REQUIREMENTS FOR ACCREDITATION OF AEROBIC BACTERIOLOGY LABORATORIES BY THE ANTIMICROBIAL RESISTANCE SURVEILLANCE PROGRAM, DEPARTMENT OF HEALTH

## RATIONALE

The continuing emergence of pathogenic microorganisms that are resistant to first-line antimicrobials is a cause of increasing concern. This emergence is associated with higher levels of mortality and morbidity which not only impacts on patients but also increases the burden on health care services as a result of additional diagnostic testing, prolonged hospital stay and increased intensity and duration of treatment.

There is evidence to suggest that more prudent usage of antimicrobials particularly in the treatment of human disease could make a significant impact on the pace and extent to which resistance emerges in microorganisms pathogenic to man. Minimizing the emergence of antimicrobial resistance to second line broad-spectrum antibiotics (such as the five antibiotics listed in PHILHEALTH circular no. 15, series 2006) could be achieved by restricting their use in favor of first line narrower spectrum but effective antibiotics **unless there is evidence to prove (i.e. through surveillance data) that significant antimicrobial resistance to the narrower spectrum antibiotics exist**. It is therefore essential that surveillance systems such as an antimicrobial resistance surveillance be in place to provide the information necessary to secure an approach to the management of communicable diseases that minimizes morbidity and mortality whilst also containing the emergence of pathogens resistant to antimicrobials. To be effective, such surveillance systems should 1) be focused on diseases of greatest public health importance (i.e. with high mortality and/or morbidity) and where therapeutic options may be severely limited by antimicrobial resistance; 2) include diseases that are readily transmissible (i.e. may give rise to outbreaks and epidemics); 3) provide information on mortality and morbidity attributable to resistant strains of the organism in the context of that attributable to susceptible strains; and 4) provide information for action at the local, intermediate and national levels. To provide reliable and valid information for action: 1) **data on culture identification and antimicrobial resistance should be of a consistently appropriate quality hence the emphasis on adherence to international standards in bacteriology**; 2) the capture, collation and analysis of data should be in accordance with protocols of appropriate quality and 3) information outputs should facilitate decision-making by clear presentation and timely distribution and should include a commentary on the limitations of the data presented as well as proposals for interventions.

I. Objectives
   A. To improve the quality of bacteriology laboratory services and ultimately, the quality of care provided to patients by assessing compliance of these laboratories with international standards
   B. To encourage hospitals/health care institutions to establish antimicrobial resistance surveillance systems and utilize information from such systems as basis for selecting appropriate antibiotic regimens for treatment of infectious diseases
   C. To promote cost-effective use of antibiotics while minimizing emergence of antimicrobial resistant microorganisms

II. Definition of Terms

A. Antimicrobial Resistance Surveillance Program – a program of the Department of Health which monitors the current levels and developing trends of antibiotic resistance of aerobic bacteria of public health importance and performs reference laboratory functions related to antimicrobial resistance, with the goal being to utilize such data as basis for rational antibiotic use

B. Aerobic bacteriology laboratory – laboratory which deals with culture, isolation, identification, susceptibility testing of aerobic pathogens from human samples

C. Tertiary Laboratory – a laboratory performing primary and secondary service capabilities in addition to but not limited to the following: special chemistry, special hematology, immunology/serology, microbiology (culture and sensitivity, aerobic and anaerobic, and KOH)

D. Accreditation – the act of granting recognition to an institution which maintains suitable standards and specific requirements set by an official review board

E. Licensing – is the process of issuance of document as proof of official or legal permission to operate a clinical laboratory

F. Hospital epidemiologist - hospital personnel who studies the causes, distribution, and control of diseases in patient populations based on data generated by the hospital. In relation to the analysis and interpretation of data from an antimicrobial resistance surveillance system, a person with training in infectious diseases may have the most relevant qualification to act as hospital epidemiologist.

G. Clinical microbiologist – a professional focusing on infectious disease diagnosis (with emphasis on identifying bacterial agents of infection), treatment and surveillance working in collaboration with health care professionals

H. Technical consultant- a professional responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be on-site at all times when testing is performed, however, he or she must be available to the laboratory on an as needed basis to provide consultation.

III. Accreditation Requirements

**1.** The laboratory applying for accreditation must have a valid license issued by the Bureau of Health Facilities and Services of the Department of Health or the appropriate Center for Health Development under whose jurisdiction the laboratory is located.

**2.** Microbiology laboratories **<u>should achieve or exceed</u>** the standards set in the following references before filing an application for accreditation:

a. Manual for the Laboratory Identification and Antimicrobial Susceptibility Testing of Bacterial Pathogens of Public Health Importance by the U.S. Centers for

Disease Control and Prevention and World Health Organization, 2003 **OR** Basic Laboratory Procedures in Clinical Bacteriology. World Health Organization, Geneva, 1991 (The former can be downloaded from the RITM website)

b. Surveillance standards for antimicrobial resistance by the World Health Organization (WHO/CDS/CSR/DRS/2001.5) (Document can be downloaded from the RITM website). The hospital antimicrobial resistance surveillance system should monitor the antimicrobial resistance patterns of the following microorganisms **at a minimum**: *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, Neisseria meningitidis, Neisseria gonorrhea, Salmonella, Shigella, Vibrio cholera, Escherichia coli, Klebsiella sp., Pseudomonas aeruginosa,* and *Staphylococcus aureus*. The ARSRL can receive bacterial isolates with unusual susceptibility patterns as listed in Annex A for confirmatory testing. Please follow the guidelines in Annex B. Cost of confirmatory tests are as follows: 1) quantitative susceptibility test **per antibiotic** - P 1,330.00; 2) **PCR for NDM1** in *E. coli/K. pneumoniae* isolates – P 3,500.00; and 3) **PCR for mecA** in *S. aureus* isolates – P3,500.00. Further, ARSRL likewise offers the following services: 1)*Salmonella* serogrouping/re-identification – P 1,680.00; 2) *Salmonella* serotyping/re-identification – P 2,900.00; and Pulsed Field Gel Electrophoresis (PFGE) of *Salmonella/Shigella*/methicillin *S. aureus/Vibrio cholera 01* – P 4,060.00

c. If the antimicrobial susceptibility method utilized in the laboratory is disk diffusion, the following are the references from the Clinical and Laboratory Standards Institute (formerly NCCLS): a) Performance Standards for Antimicrobial Disk Susceptibility Tests, 11th edition, (M02-A11, vol 32 no. 1), and b) Performance Standards for Antimicrobial Susceptibility Testing, 22nd Informational Supplement, **January 2012** (M-100-S22, volume 32 no. 3).

d. For antimicrobial resistance surveillance networks, it is equally important to realize that data generated for clinical purposes will need to be adapted for epidemiological use. Therefore, culture and antimicrobial susceptibility data should additionally be collated and managed using a valid software, preferably the WHONET in order to facilitate collation and analysis of antimicrobial susceptibility data. Laboratories with an existing software program can utilize the software BACLINK to convert the database to the WHONET format. WHONET and BACLINK can be downloaded at http://www.who.int/emc/WHONET/WHONET.html. The data outputs should contain the following information **at the minimum**: name of patient including the full middle name, date of birth, sex, patient location (ward where admitted or OPD as the case may be), date of admission (if admitted), date test requested, specimen source, name of requesting physician, type of test requested, hospital or case number, results of culture and antimicrobial susceptibility tests. For purposes of compliance with standards for reporting in accordance with International Health Regulations (IHR) of 2005 which became effective on June 2007 in all member countries of the World Health Organization, a list of

organisms that are reportable in accordance with IHR (2005) and Annex 2 of the IHR (2005) document must be available in the laboratory including evidence to prove that such organisms when identified in bacteriology lab are reported to the National Epidemiology Center (NEC) or their local counterparts. The IHR (2005) document can be accessed at the WHO website (www.who.int/eml)

**3.** Aerobic bacteriology laboratories should participate and perform satisfactorily in the External Quality Assessment Program (EQAP) to be conducted by the ARSP to be given accreditation. The EQAP guidelines are as follows:

a. Participation in the proficiency testing will require a payment of P5,500.00 per dispatch. A laboratory can request for a second sample of any of the EQAP organisms; however, such requests should be sent to the ARSP **within 2 weeks** from initial dispatch together with payment of P 1,100.0 per organism requested. Prices are subject to change without prior notice.

b. Proficiency testing samples will be distributed by the ARSP **on October 9, 2012**. However, since validity of accreditation is 3 years as stipulated in item IVC2, laboratories with valid accreditations are required to take the EQAP only at the time of application for renewal of accreditation. The yearly distribution of EQAP is intended to accommodate laboratories who wish to apply for accreditation for the first time or those who failed in the preceding year's EQAP.

c. 5 unknown samples will be given for identification and susceptibility.

d. **Answers should be sent through courier and received at the ARSP office not later than the date stipulated in the letter accompanying the unknown samples which is approximately 3 weeks after dispatch. Answers received after the set deadline will not be given a rating and will constitute non-participation in the proficiency test**.

e. Feedback will be provided 3 weeks after submission of EQAP results.

f. A rating of 75% or better is considered satisfactory performance in the EQAP. **Laboratory passing the EQAP 2012 will undergo inspection. Laboratories which failed or did not participate inthe EQAP will automatically be denied accreditation.**

**4.** A rating of at least 75% is considered satisfactory performance during inspection.

a. The laboratory shall make available to the accrediting body at any reasonable time, the premises, pertinent records, and facilities where the laboratory examinations are being performed for inspection.

b. Feedback shall be provided to each laboratory by inspectors after visit.

**5.** To get accreditation, laboratories should obtain a score of at least 75% in **BOTH** the EQAP and inspection.

6. **Accreditation will be valid from July 1, 2013-June 30, 2016.**

7. A certificate of participation will be issued to laboratories which submitted answers to proficiency testing on time.

8. **Participation in ARSP accreditation will be recognized as participation in the bacteriology component of the RITM NEQAS which is implemented beginning year 2009 as a component of the Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines (AO No. 2007-0027). Thus, laboratories with ARSP accreditation or have undergone EQAS under ARSP accreditation will no longer be asked to take the bacteriology component of the RITM NEQAS. These laboratories will then only be asked to undergo the parasitology and TB microscopy and/or culture components. Consequently, laboratories which have participated in ARSP accreditation have to pay only fifty percent (50%) of the RITM NEQAS fee.**

IV. Initial Accreditation

A. Documents to be accomplished:

1. Duly notarized application form. The application form can be downloaded from the website of the Research Institute for Tropical Medicine (RITM) – www.ritm.gov.ph. Filled up application forms **should be received** at the ARSRL office **on or before 12 noon of the last working day of August of every year**.

2. Photos of the Exterior and Interior design of the laboratory including floor plan.

B. Procedures for accreditation

1. The applicant submits his application form and pays a total of **P 7,000.00 (non-refundable) (P 1,500 application fee and P 5,500 EQAP fee) to the ARSP office by courier, in person or directly to the Research Institute for Tropical Medicine LandBank Muntinlupa Bank Account Number 0392 1024 77.** If payment will be through bank deposit, applicant should indicate in the deposit slip the purpose of payment (application for ARSP accreditation) and the name of the hospital. The applicant should FAX on the same day that the deposit was made a copy of the deposit slip to ARSP (02-8099763). A corresponding official receipt which reflects the deposit date will be sent to the applicant together with the proficiency testing samples. Sending payment by postal money order is discouraged because of logistic difficulties it can pose on ARSP.

2. The ARSP staff shall evaluate submitted documents for completeness of data. If deficiencies are noted, the ARSP shall notify the applicant to comply with the necessary requirements.

3. Only applications with completed requirements (properly filled-up application form, supporting documents, and payment of applicable fees) **RECEIVED ON TIME** will be included in the current round of evaluation.

4. **With respect to laboratory inspection, the applicant shall shoulder the cost of travel, accommodation and other reasonable expenses of the inspection team.**
   4.1 Inspection may be announced or unannounced at any reasonable time.
   4.2 The inspection team will consist of at least 2 personnel.
   4.3 The applying laboratory will be provided a bill listing down the estimate of expenses in connection with its laboratory's inspection. Please refer to attached table for schedule of fees to be shouldered by applying laboratory. Fees are subject to change without prior notice.
   4.4 Details of payment for laboratory inspection will be provided in a communication to the laboratory. Funds for expenses for inspection shall be transferred to the RITM bank account mentioned in IV. B.1 above.

C. Issuance of certificate of accreditation

1. The ARSP shall issue a certificate of accreditation to the aerobic bacteriology laboratory upon meeting the requirements. A copy will be given to the PhilHealth.

2. The certificate of accreditation is valid for 3 years.

3. A corresponding certificate of proficiency test participation will be issued to accredited laboratories yearly for the duration of the validity of their accreditation for the bacteriology laboratory to fulfill the requirements of the Bureau of Health Facilities and Services.

V. **Renewal of Accreditation**

1. **The aerobic bacteriology accreditation shall be renewed every 3 years.**

2. **Applications shall be received at the ARSRL for renewal of accreditation on or before 12 noon of the last working day of August of the year before accreditation expires.**

3. Any laboratory that fails to complete procedures and requirements for renewal of accreditation prior to the date of expiration of its accreditation shall automatically lose its accreditation on the expiry date indicated in its certificate of accreditation without prior notice. A laboratory may have its accreditation reinstated only upon submission of documents and completion of procedures for renewal of accreditation.

4. The documents and procedures required for renewal of accreditation shall be the same as those for initial accreditation.

5. The procedures for application for renewal of accreditation are contained in the initial accreditation requirements IV. A and B. Compliance to accreditation standards is expected of laboratories at all times. Laboratories shall be subjected to monitoring/inspection at any given time as deemed necessary by ARSP.

VI. Queries

1. All queries should be addressed to Dr. Celia Carlos, Head, Antimicrobial Resistance Surveillance Program, Research Institute for Tropical Medicine, Filinvest Corporate City, Alabang, Muntinlupa, Metro Manila

2. TELEFAX: (02) 809-97-63 or (02) 807-26-28 up to 32 local 243

**PLEASE CHECK THE RITM WEBSITE FROM TIME TO TIME FOR ANY UPDATES.**

## ANNEX A

## TABLE OF UNUSUAL ISOLATES 2012

| Organism Group | Resistance Phenotype Detected | | For Referral to ARSRL[1] | |
|---|---|---|---|---|
| | | | Refer All | Day 1 to 15 isolates of the month only |
| | **Intermediate or Resistant to:** | **Nonsusceptible to:** | | |
| **Gram-positive:**<br>*Enterococcus species* | High-level Aminoglycosides<br>Linezolid<br>Vancomycin | Daptomycin | x | |
| *Staphylococcus aureus* | Oxacillin/Cefoxitin | | | x |
| | Linezolid<br>Tigecycline<br>Quinupristin/Dalfopristin<br>Vancomycin | Daptomycin | x | |
| *Staphylococcus*<br>Coagulase-negative | Oxacillin/Cefoxitin | | | x |
| | Linezolid<br>Tigecycline<br>Quinupristin/Dalfopristin<br>Vancomycin | Daptomycin | x | |
| *Streptococcus* Beta-Hemolytic | Clindamycin<br>Erythromycin<br>Quinupr*i*stin/Dalfopristin | Ampicillin or Penicillin<br>Daptomycin<br>Linezolid<br>Vancomycin<br>Cefotaxime/Ceftriaxone/Cefepime | x | |
| *Streptococcus*, viridans group | Quinupristin/Dalfopristin | Daptomycin<br>Ertapenem or Meropenem<br>Linezolid<br>Vancomycin | x | |
| *Streptococcus pneumoniae* | Amoxicillin or Penicillin<br>Cefotaxime/Ceftriaxone/Cefepime<br>Gemifloxacin/Levofloxacin/<br>Imipenem or Meropenem<br>Moxifloxacin/Ofloxacin<br>Quinupristin/Dalfopristin<br>Rifampicin | Linezolid<br>Vancomycin | x | |
| **Gram-negative Organisms:**<br>*Acinetobacter species* | Doripenem/Imipenem/Meropenem | | x | |
| *Haemophilus influenzae* | | Cefotaxime/Ceftazidime/Ceftriaxone<br>Meropenem<br>Ciprofloxacin/Levofloxacin/<br>Lomefloxacin/Moxifloxacin/<br>Ofloxacin, Gemifloxacin | x | |
| *Neisseria gonorrhoeae* | Ciprofloxacin<br>Spectinomycin<br>Tetracycline | Ceftriaxone/Cefixime/Cefotaxime | x | |
| *Neisseria meningitidis* | Amoxicillin or Penicillin<br>Chloramphenicol<br>Ciprofloxacin<br>Rifampicin | Azithromycin<br>Cefotaxime/Ceftriaxone<br>Meropenem | x | |
| *Pseudomonas aeruginosa* | Cefepime<br>Doripenem/Imipenem/Meropenem | | x | |
| *Stenotrophomonas maltophilia* | Co-trimoxazole | | x | |
| **Any Enterobacteriaceae:**<br>Including Extended Spectrum beta-lactamase (ESBL) producer, ampC producer | Doripenem/Ertapenem/Imipenem/Meropenem | | x | |
| | Ceftazidime/Cefotaxime/Ceftriaxone<br>Cefepime | | | x |
| *Salmonella & Shigella species* | Ciprofloxacin/Levofloxacin<br>Cefotaxime/Ceftriaxone<br>Nalidixic Acid | | x | |
| *Vibrio cholerae* | Tetracycline | | x | |

Legend: [1] Recommended to be reported to Infectious Control Committee of the hospital
ARSRL: Antimicrobial Resistance Surveillance Reference Laboratory, Research Institute for Tropical Medicine, Dept. Of Health

**ANNEX B**
**GUIDELINES FOR SHIPMENT OF BACTERIAL ISOLATES**

**INTRODUCTION:**

Submission of bacterial isolates that must be sent to distant/ reference laboratories for further testing and confirmation requires transportation by mail or through courier services must follow the requirements of the Interstate shipment of Etiologic Agents code (Federal Regulations).

*PREPARATION OF BACTERIAL ISOLATES*

1. Revive the bacterial isolates onto desired culture media.
2. Incubate plates at 35°C – 37°C for 18-24 hours except for fastidious organisms which maybe incubated at enhance 5-10% CO2 content.
3. Check the viability and purity of the culture.
4. Inoculate the isolates onto the tube with appropriate transport media used.

| **Organism** | **Transport Medium** |
|---|---|
| *Enterobacteriaceae* | Nutrient agar butt/ slant |
| Enteric pathogens:<br>*Salmonella / Shigella*<br>*V. cholerae 01 / other Vibrios* | <br>Nutrient agar butt / slant<br>Semi-solid nutrient agar with 1% NaCl |
| *Staphylococcus spp.* | Nutrient agar butt / slant |
| *S. pneumoniae* and other *Streptococcus spp*. | Sheep blood agar / Chocolate agar slant |
| *H. influenzae* | Chocolate agar slant |
| *Neisseria gonorrhoeae* | Chocolate agar slant overlaid with mineral oil |

5. Incubate tubes to its required temperature.

**PACKING OF BACTERIAL ISOLATES (DOUBLE PACK CONTAINER)**

In most instances, microbiological specimens can be satisfactorily shipped through mail with special precautions against breakage and subsequent contamination of the mailing container.

**A. Volume not exceeding 50 ml.**

Material should be placed in a securely closed, watertight container [primary container [test tube, vial, etc]] which shall be enclosed in a second, durable watertight container [secondary container]. Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml.

The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material [e.g. paper towel] to absorb the entire contents of the primary containers[s] in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

**B. Volume greater than 50 ml.**

Packaging of material in volumes of 50 ml or more shall comply with requirements specified in paragraph [a] of this section. In addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

**C. Labels**

1. The outer shipping container of all materials containing etiologic agents transported must bear a label as illustrated and described below:

2. The label must be in the form of a square set at an angle of 45$^{o}$ (diamond shaped) with each side having a length of at least 50 mm, the width of the line must be at least 2 mm, and the letters at least 6 mm high. If an airway bill is used, the "Nature and Quantity of Goods Box" must show the text "DIAGNOSTIC SPECIMENS", "CLINICAL SPECIMENS", or "BIOLOGICAL SUBSTANCE CATEGORY B" and "UN 3373".

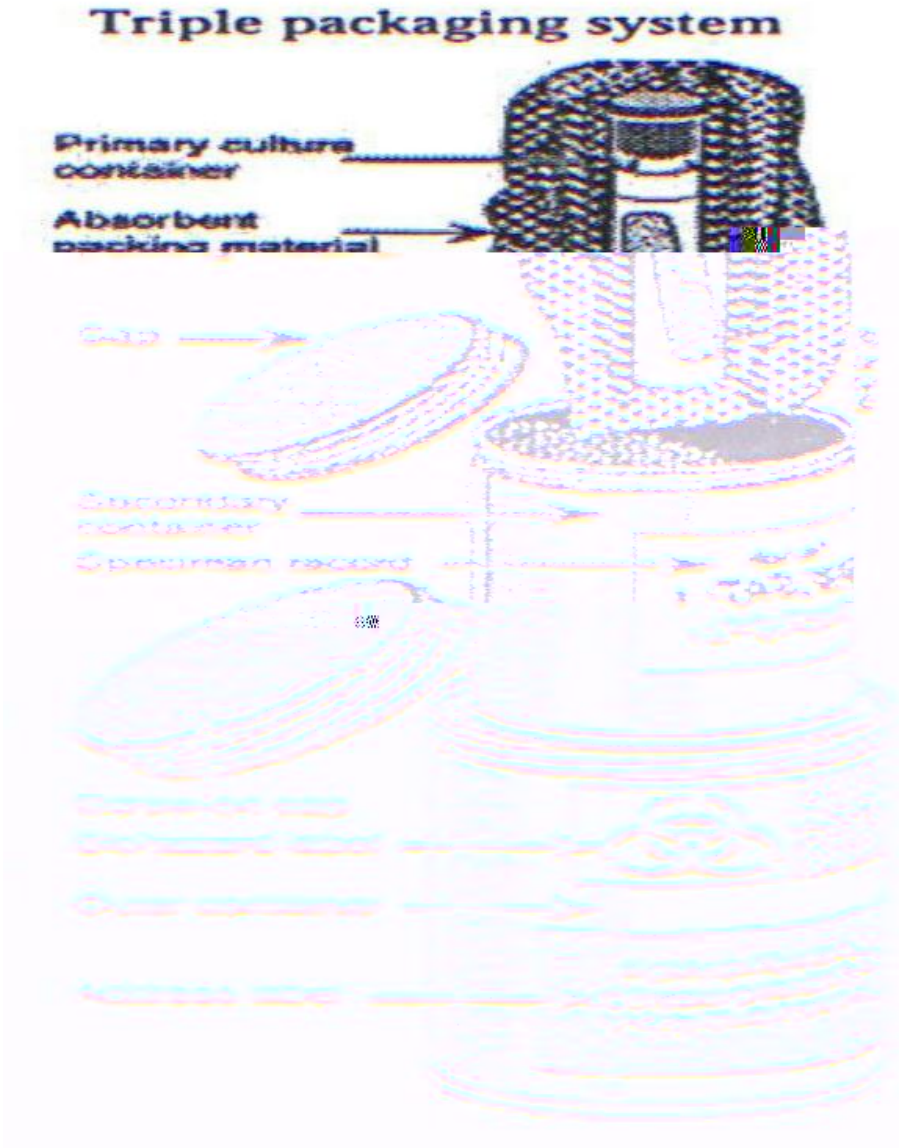
3. Other labels to be placed outside the outer shipping container include the following:

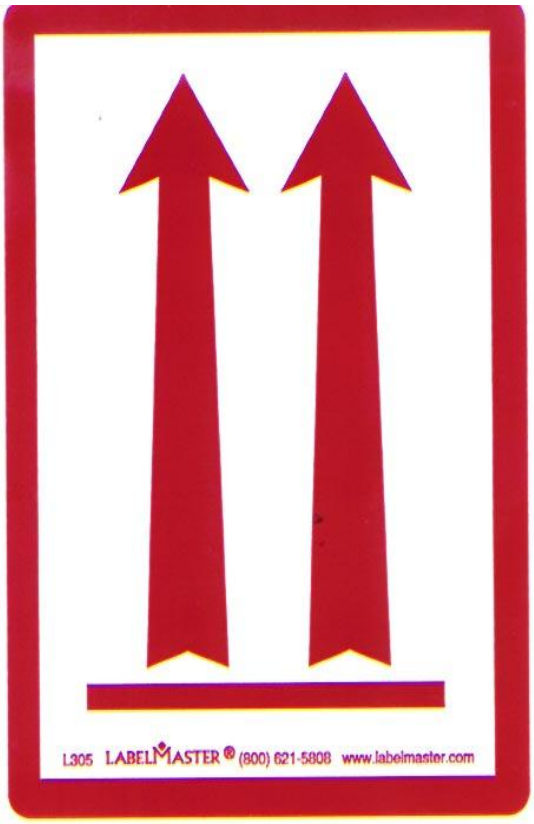
    - Name of Consignee (Label 1)
    - Name of Shipper (label 2)
    - Infectious Substance label
        - Infectious Substance Affecting Humans (Label 3)

- "Up arrows" label (Label 4)

4. **Damaged packages**

The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing Etiologic Agents/Biomedical Material label, isolate the package shall notify the Head, Antimicrobial Resistance Surveilance Program, Research Institute for Tropical Medicine, Filinvest Corporate City, Alabang, Muntinlupa, Metro Manila, by telephone (02) 809-9763 . The carrier shall also notify the sender.

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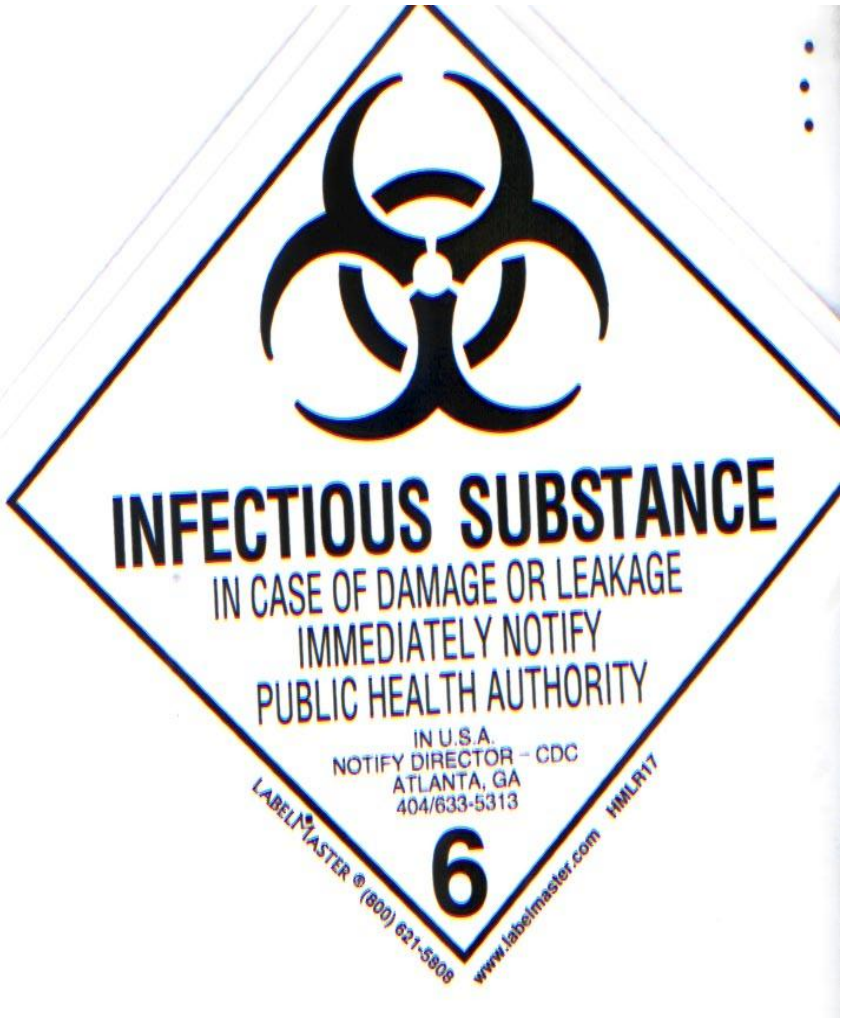
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