



# PROPOSED RULE MAKING

## CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- Preproposal Statement of Inquiry was filed as WSR ; or
- Expedited Rule Making--Proposed notice was filed as WSR ; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

**Title of rule and other identifying information:** (Describe Subject)

WAC 246-338-070--Records (for Medical Test Site)--Proposed amendments to medical test site record retention requirements for blood/blood components and individual products, and updates to histopathology report record keeping requirements.

**Hearing location(s):** Department of Health  
Town Center 2 - Conference Room 158  
111 Israel Road SE  
Tumwater, WA 98501

Date: 2/26/14

Time: 10:00 a.m.

**Submit written comments to:**

Name: Susan Walker  
Address: Department of Health  
Lab Quality Assurance/Medical Test Sites  
20425 72nd Avenue S, Ste 310  
Kent, WA 98032  
e-mail: <http://www3.doh.wa.gov/policyreview/>  
fax (253)395-6365 by (date) 02/26/2014

**Assistance for persons with disabilities:** Contact

Susan Walker by 02/19/2014

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 02/28/2014

(Note: This is **NOT** the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The proposed rule amendments are in response to Centers for Medicare & Medicaid Services' (CMS) 2013 audit findings for the department's Lab Quality Assurance/Medical Test Site program. The proposed amendments comply with federal regulations 21 CFR 606.160(b)(3)(ii), (b)(3)(v), and (7)(d) regarding records retention for blood or blood components and individual product records retention. The proposed rule amendments also update histopathology report record keeping requirements per CMS' Clinical Laboratory Improvement Amendments (CLIA) guidelines. Compliance ensures the department adheres to federal standards applicable to all U.S. facilities that test human specimens for health assessment or to diagnose, prevent, or treat disease, and maintains its CLIA exempt status for another six years per Public Law 100-578.

**Reasons supporting proposal:**

To ensure quality standards for laboratory testing per 42 CFR 493.1273(d) and (e) and retain a CLIA exempt status, the department must comply with federal regulations established in 21 CFR 606.160(b)(3)(ii), (b)(3)(v), and (7)(d) regarding records retention of blood or blood components and other individual records retention. These were noted as findings from a 2013 CMS audit of the Lab Quality Assurance/Medical Test Site program and must be amended to reinstate its exempt state status. The department must also revise rules to update histopathology report record keeping per CLIA guidelines.

**Statutory authority for adoption:**

RCW 70.42.220

**Statute being implemented:**

RCW 70.42.005 and RCW 70.42.060

**Is rule necessary because of a:**

Federal Law?

Federal Court Decision?

State Court Decision?

Yes  No

Yes  No

Yes  No

If yes, CITATION:

42 CFR 493.1273(d) and (e) and 21 CFR

606.160(b)(3)(ii), (b)(3)(v), and (7)(d),

Public Law 100-578

**DATE** 01/08/2014

**NAME** (type or print)

John Wiesman, DrPH, MPH

**SIGNATURE**

, DrPH, MPH

**TITLE**

Secretary of Health

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE:** January 09, 2014

**TIME:** 2:31 PM

**WSR 14-03-050**

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

None.

**Name of proponent:** (person or organization) Department of Health

- Private
- Public
- Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Maura Craig	111 Israel Rd, SE, Tumwater, WA 98504	360.236.4997
Implementation.... Susan Walker	20425 72nd Ave S, Ste 310, Kent, WA 98032	253.395.6745
Enforcement..... Susan Walker	20425 72nd Ave S, Ste 310, Kent, WA 98032	253.395.6745

**Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?**

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iii) exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

**WAC 246-338-070 Records.** Medical test sites must maintain records as described in this section.

(1) REQUISITIONS must include the following information, in written or electronic form:

(a) Patient name, identification number, or other method of patient identification;

(b) Name and address or other suitable identifiers of the authorized person ordering the test;

(c) Date of specimen collection, and time, if appropriate;

(d) Source of specimen, if appropriate;

(e) Type of test ordered;

(f) Sex, and age or date of birth, of the patient; and

(g) For cytology and histopathology specimens:

(i) Pertinent clinical information; and

(ii) For Pap smears:

(A) Date of last menstrual period; and

(B) Indication whether the patient had a previous abnormal report, treatment, or biopsy.

(2) TEST RECORD SYSTEMS must:

(a) Consist of instrument printouts, worksheets, accession logs, corrective action logs, and other records that ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported; and

(b) Include:

(i) The patient's name or other method of specimen identification;

(ii) The date and time the specimen was received;

(iii) The reason for specimen rejection or limitation;

(iv) The date of specimen testing; and

(v) The identification of the personnel who performed the test.

(3) TEST REPORTS must:

(a) Be maintained in a manner permitting identification and reasonable accessibility;

(b) Be released only to authorized persons or designees;

(c) Include:

(i) Name and address of the medical test site, or where applicable, the name and address of each medical test site performing each test;

(ii) Patient's name and identification number, or a unique patient identifier and identification number;

(iii) Date reported;

(iv) Time reported, if appropriate;

(v) Specimen source, when appropriate, and any information regarding specimen rejection or limitation; and

(vi) Name of the test performed, test result, and units of measurement, if applicable.

(4) CYTOLOGY REPORTS must:

(a) Distinguish between unsatisfactory specimens and negative results;

(b) Provide narrative descriptions for any abnormal results, such as the 2001 Bethesda system of terminology as published in the *Journal of the American Medical Association*, 2002, Volume 287, pages 2114-2119; and

(c) Include the signature or initials of the technical supervisor, or an electronic signature authorized by the technical supervisor, for nongynecological preparations and gynecological preparations interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial neoplasia lesions including human papilloma-virus-associated changes) or malignant category.

(5) HISTOPATHOLOGY REPORTS must include the signature or initials of the technical supervisor or an electronic signature authorized by the technical supervisor on all reports. Reports must be signed by the same qualified individual who performs the diagnostic interpretation and evaluation, and must utilize appropriate terminology such as the SnoMed system.

(6) CYTOGENETICS REPORTS must:

(a) Use the International System for Human Cytogenetic Nomenclature on final reports;

(b) Include the number of cells counted and analyzed; and

(c) Include a summary and interpretation of the observations.

(7) If a specimen is referred to another laboratory for testing, the medical test site must:

(a) Report the essential elements of the referred test results without alterations that could affect the clinical interpretation of the results; and

(b) Retain or be able to produce an exact duplicate of each testing report from the referral laboratory.

(8) The medical test site must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

(9) If the medical test site ceases operation, it must make provisions to ensure that all records and, as applicable, slides, blocks and tissue are retained and available for the time frames specified in Table 070-1.

**Table 070-1 Record/Slide/Tissue Retention Schedule**

	Two Years	Five Years	Ten Years
(a) General Requirements for all Laboratory Specialties	<ul style="list-style-type: none"> <li>• Test requisitions or equivalent;</li> <li>• Test records, including instrument printouts if applicable;</li> <li>• Test reports;</li> <li>• Quality control records;</li> <li>• Quality assurance records;</li> <li>• Proficiency testing records;</li> <li>• Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and</li> <li>• Discontinued procedures for all specialty areas</li> </ul>		

	Two Years	Five Years	Ten Years
(b) Transfusion Services((*)		<ul style="list-style-type: none"> <li>• Test requisitions or equivalent;</li> <li>• Test records;</li> <li>• Test reports;</li> <li>• Quality control records; and</li> <li>• Quality assurance records</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Individual product records*</u></li> </ul>
(c) Cytology		<ul style="list-style-type: none"> <li>• All cytology slides, from date of examination of the slide</li> </ul>	<ul style="list-style-type: none"> <li>• All cytology reports</li> </ul>
(d) Histopathology/Oral Pathology	<ul style="list-style-type: none"> <li>• Specimen blocks, from date of examination</li> </ul>		<ul style="list-style-type: none"> <li>• All histopathology and oral pathology reports; and</li> <li>• Stained slides, from date of examination of the slide</li> </ul>
(e) Histopathology/Oral Pathology-Tissues	Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic examination have been examined and diagnosed		
(f) Instrument/method Validation Studies	For life of instrument/method plus two years		

\* Must be retained for no less than ((five)) ten years in accordance with 21 C.F.R. 606.160(7)(d).