Biosafety and Health 2 (2020) 1–2

Contents lists available at ScienceDirect

Biosafety and Health

journal homepage: www.elsevier.com/locate/bsheal

Laboratory biosafety guide for 2019-nCoV (Second Edition)

National Health Commission of the People's Republic of China

According to the biological characteristics, epidemiological features, pathogenicity, clinical manifestation and other related information of the novel coronavirus (2019-nCoV) currently available, the pathogen should be provisionally managed as the Risk Group 2 pathogenic microorganisms in the classification of pathogenic microorganisms.

1. Biosafety requirements for experimental activities

1.1. Virus culture

Procedures refer to virus isolation, cultivation, titration, neutralization assay, purification of live virus and its proteins, virus freeze-drying, recombination experiment generating live viruses, etc. The above-said operations shall be performed in a BSL-3 laboratory. When extracting nucleic acid from the virus culture, the steps of adding lysis or inactivator agents must be performed in a laboratory which has the same biosafety level and protective conditions as for virus culture. After lysis or deactivation, practices shall be conducted at the same biosafety and personnel protective levels as for non-cultured infectious materials. Before carrying out these activities, the laboratory shall submit a request to the National Health Commission of the People's Republic of China for approval, in order to get the qualifications required for conducting the corresponding activities.

1.2. Animal-infection experiments

This procedure refers to experiments that involved in infecting animals with live virus, sampling infected animals, processing and testing infectious specimens, specialized examination of infected animals, and processing of excreta from infected animals etc.. It shall be performed in a BSL-3 laboratory. Before carrying out these activities, a request shall be made to the National Health Commission of the People's Republic of China for approval by the laboratory, in order to be qualified for performing the corresponding activities.

1.3. Non-cultured infectious material operation

These procedures refer to practices using uncultured infectious materials before proper deactivation, such as virus antigen detection, serological assay, nucleic acid detection, biochemistry analysis, and the deactivation of clinical specimens. These activities shall be performed in a BSL-2 laboratory. At the same time BSL-3 personal protection equipments shall be used.

1.4. Inactivated material operations

These procedures refer to practices using either infectious materials or live viruses after proper deactivation, which involving nucleic acid detection, virus-antigen detection, serological assay and biochemistry analysis. These activities shall be performed in a BSL-2 laboratory. Other operations such as molecular cloning without involving pathogenic live viruses may be performed in a BSL-1 laboratory.

2. Management of transport on pathogens and specimens

2.1. Domestic transport

Containers or packaging materials that used for transporting the 2019-nCoV strains or other potentially infectious biological materials are classified into Class-A, in corresponding with the United Nations serial number UN2814, and shall meet the regulations for Class-A packaging standards as detailed in the International Civil Aviation Organization's Document 9284 Packaging Instructions PI602, “Technical Instructions for the Safe Transport of Dangerous Goods by Air”. The containers or packaging materials used for transporting environmental specimens are classified into Class-B, corresponding with United Nations serial number UN3373, and shall meet the regulations for Class-B packaging standards as detailed in the International Civil Aviation Organization's Document 9284 Packaging Instructions PI650, “Technical Instructions for the Safe Transport of Dangerous Goods by Air”. Packing can be conducted in accordance with the standards above when transported via other modes of transport.

Transport of novel coronavirus strains or other potentially infectious materials shall be conducted under the Certificate of Approval issued in accordance with the regulation entitled “Regulations for Transport Management of Infectious and Highly Pathogenic Human Microorganisms, Bacteria, Viruses, or Specimens” (the former Ministry of Health Order No. 45).

2.2. International transport

2019-nCoV strains or specimens shall be packaged in a standard way when transported internationally, and following the procedures according to the “Regulations for Management and Health Quarantine of Import and Export of Special Products,” and to meet the relevant national and international requirements.

2.3. Management of virus strains and specimens

The 2019-nCoV strains or specimens shall be managed by designated staff members with a mastery of relevant professional knowledge and

E-mail address: biosafetyandhealth@ivdc.chinacdc.cn (Editorial Office of *Biosafety and Health*).

http://dx.doi.org/10.1016/j.bsheal.2020.01.001

operation skills. An accurate record of the source, type, quantity, and registration number is required for each virus strain and specimens. Effective measures must be in place to ensure the biosecurity of all virus strains and specimens. Any misuse, malicious use, thefty, robbery, loss, or leakage events shall be strictly prevented.

3. Waste management

3.1. Laboratories that conducting any experimental activities related to 2019-nCoV shall formulate the regulations including waste disposal procedure documents as well as operation procedures for pollutants and sewage disposal.

3.2. All the hazardous wastes shall be placed in the uniformly normalized containers and marked uniformly, with complete labelling of the waste contents in compliance with the relevant regulations.

3.3. The hazardous wastes shall be treated by properly trained personnel equipped with proper Personal Protective Equipments (PPEs) and devices.

3.4. Measures for waste disposal play key roles for the control of laboratory biosafety. To treat the infectious waste effectively and safely, it is required that designated personnel fully understand biosafety waste classification and strictly enforce the corresponding procedures, related to disposals.

3.4.1. Disposal of liquid wastes

The liquid wastes that produced from laboratories can be classified into routine sewage and infectious liquid waste.

1) Routine sewage is produced from hand-washing basins or other facilities, and shall be collected separately into the laboratory water disposal system, and treated in compliance with relevant national discharging standards before discharged.

2) Infectious liquid wastes are produced in the process of experimental operations. It shall be disinfected chemically or physically. The effect of disinfection shall be verified in order to ensure complete deactivation.

3) Disposal of the waste shall be processed timely by professional staff members. The waste shall not be taken out of the laboratory area.

3.4.2. Disposal of solid wastes

1) Solid wastes shall be collected according to the respective categories. The containers shall follow the characteristics of non-fragility, leakage-proof, moisture- and heat-resistance, and sealability. Infectious wastes in the laboratory shall not be stored in excess, but autoclaved on a timely basis. The waste shall be stored in a designated secure place in the laboratory before disposal.

2) Small-volume solid wastes such as tissue specimens, consumables, and PPEs shall be autoclaved and then moved out of the laboratory along the waste disposal channel.

3) Large-volume solid waste, such as the replaced HEPA filter, shall be sterilized by professionals in situ, and then placed into a safe container for sterilization. Articles that unable to be autoclaved, such as electronic equipment, shall be sterilized by use of ethylene oxide fumigation.

4) Solid wastes which is moved out of the laboratory after sterilization shall be delivered to the centralized solid waste disposal units.

5) Sharp instruments (including needles, knives, metals and glass, etc.) being used in the experiment shall be directly discarded to the sharps container, and then be disposed uniformly after sterilization.

3.5. Developing special records for waste disposal

It is required to regularly inspect the HEPA filters for leak-detection and to timely replace the exhausted HEPA filters if necessary. It is also required to regularly monitor the disposed sewage, and monitor the effect of autoclave by biological indicators.

4. Mitigation of mistakes or accidents in laboratory biosafety practices

4.1. Disinfectants related to limited contamination of the biological safety cabinet caused by the 2019-nCoV strains or other potentially infectious materials are required, using effective chlorine concentration of 0.55%. The disinfectant shall be prepared when needed and used within 24 h. Requirements of the effective chlorine concentration appeared in the following contents of this document, shall be in accordance with this concentration above.

4.2. Laboratory contamination caused by cracking or overturning of virus-containing culture vessels shall follow the procedures as: to keep the laboratory space confined to avoid the diffusion of contaminants and to cover the contaminated area with a towel soaked in the disinfectant with 0.55% effective chlorine. When necessary (excessive overflowing), peroxyacetic acid may be used for heating and fumigating the laboratory overnight, with a dosage of 2 g/m^3. It is also recommended to spray the 20 g/l peroxyacetic acid disinfectant solution by the use of the aerosol sprayer, with a dosage of 8 ml/m^3 and acting for 1–2 h; when necessary. Potassium permanganate-formaldehyde fumigation may be adopted and potassium permanganate of 8 g/m^3 may be placed into a container resistant to heat and corrosion (pottery jar or glass container), before formaldehyde (40%) of 10 ml/m^3 is added to the container, for fumigation for more than 4 h. The indoor humidity during the fumigation process shall be 60%–80%.

4.3. Requirements for live-virus biosafety operation shall be strictly followed when clearing the contaminants. The contaminants shall be autoclaved, with laboratory ventilated to prevent the secondary hazards.