RISK ASSESSMENT FOR BIOSAFETY

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V2.1

INTRODUCTION

This module on risk assessment for biosafety must be read in conjunction with the *WHO Laboratory Biosafety Guidelines, 3rd Ed*, your national biosafety/biosecurity standards or guidelines and forms part of a set of guideline for the safe handling of infectious micro-organisms. We also recommend consideration of the adoption of CWA 15793:2008 *Laboratory biorisk management standard* as a good approach to establishing a biorisk management system in your organization.

It is critical that organizations perform a risk assessment before performing any work on infectious micro-organisms in Risk Groups 3 and 4 and it is strongly recommend for handling Risk Group 2 organisms. The risk assessment will identify the hazards that could occur in the laboratory. An all hazards approach has been adopted for this risk assessment, as it is not only the micro-organisms that pose a risk to the health and safety of staff.

This module is design to assist laboratory staff and management perform the identification of hazards, assessment of the risks and to define the controls in order to reduce the risks to a safe level. If the level cannot be made safe, then an option that management must consider is not performing the work because it is unsafe to proceed. Another important factor that management must consider is the monitoring of the controls through audits and inspections, through identification and investigation of incidents and through regular reviews of the work and risk management.

We would like to acknowledge the use of original forms developed by the Safety Unit of the Commonwealth Scientific and Industrial Research Organization, Canberra, Australia and the input of Bio2ic , Geelong, Australia, into the revision of these forms.

CONTENTS

RISK ASSESSMENT FOR BIOSAFETY

This Risk Assessment Module forms a supplement to the *WHO Laboratory Biosafety Manual, 3rd Edition* (LBM3) and should be read in conjunction with that manual and any national standards or guidelines. It is aimed at detailing a process of establishment of the risks associated with work in Microbiology laboratories, the control of those risks and approval and monitoring of any work that takes place under the assessment.

The initial assessment involves all the staff that will work in the area being involved in the identification of the risks and controls. This assessment would be supported by safety specialists and by senior management. Once the assessment has been performed, then the assessment needs to be signed off by the Biological Safety Committee (or Safety Committee if there is not a specialist Biological Safety committee). Finally, senior management approves the assessment and the work proceeding, as well as making sure that processes are put in place to ensure that the staff training and assessment of the controls is monitored.

Assessment of the risks associated with biological work cannot be performed in the absence of a total assessment of the risks associated with the work. The micro-organisms being handled are not the only risks associated with the work: other risks include:

- Mechanical (Plant)

  This could apply to any equipment or mechanical plant. For example an electrical saw used in the autopsy of an animal, the biological safety cabinet that produces excessive noise, vacuum or pressure equipment.

- Radiation

  This applies to ionizing radiation as well as non-ionizing radiation (ultraviolet, infrared, laser, radiofrequency, electromagnetic or extremely low frequencies)

- Fire and explosion

  Flammable substances and explosives.

- Temperatures

  High temperature materials and cryogenic fluids

- Hazardous environments

  Confined spaces, working at heights, working in sea or water bodies and hot and cold stress. It could include working in -20^{o}C cold rooms.

- Electrical

  High voltage equipment, electrical equipment and static charges. Remember that many pieces of electrical equipment used in the laboratory are imported and rewired to meet local electrical connection requirements. Sometimes this is done incorrectly and the equipment might be live to touch. It is strongly recommended that all electrical equipment be tested and tagged before use and at regular intervals after that (every 1 to 2 years).

- Biological

This is a key area if you are working with micro-organisms. For this we recommend that more detailed analysis be given involving an understanding of the mode of transmission, infectious dose, pathogenesis and severity of disease and whether it is zoonotic or not. Also other issues that need to be considered are GMOs, allergens (as with handling small animals such as mice), irritants, mutagens and teratogens, handling small and large animals, handling human specimens.

- Chemical and hazardous substances

Staff in many microbiology laboratories do not seem to realise that they handle potentially dangerous chemicals. There are acids and alkalises, solvents, fixatives (gluteraldehyde and formalin), toxic and carcinogens, oxidising agents. Remember that chemicals that can kill micro-organisms are probably dangerous. It is important that material safety data sheets (MSDSs) are available for the chemicals used in the laboratory, and that they are handled and disposed of safely. Because of these and other risks, it is recommended that staff in the laboratory wear safety glasses.

- Gases

In microbiology laboratories, inert gases pose particular safety risks. Many laboratories use liquid nitrogen for storage of micro-organisms. If the storage area is not well passively ventilated and relies on mechanical ventilation, then if the ventilation fails a build up of nitrogen can occur. If the level drops below 19.5% oxygen in the air, then a warning should be given. At low oxygen levels, people breathing in nitrogen will immediately collapse and die of asphyxiation. It is therefore recommended that liquid nitrogen storage be in a passively well ventilated area. If not for security or biocontainment reasons (at BSL-3 and above the organisms should be stored in the BSL-3 or BSL4 containment area), then oxygen level meters, that are regularly checked, and alarms need to be used to ensure that the oxygen level does not drop below 19.5%. In recent years there have been 2 deaths from asphyxiation from nitrogen.

- Personal

There are a number of personal risks that are often seen in microbiology laboratories. For example repetitive strain injuries are often associated with using micropipettes, especially some of the older models where tips were difficult to put on and eject. Another problem is associated with the static posture of staff using BSCIIs, where long hours working in the cabinet can result in shoulder and wrist injuries. Another problem is not having a working alone policy, and allowing staff to work in high risk situations alone or after normal working hours.

SCOPE, APPLICATION AND DEFINITIONS

SCOPE

This Risk Management Module provides guidance on the assessment of risk in a microbiological context and the safe management of that risk. It should be considered together with the *WHO Laboratory Biosafety Management*, 3rd Edition (2004), CWA 15793 *Laboratory biorisk management standard* and any national guidelines, legislation and standards that apply.

APPLICATION

Risk management is an integral part of good management practice and is essential for the prevention of laboratory infections and environmental contamination. Any prudent manager should ensure that a through risk management process has been performed and documented. It is also critical that the identified controls are put in place and regularly monitored.

If a significant laboratory accident occurs then one of the first things that the investigators request is a copy of documented risk assessment and evidence that the controls were put in place and that they are regularly monitored. It is prudent for a risk assessment to be performed for BSL-2 work. It is essential for BSL3 and BSL4, where an incident could lead to serious disease, or death, and threaten the community and the environment.

DEFINITIONS

For the purposes of this module, the following definitions apply:

- Biological safety level 1 (BSL-1): Containment facilities and work practices sufficient to safely work with Risk Group 1 organisms. As these organisms are of very low risk they can be safely handled on the laboratory bench with goog microbiological techniques. Typically these laboratories would be teaching and basic research laboratories.

- Biological safety level 2 (BSL-2): Containment facilities and work practices sufficient to safely work with Risk Group 2 organisms can be safely handled. Organisms can be worked on the bench as long as they do not infect by the aerosol route or aerosol producing procedures are not used. Otherwise they must be handled in a biological safety cabinet. These are the most common laboratories and procedures for medical and veterinary diagnostic laboratories. They are also used for research. Staff wear laboratory gowns, safety glasses and gloves when working with micro-organisms and wash their hands and remove their PPE before leaving the laboratory

- Biological safety level 3 (BSL-3): Containment facilities and work practices sufficient to safely work with Risk Group 3 organisms. These are specially contained laboratories where the laboratory is access through an air lock, the air flows away from the laboratory entry and all infectious work is performed in biological safety cabinets. These laboratories are used f by specialist diagnostic services and some research groups working on risk Group 3 organisms. They are designed so that they can be fumigated with gasses and therefore must be totally sealable because high danger posed by these gasses. Staff wear laboratory gowns, safety glasses and gloves when working with micro-organisms and wash their hands and remove their PPE before leaving the laboratory

- Biological safety level 4 (BSL-4): Containment facilities and work practices sufficient to safely work with Risk Group 4 organisms. These are specially contained laboratories where the laboratory is access through an air lock, the air flows away from the laboratory entry and they are at negative air pressures to outside areas. All infectious work is performed in class I or class II biological safety cabinets wearing a positive pressure supply and filtered air respirator suit. Alternatively, work can be performed in Class III biological safety cabinets, which are fully contained. These laboratories are used by specialist diagnostic services and some research groups working on risk Group 4 organisms. They are designed so that they can be fumigated with gasses and therefore must be totally sealable because high danger posed by these gasses. Staff wear laboratory gowns, safety glasses and gloves when working with micro-organisms in the BSCIII and wash their hands and remove their PPE before leaving the laboratory. If wearing the positive pressure suit, they first shower out in the suit through a chemical shower. There are very special procedures for operation at BSL-4 and the risk assessment of work is much more detailed than covered in this form.

- Consequence: the outcome of an event expressed qualitatively or quantitatively, being loss, injury, and a range of other outcomes (see the detail in the Consequence Table later in this document).

- Event: occurrence f a particular set of circumstances. The event can be a single occurrence or a series of occurrences.

- Frequency: measure of the number of occurrences per unit of time.

- Genetically modified organisms (GMOs): organisms whose genetic make up has been altered by the insertion or deletion of small fragments of DNA in order to create or enhance desirable characteristics from the same or another species. Handling of such organisms is usually controlled under national legislation or regulation.

- Harm: adverse effect on the health of people, animals or plants, on the environment or on property.

- Hazard: source, situation, or act with a potential for causing harm.

- Hazard identification: process of recognising that a hazard exists and defining its characteristics.

- Hierarchy of controls: it is possible to rank risk contro9ls in a hierarchy, from most to least preferred. Normally a combination of control is used depending on the nature of the hazard and the workplace. *The hierarchy of controls are: elimination, substitution, isolation, engineering control, administrative controls and personal protective equipment. (after HB205-2004)*

    - Elimination: total removal of the hazard. *For example, substitution of mechanical freezers for liquid nitrogen storage.*

    - Substitution: use of something less hazardous. *For example, water based chemicals rather than solvent based ones or the use of a low pathogenic organism rather than a highly pathogenic one.*

    - Isolation: use of barriers to shield or isolate the hazard. *For example, guards on machinery, enclosures for noisy machinery (such as ultrasonicators).*

    - Engineering controls: design and install equipment to counteract the hazard. *For example, installing exhaust ventilation system, with directional air flows, to remove any infectious aerosols. Biological safety cabinets to contain aerosols.*

    - Administrative controls: arrange work to reduce the time people are around the hazard. *This could include training, standard operating procedures, emergency planning, etc.*

    - Personal Protective Equipment (PPE): material, including clothing (e.g., gown, gloves, respirators, safety glasses) used to prevent exposure to or contamination of a person by chemical or biological matter.

- Inherent risk: The inherent risk is that risk associated with the task or activity that is present in the absence of controls

- Ionizing radiation: radiation which is capable of producing ionization, either directly (for example, from radiation in the form of gamma rays and charged particles) or indirectly (for example, from radiation in the form of neutrons).

- Likelihood: a qualitative description of the probability or frequency of an event occurring. (see detailed description in the Likelihood Table later in this document.

- Material safety data sheet (MSDS): information on the properties of chemicals as they relate to safety and to environmental threat. These should be MSDSs available for all chemicals provided by the supplier/manufacturer of the chemical or product. The MSDS should be accessed to understand whether the chemical has any toxic properties, how they can be handled safely, exposure limits, clinical signs, treatment and disposal of the chemical. Databases of MSDS are available for most common chemicals. This will also detail the hazard warning signs required for the chemicals and the class of chemical. Same classes of chemicals cannot be stored together and segregation of chemicals must be practiced.

- Monitor: to check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change.

- Non-Ionizing radiation: means electromagnetic radiation of a wavelength greater than 100 nanometres. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (MW), radio frequency (RF), and extremely low frequency (ELF). Lasers commonly operate in the UV, visible, and IR frequencies. Non-ionizing radiation is found in a wide range of occupational settings and can pose a considerable health risk to potentially exposed workers if not properly controlled.

- Organization: a company, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration. NOTE: For organizations with more than one operating unit, a single operating unit may be defined as an organization.

- Probability: the extent to which an event is likely to occur.

- Project or work area closure: activity that must be undertaken at the termination of a project

- Risk: the chance of something happening that will have an impact on objectives. Risk is measured in terms of a combination of the consequences of an event and their likelihood.

- Residual risk: risk remaining after the implementation of a risk treatment

- Risk identification: the process of determining what, where, when, why and how something could happen.

- Risk reduction: Actions taken to lessen the likelihood, negative consequences, or both, associated with a risk.

- Risk matrix: the consequence and likelihood table used to determine the inherent risk (IR)

- Risk Group 1 organisms: No or low individual and community risk. An organism that is unlikely to cause human or animal disease. Some examples include bakers yeast, the organisms in yogurt, many food based organisms and most of the micro-organisms found in our environment.

- Risk group 2 organisms: Moderate individual risk, low community risk. A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infections, but effective treatment and preventative measures are available and the risk of spread of infection is limited. Some examples include measles and mumps viruses, *E. coli* and Salmonella spp. and Shigella spp. and a range of common viral, bacterial and fungal infections.

- Risk group 3 organisms: high individual risk, low to moderate community risk. A pathogen that usually causes serious human or animal diseases but is usually limited in its spread from one individual to another. The diseases in this group can sometimes be difficult to treat effectively and can become a serious threat to the community's health. Examples include SARS Coronavirus (sometimes worked at BSL-4 in some countries), bird flu (H5N1), multi-drug resistant *Mycobacterium tuberculosis*, *Franscella tularensis,* Brucella spp., Coccidmycosis.

- Risk group 4 organisms: High individual risk and moderate to high community risk. A pathogen that usually causes serious human or animal disease and can sometimes be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

- World Health Organisation (WHO): the WHO is based in Geneva with regional offices in WPRO, SEARO, EMRO, etc. The WHO headquarters has a biorisks management group and each regional office supports laboratory safety programs. There are also a number of Collaborating Centers in Biosafety located in Australia, Ottawa, Atlanta, Washington, and Stockholm.

ASSOCIATED DOCUMENTS

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RISK MANAGEMENT REQUIREMENTS

PURPOSE

To establish a formal process for the assessment of risk in a biological situation and for the proper documentation of controls to manage the risks. This is to supplement the guidance found within the *WHO Laboratory Biosafety Manual, 3rd Edition* (LBM3; 2004).

RISK MANAGEMENT POLICY

Each institution should develop a risk management policy as an integral part of their occupational health and safety policy. This policy should identify the organisations objectives for, and its commitment to, risk management.

The policy should require all projects/work areas to be assessed for risks and a full assessment prepared before work is approved to commence. Approval should involve the institutional biosafety (or safety) committee with sign off by senior management (and not the principal investigator). The assessment should be reviewed annually and when the work is completed, then the risk assessment and the associated approvals should be terminated. A written record of this should be kept by management.

PLANNING AND RESOURCES

The organisation should ensure that a risk management system is established, implemented and maintained in accordance with these guidelines and that the performance of the risk management system is reported to the organisation's institutional biosafety committee and to management for review and as a basis for improvement.

The responsibly, authority and interrelationship of personnel who perform and verify work affecting risk management shall be defined and documented, particularly for people who need the organizational freedom and authority to do one of the following:

- Initiate action to prevent or reduce the adverse effects of risk
- Control further treatment of risks until the level of risk becomes acceptable
- Identify and record any problems relating to the management of risks
- Initiate, recommend or provide solutions through designated channels
- Communicate and consult internally and externally as appropriate

The organization shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work, and verification activities, including internal review.

IMPLEMENTATION PROGRAM

A number of steps are required to implement an effective risk management system within an organization. Examples are provided in Appendix 1 and in subsequent sections in this document.

MANAGEMENT REVIEW

The organization's executive shall ensure a review of the risk management system is carried out at specified intervals, sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of the organization's risk management policy and objectives. A record of such reviews shall be maintained.

RISK MANAGEMENT PROCESS

ESTABLISH THE CONTEXT

It is up to the organization to establish the strategic, organizational and risk management context in which this process will take place. Criteria against which risk will be evaluated should be established and the structure of the analysis. This document, the *WHO Laboratory Biosafety Manual, 3rd Edition* (LBM3; 2004), CWA 15793 *Laboratory biorisk management standard*, national standards, guidelines and legislation, will all assist in establishing the context for risk assessment and management.

RISK IDENTIFICATION

The first stage in the process is to identify all the risks. It is useful to involve the whole work team in this process and to also use inputs from organizational experts on safety and risk management. Identify what, why and how things can arise as a basis for further analysis

The table in Part A: Section 2a. Workplace hazard identification (see Appendix1) will assist in the identification of all hazards associated with the workplace, systems of work, equipment and substances used. It is recommended that this table be used first to identify areas that need to be addressed in more details in identification and assessment of hazards.

RISK ANALYSIS

The risks are then assessed using the assessment of risks table (Part A; Section 3a). The initial assessment is to clearly state the task or activity, and then identify the specific hazard or hazards. The inherent risk is then assessed, where controls are not in place. In a risk assessment it is important first the inherent risk because in so doing you will then need to identify all the existing controls and any additional ones that need to be applied. This processes will ensure that all the identified controls can be checked to ensure that they are applied and that they are working.

RISK EVALUATION

This process will assess the risks and the specific hazards and determine the inherent risk.

INHERENT RISK ANALYSIS

The inherent risk is that risk associated with the task or activity that is present in the absence of controls. This is assessed (see section on using the Risk Assessment Module) using the consequence table and the likelihood table and then plotting the results on the risk matrix. From this process the inherent risk is identified.

IDENTIFICATION OF OPTIONS FOR TREATMENT

TREATMENT OPTIONS

THE HIERACHY OF CONTROLS

The use of the hierarchy of controls is a recognised means of risk management. These controls start with the elimination of the risk. This is the most effective control. If this is not possible, then the substitution of a process with a lower risk is one alternative. In many cases in microbiology, it is not possible to work with an agent other than a serious pathogen. Other controls need to be introduced to reduce the level of residual risk.

ELIMINATION

Elimination is the decision to remove the risk. An example is the use of liquid nitrogen for storage of organisms in a confined (secure and non-passively ventilated) space. If the mechanical ventilation fails, then the space will fill with nitrogen gas, replacing the oxygen with this inert gas. If the concentration is below 19.5% oxygen, then it can affect staff that enter the space. If there is much less oxygen, then nitrogen can cause exposed people to collapse and death by asphyxiation follows. One possible approach is to replace liquid nitrogen storage in confined spaces by ultra-low temperature storage cabinets (-135 ^{o}C).

SUBSTITUTION

Substitution of a serious pathogen with one this is much less pathogenic is sometimes possible when studying some of the organisms properties. For example, a group studying disinfection of E. coli O157:H7, a very dangerous enteropathogenic organism that causes haemolytic uraemic syndrome at low infectious doses, was used and a staff member became critically ill due to a laboratory infection. A low pathogenicity E. coli or related organism could have been successfully substituted for the highly pathogenic one, and still given valid test results.

ISOLATION

This is a control that relates to putting up a physical barrier so that it is not possible to be exposed to the risk. The most common form of this is the use of a guard to stop people putting their hands in contact with mechanical parts of machines, such as conveyor belts. This is not usually applicable to biological processes.

ENGINEERING CONTROLS

These are used extensively in biological safety in order to significantly reduce the potential and the level of exposure to pathogens. Some common examples include the following:

- Biological safety cabinets used to contain aerosols of organisms.
- Directional air flow in BSL-2 and BSL-3 laboratories, away from the laboratory entrance to the far side of the laboratory. This stops any organisms entering common spaces such as halls and staff offices.
- A high level of air flow, usually 10 to 15 changes per hour in BSL-2, BSL-3 and BSL-4 laboratories. In animal rooms where infected animals are not isolated in ventilated caging (which is another engineering control, the room becomes a primary containment barrier, an air exchanges are usually increased to 15 to 20 changes per hour, and sometimes much higher.

- HEPA filtration of the exhaust air from BSL-3 and BSL-4 laboratories, with the air not being recirculated to other areas.

- Making the laboratory air tight to facilitate gaseous decontamination. Gases such as formaldehyde are extremely toxic and it is important that they do not leak out into the surrounding areas where staff could be exposed.

- Water supplied to laboratory sinks is isolated from potable water, used for washing hands, showering and drinking, by the use of break tanks or reverse flow valves, that prevent laboratory water re-entering the potable water supply.

ADMINISTRATIVE CONTROLS

This class of control relates to controls placed upon staff in order to reduce their exposure to the risks. Some examples of administrative controls include:

- Training of staff in the safe operations within the laboratory, including on procedures to remove laboratory gowns within the laboratory and always wash hands before leaving the laboratory and after working in a biological safety cabinet.

- Production of a safety manual, including the development of Standard Operating Procedures (SOPs) that are considered safe.

- The performance of risk assessments of work and the approval of work only following a documented risk assessment

- Procedures to audit the safety of the laboratory systems and staff practices.

- The development of guidelines concerning “working alone”. Some operations such as handling large animals are considered unsafe unless they are done with more than one person.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

This is the last control in the hierarchy of controls and should only be used when other controls have been implemented. However, in many laboratories it is the first control implemented, and sometimes the only control. It must be emphasised that some PPE use introduced a new set of risks. This is particularly true of the use of respiratory protection.

Some examples of PPE are:

- Laboratory gowns should always be worn in laboratories and not taken out of the laboratory. It is strongly recommended that back fastening gowns, which better protect against spills, be used instead of front fastening laboratory coats. The gowns should be long sleeved and have elasticised wrists fittings their covering by gloves (latex surgical or nitryl vinyl gloves are usually worn).

- Safety glasses that should be worn by all staff working in microbiology laboratories and by visitors to those laboratories.

- Respiratory protection utilising particle masks such as N95 and P2. Note that these masks must be correctly fit checked at least annually and that they are uncomfortable to wear for long periods of time (and therefore there is a risk of them being touched by contaminated hands).

- Power Assisted Purifying Respirators (PAPRs) with N100 or P3 filters. These are positive pressure respirators and can be worn for longer periods of time than the negative pressure respirators (such as the N95 or P2 particle masks).

- Ø Dedicated footwear, enclosed, that remains in the BSL-3 laboratory, rather than shoe covers or no change of shoes. This is to prevent contamination being removed from the BSL-3 laboratory.

- Ø Full pressurised body suits with supplied HEPA filtered air worn in BSL-4 laboratories and decontaminated using a chemical shower. Because of the risks involved ion wearing such PPE, it is recommended that staff have an annual medical check and that they do not work alone.

RESIDUAL RISK

The residual risk is established after applying the controls that have been identified using the risk assessment module. The residual risk must fall within the low area for the work to proceed with the usual monitoring of controls. In many cases where high risk agents are handled (Risk Group 3 or 4), it is not possible, even with very good management controls, to get the residual risk below moderate. In this case the controls must be applied strictly and monitored very regularly. In these cases there might be a high application of administrative controls (training, SOPs, special staff operating rules and procedures) and use of PPE (such as pressurised suits with HEPA filtered air supply with chemical decontamination with RG4 organisms). If the residual risk remains high then further controls will be needed to reduce the risk to an acceptable level. In the case that the risk cannot be reduced, consideration needs to be given to restricting work or even not permitting it and looking for a collaborating organization that is capable of performing the work safely. For example, doing research on a Risk Group 4 agent at BSL-2 is not safe and this work should be done at BSL-4.

ESTABLISHMENT

The controls that have been identified need to be put in place following the sign off of the Safety committee and Management that they accept the results of the Risk Assessment. Staff need to be fully informed regarding the assessment, the identified risks and the controls to be put in place to reduce the risks to an acceptable level. The appropriate training and administrative controls need to be put in place. For moderate residual risk, it is suggested that staff become familiar with the controls before handling high risk organisms or procedures. Safety staff should check that all the controls have been established and that they are operating correctly before the work commences.

MONITORING CONTROLS

The controls need to be regularly monitored for work at BSL-2, BSL-3 and BSL-4. The level of monitoring will depend on the level of residual risk and the complexity of the controls. Controls that involve high levels of administrative controls and the use of personnel protective equipment need more regular monitoring. Work involving RG4 agents needs a very high level of monitoring to ensure all controls are working, and this will be at the daily level. A list of possible monitoring processes is listed below:

1. Annual or biannual safety audits and inspections of work area

2. Annual review of risk assessment

3. Review of training records and competency assessments of staff involved in the project

4. Monitoring of plant and equipment operation, especially at BSL-3 and BSL-4, usually using a building monitoring system, and ensuring all alarms are operating and that incidents of non-compliance are investigated and rectified

5. Investigation of all incidents and accidents in the work area and ensuring that changes are made to address the causes of the incidents

6. Ensuring that any changes in work practices are recorded and approved

RISK ASSESSMENT MODULE (APPENDIX 1) – PROCEDURES FOR USING THE MODULE

Systematic identification of all occupational health and safety hazards and environmental aspects and control of the risks that they present is essential for the management of health, safety and the environment in the workplace and to reduce accidents and injury. This is an extremely important process. The approach provided by this tool is based on current best practice and consultations involving safety staff.

This tool meets the requirements necessary for an acceptable assessment process. These include:

- a systematic approach applicable across the organisation.
- comprehensive, graded lists of criteria covering all types of consequences
- a realistic guide to the likelihood of adverse consequences, and
- a scheme for rating the risks so that high risks are identified for immediate action

Using this procedure involves 6 steps:

1) Identify occupational health and safety hazards and environmental aspects using the checklist.

2) Use the table on the following page (Consequences) to rate the risk associated with each hazard/aspect by looking at the possible consequences in each column. Do not look only at health and safety risks, environmental risks or risks to your project or work. Consider every type of consequence. If you see that there are possible consequences that differ from those listed, consider a risk rating equal to the type of consequence that most closely matches. For each hazard/aspect, adopt the risk rating that is given by the column indicating the most severe consequences.

3) For each hazard/aspect, use the table on the next page (Likelihood) to rate the likelihood of an incident that will lead to the consequences that you have determined. Consider all of the options for each rating and use the most likely rating that is possible for the defined consequences. Remember that likelihood is related to exposure and exposure depends upon duration and frequency of exposure (or operation) as well as on the number of people exposed. For example, exposing eight people to a moving machinery hazard for one hour each is theoretically equivalent to exposing four people for two hours each.

4) Use the Inherent Risk table on the following page to plot the consequence against the likelihood to determine the inherent risk category associated with each hazard/aspect. These are the risks posed by the hazards in the absence of any consideration of risk control strategies.

5) Using the Residual Risk table, plot the inherent risks against your perceptions of the effectiveness of the risk management controls implemented so you can estimate the residual risk associated with each hazard/aspect. Your perceptions about the effectiveness of controls might be challenged by other members of your team or by, for example, the Safety Officer.

6) Deal with high residual risks as a matter of urgency. Look at the notes on the page about significant inherent and residual risks. Treat other risks as necessary to continuously improve your control of risks to health, safety and the environment.

CONSEQENCES

Note that any appropriate (or similar) criterion in a box gives a rating. Choose highest rating.

CONSEQUENCES				
RATING	POLITICAL & CUSTOMER	INJURY/ILLNESS	ENVIRONMENT	PROGRAM
Catastrophic	§ Ministerial investigation § Public/media outrage § Concern from public or industry association § Public pressure to cease operations	§ One or more fatalities § Permanent or severe health effects for one or more staff members § Immediately dangerous to life & health	§ Major impact-probably resulting in long-term damage to environment § Possibility of criminal proceedings under environmental legislation	§ More than one department constrained for at least one month (eg. by damage to equipment or facility) § Termination of a stream of research or shutdown of a major facility § Total loss of Plant equipment
Major	§ Repeated concern from industry association or public group § Ministerial 'please explain' § External investigation § Public/media concern § reputation of organisation damaged	§ Extended absence (one week or more) from work § Moderate to severe health effects	§ Major impact-possibly resulting in long-term damage to environment § Likelihood of EPA action, civil action or compensation costs	§ Project work constrained for at least one month (eg. by damage to equipment or facility) § Project terminated or shutdown of a laboratory § Partial loss of Plant equipment
Moderate	§ Major concern from industry association or client. Cannot show application of principles § Internal investigation § Decrease in public or industry support for project § Attracts public/media attention	§ Temporary absences (of less than 1 week) for one staff member § Requires one or more visits to doctor for treatment	§ Significant impact - possibly resulting in long-term damage to environment § Does not lead to EPA fine or court action	§ Significant part of program's work delayed for less than one month (eg. by damage to equipment or facility) § Major refit of a laboratory
Minor	§ Minor concern from public § Claim of inadequate risk management or consultation in organisation § Department review	§ First aid treatment required by doctor	§ Transient impact - short-term breach of regulations § Required to inform EPA or third party of non-compliance	§ Some project work delayed for less than one month (eg. by damage to equipment or facility) § Minor refit of a laboratory § Damage to plant repairable

Insignificant	§ Concern within the Department § Review by program/project/section manager	§ No injuries § Inconsequential damage to equipment	§ Brief impact - contained on site and not requiring notification to third parties	§ Minor delays to individual's work (eg. by damage to equipment or facility)

LIKELIHOOD

Note that likelihood not only depends upon the frequency but the duration of the activity and the number of simultaneous exposures or applications of the process. Any appropriate (or similar) criterion in a box gives a rating. Choose the most likely rating if more than one is possible, for the defined consequences.

LIKELIHOOD	
RATING	
Almost Certain	§ Defined consequences are very likely to occur § Clear history of occurrence § Typical operation of this type perhaps to satisfy external demands § *Expected to occur more often than daily to several times per week*
Likely	§ Difficult to control because of some external influences § Some history of occurrence with the defined consequences § *Expected to occur once per month to several times per year*
Possible	§ Has occurred in the organisation with the defined consequences § Would not be surprised if it occurred § *Expected to occur a few times every two years to once per year*
Unlikely	§ Possible but not expected to occur with the defined consequences § Causal events have occurred within the organisation but effects have been controlled so that defined consequences did not occur § No history in this department/section of situation which resulted in the defined consequences but has occurred in other Departments § *Expected to occur once every two to five years*
Rare	§ Possible but very unlikely to occur with the defined consequences § Causal events have occurred within the Organisation but the risk is not difficult to control § *Expected to occur once every five years or less often*

INHERENT RISK (the risk that exists in the absence of control measures)
Find the ratings for the consequence and the likelihood then refer to the table below:

Consequence Table

LEVEL	DESCRIPTOR	CONSEQUENCE – DESCRIPTION
1	Insignificant	No injuries, low financial loss
2	Minor	First aid treatment, on site release immediately contained
3	Moderate	Medical treatment required, on site release contained with outside assistance, high financial loss
4	Major	Extensive injuries, loss of production capability, off site release with no detrimental effects, major financial loss
5	Catastrophic	Death, toxic release off site with detrimental effect, huge financial loss

Likelihood Table

LEVEL	DESCRIPTOR	LIKELIHOOD – DESCRIPTION
1	Rare	May occur only in exceptional circumstances
2	Unlikely	Could occur at some time
3	Possible	Might occur at some time
4	Likely	Will probably occur in most circumstances
5	Almost Certain	Is expected to occur in most circumstances

Risk Matrix

LIKELIHOOD	CONSEQUENCES				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
(5) Almost Certain	M	M	H	H	H
(4) Likely	M	M	M	H	H
(3) Possible	L	M	M	H	H
(2) Unlikely	L	L	M	M	H
(1) Rare	L	L	M	M	H

Legend:

H:	High risk immediate action required
M:	Moderate risk; management responsibility must be specified (significant and moderate combined to be moderate)
L:	Low risk; manage by routine procedures

MANAGEMENT CONTROLS

Rating	Management control examples
Very Good	Controls are best practice, involve explicit standards and are followed all of the time. Includes a high emphasise on elimination, substitution or engineering controls.
Reasonable	Controls are in place but not followed all of the time and may not include best practice. Includes a high emphasis on administration and protective equipment.
Poor	There are few or no controls in place. No standards have been identified. Controls do not address Hierarchy of Control principles.

DETERMINATION OF RESIDUAL RISK

Residual risk (the risk that remains after implementing measures to reduce it)
Plot inherent risk against the assessed quality of the existing management control of the risk

INHERENT RISK				
	High			
	Mod			
	Low			
		Very Good	*Reasonable*	*Poor*
		MANAGEMENT CONTROL		

	Residual risk is high – attend to immediately
	Residual risk is moderate –attend to in the short term
	Residual risk is low- attend to in the longer term

High indicates a high risk – it must be recorded and managed as a matter of urgency

Manage all other moderate risks and all low risks to achieve continuous improvement in the longer term

THE TABLES

In this section the use of the tables is briefly described. It is critical that a risk assessment is completed for each area of work. This might be an individual laboratory within an organisation, it might be an individual project, which might extend into a number of laboratories within an organisation and outside the organisation or it might be a specialist service area such engineering support, gene sequencing services, etc. It is not one risk assessment for the whole organisation and it needs to be specific to the work area. It is possible for a risk assessment to be performed for an individual process, such as the use of ultracentrifuges and for that assessment to be available for the whole organization to utilise in their individual work area assessment.

PART A

Section 1. Project, work or equipment details

This form needs to be completed for all assessments. It details the work area, project or equipment being assessed. It lists all the staff who are in the work area, the project or use and service the equipment.

Section 2A. Workplace hazard identification

This is also to be filled out for each risk assessment. It identifies all the work place hazards. It is not just limited to biological hazards, but the group involved in the assessment (all the people identified in Part A: Section 1) should be involved in this assessment process. Think of all aspects of the work area, project or equipment assessment. Tick those boxes which apply to this assessment. A quick walk around your project or work area might assist you in this process.

Section 2B. Description of methodology.

In this section you detail what takes place in the project, work area or equipment being assessed. Provide as much detail of what you do as you feel necessary to fully describe what is taking place, in the work area, the project or equipment use, so that your group and those reading this form from outside your group, can understand what it is you are assessing.

Section 3A. Assessment of OHS risks

This is a critical element of the assessment. You need to identify the task/activity associated with each of the areas that you identified in Part A: Section 2A. You transfer the number to column labelled No. In the example shown on the sheet, you have identified the ultracentrifuge as a piece of plant, machinery, equipment in motion. In the next column you identify the specific task or activity associated with the ultracentrifuge. In the next column the specific hazard associated with this activity is identified.

The next stage is to identify the consequence of the hazard occurring (see details in the Consequence Table earlier) and to identify the likelihood of the hazard occurring (see details in the Likelihood Table). Both these assessments are done without any of the normal controls being applied. You now use the risk assessment matrix to determine the inherent risk (IR), which is the risk without any controls. You need to then transfer all the risks with a high IR to column 1 in the table in Section 3B and give details of current and proposed controls. You will then transfer the results of this assessment to the controls column of this table. For those moderate and low IR, you can detail the controls and them assess the effectiveness of the management controls and then determine the Residual Risk (RR) from residual risk table (see earlier).

Remember that the management controls follow the hierarchy of controls discussed earlier. Very good control are elimination of the hazard, substitution of a lower risk hazard or engineering controls. None of these controls involve staff training and actions and they can be demonstrated to be effective controls that are readily

monitored. The controls applied are considered best practice. If the controls are put in place but not followed all the time and may not constitute best practice, then they may be considered reasonable. This is usually the case where there is a high emphasis on administrative controls or on the use of PPE. Finally, there are few or no controls, no standards for reducing the hazards have been identified or the controls do not address the heiracy of controls. In this case the management controls are considered poor.

If the RR is low then you only need to attend to the hazard as a low priority long term action. If the RR is moderate then the hazards can be managed in the longer term, but great care to monitor the controls needs to be exercised. If the RR is high then it must be recorded and managed as a matter of urgency. If the RR cannot be reduced to moderate then the Organization needs to consider whether it is safe to carry out the work. One option is to determine that the risk is too great and that the work cannot proceed in the present circumstances. If the work is of such a high priority then addition resources may be required to build safer facilities, provide new containment equipment and to provide additional training and staff development. If the work requires a BSL-4 facility and the organisation only has a BSL-2 facility then they should not do the work but find organizations that they can collaborate with to do it safely.

Section 3B. High OHS residual risks and catastrophic (life threatening) inherent risks, agreed additional risk controls and implementation controls

In this form the high IR hazards are entered and existing control identified. Ten any additional controls that need to be developed are identified and someone is assigned to implement these by a specific time and a process of how they will be monitored will be identified. Only if these additional controls reduce the RR to moderate should the work proceed.

Section 4A. Assessment of environmental risks

Environmental risk management is also of importance in the risk assessment process. If the organization causes significant environmental damage the community has a right to express its concern about what is taking place. Many organisations have adopted and Environmental Management System (under ISO 14000?) and the work of this risk assessment and the management of the controls would fit into such a system.

The form is similar to 3A and the process carried out is the same. There are some examples in the form together with the usual areas of environmental risk that need to be addressed.

Section 4B. Environmental aspects with high residual risks, agreed additional risk controls and implementation of controls

The high IRs from Form 4A need to be transferred to Form 4B and the same process carried out as for form 3B.

Section 5: Comments/endorsements

This section is to be filled out by all the staff identified Part A. Section 1. The staff are acknowledging that they are aware of the potential hazards identified in this process and that they are aware of the controls. It is not that they are agreeing to be bound by this document and take on management responsibility for the risk assessment and the implementation of the controls. It still remains with management to make sure resources are available to implement and monitor the controls and to make the final approval for the work to proceed.

PART B. ANNUAL REVIEW SUPPLEMENT

There is a requirement every year to review the risk assessment. If no changes have occurred and the controls are being monitored correctly, then the form can be singed off with no additional work. If there have been changes of staff, then this is noted. It is recommended that any new staff joining should be taken through the risk assessment before they commence work so that they are aware of the hazards and the controls. This

new staff member should sign off that this process has taken place. If new hazards have been introduced, they need to be identified and an assessment of them made and documented.

PART C. RADIATION SUPPLEMENT

There is usually a requirement for assessment and control of all radiation sources, both ionizing and non-ionising, to be assessed and in some cases licensed. When completing this form, please make sure of your local legislation and regulations.

Part C1: Ionizing radiation

This form is self explanatory and its completion should comply with local/national regulations related to ionizing radiation.

Part C2: Non-ionizing radiation (NIR)

This form should be filled in consistent with local/national regulations regarding non-ionizing radiation sources.

PART D. BIOLOGICAL SUPPLEMENT

This should be completed for all biological work. Details of any import or use approvals for biologicals should be listed. In many countries the Department of Agriculture issues import approvals for biological agents. Some human pathogens are approved by the Department of Health.

The use of genetically modified organisms (GMOs) is very strictly regulated in many countries. You must make sure that the local/national regulations/guidelines are complied with when using GMOs. Tissues and materials of human origin pose a number of safety and ethical issues, and collection of human samples sometimes required approval of a human ethics committee.

The biologicals, including all micro-organisms being used in the laboratory, need to be identified. Note that later you will be asked to identify the hazards and the controls. Just listing a micro-organism in a Risk Group is not sufficient to identify the hazards. For example, the organism that you wish to work with might not be listed in a Risk Group. This does not mean it is in Risk Group 1. Its properties, such as infectivity, transmissibility, clinical disease, ability to treat infection, possibility of transmitting the disease, the environmental impact, all need to be assessed (see guidance in the WHO LSM3 and National Biosafety Standards and Guidelines). Also, for all risk group 3 and 4 agents, consideration of medical monitoring of staff is essential, and for risk group 2 agents it is desirable.

Remember that Risk Group does not necessarily translate directly to Biosafety Level. For example some micro-organisms that are grown to high concentrations or put into animals can require work to be performed at a higher containment level. An example is human immunodeficiency virus, where diagnostic work with small quantities, can safely be performed at BSL-2. but once the virus is replicated or put into animals, the work is performed at BSL-3. Finally, the biological safety officer needs to review this supplement and sign off that the data is correct.

PART E: PROJECT CLOSURE SUPPLEMENT

The final thing to be completed is the closure form once the project is being completed. It is important not to leave projects risk assessments open if they have been terminated. One need to ensure that everything has been correctly stored, documented or destroyed and that the file records that this has been done correctly.

APPENDIX 1 – RISK ASSESSMENT AND CONTROL OF WORK FORM

RISK ASSESSMENT AND CONTROL OF WORK

This form is a tool to assist Staff, Supervisors and Managers in the following;

- Identification of health and safety hazards that staff and others may be exposed to at work and environmental aspects associated with activities.
- Assessment of occupational health and safety and environment risks.
- Identification / implementation of existing / proposed controls.

This form consists of six parts:

Part A - Assessment (Sections 1-5)

- To be completed for all projects, activities or major plant or equipment being assessed (or reassessed following major changes).
- Sections 1 – 4 are to be completed by the Line Manager responsible in consultation with staff and the Health and Safety Representative involved. Assistance may be sought from the OHSE staff where necessary.
- Section 5 is to be completed by staff and Line Managers as indicated and endorsed by the relevant OHSE staff and management.
- Where ionizing and non-ionizing radiation or biological material is used, Parts C1, C2 and/or D must be completed (see below).

Part B - Annual Review Supplement

- To be completed annually or when changes that involve different OHSE risks to the workplace, procedures, plan or equipment are proposed.

Part C1 - Ionising Radiation Supplement

- To be completed when ionizing radiation is used.

Part C2 - Non-Ionising Radiation Supplement

- To be completed when non-ionizing radiation is used.

Part D - Biological Supplement

- To be completed when biological materials are used.

Part E - Project Closure

- To be completed when the project is decommissioned, closed or equipment no longer used.

PART A: SECTION 1. PROJECT, WORK OR EQUIPMENT DETAILS

Department/Section	Location
Project Title	Number/code
Date of assessment	
Start date of project	End date of project
Description of work area and work tasks, e.g. water laboratory, analysis of sediment. (If applicable, attach a separate short project outline with work methods and equipment used)	
Line Manager/ Supervisor	

Staff Names	Name of Designated Work Group (DWG)	Name of Health & Safety Representative

External collaborators (include names of personnel working on site)
Location(s) of work, e.g. field site, building room number, external location

PART A: SECTION 2A. WORKPLACE HAZARDS IDENTIFICATION

Using tick boxes identify all hazards associated with workplace, system of work, equipment and substances used.

Mechanical (Plant)
- 1.1 Vehicles, transport ☐
- 1.2 Plant, machinery, equipment in motion ☐
- 1.3 Compression/tension/stored energy ☐
- 1.4 Noise ☐
- 1.5 Vibration ☐
- 1.6 Firearms ☐
- 1.7 Pressure equipment (high/vacuum) ☐
- 1.8 Tools, sharps, cutting implements ☐

2. Radiation
- 2.1 Ionising (refer to Part C1) ☐
- 2.2 Ultraviolet (refer to Part C2) ☐
- 2.3 Infrared (refer to Part C2) ☐
- 2.4 Laser (refer to Part C2) ☐
- 2.5 Radiofrequency (refer to Part C2) ☐
- 2.6 Electromagnetic field (refer to Part C2) ☐
- 2.7 Extremely low frequency (refer Part C2) ☐

3. Fire and Explosion
- 3.1 Flammable substances ☐
- 3.2 Explosives ☐

4. Temperature
- 4.1 High temperature materials ☐
- 4.2 Cryogenic fluids ☐

5. Hazardous Environments
- 5.1 Confined spaces ☐
- 5.2 Working at heights ☐
- 5.3 Working at sea or in water bodies ☐
- 5.4 Heat/cold stress ☐

6. Electrical
- 6.1 High voltage equipment ☐
- 6.2 Live electrical equipment ☐
- 6.3 Static charge ☐

7. Biological
- 7.1 Biological materials (Refer to Part D) ☐
- 7.2 Biological materials (refer to Part D) involves GMOs ☐
- 7.3 Allergens / sensitisation ☐
- 7.4 Irritants ☐
- 7.5 Genotoxins (mutagens, teratogens) ☐
- 7.6 Zoonoses (refer to Part D) ☐
- 7.7 Handling of small animals ☐
- 7.8 Handling of large animals ☐
- 7.9 Handling of human samples (refer to Part D) ☐

8. Chemical/Hazardous Substances
- 8.1 Carcinogens ☐
- 8.2 Sensitising agents ☐
- 8.3 Corrosive/oxidising agents ☐
- 8.4 Irritants ☐
- 8.5 Genotoxins (mutagens, teratogens) ☐
- 8.6 Toxic/harmful substances ☐
- 8.7 Solvents ☐
- 8.8 Generation of dusts, vapours, fumes etc. ☐
- 8.9 Asbestos ☐

9. Gases
- 9.1 Flammable ☐
- 9.2 Asphyxiant inert gas ☐
- 9.3 Toxic gas ☐
- 9.4 Gas cylinders / tanks ☐
- 9.5 Pressurised lines ☐

10. Personal
- 10.1 Manual handling incl. striking & grasping ☐
- 10.2 Slips, trips, falls ☐
- 10.3 Fixed posture, e.g. microscopy ☐
- 10.4 Repetitive and/or overuse movements, e.g. keyboarding, pipetting ☐
- 10.5 Pressure (diving/altitude) ☐
- 10.6 Working alone ☐
- 10.7 Field work ☐
- 10.8 Mental stress ☐
- 10.9 Overseas travel / work (vaccinations) ☐
- 10.10 Engulfment e.g. in sand ☐

11. Other - Specify:

PART A: SECTION 2B. DESCRIPTION OF METHODOLOGY

e.g., inactivate the MTB culture by heating at XX ^{O}C for Y minutes,.....

Describe the process being assessed and all related work activities.

PART A: SECTION 3A. ASSESSMENT OF OHS RISKS

This page is used to record each of the occupational health and safety hazards identified in Section 2 (ticked boxes) and to record the risk ratings associated with each hazard.

Refer to the Risk Assessment module for assistance in completing this section.

Transfer all high hazards, ie those with a catastrophic consequence inherent risk and/or high residual risk rating to column 1 in Section 3b and give details of current and proposed controls.

No	Description of task/activity	Specific Hazard	Inherent Risk*			Controls – Existing and Proposed	Residual Risk*	
	Examples		C	L	IR		M	RR
1.2	*Centrifuging samples – ultra centrifuge*	*Rotor/centrifuge imbalance from unbalanced tubes*	*Mod*	*Almost Certain*	*High*	*Safety cutout on centrifuge, training, correct balance and loading*	*VG*	*Mod*
7.7	*Handling adult pigs – taking blood samples*	*Kicks, bites, manual handling injury*	*Mod*	*Almost certain*	*High*	*Restraints/cradles for pigs, training, two persons*	*Reas*	*High*
10.6	*Working Alone in PC3 lab*	*Incident when no-one around*	*Mod*	*Possible*	*Mod*	*Emergency communication systems, hands-free, to monitored external station; viewing windows, advise colleagues of entry/exit times, report in every half hour*	*VG*	*Low*
8.7	*Solvents eg methanol, ethanol, phenol*	*Inhalation of vapours*	*Mod*	*Almost certain*	*High*	*Use in fume cupboard for volumes >20ml*	*VG*	*Mod*

C – consequences; L – likelihood; IR – inherent risk; M – management control; RR – residual risk

PART A: SECTION 3B. HIGH OHS RESIDUAL RISKS AND CATASTROPHIC CONSEQUENCE (LIFE THREATENING) INHERENT RISKS, AGREED ADDITIONAL RISK CONTROLS AND IMPLEMENTATION OF CONTROLS

Hazards with high risks Identified List ***high risks*** identified in Section 3a (column 'RR') and any catastrophic consequence inherent risks (column 'C') and provide details.	Existing Controls (Procedures / Equipment) Include building, facilities, personal protective clothing and equipment, etc.	Agreed additional risk controls Using the Hierarchy of Control, list agreed controls after team consensus on the justification and optimisation of controls	Dates for implementation / Person responsible	How will these risk and control options be monitored?
(eg) 7.7 handling adult pigs	*Training, cradles, work in pairs*	*Improve design of cradles*	*Day/ Month/ Year (J. Smith)*	*Inspections, review reports.*

PART A: SECTION 4A. ASSESSMENT OF ENVIRONMENTAL RISKS

Indicate environmental aspects such as forms of waste. Indicate quantities generated, potential environmental impacts and existing controls. Assess the inherent and residual risk.

Refer to the Risk Assessment module for assistance in completing this section.

Transfer all high environmental aspects, ie those with a high residual risk rating to column 1 in Section 4b and give details of proposed controls.

	Environmental aspects	*Form & quantity/year*			*Potential environmental impact*	*Inherent Risk**			*Controls – Existing and Proposed*	Residual Risk*	
		Solid	Liquid	Gas							
Eg						C	L	IR		M	RR
1	*Waste chemical*	*1 kg*	*200L*		*Waste to sewer*	*Mod*	*Likely*	*Mod*	*nil*	*Poor*	*High*
6	*Paper*	*20 kg*			*Landfill, some recycled*	*Insig*	*Likely*	*Mod*	*Landfill, some recycled*	*Reas*	*Mod*
1	Waste chemicals										
2	Waste oils										
3	Waste metals										
4	PCBs/CFCs										
5	Use of vehicles										
6	Paper										
7	Plastic										
8	Storage of chemicals										
9	Atmos contaminants										
10	Microbiological / animal/ plant waste										
11	Radioactive waste										
12	Sharps /glass										

13	Noise										

C – consequences; L – likelihood; IR – inherent risk; M – management control; RR – residual risk

PART A: SECTION 4B. ENVIRONMENTAL ASPECTS WITH HIGH RESIDUAL RISKS, AGREED ADDITIONAL RISK CONTROLS AND IMPLEMENTATION OF CONTROLS

This page is used to record each of the high environmental aspects identified in Section 4a and to outline the proposed controls, agreed controls and details on the implementation of the controls.

Environmental aspects with high residual risk Transferred from Section 4a (column 'RR') and provide details.	Existing Controls (Reuse, recycling / Procedures / Equipment etc)	Agreed additional risk controls Using the Hierarchy of Control (elimination, reduction, reuse, recycling, containment etc), list agreed controls after team consensus on the justification and optimisation of controls	Dates for implementation / Person responsible	How will these risk and control options be monitored?
eg *Waste acidic solvent* *discharged to sewer*	*Nil*	*1. Seek alternative methods* *2. Contain and recycle* *3. Treatment by neutralisation*	*1. Month xx (J. Smith)* *2. Month yy (D. Brown)* *3. Month yy (A Jones)*	*Method assessment, training, inspections, review EMS reports.*

PART A: SECTION 5. COMMENTS / ENDORSEMENTS

Staff identified in Section 1 to complete

I have noted the (potential and high risk) OHS hazards and environmental aspects identified in Sections 2, 3 and 4 of this assessment and have been advised of their existence within the workplace and the necessary risk controls.

Name	Signature	Date

Line Manger, Supervisor (or officer completing assessment)

This Project/Work has been examined in consultation with the staff members involved, OHSE staff and the Health and Safety Representative. The hazards / environmental aspects have been identified and the control measures indicated have been approved, initiated and/or implemented.

Name

Signature: _____ Date ___/___/___

OHSE Manager / Officer

Name

Signature: _____ Date ___/___/___

EMS Officer

Name

Signature: _____ Date ___/___/___

Specialist Safety Officer (eg Electrical, Diving, Boating, Chemical, Firearms)

Name

Signature: _____ Date ___/___/___

Senior Manager

Name

Signature: _____ Date ___/___/___

PART B ANNUAL REVIEW SUPPLEMENT

Project No.: ……. Date: …../…../…..

Since the last assessment, have any changes occurred in personnel or the nature or degree of the hazards or environmental aspects associated with this work?

Yes £ No £

If Yes, give details below.
If significant, fill out a new Part A.

1. Staff Changes

Name	Date Ceased	Date Commenced	Designated Work Group	Health and Safety Representative	OHS Induction (Y/N)

2. Location Changes (eg new rooms / buildings / sites)

3. New / deleted / changed Hazards / Aspects
(refer to part A – include significant hazard details, environmental aspects and controls)
*enter 'new', 'deleted' or 'changed'

Hazards, Aspects from Part A	Status of hazard/ Aspect*	Inherent Risk	Controls	Residual Risk

Note: If new high residual risks are identified, then complete new Part A assessments for Sections 3b and / or 4b to ensure risk controls are appropriate.

Comments / Endorsements

Staff identified in Part A Section 1 and new staff to complete

I have noted the potential and significant hazards and environmental aspects identified in the assessment of work form and the annual review, and have been advised of their existence within the workplace.

Name	Signature	Date

Line Manger, Project Leader, Supervisor (or officer completing assessment)

This Project/Work has been examined in consultation with the staff members involved, OHSE staff and the Health and Safety Representative. The hazards / environmental aspects have been identified and the control measures indicated have been approved, initiated and/or implemented.
Name

Signature: _____ Date ___/___/___

Occupational Health & Safety Manager / Coordinator/ Officer

Name

Signature: _____ Date ___/___/___

Environment Management System Officer

Name
Signature: _____ Date ___/___/___

Specialist Safety Officer (eg Electrical, Diving, Boating, Chemical, Firearms)

Name

Signature: _____ Date ___/___/___

Director / Officer in Charge

Name

Signature: _____ Date ___/___/___

PART C1 IONIZING RADIATION SUPPLEMENT

1. Ionizing Radiation Source and Apparatus Details

List all types of unsealed and sealed radiation sources and radiation apparatus used in the work. Give the type (eg ^{14}C) and form (eg labelled thymidine or sealed source) of the radionuclide(s). For unsealed radiation sources estimate the maximum activity stored or used at any one time and total for one year.

Unsealed sources (If insufficient space attach a list or refer to a file)

National Radiation Control Authority Hazard Code eg Yellow	Radionuclide	Form		Maximum activity used (MBq)	
		Physical (solid/liquid)	Chemical Compound	at any one time	total for one year

Sealed sources (If insufficient space attach a list or refer to a file)

National Radiation Control Authority Hazard Hazard Code eg. yellow	Radionuclide	Form	Activity		Frequency of use

Irradiating Apparatus (If insufficient space attach a list or refer to a file)

National Radiation Control Authority Hazard Hazard Code eg. Blue	Apparatus	Make and Model	Output parameters	Frequency of use

2. Staff approved to work with radiation dealing & personnel monitoring

Staff	Radiation dealing	Type of monitoring - eg film type, TLD, neutron film badge, thyroid count (^{125}I), urine count (^{3}H, ^{14}C)

3. Precautions Against Hazards

Fume cupboard or glove box facilities used (indicate room no.) _____
Shielding used _____
Type of personal protective equipment used _____
Describe training undertaken by and/or experience of staff who will use sources or equipment
Describe storage of sources _____
Are written Operating Procedures available? Yes £ No £ If Yes, attach copy Other (eg contamination monitoring, spill kits) _____
Describe methods of waste disposal
Are emergency procedures in place? Yes £ No £ If Yes, attach copy

Has environmental impact of accidental release been assessed and entered in Part 4 of Section A of form?	Yes £	No £

4. Radiation Safety Officer's Comments / Endorsements & Radiation or OHS Committee minute acknowledgement

Comments / conditions _____

National Radiation Control Authority License No. (Source or Facility) under which use is conducted _____

Work approved without conditions £ Approved with conditions £ Work not approved £

Name _____ Signature _____ Date _____

Radiation / OHS Committee part C1 items minuted:

Name _____ Signature _____ Date _____

PART C2 NON-IONIZING RADIATION (NIR) SUPPLEMENT

1. Non-Ionizing Radiation Apparatus Details

List all types of NIR apparatus used in the work. Attach a list or refer to relevant file if there are many apparatus. Give the details of the NIR apparatus and type of NIR eg UV,IR, laser, EMF.

National Radiation Control Authority Hazard Code Green	Type of apparatus and class	Type of NIR	Output parameters

2. Precautions Against NIR Hazards

Safety signs in place to warn staff of the NIR: _____

Type of shielding in place: _____

Safety interlocks in place: _____

Personal protective equipment used: _____

Describe training undertaken by, and/or experience of, staff who will use the apparatus:

Are written Operating Procedures available?	Yes £	No £	If Yes, attach copy
Are emergency procedures in place?	Yes £	No £	If Yes, attach copy

3. Test / Survey / Results

4. Radiation Safety Officer's Comments / Endorsements & Radiation or OHS Committee minute acknowledgement

Comments / conditions	
National Radiation Control Authority License No. (Source or Facility) under which use is conducted:	
Work approved without conditions £	Approved with conditions £ / Work not approved £
Name _____ Signature _____ Date _____	
Radiation / OHS Committee part C2 items minuted:	
Name _____ Signature _____ Date _____	

PART D BIOLOGICAL SUPPLEMENT

1. Biological Materials Used

Does work fall under National Agricultural Control Authority guidelines for the use of imported Biological Materials?

Yes £ No £ If Yes, provide Permit No. and Title:

Is genetic manipulation work performed?	Yes £	No £	
Is material of human origin used?	Yes £	No £	
Has sample collection been approved by Human Ethics Committee?	Yes £	No £	N/A £

In the following table, list human materials used and containment and management procedures (eg BSL2 labs, BSCII, Standard Operating Procedures):

Type of human sample (eg blood)	Source (eg blood bank)	List containment facilities & procedures to minimise/eliminate infection

In the following table, list all microorganisms, cell lines and primary cultures worked with or stored. In addition, list all plants and animals that fall under National Agricultural Control Authority guidelines and/or National Gene Control Authority regulations:

Microorganism, cell line, plant, animal	Risk Group No.[1]	IBC advice / approval sought? Y/N or N/A	Human Pathogen? Y/N	National Gene Control Authority category (exempt, NLRD, NIR, DNIR) or N/A[2]	National Gene Control Authority approval number (or N/A)

Note: (1) Risk Group No. refers to the classification of infectious microorganisms according to their degree of risk and is detailed in WHO LBM3 or National Biosafety Legislation or Standards.
(2) NLRD = Notifiable low risk dealing; DNIR = dealing not involving intentional release; DIR = dealing involving intentional release; N/A = not applicable

2. Medical Monitoring

E.g. antibody titre levels, immunisations

3. Precautions Against Hazards

List containment equipment used e.g. biological safety cabinets (indicate room no.):
Are facilities where GMO work is to be undertaken certified under National Gene Control Authority e.g. BSL2, BSL3 laboratories? Yes £ No £ N/A £ Comments:
List personal protective clothing and equipment worn:
Give details for control of aerosols e.g. during blending:
Are written procedures available? Yes £ No £ If no, provide details:
List any specialist training undertaken or required:
Are treatment/disposal methods in accordance with Agricultural Control Authority and National Gene Control Authority for all biological materials as well as the WHO LBM3 or National Biosafety legislation or Standard (where applicable)? Yes £ No £ Provide details:

4. Biological Safety Officer's Comments / Endorsement

(Ensure that this is reviewed by the IBC Chair and person responsible for National Agricultural Control Authority permits if these are different people.) Comments:
Name _____ Signature _____ Date _____

PART E PROJECT CLOSURE SUPPLEMENT

1. Work Area or Project Closure

Project Leaders are responsible for managing the clean up and safe decommissioning of the work area, facilities and equipment when work has been completed. This includes ensuring the suspension of services no longer required.

All ongoing health, safety and environmental hazards or risks are to be identified and eliminated.

- Stored mechanical or electrical energy in any apparatus has been discharged.
- Electrical equipment has been turned off and the power supply isolated and tagged.
- Gas supplies have been turned off.
- Equipment no longer required has been returned to storage or disposed of. Any malfunctions or problems detailed on tag attached to equipment. Location of equipment manuals and SOPs on tag attached to equipment.
- An inventory of all remaining chemical, biological and radioactive materials has been compiled and appropriate safety disposal methods arranged for those materials no longer required.

2. Inspection of Work Areas (Project Leader, HSR, Site Maintenance, OHSE Officer)

Comments after inspection of work areas following completion of work;

3. Health, Safety and Environment Records for Project

Records relating to the nature and magnitude of hazards, their annual review, supporting documents and provision of relevant information to staff must be kept for 75 years or permanently in project files.

These records include;

- HSE Assessment and Control of Work Form.
- Safe work practice documents developed for the project.
- List of material safety data sheets and/or chemicals used in project.
- All results of health and environmental monitoring.
- Records of personal protective equipment issued and training undertaken.

Location and reference details of the appropriate records:

4. Sign Off

Project Leader	Name		Signature		Date	
OHSE Manager	Name		Signature		Date	
Site Maintenance Mgr	Name		Signature		Date	
Chief / OIC	Name		Signature		Date	