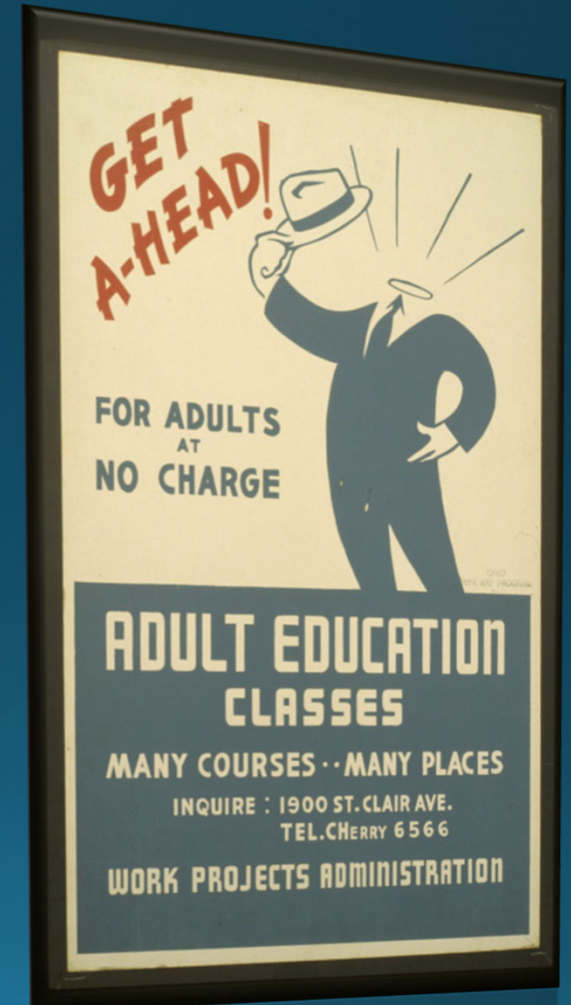
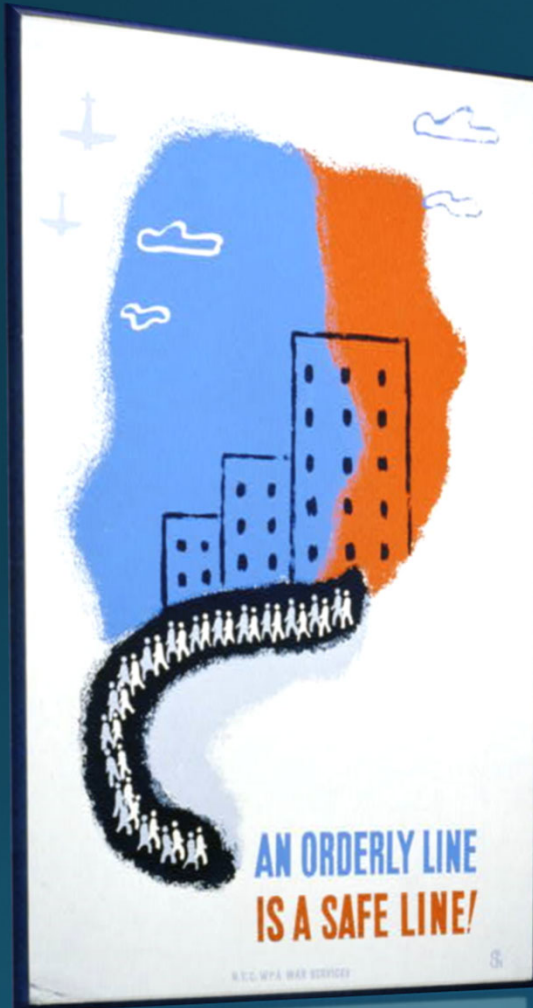


Federal Administrative Law



Posters from the WPA 1936-43

The Federal Process

retary of the Interior. The Secretary of the Interior shall make and publish such general rules and regulations as he may deem necessary and proper for the management and care of the park

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter,

On December 16, 2003, the Center for Science in the Public Interest (CSPI), the National Consumers League (NCL), 67 other organizations, and eight individuals, including four deans of schools of public health, petitioned TTB to change the alcohol beverage labeling regulations. Hereinafter, we refer to this

The regulatory repeal proposed in this rulemaking eliminates outdated regulations and makes technical amendments to reflect Congress' reauthorization of the Institute of Museum and Library Services under The Museum and Library Services Act of 2003, Public Law 108-81 (September 25, 2003). These changes

OIRA & Unified Agenda

- Office of Information and Regulatory Affairs is a key AND controversial player in the rulemaking process -major mechanism for Presidential control.
- OMB tracks rules inside the separate rulemaking agencies in semi- annual Unified Agenda.
 - Executive Order 12,866 as modified is key order governing process.

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OFFICE of INFORMATION and REGULATORY AFFAIRS
OFFICE of MANAGEMENT and BUDGET
EXECUTIVE OFFICE of the PRESIDENT

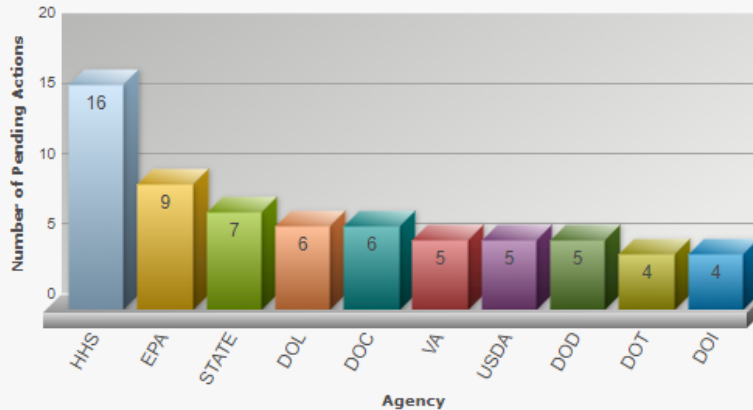
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U.S. General Services Administration **GSA**

Search: Agenda Reg Review ICR

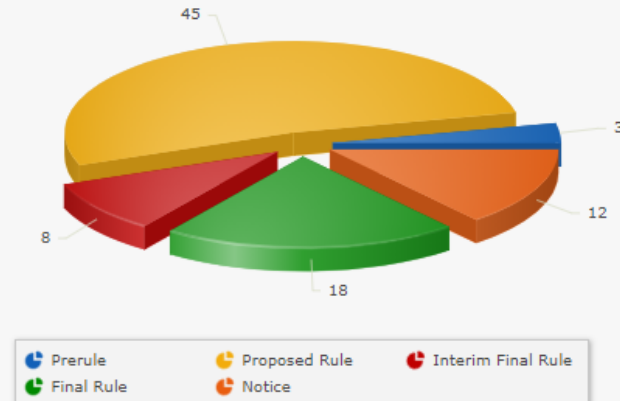
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AGENCIES WITH THE MOST REGULATORY ACTIONS CURRENTLY UNDER REVIEW



Total Pending Actions: 86

Pending Actions By Rule Stage



View

REGULATORY REVIEW

[Executive Order 12866](#) directs agencies to follow certain principles in rulemaking, such as consideration of alternatives and analysis of benefits and costs, and describes OIRA's role in the rulemaking process.

- [Regulations under EO 12866 Review](#)
- [Regulatory Reviews Completed in Last 30 Days](#)

[More about Regulatory Review >>](#)

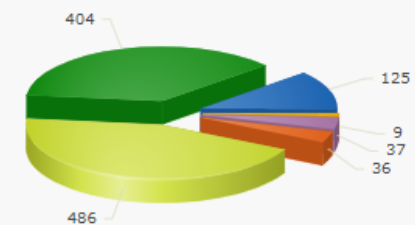
UNIFIED AGENDA and REGULATORY PLAN

The Unified Agenda and Regulatory Plan provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal government, covering over 60 departments, agencies, and commissions.

- [The 2021 Spring Agenda was published on 6/11/2021](#)

[More about Agenda >>](#)

ICR DASHBOARD INFORMATION COLLECTIONS REVIEW PENDING BY TYPE



Unified Agenda

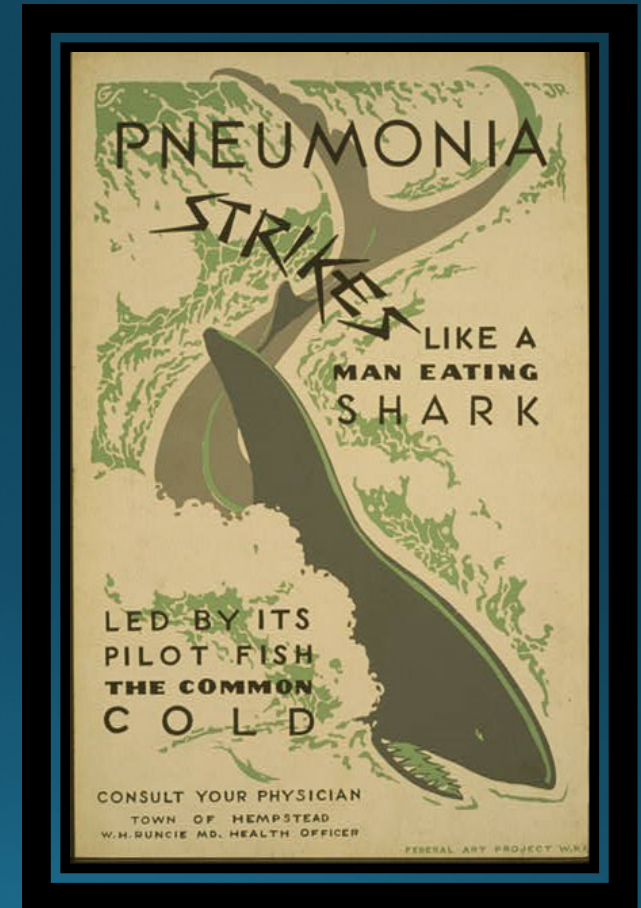
Agency Rule List - Spring 2021

Department of Health and Human Services

| Agency | Agenda Stage of Rulemaking | Title | RIN |
|----------|----------------------------|---|---------------------------|
| HHS/HRSA | Final Rule Stage | Countermeasures Injury Compensation Program; Smallpox Countermeasures Injury Table | 0906-AB22 |
| HHS/HRSA | Final Rule Stage | National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table | 0906-AB27 |
| HHS/FDA | Proposed Rule Stage | Food Standards: General Principles and Food Standards Modernization | 0910-AC54 |
| HHS/FDA | Proposed Rule Stage | Investigational New Drug Applications; Exemptions for Clinical Investigations to Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement, or Cosmetic | 0910-AH07 |
| HHS/FDA | Proposed Rule Stage | National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers | 0910-AH11 |
| HHS/FDA | Proposed Rule Stage | Post Approval Changes to Approved Applications | 0910-AH55 |
| HHS/FDA | Proposed Rule Stage | Certain Requirements Regarding Prescription Drug Marketing (203 Amendment) | 0910-AH56 |
| HHS/FDA | Proposed Rule Stage | Current Good Manufacturing Practice for Positron Emission Tomography Drugs | 0910-AH58 |
| HHS/FDA | Proposed Rule Stage | Nonprescription Drug Product With an Additional Condition for Nonprescription Use | 0910-AH62 |
| HHS/FDA | Proposed Rule Stage | Medication Guide; Patient Medication Information | 0910-AH68 |
| HHS/FDA | Proposed Rule Stage | Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food | 0910-AH77 |
| HHS/FDA | Proposed Rule Stage | Amendments to Registration of Food Facilities | 0910-AH82 |
| HHS/FDA | Proposed Rule Stage | Requirements for Tobacco Product Manufacturing Practice | 0910-AH91 |
| HHS/FDA | Proposed Rule Stage | Updated Regulations for Medical Gases | 0910-AH96 |
| HHS/FDA | Proposed Rule Stage | Harmonizing and Modernizing Regulation of Medical Device Quality Systems | 0910-AH99 |
| HHS/FDA | Proposed Rule Stage | Food Additives: Food Contact Substance Notification That Is No Longer Effective | 0910-AI01 |
| HHS/FDA | Proposed Rule Stage | Administrative Detention of Tobacco Products | 0910-AI05 |
| HHS/FDA | Proposed Rule Stage | Part 50 Protection of Human Subjects and Part 56 Institutional Review Boards | 0910-AI07 |
| HHS/FDA | Proposed Rule Stage | Institutional Review Boards; Cooperative Research | 0910-AI08 |
| HHS/FDA | Proposed Rule Stage | Medical Devices; Immunology and Microbiology Devices; Classification of Human Leukocyte, Neutrophil and Platelet Antigen or Antibody Tests | 0910-AI12 |
| HHS/FDA | Proposed Rule Stage | Nutrient Content Claims, Definition of Term: Healthy | 0910-AI13 |

The Federal Process

Continues with notices and proposed rules which appear in the Federal Register first...



Federal Register




- Created in 1935 by the Federal Register Act
- Response to *Panama Refining Co v. Ryan*, 293 U.S. 388 (1935)

"Whatever the cause of the failure to give appropriate public notice of the change in the section, with the result that the persons affected, the prosecuting authorities, and the courts, were alike ignorant of the alteration, the fact is that the attack in this respect was upon a provision which did not exist."

Federal Register

- Published daily except legal holidays and weekends
- Contains information supplied by the agencies



FEDERAL REGISTER

Vol. 86 Thursday
No. 182 September 23, 2021

Pages 52821–52950

OFFICE OF THE FEDERAL REGISTER

Federal Register / Vol. 86, No. 182 / Thursday, September 23, 2021 / Rules and Regulations 52837

(2) Calculate \bar{K} as the average of the two values of K at each tested speed ratio. Express \bar{K} to two decimal places; express \bar{v} to one decimal place; express \bar{v}^3 to two decimal places.

(3) The following example illustrates a calculation of:

$$\bar{K}_{v=0.1} = \frac{1000.0}{\sqrt{150.8}} = 81.43 \text{ r}(\text{min} \cdot (\text{N} \cdot \text{m})^{\frac{1}{2}})$$

$$\bar{v}_{\text{pmv}=0.2} = 150.4 \text{ N} \cdot \text{m}$$

$$\bar{K}_{v=0.2} = \frac{1000.0}{\sqrt{150.4}} = 81.54 \text{ r}(\text{min} \cdot (\text{N} \cdot \text{m})^{\frac{1}{2}})$$

$$\bar{K}_{\text{avg}} = \frac{81.43 + 81.54}{2} = 81.49 \text{ r}(\text{min} \cdot (\text{N} \cdot \text{m})^{\frac{1}{2}})$$

(4) Calculate $I_{\text{pmv}=0.1} = I_{\text{pmv}=0.2} = 1000.0 \text{ r/min}$
 $T_{\text{pmv}=0.1} = 150.8 \text{ N} \cdot \text{m}$

(g) Create a table of GEM inputs showing and at each tested speed ratio, v . Express \bar{v} to two decimal places; express \bar{v}^3 to one decimal place; express \bar{v}^3 to two decimal places. (FR Doc. 01-2021-0538 Filed 9-22-21; 8:41 am) BILLING CODE 8999-10-0

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52
(EPA-903-OAR-2020-0487; FRL-8931-02-93)

Air Plan Approval; West Virginia: 2020 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the State of West Virginia. This revision updates West Virginia's incorporation by reference of EPA's national ambient air quality standards (NAAQS) and the associated monitoring reference and equivalent methods. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before October 25, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-903-OAR-2020-0487. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Serena Nichols, Planning & Implementation Branch (AID-109), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103. The telephone number is (215) 814-2953. Ms. Nichols can also be reached via electronic mail at Nichols.Serena@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On February 9, 2021 (86 FR 4727), EPA published a notice of proposed rulemaking (NPRM) for the State of West Virginia. In the NPRM, EPA proposed approval of a formal SIP revision submitted on June 3, 2020. This formal SIP revision updates West Virginia's incorporation by reference of EPA's NAAQS and the associated monitoring reference and equivalent methods.

II. Summary of SIP Revision and EPA Analysis

West Virginia Department of Environmental Protection (WVDEP) has historically chosen to incorporate by reference the Federal NAAQS, found at 40 CFR part 50, and the associated Federal ambient air monitoring reference methods and equivalent methods for these NAAQS found at 40

CFR part 53. When incorporating by reference these Federal regulations, WVDEP has specified that it is incorporating by reference these regulations as they existed on a certain date. The incorporation by reference of the NAAQS that is currently approved in the West Virginia SIP incorporates by reference 40 CFR parts 50 and 53 as they existed on June 1, 2018. West Virginia's June 3, 2020 SIP revision updates the State's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods, found in 40 CFR parts 50 and 53, respectively, as of June 1, 2018. Since the last West Virginia incorporation by reference of June 1, 2018, EPA: (1) Reviewed the primary NAAQS for sulfur oxides (SO_x), as required by CAA section 109(e), and retained the current 1-hour and annual sulfur dioxide (SO₂) NAAQS without revision; (2) designated one new equivalent method for measuring concentrations of ozone in the ambient air; (3) designated one new reference method for measuring concentrations of nitrogen dioxide in ambient air; and (4) designated one new reference method for measuring concentrations of carbon monoxide in ambient air. See 84 FR 2666 (March 18, 2019), 84 FR 11973 (March 25, 2019), 84 FR 30633 (September 28, 2019), and 84 FR 24508 (May 28, 2019).

The amendments to the legislative rule include changes to the section 45-6-1 (General) and 45-6-3 (Adoption of Standards). The amendments update West Virginia's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods from June 1, 2018 to June 1, 2019. West Virginia is incorporating the Federal

Federal Register Components

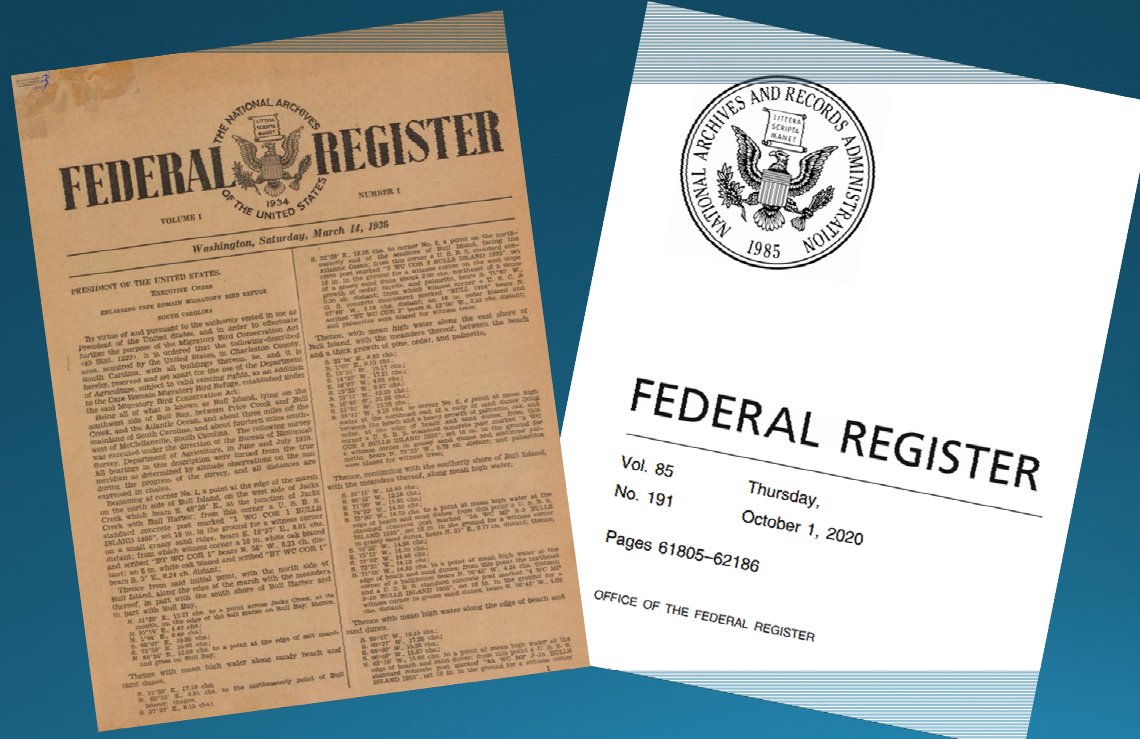
- Proposed Rules, Amendments to Existing Rules and Repeals
- Final Rules
- Presidential Documents, like Executive Orders
- Notices of other Agency Actions
- Statements of Agency Policy – few
- Some Guidance Memoranda

FEDERAL REGISTER

The Daily Journal of the United States Government

Finding the Federal Register

- HeinOnline, Lexis, and Westlaw, and Government have complete Register coverage back to 1936.



Proposed Rules

- Notice of Proposed Rulemaking [NPRM] contains text of proposed rule and preamble explaining basis and purpose for the regulation.
- NPRM asks the public for comments on the proposal, normally within 60 days.

ACTION: Proposed rule.

Rule (Final Rule)

- Agency next reviews comments and promulgates the final rule.
- Preamble addresses major comments and other rulemaking requirements.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[CC Docket No. 02–6; DA 20–1091; FRS 17084]

Schools and Libraries Universal Service Support Mechanism

AGENCY: Federal Communications Commission.

ACTION: Final rule.

I. Introduction

1. Schools across the United States continue to face unprecedented disruptions and challenges due to the coronavirus (COVID–19) pandemic. As the school year begins, many school districts are relying on remote learning, either in whole or in part, to educate students. This heightened reliance on remote learning has dramatically increased demand on school networks, creating an urgent need for additional bandwidth this school year.

2. Consistent with the relief the Federal Communications Commission (Commission) has previously provided to schools affected by natural disasters as well as recent actions the Commission has taken in response to the COVID–19 pandemic, the Bureau adopts, on an emergency basis, temporary rules to provide immediate relief to schools that participate in the E-Rate program as they continue to contend with the ongoing disruptions caused by the pandemic. These temporary rules make available additional E-Rate funding to schools in funding year 2020 to purchase additional bandwidth needed to meet the unanticipated and increased demand for on-campus connectivity resulting from the pandemic.

Proposed Regulations

- Online Rulemaking Advantages
 - See other comments/agency materials
 - Explain rulemaking in more detail
 - Broaden participation
- Some agencies better than others



The Research Process

Begins with the Code of Federal Regulations...

What does it mean
when something is
codified?



CODE OF FEDERAL
REGULATIONS

24

Parts 700 to 1699
Revised as of April 1, 2018

Housing and
Urban Development

Code of Federal Regulations

- First published in 1938 and contained the regulations in force as of June 1, 1938.
- This was the first compilation of regulations.
- Published annually in four parts (updated more frequently online).

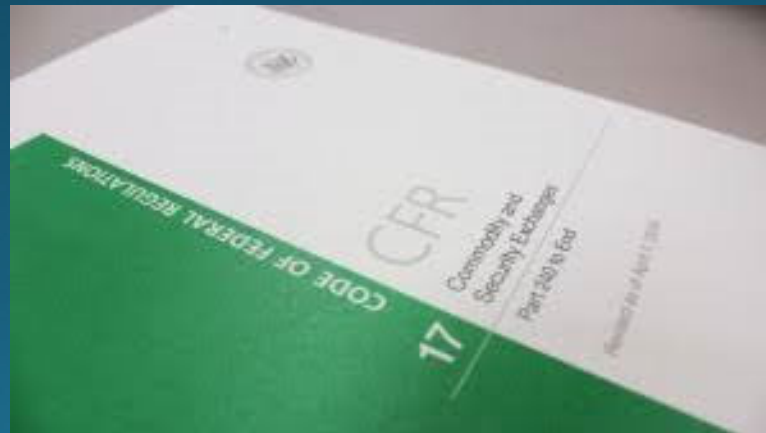


**CODE OF FEDERAL
REGULATIONS**

Code of Federal Regulations

9 C.F.R. Part 78

9 C.F.R. § 78.41



Finding the CFR



GPO publishes the set in print and in 2 electronic formats.



First online version is mirror of print set.



GPO's [e-CFR](#) updates the Code more quickly - within 2 or 3 days.



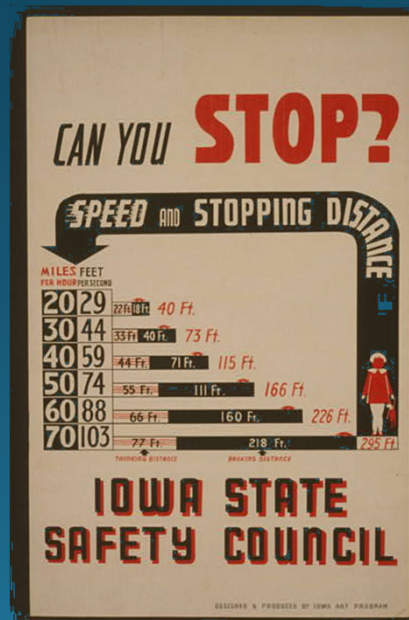
Complete CFR in Hein goes back to beginning in 1938.



CFR in Lexis and in Westlaw goes back to the early 80s.

Administrative Materials

- Use the C.F.R. Index.
- From Tables by Statute
- Notes in annotated statutes



CFR: Authorizing Statutes

Title 38: Pensions, Bonuses, and Veterans' Relief

PART 21—VOCATIONAL REHABILITATION AND EDUCATION

Subpart A—Vocational Rehabilitation and Employment Under 38 U.S.C. Chapter 31

§21.1 Training and rehabilitation for veterans with service-connected disabilities.

(a) *Purposes.* The purposes of this program are to provide to eligible veterans with compensable service-connected disabilities all services and assistance necessary to enable them to achieve maximum independence in daily living and, to the maximum extent feasible, to become employable and to obtain and maintain suitable employment.

(Authority: 38 U.S.C. 3100)

38 C.F.R. § 21.1

§ 21.1 Training and rehabilitation for veterans with service-connected disabilities.

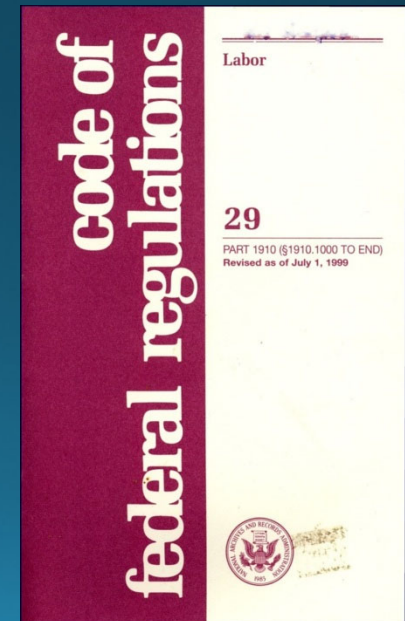
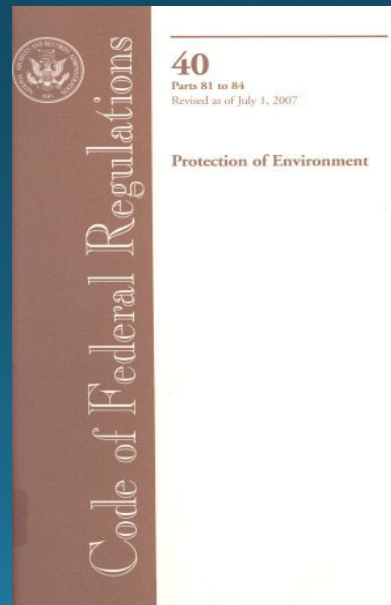
Currentness

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(Authority: 38 U.S.C. 3100)

How to update

- Start with the C.F.R.
- Check the Federal Register, or parts affected
- Federal Register for explanations



Finding Related Cases

- “Annotated” regulations, like annotated statutes
- Citator
 - Shepard’s Code of Federal Regulations Citations
 - KeyCite

← § 251.56 Terms and conditions. 🔍

Code of Federal Regulations · Title 36. Parks, Forests, and Public Property (Approx. 9 pages)

Document

Notes of Decisions (39)

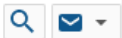
History (3) ▾

Citing References (238) ▾

Context & Analysis (20) ▾

Notes of Decisions (39)

Sort: Procedural Order ▾



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Select multiple

Date +

Jurisdiction +

Key Number +

Table of Contents Hide

1. Constitutional issues

2. Limitation of actions

3. Exhaustion of administrative remedies

4. Water rights

5. Landowners' access rights

6. Commercial uses

7. Campfires

Select all · No items selected

1. Constitutional issues

Regulation that allowed Forest Service officer issuing special-use permit to large noncommercial group to attach “[s]uch terms and conditions as ... officer deems necessary to ... otherwise protect the public interest” was not facially overbroad and thus comported with First Amendment; regulation did not confer substantial power to discriminate based on content or viewpoint, given consistent Forest Service interpretation that “public interest” referred only to public health and safety, preservation of National Forest lands and space allocation, not discrimination with regard to expressive conduct. [U.S.C.A. Const.Amend. 1](#); [16 U.S.C.A. § 551](#); [36 C.F.R. § 261.10\(k\)](#); [36 C.F.R. § 251.56\(a\)\(2\)\(vii\) \(1997\)](#). [U.S. v. Nenner, C.A.8 \(Mo.\)2003, 351 F.3d 340](#), rehearing and rehearing en banc denied. Constitutional Law 🏹 1761; Woods And Forests 🏹 8

Regulation requirement that a special use permit be obtained for noncommercial group use or occupancy of National Forest land by groups of 75 or more persons was not unconstitutionally overbroad on its face under the First Amendment in authorizing the Forest Service to attach terms and conditions to the grant of a permit “to protect the public interest,” and in any event, the regulation, as interpreted by the National Forest Service, specifically limits the discretion of the Forest Service to impose conditions directed at curtailing or censoring expression. [U.S.C.A. Const.Amend. 1](#); [36 C.F.R. § 251.56](#). [U.S. v. Kalb, C.A.3 \(Pa.\)2000, 234 F.3d 827](#), certiorari denied 122 S.Ct. 918, 534 U.S. 1113, 151 L.Ed.2d 884. Constitutional Law 🏹 1761; Woods And Forests 🏹 8

Notes

[EFFECTIVE DATE NOTE:

85 FR 41387, 41393, July 10, 2020, added paragraph (h), effective Aug. 10, 2020; as corrected at 85 FR 48475, Aug. 11, 2020, effective Aug. 10, 2020.]

Notes to Decisions

- [Administrative Law: Agency Rulemaking: Rule Application & Interpretation: General Overview](#)
- [Civil Procedure: Federal & State Interrelationships: Federal Common Law: General Overview](#)
- [Constitutional Law: Bill of Rights: Fundamental Freedoms: Judicial & Legislative Restraints: Prior Restraint](#)
- [Constitutional Law: Equal Protection: Parentage](#)
- [Environmental Law: Natural Resources & Public Lands: Forest Management](#)
- [Environmental Law: Water Quality: Clean Water Act: Water Quality Standards](#)
- [Environmental Law: Zoning & Land Use: Judicial Review](#)
- [Governments: Federal Government: Property](#)
- [Governments: Legislation: Overbreadth](#)
- [Governments: Public Lands: Forest Lands](#)
- [Real Property Law: Zoning & Land Use: Special Permits & Variances](#)

Administrative Law: Agency Rulemaking: Rule Application & Interpretation: General Overview

[United States v. Linick](#), 195 F.3d 538, 99 Cal. Daily Op. Service 8947, 99 D.A.R. 11405, 30 Env'tl. L. Rep. 20176, 1999 U.S. App. LEXIS 29343 (9th Cir. 1999).

Overview: Dismissal affirmed of information filed against permitless noncommercial group users of national forest land. Regulation's language unconstitutionally overbroad as letting government attach any terms and conditions to permit.

- The fact that 36 C.F.R. § 251.56(a)(2)(vii) is facially invalid does not end the inquiry. In evaluating the constitutionality of a regulatory scheme, courts should presume any narrowing construction to which the law is fairly susceptible. In particular, administrative interpretation of a regulation is highly relevant to the analysis. When an administrative agency offers a narrowing construction to a facially overbroad regulation, the narrowing construction can render constitutional an otherwise unconstitutional regulation because the construction can constrain the ability of officials to enforce the regulation in an illegitimate manner. [Go To Headnote](#)

[Anderson v. Eby](#), 83 F.3d 342, 1996 U.S. App. LEXIS 10463 (10th Cir. 1996).

Overview: A release from liability that the customer signed in favor of the tour operator was valid and was not rendered void by a permit that the tour operator had with the federal government that charged it with responsibility for customer safety.

- 36 C.F.R. § 251.56(a)(2)(iv) (1994) provides that each special use authorization shall contain such terms and conditions as the authorized officer deems necessary to protect lives and property. [Go To Headnote](#)

Top of Document



Statutory Authority

History

Annotations

Notes