The Numbers and Validation Games

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The Numbers (Terminology) game -Example extract from Risk Assessments

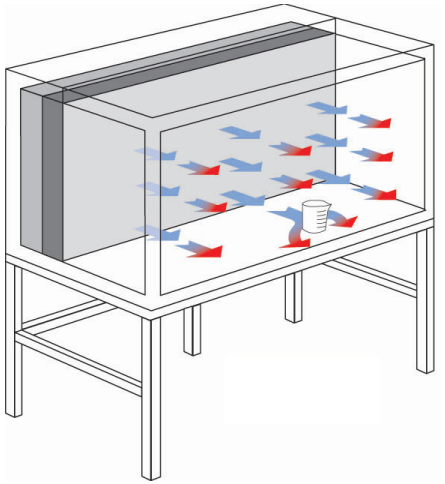
Hazards identified: *n.b.* if your assessment includes substances hazardous to health use COSHH form.

Summary of work: The work includes in vitro infection of cells with influenza A X31 virus. All the reagents and solutions are prepared under sterile conditions in a hood, in cat 2 area.

Hazards identified and control measures to reduce the level of risk:

(1) Influenza A X-31 virus has been prepared at the [redacted], where it is being routinely used for in vivo and in vitro infections.

(2) To ensure sterile preparation of the reagents preparation and dilution of working solutions will be prepared under laminar flow in sterile conditions.



Examples from Risk Assessments/Accidents/Incident reports

In a hood

We bombed The hood

In the cabinet

Class II pathogen

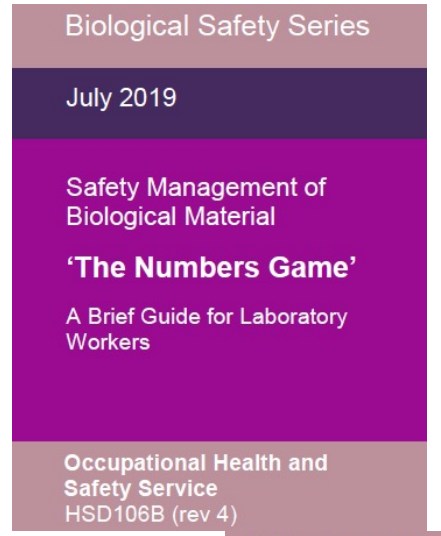
The Cat 2 lab

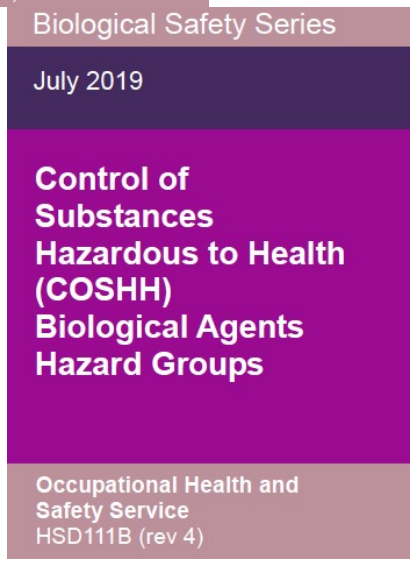
Bug plates

The Class 2 Tissue culture room

Why is this important? “You know what I mean, you’re being a pedant!”

- **Accurate and efficient communication**
- **Risk assessments or reports with incorrect use of terminology might suggest a poor understanding by those writing them**
- **Auditing/assessment by outside agencies (HSE, DEFRA etc) – correct use of terminology is an expectation of an institution that understands what it is doing.**
- **Professionalism**





https://www.safety.admin.cam.ac.uk/latest-information/biological

Microbiological Safety Cabinets
Class I, II, III

Containment level (CL) - The Laboratory
Hazard group (HG) – The Pathogen
Activity class(Class 1) – Genetic Modification

Containment level 1 (CL 1) for **hazard group 1** (HG 1) and **activity class 1** (Class 1).

Containment level 2 (CL 2) for **hazard group 2** (HG 2) and **activity class 2** (Class 2).

Containment level 3 (CL 3) for **hazard group 3** (HG 3) and **activity class 3** (Class 3)

Specified Animal Pathogens (SAPO) Groups 1,2,3 and 4

In addition to the usual risk assessments for Genetic Modification (GM), Control of Substances Hazardous to Health (COSHH), Specified Animal Pathogens Order (SAPO) etc, departments must consider if the pathogen is one listed in Schedule 5.

Eg A hazard group 3 pathogen, or a GM project assessed as class 3 clearly has to be used in a containment level (CL) 3 facility; but if the pathogen is listed in Schedule 5, stringent physical (and other) security measures over and above those required for CL3 will be required.

Categories A, B and C

Why is this important? Example

EORI No: GB 125 5067 30 065

Supplier Number	Supplier VAT Number	Customer Account No.	Payment Terms	Supplier Contact Phone	Supplier Contact Fax
2054012	GB596360800	1088	30 Days	08005830040	01865772482

Line No.	Part Number/Description	Delivery Date	Qty	UOM	Unit Price GBP	Total GBP	VAT Reference
1	Cat III dry ice delivery from Cambridge to [redacted]	Needed: 12-MAY-2022	1	Each	204.75	204.75	STANDARD
STANDARD = Standard Rate VAT					**Total Excl. VAT:**	204.75	

This is an order request raised by another University so that a HG3 pathogen could be sent from Cambridge to them. The other University selected the courier company to be used.

Q How confident would you be about this ?

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Q. How confident would you be about this ?

A. It should be a **RED** flag

Its likely one of the scientists has put the request in and its near meaningless

There is no Cat III – What is Cat III dry ice and why would the other University want us to send them dry ice?

Given this how can I have confidence the requester knows that this requires a specialist courier?

and many more questions ……..

The Validation Game

Autoclaves

- Certificates
- Theromocouple checks
- Biological monitoring
- Autoclave tape!!

Microbiological Safety Cabinets

- In flow and down flow air speeds
- Visual Inspection and operational control
- KI-DISCUS
- Real in use setup
  - Room air flows – air-conditioning units
  - in cabinet equipment
- How do you test the alarms?

Gas monitors

- alarm tests
- calibration

Temperature monitoring critical equipment

+4, -20, -80 oC etc

- eg TSCAN monitoring solution
- How do you test it works ? Required ?

Magnehelic Pressure gauges

- calibrated - who when?
- low pressure alarms – how do you test?

Legionella monitoring

- Risk assessment
- By who?
- Of what?
- What do the results mean?

Autoclaves – Validation, Calibration and Monitoring

Biological Safety Series

April 2019

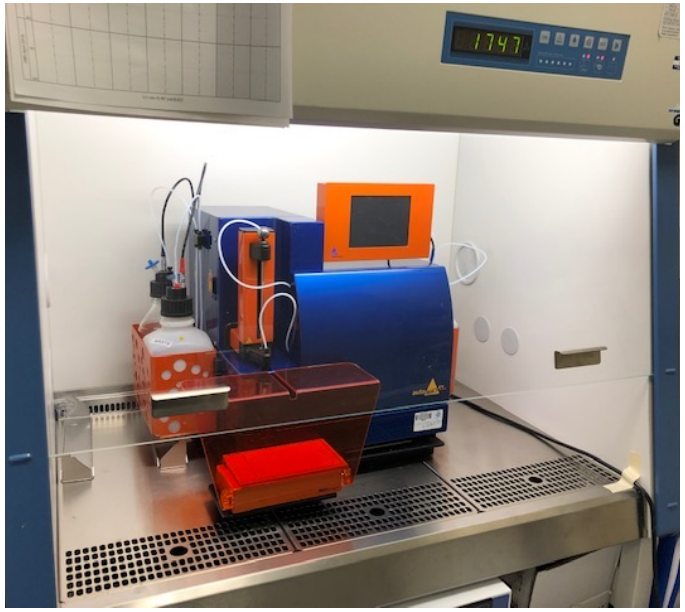
Autoclaves:

Validation and Monitoring

Occupational Health and Safety Service
HSD164B (rev 2)

Pressure Systems Safety Regulations (PSSR) 2000
Autoclaves (ALL Pressure vessels) need to be (**annually**) inspected by a representative for the University's insurers to comply. *Bureau Veritas (BV) acts as the Competent Person to carry out this inspection. All autoclaves will automatically be registered onto the BV SWIFT database to which the departmental lead contacts have access.*

Testing and validation of microbiological safety cabinets



There is a statutory requirement to carry out testing (every 6 months or 12-14 months depends on Containment Level) and validation of microbiological safety cabinets. Performance tests are carried out to BS EN12469 and include

- HEPA filter integrity
- airflow velocity and visualization tests,
- operation of airflow indicators & alarms
- KI-Discus (aperture protection factor) tests.

Is work usually carried out in an empty cabinet?

- **Equipment that is USUALLY in the MSC should be in the MSC when it is tested.**

- **If a KI test is being performed BAG and protect the equipment!!**

Environmental Validation Solutions Ltd

67 Hoylake Crescent Ickenham Middlesex UB10 8JF
Tel: 020 8335 3532 E-mail: service@evs-uk.com

Test Report Certificate No. L832902

Customer	Cambridge university	Site Contact	A.Brownlee
Building	Dept of medicine	Lab Contact	A.Brownlee
Cabinet Manufacturer	CAS	Previous Certificate	n/a
Serial No	C1423-2	Phone no	

Room	HR08 05 800 Cat 1	Job No	L8329
Type	CLII Tripass	Engineer	S.Palmer
Site No	0	Date	12-Nov-13
EVS Ref		Order no	0

Test Equipment

Anemometer	TA 460	Photometer	JM8000
Serial No	TA4600944002	Serial No	JM8-8028
Calibration Date	31/04/2013	Calibration Date	22-Nov-12

Cabinet Function and Examination

Alarm	Audible	Working	Visual	Working	
Fan	Exhaust	Working	Downflow	Working	
Fan	Run On	n/a min	Airflow Meter	Safe	
Duct Pressure	Open	n/a Pa	Closed	n/a	Pa
Sound		ok	Hour Meter	n/a	hrs
Indicator Switches		Working	Fumigation	n/a	
Gas Solenoid		n/a	Socket Test	Working	
Lighting		Working	UV Lamp	n/a	

Cabinet Condition

Exterior Surface	ok	Work Surface	ok
Interior Surfaces	ok	Viewing Panel	ok
Duct Connection	ok	Closure Panels	ok

Comments

If cabinet goes into alarm it will still have the containment protection factor as it is set up with the setting parameter high enough so as to comply if the room negative pressure drops to alarm levels.

Particle Counts Paticles per Cu m

Position	≥ 0.3µm	≥ 0.5µm	≥ 5.0µm
1			
2			
3			
4			
5			
6			

Counter
Serial No
Calibrated
Passes to GMP Class A Yes/No

Air Flow Measurements m/s

Inflow Average Velocity 0.61 m/s — *Pass*

0.63 m/s	0.56 m/s	0.64 m/s

Acceptance Criteria : Inflow to be not < 0.4 m/s

Downflow Average Velocity 0.41 m/s — *Pass*

0.40 m/s	0.38 m/s	0.38 m/s	0.41 m/s
0.41 m/s	0.40 m/s	0.46 m/s	0.44 m/s

Acceptance Criteria : Downflow to be 0.25 to 0.5 m/s +/- 20%

KI-Discus Aperture Protection Factor Results

No	X	OP	Y	OP	X1	OP	Y1	OP
M1	5	12.4	9	6.9	6	10.3	14	4.4
M2	8	7.8	5	12.4	6	10.3	8	7.8
M3	6	10.3	7	8.9	8	7.8	10	6.2
M4	2	31.0	10	6.2	6	10.3	7	8.9
M5	6	10.3	4	15.5	12	5.2	11	5.6
L1								
L2								
L3								
L4								
L5								
R1								
R2				h				
R3								
R4								
R5								

These Aperture Protection Results DO comply with the requirements of EN12469:2000

K.I Discus serial No K12/02-0163 Calibration 19-Dec-2012

Acceptance Criteria : Aperture Protection to be not less than 1 x 10 5

The above test data was correct at the time of the tests. If the equipment is moved, modified or other environmental factors change the equipment may require a re-test

Filter Tests

Down-flow/Out-flow filter	1st Exhaust / Main filter	2nd Exhaust / In-flow filter	Thimble / Room filter	Other filter
Serial No	Serial No	Serial No	Serial No	
Penetration	Penetration	Penetration	Penetration	
Media <0.003 %	Media <0.003 %	Media <0.003 %	Media n/a %	
Seals <0.003 %	Seals <0.003 %	Seals <0.003 %	Seals n/a %	
Pass	Pass	Pass		

Acceptance Criteria : Penetration to be < 0.003 %

At the time of test this Cabinet **Passes**

E.S.R. Number

Engineers Signature

Customer Signature

Date

Next Test Due May-14

Label Attached yes

The Validation Game: Check, Calibrate and Cascade

Closing the loop

- Facilities have had the equipment serviced
  - Where do the reports go?
  - What do the reports mean?
  - Actions to be taken?
  - Who needs to know the result and how is the information passed on?

Lay interpretation of engineers reports

HSE CL3 inspection question – How do you know a user understands the results of the inspection and the written report?

- Verbal report from engineer to user/facilities before leaving
  - Did it pass
  - Any concerns going forward
  - Close the loop!

Permits to work

- NOT just relevant to higher CL3 containment also CL2
- What information was the service engineer given?
- What was disinfected?
- What they can and cannot touch?
- What PPE should they wear?
- What should they do if the fire alarms go off?

The Validation Game: Check, Calibrate and Cascade

Record keeping - keeping evidence and being able to provide it for audit /inspection to HSE and others

- Permits and service reports

- Maintenance inspection schedules
  - Who is responsible
  - Who keeps the schedules
  - How do the users know service is required (before it becomes an issue)
    - Autoclaves annually under the written scheme (after that date CAN NOT BE USED)
      - *Bureau Veritas* SWIFT database

- A clear, formalized check list system to mange the schedule of inspections, servicing etc.
- A clear indication of who is responsible and who is responsible if that person is not available.
- A schedule to check the schedule – Seriously!! Comment from HSE inspection
- RECORD, RECORD, RECORD – Time, Date and Sign