The Biosafety Professional accreditation scheme

Background

The Biosafety practitioner competency framework, developed by the ISTR with the support of the Health and Safety Executive, has now been extended to include a higher level accreditation for biosafety professionals. The framework therefore provides for two distinct levels of accreditation;

- The **Biosafety Practitioner** who is able to comprehend and apply the essential concepts of 'biosafety' in executing the day-to-day tasks of advising on, monitoring and enforcing safety standards within their organisation.
- The **Biosafety Professional** (BSP) will have a detailed understanding of most aspects of biosafety and will be capable of applying this knowledge in the development and implementation of policy and strategy within their organisation. The BSP will also be capable of robust technical discussion with senior and, or expert members of staff.

Criteria for application for Biosafety Professional accreditation

Applicants will require the following in order to be considered for Level 2 accreditation;

- At least 5 years active experience in a Biosafety role **or** 3 years plus Level 1 attainment or equivalent.
- The submission of a portfolio covering all of the mandatory units plus any two of the optional units described below.

The BSP units and evidence requirements

The criteria laid out for the BSP units define the key subject areas in which basic underpinning knowledge and skills are important and in some cases essential for a Biosafety Professional.

Each unit has more than one topic. All topics must be covered in each selected unit.

The evidence presented for each unit and topic should demonstrate clearly to the reviewer that the applicant has a clear understanding of each topic and has applied this knowledge in the workplace.

With the exception of basic underpinning knowledge, evidence submitted should have been collected for the last 5 years only. Material provided for earlier than the 5 years should only be submitted in exceptional circumstances.

The minimum evidence provided for each unit is as follows;

1. Summary of a single project or similar piece of work related to the particular **topic**. It should outline the background knowledge and how you have identified, involved and consulted all relevant parties and gained their support

2. Evidence for this work. This can come in the form of reports, correspondence, statements, presentations, minutes of meetings etc. **Note that courses attended and passed during Biosafety Practitioner accreditation can be used when compiling Biosafety Professional evidence portfolios.**

3. Written justification as to why the evidence provided fulfils the requirement of the particular topic. This may require supporting statements from the applicant's line management.

4. Plans for the future (CPD)

Registering for Biosafety Professional accreditation and submitting portfolios for assessment

The first step toward registration as a Biosafety Professional (BSP) is for the applicant to register an interest by writing to the ISTR administrator, including the initial fee of £25.

The following guidance (also maintained on the ISTR biosafety section's web pages) outlines the steps required for progression with a portfolio.

A series of frequently asked questions (FAQs) have been prepared to help in the preparation of portfolios. Any other questions not covered by the FAQs should be sent to the Biosafety Accreditation Scheme Administrator in the first instance. The query will then be passed the BSP Assessor Panel for consideration and reply. If required, or at the specific request of the applicant, a mentor can be assigned to provide additional guidance on the preparation of the portfolio but is envisaged that most queries can be dealt with via the FAQs or by the assessor panel route.

Following a registration of interest, the applicant should, within 6 months, submit a brief plan as to how they intend to complete their portfolio – this should also include a timescale for submission. This plan should identify:

- Where they already have evidence for a unit (a brief summary is sufficient)

- Where there are gaps and how they intend to fill these gaps/acquire evidence.

If an applicant requires help or advice in identifying what might needed to fill a gap, they should indicate as such when submitting the plan and the Assessor Panel will provide advice as required.

When complete, the portfolio should be submitted to Biosafety Accreditation Scheme Administrator (not the mentor if assigned) with the final fee payment of £150 for members of ISTR, or £175 for non-members. A lead assessor will then be appointed to review the portfolio and either approve or provide constructive feedback (via the Scheme Administrator) to enable the applicant to make improvements up to the required standard.

When the lead assessor has approved the portfolio it will then be passed to the Assessor Panel for ratification. The Panel will then make the recommendation to the ISTR Executive Committee to add the applicant to the register of BSPs. This register is maintained on the ISTR website. The successful applicant will receive a Certificate of Competence.

Registration as a BSP will be for an initial period of 3 years. During this time a BSP will be expected to participate in the ISTR BSP CPD scheme. At the completion of each 3-year cycle a further fee of £35 is payable for CPD assessment. There is no annual fee requirement.

ISTR will at all times respect and safeguard the confidentiality of submissions. At the successful outcome of a submission, ISTR will either destroy all material held, or if the preference is indicated, will return all materials to the applicant.

The Biosafety Professional accreditation units

Definitions

For all topics the following definitions apply;

GA General awareness

The applicant will be able to demonstrate sufficient familiarity with a subject to the point of being able to "interpret" related documents for the benefit of others, including their own employer, and to be able to identify the need for and sources of information.

BU Basic understanding

The work submitted must contain evidence that the applicant has a broad understanding of the subject area. It should offer evidence of understanding beyond that of general awareness to the point where the individual is able to offer generic advice and participate in informed discussion, but not necessarily be regarded as an expert in the subject.

DU Detailed understanding

The evidence presented will provide strong support for regarding the applicant as an expert in the chosen area and apply basic principles to novel situations. This may include the ability to train others, or write papers, or offer expert advice within their own employment or to third parties.

	Unit		Topic	Evidence of experience or application in the workplace	
Mandatory unit					
1	Basic underpinning knowledge	a.	Microbiology and infectious diseases	Demonstration of an understanding of the scientific basis of biological risks by formal training to degree level or equivalent and/or scholarly publications in relevant subject	BU
		b.	Scientific trends	Provision of advice on recent developments, attendance at conferences & courses	GA
2	Organisational arrangements	a.	Development of policy, standards or codes of practice	Writing of policy and codes of practice: e.g. policy documents that candidate has authored, minutes of meetings at which candidate has made significant contribution	DU
		b.	Influencing a change in safety culture	Evidence for managing an improvement: inspection reports and/or follow up reports that demonstrate improvements achieved, evidence of increased awareness in workplace through candidate's efforts	DU
		c.	Development of a safety or 'compliance' management system	For example, a system for submission and approval of GM risk assessments or for performance validation of autoclaves	DU
		d.	Record keeping at the institutional level	Implementation of new systems and/or maintenance of an appropriate existing system.	BU
		e.	Inspection and auditing	Developing systems, programmes as well as in conducting inspections and audits	DU
		f.	Dealing with overlapping or third-party organisations or individuals	Evidence of managing co-operation between employers including transfer arrangements for materials or waste, service level agreements, decontamination certificates or Permits-to-Work. Examples could include contributing to documentation pertaining to shared responsibilities.	DU
		g.	Dealing with the enforcement agencies	Details of preparation as well as response. Examples could include facilitating inspection visits, submitting notifications, responding to requests for information etc.	BU
		h.	Incident reporting and investigation	Examples of investigation reports; developing systems for reporting and investigation, including meeting the legal reporting requirements	DU

	Unit	Topic	Evidence of experience or application in the workplace	
3	The law	a. A detailed understanding of health and safety law as applied specifically to biological agents hazardous to human, animal and plant health	Interpretation and application of the law. Examples may include (a) securing significant expenditure or changes in established work practice to ensure compliance; (b) involvement in the mitigation case following enforcement action; (c) acting as an expert witness in the Courts; (d) development of workplace specific guidance/systems for ensuring legal compliance with these regulations	DU
		b. Regulatory environment	Demonstration of an understanding of the interaction with other legislation associated with biosafety e.g. Human Tissue Act, Anti-Terrorism (Crime and Security) Act.	BU

4	Communication and training	a. Safety communication within the workplace	Development and implementation of communication processes with scientists, PIs, laboratory managers etc. and with other stakeholders for example the Trade Unions. Examples include safety notices or other communications instigated or authored by the candidate.	DU
		b. Maintaining professional competence	Examples of course attendance, further relevant qualification, conference participation etc.	DU
		c. Safety training	Development (including training needs analysis) and delivery of a training programme. Examples include course training materials, dates of delivery and feedback from trainees	DU
		d. Communication outside of the organisation	Development of links with appropriate people and groups on health and safety matters & speaking at conferences, etc	BU
		e. Influencing skills	Attainment of required level in formal course and/or examples of success in influencing for positive change, either through effecting positive changes in awareness and compliance in the workforce or through influencing senior management to effect a positive change in safety culture	BU

	Unit	Topic	Evidence of experience or application in the workplace	
5	Biological risk management	a. Risk assessment methodology and application	Provision of advice on specific projects, development of written guidance, development of institutional procedures, provision of training	DU
		b. Control measures according to hierarchy of control; includes selection, testing and maintenance	Determining and advising on appropriate control measures, for example; selection and testing of engineering controls; routine disinfection, sterilisation and decontamination; barrier systems; waste management; ergonomics and their incorporation into Codes of Practice and Local Rules.	DU
		c. Emergency preparedness and response	Preparation of emergency plans; examples of managing real events (through actual experience or training exercises).	DU
		d. Security	Provision of advice on specific projects, development of written guidance, development of institutional procedures, provision of training	BU

6	Occupational Health	a. Understanding the biosafety requirements for Occupational Health (OH) and/or Industrial/Occupational Hygiene provision and the organisational relationship between them and biosafety.	Health surveillance: legal requirements and relationship with Occupational Health department or provider Identifying OH needs and providing advice on specific hazards and risk factors, including vulnerabilities affecting immunity, resistance to biological agents and the need to refer to the OH provider and/or Industrial/Occupational Hygienist.	BU

	Unit	Topic		Evidence of experience or application in the workplace	
Optional units					
1	Work at Containment Level 3 or 4 (including animal pathogens)	a.	Facility design and operation	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		b.	Risk assessments and Codes of Practice	Provision of advice, development of written guidance, development of institutional procedures.	DU
		c.	Selection, use, maintenance and testing of control measures	Provision of advice, development of written guidance, development of institutional procedures.	DU
		d.	Fumigation, including testing for sealability	Development of procedures, including planned and/or emergency shut down,	DU
		e.	Training	Provision of training in use of the facility	DU
		f.	Emergency response	Hands on experience or participation in training exercises	DU
2	Animal facilities NOTE: Evidence may be based on experience involving one or more of the following: mammals, fish, reptiles, insects etc., including those genetically modified	a.	Facility design and operation	Provision of advice on specific projects, development of written guidance, development of institutional procedures, provision of training; ergonomic design	DU
		b.	Risk assessments and Codes of Practice	Id.	DU
		c.	Selection, use, maintenance and testing of control measures	Id. To include where appropriate, determining quarantine measures; work with infected animals; animal allergens;	DU
		d.	Monitoring performance	Provision of advice on specific projects, development of written guidance, development of institutional procedures,	DU
		e.	Emergency response	Hands on experience	DU

	Unit	Topic	Evidence of experience or application in the workplace	
3	Genetic modification NOTE: Evidence may be based on experience involving one or more of the following types of activities: i). Contained Use of genetically modified micro-organisms ii). Contained Use of genetically modified animals iii). Contained Use of genetically modified plants iv). Gene therapy v). Deliberate release of GMOs	a. Facility design and operation	Provision of advice on specific projects, development of written guidance/Codes of Practice, development of institutional procedures	DU
		b. Risk assessments.	Provision of advice on and/or conducting of risk assessments for work involving GMOs.	DU
		c. Training	Provision of specific training in risk assessment for work with GMOs and in safe use of the facility	DU
		d. Notifications	Management of notification process	DU

4	Transport of biological materials	a. Transport	IATA Class 6.2/9 certification + demonstration of understanding of application to road, rail and sea by development of guidance or policy or provision of advice, including other dangerous materials associated with the transport of biological materials, e.g. dry ice	DU
		b. Import/export	Provision of advice on the regulatory requirements for the import/export of biological material to or from the UK.	DU
		c. Emergency response	Hands on experience or participation in training exercises	DU

	Unit	Topic	Evidence of experience or application in the workplace	
5	Enforcement agencies/legal proceedings	a. Enforcement agency inspections	Demonstration of a lead role in the preparation for and response to enforcement agency inspections	DU
		b. Civil or criminal action	Contribution to the defence or prosecution of health and safety civil or criminal action and/or attendance at an approved course	DU

6	Plant Pathogens	a. Materials prohibited under Plant Health Orders	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		b. Facility design and operation and maintenance (greenhouses, waste and bulk treatment)	Id.	DU
		c. Working with contained plant/pathogens	Provision of advice on quarantine, vectors, soil, parasites, controls, development of written guidance, development of institutional procedures	DU
		d. Genetically modified plants	Provision of advice on international and national regulation including Cartagena Protocol, permits, licences, transgenic	DU
		e. Deliberate release	Provision of advice on risk assessment, field release, commercial release	DU
		f. Containment Principles	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		g. Import and Export	Id. Specific projects interaction with inspectors, development of plant materials transport	DU
		h. Waste management	Id.	DU
		i. Training	Provision of training in use of the facility or other safety procedures	DU
		j. Risk assessment	Management of full range of safety within these facilities	DU

	Unit	Topic	Evidence of experience or application in the workplace	
7	Large scale production	a. Facility design and operation	Provision of advice on design and/or operation of specific large scale projects; development of written guidance/Codes of Practice; development of institutional procedures, including planned and/or emergency shut down	DU
		b. Risk assessments	Provision of advice on and/or conducting of risk assessments for work at large scale.	DU
		c. Selection, use, maintenance and testing of control measures	Provision of advice development of written guidance/institutional procedures on specific large-scale issues.	DU
		d. Training	Provision of training in safe use of the facility	DU
		e. Waste management	Provision of advice on specific issues relating to inactivation and disposal of bulk culture fluids. Development and/or implementation of validation procedures.	DU
		f. Emergency response	Hands on experience or participation in training exercises	DU

8	Biosecurity	a. Legal context	Provision of advice on specific projects, development of written guidance. Demonstration of understanding of definitions and legal requirements	DU
		b. Physical measures	Demonstration of understanding of available technologies, either through course attainment or the provision of advice.	DU
		c. Security plans	Demonstration of the contribution to the development of site security plans	DU
		d. Assessment	Demonstration of ability to assess the threat and the risk of loss. Demonstration of the ability to determine measures to reduce risk where weaknesses identified.	BU
		e. Personnel security	Demonstration of contribution to determining access control and understanding of the requirements for personnel screening	BU
		f. Proportionate application	Demonstration of the proportionate application of Biosecurity measures, including physical and biological barriers	DU

	Unit	Topic	Evidence of experience or application in the workplace
9	Others e.g. clinical, bioethics, aerobiology, toxins,	a. Application can be made on a case by case basis for other specialist aspects of biological safety	