DANGEROUS GOODS PANEL

Dubai, 31 March to 4 April 2003

Agenda Item 2 : Development of recommendations for amendments to the Technical Instructions for incorporation in the 2005/2006 edition

DIAGNOSTIC SPECIMENS % REVISED GUIDANCE DOCUMENT

(Presented by R. Richard)

SUMMARY

A number of comments have been received by the US DOT in regard to the US update of regulations for diagnostic specimens; this update is consistent with the 2003-2004 edition of the Technical Instructions. On this basis, the US DOT have issued interpretations regarding body fluids that are believed not to be subject to the regulations.

In order to ensure a consistent interpretation, a revised guidance document is presented for the consideration of the Working Group of the Whole.

Interpretation/Guidance Document developed by ICAO Dangerous Goods Panel members nominated by Canada, United Kingdom and United States in collaboration with the World Health Organisation

Note: This document is only valid for the period of 1 January 2003 through 31 December 2004

1. INTRODUCTION

The 2003-2004 ICAO Technical Instructions include amendments for diagnostic specimens. The purpose of this document is to provide information and guidance for complying with the amendments. Specifically the document provides guidance on:

- Use of the new requirements for diagnostic specimens
- Packaging and consignment procedures
- Passenger and operator provisions

- Substances included or excluded from shipment as diagnostic specimens
- Emergency response procedures

The previous references to risk groups for determining if a substance may be transported as a diagnostic specimen have been removed (see 2;6.3.1.3.2) The 2003-2004 edition of the Technical Instructions maintains the risk group criteria for classifying infectious substances but it is anticipated that the classification criteria will be replaced in the 2005-2006 edition of the Technical Instructions when the ICAO Dangerous Goods Panel considers the infectious substances requirements that were recently adopted for the 13th revised edition of the UN Model Regulations. As a result of the 2003-2004 amendments, specimens known or suspected of containing pathogens meeting the criteria for risk groups 2 or 3 may be transported as diagnostic specimens when they are transported for diagnostic or investigational purposes. Specimens known or suspected of containing risk group 4 pathogens must be classified in Division 6.2 under UN 2814 or UN 2900, as appropriate and transported according to the requirements for these substances.

The text below is provided to explain the impact of the amendments to the diagnostic specimens requirements in the Technical Instructions. The new requirements for diagnostic specimens that were adopted by the 12th revised edition of the UN Model Regulations have been adopted in other modal regulations and in certain national and regional transport regulations effective January 1, 2003.

The definition and relevant requirements

6.3.1.3.1 Diagnostic specimens are any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected animals.

6.3.1.3.2 Diagnostic specimens must be assigned to UN 3373 unless the source patient or animal has or may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available, in which case they must be assigned to UN 2814 or UN 2900

Note 1. - Blood which has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products and any tissues or organs intended for use in transplants are not subject to these Instructions.

Note 2. - Assignment to UN 2814 or UN 2900 must be based on known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgement concerning individual circumstances of the patient or animal.

Diagnostic specimens, ~~including those taken from apparently healthy individuals,~~ may contain pathogens that meet the criteria for risk groups 1, 2, 3 or 4. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, that can cause disease in humans or animals. Pathogens are carried in blood, on the skin, in urine, saliva or faeces. Specimens containing risk group 1 pathogens are not subject to the Technical Instructions. Specimens containing risk group 4 pathogens are not permitted for transport as diagnostic specimens. Diagnostic specimens containing risk group 2 or 3 pathogens - present a lower risk in transport as compared to infectious substances containing risk group 4 pathogens or pathogens that are in intentionally propagated in high

concentrations such as those being transported for medical research. Effective treatments are available and the risk of the spread of infection is limited for risk group 2 or 3 pathogens. Additionally, the risk of transmission from one infected individual to another is not as great for these pathogens. Since the packaging requirements of packing instruction 650 afford a high level of safety, the probability of exposure is relatively low. The probability of transmission of an infection or disease to an exposed individual from a diagnostic specimen is also relatively low. Effective and cautious emergency response procedures and employee training significantly minimize the risk of exposure and subsequent transmission of infection or disease.

Consignors, who would normally be health care professionals, must make a judgement about the presence of pathogens of risk group 4., However, such judgement is not required for ~~in respect of~~ risk group 2 or 3, provided the specimens are being transported for diagnostic or investigational purposes. Specimens containing pathogens of risk group 2 or 3 transported for any other purpose must be consigned as UN2814 or UN2900.

The ICAO TI excludes from regulation infectious substances including diagnostic specimens that are unlikely to cause human or animal disease (see 2;6.3.1.1). On this basis, diagnostic specimens that do not contain a pathogen, that contain only a Risk Group 1 pathogen, or that contain a pathogen that has been neutralized or inactivated with preservative or other means are not considered to be subject to the Technical Instructions. On this basis, the following would not be required to be transported as diagnostic specimens:

- Blood which has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products and any tissues or organs intended for use in transplants;

- Urine samples from healthy individuals that are being transported for purposes of testing as part of a drug usage or diabetes monitoring program;

- Blood samples from healthy individuals that are being transported to analyze cholesterol levels or other non-infectious conditions;

- Faeces samples from healthy individuals that are being transported for testing the presence of a non-contagious disease (e.g., prostate cancer) other than one that would involve the presence of infectious pathogens.

If in the judgement of a medical professional, a diagnostic specimen does not contain or is not suspected to contain an infectious substance, then it is not subject to the requirements of the Technical Instructions. It should be noted that determining if a substance is infectious has always included subjective analysis in the absence of actual testing. This determination should be based on the known medical condition, history, and symptoms of the source patient or animal; endemic local conditions; or other individual circumstances of the source patient or animal. Classifying these materials based on the level of risk and applying transport requirements commensurate with that risk should ensure an adequate level of safety. If there is any doubt as to whether a substance may contain infectious substances of risk group 2 or 3 then the substance should be transported as subject to the Technical Instructions.

These requirements were developed in coordination with experts from the World Health Organization (WHO) and provide a level of safety commensurate with the risk in transport without imposing

an undue burden on those who are required to determine whether an infectious substance may be transported as a diagnostic specimen. In particular the amendments:

- avoid direct reference to WHO Risk Groups, which had been developed by WHO for purposes other than transport and remove ambiguity related to the previous use of the terms "reasonably expected to contain" or "those where a relatively low probability exists" ;

- limit the application of requirements in transport to those commensurate with the actual , rather than the perceived, risk;

- require easily obtainable, suitable packaging affording a high level of safety appropriate to the degree of hazard and conditions of transport. Packing instruction 650 is appropriate for the transport of diagnostic specimens containing pathogens belonging to risk group 2 and 3;

- permit ready consignment and provide for the universal and effective treatment of individuals in the healthcare system.

It should be noted that determining if a substance is infectious has always included subjective analysis in the absence of actual testing. The 2003-2004 amendment minimizes the subjectivity relative to determining if a substance may be transported as a diagnostic specimen. Classifying these materials based on the level of risk and applying transport requirements commensurate with that risk should ensure an adequate level of safety.

Packaging and consignment procedures

Packing Instruction 650 is intended to provide all the information necessary to prepare and transport safely a consignment of diagnostic specimens. Among other requirements:

· the packaging must be of good quality capable of passing a 1.2m drop test and must consist of three components:

a primary receptacle containing the diagnostic specimen;
a secondary packaging, and
an outer packaging with suitable cushioning material.

Either the primary or secondary receptacle must be capable of withstanding an internal pressure producing a pressure differential of not less than 95kPa for liquids.

· the package must be marked "DIAGNOSTIC SPECIMEN". The UN number is not required to be shown.

Passenger and Operator Provisions

Diagnostic specimens are not permitted for transport in carry-on or checked baggage and must not be carried on a person. Operators must not load or transport diagnostic specimens unless they are transported as cargo in accordance with the provisions of 7;2.1 of the Technical Instructions.

Substances that must be transported as infectious substances ~~excluded from shipment as diagnostic specimens~~

NOTE 1: The following list is not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the following list but which meet the same criteria must not be transported as a diagnostic specimen. In addition, if there is doubt as to whether or not a pathogen falls within this category it must not be transported as a diagnostic specimen.

NOTE 2: In the following table, the micro-organisms indicated in italics are bacteria, mycoplasmas, rickettsiae or fungi.

NOTE 3: Cultures (laboratory stocks) are the result of a process by which pathogens are amplified or propagated in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes. Cultures prepared for the intentional generation of pathogens may not be transported as diagnostic specimens.

NOTE 4: If a health authority list is available that shows other pathogens regarded as Risk Group 4 this should also be taken into account and the substances should not be transported as diagnostic specimens.

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES FORBIDDEN AS DIAGNOSTIC SPECIMENS IN ANY FORM UNLESS OTHERWISE INDICATED	
UN Number and Proper Shipping Name	**Micro-organism**
UN 2814 Infectious substances affecting humans	~~*Bacillus anthracis (cultures only)*~~ ~~*Brucella abortus* (cultures only)~~ ~~*Brucella melitensis* (cultures only~~) ~~*Brucella suis* (cultures only)~~ ~~*Burkholderia mallei - Pseudomonas mallei* – Glanders (cultures only~~) ~~*Burkholderia pseudomallei – Pseudomonas pseudomallei* (cultures only~~) ~~*Chlamydia psittaci* - avian strains (cultures only~~) ~~*Clostridium botulinum (cultures only)*~~ ~~*Coccidioides immitis* (cultures only~~) ~~*Coxiella burnetii* (cultures only~~) Crimean-Congo hemorrhagic fever virus ~~*Dengue virus (cultures only*~~) ~~*Eastern equine encephalitis virus (cultures only*~~) ~~*Escherichia coli*, verotoxigenic (cultures only~~) Ebola virus

UN Number and Proper Shipping Name	Micro-organism
	Flexal virus ~~*Francisella tularensis (cultures only)*~~ Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary 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
UN 2814 Infectious substances affecting humans *(cont'd)*	~~*Mycobacterium tuberculosis (cultures only)*~~ Nipah virus Omsk hemorrhagic fever virus ~~*Poliovirus (cultures only*~~) Rabies virus ~~*Rickettsia prowazekii (cultures only)*~~ ~~*Rickettsia rickettsii* (cultures only~~) Rift Valley fever virus ~~*Russian spring-summer encephalitis virus (cultures only*~~) Sabia virus ~~*Shigella dysenteriae type 1 (cultures only)*~~ ~~*Tick-borne encephalitis virus (cultures only*~~) Variola virus Venezuelan equine encephalitis virus ~~*West Nile virus (cultures only*~~) ~~*Yellow fever virus (cultures only*~~) ~~*Yersinia pestis* (cultures only~~)
UN 2900 Infectious substances affecting animals	African horse sickness virus African swine fever virus Avian paramyxovirus Type 1 - Newcastle disease virus Bluetongue virus Classical swine fever virus Foot and mouth disease virus Lumpy skin disease virus

UN Number and Proper Shipping Name	Micro-organism
	Mycoplasma mycoides - Contagious bovine pleuropneumonia Peste des petits ruminants virus Rinderpest virus Sheep-pox virus Goatpox virus Swine vesicular disease virus Vesicular stomatitis virus

Emergency response procedures

Mitigation procedures:

Isolate spill or leak area immediately in all directions.
Keep unauthorized personnel away.
Obtain identity of substance involved if possible and report the spill to the appropriate authorities.
Do not touch or walk through spilled material.
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Be particularly careful to avoid contact with broken glass or sharp objects that may cause cuts or abrasions that could significantly increase the risk of exposure.
Damaged packages containing solid CO2 as a refrigerant may produce water or frost from condensation of air. Do not touch this liquid as it could be contaminated by the contents of the parcel.
Liquid nitrogen may be present and can cause severe burns.
Absorb spilled materials with earth, sand or other non-combustible material while avoiding direct contact.
Cover damaged package or spilled material with damp towel or rag and keep wet with liquid bleach or other disinfectant. Liquid bleach will generally effectively inactivate the released substance.

DO NOT CLEAN-UP OR DISPOSE OF, EXCEPT UNDER SUPERVISION OF A SPECIALIST.

First Aid: Move exposed person(s) to a safe isolated area.

CAUTION: Exposed person(s) may be a source of contamination.

Call emergency medical services.
Remove and isolate contaminated clothing and shoes.
In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.
For further assistance, contact the appropriate public health authority.
Ensure that medical personnel are aware of the substances involved, and take precautions to protect themselves.

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