

applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

X. FDA's Tentative Findings

FDA agrees with the recommendation of the Panel and believes ADCCs should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to

this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XIII. Paperwork Reduction Act of 1995

The proposed rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C 3501-3520).

XIV. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by August 7, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

XV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 am. and 4 p.m., Monday through Friday:

1. Various authors, "The White Blood Cell Differential," Parts I & II, *Blood Cells* 11:1-314, 1985.
2. Dutcher, T. F., "Leukocyte Differentials, Are They Worth The Effort?" *Clinics in Laboratory Medicine* 4 (1): 71-87, 1984.
3. Rumke, C. L., "The Statistically Expected Variability in Differential Leukocyte Counting," In: *Differential Leukocyte Counting*, edited by J. A. Koepke, College of American Pathologists, Skokie, IL, pp. 39-45, 1977.
4. Rumke, C. L., "Statistical Reflections in Finding Atypical Cells," *Blood Cells* 11: 141-144, 1985.

List of Subjects in 21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR part 864 be amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 864.5220 is revised to read as follows:

§ 864.5220 Automated differential cell counter.

(a) *Identification.* An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells."

Dated: April 28, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01-11580 Filed 5-8-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 710

[FHWA Docket No. FHWA 2001-8624]

RIN 2125-AE82

Right-of-Way and Real Estate; Program Administration

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA is proposing to amend its right-of-way regulations for federally assisted transportation projects to provide a clarification. The proposed amendment would make it clear that

Federal financial assistance, provided by the FHWA pursuant to title 23, U.S. Code, may be applied to relocation assistance benefits, provided by State and local agencies pursuant to State law, that are in addition to the relocation benefits prescribed by the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (Uniform Act).

DATES: Comments in response to this notice must be received on or before July 9, 2001.

ADDRESSES: Mail or hand deliver comments to the docket number that appears in the heading of this document to the U.S. Department of Transportation, Dockets Management Facility, Room PL-4301, 400 Seventh Street, SW., Washington, D.C. 20590, or submit electronically at <http://dmeses.dot.gov/submit>. All comments received will be available for examination and copying at the above address 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal Holidays. Those desiring notification of receipt of comments must include a pre-addressed, stamped envelope or post card or you may print the acknowledgement page that appears after submitting comments electronically.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Satorius, Office of Real Estate Services, HEPR-10, (303) 969-5772, extension 333; FHWA, 555 Zang Street, Lakewood, CO 80228, office hours are from 8 a.m. to 5 p.m., m.t., Monday through Friday, except Federal holidays; or Mr. Reid Alsop, Office of Chief Counsel, HCC-30, (202) 366-1371; FHWA, 400 Seventh Street, SW., Washington, DC 20590, office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Document Management System (DMS) at: <http://dms.dot.gov/submit>. Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may also be downloaded by using a computer, modem and suitable communications software from the

Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may also reach the Federal Register's home page at <http://www.nara.gov/fedreg> and the Government Printing Office's web page at: <http://www.access.gpo.gov/nara>.

Background

The FHWA published a final rule on Right-of-Way Program Administration on December 21, 1999 (64 FR 71284). The final rule in 23 CFR 710.203 revised the FHWA's policy on participation in costs incurred by States in the acquisition of real property for federally assisted projects, funded pursuant to title 23 U.S. Code. The reasons for this change are described in the preamble to both the final rule and the NPRM that preceded it (63 FR 71238). The final rule provides that the FHWA can participate in those acquisition costs that are required by State law, as well as in relocation assistance and payments provided pursuant to the Uniform Act to assist persons required to move by such projects.

Basically the change was based on a desire to increase State flexibility and to reduce administrative burdens. Additionally, because Federal-aid highway funds are allocated to States on the basis of a statutory formula, the FHWA participation in costs required by State law will not result in any changes in the amount of funds available to a State.

Since publication of the final rule, questions have arisen concerning the FHWA participation in relocation payments made by some States, pursuant to State law, that are beyond and in addition to those required by the Uniform Act.

The Uniform Act prescribes benefits that the State must provide as a condition of the receipt of Federal financial assistance. It provides a floor not a ceiling, and does not prevent a State, if it so chooses, from providing relocation benefits in addition to those provided by the Uniform Act. It also does not prevent a Federal agency from participating in such additional benefits if it has the programmatic authority to do so.

The FHWA believes that its participation in such relocation payments is permissible based on the broad language in § 710.203(b)(1), as well as the FHWA's general authority to participate in costs of "construction," which term is defined in 23 U.S.C. 101(a)(3) to include both costs of right-of-way acquisition and relocation assistance.

Further, since acquisition and relocation are closely linked, it would

be more equitable and consistent for the FHWA to participate in both the real property acquisition costs and the relocation assistance costs required by State law. It is also less administratively burdensome.

However, we recognize that the final rule may lack clarity as to this matter, and accordingly are proposing to amend § 710.203 (b)(2) to clearly state that financial assistance provided by the FHWA may participate in relocation assistance payments that are made by a State or local agency pursuant to State law. Such payments may include relocation payments that are in addition to those prescribed by the Uniform Act.

This proposal would also correct an inaccurate citation in § 710.409(a).

Rulemaking Analyses and Notices

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination using the docket room at the above address. The FHWA will file comments received after the comment closing date in the docket and will consider late comments to the extent practicable. The FHWA may, however, issue a final rule at any time after the close of the comment period. In addition to late comments, the FHWA will also continue to file, in the docket, relevant information becoming available after the comment closing date, and interested persons should continue to examine the docket for new material.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866, nor is it a significant regulatory policy and procedure. It is anticipated that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not required. The FHWA does not consider this action to be a significant regulatory action because this proposal would clarify existing requirements relating to FHWA reimbursement for certain expenditures that are required by State law. Rather, this action would make certain State expenditures eligible for reimbursement by the Federal government under title 23.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), the agency has evaluated the effects of this rule on small entities and determined that this action will not have a significant economic impact on a

substantial number of small entities. This action proposes to increase the flexibility provided to States on how they choose to spend their Federal-aid highway funds. For this reason, the FHWA certifies that this action would not have a significant economic impact on a substantial number of small entities.

Environmental Impact

The FHWA has also analyzed this action for the purpose of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and has determined that this action would not have any effect on the quality of the human environment.

Executive Order 13132 (Federalism)

The FHWA has analyzed this action in accordance with the principles and criteria contained in Executive Order 13132 dated August 4, 1999, and determined that this action does not have sufficient federalism implications on States that would limit the policymaking discretion of the States. Nothing in this document directly preempts any State law or regulation.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Unfunded Mandates Reform Act of 1995

This rule does not impose a Federal mandate resulting in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, or \$100 million or more in any one year. (2 U.S.C. 1531 *et seq.*)

Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. The FHWA has reviewed this proposal and determined that it does not contain additional collection of information requirements for the purposes of the PRA. The requirements to collect information relating to the current provisions of the right-of-way regulation are covered by a currently approved information collection entitled "State Right-of-Way Operations Manuals." OMB Approval No. 2125-0586, Expires

August 31, 2003. This information collection covers the burden for the States to prepare and update their right-of-way operations manuals.

Changes in this proposal would clarify the right-of-way regulations for federally assisted transportation projects and would, therefore, not affect the current information collection burden estimates.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

The FHWA has analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

This rule will not affect a taking of private or otherwise have taking implications under Executive Order 12630. Governmental Actions and Interference with Constitutionally Protected Property Rights.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 710

Grant programs-transportation, Highways and roads, Real property acquisition, Rights-of-way.

In consideration of the foregoing, the FHWA proposes to amend title 23, Code of Federal Regulations, Chapter 1, by amending Part 710 as set forth below.

Issued on: May 2, 2001.

Vincent F. Schimmoller,
Deputy Executive Director, Federal Highway Administration.

PART 710—[AMENDED]

1. The authority citation for part 710 continues to read as follows:

Authority: 23 U.S.C. 101(a), 107, 108, 111, 114, 133, 142(f), 145, 156, 204, 210, 308, 315, 317, and 323; 42 U.S.C. 2000d *et seq.*, 4633, 4651-4655; 49 CFR 1.48(b) and (cc), 18.31, and parts 21 and 24; 23 CFR 1.32.

2. Revise § 710.203(b)(2) to read as follows:

§ 710.203 Funding and reimbursement.

* * * * *

(b) * * *

(2) *Relocation assistance and payments.* Usual cost and disbursements associated with relocation assistance and payments required under 49 CFR part 24 and under the laws of the State, including payments under State law that may exceed the requirements of 49 CFR part 24.

* * * * *

§ 710.409 [Amended]

3. Amend § 710.409(a) by revising the reference "§ 710.403(c)" to read "§ 710.403(d)."

[FR Doc. 01-11710 Filed 5-8-01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01-01-038]

RIN 2115-AE47

Drawbridge Operation Regulations; West Bay, MA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the drawbridge operating regulations for the West Bay Bridge, at mile 1.2, across West Bay in Osterville, Massachusetts. This proposed rule would allow the bridge owner to increase the advance notice requirement for April and extend the evening operating hours at the bridge during the boating season. This action is expected to better meet the present needs of navigation.

DATES: Comments must reach the Coast Guard on or before July 9, 2001.

ADDRESSES: You may mail comments to Commander (obr), First Coast Guard