



4312-52

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 1

[NPS-WASO-REGS-17326; GPO Deposit Account 4311H2]

RIN 1024-AE30

General Provisions; Electronic Cigarettes

AGENCY: National Park Service; Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service proposes to revise the regulation that defines smoking to include the use of electronic cigarettes and other electronic nicotine delivery systems. The National Park Service also proposes to allow a superintendent to close an area, building, structure, or facility to smoking when necessary to maintain public health and safety.

DATES: Comments must be received by 11:59 pm EST on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit your comments, identified by Regulation Identifier Number (RIN) 1024-AE30, by any of the following methods:

- Electronically: Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Hard copy: Mail or hand deliver to: A.J. North, Regulations Program, National Park Service, 1849 C Street, NW, MS-2355, Washington, DC 20240.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. We will only accept comments as noted above. We will not accept comments via e-

mail, fax or by any other methods. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information, see the **Public Participation** heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Sara Newman, Director, Office of Public Health, by telephone 202-513-7225, or email sara_newman@nps.gov.

SUPPLEMENTARY INFORMATION:

Background

General Authority and Jurisdiction

In the National Park Service Organic Act of 1916, Congress granted the National Park Service (NPS) broad authority to regulate the use of areas under its jurisdiction to “conserve the scenery, natural and historic objects, and wild life in [National Park] System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.” 54 U.S.C. 100101. The Organic Act authorizes the Secretary of the Interior, acting through the NPS, to “prescribe such regulations as the Secretary considers necessary or proper for the use and management of [National Park] System units.” 54 U.S.C. 100751.

NPS Smoking Regulation and Policy

The NPS protects park resources and visitors by regulating smoking within park areas. The regulation governing smoking (36 CFR 2.21) was last amended in 1983. This regulation allows the superintendent to designate a portion of a park area, or all or a portion of a building,

structure, or facility as closed to smoking when necessary to protect park resources, reduce the risk of fire, or prevent conflicts among visitor use activities. The regulation prohibits smoking in an area or location so designated and within all caves and caverns. The existing definition of “smoking” in section 1.4 is limited to combustible sources such as a tobacco cigarette; it does not include the use of electronic cigarettes and other electronic nicotine delivery systems (ENDS). Since 2009, ENDS have emerged as an alternative means of nicotine delivery, one that does not require the burning of tobacco. Essentially, when a user “draws” on an ENDS, a liquid solution containing nicotine is heated and vaporized, and inhaled by the user. The user then exhales a vapor that mimics the exhalation from a lit tobacco cigarette.

NPS policy with respect to tobacco smoking is found in Director’s Order #50D (Smoking Policy), originally issued in 2003, and then revised and reissued in 2009. The purpose of the Order – in conformity with Executive Order 13058 (Protecting Federal Employees and the Public From Exposure to Tobacco Smoke in the Federal Workplace) – is to “protect employees and park visitors from the health hazards and annoyances associated with” exposure to environmental tobacco smoke, commonly known as “second-hand” smoke, which is a known human carcinogen.

The Director issued Policy Memorandum 15-03 (Use of Electronic Nicotine Delivery Systems) on September 10, 2015. This policy establishes NPS guidance on the use of ENDS within all facilities and vehicles that are Government owned or leased, and within concessions facilities. The purpose of the Policy Memorandum is to afford all NPS employees and park visitors the same protections from exposure to nicotine and other harmful substances that may be found in ENDS vapor that are currently in place for tobacco smoke. Under this policy, use of ENDS is now treated as tobacco smoking and all provisions of Director’s Order #50D apply to

ENDS use. With regard to concessions facilities, the Policy Memorandum requires that ENDS use be treated the same as smoking for purposes of NPS Management Policies (2006).

Director's Order #50D and Policy Memorandum 15-03 are available online on the NPS Office of Policy website at <http://www.nps.gov/applications/npspolicy/index.cfm> by clicking on the drop-down menu and selecting "Smoking" from the list of policy subjects.

Proposed Revision of NPS Regulations at 36 CFR 1.4 and 2.21

The NPS proposes to apply its smoking regulations at 36 CFR 2.21 to ENDS use the same way they currently apply to tobacco smoking. The basis for this regulatory change is stated below and in Policy Memorandum 15-03 and will make NPS regulations consistent with NPS policy on this subject.

Non-smokers are exposed to nicotine and other potentially harmful components of ENDS vapor at higher than background levels when passively exposed to second hand vapor.¹ The vapor exhaled from an ENDS also contains potentially harmful levels of particulate matter in addition to nicotine, as well as potentially toxic compounds such as carbonyls, metals, and organic volatile compounds.² There has been increased attention in the scientific community to explore the level of potentially harmful constituents in ENDS vapor.³ Despite lower levels of nicotine than in second-hand smoke, exhaled ENDS aerosols result in similar nicotine uptake levels as measured by blood serum cotinine levels in bystanders.⁴ In the case of particulate matter, epidemiological studies show adverse effects of particulate matter when only slightly

¹ See "Cigarettes vs. e-cigarettes: Passive exposure at home measured by means of airborne marker and biomarkers" (<http://www.sciencedirect.com/science/article/pii/S0013935114003089>). See "Secondhand Exposure to Vapors From Electronic Cigarettes" (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565991>).

² See http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf.

³ See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499234.htm>.

⁴ See "Cigarettes vs. e-cigarettes: Passive exposure at home measured by means of airborne marker and biomarkers" (<http://www.sciencedirect.com/science/article/pii/S0013935114003089>).

elevated above background levels indicating that we should strive to achieve the lowest concentrations possible.⁵ The Division of Pharmaceutical Analysis of the Food and Drug Administration (FDA) analyzed the ingredients in a sample of cartridges from two leading brands of ENDS, and found the devices emitted (1) tobacco-specific nitrosamines (human carcinogens), and (2) diethylene glycol, a chemical used in antifreeze that is toxic to humans.⁶ Further research is required before it is known whether second hand exposure to ENDS vapor will result in negative health outcomes as with tobacco smoke.⁷ According to the World Health Organization (WHO), simply because ENDS exhaled aerosols contain lower levels of toxicants than tobacco smoke it does not mean second hand exposure is acceptable and special consideration is needed for sensitive populations like pregnant women, developing fetuses, and adolescents.⁸

The Surgeon General's 2014 report *The Health Consequences of Smoking- 50 Years of Progress (Report)* documents the devastating health consequences of tobacco smoking and also calls for “rigorous surveillance” of ENDS in order to weigh their risks and potential benefits (e.g., their possible efficacy in reducing use of combustible tobacco products).⁹ (Page 761). The Report concludes that, in light of the links between tobacco product use and ill health, “all products containing tobacco and nicotine should be assumed to be both harmful and addictive.” (Page 780). In 2016, the Surgeon General issued a report entitled “E-Cigarette Use Among Youth and Young Adults.”¹⁰ This Report emphasized that ENDS use among youth and

⁵ See http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf.

⁶ See <http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf>.

⁷ See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499234.htm>.

⁸ See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499234.htm>.

⁹ See <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/>.

¹⁰ See https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

young adults is a public health concern. The Report concluded that aerosol can contain harmful and potentially harmful constituents, including nicotine, which can cause addiction and harm the developing adolescent brain. The Report stated that the use of products containing nicotine, including ENDS, poses dangers to youth, pregnant women, and fetuses. In a report released August 26, 2014, the WHO called for a ban on the indoor use of ENDS, especially in those spaces where smoking is banned.¹¹ (See Item #41, page 11.)

On May 5, 2016, the FDA finalized a rule (81 FR 28973) extending its authority to ENDS under the Family Smoking Prevention and Tobacco Control Act (PL 111-31; 123 Stat. 1776). The rule brings ENDS in line with regulations that have governed tobacco products since 2009. The rule prohibits the sale of ENDS to minors, requires ENDS to meet applicable product standards and receive marketing authorization from the FDA, requires the reporting of ingredients, and places health warnings on product packages and advertisements. The FDA expressed concerns about the increasing use of ENDS, especially among middle and high school students, and explained that the rule will “help protect Americans from the dangers of tobacco and nicotine.”¹² The FDA stated that nicotine is dangerous and highly addictive, even when it comes from ENDS use, and that research has clearly demonstrated that exposure to nicotine at a young age increases the chance that kids will become addicted. In addition to nicotine exposure, the FDA stated there are numerous other chemicals present in ENDS that can cause disease.¹³

The General Services Administration (GSA) has advised the managers of all GSA-occupied space – which includes space rented by GSA on behalf of NPS – that ENDS are subject to the same restrictions imposed on smoking tobacco products. The U.S. Fish and Wildlife

¹¹ See http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf.

¹² See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499234.htm>.

¹³ See <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm499383.htm>.

Service's (FWS) policy found at 242 FW 13 goes even further, and prohibits “vaping” – another name for ENDS use – in all interior spaces of FWS facilities, whether Government owned or leased.¹⁴ In addition, vaping is also prohibited “in motor vehicles, heavy equipment, aircraft, and most watercraft” owned, leased, or controlled by the FWS. Similarly, on August 14, 2014, the U.S. Geological Survey (USGS) banned the use of ENDS “in all interior space, courtyards, atriums, balconies and bus stops.” See, USGS Manual 370.792.3.¹⁵

In addition to public health risks from the inhalation of vapor, ENDS also pose a risk of explosion and fire. A 2014 Federal Emergency Management Agency (FEMA) report stated that fires or explosions caused by the failure of lithium-ion batteries in ENDS are rare, but possible.¹⁶ Between 2009 and August 2014, 25 incidents of explosion and fire involving e-cigarettes were reported in the U.S. Most of the incidents occurred while the battery was charging, but serious burn injuries were also reported from explosions when the device was in the user’s mouth. FEMA stated that the shape and construction of e-cigarettes can make them more likely than other products with lithium-ion batteries to behave like “flaming rockets” when a battery fails. FEMA concluded that the number of fires and explosions will likely increase as the number of lithium-ion batteries in use continues to grow.

Acting out of an abundance of caution in light of the scientific findings and uncertainty to date, and in the interest of equity, the purpose of this proposed rule (similar to the purpose of Policy Memorandum 15-03) is to afford all NPS employees and park visitors the same protections from exposure to nicotine and other harmful substances that may be found in ENDS vapor that are currently in place for exposure to tobacco smoke.

¹⁴ See <http://www.fws.gov/policy/242fw13.html>.

¹⁵ See <http://www.usgs.gov/usgs-manual/370-600/370-7923.html>.

¹⁶ See https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf.

The proposed rule would add a new definition to 36 CFR 1.4 that defines “Electronic nicotine delivery system” as an electronic device, such as an electronic cigarette, that a person uses to simulate smoking by inhaling vapor from the device. The proposed rule would revise the definition of “Smoking” in 36 CFR 1.4 to include the direct inhalation of vapor from an electronic nicotine delivery system. The NPS also proposes to add a new basis for which a superintendent may close an area or building, structure, or facility to smoking in 36 CFR 2.21 – when necessary to maintain public health and safety. This reflects the health risks associated with smoking tobacco products and using ENDS. An existing basis in the regulations for restricting tobacco smoking – to reduce the risk of fire – also would apply to the use of ENDS for the reasons explained above. After these changes are made, the smoking regulation at 2.21 would apply to the smoking of tobacco and the use of ENDS, consistent with NPS policy.

Compliance with Other Laws, Executive Orders, and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563).

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that

the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA).

This rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on information contained in the economic analyses found in the report entitled “Benefit-Cost and Regulatory Flexibility Analyses: Proposed Regulation Revisions for Electronic Nicotine Delivery Systems” which is available online on the NPS Office of Policy website at <http://www.nps.gov/applications/npspolicy/index.cfm> by clicking on the drop-down menu and selecting “E-cigarettes” from the list of policy subjects.

Small Business Regulatory Enforcement Fairness Act (SBREFA).

This rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This rule:

- (a) Does not have an annual effect on the economy of \$100 million or more.
- (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (UMRA).

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. It addresses public use of

national park lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630).

This rule does not effect a taking of private property or otherwise have taking implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132).

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This proposed rule only affects use of NPS administered lands and waters. It has no outside effects on other areas. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988).

This rule complies with the requirements of Executive Order 12988. This rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation with Indian tribes (Executive Order 13175 and Department Policy).

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the criteria in Executive Order 13175 and under the Department's consultation policy and have determined that tribal consultation is not required because the rule will have no substantial direct effect on federally recognized Indian tribes.

Paperwork Reduction Act (PRA)(44 U.S.C. 3501 *et seq.*).

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA).

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of administrative, legal, and technical nature (43 CFR 46.210(i)). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (Executive Order 13211).

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Clarity of this rule.

We are required by Executive Orders 12866 (section 1(b)(12)) and 12988 (section 3(b)(1)(B)) and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use clear language rather than jargon;
- (d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Drafting Information: The primary authors of this rule are Jay Calhoun and Russel J. Wilson, Division of Regulations, Jurisdiction, and Special Park Uses, and Michael M. Shelton, Program Analyst, Office of Policy, National Park Service, Washington, D.C.

Public Participation.

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule by one of the methods listed in the **ADDRESSES** section. All comments must be received by midnight of the close of the comment period. We will **not** accept comments by fax, e-mail or by any other methods. Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted.

Public availability of comments.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment – including your personal identifying information – may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

List of Subjects in 36 CFR Part 1

National parks, Penalties, Reporting and recordkeeping requirements, Signs and symbols

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 1 as set forth below:

PART 1 - GENERAL PROVISIONS

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

Authority: 54 U.S.C. 100101, 100751, 320102.

2. In § 1.4 amend paragraph (a) by adding, in alphabetical order, the term “Electronic nicotine delivery system” and revising the term “Smoking” to read as follows:

§ 1.4 What terms do I need to know?

(a) * * *

Electronic nicotine delivery system means an electronic device, such as an electronic cigarette, that a person uses to simulate smoking by inhaling vapor from the device.

* * * * *

Smoking means the carrying of lighted cigarettes, cigars or pipes; or the intentional and direct inhalation of smoke from these objects; or the direct inhalation of vapor from an electronic nicotine delivery system.

* * * * *

3. In § 2.21, revise paragraph (a) to read as follows:

§ 2.21 Smoking

(a) The superintendent may designate a portion of a park area, or all or a portion of a building, structure or facility as closed to smoking when necessary to maintain public health and safety, to protect park resources, reduce the risk of fire, or prevent conflicts among visitor use activities. Smoking in an area or location so designated is prohibited.

* * * * *

Dated: December 20, 2016

Michael Bean

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks

[FR Doc. 2016-31957 Filed: 1/5/2017 8:45 am; Publication Date: 1/6/2017]