FRCP FMedSci (Chairman)
Mr Michael Beaumont CBE FCA
Mr Michael Brown
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 Inglis PhD (Director of NIBSC)
Professor David S Latchman PhD MRCPath 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
Dr Nicola Rose PhD
Professor Sir John Skehel FRS
Dr Lincoln Tsang LLB PhD FRSC FIBiol FRSA MRPharmS Barrister

Dr Stephen C Inglis
Accounting Officer
National Biological Standards Board
9 July 2008



Statement of the Board's and Director's responsibilities

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

Statement on Internal Control for the year ended 31 March 2008

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 Managing Public Money. The policies, aims and objectives of the Board are reviewed by the Minister for Public Health as part of its annual Accountability process, while the authority delegated to the Board by the Department of Health is set out in its Management Statement.

The purpose of the system of internal control

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

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

The system of internal control has been in place in the NBSB throughout the year ended 31 March 2008 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 are expressed they are considered and actioned as appropriate.

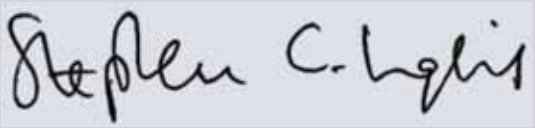
The Board operates a system of risk management in accordance with Treasury guidance. This system has been reviewed and endorsed by independent risk management experts and provides the basis for the Institute's internal audit plan.

During the year the corporate governance structure continued to adapt so that the Institute as a whole responded to its strategic targets and best aligns itself for future incorporation into an enlarged Health Protection Agency. The Board is aware of the Cabinet office requirements on the handling of personal data and no significant governance risks have come to its attention.

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 including budgetary control, staff appraisal and development, stores and computer virus protection. A plan to address weaknesses and ensure continuous improvement of the system is in place where appropriate in such areas as business continuity planning, costing systems and security.



Dr Stephen C Inglis
Accounting Officer,
National Biological Standards Board
9 July 2008

NATIONAL BIOLOGICAL STANDARDS BOARD:

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSE OF COMMONS

I certify that I have audited the financial statements of the National Biological Standards Board (NBSB) for the year ended 31 March 2008 under the Biological Standards Act 1975. These comprise the Operating Cost Statement and Statement of Recognised Gains and Losses, the Balance Sheet, the Cash Flow Statement 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 Chief Executive and auditor

The Chief Executive, as Accounting Officer, is responsible for preparing the Annual Report, which includes the Remuneration Report, and the financial statements in accordance with the Biological Standards Act 1975 and HM Treasury directions made thereunder and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of Accounting Officer'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 HM Treasury directions issued under the Biological Standards Act 1975. I report to you whether, in my opinion, certain information given in the Annual Report, which comprises the Management Commentary, the Directors' Report and the unaudited parts of the Remuneration Report 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 National Biological Standards 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 National Biological Standards 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 to form an opinion on the effectiveness of the National Biological Standards 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 opinions

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 National Biological Standards Board and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are most appropriate to the National Biological Standards Board's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error, and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

Opinions

In my opinion:

- the financial statements give a true and fair view, in accordance with the Biological Standards Act 1975 and directions made thereunder by HM Treasury, of the state of the National Biological Standards Board's affairs as at 31 March 2008, and of the net operating cost, recognised gains and losses and cash flows 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 for Health; and
- Information given within the Annual Report, which comprises the Management Commentary and Remuneration Report, 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.

T J Burr

Comptroller and Auditor General

National Audit Office

151 Buckingham Palace Road

Victoria

London SW1W 9SS

15 **July 2008**

National Biological Standards Board

Operating Cost Statement for the year ended 31 March 2008

	Notes	2007/08 £000	2006/07 £000
Gross operating costs:			
Staff costs	2	12,373	11,711
Other operating charges	3	11,175	8,637
Depreciation	4	3,934	3,392
Gross operating costs		**27,482**	**23,740**
Less: Income from operations	5	(10,100)	(8,503)
Net Operating costs before interest		**17,382**	**15,237**
Interest receivable		(25)	(97)
Cost of capital charge	4	2,710	2,548
Net operating cost for the financial year	6	**20,067**	**17,688**

All results arose from continuing operations.

Statement of Recognised Gains and Losses for the year ended 31 March 2008

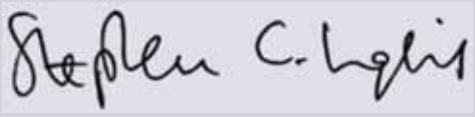
	Notes	2007/08 £000	2006/07 £000
Unrealised surplus on revaluation of fixed assets	7	3,508	3,710
Net surplus on foreign currency translation		167	4
Recognised gains and losses		**3,675**	**3,714**

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

Balance sheet as at 31 March 2008

	Notes	31 March 2008 £000	31 March 2007 £000
Fixed assets			
Intangible fixed assets	7	283	387
Tangible fixed assets	7	65,461	61,750
		65,744	**62,137**
Current assets:			
Stock	8	7,088	8,608
Debtors	9	3,552	14,198
Cash at bank and in hand	10	7,542	6,513
		18,182	**29,319**
Creditors:			
Amounts falling due within one year	11	3,721	3,263
Net current assets		**14,461**	**26,056**
Provisions for liabilities and charges	12	107	11,057
Net assets		**80,098**	**77,136**
Capital and reserves:			
General reserve	16	43,468	43,116
Revaluation reserve	16	35,482	32,789
Donated asset reserve	16	1,148	1,231
		80,098	**77,136**

Dr Stephen C Inglis
Accounting Officer
National Biological Standards Board
9 July 2008



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

Cash Flow Statement for the year ended 31 March 2008

	Notes	2007/08 £000	2006/07 £000
Net cash outflow from operating activities	17(i)	**(12,202)**	**(11,073)**
Returns on investments and servicing of finance:			
- Interest received		25	97
Capital expenditure		(3,892)	(2,748)
Receipts from disposal of fixed assets		4	-
Net cash outflow before financing		**(16,065)**	**(13,724)**
Management of liquid resources:			
Financing:			
- Government funding for revenue		13,246	12,742
- Government funding for general capital		3,848	3,743
Increase/(decrease) in cash	17(ii)	**1,029**	**2,761**

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

Notes to the Account for the year ended 31 March 2008

1 Statement of accounting policies

These accounts have been prepared in accordance with the Government Financial Reporting Manual (FReM) issued by HM Treasury. 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 under the historical cost convention, modified to include the revaluation of fixed assets and stocks.

(b) Change of Accounting Policy

There were no material changes in accounting policy in the year.

(c) Fixed assets

Tangible fixed assets are shown at current value (cost or valuation) less depreciation. The threshold for capitalising individual assets or closely related groups of 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 Secretary of State for Health, but its value is included in the Board's accounts at 31 March 2008.

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 taken to the general fund at the time of receipt (Note 16).

(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 2007/08, as specified by the Secretary of State for Health. These contributions are charged to operating expenses as they become due.

The scheme provides benefits on a "final salary" basis at a normal retirement age of 60. Benefits accrue at the rate of 1/80th of pensionable salary for each year of service. In addition a lump sum equivalent to 3 years pension is payable on retirement. Members paid contributions of 5% or 6% of pensionable earnings for the year 2007/08. 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 operated a "by-analogy" scheme, the NBSB Pension Scheme, which offered benefits similar to the Medical Research Council pension scheme for employees who transferred from the Medical Research Council on the creation of the Board in 1976. The members of the scheme were transferred to the NHS Pension Scheme on

1 September 2007 and the NBSB Pension Scheme was wound up.

(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 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.

2 Staff Costs

(a) All staff

	Notes	2007/08 £000	2006/07 £000
Salaries and wages		10,190	9,537
Social Security costs		853	792
Employers contributions to the NBSB Pension Scheme	13	23	57
NHS Superannuation contributions		1,237	1,108
Decrease in provision for early retirements	12	(291)	-
Consultancy and agency staff		361	217
		12,373	**11,711**

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

	2007/08 £000	2006/07 £000
Scientific divisions	214	207
Support and operations	83	67
Administration	25	24
	322	**298**
Of which:		
Staff with permanent contracts (over one year)	303	283
Other staff	19	15
	322	**298**

3 Other Operating Charges

(a) Other operating charges

	2007/08 £000	2006/07 £000
Consumable laboratory supplies	3,829	3,193
Central services, net of production recovery	3,726	2,055
Premises	2,829	2,673
Equipment	441	372
Travel, subsistence and hospitality:		
Chairman and other Board members	5	3
Employees	229	208
Audit fee	44	40
Bad debts provided for or written off	8	10
Loss on disposal of assets	64	83
	11,175	**8,637**

The audit fee relates to the audit of the Board's annual accounts. No fee has been paid to the statutory auditor in respect of the audit of cost statements submitted to third party grant donors (2007: £1k).

(b) Foreign currency translation

Net exchange gains of £167 k (2007: £4k) on foreign currency balances have been credited to income from operations.

(c) VAT refund

During the year 2007/08 VAT returns were submitted quarterly and the partial recovery of VAT of £1,264k (2006/07 : £1,378k) 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

(a) Depreciation

	2007/08 £000	2006/07 £000
Depreciation charge for the year based on historical cost of fixed assets	3,402	3,076
Additional charge based on current cost of fixed assets	532	316
	3,934	**3,392**
Of which the amount relating to donated assets was	83	56

(b) Notional interest

Notional interest at 3.5% of the average value of net government funded assets during the year, which is £2,710k (2006/07 £2,548k) is matched by a notional credit for the same amount in the General Reserve.

5 Income from Operations

	2007/08 £000	2006/07 £000
Grants:		
Research Councils etc	1,584	547
World Health Organization	98	61
European Commission	239	299
Other bodies	951	1,077
Total grants	**2,872**	**1,984**
Contracts	1,444	1,068
Standards distribution handling charges	3,579	3,570
Control testing fees	2,038	1,881
Foreign exchange gain	167	-
Total income from operations	**10,100**	**8,503**

6 UK Government Grants

	2007/08 £000	2006/07 £000
Received from the Department of Health	13,771	12,867
Less: Contributions to the NBSB Pension Scheme included in Department of Health grant	525	125
Department of Health financing of operating costs	**13,246**	**12,742**

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

The Board's performance against financing from the UK Government for the financial year ended 31 March 2008 is as follows:

	2007/08 £000	2006/07 £000
Net operating cost for the financial year	**20,067**	**17,688**
Less: Depreciation on assets funded by capital grant in aid from the Department of Health	3,851	3,336
Less: Charge for cost of capital	2,710	2,548
Less: Losses on disposal of assets funded by the Department of Health	64	83
	13,442	**11,721**
Financing received from the UK Government: Department of Health financing of operating costs	13,246	12,742
Over/(under)spending against financing received from the UK Government	**196**	**(1,021)**

7 Fixed Assets

	Freehold Land £000	Freehold Buildings £000	Equipment and Computers £000	Production Equipment £000	Assets Under Construction £000	Total Tangible Assets £000	Software £000	Total £000
Balances at 1 April 2007	6,307	67,422	11,535	1,373	143	86,780	609	87,389
Additions	-	-	-	137	4,009	4,146	-	4,146
Transfers	-	959	777	-	(1,774)	(38)	38	-
Disposals	-	-	(32)	(179)	-	(211)	-	(211)
Diminution	-	-	(29)	-	-	(29)	(45)	(74)
Revaluation / indexation	341	4,454	299	(66)	-	5,028	(12)	5,016
Cost or valuation at 31 March 2008	**6,648**	**72,835**	**12,550**	**1,265**	**2,378**	**95,676**	**590**	**96,266**
Accumulated depreciation at 1 April 2007	-	16,144	8,363	523	-	25,030	222	25,252
Charge for the year	-	2,860	913	59	-	3,832	102	3,934
Disposals	-	-	(32)	(102)	-	(134)	-	(134)
Diminution	-	-	(21)	-	-	(21)	(17)	(38)
Indexation	-	1,292	216	-	-	1,508	-	1,508
Accumulated depreciation at 31 March 2008	**-**	**20,296**	**9,439**	**480**	**-**	**30,215**	**307**	**30,522**
Net book value								
At 31 March 2007	6,307	51,278	3,172	850	143	61,750	387	62,137
At 31 March 2008	**6,648**	**52,539**	**3,111**	**785**	**2,378**	**65,461**	**283**	**65,744**

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

One motor vehicle with a net book value of £nil (2007: £ nil) is included in equipment and computers.

8 Stock

	31 March 2008 £000	31 March 2007 £000
Standards	6,325	7,799
Raw materials	53	57
Others	710	752
	7,088	**8,608**

The Board holds stocks of biological reference materials ('standards') which are used in regulatory control, diagnosis and research. At 31 March 2008 2.4 million standards were held of which 1.0 million standards were publicised for distribution in NBSB's reagent catalogue. The Board estimates their economic value at 31 March 2008 to be £6,325k (2006: £7,799k) 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.

When first recorded on the balance sheet at 31 March 2001 an unrealised gain of £7,320k was credited to the revaluation reserve. In subsequent years the portion of this reserve relating to stocks held at 31 March 2001 and distributed during the year is credited as a realised gain to operating costs.

9 Debtors

	31 March 2008 £000	31 March 2007 £000
Department of Health	-	10,875
Trade debtors	1,079	779
Grant income receivable	1,255	1,308
Other debtors	478	400
Prepayments	740	836
	3,552	**14,198**

The Department of Health debtor at 31 March 2007 represented the Department's obligation to fund the future liabilities of the NBSB Pension Scheme (Note 13). This was settled, at the prevailing actuarial value, following the transfer of members to the NHS Pension Scheme and winding up of the scheme on 1 September 2007.

Intra-governmental balances:	31 March 2008 £000	31 March 2007 £000
Balances with Central Government bodies	981	11,502
Balances with NHS Trusts	10	7
Balances with Local Authorities	582	-
Balances with Public Corporations	-	-
Balances with bodies external to Government	1,979	2,689
Total	**3,552**	**14,198**

10 Cash at Bank and In Hand

	31 March 2008 £000	31 March 2007 £000
Total cash at bank and in hand	**7,542**	**6,513**

11 Creditors: Amounts falling due within one year

	31 March 2008 £000	31 March 2007 £000
Taxation and social security costs	360	568
Trade creditors	866	677
Accruals	277	483
Deferred grant income	2,218	1,535
	3,721	**3,263**

Intra-governmental balances:	31 March 2008 £000	31 March 2007 £000
Balances with Central Government bodies	1,055	1,037
Balances with NHS Trusts	-	-
Balances with Local Authorities	-	-
Balances with Public Corporations	-	-
Balances with bodies external to Government	2,666	2,226
Total	**3,721**	**3,263**

12 Provisions

	NBSB Pension Scheme £000	Early Retirements £000	Other Provisions £000	Total £000
Balance at 1 April 2007	10,648	359	50	11,057
Utilised during the year	(230)	(68)	(50)	(348)
New/(reversed) provisions during the year	(10,418)	(291)	107	(10,602)
Balance at 31 March 2008	**-**	**-**	**107**	**107**

(a) The Board completed the transfer of members of the NBSB Pension Scheme and winding up of the scheme during 2007/08 as part of its preparations for the merger of NIBSC with the Health Protection Agency. The Government Actuary had 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 brought forward in the Board's accounts at 1 April 2007 was based on this valuation, less the net cost of scheme benefits paid since the valuation date. The actual transfer cost was met by a payment to the NHS Pension Scheme of £9,077k and was offset by the settlement of the amount receivable from the Department of Health in respect of the scheme (Note 9).

(b) The early retirements provision was set up in respect of early retirement of staff where the Board had a continuing liability to meet the costs involved up to and beyond the standard retirement date. During the year the Board made a commuted payment to the NHS Pension Scheme to extinguish the remaining liability.

(c) Other provisions represent the future costs of life assurance premiums for 11 staff up to their retirement dates to equalise the benefits provided to them by the former NBSB Pension Scheme.

13 NBSB Pension Scheme

The NBSB Pension Scheme was overseen by a five member Committee of Administration appointed by the Board, including two staff members of the scheme. There were 64 scheme members at 1 April 2007 of whom 11 were contributing, 44 were receiving pensions and the other 9 had preserved pension rights. The scheme first went into deficit in 1988 and since financial year 1990/91 additions were made to the Board's cash limit towards the net cost to the Board of funding it. During the year the rules of the NHS Pension Scheme were amended by the Secretary of State for Health to admit members of the NBSB Pension Scheme and on 1 September 2007 all the members of the NBSB Pension Scheme were transferred to it. The NBSB Scheme was then wound up and the NHS Pension Scheme became the only pension scheme offered by the Board to its staff.

The net cost to the Board of the benefits of the NBSB Pension Scheme up to its transfer was as follows:

	2007/08 £000	2006/07 £000
Lump sum payments	37	47
Transfers to other schemes	-	-
Benefits paid	227	390
Total payments	**264**	**437**
Less:		
Employers contributions	23	57
Employees contributions	11	28
Total contributions	**34**	**85**
Provisions utilised	**230**	**352**

14 Government grants for general capital purchases

	2007/08 £000	2006/07 £000
Received from the Department of Health	3,849	3,743

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 (Note 16).

15 Capital commitments

	2007/08 £000	2006/07 £000
Contracted capital commitments as at 31 March 2008 for which no provision has been made	2,721	1,040

16 Capital and Reserves

	General Reserve £000	Revaluation Reserve £000	Donated Asset Reserve £000	Total £000
Balance at 1 April 2007	43,116	32,789	1,231	77,136
Net operating cost for the year	(20,067)	-	-	(20,067)
Financing received from the UK Government:				
- For operating costs	13,246	-	-	13,246
- For general capital	3,848	-	-	3,848
Reversal of charge for cost of capital	2,710	-	-	2,710
Gain (loss) on revaluation – fixed assets	-	3,508	-	3,508
Current cost element of depreciation charge	532	(532)	-	-
Depreciation transfer from donated assets	83	-	(83)	-
Realised gains on standards stock	-	(283)	-	(283)
Balance at 31 March 2008	**43,468**	**35,482**	**1,148**	**80,098**

17 Notes to the Cash Flow Statement

(i) Reconciliation of operating surplus to net cash inflow from operating activities.

	2007/08 £000	2006/07 £000
Net operating cost for the year	(20,067)	(17,688)
Realised gain on stock valuation	(283)	-
Interest received	(25)	(97)
Cost of capital charge	2,710	2,548
Depreciation	3,934	3,392
Opening adjustment to reserves	-	(22)
Loss on disposal of fixed assets	71	83
Fixed assets transferred to stock	-	47
Diminution in value of computers and software	36	33
Decrease in stock	1,520	(99)
Decrease in long term debtors	-	11,000
Decrease in short term revenue debtors	10,646	(11,116)
Increase in revenue creditors	206	1,171
Decrease in provisions	(10,950)	(325)
Net cash ouflow from operating activities	**(12,202)**	**(11,073)**

(ii) Reconciliation of net cash flow to movement in net funds.

	2007/08 £000
Increase in cash and liquid resources in the period	1,029
Net funds at 31 March 2007	6,513
Net funds at 31 March 2008	7,542

18 Losses and special payments

During the year the Board wrote off balances due from trade debtors of £10,251 and incurred losses in respect of legal claims of £33,000 (2006/07: £ nil).

19 Operating leases

The Board had commitments under operating leases at the 31 March 2008 of £268k (2007: £ nil).

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 0.1% 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 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 15th July 2008.

22 Contingent liabilities

There were no contingent liabilities not otherwise provided for in the accounts (2007: £nil).

National Biological Standards Board

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

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

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

National Biological Standards Board

Declared Interests of NBSB Members relating to 2007/08

Member	Organisation	Nature of Interest	Organisation	Nature of Interest
Mr Michael Beaumont	Health Protection Agency	Non-executive director	Nottinghamshire Healthcare NHS Trust	Mental Health Act manager
	East Midlands Strategic Health Authority	Non-executive director	Newark Housing Association (a Registered Charity)	Chairman (voluntary post)
Mr Michael Brown	None	None		
Professor Derek H Calam	NBSB	Pension (to 1 September 2007)		
Professor Janet Darbyshire	Wide range of national and international pharma-ceutical companies	Director of MRC Clinical Trials Unit where research is supported in part by industry		
Professor Gordon Duff	Interleukin Genetics	Scientific Advisory Board, Shareholder		
Mr Alan Heath	None	None		
Mr Martin Hindle	University Hospitals of Leicester NHS Trust	Chairman	Health Protection Agency – Finance Committee	Member
	Leicestershire and Rutland Probation Service	Director	Sanofi Aventis Pension Fund	Member
			Cable and Wireless Pension Fund	Member
Dr Stephen C Inglis	Partnerships UK	Associate advisor		
Professor David Latchman	London First	Board member	CHI London Council	Councillor
	London Development Agency Board	Observer	London Higher (Umbrella organisation which represents all London Universities)	Chairman
	Therakind Ltd	Board member		

National Biological Standards Board

Member	Organisation	Nature of Interest	Organisation	Nature of Interest
Professor Christine Lee	Hemophilia Foundation (supported by Novo Nordisk) Biomeasure Inc –Ipsen Novo Nordisk	Council member Consultant advisor on specific product Advisor on specific product	Kogenate liposome clinical trial (supported by Bayer HealthCare) Von Willebrand Disease Prophylaxis Network (supported by ZLB Behring)	Chair of Data Safety Monitoring Board (DSMB) DSMB member
Miss Gillian Noble	Various Pharmaceutical Companies (Managed by HSBC Trust Company)	Shareholder	Meningitis Trust MRC	Director Audit Committee Member
Professor Karl Nicholson	Novartis Glaxo SmithKline Berna-Biotech	Occasional consultancy	University of Leicester and University Hospitals of Leicester NHS Trust	Member of research groups receiving support variously from Novartis, Crucell-Berna, Roche
Dr John Petricciani	World Health Organisation National Institutes of Health International AIDS Vaccine Initiative	Occasional Consultancy	International Association for Biologicals Inb Biotechnologies Inc Arbor Vita Corporation Prospect Therapeutics Inc	Board Member Scientific Advisory Committee Chairman Consulting services Consulting services
Dr Nicola Rose	Big Lottery Fund	External Assessor, Research Grants programme		
Professor Sir John Skehel	Novartis Vaccines, Cambridge, Mass Global Life Science Ventures InB Pharmaceuticals Inc Institute of Molecular Medicine, Oxford	Consultant Consultant Consultant Member of Scientific Advisory Committee	MRC Technology Novartis Foundation Animal Health Trust	Board Member Trustee Trustee and Chairman of Scientific Advisory Board

National Biological Standards Board

Member	Organisation	Nature of Interest	Organisation	Nature of Interest
Dr Lincoln Tsang	Arnold and Porter LLP	Partner providing legal advice to life sciences industry	Various pharmaceutical biotechnology companies	External legal advisor
	School of Pharmacy, University of London	Member of the Governing Council		

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