

Framework Document between the Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency

INSERT Published date

© Crown copyright 2024

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit [nationalarchives.gov.uk/doc/open-government-licence/version/3](http://nationalarchives.gov.uk/doc/open-government-licence/version/3/)

Where we have identified any third-party copyright information you will need to obtain permission from the copyright holders concerned.

Published to GOV.UK in pdf format only: [www.gov.uk/dhsc](https://www.gov.uk/dhsc)

Any enquiries regarding this publication should be sent to mhrasponsorship@dhsc.gov.uk



Table of Contents

[Introduction and Background 5](#_Toc153466331)

[1. Purpose of this document 5](#_Toc153466332)

[2. Objectives 5](#_Toc153466333)

[3. Classification 6](#_Toc153466334)

[Purposes, Aims and Duties 7](#_Toc153466335)

[4. Purposes 7](#_Toc153466336)

[5. Aims 8](#_Toc153466337)

[6. Powers and Duties 8](#_Toc153466338)

[Role of the Department 14](#_Toc153466339)

[7. The responsible minister 14](#_Toc153466340)

[8. The Principal Accounting Officer 14](#_Toc153466341)

[9. The role of the sponsorship team 16](#_Toc153466342)

[10. Roles and responsibilities within the policy framework 17](#_Toc153466343)

[11. Agreed principles on ways of working 18](#_Toc153466344)

[12. Resolution of disputes between the Agency and the Department 21](#_Toc153466345)

[13. Action in the event of underperformance 21](#_Toc153466346)

[14. Freedom of Information requests 22](#_Toc153466347)

[15. Relationships with the Department's other arm's length bodies and delivery partners 22](#_Toc153466348)

[The Agency’s Governance and Structure 24](#_Toc153466349)

[16. Governance and Accountability 24](#_Toc153466350)

[17. The Chief Executive 25](#_Toc153466351)

[18. The Board 28](#_Toc153466352)

[19. The Chair’s Role and Responsibilities 33](#_Toc153466353)

[20. Non-Executive Directors’ responsibilities 36](#_Toc153466354)

[Management and financial responsibilities and controls 37](#_Toc153466355)

[21. Income generation and fees 37](#_Toc153466356)

[22. Delegated authorities 38](#_Toc153466357)

[23. Spending authority 38](#_Toc153466358)

[24. Banking and Managing Cash 39](#_Toc153466359)

[25. Procurement 39](#_Toc153466360)

[26. Risk management 40](#_Toc153466361)

[27. Reporting on legal risk and litigation 41](#_Toc153466362)

[28. Counter Fraud and Theft 41](#_Toc153466363)

[29. Staff 42](#_Toc153466364)

[Business Plans, Financial Reporting and Management Information 46](#_Toc153466365)

[30. Corporate plan 46](#_Toc153466366)

[31. Business plan 47](#_Toc153466367)

[32. Budgeting procedures 48](#_Toc153466368)

[33. Grant-in-aid and any ring-fenced grants 48](#_Toc153466369)

[34. Annual report and accounts 49](#_Toc153466370)

[35. Reporting performance to the Department 50](#_Toc153466371)

[36. Information Sharing 52](#_Toc153466372)

[37. Data protection, information risk and assurance 52](#_Toc153466373)

[38. Information Management 53](#_Toc153466374)

[39. Sustainability 53](#_Toc153466375)

[40. Whistleblowing 54](#_Toc153466376)

[41. Equality 54](#_Toc153466377)

[Audit 55](#_Toc153466378)

[42. Internal audit 55](#_Toc153466379)

[43. External audit 55](#_Toc153466380)

[Reviews and winding up arrangements 57](#_Toc153466381)

[44. Review of the Agency’s status 57](#_Toc153466382)

[45. Arrangements in the event that the Agency is wound up 57](#_Toc153466383)

[ANNEX A – Wider guidance 59](#_Toc153466384)

# Introduction and Background

## Purpose of this document

This Framework Document (the “Framework Document”) has been agreed between the Department of Health and Social Care (“the Department”) and the Medicines and Healthcare products Regulatory Agency (“the Agency”) in accordance with HM Treasury's handbook Managing Public Money (“MPM”, as updated from time to time) and has been approved by HM Treasury.

This Framework Document sets out the broad governance framework within which the Agency and the Department operate. It sets out the Agency’s core responsibilities; describes the governance and accountability framework that applies to the roles of the Department and the Agency, as well as to other stakeholders as relevant; and sets out how the day-to-day relationship works in practice, including in relation to governance and financial matters.

This Framework Document does not convey any legal powers or responsibilities but both parties agree to operate within its terms.

Copies of the Framework Document and any subsequent amendments will been placed in the Libraries of both Houses of Parliament and made available to members of the public on gov.uk.

This Framework Document should be reviewed and updated at least every 3 years unless there are exceptional reasons that render this inappropriate that have been agreed with HM Treasury and the Principal Accounting Officer of the Department. The latest date for review and updating of this document is March 2027.

## Objectives

The Department and the Agency share the common objective of delivering safe and effective medical products which have been manufactured to sufficient quality. They are committed to enabling innovative products to reach patients as quickly as possible through the delivery of effective, risk-proportionate regulation which sets international standards and respects the expertise of equivalent regulators world-wide.

To achieve this the Agency and the Department will work together in recognition of each other's roles and areas of expertise, providing an effective environment for the Agency to achieve its objectives through the promotion of partnership and trust and ensuring that the Agency also supports the strategic aims and objective of the Department and wider government as a whole.

The Agency is responsible for delivering the regulation of medicines, medical devices and blood products for transfusion in the United Kingdom (UK), acting on behalf of the Secretary of State for Health and Social Care (the “Secretary of State”).

The Agency also plays a major national and international role in assuring the quality of biological medicines through development and provision of standards and reference materials, control testing, carrying out applied research and the provision of scientific advice.

As an Executive Agency, the Agency is able to balance the needs for public health expertise, operational delivery, scientific integrity, independence in regulatory decision-making and the necessary level of ministerial oversight and accountability to command public confidence. Executive Agency status also supports sufficient flexibility to respond to change arising from a range of scenarios including future pandemics and other emergencies, in fulfilment of the Secretary of State’s statutory duties.

## Classification

For several years, the Agency had been operating as a trading fund as established by the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (S.I. 2003/1076, “the 2003 Order”), made under the Government Trading Funds Act 1973.

In 2019, the Agency was classified to the central government subsector by the Office for National Statistics (ONS), with retrospective effect from 1 April 2003, the date it came into existence.

The Medicines and Healthcare products Regulatory Agency Trading Fund (Revocation) Order 2022 came into force on 1st April 2022. This Order revoked the 2003 Order and all other amending Statutory Instruments or provisions that became spent when the 2003 Order was revoked.

The trading fund established by the 2003 Order has ceased to exist, the operations of the Agency as defined in Schedule 1 to the 2003 Order have ceased to be funded by means of a trading fund, and the Agency’s assets and liabilities are no longer appropriated to a trading fund.

The Agency continues to be administratively classified by the Cabinet Office as an Executive Agency. The cessation of MHRA’s trading fund status has no effect on this.

From 1 April 2022 the Agency is designated by HM Treasury within the Department group accounting boundary. As a result, the Agency’s results will be incorporated within the Department’s consolidated Annual Report and Accounts and its income and expenditure will be included within the Department’s supply estimate.

# Purposes, Aims and Duties

## Purposes

The Agency has been established by the Department and, as an Executive Agency, it does not have a separate legal personality to the Department.

The Agency performs the functions of the Secretary of State under UK legislation relating to the regulation of medicines, medical devices and blood products for transfusion. The Agency has an important role in bringing innovation safely to patients as rapidly as possible.

The Agency also performs the functions of the Secretary of State in relation to the standardisation and control of biological medicines including vaccines, blood products and other substances which cannot be characterised chemically and which require special testing measures to ensure their safety and efficacy.

Together with the National Institute for Health Research (NIHR), the Agency funds the Clinical Practice Research Datalink (CPRD), whose service are delivered as part of the Agency operations. CPRD is an observational data and interventional research service, designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health. The Agency also hosts the UK Stem Cell Bank which drives innovation through the provision of quality assured stem cell lines, associated guidelines, support and training to clinical and research communities.

## Aims

The Agency’s strategic aims are set out in the Agency’s corporate and business plans. The aims include:

* + evolving and strengthening our regulatory framework to provide the basis for ensuring the safety of patients, and rapid access to innovative and established healthcare products, supporting the NHS in driving public health outcomes;
  + embedding changes into everyday practices to deliver the recommendations of the Independent Medicines and Medical Devices Safety Review[[1]](#footnote-2) to which the government has responded[[2]](#footnote-3), ensuring that patient interests are at the heart of every action the Agency takes;
  + creating and capitalising on international regulatory relationships, enabling collaboration in different ways to support the overarching aims of safety and access for patients and public health; and
  + developing and delivering a business model that drives the most effective use of resources to deliver the Agency’s functions and aims, allows the Agency to develop and invest in pursuit of those functions, and aims and supports continual learning, iteration and innovation in how the Agency operates.

## Powers and Duties

The Agency discharges, on behalf of the Secretary of State, the functions that they exercise as the “licensing authority”, “the Ministers”, the “enforcement authority” and the “competent authority” under UK legislation relating to medicines, medical devices and blood products for transfusion. The Agency will consult the Devolved Administrations on issues that relate to or affect them.

The Agency performs the functions of the Secretary of State under UK legislation relating to medicines, medical devices and blood products, amongst other things. From 1 April 2013, the Agency also performs the functions of the Secretary of State in relation to biological substances conferred under section 57 of the Health and Social Care Act 2012. These functions, which relate to ensuring the quality of biological medicines, were previously carried out by the Health Protection Agency through the non-statutory body, the National Institute of Biological Standards and Control (“NIBSC”). The Agency continues to deliver these functions via its laboratories on behalf of the Secretary of State.

The Agency is responsible for certain **statutory functions**, including the following:

* + discharging statutory obligations of the licensing authority set out in the Human Medicines Regulations 2012; ensuring compliance in the UK with statutory obligations relating to the manufacture, distribution, sale, labelling, advertising and promotion of medicines;
  + discharging the Secretary of State’s statutory functions set out in the Medical Devices Regulations 2002 for medical devices, operating a system of monitoring and enforcement to ensure that medical devices for human use, sold or supplied in the UK, are of an acceptable standard of safety, quality and efficacy, whether accessed directly by the consumer or through the NHS or other healthcare systems; including post marketing surveillance of medical devices and contributing to developing the safety and performance standards that support this work;
  + designating and monitoring the performance of approved bodies that provide conformity assessments of moderate and high-risk medical devices;
  + maintaining a register of all manufacturers placing medical devices on the UK market and a register of all such devices;
  + ensuring compliance with statutory obligations relating to the investigation of medicines in clinical trials and assessing notifications or proposals for clinical investigations from manufacturers of medical devices once new regulations take effect;
  + discharging statutory obligations set out in the Health and Social Care Act 2012 in relation to biological substances (section 57);
  + devising and drawing up standards for the purity and potency of biological substances and designing appropriate test procedures; preparing, approving, holding and distributing standard preparations of biological substances;
  + providing, or arranging for, the provision of laboratory testing facilities for the testing of biological substances, carrying out such tests, examining records of manufacture and quality control and reporting on the results; carrying out, or arranging for the carrying out, of research in connection with biological standards and control function;
  + regulating the safety and quality of blood and blood components for transfusion in the UK;
  + publishing the activities of the British Pharmacopoeia (BP) and work undertaken relating to the European Pharmacopeia;
  + discharging the functions of the UK Good Laboratory Practice Monitoring Authority (GLPMA); and
  + regulating consumer e-cigarettes in line with the Tobacco and Related Products Regulations 2016 and the Standardised Packaging of Tobacco Products Regulations 2015.

The Agency is also responsible for certain **non-statutory functions,** including:

* + managing the activities of the Clinical Practice Research Datalink (CPRD) and its services using anonymised clinical records in support of a range of public health activities; and
  + representing the United Kingdom and collaborating with international bodies, on matters concerning:
* the regulation of medicines and medical devices;
* the development of medicines and medical devices regulation; and
* in relation to the establishment of standards, for the provision of standard preparations of, and the testing of biological substances.

**Medicines**

The Human Medicines Regulations 2012 provide for certain medicines functions to be carried out by the “licensing authority”. The licensing authority means the Secretary of State, the Northern Ireland Health Minister, both acting jointly, or officials of the Agency acting on their behalf. Medicines are a reserved subject matter as regards Scotland and Wales and, as such, the Secretary of State accounts to Parliament on all matters concerning the regulation of human medicines in England, Scotland, and Wales. Medicines are transferred as regards Northern Ireland but, in practice, by agreement with the Devolved Administrations, the Agency covers medicines regulation UK-wide, which includes Northern Ireland, and regulates this in line with any relevant laws.

As regards enforcement of medicines legislation, the Agency performs the Secretary of State’s duty to enforce the Human Medicines Regulations 2012 in England, Scotland and Wales. In Scotland and Wales, enforcement of the Medicines Act 1968 is formally the responsibility of the Scottish Ministers and the Welsh Ministers (respectively), but both the Devolved Administrations have agency arrangements with the Agency, under their respective devolution legislation, under which the Agency carries out this role. Enforcement in Northern Ireland is entirely a matter for the Northern Ireland Health Minister and the Department of Health in Northern Ireland.

**Medical devices**

The UK’s medical devices regulation is set out in the Medical Devices Regulations 2002 (“the 2002 Regulations”). The Agency is also responsible for ensuring medical devices placed on the Northern Ireland market comply with the Medical Devices Regulation (Regulation (EU) 2017/745) and the in vitro Diagnostic Regulation (Regulation (EU) 2017/746). Medical devices are a reserved subject matter as regards Scotland, Wales and Northern Ireland, and the Agency discharges the functions of the Secretary of State under the 2002 Regulations on a UK-wide basis. This includes designating and monitoring “approved bodies” and enforcing the 2002 Regulations on the Secretary of State’s behalf.

**Human blood and blood components**

The regulation of blood is a reserved subject matter as regards Scotland and Wales. It is transferred as regards Northern Ireland; but in practice, by agreement with the Devolved Administrations, functions in relation to the regulation of blood are carried out by the Agency UK-wide.

The Blood Safety and Quality Regulations 2005 provide for the regulation of the collection, testing, processing and storage of human blood and blood products. Broadly speaking, they cover the handling of blood from its donation by individuals, up to (but not including) its use either by way of transfusion or in the manufacture of a medicine or medical device.

The 2005 Regulations designate the Secretary of State as the competent authority in relation to Northern Ireland for the purposes of Directive 2002/98/EC (the Blood Directive).

**British Pharmacopoeia**

The Agency is responsible for publication of the British Pharmacopoeia (BP)” which provides the only authoritative official standards for the quality of pharmaceutical substances and medicinal products in the UK.

The Human Medicines Regulations 2012 provide for the British Pharmacopoeia Commission (BPC) and the BP as the UK standard for medicinal products. The BPC is responsible for preparing new editions of the BP and the BP (Veterinary) and for keeping them up to date. Under regulation 318 of the Human Medicines Regulations 2012, the BPC is also responsible for selecting and devising British Approved Names (BANs).

The BP also acts as the National Pharmacopoeia Authority to the European Pharmacopoeia and supports the United Kingdom Delegation to the European Pharmacopoeia Commission, administered by the European Directorate for the Quality of Medicines in the Council of Europe. The UK remains a member of the Council of Europe and signatory of the Convention on the Elaboration of a European Pharmacopoeia. Standards of the European Pharmacopoeia are brought into effect in the UK through their inclusion in the BP.

**UK Good Laboratory Practice Monitoring Authority**

The Good Laboratory Practice Regulations 1999 (“the 1999 Regulations”) provide for the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

The 1999 Regulations establish the Good Laboratory Practice Monitoring Authority (GLPMA) to enforce the principles of good laboratory practice. As enforcement of good laboratory practice is a matter devolved to each of Wales, Scotland and Northern Ireland, the GLPMA consists of the Secretary of State for Health and Social Care, the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland. Any one of the above acting alone or jointly may perform the GLPMA’s functions but in practice the GLPMA’s functions are carried out by the Agency.

**Biological Standards and Control**

Section 57 of the Health and Social Care Act 2012 confers statutory functions in relation to biological substances on the Secretary of State. These functions are performed through the Agency.

Biological substances are a reserved subject matter as regards Scotland and Wales, but transferred as regards Northern Ireland. In relation to Northern Ireland, section 57 confers the biological substances functions on Secretary of State and the Northern Ireland health minister acting alone or jointly. In practice, by agreement with the Northern Ireland health minister, the MHRA performs these functions on a UK wide basis.

**Research**

The Agency has an active public health focussed research programme and works with the Research and Innovation sector of the UK and internationally in a number of different ways to support its own aims and support the wider aims of the NHS, including the NHS in the devolved administrations, in protecting public health.

# Role of the Department

## The responsible minister

The Secretary of State for Health and Social Care is the responsible minister. They may delegate functions to a Junior Minister.

The Secretary of State has ministerial responsibility for, and oversight of, the Agency’s delivery and performance. This includes being accountable to Parliament in relation to the functions and performance of the Agency. This is in the context of their responsibility for setting priorities and monitoring the whole system’s performance to ensure it delivers what patients, service users and the wider public need and value most – and determining resource allocations across the health system.

The specific ministerial responsibilities regarding the Agency include:

* + setting objectives for the Agency through approval of the corporate and business plans;
  + setting budgets across the health system and determining the financial framework in which the Agency operates;
  + being responsible for the policy and legislative framework within which the Agency operates;
  + accounting to Parliament for the Agency’s performance and the effectiveness of the health and care system overall;
  + appointing the Agency’s Chair and non-executive directors (NEDs), as well as members of the Commission on Human Medicines and British Pharmacopeia Commission, in line with the Governance Code for Public Appointments;

## The Principal Accounting Officer

The Principal Accounting Officer (PAO) is the Permanent Secretary of the Department.

**PAO's specific accountabilities and responsibilities**

The PAO of the Department has designated the Agency’s Chief Executive as the Agency’s Accounting Officer, ensuring that they are fully aware of their responsibilities. The PAO issues a letter appointing the Accounting Officer, setting out their responsibilities and delegated authorities.

The respective responsibilities of the PAO and accounting officers for ALBs are set out in Chapter 3 of MPM.

The PAO is accountable to Parliament for the issue of funding to the Agency, grant-in-aid or other.

The PAO nominates a Senior Departmental Sponsor (SDS) who acts as the Agency’s designated, consistent point of contact within the Department.

The PAO is also responsible, usually via the sponsorship team, for advising the responsible minister on:

* + the strategic aims and objectives of the Agency so that they are consistent with those of the department and government through the approval of the strategic plan and annual business plan;
  + an appropriate budget for the Agency from the Department, in the light of the Department’s overall public expenditure priorities and objectives agreed for the Agency;
  + how well the Agency is achieving its strategic objectives and whether it is delivering value for money; and
  + the exercise of the ministers’ statutory responsibilities concerning the Agency as outlined above.

The PAO, via the sponsorship team, is also responsible for ensuring arrangements are in place in order to:

* + monitor the Agency’s activities and performance;
  + address significant problems in the Agency, making such interventions as are judged necessary;
  + periodically, and at such frequency as is proportionate to the level of risk, carry out an assessment of the risks, both to the Department and the Agency’s objectives and activities, in line with the wider Departmental risk assessment process;
  + inform the Agency of relevant government policy in a timely manner; and
  + bring ministerial or Departmental concerns about the activities of the Agency to the full Agency’s Board, and, as appropriate to the Departmental Board requiring explanations and assurances that appropriate action has been taken.

## The role of the sponsorship team

The SDS acts as the link at executive level between the Agency and the senior officials of the Department, and also with Ministers. The SDS for this relationship is the Director of Medicines.

Whilst the SDS role is facilitative and recognises the need for direct engagement between the Agency and other parts of the Department and ministers, it also supports the Secretary of State, Junior Ministers and Permanent Secretary in holding the Agency to account.

The SDS will ensure that there is an annual objective setting and review process in place for the Chair, which is undertaken by the PAO, or their nominee, taking into account feedback from the Chief Executive.

The sponsorship team in the Department is the primary contact for the Agency and supports the SDS by undertaking the principal day-to-day liaison between the Department and the Agency. They are the main source of advice to the responsible minister on the discharge of their responsibilities in respect of the Agency. They also support the PAO on their responsibilities toward the Agency.

Officials of the sponsorship team in the Department will liaise regularly with the Agency’s officials to review performance against plans, achievement against targets and expenditure against its funding allocations. The sponsorship team will also take the opportunity to proactively explain wider policy developments that might have an impact on the Agency.

The sponsorship team will work alongside the Department’s finance directorate, which will act as the departmental Finance Business Partner to the Agency.

The sponsorship team’s responsibilities include:

* + enabling ministers and Parliament to have effective oversight of the Agency;
  + supporting working relationships between the Department and the Agency, highlighting wider policy developments that may impact on them, facilitating policy discussions, troubleshooting and resolving live issues;
  + helping the Agency to develop an annual business plan that reflects the government’s priorities for the organisation for the financial year;
  + ensuring that clear accountability arrangements are in place between the Agency and the Department; co-ordinating processes for assuring and constructively challenging progress against the Agency’s Business Plan and effective management of finances and risks; and feeding into wider accountability and governance processes within the Department;
  + championing the Agency within the Department, across government and internationally, helping ensure that the Agency builds and maintains the right relationships and connections to allow it to deliver its remit effectively and efficiently; and
  + helping the Agency to identify and manage risks to its delivery that arise from wider government policy or other circumstances.

## Roles and responsibilities within the policy framework

The Agency and the Department will work together in recognition of each other's roles and areas of expertise, providing an effective environment for the Agency to achieve its objectives through the promotion of partnership and trust and ensuring that the Agency also supports the strategic aims and objectives of the Department and wider government as a whole.

Ministers are responsible for the policy framework within which the Agency operates and are ultimately accountable for all decisions on the legislative and policy basis on which the Agency operates.

In practice, Ministers will be advised on those decisions by the Agency on a regular basis, given the expertise the Agency holds. Ministers will also be advised and supported in their decision-making role by officials in the Department. It is essential that officials in the Agency and the Department work productively together to support ministers with the best possible advice, in line with the Civil Service Code. This partnership approach relies on clear, proactive communication and an understanding that input from both sets of officials will produce the most robust and balanced policy advice.

Departmental officials with responsibility for medicines and medical devices will primarily lead on strategic areas of policy to deliver on wider Government priorities, while the Agency will lead on more specialist policy on how regulation can support these priorities or how the objectives of effective regulation can be achieved in practice, either through legislation or its own activities. Policy work related to the Agency’s functions can be commissioned from the Agency by the Department. This will primarily be in highly specialist and/or technical areas of work. Collaborative working means that, at all levels, the Agency and the Department will involve each other appropriately in areas of shared policy interest before senior sign-off decisions are made by each party.

The Agency operates independently in delivering its functions, notwithstanding needing to work in partnership with the department as an Executive Agency, and as set out in the Framework Agreement. The Agency will share relevant intended actions with the Department as soon as possible to enable joint communications where necessary and for wider impacts, for example on supply chains, to be understood and mitigated as needed.

## Agreed principles on ways of working

The Department, its executive agencies and ALBs share responsibility for supporting ministers in accounting to the public and to Parliament for policies, decisions and activities across the health and care sector. Accountability to Parliament will often be demonstrated through parliamentary questions, MPs' letters and appearances before parliamentary committees. Accountability to the public may be through the publication of information on the Agency’s website, as well as through responses to letters from the public and responses to requests under the Freedom of Information Act 2000.

The Agency has its own responsibilities in accounting to the public and to Parliament and its way of handling these responsibilities will be agreed with the Department. In all matters of public and parliamentary accountability the Department and its ALBs and executive agencies will work together considerately, cooperatively and collaboratively, and any information provided by the Agency will be timely, accurate and, where appropriate, consistent with information provided by the Department. To facilitate this, the Department and the Agency have agreed a public and parliamentary accountability protocol that sets out how they will work together to secure the confidence of the public and Parliament, and to maintain the service levels that MPs and the public have come to expect. This will be reviewed, as a minimum, every three years, alongside this Framework Document.

The Agency is an independent regulator and has operational autonomy in its regulatory decisions. It operates transparently and proactively and provides government (including Ministers directly), the NHS, Parliament and MPs, industry, public health professionals and the public with expert and evidence-based information and advice on regulatory matters.

The Agency can publicly set out its professional, scientific and objective judgement of the evidence base relating to regulatory matters. However, information and data shall not be published if to do so would contravene an express restriction in legislation or confidentiality obligations protected by common law.

The Agency carries out its activities transparently. It demonstrates this by, as a minimum, proactively publishing its annual report, business plan and accounts as well as information on areas including pay, diversity of the workforce, performance and the way it manages public money. It also supports those who wish to use its data by publishing information within guidelines set by the Cabinet Office and by holding board meetings in public, where appropriate.

The Agency regularly deals with the media. Prior approval is not required for dealing with the media on matters of an operational, routine or technical nature. However, on matters concerning or affecting the Government, the Department and its ALBs, the Agency will liaise with the relevant communications teams in advance.

The Agency and the Department’s communications teams shall have regular check-in points, including for the heads of communications and media and marketing teams, including to agree communication plans where required. In particular, the Agency and the Department will give each other sufficient advance notice of public facing communications to allow for necessary clearances with the relevant teams as set out in the Communications and Marketing Guidance annex of the ALB Schedule of Delegations.

The Agency is subject to Cabinet Office Advertising, Marketing and Communications Spend Controls. All proposed communications expenditure over £100,000 must be approved by the Cabinet Office, following prior approval by the Department. The Agency has delegated authority to approve communications expenditure up to £100,000 except for that funded from Grant-In-Aid which requires business case approval for expenditure above £20,000.

The Agency will maintain an internal process to record relevant spend and to provide all necessary information to the Department, including periodic forward looks and logs of expenditure, headcount and other information as required to enable audits and reporting.

The Agency engages and communicates with a wide range of stakeholders nationally and internationally, including healthcare professionals, the public and industry. Specialist digital content or content targeted at professional audiences will, where it relates to the Agency’s regulatory activities, be delivered through the corporate websites of the Department and the Agency on Gov.UK.

Requests for exemption from the use of consistent government branding for the MHRA and NIBSC were approved by Cabinet Office in 2012, while CPRD and the British Pharmacopeia were agreed as out of scope. Following the rollout of the Government Identity System, a revised logo was created in 2014 and it was agreed that it would be used in a co-branded framework with the NIBSC, CPRD and BP identities. From 2022 the Agency will continue to operate the Government Identity system and retain the BP, CPRD, Yellow Card and NIBSC identities to use with the income-generating products and services they are connected to. These product and service identities also have supporting brand websites which have also been exempted from Gov.UK.

To support the development of the relationship, the Department and the Agency agree to a set of shared principles:

* + working together for patients, people who use services and the public, demonstrating a commitment, where appropriate, to the values of the NHS set out in its Constitution;
  + respect for the importance of autonomy throughout the system, and the freedom of individual organisations to exercise their functions in the way they consider most appropriate;
  + recognition that the Secretary of State is ultimately accountable to Parliament and the public for the system overall. The Agency will support the Department in the discharge of its accountability duties, and the Department will support the Agency in the same way;
  + working together, and with other Departments and ALBs where necessary, openly and positively. This includes sharing operational and planning information with appropriate ALBs and with the consent of relevant stakeholders to deliver public health outcomes, which include promoting faster, safe patient access to medical products;
  + ensuring the sponsorship team is always aware of and copied into ministerial submissions that the Agency submits, having agreed in advance which ones will require clearance or approval by the sponsorship team before they are submitted; and
  + applying the principles of good communication and transparency and following a “no-surprises” approach, thus enabling cooperative and collaborative working between the Agency and the Department.

## Resolution of disputes between the Agency and the Department

The Department and the Agency will make all reasonable endeavours to resolve any disputes between them in a timely manner. The Department and the Agency will seek to resolve any disputes through an informal process in the first instance.

If this is not possible, then a formal process, overseen by the Senior Sponsor, will be used to resolve the issue. Failing this, the Senior Sponsor will ask the relevant policy Director General to oversee the dispute. They may then choose to ask the Permanent Secretary to nominate a non-executive member of the Department’s Board to review the dispute, mediate with both sides and reach an outcome, in consultation with the Secretary of State.

.

## Action in the event of underperformance

If the Secretary of State considers that the Agency is underperforming or significantly failing in the exercise of its functions, they are able to intervene. Depending on the urgency and nature of the underperformance, the SDS will use the quarterly accountability meetings to assess the situation with the Agency and may escalate to the Permanent Secretary and or ministers as and when required. Ministers may require the Agency to take certain steps to rectify the situation. If the Agency fails to comply, the Secretary of State may make arrangements for another body to help exercise these functions on the Secretary of State’s behalf.

## Freedom of Information requests

For FOI purposes the public authority is the Department, however for practical purposes, the Agency is responsible for addressing all requests made to it under the Freedom of Information Act 2000, the Data Protection Act 2018 and associated statutory information access requests. The Agency and the Department shall consult prior to any disclosure of information that may affect the other party’s responsibilities.

## Relationships with the Department's other arm's length bodies and delivery partners

The Chief Executive, supported by the Chair, is responsible for ensuring that there is proactive engagement across the wide range of its external stakeholders, including groups representing patients and users of healthcare products, professional organisations representing health and social care professionals and industry organisations representing manufacturers of pharmaceuticals and medical devices.

To deliver its functions efficiently and effectively and to support alignment across the whole health and care system, the Agency works collaboratively with several stakeholders, most notably the following (for which Memorandums of Understanding may be put in place):

* + Devolved Administrations (DAs), as the Agency exercises its functions on behalf of the UK. Whenever appropriate, it consults the DAs on, and keeps them informed of, proposed changes to legislation, policy and practice that affects them as well as giving advance notice of (and the opportunity to observe) any investigations or inspections of manufacturers based in their country. The Agency will also continue to develop similar partnerships with DAs’ other healthcare bodies to support fast and safe access to new innovative products.
  + The National Institute for Health Research (NIHR), which funds CPRD, and with the Health Research Authority (HRA), to deliver ethical and regulatory approval of clinical trials in the UK;
  + The National Institute for Health and Care Excellence (NICE), such as in the delivery of the Innovative Licensing and Access Pathway (ILAP) to support rapid patient access to effective new medicines; and
  + international organisations and regulators, such as in collaboration with the WHO, the FDA’s Project Orbis, and Access (the work-sharing consortium with the medicines regulators of Australia, Canada, Singapore and Switzerland).

Outside of these formal collaborations, the Agency works with other health and care sector bodies in a number of different ways to support its own aims and support the wider aims of the NHS, including the NHS in the devolved administrations, in protecting public health, maximising our impact and reach across clinical networks and more effectively sharing information to empower patients and the public to make informed decisions. This work is supported by, and where necessary overseen and co-ordinated by, the Department.

# The Agency’s Governance and Structure

## Governance and Accountability

The Agency shall operate corporate governance arrangements that, so far as practicable and in the light of the other provisions of this Framework Document or as otherwise may be mutually agreed, accord with good corporate governance practice and applicable regulatory requirements and expectations.

In particular (but without limitation), the Agency should:

* + comply with the Partnerships with Arm’s Length Bodies Code of Good Practice, which is based on the requirements set out in the Civil Service Code and the Civil Service Management Code[[3]](#footnote-4), when conducting its official business;
  + comply with the principles and provisions of the Corporate Governance in Central Government Departments Code of Good Practice[[4]](#footnote-5) (as amended from time to time), to the extent appropriate and in line with their statutory duties, or specify and explain any non-compliance in its annual report;
  + comply with MPM[[5]](#footnote-6);
  + in line with MPM, have regard to the relevant Functional Standards[[6]](#footnote-7) as appropriate, and in particular those concerning Finance, Commercial, Counter Fraud, Project Delivery, and Digital, Data and Technology; and
  + take into account the code of good practice and guidance set out in Annex A of this Framework Document, as they apply to ALBs.

In addition, the Agency will develop a code of conduct for staff reconciling the Civil Service Code with the requirements of professional bodies’ codes of conduct.

In line with MPM Annex 3.1, the Agency shall provide an account of corporate governance in its annual governance statement, including the Board’s assessment of its compliance with the Code of Good Practice with explanations of any material departures. To the extent that the Agency does intend to materially depart from the Code, the Department should be notified in advance and their agreement sought to this approach.

In addition to internal governance, cross-government clearance is required for major new policy decisions of the type set out in Cabinet Office guidance. As the Agency is part of the Department, the Secretary of State (or responsible minister) is responsible for obtaining clearance and the Agency will adhere to any conditions applied through the clearance process. There will also be cases where the Secretary of State (or responsible minister) must consult Cabinet colleagues before giving the Government’s view, even if collective agreement is not required. In such cases, the Agency will supply the minister(s) with any information they need in a timely fashion.

## The Chief Executive

The Chief Executive of the Agency is responsible for the leadership and management of the Agency and the delivery of its objectives and shall put in place appropriate governance arrangements and regularly review them.

The Chief Executive is supported by a unitary board (“the Board”).

The Chief Executive has an unfettered right of access to the Secretary of State, the minister with responsibility for MHRA-related issues and the Chief Medical Officer to raise any matters or concerns and to respond personally to any issues they wish to raise.

**Appointment**

The Chief Executive of the Agency is appointed by the Department’s Permanent Secretary in consultation with the responsible minister and the Chair of the Agency’s Board. This appointment follows a recruitment process chaired by a Civil Service Commissioner, through fair and open competition, in line with the Civil Service Commission Recruitment Principles.

**Responsibilities of the Agency’s Chief Executive as Accounting Officer**

The Chief Executive as Accounting Officer (AO) is personally responsible for safeguarding the public funds for which they have charge; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of the Agency. In addition, they should ensure that the Agency as a whole is run on the basis of the standards, in terms of governance, decision-making and financial management, that are set out in Box 3.1 of MPM. These responsibilities include the below and those that are set in the AO appointment letter issued by the PAO of the Department.

The Chief Executive shall ensure that the Agency has appropriate arrangements in place for the discharge of each of the statutory functions for which it is responsible and is clear about the legislative requirements associated with each of them, specifically any restrictions on the delegation of those functions. They ensure that it has the necessary capacity and capability to undertake those functions and ensures that it has the power to take on a function on behalf of another person or body before it does so.

**Responsibilities for Accounting to Parliament and the Public**

Accounting officer responsibilities to Parliament and the public include:

* + signing the accounts and ensuring that proper records are kept relating to the accounts and that the accounts are properly prepared and presented in accordance with any directions issued by the Secretary of State;
  + preparing and signing, for inclusion in the annual reports and accounts, a Statement of Accounting Officer’s responsibilities, and a Governance Statement covering corporate governance, and financial and risk management;
  + ensuring that effective procedures for handling complaints about the Agency, in accordance with Parliamentary and Health Service Ombudsman’s Principles of Good Complaint Handling, are established and made widely known within the Agency and published on its website;
  + acting in accordance with the terms of MPM and other instructions and guidance issued from time to time by the Department, the HM Treasury and the Cabinet Office;
  + ensuring that as part of the above compliance they are familiar with and act in accordance with:
* any governing legislation;
* this Framework Document;
* any delegation letter issued to the Agency;
* any elements of any settlement letter issued to the Department that is relevant to the operation of the Agency; and
* any separate settlement letter that is issued to the Agency from the Department.
  + ensuring they have appropriate internal mechanisms for the monitoring, governance and external reporting regarding compliance with any conditions arising from the above documents; and
  + giving evidence, normally with the PAO, when summoned before the Public Accounts Committee (PAC) on the Agency’s stewardship of public funds.

**Responsibilities to the Department**

Particular responsibilities to the Department include:

* + developing with the Board, and in agreement with the Department, the Agency’s corporate and business plans in the light of the Department’s wider strategic aims and agreed priorities;
  + informing the Department of progress in helping to achieve the Department’s policy objectives, and in demonstrating how resources are being used to achieve those objectives through discussions with the sponsorship team and at accountability meetings; and
  + ensuring that timely forecasts and monitoring information on performance and finance are provided to the Department; that the Department is notified promptly if over or under spends are likely and that corrective action is taken; and that any significant problems whether financial or otherwise, and whether detected by internal audit or by other means, are notified to the Department in a timely fashion.

**Responsibilities to the Board**

The Chief Executive is responsible for:

* + advising the Board on the discharge of the Agency’s Board responsibilities as set out in this document, in the founding legislation and in any other relevant instructions and guidance that may be issued from time to time;
  + advising the Board on the Agency’s performance compared with its aims and objectives;
  + ensuring that financial considerations are taken fully into account by the Board at all stages in reaching and executing its decisions, and that financial appraisal techniques are followed; and
  + bringing to the attention of the Board any matters which give rise to a conflict with the Chief Executive’s responsibilities as AO.

**Managing conflicts**

In executive agencies, final decisions, responsibility and accountability rest with the Chief Executive as AO. However, the expectation is that the Chief Executive will follow the advice of the Board.

If the Board, or its chairperson, is contemplating a course of action involving a transaction which the Chief Executive considers would infringe upon the requirements of propriety or regularity or does not represent prudent or economical administration, efficiency or effectiveness, is of questionable feasibility, or is unethical, the Chief Executive in their role as AO should reject that course of action.

The Chief Executive must ensure that the Board has a full opportunity to discuss the rationale for rejection of the proposed course of action. The Chief Executive should confirm the rationale for not following the advice of the Board in writing to the Chair of the Board and the PAO and copy that to the Treasury Officer of Accounts.

If the responsible minister agrees with the proposed course of action of the Board, it may be appropriate for the minister to direct the AO in the manner as set out in MPM paragraph 3.6.6 onwards.

## The Board

The Agency will comply fully with the principles and supporting provisions of good corporate governance. In line with Model 2 (set out in Cabinet Office guidance Public Bodies Handbook – Part 3), the Agency must have a unitary board with an advisory Audit Risk and Assurance Committee (ARAC) that contains both non-executive members and executive attendees. The Board will provide scrutiny and challenge to the Chief Executive and executive team, however non-executive members will not have decision making authority, as is the case with other executive agencies.

Detailed roles and responsibilities of the Board, as well as the principles that underpin these, shall be set out in the Board’s terms of reference or operating framework. Remuneration of the Board will be disclosed in line with the guidance in the Government Financial Reporting Manual (FReM).

The Board may hold some of its proceedings in public each year. Minutes of these meetings are published on the Agency’s website[[7]](#footnote-8). In particular, where there is call for it, the Board may hold a public Annual General Meeting and/or engagement sessions with stakeholders on specific topics.

The SDS and representatives from the DAs shall have a standing invitation to attend all Board meetings.

**Role of the Board**

The role of the Board is to support the Chief Executive in their responsibility for the successful operation of the Agency. The Board is responsible for:

* + the strategic aims and objectives of the Agency, consistent with its overall strategic direction, corporate and business plans, and within the capital and resource budget limits set by the Department;
  + the effective leadership of the Agency within a framework of prudent and effective controls, which enables risk to be assessed and managed;
  + the financial and human resources that are in place for the Agency to meet its objectives; and
  + reviewing management performance.

The Board should ensure that effective arrangements are in place to provide assurance on risk management, governance and internal control, and will:

* + ensure it receives and reviews regular financial and management information concerning the management of the Agency;
  + ensure that it is kept informed of any changes which are likely to impact on the strategic direction of the Agency’s Board or on the attainability of its targets, and determining the steps needed to deal with such changes and where appropriate bringing such matters to the attention of the responsible minister and PAO via the executive team, sponsorship team or directly;
  + ensure that any delegated authority is agreed with the Department, and is in accordance with any other conditions relating to the use of public funds; and that, in supporting decision-making, the Board takes into account guidance issued by the Department;
  + endorse the Agency’s recommendations to Ministers on the Agency’s key financial and performance targets in the Agency’s annual business plans and corporate plans;
  + agree the content of the Agency’s annual report to be proposed to Ministers;
  + ensure that, as part of the above compliance, it is familiar with:
* this Framework Document;
* any delegation letter issued to the Agency;
* any elements of any settlement letter issued to the Department that is relevant to the operation of the Agency;
* any separate settlement letter that is issued to the Agency from the Department;
  + ensure that, in accordance with the obligations under the above documents, it has appropriate internal mechanisms for the monitoring, governance and external reporting regarding any conditions arising from the above documents, and that the Chief Executive and the Agency as a whole act in accordance with their obligations under the above documents;
  + demonstrate high standards of corporate governance at all times, including by using the independent audit and risk committee to help the Board to address key financial and other risks;
  + put in place mechanisms for independent appraisal and annual evaluation of the performance of the Chair by the NEDs, taking into account the views of relevant stakeholders. The outcome of that evaluation should be made available to the Department; and
  + determine all such other things that it considers ancillary or conducive to the attainment or fulfilment by the Agency of its objectives.

The Board should ensure that effective arrangements are in place to provide assurance over the design and operation of risk management, governance and internal control in line with the Management of Risk – Principles and Concepts (The Orange Book).

**Composition of the Board**

The Agency’s Board is an advisory, unitary Board, which requires an equal number of executive and non-executive members, plus a non-executive Chair. There should be members who have experience of the Agency’s business, operational delivery, corporate services such as human resources, technology, property asset management, estate management, communications and performance management, as appropriate to their role. This will include as an executive and voting board member an appropriately qualified finance director as described in Annex 4.1 of MPM. The Board should include a majority of independent non-executive members to ensure that executive members are supported and constructively challenged in their role.

The Agency Board supports the Chief Executive in the effective delivery of services and overall performance of the organisation by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk. The Agency Board collectively does not exercise any line management or executive functions, nor does it have a legal or constitutional role or any liability in respect of decisions of the Executive.

**Appointments to the Board**

The Chair of the Agency’s Board and all non-executive members are appointed by the Secretary of State or responsible minister. Appointments are transparent, made on merit, and managed in a way which follows the principles of the Commissioner for Public Appointments’ Code of Practice for Ministerial Appointments to Public Bodies.

The Chair and non-executive appointments to the Board will be led and coordinated by the Department’s Appointments team with support from the sponsorship team, who may consult with the Agency’s Chair where appropriate.

The Agency’s Chair may also appoint Associate NEDs, which are non-ministerial appointments, following agreement with the Department. The number of any additional Associate NEDs, and the range of experiences sought from its non-executive members, will be agreed between the Agency and the Department.

All such appointments should have regard to the principle that appointments should reflect the diversity of the society in which we live, and appointments should be made taking account of the need to appoint Boards which include a balance of skills and backgrounds.

The travel and subsistence expenses of Board members shall be determined by the Agency’s respective policy. Members may claim reimbursement for reasonable actual expenses necessarily incurred on official business at the same rates allowed to senior staff. Payments for attending Board meetings are taxable as earnings and will be subject to tax and national insurance.

**Board Committees**

The Chair may set up assurance committees to support the Agency Board as necessary for it to fulfil its functions, each of which will provide advice, support and constructive challenge in its respective areas of responsibility and provide the Board with regular reporting. As is detailed below, at a minimum, this should include an Audit, Risk and Assurance Committee (ARAC), chaired by an appropriately qualified non-executive member of the Board.

While the Board may make use of committees to assist its consideration of relevant matters, such committees are advisory in nature and responsibility for decisions remain with the Board. The Board retains responsibility for, and endorses, advice to the Chief Executive in all of these areas. The Chair should ensure that sufficient time is allowed at Board meetings for committees to report on the nature and content of discussion, on recommendations, and to agree on actions to be taken.

Where there is disagreement between the relevant committee and the Board, adequate time should be made available for discussion of the issue with a view to resolving the disagreement. Where any such disagreement cannot be resolved, the committee concerned should have the right to report the issue to the sponsor team, PAO and responsible minister. They may also seek to ensure the disagreement or concern is reflected as part of the report on its activities in the annual report.

The Chair shall ensure Board committees are properly structured with appropriate terms of reference. The terms of each committee should set out its responsibilities as set by the Board. The Chair shall ensure that committee membership is periodically refreshed and that individual NEDs are not over-burdened when deciding the chairs and membership of committees.

**The Audit, Risk and Assurance Committee**

The Board must have an Audit and Risk Assurance Committee (ARAC) chaired by an independent and appropriately qualified NED to provide independent advice and ensure that the Department’s Audit and Risk Committee is provided with routine assurances, with escalation of any significant limitations or concerns. The Board is expected to assure itself of the adequacy and effectiveness of the risk management framework and the operation of internal control.

This committee shall report independently to the AO and the Agency Board on the adequacy of the Agency’s governance arrangements, including: the risk management framework and the associated control environment; the Agency’s financial and non-financial performance to the extent that it affects the Agency’s exposure to risk and weakens the control environment; and oversight of the financial reporting process and scrutiny of the HM Treasury management strategy and policies. It has sight of the corporate risk register at each of its meetings.

The risk register is also shared with the Department to enable the Department to assure itself on risk management. The internal and external auditors and the sponsorship team are invited to all meetings and must have access to all the papers**.**

## The Chair’s Role and Responsibilities

The Chair is responsible for leading the Board in the delivery of its responsibilities. Such responsibility should be exercised in the light of their duties and responsibilities as set out in the Chair’s contract of employment, any appointment letter, the Framework Document and the documents and guidance referred to within this document.

Communications between the Agency’s Board and the responsible minister should normally be through the Chair.

The Chair is bound by the Code of Conduct for Board Members of Public Bodies, which covers conduct in the role and includes the Nolan Principles of Public Life.

The Chair is responsible for:

* + ensuring, including by monitoring and engaging with appropriate governance arrangements, that the Agency’s affairs are conducted with probity; and
  + ensuring that policies and actions support the responsible minister’s wider strategic policies and that, where appropriate, these policies and actions should be clearly communicated and disseminated throughout the Agency.

The Chair has the following leadership responsibilities, in support of the Chief Executive who holds formal responsibility for the Agency:

* + leading the Board in development of strategic approaches to the Agency’s objectives and ensuring that, in reaching decisions, it takes proper account of guidance provided by the responsible minister or the Department;
  + establishing sound governance for the Agency including through ensuring effective non-executive leadership of ARAC and establishing and maintaining other committees and sub-committees as needed;
  + developing and maintaining a diverse and high-performing non-executive Board team, helping to foster collaborative relationships at all levels within the Agency, with the Department, across government and Devolved Administrations, and with other key stakeholders;
  + delivering high standards of regularity and propriety, including that the Agency adheres to good financial principles, as set out in MPM and the Cabinet Office’s Partnerships between Departments and Arm’s Length Bodies: Code of Good Practice;
  + ensuring the executives are supported and held to account for the Agency’s performance and delivery of the objectives as set out in the annual business plan; and
  + supporting the Chief Executive in promoting the efficient and effective use of staff and other resources, and ensuring that the appropriate organisational culture, values, behaviours and capability are in place to enable the Agency to fulfil its function and deliver its mission.

The Chair also has an obligation to ensure that:

* + the work of the Board and its members is reviewed and is working effectively, including ongoing assessment of the performance of individual Board members with a formal annual evaluation and more in-depth assessments of the performance of individual Board members when being considered for re-appointment;
  + in conducting assessments, the views of relevant stakeholders including employees and the sponsor team are sought and considered;
  + the Board has a balance of skills appropriate to directing the Agency’s business,
  + NEDs continually update their skills, knowledge and familiarity with the Agency to fulfil their role both on the Board and committees. This will include, but not be limited to, skills and training in relation to financial management and reporting requirements, risk management and the requirements of Board membership within the public sector;
  + NEDs are fully briefed on terms of appointment, duties, rights and responsibilities;
  + together with the other Board members, they receive appropriate training on financial management and reporting requirements and on any differences that may exist between private and public sector practice;
  + the responsible minister, through the Department, is advised of the Agency’s needs when Board vacancies arise;
  + there is a Board Operating Framework and Board’s Terms of Reference in place, setting out the role and responsibilities of the Board, as well the principles that underpin these, which should be consistent with the Government Code of Good Practice for Corporate Governance; and
  + there is a code of practice for Board members in place, consistent with the Cabinet Office Code of Conduct for Board Members of Public Bodies.

The Chair will meet the Secretary of State, or responsible minister (or their nominee) at least once a year, including at an annual accountability meeting.

## Non-Executive Directors’ responsibilities

The NEDs bring the skills and experience to the Board that are considered appropriate as agreed between the Agency and the Department. The NEDs are appointed to provide independent and constructive challenge to enable the Board to deliver its responsibilities; in doing so, all NEDs must be independent of management and must allocate sufficient time to the Agency Board to discharge their responsibilities effectively. This includes ensuring that high standards of corporate governance are observed at all times and ensuring that the Agency operates in an open, accountable and responsive way.

NEDs should:

* + comply at all times with the Code of Conduct for Board Members of Public Bodies, which covers conduct in the role and includes the Nolan Principles of Public Life, as well as rules relating to the use of public funds and to conflicts of interest;
  + demonstrate adherence to the 12 Principles of Governance for all Public Body Non-Executive Directors as appropriate;
  + not misuse information gained in the course of their public service for personal gain or for political profit, nor seek to use the opportunity of public service to promote their private interests or those of connected persons or organisations;
  + comply with the Board’s rules on the acceptance of gifts and hospitality, and of business appointments;
  + act in good faith and in the best interests of the Agency; and
  + ensure they are familiar with any applicable guidance on the role of Public Sector NEDs and Boards that may be issued from time to time by the Cabinet Office, HM Treasury or wider government.

NEDs must not represent any specific customer, sectoral or stakeholder interests. NEDs are subject to the stringent MHRA Conflict of Interest policy[[8]](#footnote-9) in exercising their duties.

The Secretary of State may remove the Agency’s Chair and any NED from the Board on the grounds of misbehaviour or failure to carry out their duties.

# Management and financial responsibilities and controls

## Income generation and fees

The Agency is funded mostly by income from fees for sales of products and services. Fees are charged by the Agency directly to organisations for the fulfilment of statutory or other regulatory obligations. Fees must be calculated in line with the principles as set out in MPM.

The Department may provide funding and allocate budget to areas where fees cannot be charged. This is primarily agreed as part of the Spending Review process, on which the sponsorship team will have a coordinating role between the Agency and the Department’s central Spending Review team.

In agreement with the Department, the Agency will ensure that income and expenditure related to statutory fees is aligned; this will include the process for setting and reviewing fees periodically.

Amendments to the fees for statutory services are the responsibility of the Secretary of State, who, with the consent of HM Treasury, will bring proposals before Parliament for approval.

The Agency will consult the sponsorship team and the public before making proposals to change the level of these statutory fees. The Agency must operate within its resources. If it fails to do so, the Comptroller and Auditor General may qualify its annual accounts and refer the matter to the PAC. The Agency must also operate within the delegated authorities issued by the Department.

The Agency, alongside the Department and the Cabinet Office, will review plans for income generation and the relevant risks involved.

## Delegated authorities

The Agency’s delegated authorities are set out in the delegation letter. This delegation letter may be updated and superseded by later versions which may be issued by the Department in agreement with HM Treasury.

The Agency shall obtain the Department’s and, where appropriate, HM Treasury’s prior written approval, before:

* + entering into any undertaking to incur any expenditure or recognising the risk of a contingent liability that falls outside the delegations or which is not provided for in the Agency’s annual budget as approved by the Department;
  + incurring expenditure for any purpose that is or might be considered novel or contentious, or which has or could have significant future cost implications;
  + making any significant change in the scale of operation or funding of any initiative or particular scheme previously approved by the Department;
  + making any change of policy or practice which has wider financial implications that might prove repercussive or which might significantly affect the future level of resources required; or
  + carrying out policies that go against the principles, rules, guidance and advice in MPM.

## Spending authority

Once the budget has been approved by the Department, the Agency shall have authority to incur expenditure approved in the budget without further reference to the Department, on the following conditions:

* + the Agency shall comply with the delegations set out in the delegation letter. These delegations shall not be altered without the prior agreement of the Department and as agreed by HM Treasury and Cabinet Office as appropriate;
  + the Agency shall comply with MPM regarding novel, contentious or repercussive proposals;
  + inclusion of any planned and approved expenditure in the budget shall not remove the need to seek formal Departmental approval where any proposed expenditure is outside the delegated limits or is for new schemes not previously agreed; and
  + the Agency shall provide the Department with such information about its operations, performance, individual projects or other expenditure as the Department may reasonably require.

## Banking and Managing Cash

The Agency must maximise the use of publicly procured banking services (accounts with central government commercial banks managed centrally by Government Banking).

The Agency should only hold money outside Government Banking Service accounts where a good business case can made for doing so, and HM Treasury consent is required for each account to be established. Only commercial banks which are members of relevant UK clearing bodies may be considered for this purpose.

Commercial Accounts where approved should be operated in line with the principles as set out in MPM.

The AO is responsible for ensuring the Agency has a banking policy as set out in MPM and ensuring that policy is complied with.

## Procurement

The Agency shall ensure that its procurement policies are aligned with and comply with any relevant UK or other international procurement rules and in particular the Public Contracts Regulations 2015 and their legal responsibilities within these regulations. The Agency must ensure compliance with Cabinet Office controls policy, including commercial controls.

The Agency shall establish its procurement policies and document these in a Procurement Policy and Procedures Manual.

In procurement cases where the Agency is likely to exceed its delegated authority limit, procurement strategy approval for the specific planned purchase must be sought from the sponsorship team.

Goods, services, and works should be acquired by competition. Proposals to let single-tender or restricted contracts shall be limited and exceptional, and a quarterly report explaining those exceptions should be sent to the Department.

Procurement by the Agency of works, equipment, goods, and services shall be based on a full options appraisal and value for money (VfM), i.e. the optimum combination and whole life costs and quality.

The Agency shall:

* + engage fully with Department and Government-wide procurement initiatives that seek to achieve VfM from collaborative projects;
  + comply with all relevant Procurement Policy Notes issued by Cabinet Office; and
  + co-operate fully with initiatives to improve the availability of procurement data to facilitate the achievement of VfM.

The Agency shall comply with the commercial[[9]](#footnote-10) and grants standards[[10]](#footnote-11). These standards apply to the planning, delivery, and management of government commercial activity, including management of grants in all Departments, regardless of the commercial approach used, and form part of a suite of functional standards that set expectations for management within government.

A shared or standardised value for money approach will also apply to the use of estate.

## Risk management

The Agency shall ensure that the risks that it faces are dealt with in an appropriate manner, in accordance with relevant aspects of best practice in corporate governance, and develop a risk management strategy, in accordance with the HM Treasury guidance Management of Risk: Principles and Concepts[[11]](#footnote-12).

The Agency and the Department will work together to identify, assess and mitigate cross-organisational risks, where neither party can satisfactorily mitigate the risks identified independently.

## Reporting on legal risk and litigation

The Government Legal Department (GLD) provides a monthly report to the Department on the existence of any active litigation and any threatened or reasonably anticipated litigation, where such litigation involves significant legal or reputational risk to the Secretary of State, including judicial review. The GLD also shares this report with the Agency for information. This recognises the importance of ensuring that legal risks are communicated appropriately to the Department in a timely manner.

In respect of each substantial piece of litigation involving the Agency, and which is to be reported to the Department in accordance with Section 11, the parties will agree a litigation protocol which will include specific provisions to ensure appropriate and timely reporting on the status of the litigation and the protection of legally privileged information transmitted to the Department to facilitate this. Until such time as a protocol is agreed, the parties will ensure that:

* + material developments in the litigation are communicated to the Department in an appropriate and timely manner;
  + legally privileged documents and information are clearly marked as such;
  + individual employees handling the legally privileged documents are familiar with principles to which they must adhere to protect legal privilege; and
  + circulation of privileged information within government occurs only as necessary.

## Counter Fraud and Theft

The Agency should adopt and implement policies and practices to safeguard itself against fraud and theft.

The Agency should act in line with guidance as issued by the Counter Fraud Function and in compliance with the procedures and considerations as set in in MPM Annex 4.9 and the Counter Fraud Functional Standard[[12]](#footnote-13). It should also take all reasonable steps to appraise the financial standing of any firm or other body with which it intends to enter a contract or to provide grant funding.

The Agency should notify the Department’s Anti-Fraud Unit of any unusual or major incident as soon as possible, seeking advice from their fraud specialists as required. The Agency may request that the Department’s Anti-Fraud Unit considers investigating a fraud case on its behalf. The Department will share best practice and learning from case studies within the health family with the Agency.

The Agency should keep records of, and submit to the Department’s Anti-Fraud Unit, a quarterly report on detected loss from fraud and error alongside recovered and prevented losses, in line with agreed government definitions as set out in the Counter Fraud Functional Standard.

## Staff

**Broad responsibilities for staff**

The Agency employees are Departmental civil servants and the majority of staff are employed on civil service pay and pension arrangements. Some SRI staff are currently employed on the NHS Agenda for Change terms or hybrid NIBSC terms and conditions. The Chief Executive is responsible for the staffing and structure of the Agency subject to the points below.

Within the arrangements approved by the responsible minister, the Agency shall have responsibility for the recruitment, retention and motivation of its staff. The broad responsibilities toward its staff are to ensure that:

* + the rules for recruitment and management of staff are in line with Civil Service Commission Recruitment principles and create an inclusive culture in which diversity is valued and promoted; appointment and advancement are based on merit; there is no discrimination against employees with protected characteristics under the Equality Act 2010
  + the level and structure of its staffing, including grading and staff numbers, are appropriate to its functions and the requirements of economy, efficiency and effectiveness;
  + the performance of its staff at all levels is satisfactorily appraised and the Agency performance measurement systems are reviewed from time to time;
  + its staff are encouraged to acquire the appropriate professional, management and other expertise necessary to achieve the Agency’s objectives;
  + proper consultation with staff takes place on key issues affecting them, including where that may be through recognised Trades Unions acting on behalf of staff.
  + adequate grievance and disciplinary procedures are in place;
  + whistleblowing procedures consistent with the Public Interest Disclosure Act are in place;
  + all staff are aware of the provisions of the Civil Service Code, which forms part of their terms and conditions of employment.

**Staff costs**

Subject to its delegated authorities, the Agency shall ensure that the creation of any additional posts does not incur forward commitments that will exceed its ability to pay for them.

**Pay and conditions of service**

The Agency’s staff are subject to standard civil service terms and conditions of service (including pensions) within the general pay structure approved by the Department and HM Treasury, aside from any staff who may have transferred on legacy conditions as an exception. The Agency has no delegated power to amend these pay terms and conditions without the approval of the Secretary of State.

If civil service terms and conditions of service apply to the rates of pay and non-pay allowances paid to the staff and to any other party entitled to payment in respect of travel expenses or other allowances, payment shall be made in accordance with the Civil Service Management Code[[13]](#footnote-14) and the annual Civil Service Pay Remit Guidance, except where prior approval has been given by the department to vary such rates.

SCS remuneration is subject to the recommendations of the Senior Salaries Review Body and related Cabinet Office and Treasury guidance.

In general terms, the Agency will adopt policies developed by Civil Service HR, which will be adapted where necessary to reflect the Agency’s business and workforce. These should be accessible to all staff and copies provided to the Department if requested.

The Agency shall abide by public sector pay controls, including the relevant approvals process dependent on its classification as detailed in the Senior Pay Guidance[[14]](#footnote-15) and the Public Sector Pay and Terms Guidance[[15]](#footnote-16).

The Agency shall operate a performance-related pay scheme that shall form part of the annual aggregate pay budget approved by the Department, or the general pay structure approved by the Department and HM Treasury where relevant, with due regard to the senior pay guidance and in line with Cabinet Office guidance.

The travel expenses of board members shall be tied to the rates allowed to senior staff of the ALB. Reasonable actual costs shall be reimbursed.

#### **Recruitment of senior staff**

While MHRA is responsible for the structure and staffing of its organisation, it will consult with the department when making decisions on the creation, regrading or reduction of Senior Civil Service (SCS) posts.  Any recruitment with a salary over £150,000 must be done in line with [senior pay guidance](https://www.gov.uk/government/publications/senior-civil-service-pay-and-reward) and approval is required from DHSC in advance of seeking approval from HM Treasury.

**Pensions, redundancy and compensation**

The Agency will operate in line with compensation scheme rules, pension scheme rules and legislative, Cabinet Office and HM Treasury guidance requirements regarding exit payments.

The Agency’s staff shall normally be eligible for a pension provided by the Civil Service Pension Scheme. Staff may opt out of the occupational pension scheme, but the employers’ contribution to any personal pension arrangement, including stakeholder pension, shall normally be limited to the national insurance rebate level.

Any proposal by the Agency to move from the existing pension arrangements, or to pay any redundancy or compensation for loss of office, requires the prior approval of the Department. Proposals on severance must comply with the rules in chapter 4 of MPM. For example, all novel or contentious payments require Departmental and HM Treasury approval. Special severance payments are always considered novel or contentious.

# Business Plans, Financial Reporting and Management Information

## Corporate plan

By the start of the financial year every three years (starting 2023), the Agency shall submit to the Department a draft of the corporate plan covering three years ahead. The Agency shall agree with the Department the range of strategic issues to be addressed in the corporate plan and the timetable for its approval by the Department.

The Chief Executive is responsible for preparing the corporate plan, with input from the Agency Board. It shall reflect the Agency’s statutory and/or other duties and, within those duties, the priorities set from time to time by the responsible minister (including decisions taken on policy and resources in the light of wider public expenditure decisions).

The plan shall form the agreed basis for detailed annual business planning. To do this, it shall:

* + set out how the Agency will deliver the functions delegated by the Secretary of State, in line with wider government priorities and objectives; and
  + describe the Agency’s longer-term aims and objectives and set out a strategy for achieving these.

The plan shall also demonstrate how the Agency contributes to the achievement of the Department’s medium-term plan and priorities, with appropriate performance metrics and milestones, and how the Department is supporting the Agency to deliver, through appropriate funding and resources, risk management and policy support.

The Department and the Agency will review the Agency’s corporate plan at least annually. If, as a result of this review, the Agency’s corporate plan needs to be amended, these changes will be agreed with the Department.

The first year of the corporate plan, amplified as necessary, shall form the business plan. Subject to any commercial considerations, the corporate and business plans should be published by the Agency on its website and separately be made available to staff.

The Department will contribute to the development of both the corporate and business plans through close collaboration and formal review at accountability meetings ahead of submission of plans for SDS approval. Although corporate and business plans do not require ministerial approval under current arrangements, the Department and Agency will consult ministers as appropriate.

## Business plan

By the start of each financial year, the Chief Executive develops with the Board, and in agreement with the Department, a Business Plan which demonstrates how the Agency will deliver its objectives, regulatory functions and strategic priorities as set out in the Corporate Plan. Unless otherwise agreed with the Department, the Agency will produce new business plans on an annual basis.

The Business Plan sets out the Agency’s intended activity, goals and anticipated resource requirements for the following financial year, including agreed resources from the Department for specific objectives.

The following key matters should be included in the business plan:

* + key objectives and associated key performance targets for the forward years, and the strategy for achieving those objectives;
  + key non-financial performance targets;
  + a review of performance in the preceding financial year, together with comparable outturns for the previous three years, as applicable, and an estimate of performance in the current year;
  + alternative scenarios and an assessment of the risk factors that may significantly affect the execution of the plan but that cannot be accurately forecast; and
  + other matters as agreed between the Department and the Agency.

A draft business plan will be shared in sufficient time to facilitate comment from the Department prior to being submitted to SDS for approval. Once cleared by the Agency Board and the Department, the Agency publishes its annual business plan on its website.

Progress against the objectives, targets and metrics in the Agency’s annual business plan is reviewed as part of accountability meetings.

The Agency is responsible for the delivery of its objectives as agreed in its Business Plan, and the Department will limit the circumstances in which it will intervene in its activities. The following constraints do, however, apply:

* + the Agency should charge fees in order to deliver its regulatory services as stipulated in legislation or to fulfil its functions;
  + any public money should be spent as specified; and
  + governance structures and spending controls should be in place to support propriety and regularity.

## Budgeting procedures

Each year and by an agreed date, in the light of agreed decisions between the Department and the Agency on the progress against the corporate plan, and to enable development of the business plan for the year ahead, the Department will send to the Agency:

* + a formal statement of the annual budgetary provision allocated by the Department in the light of competing priorities across the Department and of any forecast income approved by the Department; and
  + a statement of any planned change in policies affecting the Agency.

The approved annual business plan will take account both of approved funding provision and any forecast receipts and will include a budget of estimated payments and receipts together with a profile of expected expenditure and of draw-down of any Departmental funding and/or other income over the year.

## Grant-in-aid and any ring-fenced grants

The Agency does not currently give grants or grants-in-aid.

Grant-in-aid will normally be paid to the Agency in monthly instalments on the basis of written applications showing evidence of need. The Agency will comply with the general principle that there is no payment in advance of need. Cash balances accumulated during the course of the year from grant-in-aid or other Exchequer funds shall be kept to a minimum level consistent with the efficient operation of the Agency. Grant-in-aid not drawn down by the end of the financial year shall lapse. Subject to approval by Parliament of the relevant Estimates provision, where grant-in-aid is delayed to avoid excess cash balances at the year-end, the Department will make available in the next financial year any such grant-in-aid that is required to meet any liabilities at the year end, such as creditors.

In the event that the Department provides the Agency separate grants for specific, ring-fenced purposes, it would issue the grant as and when the Agency needed it on the basis of a written request. The Agency would provide evidence that the grant was used for the purposes authorised by the Department. The Agency shall not have uncommitted grant funds in hand, nor carry grant funds over to another financial year.

## Annual report and accounts

The Agency’s Board must prepare and publish on its website an annual report of its activities together with its audited accounts after the end of each financial year. The report shall be approved and signed by the Agency’s Chief Executive as AO, prior to its submission to Ministers and being laid before Parliament.

A draft of the report should be submitted to the Department at least two weeks before the proposed publication date. The draft and finalised (audited) accounts should be provided to the Department in line with the agreed annual timetable established by the Department in order for the accounts to be consolidated within the Department's accounts. The accounts should be prepared in accordance with the relevant statutes and specific accounts direction issued by the Department as well as the HM Treasury’s Financial Reporting Manual (FReM).

The annual report must:

* + comply with the FreM and in particular have regard to the illustrative statements for an Executive Agency; and
  + outline main activities and performance against objectives and its use of public funds during the previous financial year and set out in summary form forward plans.

Information on performance against key financial targets is within the scope of the audit and should be included as part of the financial performance described in the annual report. The report and accounts must be laid in Parliament and made available on the Agency’s website, in accordance with the guidance in the FReM.

## Reporting performance to the Department

The Agency shall operate management, information and accounting systems that enable it to review in a timely and effective manner its financial and non-financial performance against the budgets and targets set out in the corporate and business plans.

The Agency shall inform the Department of any changes that make achievement of objectives more or less difficult. It shall report quarterly, as part of quarterly accountability meetings, financial and non-financial performance, including performance in helping to deliver Ministers’ policies, and the achievement of key objectives.

The information provided to the Department by the Agency includes (not an exhaustive list):

* + quarterly reports on the Agency’s performance, including, as a minimum:
* finance reports, including:
  + the Agency’s cash management;
  + its draw-down of grant-in-aid;
  + forecast outturn by resource headings;
  + other data required for the Online System for Central Accounting and Reporting (OSCAR); and
  + data as required in respect of its compliance with any Cabinet Office Controls pipelines or required in order to meet any condition as set out in any settlement letter.

and

* reviews of risks and issues.
  + key regulatory insights and developments, including emerging and developing proposals for legislative change;
  + reports in support of Cabinet Office and Departmental spending controls;
  + a full set of Board papers in advance of the Agency Board meetings; and
  + a full set of papers in advance of the quarterly ARAC meetings.

The Chief Executive will notify the Department promptly if over or underspends are likely and that corrective action is taken; and that any significant problems whether financial or otherwise, and whether detected by internal audit or other means, are notified to the Department in a timely fashion.

The processes in place to enable the Department and the Agency to review performance include:

* + led by the responsible minister, an annual accountability review meeting with the Agency’s Chair and Chief Executive to formally review the Agency’s performance and strategic development, discuss the annual report and business plan, and inform the next set of annual objectives;
  + on a regular basis, meetings between the Agency’s Chair and Chief Executive and: the PAO, or their nominee; the responsible minister, or their nominee; and the SDS;
  + led by the SDS, quarterly accountability meetings with the Agency’s Chair and Chief Executive, and other key Agency Directors and Departmental officials as necessary, to discuss strategic issues and any issues of delivery which either organisation believes appropriate to bring to this meeting, including compliance with the Framework Document (secretariat is provided by the Department);
  + regular contact between the sponsorship team and the Agency, whereby the following must be reviewed periodically or as part of the quarterly accountability meetings:
* the Agency’s contributions against the Department’s strategic objectives and progress against the Agency’s business plan;
* performance against agreed key performance indicators and appropriate performance targets;
* the Agency’s internal control arrangements;
* the Agency’s governance and risk management arrangements; and
* the relationship between the Department and the Agency, and any other key issues identified in delivery of the Department’s strategic objectives.

## Information Sharing

The Department has the right of access to all the Agency’s records and personnel for any purpose including, for example, sponsorship audits, operational investigations and to support the Secretary of State and the PAO in their accountability functions.

The Department and HM Treasury may request the access to and where necessary copies of data held by the Agency in such a manner as set out in central guidance, except insofar as it is prohibited by law. This may include requiring the appointment of a senior official to be responsible for the data sharing relationship.

## Data protection, information risk and assurance

The Department is the legal data controller for MHRA data and the department data protection officer (DPO) is legally accountable for the protection of data, and in particular personal data, handled by MHRA and will be named as data controller on the ICO registration. As such:

* + The Department DPO will delegate responsibility to MHRA, which may nominate its own SIRO and Caldicott Guardian, to conduct all low to medium risk level data actions and will require MHRA to seek advice from and to consult with the Department DPO before a decision is taken on high risk level data actions
  + The Department SIRO will delegate responsibility for management of low to medium information risks across all data types but will require advice and consultation to be sought from the Department SIRO before an information risk is accepted for high risk activities
  + The MHRA will at a minimum adhere to relevant departmental policies and standards across data protection, information risk management, information assurance, information security, information management and other data protection and information risk and assurance related compliance policies as they arise.

The Department will seek periodic assurance that the MHRA is adhering to these policies and relevant standards.

The Department will ensure it shares all appropriate policies and standards with the Agency in good time to enable the Agency to discharge these responsibilities. It will also support the Agency in responding to emerging best practice across government.

## Information Management

In addition to the requirements laid out on both parties in paragraph 37, the Agency will also take all necessary measures to ensure that:

* + patient, personal and/or sensitive information within its care is well managed and protected through all stages of its use including through compliance with the Data Protection Act 2018;
  + it provides public assurance in respect of its information governance practice by completing and publishing an annual information governance assessment using an agreed assessment mechanism; and
  + it meets its legal obligations for records management, accountability and public information by compliance with relevant standards, including government codes of practice on confidentiality, security and records management.

The Agency’s Senior Information Risk Owner and its Caldicott Guardian work together to ensure that both patient and other personal information are handled in line with best practice in government and the wider public sector.

**Business continuity**

The Agency must ensure it has effective and tested business continuity management (BCM) arrangements in place to be able to respond to disruption to business and to recover time-critical functions where necessary. In line with Cabinet Office guidelines, the BCM system should aim to comply with ISO 22301 Societal Security – Business Continuity Management Systems.

## Sustainability

The Agency has a key role to play in driving forward the public sector commitment to sustainability and reaching net zero greenhouse gas emissions. This includes by ensuring alignment with the Greening Government Commitments, which the Agency will report on via the Department. Sustainability representatives from the Agency will also attend quarterly Sustainable Development Forums, chaired by the Department, to share knowledge and best practice amongst other ALBs, and support progress towards these shared goals.

## Whistleblowing

The Agency must have whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998 and the Civil Service Code. The internal Raising Concerns Policy and Procedure is modelled on the civil service best practice policy.

The Agency encourages its staff to speak up about any concerns and provides a variety of routes in which to do so. A Non-Executive Director Raising Concerns Champion must oversee the application of the policy to ensure that internal mechanisms are working effectively to support staff in raising concerns, appropriate action is being taken, and any lessons are being learned.

## Equality

The Public Sector Equality Duty (PSED) requires the Agency (as a public body) to have due regard to the need to:

* + eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
  + advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
  + foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

The provisions of the Equality Act 2010 (Specific Duties and Public Authorities) 2017 require the Agency to:

* + annually publish information to demonstrate compliance with the PSED, which must include, in particular, information relating to persons who share a relevant protected characteristic who are its employees and other persons affected by its policies and procedures; and
  + prepare and publish one or more objectives the Agency thinks it should achieve to meet the PSED.

# Audit

## Internal audit

The Agency must:

* + establish and maintain arrangements for internal audit in accordance with HM Treasury’s Public Sector Internal Audit Standards (PSIAS)[[16]](#footnote-17);
  + ensure the Department is satisfied with the competence and qualifications of the Head of Internal Audit and the requirements for approving appointments in accordance with PSIAS;
  + set up an audit committee of its Board in accordance with the Code of Good Practice for Corporate Governance and the Audit and Risk Assurance Committee Handbook;
  + keep records of and prepare and forward to the Department an annual report on fraud and theft suffered by the Agency and notify the Department of any unusual or major incidents as soon as possible; and
  + share with the Department information identified during the audit process and the Annual Audit Opinion Report (together with any other outputs) at the end of the audit, in particular on issues impacting on the Department's responsibilities in relation to financial systems within the Agency.

## External audit

The Comptroller & Auditor General (C&AG) audits the Agency’s annual accounts and lays them before parliament, together with their report.

The C&AG:

* + will consult the Department and the Agency on who shall undertake the audit(s) on their behalf – the NAO or a commercial auditor – though the final decision rests with the C&AG;
  + has a statutory right of access to relevant documents, including by virtue of section 25(8) of the Government Resources and Accounts Act 2000, held by another party in receipt of payments or grants from the Agency;
  + will share with the Department information identified during the audit process and the audit report (together with any other outputs) at the end of the audit, in particular on issues impacting on the Department's responsibilities in relation to financial systems within the Agency; and
  + will consider requests from Departments and other relevant bodies to provide Regulatory Compliance Reports and other similar reports at the commencement of the audit. Consistent with the C&AG’s independent status, the provision of such reports is entirely at the C&AG’s discretion.

The C&AG may carry out examinations into the economy, efficiency and effectiveness with which the Agency has used its resources in discharging its functions. For the purpose of these examinations the C&AG has statutory access to documents as provided for under section 8 of the National Audit Act 1983. In addition, the Agency shall provide, in conditions to grants and contracts, for the C&AG to exercise such access to documents held by grant recipients and contractors and sub-contractors as may be required for these examinations; and shall use its best endeavours to secure access for the C&AG to any other documents required by the C&AG which are held by other bodies.

# Reviews and winding up arrangements

## Review of the Agency’s status

The Agency will be reviewed as part of the wider Public Bodies Reviews programme, at a time determined by the Department’s ministers and the PAO.

## Arrangements in the event that the Agency is wound up

The Department shall put in place arrangements to ensure the orderly winding up of the Agency. In particular, it should ensure that the assets and liabilities of the Agency are passed to any successor organisation and accounted for properly. In the event that there is no successor organisation, the assets and liabilities should revert to the Department. To this end, the Department shall:

* + have regard to Cabinet Office guidance on closing agencies and removing agency status[[17]](#footnote-18);
  + ensure that procedures are in place in the Agency to gain independent assurance on key transactions, financial commitments, cash flows and other information needed to handle the wind-up effectively and to maintain the momentum of work inherited by any residuary body;
  + specify the basis for the valuation and accounting treatment of the Agency’s assets and liabilities;
  + ensure that arrangements are in place to prepare closing accounts and pass to the C&AG for external audit, and that, for non-Crown bodies, funds are in place to pay for such audits. It shall be for the C&AG to lay the final accounts in Parliament, together with their report on the accounts; and
  + arrange for the most appropriate person to sign the closing accounts. In the event that another ALB takes on the role, responsibilities, assets and liabilities, the succeeding ALB AO should sign the closing accounts. In the event that the Department inherits the role, responsibilities, assets and liabilities, the Department’s AO should sign.

The Agency shall provide the Department with full details of all agreements where the Agency or its successors have a right to share in the financial gains of developers. It should also pass to the Department details of any other forms of claw-back due to the Agency.

# ANNEX A – Wider guidance

The Agency shall comply with any statutory duties that are applicable to the Agency, and with the following guidance, documents and instructions:

**Corporate governance**

* This Framework Document
* Executive agencies: characteristics and governance: [Executive agencies: characteristics and governance - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/executive-agencies-characteristics-and-governance)
* Corporate Governance Code for Central Government Departments (relevant to Arm’s Length Bodies) and supporting guidance: [Corporate governance code for central government departments 2017 - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments-2017)
* Code of conduct for Board members of Public Bodies: [Code of conduct for board members of public bodies - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/code-of-conduct-for-board-members-of-public-bodies)
* Code of practice for partnerships between Departments and Arm’s Length Bodies: [Partnerships with arm's length bodies: code of good practice - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/partnerships-with-arms-length-bodies-code-of-good-practice#:~:text=This%20code%20of%20good%20practice,partnership%20approach%20to%20shaping%20relationships)

**Financial management and reporting**

* Managing Public Money (MPM), including Fees and Charge Guide (chapter 6): <https://www.gov.uk/government/publications/managing-public-money>
* Consolidated Budgeting Guidance (CBG). [Consolidated budgeting guidance - GOV.UK (www.gov.uk)](https://www.gov.uk/government/collections/consolidated-budgeting-guidance)

* Government Financial Reporting Manual (FReM): [www.gov.uk/government/collections/government-financial-reporting-manualfrem](http://www.gov.uk/government/collections/government-financial-reporting-manualfrem)
* Relevant Dear Accounting Officer (DAO) letters: [www.gov.uk/government/collections/dao-letters](http://www.gov.uk/government/collections/dao-letters)
* Relevant guidance and instructions issued by the Treasury in respect of Whole of Government Accounts: <https://www.gov.uk/government/collections/whole-ofgovernment-accounts>
* The most recent letter setting out the delegated authorities, issued by the parent department.

**Management of risk**

* Management of Risk: [www.gov.uk/government/publications/orange-book](http://www.gov.uk/government/publications/orange-book) and [Management of risk in government: framework - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/management-of-risk-in-government-framework)
* Public Sector Internal Audit Standards: [www.gov.uk/government/publications/public-sector-internal-audit-standards](http://www.gov.uk/government/publications/public-sector-internal-audit-standards)
* HM Treasury approval processes for Major Projects above delegated limits: [Treasury approvals process for programmes and projects - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/treasury-approvals-process-for-programmes-and-projects)
* The Government cyber-security strategy and cyber security guidance: [National Cyber Strategy 2022 (HTML) - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/national-cyber-strategy-2022/national-cyber-security-strategy-2022) and [Cyber security guidance for business - GOV.UK (www.gov.uk)](https://www.gov.uk/government/collections/cyber-security-guidance-for-business)

**Commercial management**

* Relevant sections of the Public Procurement Policy, including the Public Contracts Regulations 2015. [Public procurement policy - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/public-sector-procurement-policy#:~:text=The%20Public%20Contract%20Regulations%202015,already%20required%20of%20contracting%20authorities.)
* Procurement Policy Notes: <https://www.gov.uk/government/collections/procurement-policy-notes>
* Cabinet Office spending controls: <https://www.gov.uk/government/collections/cabinet-office-controls>
* Transparency in supply chains - a practical guide: [transparency in supply chains (publishing.service.gov.uk)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1040283/Transparency_in_Supply_Chains_A_Practical_Guide_2017_final.pdf)

**Public appointments**

* Guidance from the Commissioner for Public Appointments: <https://publicappointmentscommissioner.independent.gov.uk/>
* Governance Code on Public Appointments: [Governance Code for Public Appointments - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/governance-code-for-public-appointments)
* Procurement Policy Note 08/15 – Tax Arrangements of Public Appointees: [Procurement Policy Note 08/15: tax arrangements of appointees - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/procurement-policy-note-0815-tax-arrangements-of-appointees)
* 12 Principles of Governance for all Public Body NEDs. [12 Principles of Governance for all Public Body NEDs - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/public-bodies-non-executive-director-principles/12-principles-of-governance-for-all-public-body-neds)

**Staff and remuneration**

* Civil Service management code: [Civil Service management code - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/civil-servants-terms-and-conditions)
* HM Treasury guidance on senior pay and reward: [www.gov.uk/government/publications/senior-civil-service-pay-and-reward](http://www.gov.uk/government/publications/senior-civil-service-pay-and-reward)
* Civil Service pay guidance (updated annually): [www.gov.uk/government/collections/civil-service-pay-guidance](http://www.gov.uk/government/collections/civil-service-pay-guidance)
* Public sector pay and terms: [Public sector pay and terms: guidance note - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/public-sector-pay-and-terms-guidance-note)
* Whistleblowing Guidance and Code of Practice: [Whistleblowing: guidance and code of practice for employers - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/whistleblowing-guidance-and-code-of-practice-for-employers)
* The Equalities Act 2010: [www.gov.uk/guidance/equality-act-2010-guidance](http://www.gov.uk/guidance/equality-act-2010-guidance)

**Estates and Sustainability**

* Greening Government Commitments: Greening Government Commitments 2021 to 2025 - GOV.UK (www.gov.uk)
* Office of Government Property Controls and standards for office accommodation (available from DHSC)
* The Department of Health & Social Care Property Asset Management procedures (available from DHSC)

**Information Governance and Security**

* All documents relating to [Government security](https://www.gov.uk/government/collections/government-security): [Government security - GOV.UK (www.gov.uk)](https://www.gov.uk/government/collections/government-security)
* HMG IA Standard No. 6: Protecting Personal Data and Managing Information Risk (available from DHSC)
* Confidentiality: [NHS Code of Practice](https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice): [Confidentiality: NHS Code of Practice - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice)
* Records Management: [Code of practice](https://www.nhsx.nhs.uk/information-governance/guidance/records-management-code/#:~:text=The%20Records%20Management%20Code%20of%20Practice%20provides%20a,provision%20has%20an%20element%20of%20NHS%20funded%20care.) for health and social care: [Records management: code of practice for health and social care - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care)
* Data Security and Protection [Toolkit](https://www.dsptoolkit.nhs.uk/): [Data Security and Protection Toolkit (dsptoolkit.nhs.uk)](https://www.dsptoolkit.nhs.uk/)

**General**

* Freedom of Information Act guidance and instructions, as relevant: [www.legislation.gov.uk/ukpga/2000/36/contents](http://www.legislation.gov.uk/ukpga/2000/36/contents) , [Guide to freedom of information | ICO](https://ico.org.uk/for-organisations/guide-to-freedom-of-information/) and [Freedom of Information Code of Practice - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/freedom-of-information-code-of-practice)
* Guidance on the keeping, management and destruction of records <https://www.gov.uk/government/publications/code-of-practice-on-the-management-of-records-issued-under-section-46-the-freedom-of-information-act-2000>
* The Parliamentary and Health Service Ombudsman’s Principles of Good Administration: <https://www.ombudsman.org.uk/about-us/our-principles>
* Other relevant instructions and guidance issued by the central Departments (Cabinet Office and HM Treasury)
* Recommendations made by the Public Accounts Committee, or by other Parliamentary authority, that have been accepted by the Government and are relevant to the Agency
* Guidance from the Public Bodies team in Cabinet Office: [www.gov.uk/government/publications/public-bodies-information-and-guidance](http://www.gov.uk/government/publications/public-bodies-information-and-guidance)
* The Civil Service diversity and inclusion strategy (outlines the ambition, to which Arm’s Length Bodies can contribute): [Civil Service Diversity and Inclusion Strategy: 2022 to 2025 - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/civil-service-diversity-and-inclusion-strategy-2022-to-2025)
* Guidance produced by the Infrastructure and Projects Authority (IPA) on management of major projects: [www.gov.uk/government/organisations/infrastructure-and-projects-authority](http://www.gov.uk/government/organisations/infrastructure-and-projects-authority)
* The Government Digital Service: [www.gov.uk/government/organisations/government-digital-service](http://www.gov.uk/government/organisations/government-digital-service)
* The Government Fraud, Error, Debt and Grant Efficiency function: [www.gov.uk/government/collections/fraud-error-debt-and-grants-function](http://www.gov.uk/government/collections/fraud-error-debt-and-grants-function) and [www.gov.uk/government/publications/grants-standards](http://www.gov.uk/government/publications/grants-standards)
* Code of Practice for Official Statistics: [Code of Practice for Statistics (statisticsauthority.gov.uk)](https://code.statisticsauthority.gov.uk/#:~:text=The%20Code%20of%20Practice%20for%20Statistics%20sets%20the,produced%20by%20people%20and%20organisations%20that%20are%20trustworthy)
* Accounting Officer System Statements (AOSS are produced by departments with input from ALBs): [Accounting officer system statements - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/accounting-officer-system-statements)

1. <https://immdsreview.org.uk/> [↑](#footnote-ref-2)
2. <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-government-response> [↑](#footnote-ref-3)
3. [https://www.gov.uk/government/publications/partnerships-with-arms-length-bodies-code-of-good-practice](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fpartnerships-with-arms-length-bodies-code-of-good-practice&data=05%7C01%7CAndrew.Haines%40dhsc.gov.uk%7C80b4f41f32e140f837a708dac19e2df4%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C638035182357403053%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=UgBC6FJeHUFUiR81sPToi%2BIX8FhA4JP7oDR71Q3K4sA%3D&reserved=0) [↑](#footnote-ref-4)
4. <https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments-2017> [↑](#footnote-ref-5)
5. <https://www.gov.uk/government/publications/managing-public-money> [↑](#footnote-ref-6)
6. <https://www.gov.uk/government/collections/functional-standards> [↑](#footnote-ref-7)
7. 1. <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance#the-board> [↑](#footnote-ref-8)
8. https://www.gov.uk/government/publications/mhra-policy-for-handling-conflicts-of-interest [↑](#footnote-ref-9)
9. [Government Functional Standard GovS 008: Commercial and Commercial Continuous Improvement Assessment Framework - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/commercial-operating-standards-for-government) [↑](#footnote-ref-10)
10. [Government Functional Standard GovS 015: Grants - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/grants-standards) [↑](#footnote-ref-11)
11. [Orange Book - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/orange-book) [↑](#footnote-ref-12)
12. [Government Functional Standard GovS 013: Counter Fraud - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/government-functional-standard-govs-013-counter-fraud) [↑](#footnote-ref-13)
13. [Civil Service management code - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/civil-servants-terms-and-conditions) [↑](#footnote-ref-14)
14. [Guidance for approval of senior pay - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/senior-civil-service-pay-and-reward) [↑](#footnote-ref-15)
15. [Public sector pay and terms: guidance note - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/public-sector-pay-and-terms-guidance-note) [↑](#footnote-ref-16)
16. [Public Sector Internal Audit Standards - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/public-sector-internal-audit-standards) [↑](#footnote-ref-17)
17. [Executive agencies: characteristics and governance - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/executive-agencies-characteristics-and-governance) [↑](#footnote-ref-18)