

charts issued by the Federal Aviation Administration (FAA).”

■ 3. Amend § 301–10.306 by revising the section heading to read as follows:

**§ 301–10.306 What will I be reimbursed if authorized to use a POV instead of a taxi between my residence and office to a common carrier terminal, or from my residence directly to a common carrier terminal on travel requiring an overnight stay?**

**§ 301–10.310 [Amended]**

■ 4. Amend § 301–10.310 in paragraph (a) by removing “vehicle” and “27.0 cents” and adding “automobile” and “28.5 cents” in its place, respectively; and by removing from paragraph (b) “10.5 cents” and adding “12.5 cents” in its place.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### 42 CFR Part 73

#### Possession, Use, and Transfer of Select Agents and Toxins— Reconstructed Replication Competent Forms of the 1918 Pandemic Influenza Virus Containing Any Portion of the Coding Regions of All Eight Gene Segments

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Interim final rule.

**SUMMARY:** We are adding reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the list of HHS select agents and toxins. We are taking this action for several reasons. First the pandemic influenza virus of 1918–19 killed up to 50 million people worldwide, including an estimated 675,000 deaths in the United States. Also, the complete coding sequence for the 1918 pandemic influenza A H1N1 virus was recently identified, which will make it possible for those with knowledge of reverse genetics to reconstruct this virus. In addition, the first published study on a reconstructed 1918 pandemic influenza virus demonstrated the high virulence of this virus in cell culture, embryonated eggs, and in mice relative to other human influenza viruses. Therefore, we have determined that the reconstructed

replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments have the potential to pose a severe threat to public health and safety.

**DATES:** The interim final rule is effective on October 20, 2005. Written comments must be submitted on or before December 19, 2005.

**ADDRESSES:** Comments on the change to the list of HHS select agents and toxins should be marked “Comments on the reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments” and mailed to: Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Rd., MS E–79, Atlanta, GA 30333. Comments may be e-mailed to: [SAPcomments@cdc.gov](mailto:SAPcomments@cdc.gov).

#### FOR FURTHER INFORMATION CONTACT:

Mark Hemphill, Chief of Policy, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Rd., MS E–79, Atlanta, GA 30333. Telephone: (404) 498–2255.

**SUPPLEMENTARY INFORMATION:** The complete coding sequence for the 1918 pandemic influenza A H1N1 virus has been recently identified (Taubenberger *et al.*, 2005, *Nature*, vol. 437, pp. 889–893). Scientists from the Centers for Disease Control and Prevention together with collaborators at Mount Sinai School of Medicine, NY, Armed Forces Institute of Pathology, MD, and Southeast Poultry Research Laboratory, U.S. Department of Agriculture, GA, reconstructed the 1918 pandemic influenza virus by using reverse genetics to study the properties associated with its extraordinary virulence (Tumpey *et al.*, Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus, *Science* 2005 310: 77–80). With the publication of the complete coding sequence, it will be possible for other scientists with knowledge of reverse genetics technology to reconstruct the 1918 pandemic influenza virus at other institutions.

The pandemic influenza virus of 1918–19 killed up to 50 million people worldwide, including an estimated 675,000 deaths in the United States. The 1918 pandemic influenza virus’ (H1N1) most striking feature was the unusually high death rate among healthy adults aged 15 to 34 years. The question of whether the reconstructed 1918 pandemic influenza virus should be regulated as a select agent was considered by the Intragovernmental

Select Agents and Toxins Technical Advisory Committee (ISATTAC). The criteria used by the ISATTAC for reviewing the reconstructed 1918 pandemic influenza virus for inclusion on the select agent list were: degree of pathogenicity, communicability, ease of dissemination, route of exposure, environmental stability, ease of production, ability to genetically manipulate or alter, long-term health effects, acute morbidity, acute mortality, available treatment, status of immunity, vulnerability of special populations, and the burden or impact on the health care system. Based on these criteria, the ISATTAC determined that the reconstructed 1918 pandemic influenza virus could pose an immediate severe threat to public health and safety if it is not safely and securely maintained. Further, the ISATTAC noted that the biological and molecular properties that enabled the 1918 pandemic influenza virus to cause such widespread illness and death are not completely understood and that it is not known how virulent the reconstructed virus would be in the population today. In making its determination, the ISATTAC considered both the historical data regarding the original 1918 pandemic influenza virus and data from current in vitro and in vivo animal studies. The apparent virulence of this virus, together with the fact that the level of immunity in the general population and the ability of the virus to readily transmit among persons are unknown at this time, makes it prudent to immediately regulate this virus as a select agent. Although studies with this virus can lead to significant public health benefits for understanding pandemic influenza, improved diagnostics, and the development of more effective countermeasures, there are also potential risks of the misuse of this agent for purposes of bioterrorism as well as accidental release. Thus, if misused, the 1918 pandemic influenza virus may pose a biological threat to public health and/or national security.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires the regulation of each biological agent that has the potential to pose a severe threat to public health and safety. Congress recognized that a delay in the regulation of such biological agents was contrary to the public interest by requiring in the Bioterrorism Act that the initial Select Agent regulations be promulgated as an interim final rule. Therefore, the Secretary has determined that prior notice and opportunity for public

comment are contrary to the public interest and there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments that will be made to the rule as a result of the comments. In addition to seeking comments on the addition of this agent to the HHS list of select agents and toxins, we are also seeking comments on the regulation of reconstructed viruses that contain less than all eight gene segments from the 1918 pandemic influenza virus and if there are certain experiments with such constructs or with the fully reconstructed 1918 pandemic influenza virus that should be added to the "Restricted experiments" provisions of the regulation.

An entity must apply to the CDC Division of Select Agents and Toxins to possess, use, or transfer reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments. The CDC Division of Select Agents and Toxins will review the entity's biosafety plan to ensure that it provides a comprehensive risk assessment of the proposed research and adequately ensures appropriate biosafety measures. The CDC Division of Select Agents and Toxins will conduct a biosafety review of proposed experiments with the reconstructed 1918 pandemic influenza virus on a case-by-case basis. The "Interim CDC-NIH Recommendation for Raising the Biosafety Level for Laboratory Work Involving Noncontemporary Human Influenza Viruses" excerpted from the draft CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th edition will be used as the minimum containment for such experiments. However, in some cases supplemental biosafety measures may be deemed appropriate after review of the proposed experiments.

The case-by-case review by CDC's Division of Select Agents and Toxins will continue until further data are available that may result in changes to biosafety guidelines for work with the reconstructed 1918 pandemic influenza virus. Until such revised guidelines are available, entities should refer to the "Interim CDC-NIH Recommendation for Raising the Biosafety Level for Laboratory Work Involving Noncontemporary Human Influenza

Viruses." In accordance with these interim guidelines, work with such viruses should proceed with extreme caution and the viruses should be handled, at a minimum, under high-containment (Biosafety Level 3-enhanced) laboratory conditions. Enhancements should include the use of powered air purifying respirators, change-of-clothing and shower-out requirements, use of HEPA filtration for treatment of exhaust air, and a stringent medical surveillance and response plan. In addition to these currently published interim guidelines, annual vaccination with the currently licensed influenza vaccine is strongly recommended and antiviral prophylaxis should be available for individuals working with reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

The addition of the 1918 pandemic influenza virus to the HHS select agents and toxins list is effective immediately. Entities that intend to possess, use, or transfer this agent will be required to either register in accordance with 42 CFR part 73, or amend their current registration in accordance with § 73.7(h).

#### **Paperwork Reduction Act**

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this interim final rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0920-0576.

Please send written comments on the new information collection contained in this interim final rule to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333. Copies of this information collection may be obtained from Seleda Perryman, CDC Assistant Reports Clearance Officer, at (404) 639-4794 or via e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

We expect that the entities who will register for possession, use, or transfer of reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments will already be registered with the Select Agent Program. This interim final rule will require such an entity to amend its registration with the Select Agent Program using relevant portions of APHIS/CDC Form 1 (Application for Laboratory Registration for Possessing, Use, and Transfer of Select Agents and

Toxins). Estimated time to amend this form is 45 minutes for one select agent. Additionally, any registered entity that wishes to transfer reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments will be required to submit information using APHIS/CDC Form 2 (Report of Transfer of Select Agent and Toxins). Estimated average time to complete this form is 1 hour, 30 minutes. We estimate that only one to five registered entities may add or transfer reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to their registration. Therefore, we calculate that there is no increase in the number of respondents, the total number of responses may increase by 9, and the total burden hours may increase to 9 hours and 45 minutes.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This interim final rule has been determined to be significant for the purposes of Executive Order 12866 and has been reviewed by the Office of Management and Budget.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

#### **Unfunded Mandates**

The Unfunded Mandates Reform Act at 2 U.S.C. 1532 requires that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any given year. This interim final rule is not expected to result in any one-year expenditure that would exceed \$100 million.

#### **Executive Order 12988**

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Would preempt all State and local laws and regulations that are inconsistent with this rule; (2) would have no retroactive effect; and (3) would not require administrative proceedings before parties may file suit in court challenging this rule.

**Executive Order 13132**

This rule has been reviewed under Executive Order 13132, Federalism. This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

**List of Subjects in 42 CFR Part 73**

Biologics, Incorporation by reference, Packaging and containers, Penalties, Reporting and Recordkeeping requirements, Transportation.

Dated: October 7, 2005.

**Michael O. Leavitt,**  
Secretary.

■ For the reasons stated in the preamble, we are amending 42 CFR part 73 as follows:

**PART 73—SELECT AGENTS AND TOXINS**

■ 1. The authority citation for part 73 continues to read as follows:

**Authority:** 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law No. 107–188, 116 Stat. 637 (42 U.S.C. 262a).

■ 2. Amend paragraph (b) of § 73.3 by adding the following entry in alphabetical order to read as follows:

**§ 73.3 HHS select agents and toxins.**

\* \* \* \* \*

(b) \* \* \*

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

\* \* \* \* \*

[FR Doc. 05–20946 Filed 10–17–05; 12:02 pm]

BILLING CODE 4160–17–P

**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Parts 1, 22, 24, 27 and 90**

[WT Docket No. 03–264; FCC 05–144]

**Amendment of Various Rules Affecting Wireless Radio Services**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Federal Communications Commission (“Commission”) streamlines and harmonizes licensing provisions in the wireless radio services (WRS) that were identified in part during the Commission’s 2000 and 2002 biennial regulatory reviews. The Commission concludes that streamlining and harmonizing these rules will clarify spectrum rights and obligations for affected licensees and support recent efforts to maximize the public benefits derived from the use of the radio spectrum. Among other matters, the Commission retains the references to ERP and EIRP in its rules, eliminates the transmitter-specific posting requirement of part 22 licensees, conforms the Emission Mask G to a modulation-independent mask that places no limitation on the spectral power density profile within the maximum authorized bandwidth, eliminates a rule which required the filing of certain outdated supplemental information, and eliminates certain transmitter output power limits rules. Further, in this document, the Commission eliminates many filing and data reporting requirements, some output power limits, and seeks comment on whether the Commission should increase other power limits.

**DATES:** Effective December 19, 2005.

**FOR FURTHER INFORMATION CONTACT:** Wilbert E. Nixon, Jr. and/or B.C. “Jay” Jackson, Jr. of the Mobility Division, Wireless Telecommunications Bureau, at 202–418–0620 or via e-mail at [Wilbert.Nixon@fcc.gov](mailto:Wilbert.Nixon@fcc.gov) and/or [Jay.Jackson@fcc.gov](mailto:Jay.Jackson@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Report and Order portion (*Report and Order*) of the Commission’s *Report and Order and Further Notice of Proposed Rulemaking*, FCC 05–144, in WT Docket Nos. 03–264, adopted July 22, 2005, and released August 9, 2005. The Further Notice of Proposed Rulemaking portion (*FNPRM*) of the document is summarized elsewhere in this publication. The full text of the document is available for public inspection and copying during regular business hours at the FCC Reference Information Center, 445 12th St., SW., Room CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission’s duplicating contractor: Best Copy & Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 800–378–3160, facsimile 202–488–5563, or via e-mail at [fcc@bcpiweb.com](mailto:fcc@bcpiweb.com). The full text may also be downloaded at: <http://www.fcc.gov>. Alternative formats are available to

persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365 or at [Brian.Millin@fcc.gov](mailto:Brian.Millin@fcc.gov).

**Paperwork Reduction Act of 1995 Analysis**

This document contains modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public to comment on the information collection requirements contained in this R&O as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due December 19, 2005. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

**Synopsis of the Report and Order****I. Introduction**

1. On January 7, 2004, the Commission released a *Notice of Proposed Rulemaking*, (*NPRM*) published at 69 FR 8132, February 23, 2004, which commenced a proceeding to streamline and harmonize licensing provisions in the wireless radio services (WRS) that were identified in part during the Commission’s 2000 and 2002 biennial regulatory reviews pursuant to section 11 of the Communications Act of 1934, as amended (“Communications Act” or “Act”) (47 U.S.C. 161). The Commission proposed various amendments to parts 1, 22, 24, 27, and 90 of the rules to modify or eliminate provisions that treat licensees differently and/or have become outdated as a result of technological change, supervening changes to related Commission rules, and/or increased competition within WRS. We believe streamlining and harmonizing these rules will clarify spectrum rights and obligations and optimize flexibility for WRS licensees, fulfill our mandate under Section 11 of the Communications Act, and support efforts to maximize the public benefits derived from the use of the radio spectrum. Accordingly, in this *Report and Order*, we:

- Modify our rules to classify a deletion of a frequency and/or transmitter site from a multi-site authorization under part 90 as a minor modification.