

fluoroscopy." As a concept for discussion, fluoroscopic systems designed for interventional radiology might be defined as systems that permit the beam axis to be positioned at an angle relative to the normal to the table top. Systems in which the x-ray beam direction is fixed with respect to the plane of the tabletop, such as conventional radiographic/ fluoroscopic systems, would not be included in this definition.

5. Amendment to require improved x-ray field limitation (21 CFR 1020.32(b)(2)(v)). This proposal would require improved limitation of the x-ray field for fluoroscopic equipment to match the actual area of the image receptor being used for image capture, thereby reducing the amount of non-useful beam striking the patient.

6. Amendment to clarify the requirements for the minimum source-skin distance for small, mobile, or portable mini C-arm systems (§ 1020.32(g)). This amendment would address numerous requested and granted variances for fluoroscopic systems that have limited source-image receptor distances. The amendment would specify the conditions under which a shorter-than-standard source-skin distance is permitted and would obviate the need for continued variances from the standard.

7. Amendment to require indication of cumulative exposure time on fluoroscopic systems (§ 1020.32(h)). The proposed amendment would require the means to indicate the cumulative time of fluoroscopic irradiation of a patient during an examination or procedure.

8. Amendment to require provision of "last-image-hold" feature on fluoroscopic systems (§ 1020.32(j)). This amendment would require that all fluoroscopic x-ray systems be provided with a means to continuously display the last image acquired following termination of any exposure period.

9. Amendment to require indication of air kerma rate and cumulative air kerma on fluoroscopic systems (§ 1020.32(k)). The proposed amendment would require the means to display to the fluoroscopist at the fluoroscopist's working position the cumulative air kerma and the air kerma rate (air kerma per unit time) at which air kerma accrues during irradiation of a patient in an examination or procedure.

III. Electronic Access

The summary of concepts for amendments entitled "Concepts for Proposed Amendments to the Performance Standard for Diagnostic X-ray Systems, August 1, 1997," may be

accessed at the CDRH Home Page on the World Wide Web. It is available on the Topic Index page at: <http://www.fda.gov/cdrh/topindx> under "Fluoroscopy". A text-only version of the CDRH site is also available from a computer or VT-100 compatible terminal by dialing 800-222-0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there, follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA Home Page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there, select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

The document may also be obtained by fax by calling the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 591 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

A summary of the TEPRSSC April 8 through 9, 1997, meeting is available on the CDRH Home Page at the same address given above for the concepts for amendments document.

IV. Comments

Interested persons may, on or before March 11, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed amendment. 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.

Interested persons also are invited to participate in the development of proposed amendments by submitting written data, views, or arguments concerning the subject matter of the amendments, or related topics suggested for inclusion in the amendments. In addition to general comments and recommendations, respondents are encouraged to include suggested text for provisions of the proposed amendments that reflect their recommended performance requirements. A statement of rationale should accompany any such proposed text. When a determination is

made on the content of the proposed amendments, they will be published as notices of proposed rulemaking with opportunity given for public comment. Information and comments are specifically invited on the following topics:

1. For concepts 4 through 9 in section II of this document, recommendation for whether the amendments should be limited only to equipment designed for interventional procedures or for all fluoroscopic systems. If only for interventional systems, how should "interventional fluoroscopic systems" be defined?

2. The desirability and technical feasibility of amendments of the type described in section II of this document.

3. Recommended performance requirements to be included in the proposed amendments, including attendant methods and conditions of measurement.

4. Suggestions and supporting data for other amendments to the performance standard for radiographic or fluoroscopic equipment, including moving towards more outcome-based performance standards, which may be needed to provide for adequate radiation safety.

5. The possible environmental impact of this action, including factors such as radiation exposure reduction or prevention and economic consequences in relation to expected benefits (cost-benefit relationship), and the anticipated costs of providing such features or meeting the requirements.

6. Any additional terms or definitions that are needed to better specify the intent or meaning of the regulations as they apply to the equipment.

This ANPRM is issued under 21 U.S.C. 321 and under the authority of the Commissioner of Food and Drugs.

Dated: October 29, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-32462 Filed 12-10-97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AE45

Endangered and Threatened Wildlife and Plants; Proposed Revision of Special Regulations for the Gray Wolf

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: On November 22, 1994, the U.S. Fish and Wildlife Service published special rules to establish nonessential experimental populations of gray wolves (*Canis lupus*) in Yellowstone National Park and central Idaho. The nonessential experimental population areas include all of Wyoming, most of Idaho, and much of central and southern Montana. A close reading of the special regulations indicates that, unintentionally, the language reads as though wolf control measures apply only outside of the experimental population area. This proposed revision is intended to amend language in the special regulations so that it clearly applies within the Yellowstone nonessential experimental population area and the central Idaho nonessential experimental population area. This proposed change will not affect any of the assumptions and earlier analysis made in the environmental impact statement or other portions of the special rules.

DATES: Comments must be received by January 12, 1998.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Gray Wolf Recovery Program, U.S. Fish and Wildlife Service, 100 North Park, Suite 320, Helena, Montana 59601. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Edward E. Bangs, Wolf Recovery Coordinator, at the above address, or telephone (406) 449-5202, extension 204.

SUPPLEMENTARY INFORMATION:

Background

1. *Legal:* The Endangered Species Act Amendments of 1982, Public Law 97-304, made significant changes to the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 *et seq.*), including the creation of section 10(j) which provides for the designation of populations as "experimental." It was under this provision of the Act that on November 22, 1994, the Service by special rule established two areas for nonessential experimental populations of gray wolves (59 FR 60252 and 60266; 50 CFR 17.84(i)). One area was the Yellowstone National Park experimental population area which included all of Wyoming, and parts of Montana, and Idaho. The other area, called the central Idaho experimental population area, included much of Idaho and parts of southwestern Montana. These rules

allowed the Service and other cooperating agencies to manage wolf recovery so that conflicts with people were minimized. Under certain circumstances the rules allowed for wolves to be captured, relocated, held in captivity, or killed. Subparts A, B, and C 50 CFR 17.84 (i)(7)(iii) addressed the management of reintroduced wolves that traveled outside the experimental areas or wolves of unknown status outside the experimental population. Subpart D in 50 CFR 17.84 (i)(7)(iii) D, addressed the management of wolves and wolf-like canids of unknown but questionable status. Examples given under 50 CFR 17.84 (i)(7)(iii) D include wolves or wolf-like canids that exhibited behavioral or physical evidence of hybridization with other canids, or wolf-like canids that may have been raised or held in captivity other than as part of a Service approved wolf recovery program. The rule in 50 CFR 17.84 (i)(7)(iii) is currently worded as follows:

All wolves found in the wild within the boundaries of this paragraph (50 CFR 17.84 (i)(7)) after the first releases will be considered nonessential experimental animals. In the conterminous United States, a wolf that is outside an experimental area (as defined in 50 CFR 17.84 (i)(7) of this section) would be considered as endangered (or threatened if in Minnesota) unless it is marked or otherwise known to be an experimental animal; such a wolf may be captured for examination and genetic testing by the Service or Service-designated agency. Disposition of the captured animal may take any of the following courses:

(A) If the animal was not involved in conflicts with humans and is determined to be an experimental wolf, it will be returned to the reintroduction area.

(B) If the animal is determined likely to be an experimental wolf and was involved in conflicts with humans as identified in the management plan for the closest experimental area, it may be relocated, placed in captivity, or killed.

(C) If the animal is determined not likely to be an experimental animal, it will be managed according to any Service-approved plans for that area or will be marked and released near its point of capture.

(D) If the animal is determined not likely to be a wild gray wolf or if the Service or agencies designated by the Service determine the animal shows physical or behavioral evidence of hybridization with other canids, such as domestic dogs or coyotes, or of being an animal raised in captivity, it will be returned to captivity or killed.

The rule in 50 CFR 17.84(i)(7)(iii) was intended to allow the Service, or agencies designated by the Service, management flexibility should experimental wolves travel outside the experimental population areas, and the ability to (1) manage wolves of unknown origin, (2) manage wolves that exhibit abnormal behavior or physical characteristics (indicative of hybridization with other canids), and (3) manage canids suspected of being raised in captivity and released to the wild independently of the Service wolf recovery program. Furthermore, subpart D was intended to allow for management of those rare instances where an individual wild wolf may exhibit abnormal behavior that is not conducive to the recovery and conservation of wild gray wolf populations in the northern Rocky Mountains of Montana, Idaho, and Wyoming. The section was intended to enhance the survival and reproductive potential of wild wolves and to remove canids that could have a negative impact on the survival and reproductive potential of wild wolves.

Through an unintentional oversight in the wording in 50 CFR 17.84 (i)(7)(iii) subpart D appears to apply only to activities conducted outside the experimental population area. This revision is being proposed to correct that oversight and clarify that management of wild wolves and wolf-like canids that exhibit abnormal behavior, wolf hybrids, or wolves that may have been raised in captivity, also applies within each experimental area.

2. *Biological:* This proposed revision of the special regulations is intended to clarify that the management flexibility addressed by 50 CFR 17.84 (i)(7)(iii) subpart D applies to wolves of questionable status or wolf-like canids within the nonessential experimental population areas. As currently written the special regulations could be interpreted to imply that wolf hybrids or captive wolves that were not part of a Service-approved recovery program but that escaped or were released to the wild within the experimental area, would be managed in a manner identical to wild wolves within the experimental population area. Wolves or wolf-like canids that are raised in captivity and released in the wild do not behave like wild wolves. They often associate with people or domestic livestock, raising concerns about human safety and depredations on domestic animals. These types of canids also often cause problems by attacking domestic animals because they usually are not able to survive entirely in the wild. While they have some of the

predatory instincts of wild canids, they are most comfortable around people. They are likely to be dependent on humans for food and this increases the probability that they may attack domestic animals since domestic animals are the most common types of animals near people. The tolerance of captive raised and released canids for people also contributes to the perception that human safety may be in danger from wild wolves. There are numerous documented instances of domesticated wolves and wolf hybrids attacking and killing people. Although unlikely, captive wolves or wolf hybrids associating with wild wolves could teach young wolves or any hybrid offspring these undesirable traits. For these reasons wolves exhibiting the characteristics described above do not contribute to the recovery of wild gray wolf populations in the northern Rocky Mountains.

When local residents believe wild wolves behave like captive wolves or wolf hybrids, public tolerance for wild wolves is likely reduced. This can lead to illegal killing of wolves. It was not the intent of the wolf recovery program to protect or manage captive wolves or wolf hybrids that were not part of a Service approved recovery program. Those types of canids will not contribute to the conservation and recovery of wild gray wolves. The Service intends to manage such canids when necessary, to resolve potential conflicts with humans and to minimize the likelihood that undesirable genetic or behavioral characteristics could be passed on by such animals to wild wolves within the experimental population areas.

Captive wolves that have not been specifically raised for release into the wild, or wolf hybrids, can also carry diseases or parasites that are common in domestic dogs. If released into the wild, such animals can transmit those diseases or parasites to wild gray wolves as well as other wildlife species. Current DNA and other types of testing can not reliably distinguish wild wolves from wolves raised in captivity or from wolf hybrids. Because captive wolves and wolf hybrids may look identical to wild wolves, they can often only be reliably distinguished from wild wolves by their behavior in the wild. Their presence can often confuse the public about what behavior to expect from wild wolves, reduce local human tolerance of wild wolves and lead to an increase in human related wolf mortality. Local tolerance of wolves is important for wolf recovery and conservation since a majority of wolf mortality in Montana is caused by humans.

The presence and management of wolves or wolf-like canids that are not part of an approved recovery program may result in substantial expense and thereby compete for limited gray wolf recovery program resources, particularly if their management requires the same level of effort as that afforded to wild wolves. Because wolf hybrids and captive wolves released into the wild can demand considerable management time and attention at the expense of wild wolf conservation, prompt control of these animals is essential. The selective removal from the wild of captive raised and released wolves, wolf hybrids, and/or wolf-like canids exhibiting behavior considered abnormal for wild gray wolves furthers the conservation and recovery of the gray wolf by minimizing the probability of unresolved conflicts with humans.

Wild wolves were taken from the wild in remote areas of Canada and reintroduced in January of 1995 and 1996 to the Yellowstone and central Idaho experimental population areas and have adapted much better than predicted. As expected, they continue to behave like wild wolves. If current trends continue, it is unlikely that further reintroductions in the experimental population areas will be required. All the wolves that were reintroduced were radio-collared and monitored by means of radio-telemetry, and a number these wolves have successfully reproduced in the wild. Current plans do not call for all of the pups to be individually captured and radio-collared. As the population grows, there will be an increasing number of wolves that have not been marked and it will not be possible to determine where most of these wolves originated. It is also estimated that there may be up to 300,000 captive wolves and wolf/dog hybrids (which in many cases are physically and genetically indistinguishable from wild wolves) in North America. Therefore, the special regulations for establishment of nonessential experimental populations of gray wolves need to clearly address the manner in which wolves, whose origin is unknown or wolves that exhibit abnormal behavior will be managed in the wild when conflicts develop.

In several areas of the northern Rocky Mountains, wolf-like canids have been identified through their behavior or physical characteristics as released or escaped wolves that were not part of Service approved programs or wolf hybrids of captive origin. Such animals usually do not survive in the wild long enough to successfully reproduce and raise young. In several instances these

animals have been removed from the wild because they have become a nuisance or potential human or domestic animal safety concerns arose.

All wolves, including wild ones, are individuals, and some wild wolves may exhibit abnormal or other behavior that is inconsistent with the continued survival, reproduction, and recovery of wild gray wolf populations. For example, some individual wolves may attack livestock or domestic pets. The Service recognizes that such individuals must be managed (through removal to another location or placement in captivity, or lethal means) to minimize chronic conflicts with domestic animals if local people are expected to continue to tolerate the presence of a resident wolf population. The Service has determined that removal of such individuals furthers the conservation and recovery of the wild gray wolf population. In a similar although extremely rare situation, individual wolves may on occasion exhibit behaviors that are uncharacteristic of those normally observed in wild wolves. Although highly unlikely, it is possible that a wild wolf may demonstrate physical or behavioral evidence of hybridization with other canids, such as domestic dogs or coyotes. It also is possible that an individual wolf may become a nuisance, or pose a potential risk to people or livestock because of habituation to food sources, human and domestic animal companionship, or other factors. The Service intended that 50 CFR 17.84(i)(7)(iii) subpart D allow for the management and/or removal of all such individuals within the nonessential experimental population areas for the benefit and conservation of the wild gray wolf populations.

Location of the Experimental Population

The Yellowstone experimental population area includes the State of Wyoming, that portion of Idaho east of Interstate Highway 15, and the State of Montana east of Interstate Highway 15 and south of the Missouri River east of Great Falls, Montana, to the Montana/North Dakota border.

The central Idaho experimental population area includes that portion of Idaho west of Interstate 15 and south of Interstate 90, and that portion of Montana south of Interstate 90, Highway 93 and 12 near Missoula, Montana, and west of Interstate 15.

Management

Management of wild wolves would not change from that established by the special rules, except in those rare instances when a wild wolf exhibits

abnormal behavior. This proposed revision would apply 50 CFR 17.84(i)(7)(iii) subpart D within the experimental population areas, which would further the conservation and recovery of wild gray wolves in the northern Rocky Mountains of the United States. The rule in 50 CFR 17.8e(i)(7)(iii) would apply to all wolves and wolf-like canids found within and adjacent to the experimental population areas in Montana, Idaho, and Wyoming.

National Environmental Policy Act

This proposed revision does not significantly change the special regulations or the effect of the special regulations on the human environment. An environmental action statement has been prepared that determined the proposed revision is a categorical exclusion as provided by 516 DM 2, Appendix 1 and 516 DM 6, Appendix 1. No further NEPA documentation will therefore be made.

Required Determinations

This is not a significant rule subject to Office of Management and Budget review under Executive Order 12866. The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The proposed revision is purely technical in nature and intended to correct a technical oversight in the rule originally adopted in 1994; it will not increase or alter the effects brought by the original rule. The Service has determined and certifies pursuant to the Unfunded Mandates Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of \$100 million or more in any given year on local or State governments or private

entities. The Department has determined that this proposed regulation meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive order 12988.

Author: The principle author of this rule is Edward E. Bangs (see ADDRESSES section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and record keeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, the Service hereby proposes to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: 16 U.S.C. 1361-1407; 16 U.S.C. 1531-1544; 16 U.S.C. 4201-4245; Public Law No. 99-625, 100 Statute 3500; unless otherwise noted.

2. Revise § 17.84(i)(7)(iii) to read as follows:

§ 17.84 Special rules—vertebrates.

* * * * *

(i) * * *

(7) * * *

(iii) All wolves found in the wild within the boundaries of this paragraph (i)(7) after the first releases will be considered nonessential experimental animals. In the conterminous United States, a wolf that is outside an experimental area (as defined in paragraph (i)(7) of this section) would be considered as endangered (or threatened if in Minnesota) unless it is marked or otherwise known to be an experimental animal. Wolves in the wild may be selectively captured,

removed, or killed for examination and genetic testing by the Service or Service designated agency. Disposition of such wolves outside the experimental areas and in the case of subpart D, those both outside of and within the experimental population areas, may take any of the following courses:

(A) If the animal was not involved in conflicts with humans and is determined likely to be a wild experimental wolf, it will be returned to the reintroduction area.

(B) If the animal is determined likely to be a wild experimental wolf and was involved in conflicts with humans as identified in the management plan for the closest experimental area, it may be relocated, placed in captivity or killed.

(C) If the animal is determined not likely to be a wild experimental wolf, it will be managed according to any Service-approved plans for that area or will be marked and released near its point of capture.

(D) If the animal is determined not likely to be a wild gray wolf or if the Service or agencies designated by the Service determine that any wild wolf exhibits abnormal behavior or that any wolf or wolf-like canid shows physical or behavioral evidence of hybridization with other canids, such as domestic dogs or coyotes, or of being an animal raised in captivity other than as part of a Service-approved wolf recovery program, it will be killed, or placed in captivity.

* * * * *

Dated: November 13, 1997.

Donald J. Barry,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 97-32440 Filed 12-8-97; 3:42 pm]

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