concerning infant/child apnea monitors. This draft guidance sets forth the agency's current position regarding minimum performance characteristics, test procedures and criteria, labeling, and, as appropriate, clinical testing that will provide reasonable assurance of the safety and effectiveness of this kind of apnea monitor device. This guidance includes basic concepts that were included in the proposed standard for infant apnea monitors, but updates, consolidates, or eliminates certain elements of the proposed standard on the basis of comments received in response to the proposal and the continuing development and FDA recognition of appropriate consensus standards. Although the proposed standard did not require clinical testing, the guidance document addresses this subject.

As noted above, FDA believes the performance, testing, labeling, and clinical parameters in the draft industry guidance for infant/child apnea monitors are applicable as well to apnea monitors used on patients in every age group. After considering comments on this guidance and further evaluating clinical criteria, FDA will issue final industry guidance identifying minimum performance, testing, labeling, and clinical criteria as the special control for the entire apnea monitor group of devices. Once this special control is established, new products seeking to enter the market will be required to conform with the special control. The final guidance document will describe a means by which an apnea monitor device may comply with the requirements of special controls for class II devices.

Designation of the agency's guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate apnea monitor, including one used to monitor apnea in children under 3 years of age, should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternative control that provides equivalent assurances of safety and effectiveness. FDA recognizes that older products already on the market will not be required to meet this special control. The agency expects, however, that labeling on the newer devices and other market forces will encourage manufacturers of these older devices to comply with the guidance. FDA also expects the education program, described below, to accelerate the improvement of these older products.

FDA is participating with the Association for the Advancement of Medical Instrumentation in a separate effort to develop clinically-based test methods and clinically-derived bench tests for measuring the effectiveness of monitoring modalities in detecting apnea. At the conclusion of this effort, the agency may consider these tests to be referee test methods.

C. Education Program

FDA intends to develop an education program targeted to reach manufacturers of the infant/child apnea monitor, manufacturers of accessories marketed for use with this device, distributors and rental companies handling the devices, users, including hospitals and other health care services, and other consumers. This particular audience is targeted initially because infants and children under 3 years of age are particularly subject to the pathophysiological consequences of prolonged apneas lasting over 20 seconds in duration.

The purpose of this program will be to inform the target audience of FDA's current position regarding performance characteristics and specifications, test methods and results, and labeling information the agency believes are appropriate for the infant/child apnea monitor. The program also will advise the target audience that some monitors previously cleared for marketing prior to November 1993 may not meet the agency's current recommendations and, although they may adequately detect and alarm upon prolonged episodes of central apnea, they may not be adequate for detection of episodes of obstructive apnea or mixed apnea.

As circumstances warrant, FDA may direct additional educational efforts at parties involved with apnea monitors used on patient populations of other ages.

Dated: September 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–24335 Filed 9–21–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6874–5]

Tennessee: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Tennessee has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Tennessee. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble to the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we get comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

DATES: Send your written comments by October 23, 2000.

ADDRESSES: Send written comments to Narindar Kumar, Chief, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104. You can examine copies of the materials submitted by Tennessee during normal business hours at the following locations: EPA Region 4 Library, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104, Phone number: (404)562–8190; or Tennessee Department of Environment and Conservation, Division of Solid Waste Management, 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535, Phone number: (615) 532–0850.

FOR FURTHER INFORMATION CONTACT: Narindar Kumar, Chief, RCRA Programs

Branch, Waste Management Division, U.S. Environmental Protection Agency at the above address and phone number.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: September 12, 2000.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 00–24433 Filed 9–21–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[I.D. 091800E]

RIN 0648-AO41

Fisheries off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Amendment 13

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of an amendment to a fishery management plan; request for comments.

SUMMARY: NMFS announces that the Pacific Fishery Management Council (Council) has submitted Amendment 13 to the Pacific Coast Groundfish Fishery Management Plan (FMP) for Secretarial review. Amendment 13 is intended to make the FMP consistent with Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) bycatch provisions,to increase flexibility in the annual management measures framework to manage for protection of overfished and depleted stocks, and to remove outdated and unused limited entry permit endorsements.

DATES: Comments on Amendment 13 must be received on or before November 21, 2000.

ADDRESSES: Comments on Amendment 13 or supporting documents should be sent to Donna Darm, Acting Administrator, Northwest Region, NMFS, Sand Point Way NE., BIN C15700, Seattle, WA 98115-0070; or to Rebecca Lent, Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213.

Copies of Amendment 13 and the Environmental Assessment/ Regulatory Impact Review (RIR) are available from Donald McIsaac, Executive Director, Pacific Fishery Management Council, 2130 SW Fifth Ave., Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Yvonne deReynier at 206-526-6140, Svein Fougner at 562-980-4000; or the Pacific Fishery Management Council at 503-326-6352.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that each regional fishery management council submit any new FMP or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, immediately publish a notification in the Federal Register that the FMP or amendment is available for public review and comment. NMFS will consider the public comments received during the comment period described here in determining whether to approve the FMP or amendment.

Amendment 13 would address the Magnuson-Stevens Act National Standard 9 bycatch provisions by: revising the FMP definition of the term ''bycatch'', changing the standardized reporting methodologies, and recommending new bycatch reduction measures. Amendment 13 would establish an increased utilization program in the at-sea whiting fisheries. This program would allow at-sea whiting processing vessels that carry more than one observer to retain all of their non-whiting groundfish bycatch for processing into fish meal or for donating to food banks. Measures that would be authorized and may be considered for future Council development include: shorter fishing seasons and higher cumulative landing limits; permit stacking in the limited entry fleet; gear modification requirements; catch allocation to, or gear flexibility for, gear types with lower bycatch rates; improvements in the species-to-species landings limit ratio; and time/area closures to protect incidentally caught species.

In addition to addressing bycatch, Amendment 13 would increase flexibility in the groundfish annual specifications and management measures process to allow the Council to more easily develop measures that protect overfished and depleted species. This increased flexibility would include: achieving the overfished species rebuilding plans, reducing bycatch, preventing overfishing, allowing the harvest of healthy stocks as much as possible while protecting and rebuilding overfished and depleted stocks, and equitably distributing the burdens of rebuilding among the various fishing sectors.

Finally, Amendment 13 would amend the limited entry permit provisions to remove unused and outdated limited entry permit endorsements. This last revision is essentially a housekeeping measure to address changes in the character of the groundfish fisheries, particularly the fully utilized status of all FMP-managed Pacific coast groundfish stocks.

Public comments on Amendment 13 must be received by November 21, 2000 to be considered by NMFS in the decision whether to approve Amendment 13. A proposed rule to implement Amendment 13 has been submitted for Secretarial review and approval. NMFS expects to publish and request public comment on the proposed regulations to implement Amendment 13 in the near future.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 19, 2000.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00–24458 Filed 9–21–00; 8:45 am]

BILLING CODE 3510–22–S