Biorisk Professional Registration Scheme

Application guide

Royal Society of Biology

Contents

Introduction

The Biorisk Professional Registration Scheme

(BPRS) is a programme from the Royal Society of Biology (RSB) to provide a mechanism for those involved in management, control or containment of biorisk to develop and evidence their professional skills and to provide a benchmark of professional competence for duty-holders.

BPRS has been developed by the Biorisk Strategic Leadership Group (BSLG) in conjunction with the RSB. The RSB has an established track record of hosting professional registration and accreditation schemes across the life sciences. BSLG was established in 2017 as part of the HSE Sector Plan for the Bioeconomy and, as its name suggests, its scope covers strategic matters at leadership level, and its members include the UK's main high containment facilities, several leading UK universities and research institutes, NHS England and industry partners. We use the internationally recognised terms 'biorisk' and 'biorisk management' to encompass terms such as 'biosafety', 'biosecurity', 'biocontainment' etc. BPRS has been developed over several years, with input from a wide range of biorisk experts and sector leaders.

Who is the scheme for?

BPRS is for anyone acting as a biorisk practitioner providing advice, support or oversight on the management, control or containment of biological risk. In practice, there are currently a wide range of job titles covering such roles – biological safety or risk officer, adviser or manager, and several more. These roles can be in a wide range of organisations – universities, research institutes, government labs, NHS pathology labs, biotechnology, pharmaceuticals; and in a wide range of contexts – research labs, diagnostic testing labs, animal facilities, manufacturing facilities etc.

The **Registered Biorisk Adviser (RBA) pathway** is intended for new biorisk practitioners and/or those who require a basic level of recognised competence and/or those who are supporting work of lesser inherent risk at lower biocontainment levels.

The advanced **Registered Biorisk Specialist (RBS) pathway** is intended for biorisk practitioners developing a career as a biorisk adviser/specialist and/or who need a higher level of recognised competence and/or are supporting more complex work of greater inherent risk at higher biocontainment levels.

RBS thus builds on RBA, which is a prerequisite for RBS. RBA and then RBS provides a career development pathway for registrants that unlocks career opportunities, facilitates progression and equips them with the right knowledge and skills.

BPRS recognises that not all registrants will, in their current role, directly need all of the knowledge and skills that the scheme specifies, but the objective is to produce biorisk professionals with comprehensive all-round capabilities who can respond flexibly to different situations and are well-equipped to progress their careers to new roles. BPRS not only directly benefits registrants by extending their knowledge, but also enables them to demonstrate defined, recognised and maintained (via continuing professional development, or CPD) skills and competence to employers, clients and stakeholders. It is recognised that some applicants may not be able to directly evidence certain skills if not part of their current role – the scheme recommends alternative means in such situations (see the appendix to this guide for more details) and welcomes queries where registrants are struggling to evidence a particular skill.

What are the key benefits of BPRS?

- Provides registrants with recognised professional status, and a clear career development pathway.
- Has credibility under the RSB as a professional body with a Royal Charter.
- Is sponsored and supported by the major organisations within the bioeconomy sector via BSLG.
- Allows registrants to demonstrate commitment to continuing professional development (CPD) and facilitates this via the recognised RSB CPD scheme and recording tool.
- Provides duty-holders, decision-makers and budget-holders with a robust, credible and
- recognised benchmark of biorisk practitioner competency, which can be verified through a searchable online register maintained by the RSB.

Is BPRS approved or accredited by the Health and Safety Executive (HSE)?

No. HSE does not currently approve or accredit any training or registration schemes for biorisk practitioners, and nor does it plan to. Although HSE is a member of BSLG, this does not imply any kind of approval or endorsement. However, BPRS registration should help registrants, and employers and duty holders, demonstrate compliance with regulatory requirements for 'competent assistance'.

Aims and objectives of BPRS

Aims:

- To define a competency framework of the key technical knowledge and essential skills required for biorisk professionals to successfully provide reliable professional biorisk advice and support to their stakeholders, for all levels and types of biocontainment.
- To maintain a professional accreditation scheme as an objective benchmark of the above biorisk competency for stakeholders across the bioeconomy sector, including (but not limited to) research, healthcare and industry.
- To raise standards and consistency of biorisk management across the bioeconomy sector by advancing the quality and reliability of advice and support available to users, managers and duty-holders.
- To provide objective assurance and benchmarking of the competence of biorisk advisers, to thus empower stakeholders to obtain advice and choose advisers with confidence.
- To enhance the containment of hazardous biological agents and control of biorisk, to improve protection of people, animals, plants and the environment to the benefit of organisations and wider society.
- To foster international equivalence and recognition of biorisk management practice.
- To enhance the professional status of biorisk advisers.

Objectives:

- Cultivate a balance of knowledge and skills, focusing on what biorisk professionals can do for stakeholders, rather than on what they know.
- Develop biorisk professionals who, through appropriate assessment, have evidentially and objectively demonstrated the defined core knowledge and essential skills.
- Accommodate the whole range of biorisk practice, including work at all containment levels, and either full-time, part-time or as part of another role.
- Provide a benchmark of biorisk practitioner competence across the bioeconomy sector, and a public database for verification of registration status.

Structure of BPRS

BPRS consists of two levels of registration: **Registered Biorisk Adviser** (RBA) and **Registered Biorisk Specialist** (RBS). RBS is intended as a 'higher' level to RBA. For both levels, there is a **key knowledge** component and an **essential skills** component. The former will be evidenced largely from training, and the latter will be demonstrated largely from a portfolio of evidence. The intention is to ensure registrants have both an understanding of technical and organisational measures for biorisk containment and control, and a set of wider applied skills (sometimes referred to as 'soft' skills) that enable them to be effective in their role.

Both RBA and RBS are built around 12 elements of biorisk management practice:

- Management systems
- Hazard identification
- Risk assessment
- Containment and control
- Genetic modification (GM)
- Waste management
- Transport
- Competence and training
- Incident management
- Monitoring
- Engagement and impact
- Ethics and sustainability

The detailed knowledge and skills requirements for RBA and RBS under each of these 12 elements are set out in detail in the appendix to this guide.

Compliance with the RSB Code of Professional and Ethical Conduct is a requirement, both for entry and for continuing registration. The Code can be found at found at www.rsb.org.uk/images/Governance/Code_of_Professional_and_Ethical_Conduct.pdf

RBA entry requirements

To join the scheme at RBA level, a qualification in life sciences (or a related subject) at RQF5 level (Diploma/HND) or above is required. There is scope for recognition of alternative qualifications, experiential learning and/or other STEM subjects – please contact the RSB team at registers@rsb.org.uk to discuss.

Applicants for RBA are also required to join the RSB at a minimum of Associate (AMRSB) level. For details see www.rsb.org.uk/membership/individual-membership/associate-amrsb

Other non-UK qualifications and accreditations in biorisk management may be considered as alternative entry routes for RBA – please contact the RSB team at registers@rsb.org.uk to discuss.

RBS entry requirements

To join the scheme at RBS level, prior registration in BPRS as RBA is required, along with a minimum of four years' full-time equivalent work with biological agents at Containment Level 2 or in an 'open' uncontained laboratory (or operational management or support of such work), or a minimum of two years' full-time equivalent work with biological agents at Containment Level 3 or 4 (or operational management or support of such work). There is scope for recognition of a variety of relevant other experience and work backgrounds – please contact the RSB team at registers@rsb.org.uk to discuss.

For RBS, formal training as an auditor and as a trainer is also required. An example of courses that would meet these respective requirements are the ISO 45001, OHSAS 18001, ISO 14001 or ISO 9001 auditor courses, the RQF3 certificate in Education & Training (or the previous PTLLS certificate), or a suitable 'Train-the-trainer' course. Significant equivalent professional experience to demonstrate these requirements may be acceptable as an alternative to formal training – please contact the RSB team at registers@rsb.org.uk to discuss.

Applicants for RBS are also required to join the RSB at a minimum of Member (MRSB) level. For details see www.rsb.org.uk/membership/individual-membership/member-mrsb

Other non-UK qualifications and accreditations in biorisk management may be considered as alternative entry routes for RBS – please contact the RSB team at registers@rsb.org.uk to discuss.

Alternative routes to entry until 30 June 2026

Until 30 June 2026, Level 1 Biosafety Practitioners (BSP1) can become RBA, subject to verification of BSP1 status, joining the RSB at a minimum of Associate (AMRSB) level, and providing the evidence for the essential skills component of RBA.

Until 30 June 2026, Level 2 Biosafety Practitioners (BSP2) can directly become RBS, subject to verification of BSP2 status, joining the RSB at a minimum of Member (MRSB) level, and to final approval by the BPRS Committee. There is no requirement for evidence for the essential skills component of RBS via this route.

Meeting registration requirements

The Key Knowledge component of RBA is attained through successful completion of a suitable training programme, evidenced by certificates of assessment and confirmation of assessments passed. The course(s) used must be ones approved for this purpose by BPRS – please see rsb.org.uk/biorisk-register for a list of these.

The Key Knowledge component of RBS is attained through either successful completion of suitable training modules, evidenced by certificates of assessment and confirmation of assessments passed, or through provision of evidence that the applicant has otherwise acquired the relevant knowledge, usually by showing how it was acquired, applied and maintained through CPD. Any course(s) used must be ones approved for this purpose by BPRS – please see rsb.org.uk/biorisk-register for a list of these or contact the RSB team at registers@rsb.org.uk if unsure.

The Essential Skills component of both RBA and RBS are demonstrated by a combination of written evidence and supporting materials, which together make up a portfolio of evidence. Where this evidence includes documents containing confidential or sensitive material, then such information may be redacted. Please contact the RSB team at registers@rsb.org.uk if you have queries or concerns on confidentiality.

See the appendix to this guide for more details.

Maintenance of registration

Once awarded, the maintenance of RBA or RBS status is contingent on:

- Continuing membership of the RSB at the requisite minimum level (AMRSB for RBA and MRSB for RBS)
- Continuing compliance with the RSB Code of Professional and Ethical Conduct
- Fulfilment of RSB continuing professional development (CPD) requirements

Registrants who don't conform with any of these conditions will receive a written warning and three months' notice to remedy the situation, and then their registration will be terminated. Re-entry to BPRS is at the discretion of the BPRS Committee. Breaches of the Code of Conduct are dealt with by the RSB under its disciplinary procedures, and can result in immediate termination of registration.

If you are taking a career break, this can usually be accommodated – please contact the RSB team at registers@rsb.org.uk to discuss.

Continuing professional development (CPD)

CPD is a mandatory part of maintaining professional registration. It is a mechanism by which you document the work you do above and beyond your role, aiding career progression. The RSB CPD scheme is wide-ranging, as the RSB appreciates members come from a wide range of life science sectors. To retain BPRS registration, you must pass the annual requirements for RSB CPD every year. There is a single system used for all RSB registrants. If you experience circumstances that may prevent you from partaking in CPD (for instance, long-term leave), please contact the RSB team on registers@rsb.org.uk.

The CPD scheme is points-based, with 50 points required each year. These are achieved in quanta of one to three points per hour, depending on the activity. Almost any activity that develops your skills in relation to BPRS will qualify for CPD, and if you allocate points for an activity not automatically awarding CPD points you will have to evidence this. A small selection of examples includes: training staff, learning a new technique, presenting at a conference or seminar, self-study in any relevant area of interest etc. For full guidance on RSB CPD, please see rsb.org.uk/careers-and-cpd/cpd

As a registrant on BPRS, you will have automatic access to the RSB online members' portal, where you can manage your CPD. Here you can upload details of each activity, time spent on it, and reflect on how it affected your professional development. You can add activities as often as you wish, up to a maximum of 10, 20 or 30 points per area depending on activity (1. Work-based learning, 2. Professional activity, 3. Formal/educational, 4. Self-directed learning, 5. Other). On completion of your CPD year, if the full 50 points have been achieved, you will receive certification confirming this. You will receive reminders throughout the year on how many points you have achieved so far, and how many you have left to record.

The RSB understands that some BPRS registrants may be subject to other CPD schemes, such as for the Institution of Occupational Safety and Health (IOSH). The RSB recognises that the IOSH CPD scheme follows similar requirements, and so any registrant using the IOSH CPD scheme can be exempt from the RSB CPD scheme. Please email registers@rsb.org.uk if this is the case. Once each year, we will ask that anyone using IOSH CPD sends a documented confirmation of their successful CPD.

The RSB audits a randomly selected group of registrants a year. Those selected have their records reviewed by qualified assessors. Registrants will be contacted by email to advise of the audit, and following initial review, will be given eight weeks to submit any additional information necessary. If the audit concludes that the registrant has not sufficiently maintained CPD to the required standard, the registrant will be given two months to submit further information and guidance on what is required. If this is not provided by the two-month deadline, BPRS registration may be terminated.

Appendix: Application requirements

This appendix sets out the detailed knowledge and skills requirements for both BPRS pathways: Registered Biorisk Adviser (RBA) and Registered Biorisk Specialist (RBS); under each of the 12 elements of biorisk management practice set out in the guide.

Important notes for applicants

The examples given in this appendix of evidence for each of the essential skills requirements were provided by practising biorisk advisers, and show the kinds of evidence that they would use to demonstrate essential skills. These examples are not intended to be an exhaustive list, but rather as indicative suggestions to illustrate possible approaches – there will be other possibilities. More than one example is provided in many cases, but applicants need only submit sufficient evidence to demonstrate the requirement. If you are unsure whether a particular piece of evidence is relevant, are struggling to produce evidence or are unsure whether your evidence is suitable or sufficient, please contact the RSB team at registers@rsb.org.uk for further support.

If any submitted evidence is not suitable and sufficient, then BPRS assessors will usually explain why, provide guidance on what is needed to fulfil requirements and give the applicant an opportunity to submit revised and/or additional evidence. Where an applicant has difficulty evidencing particular elements owing to factors such as the size, structure or work of their employer, it is strongly advised that the applicant seeks advice and support from the RSB team at registers@rsb.org.uk before submission.

When submitting evidence, it is very important that applicants make clear which of the 12 elements each item of submitted evidence supports. A particular evidence item can support more than one of the 12 elements (different evidence is not necessarily required for each of the elements), but again, this should be clearly stated. The element number(s) (01-12) should be included as a prefix in the filename of uploaded documents to help identify them. It will also assist assessors if evidence items are submitted in the same order as they appear in this BPRS Guide. It may be useful to add short cover notes to items of evidence to place that evidence and the applicant's contribution into perspective.

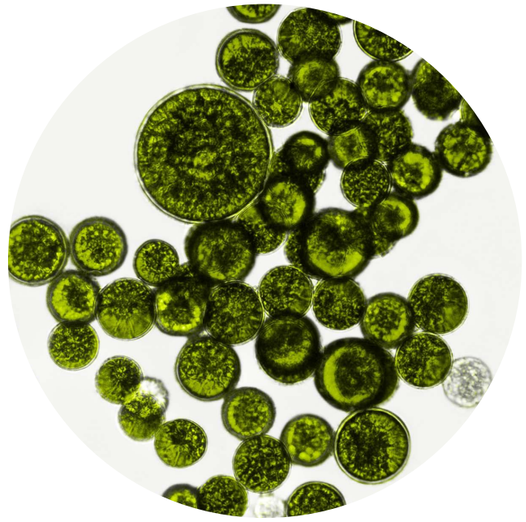
Any personal data (ie, information relating to a person who can be identified, directly or indirectly, by an identifier such as name, location, photo, or other factor) in submitted evidence must be redacted. If any submitted evidence could compromise national security or the commercial interests or intellectual property of employer/client, the applicant must discuss with both their employer/client and the RSB team at registers@rsb.org.uk. The RSB keeps submitted evidence confidential and secure, and submitted evidence is accessed and viewed only by the RSB staff administrating the scheme and by the BPRS assessors assigned to review the submission. Details of the RSB's privacy policy can be found at my.rsb.org.uk/item.php?privacy=1

Submitted evidence remains the intellectual property (IP) of the applicant and/or their employer/client, and will not be used (other than for assessment as above) or shared with any third party without the express permission of the applicant. Where the submitted evidence includes the IP of others, applicants are expected to make that clear.

If you do not have direct experience or evidence from your workplace for an essential skills element, applicants may include a written explanation of their relevant knowledge and provide a written worked example based on an appropriate hypothetical scenario. Such worked examples can also be drawn from liaison with colleagues or other peers outside your workplace who have direct experience of the skills element concerned. In evidencing skills, applicants can also draw on evidence from relevant external training or from experience gained in a previous job-role or through a third party.

"When submitting evidence, it is very important that applicants make clear which of the 12 elements each item of submitted evidence supports"

Use of artificial intelligence (AI) in register applications: Register competencies are designed to facilitate effective review of an applicant's personal responsibility, competencies and skills within their professional experience. In this context, the RSB acknowledges that AI tools or large language models (such as ChatGPT) may appropriately and ethically be employed as aids in composing a register application (for example, for translation, spelling and grammar/restructuring purposes). Applicants bear responsibility for the originality, validity and integrity of the content in their application, even when employing AI tools for certain elements. Unethical use of AI (for example, generating generic or untrue evidence statements that don't relate (or pertain) to the applicant's personal experiences) may result in a misconduct investigation.



RBA (Registered Biorisk Adviser)			
Prerequisites	Minimum RQF5 (ie, Diploma/HND level or above) in a life science or related subject		
Co-requisites	RSB Associate Member (AMRSB) or higher and compliance with the RSB Code of Professional and Ethical Conduct		
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
	Defined basic knowledge of biorisk and its management from successful completion of an approved training course	Suitable and sufficient evidence of development and application of basic skills in biorisk management	
1 Management systems	Duties, roles and responsibilities for planning, organisation, control, monitoring and review in the management of biorisk	A biorisk management or related policy developed by the applicant, or else a critical review of an existing such policy; with (in either case) evidence of implementation and testing	A 'Biological Agents Policy and Procedure' and 'Occupational Exposure to Biological Agents Policy and Procedure' that I helped to develop and apply, and presented at relevant committees for consultation, as recorded in minutes of those committees (CL3 User Group, Main H&S Committee and Biological Safety Sub-Committee) My implementation of policy and procedure through H&S Bulletin and then monitoring of testing, evidenced through my reports to the Main H&S Committee providing updates on any feedback or issues in use of these policies
2 Hazard identification	Classification of biohazard, including human, animal and plant pathogens Relationship to biohazard to pathogenicity, epidemiology, infectious dose, transmission routes, medical data, environmental stability Relationship to biohazard of sample type, methods, equipment, frequency	Evidence of accurate determination of biological hazard including (as applicable) consideration of: ● Relevant regulations ● Published guidance and information ● Scientific literature ● Effects of genetic modification ● Effects of different work practices and methods ● Input from subject matter experts	Emails and meeting minutes showing my reference and application of appropriate legislation such as SAPO, COSHH, ATCSA to determine biological hazard rating My attendance certificates for training courses relevant to biological hazard identification Opinions (via emails) solicited by me from disease consultant or other experts where required My provision of advice given to project planning regarding biohazard, via meeting minutes and project plans Minutes of GMO Committee showing my attendance, and Terms of Reference confirming my role, responsibility and inputs to decision-making Emails and minutes showing my review of a GM risk assessment, determining what control measures are already in place and what further controls need to be deployed Audit and inspection reports of a CL2 facility that I conducted / was a part of A literature review that I prepared A general biological risk assessment I wrote covering human, animal, plant pathogens and GMOs, providing case studies, scenarios and literature review, and taking account of relevant pathogen transmission routes and infection doses
3 Risk assessment	Basic biorisk assessment Application of the ALARP principle Selection of containment measures based on risk and on hazard properties	Two suitable and sufficient risk assessments of different types of biohazard (not GM), either produced by the applicant, or which the applicant directly facilitated; with (in either case) evidence of application of ALARP and selection of containment measures based on hazard properties and risk	Minutes of the safety meetings where, as BSO, I led discussion of COSHH risk assessments and COSHH risk assessments with my track changes and comments This shows my inputs on bio agent identification, hazards associated with the technique(s) used, and the containment and controls required Two risk assessments I prepared related to different biohazards, with different modes of transmission (one airborne, one vector-borne) and different hosts (human-only pathogen versus animal pathogen)

RBA (Registered Biorisk Adviser)			
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
4 Containment and control	Design and operational requirements for Containment Level 2 facilities Basic operating principles of Containment Level 3 and 4 facilities Good microbiological practice Function, use, maintenance and testing of Microbiological Safety Cabinets, centrifuges, autoclaves and other equipment impacting biorisk Basic security considerations	Evidence of provision of substantive, accurate and reliable advice to workers and other stakeholders on containment requirements, safe methods and working practices, personal protective equipment, disinfection, control hierarchy, and competence, training and supervision	Emails, meeting minutes and annotated documents demonstrating my advice to staff, facility management and contractors on new or refurbishment of CL2 biocontainment laboratory infrastructure design or containment systems Emails, meeting minutes and risk assessment advice and reviews demonstrating my knowledge and application of the controls hierarchy Emails, meeting minutes and risk assessment reviews demonstrating my guidance to staff and workplace and facility managers on containment systems or equipment, from selection of most appropriate equipment and control measures to effectively control the hazard(s), to advice on its safe use or application for the work, and frequency and standard of testing requirements Emails, meeting minutes, technical reviews and audit and inspection reports showing my guidance on biosecurity matters or changes impacting facilities holding or using Schedule 5 materials Records showing my liaison with a contractor for regular checks and maintenance of safety cabinets and autoclaves
5 Genetic modification	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 and approach Role of GM Safety Committees	Two suitable and sufficient GM risk assessments with at least two of the following being different: Technology, target agent, vector, inserts, or host range/tropism, either produced by the applicant, or which the applicant directly facilitated; with (in either case) evidence of identification of both human and environmental hazards, assessment of consequent risk, and selection of appropriate containment measures	Risk assessments that show my contribution to discussion of GM hazards through tracked changes or written comments on relevant documents, covering a range of GM hazards Risk assessments I helped prepare, showing both human and environment hazards, and where I helped justify a GM hazard classification, and where the GM changed the hazard classification of the pathogen used Minutes from GM Safety Committee meetings, with my attendance and inputs demonstrated, including Terms of Reference confirming my role on the committee Note: If applicant's employer or clients do not carry out GM work, then this element can be evidenced through either assisting with GM risk assessment at a suitable third-party partner, or using a case study (contact the RSB team at registers@rsb.org.uk for details)
6 Waste management	Basic principles of infectious waste management, including classification, storage, documentation, duty of care, inactivation and disposal Methods of infectious waste treatment including autoclaving, disinfection, incineration and fumigation	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 (in either case) evidence of implementation and testing	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 (in either case) evidence of implementation and testing
7 Transport	Packing and documentation requirements for transport of IATA Category A and B infectious materials and human samples Import and export licensing and notification requirements for infectious and other bio materials Requirements for transport under cryogen preservation Role of dangerous goods safety advisers	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	Guidance I wrote outlining internal processes for import and export of biological material, which includes description of packaging and document requirements for Category A and B materials Certificate and course materials showing my successful completion of a three-day IATA training course Note: If applicant's employer or clients do not transport infectious materials, then this element can be evidenced through either an experiential visit assisting at a suitable third-party partner, or using a case study (contact the RSB team at registers@rsb.org.uk for details)

RBA (Registered Biorisk Adviser)			
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
8 Competence and training	Techniques for at-the-bench guidance and toolbox talks Defining and setting competence, training and supervision requirements	Evidence that applicant has defined, and taken action to address, competence requirements and training needs of workers Evidence of at least five hours of delivery of training via at least one of: Inductions, briefings, coaching, toolbox talks, assessed courses	Induction and training checklists I prepared and used for new staff or new tasks Evidence showing my contribution to microbiological specific Health & Safety training, both desktop and practical, including training needs analysis, detailed lesson plans and training slides created
9 Incident management	Emergency preparedness and drills Incident reporting strategies Basic incident investigation methods, including 5-whys and ABC analysis Statutory reporting Role of immunisation	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 learned Two substantive incident investigations, applying two different methods (eg 5-whys, ABC analysis), and including delineation, planning, tracking and verification of corrective actions	Emails, meeting minutes, documents with track changes showing my contribution to development of site incident management procedures, particularly for specific incident procedures for high containment laboratories. These are under a wider set of business continuity plans that include testing of plans and ensuring lessons learned processes are carried out following an incident, and minutes and reports show that I was part of the incident team acting as H&S expert on biorisk activities Documents demonstrating my role as lead investigator in the 'Accident and Incident Reporting and Investigation Procedure'. Certification of my training in use of human factors in accident and incident investigations, including 5-whys and ABC analysis, and examples of investigation reports that I led on
10 Monitoring	Analysis, use and limitations of incident metrics Key performance indicators (KPIs) and benchmarking Workplace inspection programmes Health surveillance, including allergens; role of occupational health practitioners	Evidence of establishment of a workplace inspection programme, or of substantive contribution to an established inspection programme, including planning, development of checklists or other frameworks, involvement of workers and other stakeholders, reporting of findings delineation and planning corrective and improvement actions, tracking and verifying actions, and assessment of programme efficacy Evidence of collection, collation and analysis of lagging indicators, such as incident metrics, and of basic leading safety performance indicators such as training data, including setting performance targets and benchmarking against national and relevant sector statistics	Copies of inspections that I carried out, and evidence such as emails showing my input into the generation of metrics and KPIs. Slides and minutes showing my presentation of KPIs and benchmarking to internal stakeholders Reports I wrote communicating findings from various monitoring activities, and evidence from meeting minutes of my discussion of corrective and improvement actions with stakeholders Evidence of my involvement with the setting of lagging or leading indicators through minutes from safety meetings or management one-to-ones Evidence of my attendance at meetings discussing benchmarking, and my involvement in discussions related to relevant comparable institutions
11 Engagement and impact	Consultation methods for users and managers Strategies for building participation and engagement Clarity and parsimony of communication	At least one example for each of: Effective consultation with workers and stakeholders, on an informal basis, and via formal governance Clear and effective communication with workers and stakeholders, using two different types of communication Active participation of workers Written feedback from stakeholders on applicant's communication and engagement, and action on feedback	Evidence (such as emails, document versions) of advice I gave during the update of a risk assessment and procedure Evidence (such as minutes, papers and presentations) of my circulating an updated policy and procedure to the formal groups of H&S Committee and Biosafety & GMO Committee, with detail provided on outcomes and following actions Evidence of my interaction with users of a biological facility, including being part of a risk assessment team, providing on-the-job training, and involvement with inspections and agreeing subsequent actions with lab workers A reference from a project sponsor, including examples of my involvement, areas of successful contribution and opportunities for future development or focus
12 Ethics and sustainability	Potential environmental impacts of, and ethical matters arising from, biological containment work	Evidence of a basic assessment of the environmental impact of biological containment An example of where an ethical consideration was applied to work	A review I carried out of waste management procedures Documents showing my involvement in the development of an aspects and impacts register covering biological facilities Evidence that I conducted a waste management duty-of-care audit, including attending contractor processing sites, and checking licences and transfer notes Evidence that I carried out inspections that include environmental requirements Evidence of me seeking and obtaining ethical approval for work with human blood or tissue samples

RBS (Registered Biorisk Specialist)			
Prerequisites	RBA registration and a minimum of four years' full-time equivalent work with biological agents at Containment Level 1 or 2 (or operational management or support of such work) or a minimum of two years' full-time equivalent work with biological agents at Containment Level 3 or 4 (or operational management or support of such work)		
Co-requisites	RSB Member (MRSB) or higher and compliance with the RSB Code of Professional and Ethical Conduct, and ISO 45001 Internal Auditor training or equivalent qualification or experiential learning (see guide), and RQF3 Certificate in Education & Training or equivalent qualification or experiential learning (see guide)		
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
	Defined expanded knowledge of biorisk and its management from either successful completion of suitable training modules and/or provision of evidence that the relevant knowledge has been otherwise acquired, showing how it was acquired and applied	Suitable and sufficient evidence of development and application of extended skills in biorisk management	
1 Management systems	Overview of the PDCA management cycle and standards Features of effective leadership	Evidence of development and implementation of a biorisk management system in broad alignment with the PDCA approach (eg ISO 35001, ISO 45001, HSG65) or evidence of alignment of biorisk management with an existing organisational PDCA-based management system Evidence of setting strategic objectives for biorisk management or evidence of alignment of biorisk management with existing organisational strategic objectives Evidence of operational planning and of how that planning is informed by risk, by monitoring (audit and investigation findings) and by strategy	H&S policy that I developed for my employer (with email from CEO confirming I led on this) that outlines overall scope of the OH&S management system including alignment with HSG65 for biorisk activities and Process Safety Leadership Group (PSLG) principles for Major Hazard Work Mandatory training requirements that I coordinated (with email from COO confirming I led on this) for all staff based on PDCA process for the H&S management system H&S strategy that I led, evidenced by emails and meeting minutes, that includes objectives for biorisk management H&S reports to my employer's Audit & Risk Assurance Committee showing via meeting agenda and minutes how I ensured risks, issues and trends were escalated appropriately and linked to H&S strategy action plan
2 Hazard identification	Interactions between biohazard and other health and safety hazards Potential 'dual use'/security threats associated with biological agents	Evidence of development of wider skills in biohazard identification outside applicant's normal work and workplace, via at least two visits or short secondments at other sites with different biohazards	A multi-species risk assessment that I prepared, with documented evidence of drafting, collecting feedback and seeking management review and approval Confirmation from hosts of my visits to organisations to assist with biohazard identification, to include report and outputs of learning outcomes and changes made following the visit Evidence of my facilitating hazard identification and risk analysis using developed case studies, such as: ● Risk assessment of an unclassified pathogen ● Diagnostic samples from patient with travel history ● Multiple pathogens present ● SAPO pathogen ● Dual-use considerations Relevant guidance, codes of practice and similar I prepared, with verification by a senior manager of my authorship
3 Risk assessment	Overview of process and functional safety assessments (eg SWIFT, HAZOP, LOPA) of containment Application of human factors safety critical task analysis to containment	Evidence of application of, or observation of, at least two different formal risk assessment methods such as SWIFT, HAZOP, LOPA Evidence of integration of biorisk assessment with the assessment of wider risks such as health and safety, environment, security, quality, reputation, enterprise, financial or strategic risks	HAZOP study that I organised and supported of interlocking system in a CL3 laboratory with a pressure cascade, including scenario testing of fans failure; and a SWIFT assessment that I organised and supported for removal of casualties from a CL3 laboratory by emergency services, e.g. accident while person handling a GM SAPO3 agent that is also listed in the Schedule 5 of ATCSA

RBS (Registered Biorisk Specialist)			
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
4 Containment and control	Design, operational, maintenance and testing requirements for Containment Level 3 and 4 facilities, including decontamination, fumigation and sealability Principles of human factors critical task analysis Physical, people and cybersecurity requirements of Containment Level 3 and 4 facilities and of dual-use agents	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	Evidence (emails, meeting minutes, document reviews) of my advising staff, facility managers, contractors on standards and design requirements for refurbishment of a CL3 laboratory, including infrastructure and containment systems Evidence (policy and guidance I wrote) of my review of lab sealability testing and disinfection processes, establishing validation processes and applying the controls hierarchy A critical task analysis that I organised and contributed to, and evidence of role and of outputs of improved process, better structured procedures and job-aids. Also evidence of my basic training in this area, and its application into policy and guidance documents, and awareness training of others Evidence (emails giving guidance on this topic, inspection and audit reports on facility security and copies of actions) of my identifying and implementing improvements to biosecurity and cybersecurity for a high containment facility holding ATCSA Schedule 5 materials. Also evidence of basic cybersecurity training I undertook, copies of biosecurity and cybersecurity risk assessments I wrote, and my correspondence with regulators including CTSA and HSE on such matters Note: If applicant's employer or clients do not require security above routine levels, then this element can be evidenced through either an experiential visit with a suitable third-party partner, or using a case study (contact the RSB team at registers@rsb.org.uk for details)
5 Genetic modification	Principles regarding properties, hazards and mitigations of: • 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	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	Evidence from minutes of having supported GM Safety Committee as BSO and at some meetings as chair, and document reviews showing my detailed scrutiny of GM risk assessments with multiple complex principles and multiple hazards, both human and environmental Evidence from Terms of Reference of how I set up and organised the GM Safety Committee, and the copies of my submissions of GM proposals and assessment to the national competent authority (HSE) for approval Evidence from line manager verification of significant time I spent working with GMOs in a regulated environment, demonstrating my knowledge of the work involved and responsibilities for getting the work assessed and approved by internal and external stakeholders Document reviews and emails showing my provision of advice on non-standard GM hazard, e.g. work with animal or plant pathogens where hazard group is not pre-defined Copies of notifications I completed to the national competent authority (HSE) of new GM work Document reviews and emails highlighting my in-depth understanding of the potential pathogenic, toxic and environmental hazards of GMOs Note: If applicant's employer or clients do not carry out GM work at Containment Level 2 or above, then this element can be evidenced through either assisting with GM Safety Committee work at a suitable third-party partner, or using a case study (contact the RSB team at registers@rsb.org.uk for details)
6 Waste management	Selection and validation of treatment methods for infectious waste	Evidence of planning and actions to reduce waste, mitigate hazardous waste and minimise environmental impact	Document reviews showing my involvement in assessment of waste contractors, including a sustainability focus Copies of documents showing my development and implementation of an autoclave validation and servicing programme, including assessment of suitability for different type of loads, and my advice on suitable performance monitoring of autoclave runs

RBS (Registered Biorisk Specialist)			
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
7 Transport	Moving material from Containment Level 3 or 4 to lower containment – inactivation and innocuity testing Security and emergency planning for transport of infectious materials	Evidence of provision of substantive advice and support to workers on IATA packing and documentation requirements for Category A infectious material, including compliance with licensing requirements	Standard operating procedures I prepared, as verified by head of faculty, for sending and receiving category A materials, together with the guidance I wrote for import and export of materials that covers the licensing requirements for different types of materials Note: If applicant's employer or clients do not transport Category A infectious materials, then this element can be evidenced through either an experiential visit assisting at a suitable third-party partner, or using a case study (contact the RSB team at registers@rsb.org.uk for details)
8 Competence and training	Strategies for development, delivery and assessment of effective biorisk training Note: this is covered by the training qualification requirement in the co-requisites, and does not need to be further covered beyond outlining its importance for effective biorisk management	Evidence of development and delivery of a substantial training course on, or related to, biorisk management, containment or control, including appropriate learning objectives and assessment thereof, and effective supporting materials. This course can be either classroom-based or online, or a hybrid of both, and should involve at least one hour of participant learning time	Evidence of my development, delivery, assessment and evaluation of efficacy of training courses on biorisk topics (GM, CL3, Safety Cabinets), including learning objectives, plans, slides, handouts, assessments, feedback sheets and evaluation briefs, as verified by relevant managers
9 Incident management	Incident and crisis management planning Root cause analysis Events and causal factors analysis	Evidence of incident and crisis management planning, or else evidence of direct engagement with existing wider organisational incident and crisis management planning; including testing and development via application of both desktop and live exercises A substantive incident investigation applying events and causal factors analysis and root cause analysis, and including delineation, planning, tracking and verification of SMARTER corrective actions	Evidence (emails, meeting minutes, document reviews, reports) of my direct support to the business continuity and incident response leads for my employer, providing biosafety inputs to plans and incident support, and including participation in drills and exercises Evidence of my training in incident response planning and processes, and also on the lead investigator role for carrying out root cause analysis, corrective action planning, and lessons learned reviews following incidents Evidence (summary reports) of my acting as the lead in a bio-based incident scenario exercise involving a major spill and another based on a fumigant leak, including evidence of seeking and applying best practice
10 Monitoring	Safety Performance Indicators (SPIs) Development and maintenance of a risk and opportunity register Development and implementation of process and management audits Note: Audit is covered by the audit qualification requirement in the co-requisites, and does not need to be further covered beyond outlining its importance for effective biorisk management	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 and analysis of SPIs, including management review and benchmarking	Evidence from reports and similar of my leading audits relevant to biorisk management, working within a recognised quality framework, including showing how I scoped and planned the audit and presented findings to stakeholders Evidence from emails and meeting minutes of my active involvement in the development of an audit programme that includes audits of, or related to, biorisk management Minutes from internal and external meetings where I presented SPIs and other assurance data to stakeholders Evidence from emails, meeting minutes and similar of my inputs on action tracking and my support for verification of actions and assessment of their effectiveness

RBS (Registered Biorisk Specialist)			
Biorisk management element	**Key Knowledge requirements**	**Essential Skills requirements**	**Examples of evidence demonstrating Essential Skills requirements**
11 Engagement and impact	Working within formal governance structures Fostering stakeholder relationships Communication strategies	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 learned Evidence of active ongoing 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	Documented evidence of my attendance and presentations at relevant internal and external meetings Document reviews showing my inputs to codes of practice, showing changes made, consultation undertaken, and implementation and effectiveness review of changes Evidence of development of a safety engagement programme involving team safety champions and a programme of safety moments, including Terms of Reference, a Champion Charter, and evidence of safety moments via documents, presentations, meeting minutes, and my drafting of learning outcomes Examples of an EHS newsletter I edited with focus on biosafety and biosecurity topics, and learning campaigns My presentations providing biorisk updates at Institute H&S committee, and updating leadership committee on biosafety performance, impacts and recommended actions Evidence of preparations for a regulatory inspection, including emails, meeting minutes, action plans, review and update of risk assessment and procedures, consultation and briefing of research groups, presentations of the agenda, and communication of findings and learnings from the visit
12 Ethics and sustainability	Strategies to reduce environmental impacts of bio containment work Ethical practice, including integrity and confidentiality International treaties relevant to ethics, including Nagoya Protocol, Biological & Toxin Weapons Convention (BTWC) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)	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, such as Nagoya, BTWC or CITES	Evidence from reports and meeting minutes of my involvement in annual review of air handling efficiency, including proactive PPM Evidence from reports and meeting minutes of my involvement in supplier audit and review in relation to environmental accreditation and performance, and to ethical supply sourcing Documents for a plastic packaging audit across bio labs that I organised, including key supplier reviews Guidance that I prepared to educate lab workers on what can be recycled, and how they can improve recycling output Evidence from emails and meeting minutes of my involvement in implementation of sustainable lab initiatives

Further information/ contact details

If you have any questions regarding BPRS or the information provided in this guide, or have any concerns that have not been addressed, please contact the RSB team at registers@rsb.org.uk

Royal Society of Biology

1 Naoroji Street, London WC1X 0GB
info@rsb.org.uk
+44 (0)20 3925 3440
Registered Charity No.277981
Incorporated by Royal Charter