Risk Assessment: Biological Agents

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Corporate Health and Safety Advisor
Risk Assessment: Biological Agents

Content

• Risk assessment – what is it (for)?
• What are you assessing?
• Competence to risk assess
• Factors influencing risk
• Quantifiable risk assessments
• Tolerability of risk
• Review and audit – how good are your risk assessments?
Risk Assessment: Biological Agents

The Animal and Plant Health Agency

• To prevent, detect and control threats to animal and plant health
• To protect public health from risks from animals and plants
• To facilitate safe trade
• To protect animal and plant welfare
• Included are bees, seeds and fish!
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Department for Environment Food & Rural Affairs

- 2,500 staff
- Laboratories
- Farms / animal facilities
- Offices

Working with:
- TB (bovine TB problem currently in the UK)
- Newcastle Disease
- Rabies
- Other HG3 and HG4 agents e.g. bird flu
"We've considered every potential risk except the risks of avoiding all risks."
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Risk

Hazard – something with the potential to cause harm

Risk – the likelihood (chance or probability) the hazard will cause harm and the degree of harm (number of people affected and how badly – human harm)

Risk = probability v consequence (includes all harm)

Danger - Exposure or vulnerability to harm or risk

Peril - Imminent danger
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Risk assessment

“The backbone of the practice of biosafety is risk assessment. While there are many tools available to assist in the assessment of risk for a given procedure or experiment, the most important component is professional judgement.”

Laboratory Biosafety Manual 3rd Edition  WHO
Risk assessment

“Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person’s exposure to an agent, the likelihood that such exposure will cause a LAI, and the probable consequences of such an infection.”

BMBL 5th Edition  CDC
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“Risk assessment is simply a means of determining the risk associated with work with a particular hazard.”

Risk assessment needs to be ‘suitable and sufficient’. It should:
• reflect the nature of the work activity being assessed
• draw on specialist advice as required;
• consider all those who may be affected by the work
• anticipate foreseeable risks; and
• be appropriate to the nature of the work and identify how long the assessment is likely to remain valid.
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“Process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable.”

The risk assessment should categorize risks to identify those which need to be eliminated or controlled. Descriptions of likelihood and consequence, together with the acceptability of risk levels should be defined and used in the assessment. Such a classification can be achieved for example through the use of a risk matrix identifying likelihood and consequence categories.

CEN Workshop Agreement (CWA) 15793 Laboratory biorisk management standard
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What are you assessing?
• A pathogen – to determine?
• An ‘overarching’ risk assessment to identify mitigation strategies
• A process / procedure that includes (a) biological agent(s)
• An activity based risk assessment (local risk assessment)
• A project involving biological agents?
• What about generic risk assessments?
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What are you assessing?

Risk of what?
• Laboratory acquired infection
• Loss or release of the agent including biosecurity risk (environmental risk and misuse risk)

Identify the scope of your risk assessment and what you and risk assessing!
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What are you risk assessing?
• Infection from a biological agent (LAI)
• Sharp injuries
• Musculoskeletal disorders
• Electric shock
• Burns / scalds
• Slips, trips and falls
• Working alone

And under what circumstances - presume ‘normal’ conditions?
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‘Normal’ conditions

- **Staff are perfect!** (Competent, sober, concentrated, good mood, enthusiastic, motivated (and well paid), not stressed etc.
- Ambient air temperature
- No time pressure
- Plenty space
- Right equipment / tools – all well maintained working optimally
- PPE all fits and working (and worn!)
- Good lighting
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Competence to assess?

- Individual or group?
- Expertise in organism?
- Experience in similar work / procedure?
- Understanding of risk appetite tolerance?
- Understanding of legal and other local requirements to comply with?
- Understanding of what might go wrong?
- Observational skills?
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Common factors to consider

1. Pathogenicity of the agent and infectious dose
2. Potential outcome of exposure
3. Natural route of infection
4. Other routes of infection, resulting from laboratory manipulations
5. Stability of the agent in the environment
6. Concentration of the agent and volume of concentrated material
7. Presence of a suitable host (human or animal)
8. Information from animal studies, reports of LAI’s or clinical reports
9. Laboratory activity planned (sonication, aerosolization, centrifugation)
10. Any genetic manipulation that may extend the host range or alter the agent’s sensitivity to known, effective treatment regimens
11. Local availability of effective prophylaxis or therapeutic interventions
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Common questions to ask (pro forma)

1. Frequency and duration of exposure
2. Agent titre / concentration and quantity used
3. Consider inadvertent culture of other agents that may present in specimen
4. Species at risk
5. Infectious dose
6. Routes of transmission
7. Vulnerable individuals at additional risk
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Common questions to ask (pro forma)

1. Is it likely that severe illness or death could occur if disease was contracted?
2. Is it likely that an infected person could infect others?
3. Could agents be harmful to the human reproductive process?
4. Is there a potential to cause cancer?
5. Primary containment required?
6. Storage conditions?
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Control Check

With the current control measures in place will the persons identified in this assessment be put at significant risk if they:

1. Handle the agents – yes or no?
2. Are in the vicinity of where the agents are being handled, transported, stored, disposed of – yes or no?
3. Are in the vicinity of an accidental release or spillage of the agent – yes or no?
4. Come into contact with surfaces contaminated with the agent(s) – yes or no?
(Semi) Quantifiable risk assessment

Probability (chance) v Consequence

10 x 10

5 x 5

4 x 4

3 x 3

2 x 2 (Noah)

(Very high, high, medium, moderate, low, very low)
(Semi) Quantifiable risk assessment

Consequence:

- Human harm - LAI
- Escape or release
- Reputational harm
- Financial damage
- Theft / misuse
- Media and the public

26 May 2011 Last updated at 16:25
'Safety incidents' at animal lab
By Pallab Ghosh
Science correspondent, BBC News

The Health and Safety Executive has taken action against an animal health laboratory at the centre of a foot and mouth outbreak four years ago.

The agency has served the Institute for Animal Health (IAH) with two ‘improvement notices’ following two incidents earlier this year involving infectious material.

The institute in Pirbright, Surrey, has appealed against one of the incidents.

Both were reported to the Health and Safety Executive by IAH managers.

The first incident occurred in January when a flask containing Foot and Mouth Virus cracked and leaked. The flask was over a sink and infectious material went down a secure drainage system. It therefore did not leak into the environment.
Risk appetite / tolerability of risk

"Surprisingly enough, this is in the range of acceptable risk."

S. Harris
(Semi) Quantifiable risk assessment

<table>
<thead>
<tr>
<th>Likelihood of harm occurring</th>
<th>Potential severity of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly unlikely 1</td>
<td>Slightly Harmful 1</td>
</tr>
<tr>
<td></td>
<td>Harmful 2</td>
</tr>
<tr>
<td></td>
<td>Extremely Harmful 3</td>
</tr>
<tr>
<td>Unlikely 2</td>
<td>Trivial 1</td>
</tr>
<tr>
<td></td>
<td>Tolerable 2</td>
</tr>
<tr>
<td></td>
<td>Moderate 3</td>
</tr>
<tr>
<td>Likely 3</td>
<td>Tolerable 2</td>
</tr>
<tr>
<td></td>
<td>Moderate 4</td>
</tr>
<tr>
<td></td>
<td>Substantial 6</td>
</tr>
<tr>
<td></td>
<td>Intolerable 9</td>
</tr>
</tbody>
</table>
# (Semi) Quantifiable risk assessment

<table>
<thead>
<tr>
<th>Likelihood of Harm Occurring</th>
<th>1 Insignificant</th>
<th>2 Minor</th>
<th>3 Moderate</th>
<th>4 Severe</th>
<th>5 Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare</td>
<td>1 = Low</td>
<td>2 = Low</td>
<td>3 = Low</td>
<td>4 = Low</td>
<td>5 = Low</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2 = Low</td>
<td>4 = Low</td>
<td>6 = Low</td>
<td>8 = Medium</td>
<td>10 = Medium</td>
</tr>
<tr>
<td>Possible</td>
<td>3 = Low</td>
<td>6 = Low</td>
<td>9 = Medium</td>
<td>12 = Medium</td>
<td>15 = High</td>
</tr>
<tr>
<td>Likely</td>
<td>4 = Low</td>
<td>8 = Medium</td>
<td>12 = Medium</td>
<td>16 = High</td>
<td>20 = High</td>
</tr>
<tr>
<td>Almost Certain</td>
<td>5 = Low</td>
<td>10 = Medium</td>
<td>15 = High</td>
<td>20 = High</td>
<td>25 = High</td>
</tr>
</tbody>
</table>

Likelihood of Harm Occurring:
- 1 Rare
- 2 Unlikely
- 3 Possible
- 4 Likely
- 5 Almost Certain

Severity of Harm:
- 1 Insignificant
- 2 Minor
- 3 Moderate
- 4 Severe
- 5 Catastrophic
(Semi) Quantifiable risk assessment
(Semi) Quantifiable risk assessment
### (Semi) Quantifiable risk assessment

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Action &amp; Action Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trivial 1</td>
<td>No Action Required</td>
</tr>
<tr>
<td>Tolerable 2</td>
<td>No additional controls required. Consideration may be given to a more cost effective solution or improvement that imposes no additional burden.</td>
</tr>
<tr>
<td>Moderate 3 or 4</td>
<td>Efforts required to reduce risk. The cost of prevention should be carefully measured and limited. Risk reduction measures should be implemented within a time period. Where moderate risk is associated with extremely harmful consequences, further assessment may be necessary to establish more precisely the likelihood of harm as a basis for determining the need for control measures.</td>
</tr>
<tr>
<td>Substantial 6</td>
<td>Work should not be started or continued until the risk has been reduced. Considerable resources may have to be allocated to reduce risk. Where the risk involves work in progress, URGENT action should be taken</td>
</tr>
<tr>
<td>Intolerable 9</td>
<td>Work should not be started or continued until the risk is tolerable/reduced to an acceptable level. If it is not possible to reduce the risk (even with unlimited resource,) work should remain prohibited. Note: Tolerable here means that the risk has been reduced to the lowest level that is reasonably practical.</td>
</tr>
</tbody>
</table>
Foreseeability and So What If!
(So What If Techniques – SWIFT)

• All power is lost (and back up power)
• Someone goes mad! (or just collapses)
• Autoclave goes down
• Someone has to leave in an emergency – lone working
• Fire or other evacuation emergency
• Negative pressure lost
Authorisation / Sign off

Statement of Departmental / workgroup Approval:

“I confirm that this RA has been thoroughly and stringently reviewed locally within my workgroup by at least 4 senior, qualified members of the workgroup (list or state committee)”
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Less common factors considered in risk assessments:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedures / work and /or biological agent
3. Competence – staff experience
4. Speed and pressure of work
Risk Variables

Human Error Laboratory Incidents: Time of day

![Bar chart showing the frequency of human error laboratory incidents by time of day. The chart has bars representing the number of incidents at different time intervals, with the y-axis indicating the number of incidents ranging from 0 to 35. The x-axis shows the time of day in 30-minute intervals, from 00:30 to 23:30.]
Risk Assessment: Biological Agents

Less common factors to consider:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedure / work and /or biological agent
3. Competence – staff experience
4. Speed and pressure of work
Risk Variables

Familiarity of work

Risk
Factor

Common / everyday  Regular / frequent  Common  Irregular / infrequent  One off / novel

0  2  4  6  8  10  12  14  16  18  20
Risk Assessment: Biological Agents

Less common factors to consider:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedure / work and /or biological agent
3. Competence – staff experience
4. Speed and pressure of work
Risk Variables

Human Error: Competence / inexperience

- Expertly competent
- Very competent
- Competent
- Newly competent
Risk Assessment: Biological Agents

Less common factors to consider:

1. Time of day – how long working in a single period (control length of time and breaks)
2. Newness of the procedure / work and /or biological agent
3. Competence – staff experience
4. Speed and pressure of work
Risk Variables

Time pressure / speed of work

![Graph showing the relationship between risk factor and time pressure/work speed.

- Low risk (Relaxed/slow) is at the bottom.
- High risk (Very rushed) is at the top.

- As time pressure/work speed increases, the risk factor also increases.

<table>
<thead>
<tr>
<th>Work Rate</th>
<th>Risk Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relaxed/slow</td>
<td>0</td>
</tr>
<tr>
<td>Normal work rate</td>
<td>2</td>
</tr>
<tr>
<td>Some time pressure</td>
<td>4</td>
</tr>
<tr>
<td>Very rushed</td>
<td>10</td>
</tr>
</tbody>
</table>
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Other less common factors to consider:

1. Environmental conditions – temperature, humidity etc.
2. Space – sufficient
3. State of equipment – fit for purpose, maintained
4. Psychological state of workers – stress
5. Physical state of workers – meet the demands of the work
6. Lessons from incidents and LAI cases
7. Other factors – noise, distractions, sexual tension, etc.
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How good are yours?

• ‘Normal’ factors?
• Additional factors affecting risk?
• Emergency and ‘what if’ situations?
• Incident and accident investigations?
• Observational audits?
• SoP’s – compatibility with risk assessments?
• Assesses and test staff?
• Risk assessment part of risk management and health and safety culture – survey?
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Audit / review questions

• Are you asking the right questions?
• How are risk assessments (controls) being monitored by management?
• Do risk assessments cover routine and non-routine activities?
• Were those who took part in the assessment competent?
• Are they suitable and sufficient and fit for purpose?
• Is there an understanding of ‘acceptable’
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Survey (anonymous)

• Some risk assessments are not really practical
• Some RA’s do not reflect how the job is actually done
• Some risk assessments are difficult to follow
• Some RA’s are only there to protect management's back
• Not all the risk assessments are strictly followed here
• I sometimes turn a blind eye to some less important risk assessment controls/procedures
• Management sometimes turn a blind eye to risk assessment controls/procedures being broken
• Managers sometimes turn a blind eye to people who are not working to the risk assessments
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Q21. "Not all the health and safety procedures are strictly followed here" by role for All Respondents

<table>
<thead>
<tr>
<th>Role</th>
<th>Unfavourable</th>
<th>Neutral</th>
<th>Favourable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>37.6%</td>
<td>31.4%</td>
<td>36.5%</td>
</tr>
<tr>
<td>Director/Senior Manager</td>
<td>39.8%</td>
<td>23.6%</td>
<td>36.7%</td>
</tr>
<tr>
<td>Manager (not first line)</td>
<td>39.5%</td>
<td>32.6%</td>
<td>34.9%</td>
</tr>
<tr>
<td>Supervisor/First Line Manager</td>
<td>34.0%</td>
<td>26.9%</td>
<td>38.2%</td>
</tr>
<tr>
<td>Employee</td>
<td>39.5%</td>
<td>34.8%</td>
<td>35.6%</td>
</tr>
<tr>
<td>Other (e.g. contractor / agency staff)</td>
<td>43.5%</td>
<td>34.8%</td>
<td>21.7%</td>
</tr>
</tbody>
</table>
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Q14. "Some health and safety procedures are difficult to follow" by role for All Respondents

- Overall: 34.9% Unfavourable, 33.0% Neutral, 31.5% Favourable
- Director/Senior Manager: 31.4% Unfavourable, 36.7% Neutral, 32.0% Favourable
- Manager (not first line): 36.5% Unfavourable, 32.9% Neutral, 30.6% Favourable
- Supervisor/First Line Manager: 37.0% Unfavourable, 28.5% Neutral, 33.6% Favourable
- Employee: 32.0% Unfavourable, 35.2% Neutral, 31.2% Favourable
- Other (e.g. contractor / agency staff): 33.3% Unfavourable, 52.5% Neutral, 29.2% Favourable
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Risk Assessment: Working with chlamydia trachomatis:

On the 20th page of the 23 page risk assessment the result was:
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“The final assessment is MODERATE”
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A better way?

Calculate the risk under ‘normal’ circumstances

e.g. the chance of a LAI is 500,000:1

Is this acceptable?
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However:

• It is always 6 degrees too hot in the lab (x3)
• It’s a bit cramped but we have no alternative at that containment level (x2)
• We’ve only done this once 2 years ago (x10)
• We have 3 weeks to get this done before the lab goes down (x6)
• 2 of the 4 staff we need to use and are competent are ‘at risk’ of redundancy (x4)
• We are suffering periodic equipment failures in that room (x3)
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The risk under our actual circumstances

The chance of a LAI is 115:1

Is this acceptable?
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Challenge

- How can we make risk assessments more dynamic to better reflect actual work and conditions (and changing circumstances)?
- What is ‘acceptable’ risk (tolerable)?
- What is foreseeable in terms of emergencies and ‘so what if x was to happen’?
- How can we nationally and internationally share best practice and determine an acceptable common approach to risk assessment?
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THANK YOU

QUESTIONS