

Biorisk Professional Registration Scheme (BPRS)

Draft proposal



Version: June 2022 (1)

BPRS Aims 1 (of 2)

- To define a **competency framework** of the **key technical knowledge and essential skills** required to successfully provide reliable professional biorisk advice and support
- To maintain a **professional accreditation scheme** as an objective benchmark of the above biorisk competency for application by stakeholders in the bioeconomy sector (research, manufacturing, health)
- To administer and govern the above accreditation scheme under the auspices of the **Royal Society of Biology** as an incorporated chartered body, with joint ownership by the **Biosafety Strategic Leadership Group** and by the **Institute of Safety in Technology & Research**

BPRS Aims 2 (of 2)

- To **enhance standards and consistency of biorisk management** across the bioeconomy sector by increasing the quality and reliability of advice and support available to users, managers and duty-holders
- To **give objective assurance and benchmarking of the competence of biorisk advisers**, to empower stakeholders to obtain advice and choose advisers with confidence
- To **supersede the ISTR *BioSafety Professional* scheme**, encompassing and building on its established foundation
- To **foster international equivalence and recognition** for UK biorisk management practice
- To **enhance the professional status of biorisk advisers**

BPRS Objectives 1 (of 2)

- **Balance knowledge v skills** – not to be ‘knowledge dense and skills light’, but to focus on what biorisk professionals can do for stakeholders rather on than what they know
- Produce biorisk professionals who, through **appropriate assessment**, have evidentially objectively demonstrated the defined core knowledge and essential skills
- Be sufficiently **rigorous** to be worthwhile for participants and to develop stakeholder assurance, but not so onerous that participation is low and engagement reluctant

BPRS Objectives 2 (of 2)

- Accommodate the **whole range of biorisk practice**, from advisers acting part-time in wider roles to advisers in full-time dedicated roles, from advisers in simple low risk / low containment contexts to advisers in complex high risk / high containment contexts
- Include a workable **transition** from the ISTR BSP scheme, without requiring a full de novo 'reboot' for extant members
- Have a supporting **administration framework and governance structures** via RSB

BPRS Basic Structure

- Two pathways:
 - **Registered Biorisk Adviser ('RBA')**
 - corequisite associate membership of RSB (AMRSB)
 - **Registered Biorisk Specialist ('RBS')**
 - corequisite full membership of RSB (MRSB)
- For each of the two pathways:
 - **Key knowledge** – approved assessed training course
 - +
 - **Essential skills** – portfolio of evidence
- Key knowledge and essential skills mapped to
12 elements of biorisk management practice

BPRS 12 elements of biorisk management practice

- 1. Management systems
- 2. Hazard identification
- 3. Risk assessment
- 4. Containment & control
- 5. Genetic Modification (GM)
- 6. Waste management
- 7. Transport
- 8. Competence & training
- 9. Incident management
- 10. Monitoring
- 11. Engagement & impact
- 12. Ethics & sustainability

BPRS Core Requirements 1 (of 2)

	Registered Biorisk Adviser (RBA)	Registered Biorisk Specialist (RBS)
Co-requisites	<ul style="list-style-type: none">• RSB Associate (AMRSB)*• Compliance with RSB <i>Code of Professional & Ethical Conduct</i>	<ul style="list-style-type: none">• RSB Member (MRSB)*• Compliance with RSB <i>Code of Professional & Ethical Conduct</i>• <i>ISO 45001 Internal Auditor</i> training**• RQF3 Certificate in <i>Education & Training</i>**
Pre-requisites	<ul style="list-style-type: none">• Min RQF5* (ie, Diploma/HND level) in a Life Science or related subject	<ul style="list-style-type: none">• RBA accreditation• Min 4 years full-time** work with, or operational management of work with, biological agents at Containment level 1 or 2 or Min 2 years full-time** work with, or operational management of work with, biological agents at Containment Level 3 or 4

* or higher

** or equivalent

BPRS Core Requirements 2 (of 2)

	Registered Biorisk Adviser (RBA)	Registered Biorisk Specialist (RBS)
Key knowledge	<ul style="list-style-type: none">Defined basic knowledge; successful completion of a course with approved provider – see next slides	<ul style="list-style-type: none">Defined expanded knowledge; successful completion of a course with approved provider – see next slides
Essential skills	<ul style="list-style-type: none">Suitable & sufficient evidence of development & application of basic skills set – see next slides	<ul style="list-style-type: none">Suitable & sufficient evidence of development & application of extended skills set – see next slides

BPRS Key knowledge 1 (of 4)

	Registered Biorisk Adviser (RBA)	Registered Biorisk Specialist (RBS)
Management systems	<ul style="list-style-type: none">Duties, roles & responsibilities for planning, organisation, control, monitoring and review in the management of biorisk	<ul style="list-style-type: none">Overview of the PDCA management cycle and standardsFeatures of effective leadership
Hazard identification	<ul style="list-style-type: none">Classification bio hazard, including human, animal and plant pathogensRelationship to bio hazard to pathogenicity, epidemiology, infectious dose, transmission routes, medical data, environmental stabilityRelationship to bio hazard of sample type, methods, equipment, frequency	<ul style="list-style-type: none">Interactions between bio hazard and other health & safety hazardsPotential 'dual use' / security threats associated with biological agents
Risk assessment	<ul style="list-style-type: none">Basic biorisk assessmentApplication of the ALARP principleSelection of containment measures based on risk and on hazard properties	<ul style="list-style-type: none">Overview of functional safety assessments (eg, SWIFT, HAZOPS, LOPA) of containmentApplication of human factors safety critical task analysis to containment

BPRS Key knowledge 2 (of 4)

	Registered Biorisk Adviser (RBA)	Registered Biorisk Specialist (RBS)
Containment & control	<ul style="list-style-type: none">• Design & operational requirements for Containment Level 2 facilities• Basic operating principles of Containment Level 3 & 4 facilities• Good Microbiological Practice• Function, use, maintenance and testing of Microbiological Safety Cabinets, centrifuges, autoclaves and other equipment impacting biorisk• Basic security considerations	<ul style="list-style-type: none">• Design, operational, maintenance and testing requirements for Containment Level 3 & 4 facilities, including decontamination, fumigation and sealability• Principles of Human Factors critical task analysis• Physical, people and cyber security requirements of Containment Level 3 & 4 facilities and of dual-use agents
GM	<ul style="list-style-type: none">• Key factors in GM risk assessment; including harmful inserts, changed pathogenicity, host range or tropism, human and environmental hazard• Influence of practical parameters such as vector design, technologies used, scale, inherent hazard of agents used• GM risk assessment format & approach• Role of GM Safety Committees	<ul style="list-style-type: none">• Principles re properties, hazards and mitigations of:<ul style="list-style-type: none">- potentially harmful inserts- bacterial gene delivery systems- viral vectors- cell culture technologies- incidents involving GM agents• GM of animals and plants• GM Safety Committees as peer review and governance bodies

BPRS Key knowledge 3 (of 4)

	Registered Biorisk Adviser (RBA)	Registered Biorisk Specialist (RBS)
Waste management	<ul style="list-style-type: none">Basic principles of infectious waste management, including classification, storage, documentation, duty of care, inactivation and disposalMethods of infectious waste treatment including autoclaving, disinfection, incineration and fumigation	<ul style="list-style-type: none">Selection and validation of treatment methods for infectious waste
Transport	<ul style="list-style-type: none">Packing & documentation requirements for transport of IATA Category A and B infectious materials and human samplesImport and export licensing and notification requirements for infectious and other bio materialsRequirements for transport under cryogen preservationRole of Dangerous Goods Safety Advisers	<ul style="list-style-type: none">Moving material from Containment Level 3 or 4 to lower containment – inactivation and innocuity testingSecurity and emergency planning for transport of infectious materials
Competence & training	<ul style="list-style-type: none">Techniques for at-the-bench guidance and toolbox talksDefining and setting competence, training & supervision requirements	<ul style="list-style-type: none">Strategies for development, delivery and assessment of effective biorisk training <p>see co-requisites</p>

BPRS Key knowledge 4 (of 4)

	Registered Biorisk Adviser (RBA)	Registered Biorisk Specialist (RBS)
Incident management	<ul style="list-style-type: none">Emergency preparedness & drillsIncident reporting strategiesBasic incident investigation methods, including 5-whys and ABC analysisStatutory reportingRole of immunisation	<ul style="list-style-type: none">Incident and crisis management planningRoot cause analysisEvents & Causal Factors Analysis
Monitoring	<ul style="list-style-type: none">Analysis, use and limitations of incident metricsKey performance indicators and benchmarkingWorkplace inspection programmesHealth surveillance, including allergens; role of Occupational Health practitioners	<ul style="list-style-type: none">Safety Performance IndicatorsDevelopment and maintenance of a Risk & Opportunity RegisterDevelopment and implementation of process and management audits see co-requisites
Engagement & impact	<ul style="list-style-type: none">Consultation methods for users and managersStrategies for building participation and engagementClarity and parsimony of communication	<ul style="list-style-type: none">Working within formal governance structuresFostering stakeholder relationshipsCommunication strategies
Ethics & sustainability	<ul style="list-style-type: none">Potential environmental impacts of, and ethical matters arising, from biological containment work	<ul style="list-style-type: none">Strategies to reduce environmental impacts of bio containment workEthical practice, including integrity and confidentiality

BPRS Basic skills (for RBA) 1 (of 3)

Evidence for RBA	
Management systems	<ul style="list-style-type: none">• A biorisk management or related policy developed by applicant; or else a critical review of an existing such policy; with evidence of implementation & testing in both cases
Hazard identification	<ul style="list-style-type: none">• Evidence of accurate determination of biological hazard including (as applicable) consideration of: Relevant regulations, published guidance & information, scientific literature, effects of genetic modification, effects of work practices & methods, and input from subject matter experts
Risk assessment	<ul style="list-style-type: none">• Two suitable & sufficient risk assessments of different types of bio hazard (not GM), either produced by the applicant, or which the applicant directly facilitated, with evidence of application of ALARP and selection of containment measures based on hazard properties and risk
Containment & control	<ul style="list-style-type: none">• Evidence of provision of substantive, accurate and reliable advice to workers and other stakeholders on containment requirements, safe methods & working practices, personal protective equipment, disinfection, control hierarchy, and competence, training & supervision
GM	<ul style="list-style-type: none">• Two suitable & sufficient GM risk assessments with at least two of the following different: technology, target agent, vector, inserts, host range / tropism; either produced by the applicant, or which the applicant directly facilitated, with evidence of identification of both human and environmental hazards, assessment of consequent risk, and selection of appropriate containment measures. <p>Can be via a suitable third party, if applicant's employer / clients does not carry out GM work</p>

BPRS Basic skills (for RBA) 2 (of 3)

Evidence for RBA	
Waste management	<ul style="list-style-type: none">• Evidence of provision of substantive, accurate and reliable advice to workers and other stakeholders on treatment of waste• A relevant waste management process developed by applicant; or else a critical review of an existing such process; with evidence of implementation & testing in both cases
Transport	<ul style="list-style-type: none">• Evidence of provision of substantive, accurate and reliable advice to workers on IATA packing and documentation requirements for at least Category B infectious material or human samples Can be via experiential visits with a suitable third party, if applicant's employer / clients does not transport infectious materials
Competence	<ul style="list-style-type: none">• Evidence that applicant has defined, and taken action to address, competence requirements and training needs of workers• Evidence of at least 5 hours of delivery of training via at least one of: inductions, briefings, coaching, toolbox talks, assessed courses
Incident management	<ul style="list-style-type: none">• Evidence of development and implementation of appropriate and effective emergency plans, of carrying out drills to test those plans, and of identification and application of lessons learnt• Two substantive incident investigations, applying two different methods (eg, 5-whys, ABC analysis), and including delineation, planning, tracking and verification of corrective actions

BPRS Basic skills (for RBA) 3 (of 3)

Evidence for RBA	
Monitoring	<ul style="list-style-type: none">• Evidence of establishment of a workplace inspection programme, including planning, development of checklists or other frameworks, involvement of workers & other stakeholders, reporting of findings, delineation and planning corrective and improvement actions, tracking and verifying actions, assessment of programme efficacy• Evidence of collection, collation and analysis of lagging indicators such as incident metrics, and of basic leading indicators such as training data, including setting performance targets and benchmarking against national and relevant sector statistics
Engagement & impact	<ul style="list-style-type: none">• At least two examples of each of the following:<ul style="list-style-type: none">◦ Effective consultation with workers and other stakeholders, on an informal basis and via formal governance structures◦ Clear, concise and effective communication with workers and other stakeholders, using different types of communication◦ Where active participation of workers has been obtained◦ Relevant written feedback from workers and other stakeholders on applicant's consultation, communication and engagement activities, and actions taken by applicant to address feedback
Ethics & sustainability	<ul style="list-style-type: none">• Evidence of a single basic assessment of the environmental impact of biological containment work• An example of an ethical consideration being applied to work

BPRS Extended skills (for RBS) 1 (of 4)

Evidence for RBS	
Management systems	<ul style="list-style-type: none">• Evidence of development and implementation of a biorisk management system in broad alignment with the PDCA approach (eg, ISO 35001, ISO 45001, HSG65); or else evidence of alignment of biorisk management with an existing organisational PDCA-based management system• Evidence of setting strategic objectives for biorisk management; or else alignment of biorisk management with existing wider organisational strategic objectives• Evidence of operational planning, and that planning is informed by risks, monitoring (findings of audits, investigations etc) and strategy
Hazard identification	<ul style="list-style-type: none">• Evidence of development of wider skills in bio hazard identification outside applicant's normal work and workplace, via at least two visits and/or short secondments at other sites with different bio hazards
Risk assessment	<ul style="list-style-type: none">• Evidence of application of, or observation of, at least two different formal risk assessment methods such as SWIFT, HAZOPS, LOPA• Evidence of integration of biorisk assessment with the assessment of wider risks such as health & safety, environment, security, quality, reputation, enterprise, financial or strategic risks

BPRS Extended skills (for RBS) 2 (of 4)

Evidence for RBS	
Containment & control	<ul style="list-style-type: none">• Evidence of collaboration with relevant colleagues, contractors or consultants on the critical maintenance and examination activities required for compliant and reliable bio containment• Evidence of at least one Human Factors safety critical task analysis• Evidence of operational control of security of hazardous biological agents, including appropriate physical and people security measures Can be via experiential visits or secondment with a suitable third party, if applicant's employer / clients does not require high security
GM	<ul style="list-style-type: none">• Evidence of provision of substantive advice and support to a GM Safety Committee carrying out peer review based assessment of risk from GM work up to and including Containment Level 2 (or above), for at least three meetings and at least six assessments Can be via a suitable third party, if applicant's employer / clients does not carry out GM work at Containment Level 2
Waste management	<ul style="list-style-type: none">• Evidence of planning & actions to reduce waste, mitigate hazardous waste, and minimise environmental impact
Transport	<ul style="list-style-type: none">• Evidence of provision of substantive advice and support to workers on IATA packing and documentation requirements for Category A infectious material, including compliance with licencing requirements Can be via experiential visits with a suitable third party, if applicant's employer / client does not transport such materials

BPRS Extended skills (for RBS) 3 (of 4)

Evidence for RBS	
Competence	<ul style="list-style-type: none">• Evidence of development and implementation of a competence management system, including a requirements matrix, and processes for development, verification, maintenance and monitoring of the competencies necessary for biorisk control• Evidence of at least 5 hours of delivery of formal assessed training
Incident management	<ul style="list-style-type: none">• Evidence of incident and crisis management planning; or else evidence of direct engagement with existing wider organisational incident and crisis management planning; and including testing and development via application of both desktop & live exercises• A substantive incident investigation applying Events & Causal Factors Analysis and Root Cause Analysis, and including delineation, planning, tracking and verification of SMARTER corrective actions
Monitoring	<ul style="list-style-type: none">• Evidence of development and implementation of an internal biorisk audit programme in alignment with ISO 19011 or similar framework, including scoping, planning, definition of criteria, presentation of findings, report writing, and delineation, planning, tracking and verification of SMARTER improvement actions• Evidence of collection, collation & analysis of Safety Performance Indicators, including management review and benchmarking

BPRS Extended skills (for RBS) 4 (of 4)

Evidence for RBS

Engagement & impact	<ul style="list-style-type: none">• Evidence of a substantive initiative to increase participation and improve safety culture, including collection and analysis of feedback, evaluation of impact, and identification of lessons learnt• Evidence of active on-going engagement, such as newsletters, posters, staff bulletins, blogs, social media activity, websites etc• Evidence of contribution to decision-making and organisational development, such as membership of formal committees, involvement in project management, facilitating working groups etc• Written feedback from a relevant senior leader assessing efficacy of applicant's consultation, communication and engagement activities• Evidence of support of either a review of biorisk management by relevant stakeholders or a regulatory intervention
Ethics & sustainability	<ul style="list-style-type: none">• Evidence of development and implementation of a measure to reduce the environmental impact of biological containment work• An example of an ethical consideration being applied to work

Possible BPRS / ISTR BSP Grandfather Rights 1

- **ISTR BSP1 → Registered Biorisk Adviser ('RBA')**
 - Meet RBA pre-requisite qualification requirement
 - Comply with RSB *Code of Professional & Ethical Conduct*
 - Register intention to convert by **01 April 2024**
 - Join RSB as Associate and start paying BRPS fee by **01 April 2025**
 - No additional training required
 - Submit evidence portfolio covering gaps*
ISTR BSP1 vs BPRS RBA Essential Skills by **01 April 2028**
 - ISTR BSP1 no longer recognised from **01 April 2025**

* ISTR to carry out a gap analysis to determine this

Possible BPRS / ISTR BSP Grandfather Rights 2

- **ISTR BSP2 → Registered Biorisk Specialist ('RBS')**
 - Meet RBA pre-requisite qualification requirement
 - Comply with RSB *Code of Professional & Ethical Conduct*
 - Register intention to convert by **01 April 2024**
 - Join RSB as Member and start paying BRPS fee by **01 April 2025**
 - RBS training not required, but RBS co-requisite training *ISO Internal Auditor* and *RQF3 Education & Training* to be completed by **01 April 2028**
 - Submit evidence portfolio covering gaps*
ISTR BSP2 vs BPRS RBS Essential Skills by **01 April 2028**
 - ISTR BSP2 no longer recognised from **01 April 2025**

* ISTR to carry out a gap analysis to determine this

Possible BPRS Next Steps

- **06 May 2022** – BSLG approval in principle? start-up funding?
- June 2022 – constitute Steering Group (BSLG / ISTR / RSB)
 - with formal agenda / decisions & actions log
- June-September 2022 – ISTR consultation / BSP gap analysis
- June-September 2022 – consultation with NHS, ABPI etc
- October 2022 – final detailed proposal & plan
- November 2022 – approval by ISTR executive committee
- November 2022 – final approval by BSLG
- December 2022 - March 2023 – implementation and **comms**
- **01 April 2023** – launch scheme