



[Laboratory biosafety manual, fourth edition]

(/Laboratory biosafety manual, fourth edition and associated monographs)

ISBN 978-92-4-005924-5

ISBN 978-92-4-005925-2

NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo/deed.zh> CCBY-

“ ”
(<http://www.wipo.int/amc/en/mediation/rules/>)

[Laboratory biosafety manual, fourth edition]
2023 (/Laboratory biosafety manual, fourth edition and associated monographs) CC BY-NC-SA 3.0 IGO

<http://apps.who.int/iris>

<http://apps.who.int/bookorders>

<https://www.who.int/zh/copyright>

1	1
1.1	2
1.2	2
2	
2.1	8
2.2	9
2.3	14
2.4	15
2.5	20
3	23
3.1	23
3.2	26
3.3	26
3.4	28
3.5	29
3.6	34
3.7	35
3.8 /	37
3.9	38

4	39
4.1	39
4.2	39
4.3	40
4.4	40
4.5	40
4.6	41
4.7	43
4.8 /	44
4.9	44
5	47
5.1	47
5.2	48
5.3	48
5.4	49
5.5	49
5.6	50
5.7	50
5.8 /	50
5.9	50
6	53
6.1	53
6.2	54
6.3	54
6.4	55

7**63**

7.1	64
7.2	64
7.3	64
7.4	65
7.5	65
7.6	65
7.7	66

8**69**

8.1	69
8.2	70
8.3	71
8.4	71
8.5	71
8.6	72
8.7 /	72
8.8	72
8.9	73

9**75****77****81**

KazunobuKojima

Allan Bennett

Stuart Blacksell / -

Marianne Heisz

Catherine Makison Booth

Michelle McKinney

Kathrin Summermatter

Lisa Stevens

Rica Zinsky

—

Amadou AlphaSall

William Ampofo

ÅsaSzekely Bjørndal

ChristinaCarlson

Mike Catton .

- WHO —Carmem Lucia Pessoa da Silva
- WHO —Jaouad Mahjour
- WHO —Pierre Formenty
- WHO —Jorge Raul Matheu Alvarez, Amina Benyahia Chaieb, Kazuaki Miyagishima
- WHO —Patrick Anthony Drury
- WHO —Sylvie Briand, Tim Nguyen, Matthew Lim
- WHO —Magdi Samaan, Wenqing Zhang, Terry Gail Besselaar, Sandra Jackson
- WHO —Andrea Bosman, Jane A. Cunningham
- WHO —Christopher Gilpin, Karin Weyer
- WHO —Ivana Knezevic, Tiequn Zhou, Hye-na Kang, Francis Gabriel Moussy
- WHO —Meg Doherty, Lara Vojnov, Silvia Bertagnolio
- WHO —Mick Mulders, Fatima Serhan, Deepa Sharma, Varja Grabovac
- WHO —Mark Perkins, Karin von Eije, Mariavan Kerkhove
- WHO —Daphne Moffett, Nicoletta Claudia Previsani, Ousmane (Madiagne) Diop, Harpal Singh
- WHO —Virginie Dolmazon, Cécile Marie Josephine Barnadas, Josè Guerra, Christopher John Oxenford, Evelyne Chaignat Wyssen, Lisa Louise Carter
- WHO —Irena Prat, Mark Lanigan, Anita Sands
- WHO —Vaseeharan Sathiyamoorthy

/

BSC

/

/

HEPA

I II III)

/

/

/

“ R_0 ”

R_0 R_0

/

)

“ ”

WHO

/

/

/

BSC

/

GMPP

/

“ ”

/

50%

ID₅₀

/

/

/

PPE

PPE

/

/ /

(BSCs)

HEPA

/

/

SOPs

/

/

WHO

1983

1993

2004

WHO

/

/

1

(1 - 3) WHO

(4,5) (6,7) (8)

PPE SOPs (9) (10,11) / (12)

2005 (13)

196



—

1.1

GMPP LBM4 “ ”
SOPs

OIE

(14)

(15)

OIE (14)

1 /

2
LBM4

LBM4
(16)

1.2

-
-
-



▪

▪

▪

▪

▪

▪ (17)

▪ (18)

▪ (19)

▪ (20)

▪ (21)

▪ (22)

▪ (23)

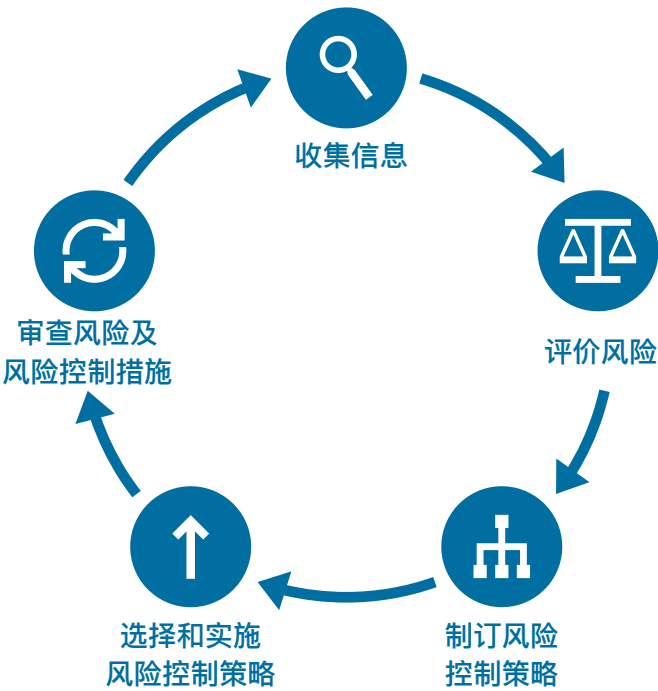
2

2.1

/

(24,25)

2.1



2.1

2.1

(26)

[illegible]

GMPP

2.1.1

(23)

-
-
-

WHO /

2.2

- /
-
-



—

3

2.2.1

/

2.2



/

/

2.2 2.4

2.2

	SOP GMPP

GMPP=

SOP=



2.2.2

2.5

2.5

/



—

(27)

/

2.3

2.6

- ,
-
-
-

/

2.4

2.4.1

/

GMPP

GMPP³

2.4

/

2.2

/

/

4

- /
-
-
-
- /
-
-

/

/

/

/

5

2.2

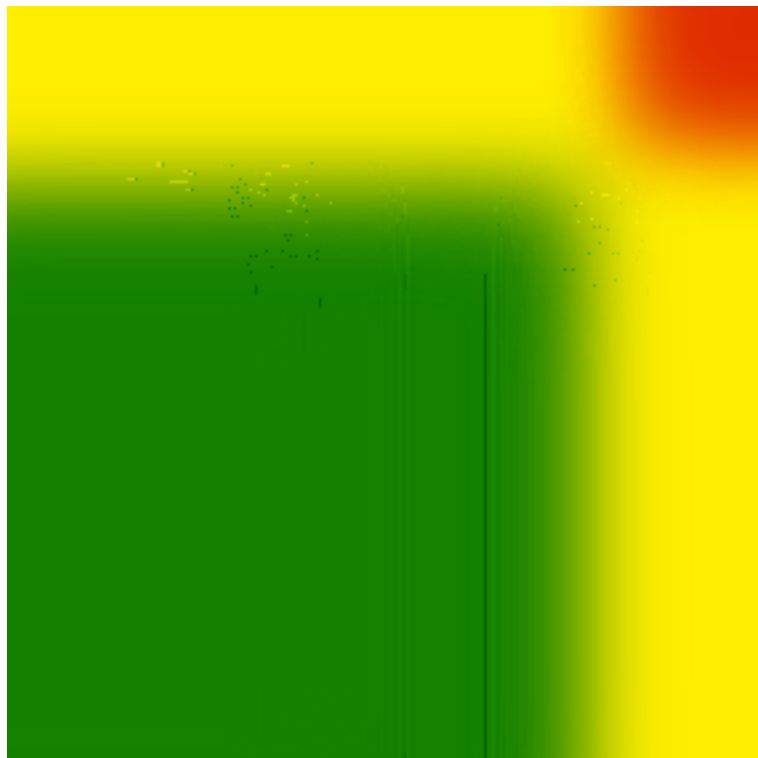
2.5

-
-
-

2.4.2

SOP

PPE



SOP

2.7

	(/	CR	
	/	CR	
	/	HCM CR	
<50mL	/	HCM CR	/
>10L	/	HCM CR	
	/	MCM	

CR=

HCM=

MCM=



—

2.5

-
-
-
-
-
-



■

■

■

■ /

■

■



3

5

/

4

7

3.1

GMPP

GMPP

GMPP

GMPP

GMPP

4,28-30

GMPP

GMPP

GMPP

4 5

GMPP

GMPP

/

3.1.1

▪

▪

▪ /

▪

▪

▪

▪

▪

▪

▪

▪

▪

▪

▪

GMPP

/

-

(20)



—

▪

▪

▪

▪

/

▪

▪

▪

▪

▪

/

▪

▪

3.2

/

3.1

GMPP

3.3

▪



- / / —
- /
-
-
-
-
-
- /
-
-
-

(21)

3.4

6 “ ”

3.4.1

/

-
- GMPP

-
-

3.4.2

-
-
-
-
-
-

/

/

3.4.3

(22) PCR

3.5

/



—

3.2

/

(22)

3.5.1

/



-
-
-

/

(22)

3.5.2

121°C 134°C
100°C

3.1





(22)

-
-
-
-
-
-
-
-
-
-
-

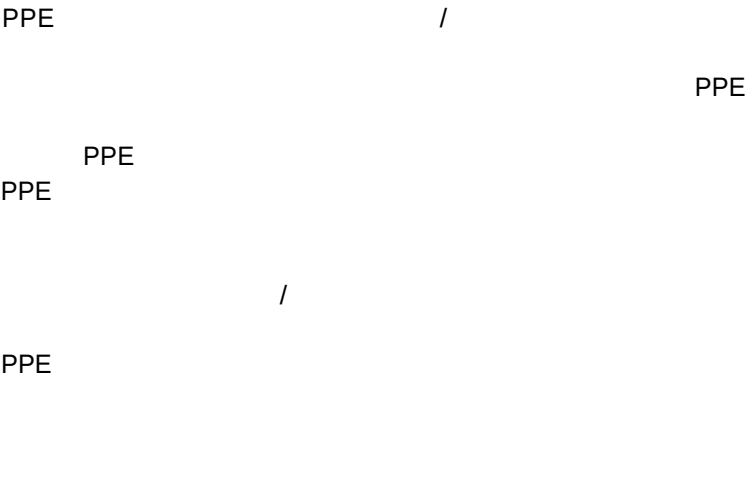
(22)

3.5.3



—

3.6



3.6.1

3.6.2



3.6.3

3.6.4

3.6.5

3.7

GMPP

/

-
-



—

-
-
-

SOP

3.7.1

/

/

GMPP



SOP

3.8 /

SOP SOP



—

-
-
-
-
-

(22)

3.9

(17)



4

/

3

4.1

GMPP

- /
-
-

4.2

4.3

/

- /
-
-
- /
- /
-
-

(21)

4.4

- / PPE
-
-

4.5



(22)

6

4.6

PPE / PPE

4.6.1

ÄÄ■



—

4.6.4

4.6.5

/ PPE BSC
/

-
-
-
- /
-
- PPE



/

(20)

(20)

4.7

-
-
-

4.1

(19)

4.8 /

-
-
-

4.9

-

	- HEPA
II	- II / - CEN12469 II A2 - II - I /
	/ - III HEPA /
	“ ”
	BSC

BSC=
HEPA=

5

BSL4/P4 (3)

(21)

BSC

BSC

5.1

/

-
-
-
-
-

5.2

5.3

5.2

5.3

5.1

/	- I II BSC

BSC=

PPE	

PPE=



- BSC - III - HEPA	- HEPA - HEPA
- HEPA (SOP HEPA /	
BSC=	HEPA= SOP=

5.4

5.5

BSC

pH



—

(22)

5.6

SOP

SOP

5.7

SOP

5.8 /

/

5.9

/

/



6

/

/

/

/

6.1

BSC

GMPP

-
-
-
-
-



—

6.2

(31)

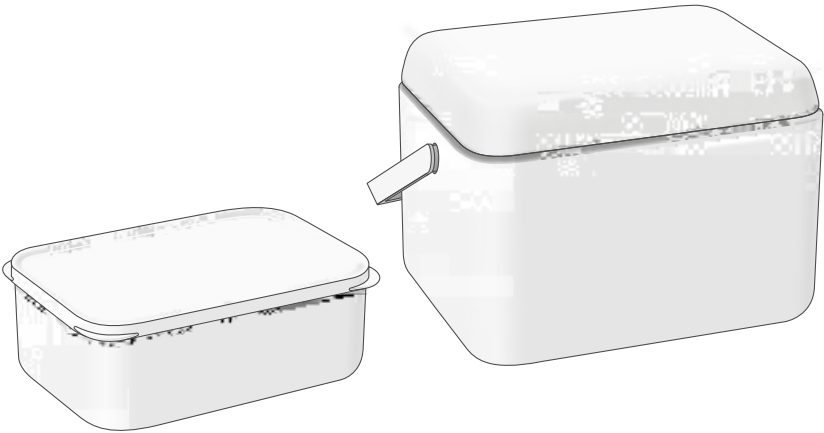
6.2.1

/ /

/

6.3

-
- 6.1



▪ 6.4.3

▪

▪

6.1

▪

▪

▪

▪

6.4

/

- /
(32)

”

“

/

6.4.1

(32)

(33,34)

(35)

(36,37)

(38)

“ ”

/

/

6.4.2

/

A

B

/

(32)

/

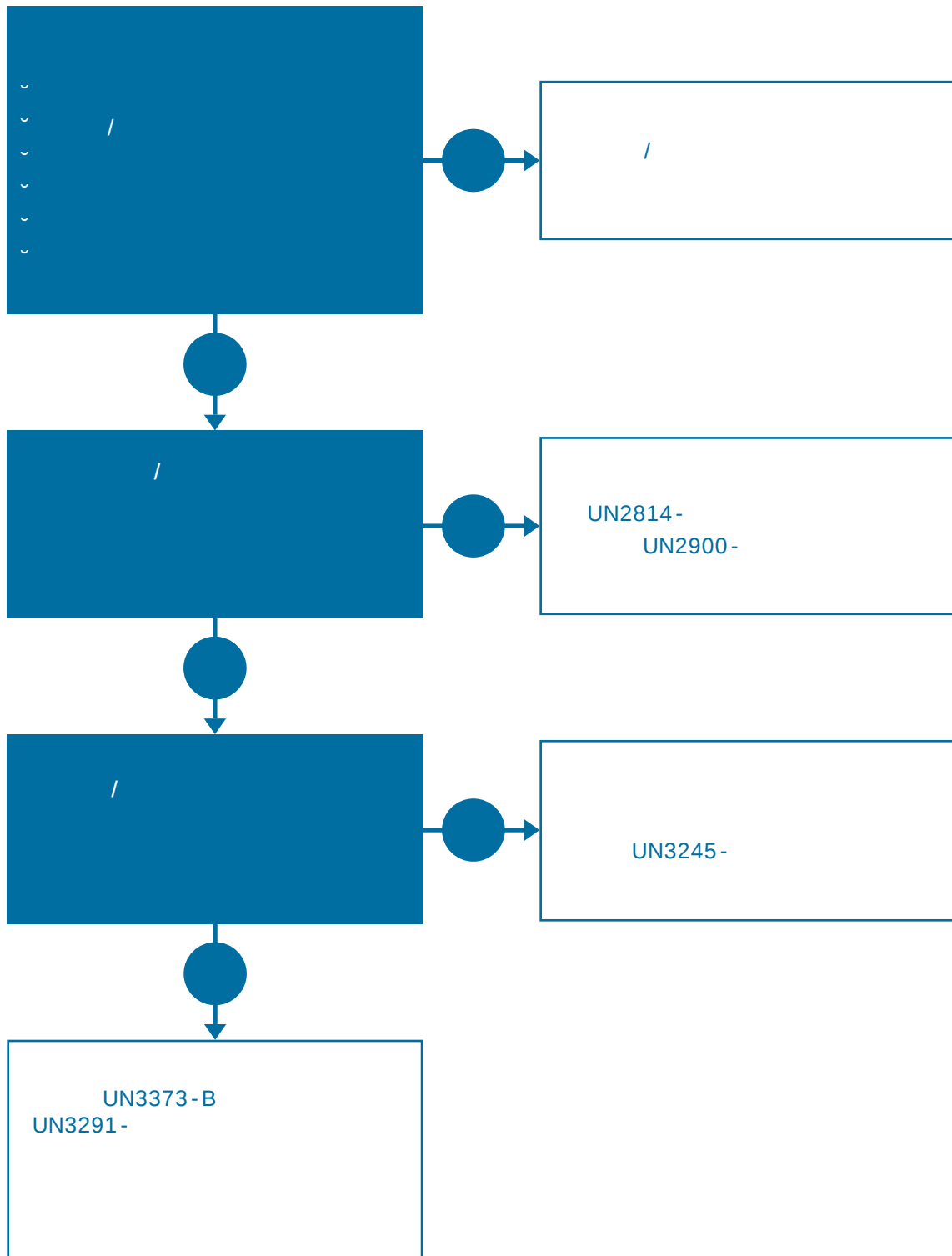
6.2

WHO

(39)

A

B



A

A

(32-37) WHO

(39)

A

A

B

A

6.1

A B

		A
	▪ UN2814 A ▪ UN2900 A ▪ UN3549 A	▪ UN3291 B ▪ UN3373 B
	▪ ▪ ▪ ▪	▪ ▪ ▪
	▪ P620 ▪ A	▪ UN3291 ▪ UN3373 P650

UN=

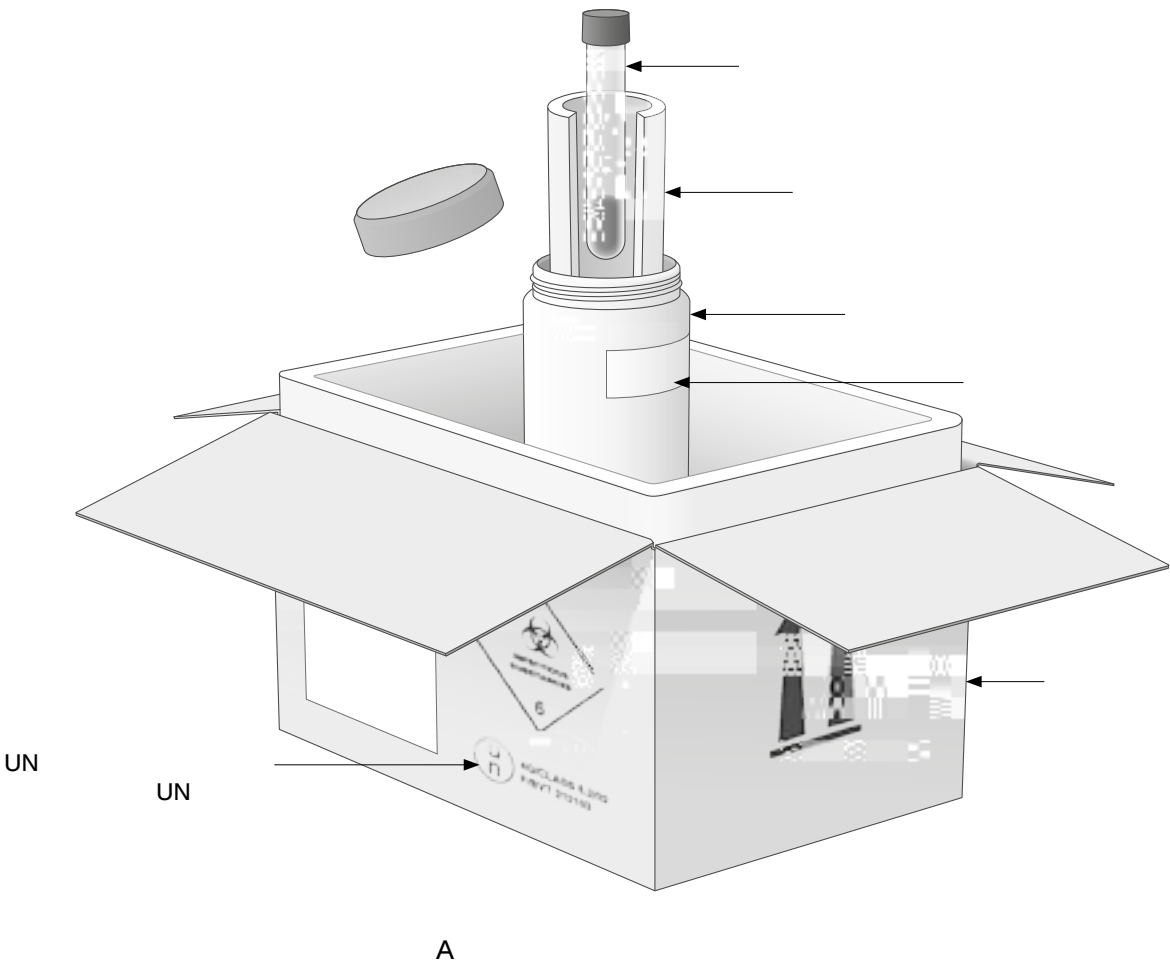


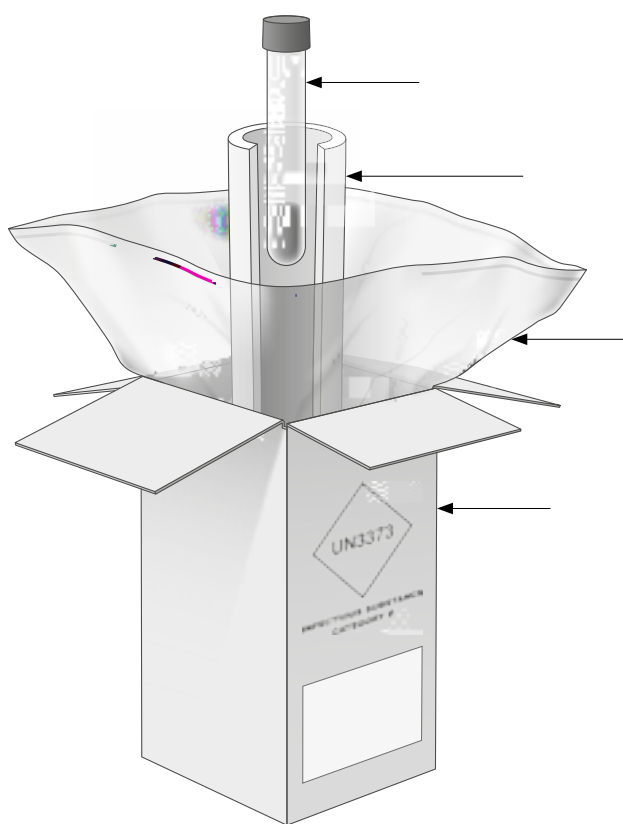
6.4.3

/

6.3

c





B



—

A B

“ ”

UN2814 UN2900

P620

A

A

6.4

P620

P650

A

—B

6.5

P650



7

-
-
-
-
-
-



—

7.1

7.2

7.3

7.3.1

7.3.2

7.3.3

7.3.4

/

—

-
- /
-
-
-

(17) 3 4
5

7.7

7.7.1

7.7.2

/ /

7.7.3

(17)

∞

/

(18)

.

(40)

8.1

8.1.1



—

8.1.2

/

8.1.3

8.1.4

8.1.5

8.2

/

/

8.3

IT

/

8.4

8.5

/



—

/

/

8.6

6

8.7

/

8.8

/

▪

▪

/

/

▪

/

(13)

(23)

/

—

/

/

†

—

(41,42)

9.1

	DNA
	“ ”
	/
	1 1 - 4

/

/

(43,44)

¹1

3

2

4

3 2004

1. . 1983
2. . 1993
3. . 2004
(<https://apps.who.int/iris/handle/10665/42981>, 2022 12 17 2022)
4. Wurtz N, Papa A, Hukic M, Di Caro A, Leparç-Goffart I, Leroy E, et al. Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories. *Eur J Clin Microbiol Infect Dis*. 2016 Aug;35(8):1247-58. doi: 10.1007/s10096-016-2657-1
5. Choucrallah D, Sarmiento L, Ettles S, Tanguay F, Heisz M, Falardeau E. Surveillance of laboratory exposures to human pathogens and toxins: Canada 2018. *Can Commun Dis Rep*. 2019 Sep 5;45(9):244-51. doi: 10.14745/ccdr.v45i09a04
6. Sejvar JJ, Johnson D, Popovic T, Miller JM, Downes F, Somsel P, et al. Assessing the risk of laboratory-acquired meningococcal disease *J Clin Microbiol*. 2005 Sep;43(9):4811-4. doi: 10.1128/JCM.43.9.4811-4814.2005
7. Barry M, Russi M, Armstrong L, Geller D, Tesh R, Dembry L, et al. Brief report: treatment of a laboratory-acquired Sabiã virus infection. *N Engl J Med*. 1995 Aug3;333(5):294-6. doi: 10.1056/NEJM199508033330505
8. Bouza E, Sanchez-Carrillo C, Hernangomez S, Gonzalez MJ. Laboratory-acquired brucellosis: a Spanish national survey. *J Hosp Infect*. 2005 Sep;61(1):80-3. doi: 10.1016/j.jhin.2005.02.018
9. Ergonul O, Celikbaş A, Tezeren D, Guvener E, Dokuzođuz B. Analysis of risk factors for laboratory-acquired brucella infections. *J Hosp Infect*. 2004 Mar;56(3):223-7. doi: 10.1016/j.jhin.2003.12.020
10. Hsu CH, Farland J, Winters T, Gunn J, Caron D, Evans J. Laboratory-acquired vaccinia virus infection in a recently immunized person - -Massachusetts, 2013. *MMWR Morb Mortal Wkly Rep*. 2015 May 1;64(16):435-8.
11. Kortepeter MG, Martin JW, Rusnak JM, Cieslak TJ, Warfield KL, Anderson EL, et al. Managing potential laboratory exposure to ebola virus by using a patient biocontainment care unit. *Emerg Infect Dis*. 2008 Jun;14(6):881-7. doi: 10.3201/eid1406.071489
12. Lim PL, Kurup A, Gopalakrishna G, Chan KP, Wong CW, Ng LC, et al. Laboratory-acquired severe acute respiratory syndrome. *N Engl J Med*. 2004 Apr 22;350(17):1740-5. doi: 10.1056/NEJMoa032565

13. 2005 2016 (<https://apps.who.int/iris/handle/10665/246107>, 2022 12 19 2022)
14. Biosafety and biosecurity: standard for managing biological risk in the veterinary laboratory and animal facilities. In: Manual of diagnostic tests and vaccines for terrestrial animals, 8th edition. Paris: World Organisation for Animal Health (OIE); 2018 (https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.04_BIOSAFETY_BIOSECURITY.pdf, accessed 6 December 2019).
15. 2006 (<https://apps.who.int/iris/handle/10665/69390>, 2022 12 16)
16. WHO Global Plan of Action on Workers' Health (2008-2017): Baseline for Implementation. Geneva: World Health Organization; 2013 (<https://apps.who.int/iris/handle/10665/341021>, accessed 16 December 2022).
17. 2023
18. 2023
19. 2023
20. 2023
21. 2023
22. 2023
23. 2023
24. The International Federation of Biosafety Associations Laboratory biosafety and biosecurity risk assessment technical guidance document. Albuquerque: Sandia National Laboratories; 2014 (<https://www.biosecuritycentral.org/resource/training-materials/biorisk-assessment-technical-guidance/>, accessed 16 December 2022).
25. Responsible life sciences research for global health security. Geneva: World Health Organization; 2010 (https://apps.who.int/iris/bitstream/handle/10665/70507/WHO_HSE_GAR_BDP_2010.2_eng.pdf?sequence=1, accessed 6 December 2019).

26. Renn O. White Paper on risk governance: toward an integrative framework. In: Renn O, Walker KD, editors. Global risk governance. Dordrecht: International Risk Governance Council; 2008. doi:10.1007/978-1-4020-6799-0_1.
27. Laboratory safety guidance. Washington, DC: Occupational Safety and Health Administration, US Department of Labor; 2011 (<https://www.osha.gov/sites/default/files/publications/OSHA3404laboratory-safety-guidance.pdf>, accessed 16 December 2022).
28. Pedrosa BS, Cardoso, TA. Viral infections in workers in hospital and research laboratory settings: a comparative review of infection modes and respective biosafety aspects. *Int J Infect Dis.* 2011 Jun;15(6):e366-76. doi: 10.1016/j.ijid.2011.03.005
29. Siengsanant-Lamont J, Blacksell SD. A review of laboratory-acquired infections in the asia-pacific: understanding risk and the need for improved biosafety for veterinary and zoonotic diseases. *Trop Med Infect Dis.* 2018 Mar 26;3(2):36. doi: 10.3390/tropicalmed3020036
30. Kimman TG, Smit E, Klein, MR. Evidence - based biosafety: a review of the principles and effectiveness of microbiological containment measures. *Clin Microbiol Rev.* 2008 Jul;21(3):403-25. doi: 10.1128/CMR.00014-08
31. Baldwin CL, Runkle RS. Biohazards symbol: development of a biological hazards warning signal. *Science.* 1967 Oct 13;158(3798):264-5. doi: 10.1126/science.158.3798.264
32. United Nations. Recommendations on the transport of dangerous goods: model regulations, 21st revised edition. New York, Geneva: United Nations; 2019 (https://www.unece.org/trans/danger/publi/unrec/rev21/21files_e.html, accessed 13 November 2020).
33. Technical instructions for the safe transport of dangerous goods by air (Doc 9284), 2017 - 2018 edition. Montreal: International Civil Aviation Organization; 2017 (<https://www.icao.int/safety/DangerousGoods/AddendumCorrigendum%20to%20the%20Technical%20Instructions/Doc%209284-2017-2018.AddendumNo2.en.pdf>, accessed 6 December 2019).
34. Infectious substances shipping guidelines, 15th edition (2019/2020). Montreal, International Air Transport Association; 2019
35. IMDG code. International maritime dangerous goods code: incorporating amendment 39 - 18. 2018 edition. London: International Maritime Organization; 2018 (<https://www.imo.org/en/publications/Pages/IMDG%20Code.aspx>, accessed 16 December 2022).

36. ADR, applicable as from 1 January 2019. European agreement concerning the international carriage of dangerous goods by road, Volumes I and II. New York and Geneva: United Nations; 2019. (<http://www.unece.org/trans/danger/publi/adr/adr2019/19contentse.html>, accessed 6 December 2019).
37. Regulation concerning the international carriage of dangerous goods by rail (RID). Berne: Intergovernmental Organisation for International Carriage by Rail; 2019. (https://otif.org/en/?page_id=1105, accessed 6 December 2019).
38. Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity. Montreal: Secretariat of the Convention on Biological Diversity; 2014 (<https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>, accessed 6 December 2019).
39. Guidance on regulations for the transport of infectious substances 2021-2022. Geneva: World Health Organization; 2021 (WHO/WHE/CPI/2019.20) (https://iris.who.int/handle/10665/339825?search-result=true&query=guidance+on+transport+infectious+substances+2021&scope=%2F&rpp=10&sort_by=score&order=desc, accessed 10 November 2023).
40. Biorisk management. Laboratory biosecurity guidance. Geneva: World Health Organization; 2006 (<https://apps.who.int/iris/handle/10665/69390>, accessed 16 December 2022).
41. WHO guidance on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories – a stepwise approach. Geneva: World Health Organization; 2020 (<https://apps.who.int/iris/bitstream/handle/10665/332244/9789241516266-eng.pdf?sequence=1&isAllowed=y>, accessed 15 June 2020)
42. An analytical approach: biosafety and biosecurity oversight framework [e-learning course]. Government of Canada; 2020 (<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/analytical-approach.html>, accessed 20 April 2020 [subscription required])
43. The Biological Weapons Convention. Convention on the Prohibition of the

Biological safety cabinet (BSC) 1: Introduction [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/KHCT9OJqxPo>, accessed 6 December 2019).

Biological safety cabinet (BSC) 2: Preparatory steps [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/4DoHJS8JL4U>, accessed 6 December 2019).

Biological safety cabinet (BSC) 3: Best practices for safe usage [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://www.youtube.com/watch?v=18QEJUA9XBs>, accessed 6 December 2019).

Biological safety cabinet (BSC) 4: Incident management [Biosafety video series]. Geneva: World Health Organization; 2019 (https://www.youtube.com/watch?v=aS_TCZTCcsI, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 1: personal protective equipment (PPE) [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/Cuw8fqhwdZA>, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 2: pipettes [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/-zeCl8ESrpU>, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 3: sharps [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/yqX8hhzX7xU>, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 4: surface decontamination [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/b0PtPEnNakc>, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 5: autoclaves [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/Yfc1yjEuuhE>, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 6: workflow [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/TeYA2KqIU5k>, accessed 6 December 2019).

Good microbiological practices and procedures (GMPP) 7: transport [Biosafety video series]. Geneva: World Health Organization; 2019 (<https://youtu.be/RC9QHf2wdX0>, accessed 6 December 2019).



世界卫生组织