

Notifiable Conditions Rule Revision and Clinical Laboratories

by Tracy Sandifer, DOH/EHSPHL

Reporting specific notifiable conditions is the basis for communicable disease surveillance. New communicable conditions, new laboratory methods, and changes in national and international disease reporting standards occur constantly. The Washington State Board of Health recently revised Chapter 246-101 of the Washington Administrative Code (WAC) that updates the notifiable conditions rule to address public health needs identified over the past years. The revised rule goes into effect on February 5, 2011.

During 2010, the Board of Health and the Department of Health (DOH) worked together to update the notifiable conditions rule. The last major revision of this rule was in 2001, with limited revisions in 2005 for reporting HIV/AIDS. The 2010 rule revision addressed new surveillance needs due to new conditions such as SARS and prion disease, new international targets for disease surveillance, new laboratory methods, and new ways to improve public health efficiency based electronic systems. The rule revision process involved major stakeholder groups including clinical laboratories, health care providers, health care facilities, consumers, and public health agencies. Clinical laboratories provided input through representatives on the rule revision ad hoc advisory panel, as well as additional focus groups and consultations conducted through in-person meetings, telephone conferences, and emails.

The final text of the revised rule is available at <http://www.doh.wa.gov/Rules/adoptedrules.htm>. Please see the text of the rule for full details but, in summary, these are the revisions most pertinent to clinical laboratories:

New notifiable conditions for clinical laboratories: The list of conditions notifiable by clinical laboratories has been made consistent with the lists of diseases notifiable by health care providers and facilities, resulting in the addition of the following conditions:

Bacillus anthracis (anthrax), *Borrelia burgdorferi* (Lyme disease), *Borrelia hermsii* or *recurrentis* (Relapsing fever), *Burkholderia mallei* and *pseudomallei*, *Campylobacter*

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Acute Diarrhea	Lipid Screening
Anemia	PAP Smear Referral
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Group B Streptococcus	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Infectious Diarrhea	Wellness
Intestinal Parasites	

CMS Clarifies the Definition of Grossing

by Susan Walker, DOH/LQA

In a February 4, 2010 letter, Judy Yost, the national director of the federal Clinical Laboratory Improvement Amendments (CLIA) program, clarified the requirements for examining tissue specimens for the College of American Pathologists (CAP). The letter concerned the Centers for Medicare & Medicaid Services (CMS) definition of “grossing”. Since that time, the Washington State Laboratory Quality Assurance (LQA) program has been in discussion with CMS to better understand this issue and our responsibility to enforce the requirements.

According to CMS, the definition of “grossing” includes the following activities: “Examination (of tissue) includes color, weight, measurement, other characteristics of the tissue, or other mechanical procedures for which a written protocol has been developed. Other mechanical procedures include dissection, orientation, mapping, and inking prior to cutting or placement into the cassette. Anyone performing these tasks must meet the personnel requirements of CLIA high complexity testing.”

CMS confirmed that as a CLIA exempt program, LQA must enforce the “grossing” personnel requirements. This means anyone in your laboratory who describes the tis-

sue and /or performs any of the other activities described above must qualify as high complexity testing personnel. The requirements for high complexity testing personnel are:

1. MD, DO, DPM w/State license, PhD, Master’s, or Bachelor’s degree in science
2. Associate’s degree in lab science or medical lab technology or 60 semester hours from an accredited institution to include 6 semester hours of chemistry, 6 semester hours of biology, and 12 semester hours of a combination of chemistry, biology, or laboratory technology, and completion of an approved lab training program or at least 3 months documented lab training in the specialty of testing
3. On 2/28/92, previously qualified or could have qualified as a technologist under previous Medicare/CLIA independent lab personnel requirements
4. On 4/24/95, high school graduate performing high complexity testing and completed medical laboratory clinical training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS, or a 50-week U.S. military medical laboratory training course
5. On 4/24/95, high school graduate performing high complexity testing with appropriate training in the specialty performed

Effective with your next on-site routine inspection, Washington State Laboratory Quality Assurance will enforce these requirements. As part of Washington State’s CLIA exemption process, we are required to accept the CMS personnel requirements in their entirety. During our inspection of your laboratory, the surveyors will review your records to assure that your staff qualify as high complexity testing personnel if they are performing grossing.

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<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

Notifiable Conditions Rule Revision, cont'd from page 1

species, *Chlamydomphila psittaci* (psittacosis), *Coxiella burnetii* (Q fever), *Giardia lamblia*, *Haemophilus influenzae* (children < 5 years of age), hantavirus, Hepatitis D, Hepatitis E, novel or unsubtypeable influenza, *Legionella* species, *Leptospira* species, mumps virus, *Plasmodium* species, poliovirus, SARS-associated coronavirus, *Trichinella* species, vancomycin-resistant *S. aureus* (not to include vancomycin intermediate), variola virus, *Vibrio* species, viral hemorrhagic fever viruses, yellow fever virus, and *Yersinia enterocolitica* or *pseudotuberculosis*. Please refer to Table Lab-1 in WAC Section 246-101-201 for reporting timeframes.

All conditions are now listed by the scientific name of the organism instead of by clinical syndrome names. In addition, Enterohemorrhagic *E. coli* is now referred to as Shiga toxin-producing *E. coli*.

New specimen submission requirements for clinical laboratories: Many of the conditions listed above that are new for reporting by clinical laboratories have associated specimen submission requirements (see Table Lab-1, WAC Section 246-101-201). Among the previously existing list of laboratory notifiable conditions, the following specimen submission requirements are new:

- *Bordetella pertussis* cultures when available, *Listeria monocytogenes* cultures, and Shiga toxin-producing *E. coli* specimens when no culture is available.
- For *Neisseria meningitidis* and *Haemophilus influenzae*, there is an increased focus on submitting specimens only from normally sterile sites.

Patient Identifiers: Please note that Washington State Public Health Laboratories (PHL) require that all clinical specimens have two patient identifiers, a name and a second identifier (e.g., date of birth) both on the specimen label and on the submission form. Due to laboratory accreditation standards, specimens will be rejected for testing if not properly identified. Also, include specimen source and collection date.

Patient identifying information accompanying case reports: By July 1, 2011, health care providers and health care facilities are required to provide a specific list of patient identifying information to clinical laboratories when ordering a test for a notifiable condition. This list includes patient name, date of birth, address with zip code, and sex. Clinical laboratories are required to include this patient identifying information in notifiable condition reports to public health. By January 1, 2013, clinical laboratories are required to maintain databases capable of storing and retrieving all of the specified elements of patient identifying information (from WAC Section 246-101-225):

- (a) Type of specimen tested
- (b) Name of reporting laboratory
- (c) Telephone number of reporting laboratory
- (d) Date of specimen collection
- (e) Date specimen received by reporting laboratory
- (f) Requesting health care provider's name
- (g) Requesting health care provider's phone number
- (h) Requesting health care provider's address, when available
- (i) Test result
- (j) Name of patient
- (k) Sex of patient, when available in laboratory data base
- (l) Date of birth or age of patient, when available in laboratory data base, and
- (m) Full address of patient, or patient zip code at a minimum, when available in laboratory data base

Notifiable Conditions & Washington's Laboratories



The following laboratory results (preliminary or confirmed) are notifiable to local public health authorities in Washington in accordance with WAC 246-101. Timeframes for notification are indicated in footnotes.

Immediately notifiable results are indicated in bold. Information provided must include: specimen type; name and telephone number of laboratory; date specimen collected; date specimen received; requesting health care provider's name and telephone number or address; test result; name of patient (if available) or patient identifier; sex and date of birth or age of patient (if available).

Arboviruses^{2d *}

(West Nile virus, eastern and western equine encephalitis, dengue, St. Louis encephalitis, La Crosse encephalitis, Japanese encephalitis, Powassan, California serogroup, Chikungunya)

Acute: IgM positivity, PCR positivity, viral isolation

Bacillus anthracis (Anthrax)^{Imm *!}

Blood lead level (elevated)^{2d & i}

Blood lead level (non-elevated)^{Mo & i}

Bordetella pertussis (Pertussis)^{24h *!}

Borrelia burgdorferi (Lyme disease)^{2d*}

Borrelia hermsii or *recurrentis* (Relapsing fever, tick- or louseborne)^{24h *}

Brucella species (Brucellosis)^{24h *!}

Burkholderia mallei* and *pseudomallei^{Imm *}

Campylobacter species (Campylobacteriosis)^{2d *}

CD4 + (T4) lymphocyte counts and/or CD4 + (T4)^{Mo & i}

(patients aged thirteen or older)

Chlamydia psittaci (Psittacosis)^{24h *}

Chlamydia trachomatis^{2d *}

***Clostridium botulinum* (Botulism)**^{Imm *!}

***Corynebacterium diphtheriae* (Diphtheria)**^{Imm *!}

Coxiella burnetii (Q fever)^{24h *!}

Cryptococcus non v. neoformans[!]

Cryptosporidium (Cryptosporidiosis)^{2d *}

Cyclospora cayetanensis (Cyclosporiasis)^{2d *!}

E. coli^{Imm *!} (refer to "Shiga toxin-producing *E. coli*")

***Francisella tularensis* (Tularemia)**^{Imm *!}

Giardia lamblia (Giardiasis)^{2d *}

***Haemophilus influenzae* (children < 5 years)**^{Imm *!}

Hantavirus^{24h *}

Hepatitis A virus (acute) by IgM positivity^{24h *}

(Hepatocellular enzyme levels to accompany report)

Hepatitis B virus (acute) by IgM positivity^{24h *}

Hepatitis B virus, by:

HBsAg (Surface antigen); HBeAg (E antigen);

HBV DNA^{Mo *}

Hepatitis C virus^{Mo *}

Hepatitis D virus^{2d *}

Hepatitis E virus^{24h *}

Human immunodeficiency virus (HIV) infection^{2d & ii}
(for example, positive Western blot assays, P24 antigen or viral culture tests)

Human immunodeficiency virus (HIV) infection^{Mo & ii}

(II viral load detection test results - detectable and undetectable)

Influenza virus, novel or untypable strain^{Imm *!}

Legionella species (Legionellosis)^{24h *!}

Leptospira species (Leptospirosis)^{24h *}

Listeria monocytogenes (Listeriosis)^{24h *!}

Measles virus (rubeola)^{Imm *!}, acute, by: IgM positivity, PCR positivity

Mumps virus, acute, by IgM positivity; PCR positivity^{24h *!}

Mycobacterium tuberculosis (Tuberculosis)^{2d & iii ! @}

Neisseria gonorrhoeae (Gonorrhea)^{2d *}

***Neisseria meningitidis* (Meningococcal disease)**^{Imm *!}

Plasmodium species (Malaria)^{2d *}

Poliovirus^{Imm *!}, acute, by: IgM positivity, PCR positivity

Rabies virus (human or animal)^{Imm *!}

Salmonella species (Salmonellosis)^{24h *!}

SARS-associated coronavirus^{Imm *!}

Shiga toxin-producing *E. coli*^{Imm *!} (enterohemorrhagic *E. coli* including, but not limited to, *E. coli* O157:H7)

Shigella species (Shigellosis)^{24h *!}

Treponema pallidum (Syphilis)^{2d *!}

Trichinella species^{2d}

Vancomycin-resistant *Staphylococcus aureus*^{24h *!}

Variola virus (smallpox)^{Imm *!}

***Vibrio cholerae* O1 or O139 (Cholera)**^{Imm *!}

Vibrio species (Vibriosis)^{24h *!}

Viral hemorrhagic fever^{Imm *!}

Arenaviruses, Bunyaviruses, Filoviruses, Flaviviruses

Yellow fever virus^{Imm *!}

Yersinia enterocolitica or *pseudotuberculosis*^{24h *}

***Yersinia pestis* (Plague)**^{Imm *!}

CODE LEGEND

^{Imm} Immediately notifiable

^{24h} Notifiable within 24 hours

^{2d} Notifiable within 2 business days

^{Mo} Notifiable on a monthly basis

* Notifiable to the local health jurisdiction of the patient's residence

^{&i} Notifiable to DOH Lead Program **360-236-3359**

^{&ii} Notifiable to DOH IDRH Assessment **360-236-3419**

^{&iii} Notifiable to DOH TB Reporting Line **360-236-3397**
or TB Reporting Fax Line **360-236-3405**

[!] Specimen submission required

[@] Antibiotic sensitivity testing (first isolates only)

To report a Notifiable Condition, contact the local health jurisdiction of the patient's residence, unless the condition is reportable directly to DOH. If the patient's local health jurisdiction is unknown, please notify the local health jurisdiction of the health care provider that ordered the diagnostic test.

If no one is available at the local health jurisdiction and a condition is immediately notifiable, please call 1-877-539-4344

For more information, please see WAC 246-101 or <http://www.doh.wa.gov/notify/forms/>

REPORT A NOTIFIABLE CONDITION

Local Health Jurisdiction (LHJ) Contact Numbers At-A-Glance

In accordance with Washington State law (<http://www.doh.wa.gov/notify/other/legal.htm>), public health and health care professionals should report notifiable conditions to the local health jurisdiction in the county of the patient's residence. Disease reporting telephone numbers are provided below. This list is current as of December 16, 2010. To check for the most updated numbers, go online to: <http://www.doh.wa.gov/PHSD/localph/contact.htm> .

If no one is available at the local health jurisdiction and a condition is immediately notifiable, please call the Department of Health 24-hour reporting line: 1-877-539-4344. For a complete list of notifiable conditions for health care providers, hospitals, laboratories and veterinarians, please refer to the Posters section on this page: <http://www.doh.wa.gov/notify/forms/> .

	LHJ	LHJ Main Phone Number	LHJ Emergency After-Hours (24/7) Number	Notifiable Condition (NC) Reporting Phone Number (Business Hours) * See LHJ Main Phone Number	Notifiable Condition (NC) Reporting Emergency After-Hours (24/7) Number * See LHJ Emergency After-Hours Number
1	Adams	(509) 488-2031	(509) 488-2061	(509) 488-2031	*
2	Asotin	(509) 758-3344	(509) 552-0049	*	*
3	Benton-Franklin	(509) 460-4200	(509) 543-3851	(509) 460-4232	*
4	Chelan-Douglas	(509) 886-6400	(509) 886-6499	*	*
5	Clallam	(360) 417-2274	(360) 415-2005	(360) 417-2274	*
6	Clark	(360) 397-8000	1-888-727-6230	(360) 397-8408	*
7	Columbia	(509) 382-2181	(509) 382-2518	*	*
8	Cowlitz	(360) 414-5599	(360) 636-9595	*	*
9	Garfield	(509) 843-3412	(509) 843-3494	*	*
10	Grant	(509) 754-6060	(509) 398-2083	(509) 766-7960	*
11	Grays Harbor	(360) 532-8631	(360) 581-1401	(360) 532-8631	*
12	Island	(360) 679-7350	(360) 679-9567	(360) 679-7351	(360) 914-0840
13	Jefferson	(360) 385-9400	(360) 415-2005	*	*
14	Kitsap	(360) 337-5235	(360) 415-2005	*	*
15	Kittitas	(509) 962-7515	1-800-839-1922	*	*
16	Klickitat	(509) 773-4565	(509) 773-4547	*	*
17	Lewis	(360) 740-1223	(360) 740-1105	Immediately NC: (360) 740-1222 Other NC - 24/7 message line: (360) 740-1275	*
18	Lincoln	(509) 725-1001	(509) 725-3501	*	*
19	Mason	(360) 427-9670, x 400	(360) 427-7761	(360) 427-9670 ext 274	*
20	NE Tri Ferry Pend Oreille Stevens	(509) 684-1301 (509) 775-3111 (509) 447-3131 (509) 684-1301	(509) 775-3132 (509) 447-3151 (509) 684-2555	(509) 775-3111 (509) 447-3131 (509) 684-5048	*
21	Okanogan	(509) 422-7140	(509) 422-7232	*	(509) 422-7232
22	Pacific	(360) 875-9343	(360) 875-9397	*	*
23	Public Health Seattle-King Co	(206) 296-4600	(206) 296-4606	Immediately NC: (206) 296-4774 AIDS/HIV: (206) 296-4645 STDs: (206) 744-3954 TB: (206) 744-4579 Other NC - 24/7 message line: (206) 296-4782	(206) 726-2128
24	San Juan	(360) 378-4474	(360) 378-4151	*	*
25	Skagit	(360) 336-9380	(360) 336-3131	(360) 336-9397	(360) 336-9397
26	Skamania	(509) 427-3881	(509) 427-3850	*	*
27	Snohomish	(425) 339-5210	(425) 339-5295	(425) 339-5278 Non-urgent or STDs - 24/7 message line: (425) 339-5235	*
28	Spokane	(509) 324-1500	(509) 324-1500	(509) 324-1442	(509) 869-3133
29	Tacoma-Pierce	(253) 798-6500	1-800-726-6404	(253) 798-6410	(253) 798-6534
30	Thurston	(360) 867-2500	(360) 867-2661	(360) 867-2672 Other NC - 24/7 message line: (360) 786-5470	(360) 786-5470
31	Wahkiakum	(360) 795-6207	(360) 795-6207	*	*
32	Walla Walla	(509) 524-2650	(509) 524-2650	*	*
33	Whatcom	(360) 676-6724	(360) 715-2588	Immediately NC: (360) 676-6724 Other NC - 24/7 message line: (360) 738-2503	*
34	Whitman	(509) 397-6280	(509) 397-4341	*	*
35	Yakima	(509) 575-4040	(509) 575-4040	(509) 249-6541	*

Shipping Changes for Category A, Infectious Substances

by Chuck Talburt, DOH/PHL

Since January 1, 2011, the International Air Transport Association rules changed for laboratories shipping category A infectious substances by air. The Packing Instructions (PI) for UN2814 and UN2900 changed from 602 to 620. The PI for dry ice, UN 1845, changed from 904 to 954.

The PI for genetically modified organisms, UN3245, changed from 913 to 959. The PI for biological substances, category B, UN3373, are unchanged.

Packing Instructions are required for category A infectious substances when completing a Shipper's Declaration of Dangerous Goods form. These Packing Instructions are also required on the Shipper's Declaration of Dangerous Goods form when using dry ice as a refrigerant for category A infectious substances.

Non-compliance with these new changes may result in your package being refused for pick up. If you have any questions, please contact Chuck Talburt in our training section at (206) 418-5404 or by email at chuck.talburt@doh.wa.gov.

MTS License Renewal

**Current MTS licenses expire on
June 30, 2011**

**Renewal Notices will be
mailed in April.**

The March/April issue of Elaborations will contain more information about the renewal process and how to update information for your facility.

Calendar of Events

PHL Training Classes:

<http://www.doh.wa.gov/ehsphl/phl/training/train.htm>

Packaging and Shipping of Infectious Substances

February 10 Shoreline

Intestinal Parasitology: A Two-Day Course

February 23 & 24 Shoreline

Gram Stain Training

March 10 Shoreline

2011 ASCLS-WA Spring Meeting

April 28-30 Vancouver, WA

Northwest Medical Laboratory Symposium

October 12-15 Seattle

18th Annual Clinical Laboratory Conference

November 7 Tukwila

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.