The changes to Diagnostic Specimens must be seen in light of past and recent decisions taken by the UN Sub-committee of Experts on the Transport of Dangerous Goods. But before I speak of the decisions taken by the UN Sub-committee let me give you some background information.

Background

UN – Sub-committees role in shaping global TDG Regulations

The United Nations Sub-committee of Experts on the Transport of Dangerous Goods is responsible for the development and maintenance of the United Nations Transport of Dangerous Goods - Model Regulations that is the primary source of global regulations on the transport of dangerous goods. The UN TDG Model Regulations are adopted by each of the modal authorities including the ICAO Dangerous Goods Panel (ICAO DGP) to which I am the Canadian member.

The UN Sub-committee works in a two-year cycle (biennia) and the product of that cycle the revised UN TDG - Model Regulations is then given to the Modal authorities, e.g., the ICAO DGP, for their review and incorporation into their regulations, e.g., the ICAO TI's.

The ICAO DGP also works in a two-year cycle. This means that whatever the ICAO DGP receives from the UN Sub-committee will come into effect in the ICAO TI's two years later. For example the changes that the UN Sub-committee have just agreed to have been incorporated into the 13th edition of the UN TDG - Model Regulations.

The text of the 13th edition is currently under review by the ICAO DGP and with amendments to reflect the aviation environment will be incorporated in the 2005-2006 edition of the ICAO TI's.

UN Sub-Committee Work on Infectious Substances

For the past number of years, the UN TDG - Model Regulations have classified infectious substances using the World Health Organization (WHO) Risk Group criteria (Risk Groups 2 to 4). Although the WHO Risk Group criteria was originally intended for laboratory use the UN chose to adopt it to classify infectious substances in preparation for transport as it was recognized that, at the time, there was no other classification system in place for infectious substances.

Unfortunately, the WHO did not have an indicative list of substances for each Risk Group and it was left to individual countries and scientific groups to determine what substances were included in which risk group. This led to inconsistencies in classification for international transport and for transport within countries.

The UN Sub-Committee decided to create a Working Group to resolve this issue. That group included:

- UN Sub-committee members from Canada, the Czech Republic, France, Germany, Italy, Norway, the United Kingdom and the United States, and
- Representatives from the Basel Convention Secretariat, the World Health Organization (WHO), the American Biological Safety Association (ABSA), the Dangerous Goods Advisory Council (DGAC), the European Biosafety Association (EBSA), the International Air Transport Association (IATA) and the International Express Carriers Conference (IECC).

In the 12th Edition of the UN TDG – Model Regulations, which is now included in the 2003/2004 Edition of the ICAO TI's, a decision was taken to eliminate the use of Risk Groups with respect to Diagnostic Specimens and to clearly define what constitutes a diagnostic specimen so that their transport could be facilitated.

The 13th Edition of the UN TDG - Model Regulations, to be included in the 2005/2006 ICAO TI's, is going one step further by eliminating any reference to Risk Groups for Infectious Substances and by classifying infectious substances into the following categories:

- Category A, and
- Category B.

Category A is for high risk infectious substances which when transported in a form that, when exposure occurs, are capable of causing permanent disability, life-threatening or fatal disease to humans or animals and includes cultures. Category A consists of substances that would normally be classified as risk group 4 and also a number of substances that would be classified as risk group 2 or 3.

The UN Sub-committee has developed an indicative list of substances included in Category A. If a substance is not on the list but has similar characteristics and properties as a substance on the list then it should be classified as Category A. If a consignor has any doubt as to whether or not a substance should be in Category A, then the consignor should classify it as Category A.

Category A substances are assigned to **Infectious Substances affecting humans, UN 2814 and Infectious Substances affecting animals only, UN 2900**, as appropriate.

Category B consists of those infectious substances that do not meet the criteria for inclusion in Category A.

Category B substances are assigned to '**Diagnostic Specimens'** or **'Clinical Specimens', UN3373.**

Current Situation with Diagnostic Specimens

Given the context within which the 2003/2004 ICAO TI regulatory text concerning Diagnostic Specimens was made you can see that the use of the concept of Risk Groups no longer applies and will in fact become obsolete for transporting Infectious Substances within the next couple of years. It is a whole new way of thinking.

The people making the decisions whether or not to classify something as a Diagnostic Specimen continue to be a *doctor, scientist, veterinarian, epidemiologist, genetic engineer, microbiologist, pathologist, nurse, coroner or laboratory technologist or technician.* However, in making the decision as to whether or not something is a Diagnostic Specimen they need only consider the following text from the 12th Edition of the UN Model Regulations:

> 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, endemiclocal conditions, symptoms of the patient or animal, or professional judgement concerning individual circumstances of the patient or animal.

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