2008/09

Annual Report & Accounts

NBSB

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1st April 2008 to 31st March 2009

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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.

National Biological Standards Board
Annual Report and Accounts
for the year ended 31st March 2009

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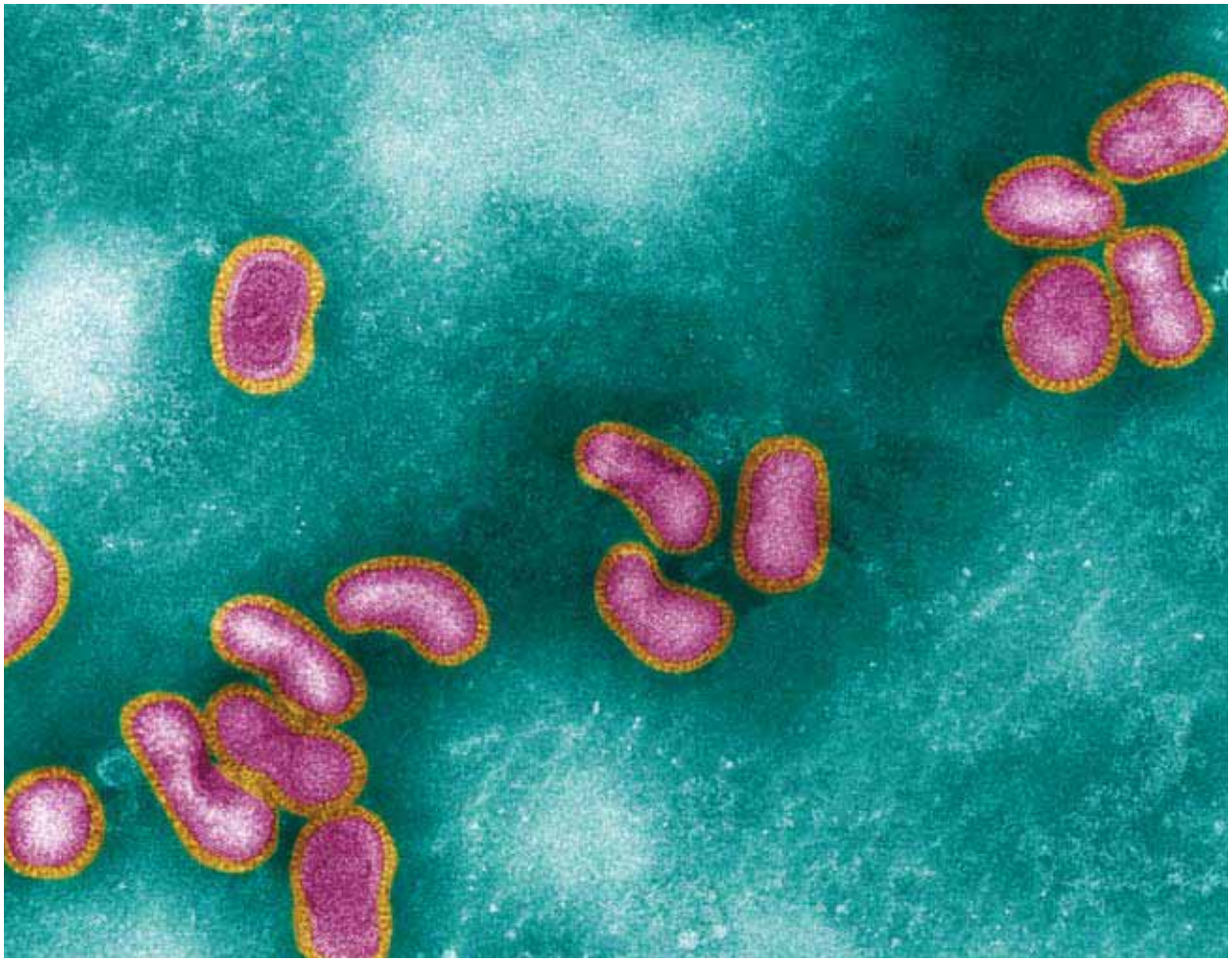

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Chairman's Report

With a shade of sadness I introduce this final Report of the National Biological Standards Board (NBSB) before it passes into history following the merger of the NIBSC with the Health Protection Agency (HPA). At this time, a public vote of thanks must go to Mr Victor Knight, the Board's Secretary, for superb work in support of the Board.

The Board was established by Act of Parliament in 1975 to oversee the establishment of a new Institute to bring together the crucial research sciences that underpin biological standardisation – to devise accurate ways of measuring the activity of biological medicines that are too complex for chemical analyses – and to control those medicines to provide independent assurance of the quality and safety of manufactured lots before they are released to the public.

Over the last 34 years the task has grown ever more challenging and important as dramatic scientific advances created a huge array of new types of medicinal products, ranging from recombinant proteins and antibodies, through innovative vaccines, to gene-based and cell-based therapies. Though remaining relatively modest in size, the Institute responded to these developments extraordinarily well and remains, without doubt, the foremost scientific laboratory of its kind in the world. The NIBSC continues to produce over 90% of the world's international standards for biological medicines in partnership with the World Health Organisation, and has earned a tremendous reputation for the quality of its work, its scientific expertise and its integrity. The past year's performance has been no less exceptional, as will be easily seen in this report.

As chairman of the NBSB, it has been a privilege to be associated with the Institute over the last seven years, and I will take this opportunity to pay warm tribute to those past and present members of the Board, the staff of the Institute, and its supporters within the Department of Health and elsewhere who have contributed to such remarkable success since 1975. Their efforts have created a wonderful scientific Institution, indeed to quote from a recent independent review, "a national treasure" that brings international prestige and influence as well as providing vital protection of the public health.

Preparations for merger with HPA began soon after the decision in 2004 to bring the organisations together. I am delighted to say, on behalf of the outgoing Board, that the process of integration has been very smooth and that excellent working relationships are already established at all levels. Great credit for this must go to the Institute's scientific and support staff, across all categories, and to its exceptional management team under the superb leadership of Dr Stephen Inglis, the Institute's Director. The NIBSC joins the HPA in excellent shape, scientifical-

ly, organisationally and financially. I am confident that its future is secure within its new home, and we can look forward to seeing its work on behalf of patients everywhere continue for many years to come.

Sir Gordon Duff FRCP FMedSci FRSE

Chairman, National Biological Standards Board

Director's Report

I am delighted to report another year of excellent achievements from the Institute. The core of our work is the development of tests and reference materials for measuring the effectiveness of biological medicines and our outputs continued to grow, both in terms of the numbers of new materials available but also their use around the world. Over the past year we distributed over 130,000 standards to 83 different countries. As medicines development and manufacture becomes ever more globalised, the introduction of uniform and universal standards for measurement and quality assurance of medicines is of paramount importance. Our role as the leading World Health Organisation laboratory for International Standards places us in a very strong position to support this goal, as does our increasingly close relationship with the International Pharmacopeias.

Independent testing of biological medicines remains an extremely important safeguard to public health and we have continued to meet the demands placed on us as the UK's Official Medicines Control Laboratory working within the European regulatory framework. Our world class expertise in medicines testing has also, as on many previous occasions, proved invaluable in an international context in particular to support the safe deployment of vaccines in developing countries.

Finally maintenance of an extremely strong scientific research base is a vital ingredient of the Institute's success and it is pleasing to report impressive outputs in terms of scientific publications and to note a substantial increase in research grant funded activity this year, reflecting the high quality translational research base of the Institute and our ability to compete effectively at national and international level.

Towards the end of the year the Institute was subject to a strategic review by an independent review panel of national and international experts. The feedback from this review was highly positive, emphasising the uniqueness of the Institute's role and underlining the importance of its achievements.

All this has been achieved against the backdrop of final preparations for merger with the Health Protection Agency. This major change has put considerable extra pressure on the Institute, especially over the last 6 months, but all the necessary steps were completed for smooth integration on April 1st 2009 without detriment to the scientific work and morale remains high. This was a major achievement I would like to record in this last Annual Report my sincere thanks to all at NIBSC for their help and support in preparing the Institute for the next phase of its development.

NBSB And NIBSC

The National Biological Standards Board (NBSB) was a non-departmental public body (NDPB) of the UK government, established in 1975 as a Statutory Body by Act of Parliament. The Board was 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). In July 2008 the Health and Social Care Act abolished the NBSB and transferred its functions to the Health Protection Agency (HPA), another NDPB of the UK government, established in 2004 by the Health Protection Agency Act.

As part of the HPA, NIBSC continues to 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.

The NBSB considered 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 2008. NIBSC has been asked to serve as the principal OMCL for the release of a new tetravalent meningococcal conjugate vaccine. NIBSC staff are making important contributions to WHO and European working groups and parties dealing with up-and-coming issues such as biosimilars, which are new variations of biological medicines whose patents have expired and which present particular challenges to regulators.

Batch Release Activity Calendar Year 2008 (1 January to 31 December 2008)

Product groups	No of batch release certificates in 2008 (2007)
Bacterial vaccines, toxins, antitoxins	331 (289)
Viral vaccines	154 (109)
Blood products: Albumin, coagulation factor concentrates, virus inactivated plasma and fibrin sealants	801 (772)
Total batch release certificates	1,286 (1,170)
Plasma pools tested (virus testing)	1,475 (1,428)

Standardisation

The complex assays used to assure the potency of biologicals require the use of a standard of biological activity (a batch of a substance that has been assigned units of activity and is used as a "benchmark"). The system of World Health Organization (WHO) International Standards provides a set of "gold standards" from which countries and manufacturers can calibrate their own standards for biological testing. 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.

Standards distribution and derived income remained comparable with previous years.

Sales & Distribution of Existing Standards (1 January 2008 to 31 December 2008)
5,021 shipments of 172,829 ampoules/vials
5,906 shipments including collaborative studies and other shipments
92 fills of 526,250 ampoules/vials plus validation fills (vs. 90 fills of 525,156 in 2007)
Overall income from the sale of reference materials during 12 months to December 2008 was £3,506k (excluding carriage), a 0.3% decrease from 2007 on a like for like basis for 12 months to December 2007.

Once again NIBSC established a wide range of new reference materials and International Standards during the year in response to public health need. Nineteen standards comprising twelve new and seven replacements produced by the Institute were established at the WHO's Expert Committee for Biological Standards in Geneva in October 2008. NIBSC scientists also played an important role in developing a number of new guidance documents.

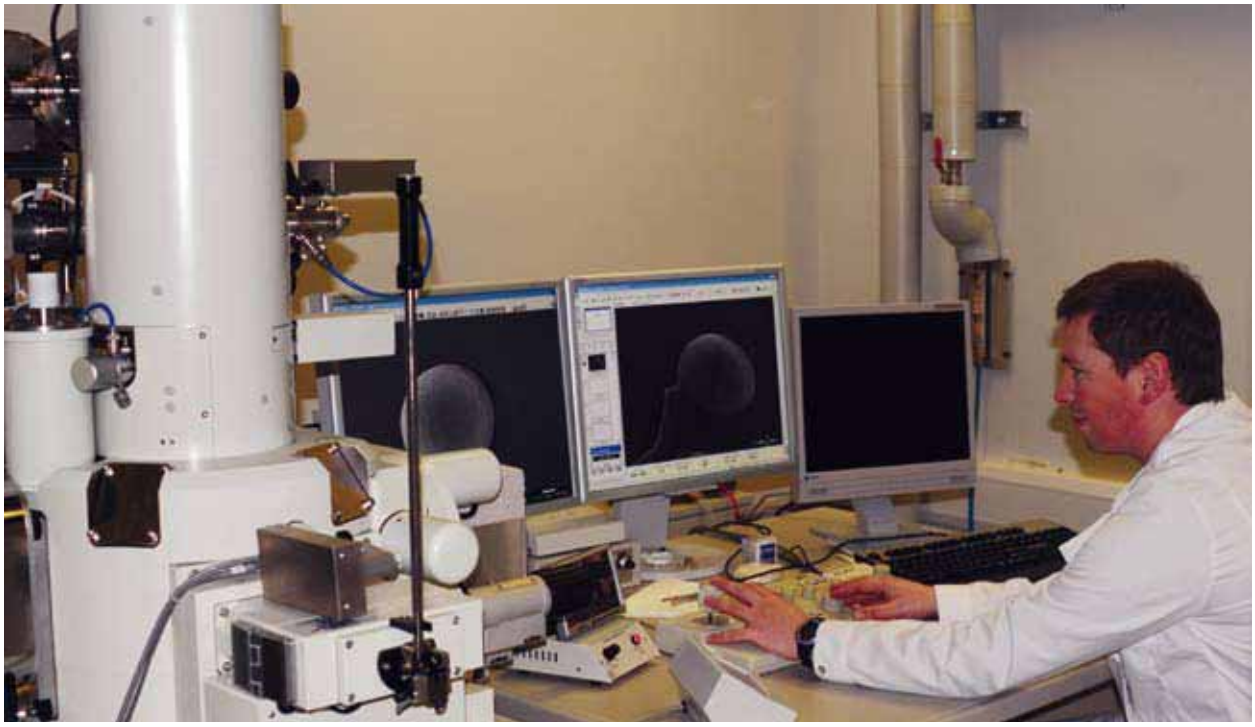
New Standards Established 2008

Influenza H5N1 antibody (human) (1st International Standard)
Human papillomavirus type 18 DNA (1st International Standard)
Anti-A antibodies in intravenous immunoglobulin, human (WHO Reference Reagent)
Anti-B antibodies in intravenous immunoglobulin, human(WHO Reference Reagent)
Anti-hepatitis B core antigen (anti-HBc), plasma, human (1st International Standard)
Haemophilia A intron 22 inversion (1st International Genetic Reference Panel)
Fragile X syndrome (1st International Genetic Reference Panel)
Acellular pertussis vaccine (1st International Standard)
Pertussis antiserum (1st International Standard)
Pertussis antiserum (human) (1st WHO Reference Reagent)
Alpha-1 anti-trypsin (1st International Standard)
Replacement Standards Established 2008
Rabies vaccine (6th International Standard)
Anti-hepatitis B surface antigen (anti-HBs) immunoglobulin, human (2nd International Standard)
Blood coagulation factor IX, concentrate (4th International Standard)
Factor VIIa concentrate (2nd International Standard)
Parvovirus B19 DNA, plasma, human (2nd International Standard)
Insulin-like growth factor (IGF-1) (2nd International Standard)
Parvovirus B19 plasma (2nd International Standard)

Mission Orientated Research

The Institute maintains a vigorous research programme in all of its scientific areas, 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 continues to be high with 127 staff publications listed for January to December 2008.

We have enjoyed a substantial rise in grant income during the year (£4,435k vs £2,872k for 2007/08). This reflects the ability of our scientists to attract funding on a competitive basis.



Supporting Pandemic And Seasonal Influenza Vaccine Production

NIBSC plays a key role in this area through production and distribution of reference materials for vaccine quality assessment and development of virus strains suitable for vaccine manufacture. In particular we have continued to strengthen preparedness to face a potential pandemic by extending our library of strains covering different posible antigentic types.

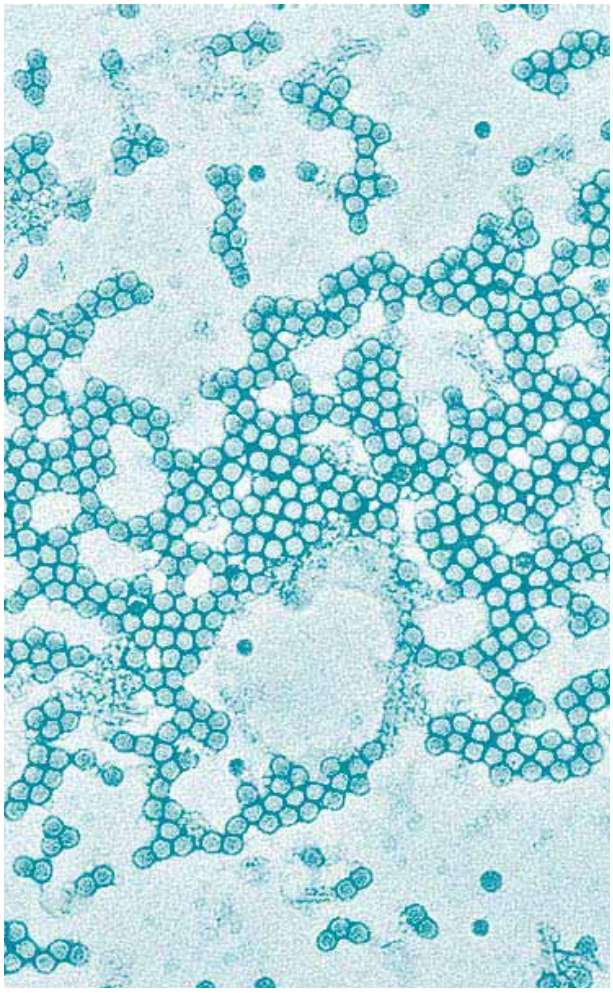
This work will be greatly facilitated by construction of our new Influenza Resource Centre. Work began on the new building during 2008 and completion is anticipated by the end of 2009/10.

As with many of our activities our influential work has a very strong international dimension.

Institute scientists have continued to play an important role in the WHO-coordinated Inter-Governmental discussions on influenza virus sharing, helping to develop and support UK policy and working with WHO to devise possible solutions to what has become a major international health issue. One of the most important practical outcomes from these discussions was the decision to establish a new mechanism to enable the tracking of virus strains as they are transferred between laboratories in the global network.

Polio – New Vaccines For The Post-Eradication Era

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.



It seems clear that continued vaccination against possible resurgence of poliovirus will be necessary for many years even after the disease is eradicated. This would need to be based on use of inactivated vaccine to avoid the risk that live vaccine could itself seed new outbreaks. Currently inactivated vaccines are manufactured from fully virulent poliovirus strains and so the production process, which involves handling large amounts of live virus, could also pose a risk. Hence there is considerable interest in switching to use of the attenuated strains vaccine production.

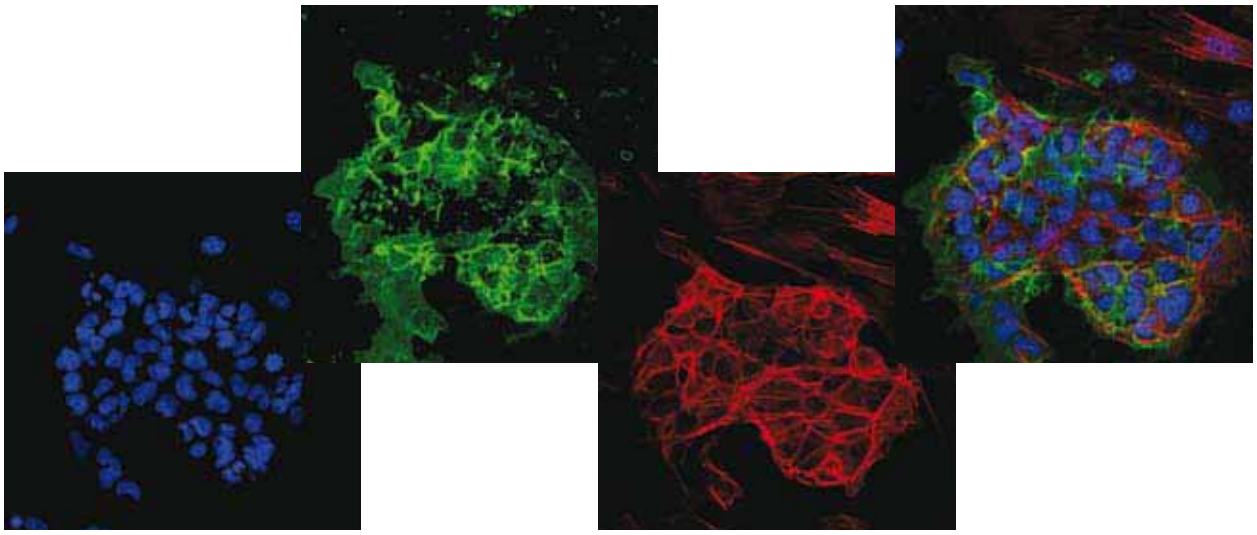
Work carried out over the past three years at the Institute has led to the creation of completely new genetically-engineered non-virulent strains that appear to retain the full vaccine capabilities of the vaccine virus and, during the last year, extensive testing has shown that they are likely to be safe for vaccine production.

Cell-based Medicines

The UK Stem Cell Bank is now a well established operation. 48 stem cell lines have been acquired by the bank and of these, 32 have been fully banked and 15 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, its 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 stand out.

The next phase of the Bank's development, provision of a permanent set of laboratories to house its expanded work programme is in progress. The new laboratories are being built as part of a joint development alongside the Influenza Resource Centre and are expected to be available by mid 2010.



Investigation of Adulterated Biologicals

During the year NIBSC was been increasingly involved in the investigation of counterfeit, contaminated and adulterated biological medicines.

NIBSC scientists have been active in the investigation of contaminated heparin batches that were sold in the USA and 12 other countries and that caused serious adverse reactions and deaths. The contaminant was a substance that reacts like heparin in standard potency tests. NIBSC was able to make significant scientific contributions to this issue, at both national and international levels, by providing scientific advice and expertise and carrying out investigational testing of heparin batches, including screening of UK heparin batches, for the presence of the contaminant, and providing reference materials to other testing laboratories to allow detection of the contaminating material.

We also carried out testing on a number of potentially counterfeit hormone products (growth hormone, insulin-like growth factor-1, chorionic Gonadotrophin) highlighting that the problem of counterfeiting, already a major problem for chemical drugs, is now also increasingly found in biological medicines.

Our poliovirus experts provided invaluable support to WHO, identifying live virus contamination in novel experimental vaccine batches currently in clinical development by a manufacturer in Asia. This demonstrated once again the need for extreme caution and regulatory vigilance in the development of new vaccines, even in very well established fields.

Scientific Communications And Training Activities

Development of the Institute as an international hub for general training in biological standardization, and in more specialized areas relating to particular issues around biological medicines, is a key strategic goal.

During the last year we continued to help developing countries strengthen their preparedness for pandemic influenza, supporting a key resolution from the World Health Assembly. In November 2008, under the auspices of WHO, NIBSC provided training in vaccine quality assurance for staff from the National Control Laboratories (NCLs) of Brazil, Indonesia, Thailand and Vietnam and also several prospective vaccine manufacturers.

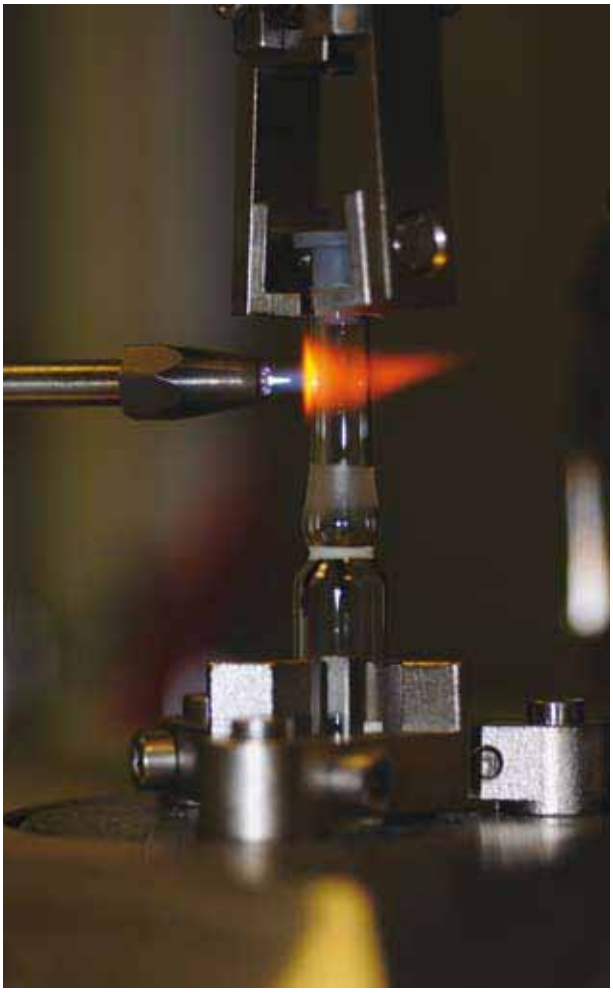
We also strengthened our relationship with the National Institute for Chinese Pharmaceutical and Biological Products (NICPBP), a key part of China's medicines regulation system, and have now establishing a rolling programme of training for their staff.

We further expanded our internally funded graduate student programme in collaboration with Imperial College in line with our objective to ensure that NIBSC maintains its vigorous research programme. New projects initiated include investigating a model for hepatitis virus infection, exploring vaccine candidate proteins on the surface of meningococcal bacteria and development of improved vaccines for the polio post-eradication era.

Preparation for Merger

NIBSC's merger with the Health Protection Agency (HPA) took place on 1 April 2009 and up to that point we continued to build excellent working relationships throughout the two organisations. IT systems have been effectively integrated, a unified security access system has been introduced, and during the year NIBSC was 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 development 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 DH to cover 2006-2009. The extensive refurbishment of our laboratories is now complete and this year has seen the completion of programmes to improve more general facilities and amenities. These have included:

- Installation of a site-wide cooling system to replace the current energy-inefficient piecemeal system
- The refurbishment of our reception area
- The improvement and future-proofing of the Institute's power supply
- Landscaping of the areas outside the canteen and library to provide attractive outdoor seating for staff
- Completion of a new flexible containment suite for use with dangerous pathogens.

In addition, construction began on an important addition to the Institute's facilities - a new building to house the Influenza Resource Centre and UK Stem Cell Bank.

The NIBSC intranet website was re-launched and now features user-controlled content making it more flexible and responsive. NIBSC staff also have access to the HPA information technology network.

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 have continued to play a major contributory role to a very wide range of policy-making and regulatory bodies both nationally and internationally.

During 2008, 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
- Association of Clinical Electron Microscopists
- 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 BIO: Biological and Biotechnological Products
  - Panel of Experts on Blood Related Products
  - Committee H
  - Expert Advisory Group 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
- Freshwater Biological Association
  - Grants & Awards Committee
- Fund for the Replacement of Animals in Medical Experiments
- Health Protection Agency
  - Forum on Deliberate Release Agents-Strategy Group
  - Meningococcal Forum
  - Pheumococcal and Hib Forum
  - Vaccine Programme Board
- 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
- Imaging & Microscopy
- National Vaccine Evaluation Consortium
- National Measurement System Steering Group
- National Genetics Reference Laboratory Steering Group
- NEQAS Specialist Advisory Groups
- NHS Modernising Scientific Careers Programme
- Meningitis Trust Scientific Committee
- Meningitis Research Foundation Research Advisory Panel
- MRC College of Experts
- Parenteral Society: Freeze Drying Working Group
- Presidents Advisory Group for The Institute of Animal Technology (UK)
- RCOG Scientific Working Party on Cord Blood Banking
- United Kingdom Accreditation Service
  - Biological and Medical Sciences Technical Advisory Committee
  - Reference Materials Project Steering Committee
- UK Federation of Culture Collections
- United Kingdom NEQAS for Blood Coagulation Steering committee
- United Kingdom Thrombosis and Haemostasis Task Force
- UK Pediatrics group
- UK Reference Materials Working Group
- UK Stem Cell Bank Steering Committee
- Veterinary and Public Health Standardisation Committee

Europe

- EDQM
  - Biological Standardisation Programme Steering Committee
  - Working party on in vitro pyrogen testing
  - Working group on pertussis toxin testing
- EMEA
  - Vaccine Expert group
  - Gene Therapy Expert group
  - Biosimilars Working Party
  - Low Molecular Weight Heparin Expert Group
  - 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.
- JCTLM (Joint Committee for Traceability in Laboratory Medicine): Coagulation Factors Review Team, Working Group I and II.
- 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 6 (Biologicals/Biotechnology)
  - Group of Experts 6B (Human Blood and Blood products)

- Expert Group on Heparin
- Working Party on Monoclonal Antibodies
- Working Group on Botulinum toxin
- Working Group on Pneumococcal vaccine OPKA Standardisation

- EU FP6 AIDS Vaccine Integrated Project (AVIP) Steering Committee
- ECVAM Collaborative Programme
- EuroGentest Reference Material Committee
- European Task Force on Haemophilia
- OMCL Laboratory network

WHO

- Consultation Group on Cytokine Standardisation
- Working Groups on
  - Pertussis Vaccines;
  - Diphtheria and Tetanus Vaccines;
  - Cholera Vaccines;
  - Stability of reference materials;
  - Influenza vaccines;
  - Measles
  - Expert Committee on Biological Standardisation
  - Regulatory Evaluation of Therapeutic Biological Medicines
- 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
- Consultation group on Lot Release
- Consultation group on WHO Regional Standards development
- Consultation group on whole cell pertussis vaccine potency test in combination vaccines
- Consultation group on pneumococcal vaccines
- Consultation group on BCG and new TB vaccines

Other International

- Bioanalysis working group (BIPM)
- Biometrics Subcommittee
- Chemokines Nomenclature Committee
- Consultative Committee on Quantities of Material (Bureau International des Poids et Measures, BIPM)
- Consultative Committee for Amount of Substance, Bioanalysis Working Group
- Cryobiology Society 2010
- HPA Nomenclature Committee
- International Atomic Energy Agency (IAEA) consultation group on radiolabelled biological proteins and peptides
- ICH Gene Therapy Expert Group (EU representative)
- International Stem Cell Banking
- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Groups
- 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
- International Standardisation Office (ISO) EU representatives
- Meningitis Vaccine Project (PATH/WHO)

- Society for Low Temperature Biology
- Standardization Committee
- TB Vaccine Task Force
- United States Pharmacopoeia-glycan analysis advisory panel
- United State Pharmacopoeia Blood and Blood Products Expert Committee
- United State Pharmacopoeia Human Plasma Ad Hoc Panel
- United State Pharmacopoeia Heparin Ad Hoc Panel
- United States Pharmacopoeia ad hoc panel on Immunological Test Methods
- USP Expert Committee and Advisory Panel on Flow Cytometry

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 standardization 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.

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

NIBSC addresses a series of key annual performance targets that are agreed between the Minister of State for Public Health and the NBSB. The main purpose of the targets is to provide the Department of Health with a measure of how well NIBSC has carried out its key activities. They also help to focus the work of the Board, NIBSC Management and staff on the core function of assuring the quality of biological medicines. Performance against the 2008/09 Key Targets is shown below.

	Key Target	Outcome
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/replacement WHO International Standards and reference materials	Achieved – 12 new and 7 replacement standards established
Research & Development	Publish at least 100 scientific papers and utilise in excess of £3m in external research funding	Achieved – 127 publications and utilised £4,435k in grant funding
	Develop a targeted strategy for long term development and maintenance of scientific expertise	Graduate student programme in conjunction with Imperial College extended further. New initiative underway to develop long term training portfolio for standardization and control leaders of the future.
Quality	Maintain existing accreditation/certification for batch release, supply of standards and stem cell work (ISO/IEC17025, ISO13485, ISO9001).	Achieved

	Key Target	Outcome
Quality	Ensure compliance with all relevant Healthcare Commission standards	NIBSC has achieved the same level of compliance as the Health Protection Agency
	Reference Standards: Implement quality system for newly initiated projects according to new manual; complete implementation of electronic Instructions for Use system	Achieved
Influenza vaccines – seasonal and pandemic	Construct further 3 new potential influenza pandemic vaccine strains for 'library'	Two new strains achieved (H2 and H7). An additional H2 in preparation.
	Complete collaborative study to establish international Standard for H5 serum for submission to ECBS 2008	Achieved
	Carry out research aimed at improving vaccine yields from pandemic vaccine strains	Research programme has continued, leading to scientific publication.
	Support Health Protection Agency/ Department of Health programme to assess the value of prepandemic vaccination	PIVEC project has not yet begun. Now likely to be supplanted by need for swine influenza vaccine testing.
Polio eradication	Complete construction and in house characterisation of novel poliovirus strains for production of inactivated polio vaccines and begin to establish the regulatory development pathway	Pre-clinical studies advanced and promising. Companies in discussion on evaluating the strain.

	Key Target	Outcome
Biosimilar Medicines	Initiate new work programme based on strategy developed with MHRA and EMEA, focusing on key areas of need	Achieved - intial studies have focussed on quality aspects of biosimilar Interferons and Erythropoeitins
Meningitis vaccines	Initiate studies on the structural integrity and stability of novel protein antigens in candidate meningococcal vaccines	Structural characterisation of recombinant proteins in a manufacturer's candidate vaccine has been completed. Cross protection under evaluation.
Monoclonal Antibody-based Medicines	Establish a new laboratory with 'state of the art' expertise in the field of monoclonal antibody analysis	Achieved - external recruitment successful and laboratory now up and running
Clinical Virology Working Standards	Develop panels of working standards for infections relevant to CSF samples and for transplantation	Achieved - panels in place for HSV
ORGANISATIONAL OBJECTIVES		
Provision of External Training	Develop integrated HPA-NIBSC training strategy and implementation plan	Achieved - new combined strategy developed and endorsed by HPA Executive Group
Information Technology	Replace all switches to deliver 1000 Mbps to the desktop environment	Achieved
	Expand the scope of existing quality procedures to cover all key central IT systems. Work with Quality Assurance to identify gaps with a view to formal accreditation consistent with the Institute Quality Model	Deferred due to change of staff. Change control procedure introduced as first step.

	Key Target	Outcome
Information Technology	Develop NIBSC as a second data storage site within the HPA for disaster recovery	Outline plan developed. On hold pending review of overall HPA resilience.
Capital Development Programme	Maintain IRC/Stem Cell Bank design/build programme to achieve Dec 09 completion	Building underway and on schedule for completion in 2009/10
	Complete new flexible containment suite	Achieved
	Obtain business case approval for Training / Seminar Hall	Not achieved. Sight held for other potential building requirement.
	Complete the Installation of a higher capacity, more secure electricity supply to site	Connection from Borehamwood completed. Potters Bar link under construction.
Porton Programme	Work with all relevant stakeholders to develop a coherent and rational strategy for the UK, ensuring that NIBSC/HPA's needs are fully met.	Joint strategy developed with HPA. Management of Porton facility to be integrated with DSTL facility. Long term development plan in progress.
Stakeholder Satisfaction: working effectively with partners	Gather and review feedback from all key stakeholder groups	Completed for batch release and standards customers. Strategy for regular feedback to be integrated with HPA processes.
Communications	Develop and begin to implement a comprehensive communication strategy for the Institute	Not achieved. Will developed in conjunction with HPA post merger.
	Develop the NIBSC internal and external website using Immediacy Content management system. Co-ordinate the work of content providers to ensure currency of information internally	NIBSC intranet launched and fully in use. Work undertaken on new external site-launched in conjunction with merged HPA website.

	Key Target	Outcome
Communications	Develop specific marketing materials for scientific recruitment and targeted plan for enhancing NIBSC profile in the scientific community	A new range of literature produced to cover NIBSC's main areas of activity and including dual HPA-NIBSC branding
HPA Merger	Complete all the necessary legal & business arrangements for merger by year end	Merger workstreams project initiated and completed
	Devise and implement communication plan for NIBSC and HPA staff to support successful merger	Achieved - through mix of seminars, email and intranet communication and Institute-level updates
	Identify key policy differences between HPA and NIBSC and devise plan to achieve successful harmonisation	Achieved
	All preparatory work completed so that AfC terms and conditions can be implemented in April 2009	Not achieved. All job evaluations done, but took longer than anticipated and final consistency checking stage still to be completed.
	Ensure alignment of all key governance systems between HPA and NIBSC	Achieved
Maintaining & Extending expertise	Build continuity of expertise in virology and biostatistics	Achieved - new expertise recruited to cover live vaccines area and biostatistics strengthened
Sustainable Development	Implement 2008/9 actions from joint HPA/NIBSC Sustainable Development Action Plan	Joint HPA/NIBSC Sustainable Development Action Plan with implementation details and timescales being set
	Complete site-wide cooling project	Achieved

	Key Target	Outcome
Sustainable Development	Develop and implement comprehensive performance monitoring systems for energy use, carbon consumption, generation of waste and recycling	New electricity panel with individual metering for the main site is now installed and awaiting commissioning. Waste and recycling initiatives are being optimised. Condition survey complimented NIBSC on its approach and suggested that it should be rolled out across the HPA.
Finance and Commercial	Achieve break-even against DH revenue budget	Achieved – small surplus £189k
	Maintain actual staff in post within 325 WTE target including grant funded and PhD student posts	Actual 330 – increase due to unexpected success in winning competitive research funding
	Increase sales of goods and services to >£7.5m by year end (15% increase on 07/08 target)	Actual £6.8m. Decision taken to defer in-year income in favour of royalty streams for long term sustainability. Shortfall offset by strong grant income.
	Improve contract revenue by £400k	Decision taken to defer in-year income in favour of royalty streams for long term sustainability. Shortfall offset by strong grant income.
	Achieve year 3 target of 3-year capital programme (cumulative commitment of £11.4m)	Achieved

Management Commentary

During the year under review the National Institute for Biological Standards and Control (NIBSC) was the operational unit of the National Biological Standards Board (NBSB). Its activities will continue undiminished from 1 April 2009 following the transfer of its assets, liabilities and functions from the NBSB to the Health Protection Agency (HPA). NIBSC 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. Up to the merger date, NIBSC's activities were determined by the Board and agreed by the Minister for Public Health through an annual planning cycle. The process identified 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 2008/09

The Institute made good use of a further year of stable finances with growth in its staff and the quality of its estate. The three year capital expenditure programme reached its final year with a cumulative expenditure of £11.5 million. In addition a specific grant of £6.7 million (out of a total £9.5 million) was received from the Department of Health towards the new Influenza Resource Centre for which the full business case was approved during the year. This modern facility has made excellent progress during its construction phase and will be completed during 2009/10. On its upper floor is the permanent building to house the UK Stem Cell Bank, funded by the Medical Research Council, which will replace the existing temporary facility. Other capital improvements were the refitting of the former standards production area as containment laboratories, and improvements to the reception and staff dining areas, site-wide cooling and security systems.

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 a further appointment to its PhD student programme funded from income on commercial sales contracts so that at the end of the year there were three such studentships plus five other PhD students funded from research grants.

For a second year the annual pay award (due from 1 July 2008) was negotiated locally and in compliance with the Treasury's 2% pay limit for public sector employees.

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.

Financial Results for the year 2008/09

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 £28,839k (2007/08: £27,482k). After offsetting £11,195k 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 £20,683k (2007/08: £20,067k). This cost was offset by contributions from the Department of Health of £13,226k for revenue spending, £10,600k for capital and the funding of notional interest of £3,045k. The balance of the general reserve increased by £6,863k over the year to £50,331k.

The year saw a strong increase in activity funded by academic grants. Funding received for project expenditure rose to £4,435k from £2,872k reflecting successful bids for grant funding in a very competitive environment. Handling fees for biological reference standards increased by 4% on the previous year, to £3,718k, after several years of growth, while fee income for control testing and other contractual income were lower than in 2007/08. Overall income from operations was up 11% at £11.2 million.

Capital expenditure was £9.4 million on an accruals basis (£8.5 million cashflow).

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 £6.0 million (2007/08 £6.3 million).

Included in the operating result is a gain from the increase in standards stock values of £335k. This follows a loss in the previous year when increasing production capacity and output of standards reduced their replacement cost. As stocks are valued at the lower cost and net realisable value, their carrying cost decreased in 2007/08, but has now stabilized at the higher output capacity.

The Institute's position at the end of the year (31 March 2009)

The financial position at the end of the year was strong. The budget was balanced, working capital was ample and the capital programme was on target. The assets and liabilities of the Board became the property of the Health Protection Agency from 1 April 2009.

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

Prior to the merger of NIBSC with the Health Protection Agency, the Board took care that changes arising from the merger would not upset the balance of the merged organization.

Two significant areas were identified – the adoption of new terms for staff after merger and the change in the Value Added Tax treatment of NIBSC once it ceased to be an autonomous body with its own VAT registration.

NIBSC modeled the cost of changing from its prevailing terms of employment based on the Biotechnology and Biological Sciences Research Council (BBSRC) to those used by the Health Protection Agency and the UK National Health Service, known as 'Agenda for Change' terms. The net cost identified for 2009/10 was provided by the Department of Health to the Health Protection Agency in its funding for the first year of the merged organizations.

The future VAT treatment of NIBSC as a part of the Health Protection Agency, and of the Agency itself, has been resolved with HM Revenue and Customs to the satisfaction of all parties.

The deteriorating economic climate in the United Kingdom and worldwide may be expected to affect the Institute despite its specialist fields of activity in health and product research. This may be reflected in reduced budgets available to the organizations that use NIBSC's products and services and in the default of commercial customers. NIBSC's activities are well diversified across product types and between the public and private sectors and between UK, Europe and the wider world. This provides a measure of resilience against the circumstances of particular sectors and products. NIBSC is fortunate to receive significant funding from the Department of Health to maintain its core infrastructure and it is important this funding continues within the Health Protection Agency.

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. The necessary legislation was passed in July 2008 and the transfer took place 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 immunization 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 requirementsrelating 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 2008/09 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 2008/09, the Board paid 84% (2007/08: 72%) of invoices within 30 days, representing 83% (2007/08: 57%) 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

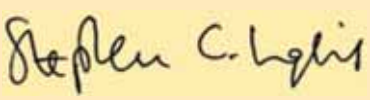
The Board's auditor is the Comptroller and Auditor General. Details of the audit fee for the year are disclosed in Note 3 to the financial statements. The Board can confirm that there is no relevant audit information of which the auditors are unaware. The Accounting Officer has taken all necessary steps 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 2009.

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

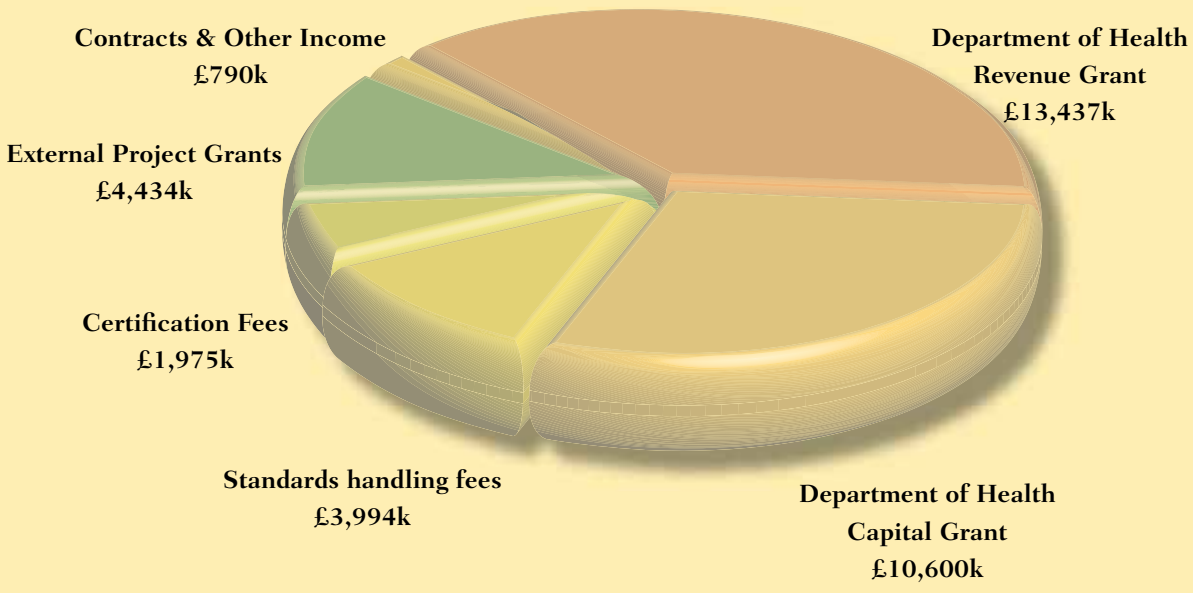
Funding Sources

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

Additional funding includes:

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

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



Remuneration Report

Remuneration and Terms of Service Committee

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

Professor Sir Gordon Duff, non-executive Chairman of the Board

Professor Janet Darbyshire, non-executive Deputy Chairman of the Board

Gill Noble, non-executive Board member

Tony Jowett, Head of 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 has been 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. This link was loosened in 2007 when 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 expected 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 from 1 July 2007, with the approval of the Department of Health.

A similar local pay negotiation was conducted for the pay award due from 1 July 2008 and was the subject of a 'pay remit' approved by the Department of Health. The increase in basic salary from 2007/08 to 2008/09 was 2.0 per cent in line with Government policy.

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 2008/09 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 2009 amount to £16,191. In 2007/08 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:

	2008/09 £	2007/08 £
M Beaumont	1,168	730
M Brown	1,752	584
Professor D Calam	584	435
Professor J Darbyshire	584	730
M Hindle	1,606	1,168
Professor D Latchman	584	290
Professor C Lee	1,606	1,022
Professor K Nicholson	438	584
G Noble	1,898	1,459
Dr J Petricciani	730	438
A Robertson	-	580
Professor Sir J Skehel	438	290
Dr L Tsang	1,022	438
	12,410	8,748

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 2008/09 was £180,209, including arrears of £5,978. In 2007/08 his remuneration was £162,489. 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 2009, classified into bands of £5,000, were as follows:

	Salary 2008/09 £'000	**Salary 2007/08 £'000**
Dr S Inglis Director	180-185	160-165
V Knight Head of Finance/ Board Secretary	65-70	65-70
S Murray Head of Operations	65-70	65-70
A Jowett Head of Human Resources	55-60	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.

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) £'000	Real Annual Increase In Lump Sum (bands of £2,500) £'000	Accrued Pension as at 31 March 2009 (bands of £2,500) £'000	Lump Sum Value as at 31 March 2009 (bands of £2,500) £'000	Cash Equivalent Transfer Value as at 31 March 2009 (bands of £1,000) £'000	Cash Equivalent Transfer Value as at 31 March 2008 (bands of £1,000) £'000	Real Annual Increase in Cash Equivalent Transfer Value (bands of £1,000) £'000
Dr S Inglis Director	0.0-2.5	5.0-7.5	25.0-27.5	80.0-82.5	614	409	191
V Knight Head of Finance/ Board Secretary	0.0-2.5	2.5-5.0	15.0-17.5	47.5-50.0	378	233	139
S Murray Head of Operations	0.0-2.5	2.5-5.0	5.0-7.5	15.0-17.5	131	82	47
A Jowett Head of Human Resources	0.0-2.5	0.0-2.5	5.0-7.5	17.5-20.0	0	0	0

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

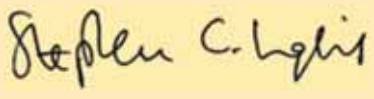
that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The CETV figures include the value of any pension benefit in another scheme or arrangement which the individual has transferred to 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 nonexecutive 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

12 June 2009

Statement of the Board's and Director's responsibilities

12 June 2009

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 2009

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 2009 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 aligned 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

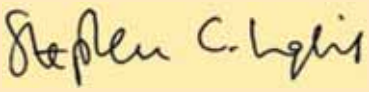
As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. This review is informed by the work of the internal auditors, by comments made by the external auditors in their management letter and by the Audit Committee. I also place reliance on the executive managers within the organisation, who have responsibility for the development and maintenance of the system of internal control and the assurance framework. In the opinion of the Head of Internal Audit, based on the work undertaken in 2008/09, significant assurance can be given that there is a generally sound system of internal control, designed to meet the organisations objectives, and that controls are generally being applied consistently.

I have been advised in my review of the effectiveness of the system of internal control by the Audit committee.

During the year the Audit Committee provided substantial assurance of the internal control framework through

examination of key areas of the Board's activity including the provision of reference materials, training and development, disaster recovery, the general ledger and budgetary control and reporting. Examination of other areas which support the assurance framework or the work of the external auditors, including corporate management systems, financial systems and the merger project plan with the Health Protection Agency, provided adequate assurance of controls in these areas. Where audit recommendations were made, executive managers accepted them and provided an action plan, the implementation of which itself was subject to audit followup.

As a result of my review I am satisfied that the Board's governance policies have been followed and that internal controls are effective and remained appropriate up to the time of the Board's dissolution and the transfer of its responsibilities to the Health Protection Agency.



Dr Stephen C Inglis

Accounting Officer of the National Biological Standards Board up to the date of its abolition on 1 April 2009 and the transfer of NIBSC to the Health Protection Agency.

12 June 2009

National Biological Standards Board

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

I certify that I have audited the financial statements of the National Biological Standards Board (NBSB) for the year ended 31 March 2009 under the Biological Standards Act 1975. These comprise the Operating Cost Statement, the Balance Sheet, the Cash Flow Statement and Statement of Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the NBSB, the Accounting officer and auditor

The National Biological Standards Board and Accounting Officer, are 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 the Board's and Director's Responsibilities.

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

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Biological Standards Act 1975 and HM Treasury directions made thereunder. I report to you whether, in my opinion, the information, which comprises the management commentary included in the Annual 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. This other information comprises the management commentary. 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.

National Biological Standards Board

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 Accounting officer 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 NBSB's affairs as at 31 March 2009, 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 HM Treasury directions made thereunder; and
- Information which comprises the management commentary, included within the Annual Report, is consistent with the financial statements.

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.

Amyas C E Morse
Comptroller and
Auditor General

National Audit Office
151 Buckingham Palace Road
Victoria
London SW1W 9SS

18 June 2009

National Biological Standards Board

Operating Cost Statement for the year ended 31 March 2009

	Notes	2008/09 £000	2007/08 £000
Gross operating costs			
Staff costs	2	13,873	12,373
Other operating charges	3	10,621	11,175
Depreciation	4	4,345	3,934
Gross operating costs		**28,839**	**27,482**
Less: Income from operations	5	(11,195)	(10,100)
Net Operating costs before interest		**17,644**	**17,382**
Interest receivable		(6)	(25)
Cost of capital charge	4	3,045	2,710
Net operating cost for the financial year	6	**20,683**	**20,067**

All results arose from continuing operations, the merger with the Health Protection Agency on 1 April 2009 notwithstanding (Note 19)

Statement of Recognised Gains and Losses for the year ended 31 March 2009

	Notes	2008/09 £000	2007/08 £000
Unrealised surplus on revaluation of fixed assets	7	9,929	3,508
Net deficit on foreign currency translation		(9)	167
Recognised gains and losses		**9,920**	**3,675**

The notes on pages 57 to 73 form part of this account.

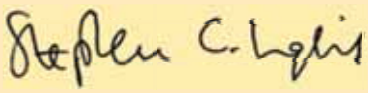
National Biological Standards Board

Balance sheet as at 31 March 2009

	Notes	2009 £000	2008 £000
Fixed assets			
Intangible fixed assets	7	189	283
Tangible fixed assets	7	80,471	65,461
		80,660	**65,744**
Current assets			
Stock	8	7,232	7,088
Debtors	9	4,450	3,552
Cash at bank and in hand	10	7,351	7,542
		19,033	**18,182**
Creditors			
Amounts falling due within one year	11	3,266	3,721
Net current assets		**15,767**	**14,461**
Provisions for liabilities and charges	12	87	107
Net assets		**96,340**	**80,098**
Capital and reserves			
General reserve	16	50,569	43,468
Revaluation reserve	16	44,640	35,482
Donated asset reserve	16	1,131	1,148
		96,340	**80,098**

The notes on pages 57 to 73 form part of this account.

Dr Stephen C Inglis
Accounting Officer
National Biological Standards Board
12 June 2009



National Biological Standards Board

Cash Flow Statement for the year ended 31 March 2009

	Note	2008/09 £000	2007/08 £000
Net cash outflow from operating activities	17(i)	(14,510)	(12,202)
Returns on investments and servicing of finance			
- Interest received		6	25
Capital expenditure		(9,731)	(3,892)
Receipts from disposal of fixed assets		7	4
Net cash outflow before financing		**(24,228)**	**(16,065)**
Management of liquid resources			
Financing:			
- Government funding for revenue		13,437	13,246
- Government funding for general capital		10,600	3,848
Increase/(decrease) in cash	17(ii)	**(191)**	**1,029**

The notes on pages 57 to 73 form part of this account

National Biological Standards Board

Notes to the Account for the year ended 31 March 2009

1 Statement of accounting policies

These accounts have been prepared in accordance with the Government Financial Reporting Manual (FReM) issued by the 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 changes in accounting policy during the year.

(c) Fixed assets

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

Buildings are shown at depreciated replacement cost based on the most recent valuation by the District Valuer at 31 March 2009 in accordance with the RICS Appraisal and Valuation Standards published by the Royal Institution of Chartered Surveyors and effective as from 1 May 2003, modified for the requirements of HM Treasury. Land is owned by the Secretary of State for Health, but its value is included in the Board's accounts at 31 March 2009.

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.

National Biological Standards Board

(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. Governments 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 2008/09, 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 between 5% and 8.5% of pensionable earnings for the year 2008/09. 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, up to 31 August 2007. This 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) Deferred grant income

Income received from third parties, primarily for academic research grants, is recognised in the accounting year in which matching costs are incurred. Amounts received but not expended are reported as 'deferred grant income' in creditors (Note 11) and amounts expended before funding is received are reported as 'grant income receivable' in debtors (Note 9).

(m) 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.

(n) 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.

National Biological Standards Board

2 Staff Costs

(a) All staff

	Note	2008/09 £000	2007/08 £000
Salaries and wages		11,265	10,190
Social Security costs		926	853
NHS Superannuation contributions		1,438	1,237
Decrease in provision for early retirements	12	-	(291)
Consultancy and agency staff		244	361
		13,873	**12,373**

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

	2008/09 No	2007/08 No
Scientific divisions	216	214
Support and operations	98	83
Administration	16	25
	330	**322**
Of which:		
Staff with permanent contracts (over one year)	306	303
Other staff	24	19
	330	**322**

3 Other Operating Charges

(a) Other operating charges

	2008/09 £000	2007/08 £000
Consumable laboratory supplies	4,793	3,829
Central services, net of production recovery	1,978	3,726
Premises	2,830	2,829
Equipment	612	441
Travel, subsistence and hospitality:		
Chairman and other Board members	11	5
Employees	294	229
Audit fee	59	44
Bad debts provided for or written off	(1)	8
Loss (profit) on disposal of assets	45	64
	10,621	**11,175**

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.

(b) Foreign currency translation

Net exchange losses of £9k (2007/08: £167k gain) on foreign currency balances have been credited to the Operating Cost Statement.

(c) VAT refund

During the year 2008/09 VAT returns were submitted quarterly and the partial recovery of VAT of £1,999k (2007/08: £1,264k) on purchases has been reflected in the accounts as a reduction in the cost of capital additions or revenue expenditure as appropriate. At the year-end an amount of £3.5 million in respect of VAT due for earlier periods between 1992 and 1997 was under negotiation with HMRC, plus a claim for interest.

National Biological Standards Board

4 Capital charges

Depreciation

	2008/09 £000	2007/08 £000
Depreciation charge for the year based on historical cost of fixed assets	3,755	3,402
Additional charge based on current cost of fixed assets	590	532
	4,345	**3,934**
Of which the amount relating to donated assets was	112	83

Notional interest

Notional interest at 3.5% of the average value of net government funded assets during the year, which is £3,045k (2007/08 £2,710k) is matched by a notional credit for the same amount in the General Reserve.

5 Income from Operations

	2008/09 £000	2007/08 £000
Grants:		
Research Councils etc	2,254	1,584
World Health Organization	48	98
European Commission	801	239
Other Bodies	1,332	951
Total grants	**4,435**	**2,872**
Contracts	790	1,444
Standards distribution handling charges	3,995	3,579
Control testing fees	1,975	2,038
Foreign exchange gain	-	167
Total income from operations	**11,195**	**10,100**

National Biological Standards Board

6 UK Government Grants

	2008/09 £000	2007/08 £000
Received from the Department of Health	13,437	13,771
Less: Contributions to the NBSB Pension Scheme included in Department of Health grant	-	525
Department of Health financing of operating costs	**13,437**	**13,246**

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 2009 is as follows:

	2008/09 £000	2007/08 £000
Net operating cost for the financial year	20,683	20,067
Less: Depreciation on assets funded by capital grant in aid from the Department of Health	4,345	3,851
Less: Charge for cost of capital	3,045	2,710
Less: Losses on disposal of assets funded by the Department of Health	45	64
	13,248	**13,442**
Financing received from the UK Government:		
Department of Health financing of operating costs	13,437	13,246
Under (over) spending against financing received from the UK Government	**189**	**(196)**

National Biological Standards Board

7 Intangible and Tangible Fixed Assets

	Freehold land	Freehold buildings	Equipment and computers	Production equipment	Assets Under construction	Total tangible assets	Intangible assets : Software	Total
	£000	£000	£000	£000	£000	£000	£000	£000
Balances at 1 April 2008	6,648	72,835	12,550	1,265	2,378	95,676	590	96,266
Additions	-	-	-	145	9,260	9,405	-	9,405
Transfers from assets under construction	-	3,086	1,433	-	(4,542)	(23)	23	-
Disposals	-	-	(401)	(95)	-	(496)	(36)	(532)
Diminution	-	-	(23)	-	-	(23)	(28)	(51)
Revaluation / indexation	(828)	11,140	315	(4)	-	10,623	-	10,623
Cost or valuation at 31 March 2009	**5,820**	**87,061**	**13,874**	**1,311**	**7,096**	**115,162**	**549**	**115,711**
Accumulated depreciation at 1 April 2008	-	20,296	9,439	480	-	30,215	307	30,522
Charge for the year	-	3,098	1,079	65	-	4,242	103	4,345
Disposals	-	-	(401)	(43)	-	(444)	(36)	(480)
Diminution	-	-	(16)	-	-	(16)	(14)	(30)
Backlog depreciation / indexation	-	457	237	-	-	694	-	694
Accumulated depreciation at 31 March 2009	**-**	**23,851**	**10,338**	**502**	**-**	**34,691**	**360**	**35,051**
Net book value								
At 31 March 2008	6,648	52,539	3,111	785	2,378	65,461	283	65,744
At 31 March 2009	**5,820**	**63,210**	**3,536**	**809**	**7,096**	**80,471**	**189**	**80,660**

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

There are no motor vehicles.

National Biological Standards Board

8 Stock

	31 March 2009 £000	31 March 2008 £000
Standards	6,660	6,325
Raw materials	49	53
Others	523	710
	7,232	**7,088**

The Board holds stocks of biological reference materials ('standards') which are used in regulatory control, diagnosis and research. At 31 March 2009 2.7 million standards were held of which 1.0 million were publicised for distribution in NBSB's reagent catalogue. The Board estimates their economic value at 31 March 2009 to be £6,660k (2008: £6,325k) 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.

National Biological Standards Board

9 Debtors

	31 March 2009 £000	31 March 2008 £000
Trade debtors	2,220	1,079
Grant income receivable	917	1,255
Other debtors	444	478
Prepayments	869	740
	4,450	**3,552**

Intra-governmental balances:	31 March 2009 £000	31 March 2008 £000
Balances with Central Government bodies	1,582	981
Balances with NHS Trusts	10	10
Balances with Local Authorities	572	582
Balances with Public Corporations	-	-
Balances with bodies external to Government	2,286	1,979
	4,450	**3,552**

10 Cash at Bank and In Hand

	31 March 2009 £000	31 March 2008 £000
Balances with the Office of the Paymaster General	6,712	4,998
Balances held in commercial banks	639	2,544
Cash at bank and in hand	**7,351**	**7,542**

National Biological Standards Board

11 Creditors: Amounts falling due within one year

	31 March 2009	31 March 2008
	£000	£000
Taxation and social security costs	-	360
Trade creditors	807	866
Accruals	325	277
Deferred grant income	2,134	2,218
	3,266	**3,721**

Intra-governmental balances:	31 March 2009 £000	31 March 2008 £000
Balances with Central Government bodies	980	1,055
Balances with NHS Trusts	-	-
Balances with Local Authorities	-	-
Balances with Public Corporations	-	-
Balances with bodies external to Government	2,286	2,666
	3,266	**3,721**

12 Provisions

	Total £000
Balance at 1 April 2008	107
Utilised during the year	(20)
New/(reversed) provisions during the year	-
Balance at 31 March 2009	**87**

Provisions represent the future costs of life assurance premiums for 8 staff up to their retirement dates, between 2009 and 2022, to equalise the benefits provided to them by the former NBSB Pension Scheme.

National Biological Standards Board

13 Operating leases

The Board had commitments under operating leases at 31 March 2009 of £153k (2008: £268k).

14 Government grants for general capital purchases

	2008/09 £000	2007/08 £000
Received from the Department of Health	10,600	3,849

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

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

15 Capital commitments

	2008/09 £000	2007/08 £000
Contracted capital commitments as at 31 March for which no provision has been made	8,520	2,721

Of the commitment at 31 March 2009 £6,889k was for the Influenza Resource Centre / permanent UK Stem Cell Bank.

National Biological Standards Board

16 Capital and Reserves

	General Reserve £000	Revaluation Reserve £000	Donated Asset Reserve £000	Total £000
Balance at 1 April 2008	43,468	35,482	1,148	80,098
Net operating cost for the year	(20,683)	-	-	(20,683)
Financing received from the UK Government:				
For operating costs	13,437	-	-	13,437
For general capital	10,600	-	-	10,600
Reversal of charge for cost of capital	3,045	-	-	3,045
Gain (loss) on revaluation – fixed assets	-	9,972	(10)	9,962
Donated assets	-	-	105	105
Current cost element of depreciation charge	590	(590)	-	-
Depreciation transfer from donated assets	112	-	(112)	-
Realised gains on standards stock	-	(224)	-	(224)
Balance at 31 March 2009	**50,569**	**44,640**	**1,131**	**96,340**

National Biological Standards Board

17 (i) Notes to the Cash Flow Statement

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

	2008/09 £000	2007/08 £000
Net operating cost for the year	(20,683)	(20,067)
Realised gain on stock valuation	(224)	(283)
Donated assets	138	-
Interest received	(6)	(25)
Cost of capital charge	3,045	2,710
Depreciation	4,345	3,934
Loss on disposal of fixed assets	45	71
Diminution in value of computers and software	21	36
Increase in stock	(144)	1,520
Increase in short term revenue debtors	(898)	10,646
Decrease in revenue creditors	(129)	206
Decrease in provisions	(20)	(10,950)
Net cash ouflow from operating activities	**(14,510)**	**(12,202)**

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

	2008/09 £000
Decrease in cash and liquid resources in the period	(191)
Net funds at 31 March 2008	7,542
Net funds at 31 March 2009	**7,351**

National Biological Standards Board

18 Losses and special payments

During the year the Board made payments for losses and compensation of £3,213 and incurred losses in respect of legal claims of £9,552 (2007/08: £33,000).

19 Post balance sheet events

Following the Department of Health's review of its Arm's Length Bodies, the Sectrectary of State announced in 2004 that the National Biological Standards Board should be abolished and its functions merged with the Health Protection Agency, subject to consultation and legislation. The Health and Social Care Act 2008 authorised the merger. On1 April 2009 the functions, assets and liabilities of the National Biological Standards Board, including NIBSC, were transferred to the Health Protection Agency.

The financial statements were authorised to be issued on 18 June 2009 by Dr Stephen C. Inglis, Accounting Officer of the National Biological Standards Board for the year up to the date of its abolition.

There were no other post balance sheet events.

20 Contingent liabilities

There were no contingent liabilities not otherwise provided for in the accounts (2008: £nil).

21 Financial instruments

Financial Reporting Standard 26 (Financial Instruments: Recognition and Measurement) and Financial Reporting Standard 29 (Financial Instruments: Disclosures), requires 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. Due to the nature of its activities, and the way in which it is financed, the National Biological Standards Board is not exposed to the degree of financial risk faced by other business entities. Moreover, financial instruments play a much more limited role in creating or changing risk than would be typical of UK listed companies. The Board has no authority to borrow or to invest without the prior approval of the Department of Health and the Treasury. Generally, financial assets and liabilities are generated by day-to-day operational activities and are not held to change the Board's risk profile.

a) Liquidity risk

The Board has no borrowings and relies primarily on grant in aid funding from the Department of Health for its own cash requirements. It is therefore not exposed to significant liquidity risks. It also has no material deposits, and all material assets and liabilities are denominated in sterling.

The Office of HM Paymaster General (OPG) is responsible for holding the working balances of Government Departments and other public bodies in high level accounts at the Bank of England. By transacting

principally through such accounts, the Board is able to minimize its exposure to the liquidity risk associated with bank failure.

b) Interest rate risk

Interest rate risk arises from the Board's use of interest bearing bank accounts for funds provided by third parties. Such use was very limited and the Board is not exposed to significant interest rate risk.

c) Foreign currency risk

The Board operates foreign currency bank accounts to handle transactions denominated in Euro and US Dollars. The balances on these accounts are converted regularly to sterling so that no material position is held in foreign currency except to cover a known commitment in that currency. In addition the Board invoices for its goods services in sterling, in as far as that is acceptable to its customers, which limits its exposure to mismatches between its income from foreign customers and its costs which are predominantly in sterling.

The fair value of cash is the same as the book value as at the balance sheet date.

During the year to 31 March 2009, the Board received Euro income equivalent to £940k (2008: £1,215k) and US Dollar income equivalent to £200k (2008: £158k), upon which there was some currency risk.

The only other currency risk is that of a Euro currency bank balance, valued at £1k on 31 March 2009 (2008: £1,431k), and a US Dollar bank balance valued at £3k (2008: £23k).

d) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss. The Board deals substantially with credit worthy customers though some are in distant and developing economies and others are commercial entities with short credit histories . The Board mitigates against financial loss from defaults by limiting credit to new customers, by obtaining payment in advance of shipment for certain customers and by judicious application of credit management techniques consistent with its role as a provider of goods and services to public health organisations worldwide.

The debtor amounts within note 9 represent the Board's maximum exposure to credit risk at the balance sheet date. The Board believes that no further credit provision is required in excess of the allowance for doubtful debts.

e) Summary of financial instruments

A financial instrument is defined as any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. The financial instruments held by the Board at the balance sheet date were as follows:

Categories of financial instruments	Balance at 31 March 2009 £'000	Charged for the year 2009 £'000	Balance at 31 March 2008 £'000
Investments	-		-
Sub-total: Financial assets available for resale	**-**		**-**
Other debtors, due after 1 year	-		-
Trade debtors	2,220	1,141	1,079
Accrued income	917	(338)	1,255
Other debtors, due within 1 year	869	129	740
Cash and cash equivalents	7,351	(190)	7,541
Sub-total: loans and receivables	**11,357**	**742**	**10,615**
Accruals	325	48	277
Other creditors, due within 1 year	818	(48)	866
Provisions	87	(20)	107
Sub-total: financial liabilities	**1,230**	**20**	**1,250**
Total financial instruments	**10,127**	**762**	**9,365**

Amounts due from tax authorities are not treated as financial instruments for the purpose of Financial Reporting Standards 25, 26 and 29 and are, therefore, excluded from this table.

National Biological Standards Board

Declared Interests of NBSB Members relating to 2008/09

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	None	None		
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 Sir 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 Inglis	None	None		
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		
Professor Christine Lee	Hemophilia Foundation (supported by Novo Nordisk)	Board Member	Kogenate Liposome Data Safety Monitoring Board (supported by Bayer)	DSMB Member
			Von Willebrand Disease Prophylaxis Network (supported by ZLB Behring)	DSMB Member

National Biological Standards Board

Member	Organisation	Nature of Interest	Organisation	Nature of Interest
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 Lleicester and University Hospitals of Leicester NHS Trust	Member of reseach groups receiving suport variously from Novartis, Crucell-Berna, Roche
Dr John Petricciani	World Health Organisation International Association for Biologicals Arbor Vita Corporation	Committee chair Board member Consulting services	US Army iBiopharma Glaxo SmithKline	Consulting services Scientific Advisory Committee Chairman Consulting services
Dr Nicola Rose	None	None		
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
Dr Lincoln Tsang	Arnold and Porter LLP School of Pharmacy, University of London	Partner providing legal advice to life sciences industry Member of the Governing Council	Various pharmaceutical biotechnology companies BioIndustry Association	External legal advisor Chair, Regulatory Affairs Advisory Committee

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