



RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Department of Health

Permanent Rule Only

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

Yes No If Yes, explain:

Purpose: WAC 246-338-070--Records (for Medical Test Sites). Adopting amended rule for medical test site record retention requirements for blood/blood components and individual products, and updates to histopathology report record-keeping requirements.

Citation of existing rules affected by this order:

Repealed: None
Amended: WAC 246-338-070 Records (for Medical Test Sites)
Suspended: None

Statutory authority for adoption: RCW 70.42.220

Other authority : 42 CFR 493.1273(d) and (e) and 21 CFR 606.160(b)(3)(ii), (b)(3)(v), and (7)(d) a

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 14-03-050 on 01/09/2014 (date).

Describe any changes other than editing from proposed to adopted version: There are no changes from proposed to adopted version.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: phone
Address: fax
e-mail

Date adopted: 04/02/2014

NAME (TYPE OR PRINT)
Jessica Todorovich for John Wiesman, DrPH, MPH

SIGNATURE

for John Wiesman, DrPH, MPH

TITLE
Deputy Secretary for Secretary of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 02, 2014
TIME: 2:53 PM

WSR 14-09-001

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in the agency's own initiative:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>

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"> • Test requisitions or equivalent; • Test records, including instrument printouts if applicable; • Test reports; • Quality control records; • Quality assurance records; • Proficiency testing records; • Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and • Discontinued procedures for all specialty areas 		

	Two Years	Five Years	Ten Years
(b) Transfusion Services((*)		<ul style="list-style-type: none"> • Test requisitions or equivalent; • Test records; • Test reports; • Quality control records; and • Quality assurance records 	<ul style="list-style-type: none"> • <u>Individual product records*</u>
(c) Cytology		<ul style="list-style-type: none"> • All cytology slides, from date of examination of the slide 	<ul style="list-style-type: none"> • All cytology reports
(d) Histopathology/Oral Pathology	<ul style="list-style-type: none"> • Specimen blocks, from date of examination 		<ul style="list-style-type: none"> • All histopathology and oral pathology reports; and • Stained slides, from date of examination of the slide
(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).