

3.6.2 Division 6.2—Infectious Substances

STATE VARIATIONS: AUG-03, CAG-08, VUG-02

OPERATOR VARIATIONS: 4C-04, BZ-07, CM-05, FX-04, JJ-04, L7-04, LA-07, LP-04, LU-04, M3-04, P5-05, SN-03, UC-04, XL-04

3.6.2.1 Definitions

For the purposes of these Regulations:

3.6.2.1.1 Infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

Note:

Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Division 6.1 and assigned to UN 3172 or UN 3462.

3.6.2.1.2 Biological products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

3.6.2.1.3 Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined below in 3.6.2.1.4.

3.6.2.1.4 Patient specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

3.6.2.1.5 Medical or clinical wastes are wastes derived from the veterinary treatment of animals, the medical treatment of humans or from bio-research.

3.6.2.2 Classification of Infectious Substances

3.6.2.2.1 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291, UN 3373 or UN 3549, as appropriate.

3.6.2.2.2 Infectious substances are divided into the following categories:

3.6.2.2.2.1 Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D.

Note:

An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

- (a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.
- (b) Assignment to UN 2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

Notes:

1. *The proper shipping name for UN 2814 is **Infectious substance, affecting humans**. The proper shipping name for UN 2900 is **Infectious substance, affecting animals** only.*
2. *The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must be included in Category A.*
3. *In the following table, the micro-organisms written in italics are bacteria or fungi.*

TABLE 3.6.D
Indicative Examples of Infectious Substances Included in Category A in
Any Form Unless Otherwise Indicated (3.6.2.2.1)

UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substance affecting humans	<i>Bacillus anthracis</i> (cultures only) <i>Brucella abortus</i> (cultures only) <i>Brucella melitensis</i> (cultures only) <i>Brucella suis</i> (cultures only) <i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> –Glanders (cultures only) <i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only) <i>Chlamydia psittaci</i> –avian strains (cultures only) <i>Clostridium botulinum</i> (cultures only) <i>Coccidioides immitis</i> (cultures only) <i>Coxiella burnetii</i> (cultures only) Crimean-Congo haemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli</i> , verotoxigenic (cultures only) Ebola virus Flexal virus <i>Francisella tularensis</i> (cultures only) Guaranito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus (cultures only) ¹ <i>Mycobacterium tuberculosis</i> (cultures only) Nipah virus Omsk haemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) <i>Rickettsia prowazekii</i> (cultures only) <i>Rickettsia rickettsii</i> (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only)

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TABLE 3.6.D
Indicative Examples of Infectious Substances Included in Category A in
Any Form Unless Otherwise Indicated (3.6.2.2.1) (continued)

UN Number and Proper Shipping Name	Micro-organism
	Sabia virus <i>Shigella dysenteriae type 1</i> (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis</i> (cultures only)
UN 2900 Infectious substances affecting animals	African swine fever virus (cultures only) Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Goatpox virus (cultures only) Lumpy skin disease virus (cultures only) <i>Mycoplasma mycoides</i> –Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

□ 1. “Monkeypox” was renamed “mpox” by the World Health Organization.

3.6.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373.

Note:

The proper shipping name of UN 3373 is **Biological substance Category B**.

3.6.2.2.3 Exceptions

3.6.2.2.3.1 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.2 Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.4 Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection are not subject to these

Regulations, unless they meet the criteria for inclusion in another class.

3.6.2.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material are not subject to these Regulations.

3.6.2.2.3.6 Faecal occult blood screening samples are not subject to these Regulations.

3.6.2.2.3.7 Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation as well as samples drawn in connection with such purposes are not subject to these Regulations.

3.6.2.2.3.8 Patient specimens for which there is minimal likelihood that pathogens are present are not subject to other provisions of these Regulations provided:

- (a) The specimen must be packed in a packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen,” as appropriate;
- (b) The packaging must consist of three components:
 1. a leak-proof primary receptacle(s);
 2. a leak-proof secondary packaging; and

3. an outer packaging of adequate strength for its capacity, mass and intended use and with at least one surface having minimum dimensions of 100 mm × 100 mm;
- (c) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;
- (d) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.
- (e) If refrigerated or frozen specimens are to be transported the following conditions must be met:
 1. when dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed between the secondary packaging and the outer packaging. Interior supports must be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging must be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings;
 2. the primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

Note:

In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.).

3.6.2.2.3.9 Medical devices or equipment potentially contaminated with or containing infectious substances which are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation are not

subject to the provisions of these Regulations when carried as cargo if packed in packagings designed and constructed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents. Packagings must be designed to meet the construction requirements listed in 6.2.

3.6.2.2.3.9.1 Medical devices or equipment must be drained of free liquid to the extent practicable. They must be packed in a strong rigid outer packaging fitted with sufficient cushioning material to prevent movement within the outer packaging. These packagings must meet the general packing requirements of 5.0.2.4.1, 5.0.2.6.1.1, 5.0.2.6.1.2 and 5.0.2.7.1. If the outer packaging is not liquid tight and the medical devices or equipment are contaminated with or contain liquid infectious substances, a means of containing the liquid in the event of leakage must be provided in the form of a leakproof liner, plastic bag or other equally effective means of containment. These packages must be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m.

Note:

A packaging's capability of retaining medical devices or equipment when dropped from a height of 1.2 m should be determined through testing a sample package as prepared for transport or through alternative means such as non-destructive testing and engineering analysis, testing with an article of similar mass and size, or other equivalent means.

3.6.2.2.3.9.2 Packages must be marked "Used Medical Device" or "Used Medical Equipment". When packages are placed in an overpack this mark must be reproduced on the outside of the overpack unless the mark remains visible.

3.6.2.2.3.9.3 This exception does not apply to:

- (a) medical waste (UN 3291 and UN 3549);
- (b) medical devices or equipment contaminated with or containing infectious substances in Category A (UN 2814 or UN 2900); and
- (c) medical devices or equipment contaminated with or containing other dangerous goods that meet the definition of another hazard class.

3.6.2.3 Biological Products

3.6.2.3.1 For the purposes of these Regulations, biological products are divided into the following groups:

- (a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations;
- (b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

Note:

Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

3.6.2.4 Genetically Modified Micro-organisms and Organisms

Genetically modified micro-organisms not meeting the definition of an infectious substance must be classified according to Subsection 3.9.

3.6.2.5 Medical or Clinical Wastes

3.6.2.5.1 Medical or clinical wastes containing:

- (a) Category A infectious substances must be assigned to UN 2814, UN 2900 or UN 3549, as appropriate. Solid medical waste containing Category A infectious substances generated from the medical treatment of humans or veterinary treatment of animals may be assigned to UN 3549. The UN 3549 entry must not be used for waste from bioresearch or liquid waste;
- (b) Category B infectious substances must be assigned to UN 3291.

3.6.2.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances must be assigned to UN 3291. For the assignment, international, regional or national waste catalogues may be taken into account.

Note:

*The proper shipping name for UN 3291 is **Biomedical waste, n.o.s., Clinical waste, unspecified, n.o.s. or Medical waste, n.o.s. or Regulated medical waste, n.o.s.***

3.6.2.5.3 Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.6 Infected Animals

3.6.2.6.1 Infected Live Animals

Live animals must not be used to consign infectious substances unless such a substance cannot be consigned by any other means. A live animal that has been intentionally infected and is known or suspected to contain an infectious substance may only be transported by air under terms and conditions approved by the appropriate national authority of the States of origin, transit, destination and operator in accordance with the Supplement to the Technical Instructions (Part S-1;2).

3.6.2.7 Patient Specimens

Patient specimens must be assigned to UN 2814, UN 2900 or UN 3373 as appropriate except if they comply with 3.6.2.2.3.