

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large winter pear handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule.

In addition, the Committee's meetings were widely publicized throughout the winter pear industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the March 30, May 4, and June 2, 2000, meetings were public meetings and all entities, both large and small, were able to express views on this issue. The Committee itself is composed of twelve members, of whom six are handlers and six are producers. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 15-day comment period is provided to allow interested persons to respond to this proposal. Fifteen days is deemed appropriate because this rule would need to be in place by August 15, 2000, because shipments of Anjou pears are expected to begin shortly thereafter. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 927 is proposed to be amended as follows:

PART 927—WINTER PEARS GROWN IN OREGON AND WASHINGTON

1. The authority citation for 7 CFR part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. A new § 927.316 is added to read as follows:

§ 927.316 Handling regulation.

During the period August 15 through November 1, no person shall handle any Beurre D'Anjou variety of pears for shipments to North America (Continental United States, Mexico, or Canada), unless such pears meet the following requirements:

(a) Beurre D'Anjou variety of pears shall have a certification by the Federal-State Inspection Service, issued prior to shipment, showing that (1) the core/pulp temperature of such pears has been lowered to 35 degrees Fahrenheit or less and

(2) Any such pears have an average pressure test of 14 pounds. The handler shall submit, or cause to be submitted, a copy of the certificate issued on the shipment to the Control Committee.

(b) Each handler may ship on any one conveyance 8,800 pounds or less of Beurre D'Anjou variety of pears without regard to the quality and inspection requirements in paragraph (a) of this section.

Dated: June 27, 2000.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 00–16737 Filed 6–30–00; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 55

RIN 3150–AG40

Operator License Eligibility and Use of Simulation Facilities in Operator Licensing

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations by allowing applicants for operator and senior operator licenses to fulfill a portion of the experience prerequisites for license eligibility by manipulating a plant-referenced simulator as an alternative to use of the actual plant. The proposed rule would allow applicants for operator and senior operator licenses to fulfill a portion of the experience prerequisites by manipulating a plant-referenced simulator as an alternative to use of the actual plant. In addition, the proposed rule would remove current requirements for certification of simulation facilities and routine submittal of simulator performance test reports to the NRC for review. Also, the proposed rule would

revise the definitions of “Performance testing,” “Plant-referenced simulator,” and “Simulator facility.”

DATES: Submit comments by September 18, 2000. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, Mail Stop O–16C1. Deliver written comments to One White Flint North, 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (<http://www.nrc.gov>). This site provides the capability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (e-mail: cag@nrc.gov). Copies of any comments received and certain documents related to this rulemaking may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents may be viewed and downloaded electronically via the rulemaking website.

Documents created or received at the NRC after April 1, 2000, are also available electronically at the NRC's Public Electronic Reading room on the internet at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agency Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 202–634–3273 or toll-free at 1–800–397–4209, or by e-mail at pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Glenn Tracey, Operator Licensing, Human Performance and Plant Support Branch, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: (301) 415–1031; or by Internet electronic mail to gmt@nrc.gov.

SUPPLEMENTARY INFORMATION:

Introduction

Section 107 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2137), requires the NRC to prescribe uniform conditions for licensing individuals as operators of production and utilization facilities to determine the qualifications

of these individuals, and to issue licenses to these individuals. The regulations implementing these requirements are set out in Part 55 of Title 10, Chapter 1, of the Code of Federal Regulations. To assist licensees and others, the Commission has issued regulatory guides and generic letters that provide guidance on acceptable methods of meeting these regulatory requirements.

The Commission has become increasingly aware of the need to update its operator licensing regulations and related regulatory guides. These revisions are needed to clarify the extent to which applicants for operator and senior operator licenses may fulfill a portion of the experience prerequisites for license eligibility with the performance of five significant control manipulations on a plant-referenced simulator as an alternative to use of the actual plant, and to remove current requirements for certification of simulation facilities and routine submittal of simulator performance test reports to the NRC for review. The proposed rule changes would improve the operator licensing process. If adopted, these revisions would achieve the following objectives: (1) Allow applicants for operator and senior operator licenses to fulfill a portion of the experience prerequisites by performing five significant control manipulations on a plant-referenced simulator and/or the actual plant facility for which a license is sought; (2) maintain training integrity through a requirement that ensures adequate simulator replication of the plant and demonstrated fidelity for those simulators used to provide control manipulation experience; (3) remove current requirements for certification of simulation facilities; (4) eliminate routine submittal of simulator performance test reports to the NRC for review; and (5) maintain safety through NRC reviews to ensure simulator suitability for providing effective training in performance assessment of operator license applicants.

Background

On March 25, 1987 (52 FR 9453), the Commission published a final rule in the **Federal Register** that amended 10 CFR Part 55 and became effective May 26, 1987. The amendment requires that an applicant successfully manipulate the controls of the facility for which a license is sought. Five significant control manipulations must be performed which affect reactivity or power level. The final rule also included requirements for the use of simulators in the qualification and

requalification of nuclear power plant operators, and required certification of simulation facilities.

Discussion of Proposed Rule Changes

Subpart A—Revision of § 55.4, Definitions

Three definitions would be revised. The definition of “Performance testing,” which is testing conducted to verify a simulation facility’s performance as compared to actual or predicted reference plant performance, would be revised in a manner that would not impose additional requirements on licensees, to comport with the definition for such testing in the most recent edition of the industry standard for use of nuclear plant simulators in operator training and examination (ANSI/ANS-3.5-1998). The definition of a “Plant-referenced simulator,” which is a simulator modeling the systems of the reference plant, would be revised to reference within the definition existing simulator requirements in Part 55, and the proposed revision allowing completion of certain on-the-job training prerequisites for license applicant eligibility on the simulator. The definition of “Simulation facility,” which describes the components that alone, or in combination, can be used for partial conduct of operating tests, would be revised to include part-task and limited-scope simulator devices because these devices are now referenced in the most recent edition of ANSI/ANS-3.5, and a request could be received for Commission approval of their use.

Conforming Changes to § 55.8 Information Collection Requirements: OMB Approval

As a result of the previously described proposed changes to § 55.45(b) that eliminate the simulator certification requirement, a conforming change to § 55.8(c)(3) would delete Form 474, “Simulation Facility Certification,” OMB approval No. 3150-0138, as currently referred to § 55.45(b)(1)(iii) and § 55.45(b)(3)(iii).

Section 55.8(c)(4) would be deleted because its requirements have been incorporated into this 10 CFR part.

Subpart D—Revision of § 55.31 To Allow Performance of Control Manipulations on the Plant-Referenced Simulator

Section 55.31(a)(5), currently requires that five significant control manipulations that affect reactivity or power level be performed on the actual plant would be revised to allow those manipulations to be performed either on

a plant-referenced simulator or on the actual plant, at the facility licensee’s discretion. Eligibility for an operator license encompasses education, training, and experience factors. Reactivity manipulations are an operating experience requirement addressed by on-the-job training (OJT). Use of a plant-referenced simulator of appropriate fidelity for these manipulations is appropriate based upon improvements in simulator technology and 13 years of successful experience in using plant-specific simulation facilities since the 1987 final rule. Modern plant-referenced simulation facilities in operation today are providing accurate and validated operator training and examination scenarios that convey realism in reactivity manipulations, other normal and abnormal procedure operations, complex plant operations, and emergency operating procedure evolutions, including simultaneous task management and faulted conditions. The proposed rule change would allow part of the plant operating experience requirement for license eligibility to be fully satisfied in a timely manner within the facility’s accredited training program without impacting operation of the actual plant.

The requirement of § 55.31(a)(4) to complete the facility licensee’s program of education, experience, and OJT as a prerequisite of license eligibility would not be affected by the proposed rule change. Performance of control manipulations that affect reactivity or power level constitutes only a small part of an applicant’s preparedness to perform licensed duties and would continue to be implemented as a subset of OJT. If adopted, the proposed rule would alternatively allow use of the actual plant and/or the plant-referenced simulator for control manipulations, thus broadening the range of options available to facility licensees for selecting the most advantageous training method.

Although facility licensees’ simulation facilities are, for the most part, state-of-the-art, the NRC has identified two areas of concern with respect to considering a plant-referenced simulator suitable for fulfilling the experience requirements of a license applicant. First, recognizing that the simulator may differ to a degree from the reference unit and to provide experience essentially replicating that obtained from control manipulations on the plant, reasonable measures should be taken to ensure that the simulated reactor core, at least for the directly associated models such as those for nuclear and thermal-hydraulic

characteristics, represents the actual reactor core that will exist in the plant at the time the applicant is tested for a license. Second, the performance of the nuclear and thermal-hydraulic characteristics models must be tested to ensure that the simulator is capable of being used to satisfy predetermined objectives without significant performance discrepancies or deviation from the approved scenario sequence. To address these concerns and thereby maintain plant safety, the proposed rule would add a requirement under § 55.45(b) for licensees using a plant-referenced simulator to satisfy reactivity manipulation experience requirements to ensure that: Simulator models relating to nuclear and thermal-hydraulic characteristics replicate the core load that exists in the nuclear power unit for which a license is being sought at the time of the applicant's operating test; and simulator fidelity has been demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviations from the approved training scenario sequence. This provision in the proposed rule thus links § 55.45(b) with the proposed § 55.31(a)(5).

Subpart E—Revision of § 55.45 To Remove Current Requirements for Simulator Certification and Routine Submittal of Performance Test Reports

The proposed rule would delete requirements that have become outdated and burdensome to the facility licensees and are of limited value to the NRC in the following areas of § 55.45(b): (1) Certification of simulation facilities; (2) submittal of test schedule information; and (3) submittal of quadrennial test reports.

The March 25, 1987, final rule provided a phased implementation schedule for the requirement that facility licensees who propose to use a simulation facility consisting solely of a plant-referenced simulator certify, by means of NRC Form 474, "Simulation Facility Certification," the availability of a simulation facility meeting Commission regulations. The certification requirement also contained associated requirements for submittal of test documentation and test schedules on a quadrennial basis. Licensees have certified plant-referenced simulators at all power reactor facilities, and the NRC staff's experience has shown the quadrennial reports to be of minimal value in assessing simulator suitability for testing of operators.

The proposed rule would, by means of an alternative regulatory approach that would not change substantive

existing requirements, eliminate the need for certification and quadrennial reports. Absent certification, assurance of simulator suitability would be provided through NRC reviews and validation of operating test scenarios, with review of performance test results, and uncorrected modeling or hardware discrepancies, if needed. If the simulator is found by this review to be unsuitable, the simulator may not be used to conduct an operating test, requalification training, or for performing control manipulations to establish license applicant eligibility. The current requirement for more recent simulator test and performance data to remain onsite would not be changed.

Facility licensees proposing to use a simulator facility meeting the definition in § 55.4 for a plant-referenced simulator are not required to submit an application for Commission approval of that simulator.

For cases in which licensees propose to use a simulation facility not meeting the definition of a plant-referenced simulator, the Commission would require additional information to determine the acceptability of the simulator, and thus would require an application for Commission approval.

Since 1987, the last time the Commission amended its regulations regarding the use of simulators, facility licensees have trained licensed operators and applicants for operator and senior operator licenses on plant-referenced simulators that were certified in accordance with the 1985 edition of ANSI/ANS-3.5. This standard specifies full-scope, stand-alone testing of system models and simulator training capabilities as part of initial simulator acceptance testing. Licensees continue to test their plant-referenced simulators in the manner of initial development and to submit test schedules and reports on a quadrennial basis to comply with the 1987 final rule that requires periodic scheduling and reporting of test results to the NRC. The industry's approach to computer software development and simulator testing has changed considerably since 1987, and a new approach has been codified through the issuance of the 1998 version of ANSI/ANS-3.5, Nuclear Power Plant Simulators for Use in Operator Training and Examination. The standard has moved away from continued full-scope, stand-alone testing of system models and simulator training capabilities toward a scenario-based testing and quality control philosophy that is associated with the facility's planned simulator usage.

The proposed rule would eliminate the need for certification of simulation

facilities to the NRC and the associated testing and reporting requirements that have been become outdated by the 1998 revision of the national consensus standard ANSI/ANS-3.5.

The proposed rule would eliminate duplicate testing for those licensees that choose to adopt the revised national standard. The proposed rule changes would neither require facility licensees to adopt a newly revised version of the national consensus standard, nor would it require facility licensees to modify existing simulator support programs or practices. The proposed rule changes would not impose additional burden or increase the risks to the health and safety of any segment of the nuclear industry or the public.

The proposed rule would allow facility licensees to voluntarily adjust their performance test programs consistent with end-user needs as defined by their accredited systems-approach-to-training (SAT) programs or to voluntarily conform existing simulation facility programs to new revisions of ANSI/ANS-3.5. Facility licensees' plant-referenced simulators are continually in the update and maintenance mode of their life-cycle as new computer technology and new plant information is incorporated into the simulation facility. Earlier revisions of the national consensus standard were not intended for today's highly technical, very complex, and sophisticated computer simulation programs that routinely encompass verification, validation, and documentation of a simulator's performance. Identification and resolution of discrepancies are a function of the licensees discrepancy reporting and resolution practices. The proposed rule and associated proposed Regulatory Guide 1.149, "Nuclear Power Simulation Facilities for Use in License Examinations," which would endorse ANSI/ANS-3.5-1998 without exception, would reduce apparent inconsistencies between the operational needs of facility licensee programs and simulator testing requirements, thereby relieving unnecessary regulatory burden and freeing resources for more effective developmental and validation testing associated with either simulator modification programs or the operator licensing training and examination processes.

Subpart F—Licenses

Conforming Changes to § 55.59, Requalification

As a result of the proposed changes to § 55.45(b) that would eliminate the simulator certification requirement, a

conforming change to § 55.59(c)(4)(iv) is proposed that would delete the terms “certified or approved” when referring to a simulation facility in this section.

Section-by-Section Analysis

Subpart D—Revisions To Allow Performance of Control Manipulations on the Plant-Referenced Simulator

The proposed rule would add a statement that “The Commission may accept evidence of satisfactory performance of control manipulations as part of a Commission-approved training program by a trainee on a plant-referenced simulator acceptable to the Commission under Section 55.45(b) of this part in lieu of use of the actual plant. Control manipulations performed on the simulator may be chosen from a representative sampling of the control manipulations and plant evolutions described in Section 55.59(c)(3)(A–F), (R), (T), (W), and (X) of this part, as applicable to the design of the plant for which the license application is submitted.”

By providing an option for licensee to use plant-referenced simulators for control manipulations, the proposed rule obviates the need for current provisions in Section 55.31(a)(5) addressing the use of simulators for performance of control manipulations for facilities that have not yet completed pre-operational testing and initial startup test programs and provisions addressing plants in extended shutdowns. Thus those provisions are removed.

Subpart E—Remove Current Requirements for Simulator Certification and Routine Submittal of Performance Test Reports

10 CFR 55.45(b) provides regulations associated with the implementation and use of simulation facilities in operator licensing. Section 55.45(b)(1) addresses “Administration” of the operating test on a simulation facility. Section 55.45(b)(2) addresses “Schedule for facility licensees” with respect to submitting a plan by which its simulation facility will be developed and by which an application will be submitted for its use. Section 55.45(b)(3) addresses “Schedule for facility applicants” with respect to submitting a plan which identifies whether its simulation facility will conform with paragraph (b)(1)(i) or (b)(1)(ii) of this section at the time of application. Section 55.45(b)(4) addresses “Application for and approval of simulation facilities” with respect to using a simulation facility that is other than solely a plant-referenced simulator

as defined in § 55.4. Section 55.45(b)(5) addresses “Certification of simulation facilities” with respect to those facility licensees which propose, in accordance with paragraph (b)(1)(ii) of this section, to use a simulation facility consisting solely of a plant-referenced simulator. Facility licensees have communicated to the NRC and the NRC agrees that some or portions of the rule provisions discussed and identified in this paragraph are unnecessarily burdensome.

Section 55.45(b)(1)(ii) requires that, “A simulation facility consisting solely of a plant-reference simulator which has been certified to the Commission” be used in administering the operating test. The proposed rule would eliminate the requirement for certification of the simulation facility and more appropriately refer to the definition of a simulation facility as described in § 55.4.

Section 55.45(b)(2) discusses, “Schedule for facility licenses.” The proposed rule would eliminate this outdated item in its entirety.

Section 55.45(b)(2)(i) requires that, “Within one year after the effective date of this part, each facility licensee which proposes to use a simulation facility pursuant to paragraph (b)(1)(i) of this section, except test and research reactors, shall submit a plan by which its simulation facility will be developed and by which an application will be submitted for its use” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(2)(ii) requires that, “Those facility licensees which propose to conform with paragraph (b)(1)(i) of this section, not later than 42 months after the effective date of this rule, shall submit an application for use of this simulation facility to the Commission, in accordance with paragraph (b)(4)(i) of this section” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(2)(iii) requires that, “Those facility licensees which propose to conform with paragraph (b)(1)(ii) of this section, not later than 46 months after the effective date of this rule, shall submit a certification for use of this simulation facility to the Commission on Form NRC-474, “Simulation Facility Certification,” available from Records and Reports Management Branch, Division of Information Support Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555, in accordance with paragraph (b)(5)(i) of this section.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(2)(iv) requires that, “The simulation facility portion of the operating test will not be administered on other than a certified or an approved simulation facility after May 26, 1991.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(3) discusses, “Schedule for facility applicants.” The proposed rule would eliminate this outdated item in its entirety.

Section 55.45(b)(3)(i) requires that, “For facility licensee applications after the effective date of this rule, except test and research reactors, the applicant shall submit a plan which identifies whether its simulation facility will conform with paragraph (b)(1)(i) or (b)(1)(ii) of this section at the time of application.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(3)(ii) requires that, “Those applicants which propose to conform with paragraph (b)(1)(i) of this section, not later than 180 days before the date when the applicant proposes that the Commission conduct operating tests, shall submit an application for use of its simulation facility to the NRC, in accordance with paragraph (b)(4)(i) of this section.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(3)(iii) requires that, “Those applicants which propose to conform with paragraph (b)(1)(ii) of this section, not later than 60 days before the date when the applicant proposes that NRC conduct operating tests, shall submit a certification for use of its simulation facility to the Commission on Form NRC-474, in accordance with paragraph (b)(5)(i) of this section.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(4) requires that, “Application for and approval of simulation facilities. Those facility licensees which propose, in accordance with paragraph (b)(1)(i) of this section, to use a simulation facility that is other than solely a plant-referenced simulator as defined in § 55.4 shall—” The proposed rule would eliminate in its entirety this requirement and replace it with language to address “Commission-approved simulation facilities” whereby the Commission would approve a simulation facility if it finds that the simulation facility and its proposed use are suitable for the conduct of operating test for the facility licensee’s reference plant, in accordance with paragraph (a) of this section.

Section 55.45(b)(4)(i) requires that, “In accordance with the plan submitted pursuant to paragraph (b)(2)(i) or (b)(3)(i) of this section, as applicable,

submit an application for approval of the simulation facility to the Commission, in accordance with the schedule in paragraph (b)(2)(ii) or (b)(3)(ii) of this section, as appropriate. This application must include:” The proposed rule would eliminate the phrases “In accordance with the plan submitted pursuant to paragraph (b)(2)(i) or (b)(3)(i) of this section, as applicable” and “ * * * in accordance with the schedule in paragraph (b)(2)(ii) or (b)(3)(ii) of this section, as appropriate.” and replace its language to address those facility licensees that propose, in accordance with paragraph (b)(1)(i) of this section, to use a simulation facility that is other than solely a plant-referenced simulator as defined in § 55.4 and to also submit an application for approval of the simulation facility to the Commission that include certain items as described in § 55.45(b)(2)(i)(A), (B), and (C).

Section 55.45(b)(4)(i)(A) requires that, “A statement that the simulation facility meets the plan submitted to the Commission pursuant to paragraph (b)(2)(i) or (b)(3)(i) of this section, as applicable;” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(4)(ii) requires that, “The Commission will approve a simulation facility if it finds that the simulation facility and its proposed use are suitable for the conduct of operating tests for the facility licensee’s reference plant, in accordance with paragraph (a) of this section.” The proposed rule would eliminate in its entirety this requirement and replace it with language applicable to those facility licensees which use a plant-referenced simulator to establish prerequisites for operator license eligibility in accordance with § 55.31(a)(5) and to provide in addition to existing performance testing required for significant control manipulations which affect reactivity; that simulator models relating to nuclear and thermal-hydraulic characteristics replicate the core load that exist in the nuclear power unit for which a license is being sought at the time of the applicants’s operating test and that simulator fidelity has been demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

Section 55.45(b)(4)(iii) requires that facility licensees, “Submit, every four years on the anniversary of the application, a report to the Commission which identifies any uncorrected performance test failures, and submit a

schedule for correction of these performance test failures, if any.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(4)(iv) requires that facility licensees, “Retain the results of the performance test conducted until four years after the submittal of the application under paragraph (b)(4)(i), each report pursuant to paragraph (b)(4)(iii), or any reapplication under paragraph (b)(4)(iv) of this section, as appropriate.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(4)(v) requires that, “If the Commission determines, based upon the results of performance testing, that an approved simulation facility does not meet the requirements of this part, the simulation facility may not be used to conduct operating tests.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(4)(vi) requires that, “If the Commission determines, pursuant to paragraph (b)(4)(v) of this section, that an approved simulation facility does not meet the requirements of this part, the facility licensee may again submit an application for approval. This application must include a description of corrective actions taken, including results of completed performance testing as required for approval.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(4)(vii) requires that, “Any application or report submitted pursuant to paragraphs (b)(4)(i), (b)(4)(iii) and (b)(4)(vi) of this section must include a description of the performance testing completed for the simulation facility, and must include a description of performance tests, if different, to be conducted on the simulation facility during the subsequent four-year period, and a schedule for the conduct of approximately 25 percent of the performance tests per year for the subsequent four years.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(5), “Certification of simulation facilities” requires that, “Those facility licensees which propose, in accordance with paragraph (b)(1)(ii) of this section, to use a simulation facility that is other than solely a plant-referenced simulator as defined in § 55.4 shall—.” The proposed rule would eliminate in its entirety this requirement and replace it with language to address “Acceptability of simulation facilities” such that facility licensees which maintain a simulation facility for the conduct of operating test shall conform

to the revised proposed rule and to provide assurance that approved or certified simulation facilities remain acceptable over a period time to meet the requirements paragraph (a) of this section.

Section 55.45(b)(5)(i) requires that facility licensees, “Submit a certification to the Commission that the simulation facility meets the Commission’s regulations. The facility licensee shall provide this certification on Form NRC 474 in accordance with the schedule in paragraph (b)(2)(iii) or (b)(3)(iii) of this section, as applicable.” The proposed rule would eliminate in its entirety this requirement.

Section 55.45(b)(5)(ii) requires that facility licensees, “Submit, every four years on the anniversary of the certification, a report to the Commission which identifies any uncorrected performance test failures, and submit a schedule for correction of such performance test failures, if any.” The proposed rule would partially eliminate this requirement. The facility licensee would have to make available for NRC review, prior to or concurrent with preparations for each operator licensing operating test or requalification program inspection results of any uncorrected performance test failures that will exist at the time of the operating test or requalification program inspection.

Section 55.45(b)(5)(iii) requires that facility licensees, “Retain the results of the performance test conducted until four years after the submittal of certification under paragraph (b)(5)(i), each report pursuant to paragraph (b)(5)(ii), or recertification under paragraph (b)(5)(v) of this section, as applicable.” The proposed rule would revise the rule to require facility licensees to provide recurring assurance of fidelity by performance testing throughout the life of the simulation facility consistent with paragraphs 55.45(b)(2)(ii) and 55.45(b)(3)(i)(B) and only retain the results of performance test conducted for four years or until superseded by updated test results. The proposed rule would require the inclusion of provisions for maintaining examination and test integrity consistent with § 55.49.

Section 55.45(b)(5)(iv) requires that, “If the Commission determines, based upon the results of performance testing, that a certified simulation facility does not meet the requirements of this part, the simulation facility may not be used to conduct operating tests.” The proposed rule revises the language such that if the Commission determines, based upon the results of pre-examination scenario validation, a review of performance testing results, or

uncorrected modeling or hardware discrepancies, that a simulation facility consisting solely of a plant-referenced simulator does not meet the requirements of this part as defined in § 55.4 or the criteria in § 55.45(b)(2)(ii), then the plant-referenced simulator may not be used to conduct operating tests, requalification, or control manipulations as described in §§ 55.31(a), 55.45(b)(1), and 55.59(c)(3) of this part. Facility licensees proposing to use simulation facilities meeting the definition in § 55.4 of a plant-referenced facility would not be required to submit an application for Commission approval.

Section 55.45(b)(5)(v) requires that, "If the Commission determines, pursuant to paragraph (b)(5)(iv) of this section, that a certified simulation facility does not meet the requirements of this part, the facility licensee may submit a recertification to the Commission on Form NRC-474. This recertification must include a description of corrective actions taken, including results of completed performance testing as required for recertification." The proposed rule eliminates this provision.

Section 55.45(b)(5)(vi) requires that, "Any certification report, or recertification submitted pursuant to paragraph (b)(5)(i), (b)(5)(ii) or (b)(5)(v) of this section must include a description of performance testing completed for the simulation facility, and must include a description of the performance tests, if different, to be conducted on the simulation facility during the subsequent four-year period, and a schedule for the conduct of approximately 25 percent of the performance tests per year for the subsequent four years." The proposed rule would eliminate in its entirety this requirement.

The proposed rule requirements associated with the implementation and use of simulation facilities would significantly reduce unnecessary burden for facility licensees and the NRC. The proposed rule would allow facility licensees greater flexibility to adjust their performance test programs consistent with user needs as defined by their accredited training programs, and encourage implementation of improved revisions of the national standard which, as endorsed by the NRC, would improve focus on the training and examination environment in which the plant-referenced simulator is used. In addition, the proposed rule would allow facility licensees to reduce cost.

Since § 55.45(b) was last revised on March 25, 1987 (52 FR 9453), facility licensees have continually improved

and implemented sophisticated simulator modeling and replaced outdated computer hardware to ensure that operator and senior operator applicants as well as licensed operators are trained and qualified on a plant-referenced simulator.

Subpart A—Revisions of § 55.4 Definitions

Section 55.4 defines performance testing as "Performance testing means testing conducted to verify a simulation facility's performance as compared to actual or predicted reference plant performance." The proposed rule would redefine performance testing as "Performance testing means validation, scenario-based, or operability testing conducted to verify a simulation facility's performance as compared to actual or predicted reference plant performance."

Section 55.4 defines plant-referenced simulator as "Plant-referenced simulator means a simulator modeling the systems of the reference plant with which the operator interfaces in the control room, including operating consoles, and which permits use of the reference plant's procedures. A plant-referenced simulator demonstrates expected plant response to operator input, and to normal, transient, and accident conditions to which the simulator has been designed to respond." The proposed rule would enhance the definition of plant-referenced simulator as "Plant-referenced simulator means a simulator modeling the systems of the reference plant with which the operator interfaces in the control room, including operating consoles, and which permits use of the reference plant's procedures. A plant-referenced simulator demonstrates expected plant response to operator input, and to normal, transient, and accident conditions to which the simulator has been designed to respond. A plant-referenced simulator is designed, implemented, and maintained such that it: (1) Is sufficient in scope and fidelity to allow conduct of the evolutions listed in paragraphs 55.45(a)(1) through (13), and 55.59(c)(3)(i)(A) through (AA), as applicable to the design of the reference unit; (2) allows for the completion of on-the-job training experience prerequisites for license operator eligibility consistent with paragraph 55.45(b)(2)(ii)."

Section 55.4 defines simulation facility as "Simulation facility means one or more of the following components, alone or in combination, used for the partial conduct of operating tests for operators, senior operators, and candidates: (1) The plant, (2) a plant-referenced simulator, (3) another

simulation device." The proposed rule would update the definition of simulation facility to "Simulation facility means one or more of the following components, alone or in combination, used for the partial conduct of operating tests for operators, senior operators, and license applicants: (1) The plant, (2) a plant-referenced simulator, (3) a Commission-approved simulator in accordance with § 55.45(b)(2), (4) another simulation device, including part-task and limited scope simulation devices."

Subpart A—General Provisions, § 55.8 Information Collection Requirements: OMB Approval

Section 55.8(c)(3) identifies the information collection requirement and the control number under which the requirement is approved for NRC Form 474, "Simulation Facility Certification," OMB approval No. 3150-0138. If adopted, the proposed rule would eliminate the need for the certification form.

Section 55.8(c)(4) would be deleted because its requirements have been incorporated into this 10 CFR part.

Subpart F—Licenses, § 55.59, Requalification

Section 55.59(c)(4)(iv) requires that, "* * * After the provisions of § 55.45(b) have been implemented at a facility, the certified or approved simulation facility must be used to comply with this paragraph." The proposed rule would eliminate the words "certified or approved" as a result of eliminating the certification requirement as described in the proposed rule § 55.45(b).

Issues for Public Comment

Comments concerning the content, level of detail specified, and the implementation of the proposed amendments are encouraged. Suggestions of alternatives other than those described in this notice and estimates of cost for implementation are encouraged. Because the intent of the proposed rule changes to § 55.31(a)(5) and § 55.45(b)(1) is to reduce unnecessary regulatory burden by providing acceptable methods to comply with the Commission's regulations, the NRC is particularly interested in receiving from the public comments on the following issues related to this proposed rule:

1. Are there rulemaking alternatives to this proposed rule that were not considered in the regulatory analysis for this proposed rule?
2. Are the revised definitions as used in § 55.4 clearly defined?

3. Would the revised requirements permitting control manipulations to be performed on a plant-referenced simulator as prescribed in § 55.31(a)(5) reduce unnecessary regulatory burden associated with establishing license eligibility for operators and senior operators and yet continue to maintain safety by ensuring that experience gained on the simulator essentially replicates that obtained from control manipulations on the plant?

4. Would the revised requirements in § 55.45 to eliminate the need for certification of simulation facilities and duplicate testing and reporting requirements accomplish their intended purpose of eliminating unnecessary regulatory burden?

5. Would the proposed NRC reviews of simulators ensure requisite simulator suitability to support effective training and operator performance assessment and thereby maintain plant safety?

Related Regulatory Activity

NRC Endorsement of ANSI/ANS 3.5–1998

The NRC staff has reviewed ANSI/ANS 3.5–1998 with respect to the revision of Regulatory Guide 1.149, “Nuclear Power Plant Simulation Facilities for Use in License Examinations.” The 1998 revision of the standard was developed with full NRC participation and insight. Accordingly, the staff believes that those testing and fidelity concerns that have required exceptions and clarifications in the regulatory positions of the previous revisions of Regulatory Guide 1.149, are adequately addressed in this latest revision of the standard. The staff further believes that industry’s concerns have been addressed in this latest revision of the standard. As noted in the introductory paragraph to the standard, “the consensus committee was balanced to ensure that competent, concerned, and varied interests have had an opportunity to participate.” The staff is considering endorsing ANSI/ANS 3.5–1998 without the exceptions or clarifications that have characterized NRC’s endorsement of previous revisions.

The staff published in the **Federal Register** for public comment a notice of availability of Draft Guide DG–1080 (proposed Revision 3 of Regulatory Guide 1.149) on August 23, 1999 (64 FR 162). The public comment period closed on November 12, 1999. NRC Form 474 and the associated OMB clearance will also be modified to reflect NRC’s endorsement of the 1998 revision of the standard upon final issuance of Regulatory Guide 1.149 and final

Commission action on changes described in this proposed rule.

Facility licensees would not be required to automatically adopt the new standard. The 1993 revision is still recognized by ANS, and the 1985 revision is considered to be a “historical” standard. Simultaneous endorsement of more than one version of the standard is consistent with both the NRC policy of evaluating the latest version of national consensus standards in terms of their suitability for endorsement by regulations or regulatory guides and the established regulatory position regarding simulators, allowing industry to establish recommended and required capabilities and acceptability criteria.

Referenced Documents

Copies of SECY–99–0225, DG–1080 (Proposed Revision 3 to Regulatory Guide 1.149), NRC Form 474, NUREG–1262, NUREG–1258, and NUREG–1021 are available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Plain Language

The Presidential memorandum dated June 1, 1998, entitled, “Plain Language in Government Writing,” directed the government’s writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in this proposed amendment to improve readability of the existing language of the provisions being revised. These types of changes are not discussed further in this document. The NRC requests comment on the proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** caption of the preamble.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for

review and approval of the paperwork requirements.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by 120 hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for further reducing the burden, to the Records Management Branch (T–6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0138), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by August 2, 2000. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

National Technology Transfer and Advancement Act Statement

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise

impractical. Regulatory Guide 1.149 describes an acceptable method by which facility licensees might implement specific parts of this proposed rule and references the 1985, 1993, and 1998, revisions of voluntary standard American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.5, "Nuclear Power Plant Simulators for Use in Operator Training and Examination."

Comments are being solicited, particularly with respect to effects of application of ANSI/ANS 3.5-1998 on existing simulator support and operator training programs and perceived compatibility with the proposed regulations. Comments are also being solicited with respect to applicability of earlier versions of ANSI/ANS 3.5 or applicability of standards and guidance other than ANSI/ANS 3.5 for use in training and examination of operators at nuclear power plants.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC. Single copies of the analysis may be obtained from the Branch Chief, Operator Licensing, Human Performance and Plant Support Branch, Office Nuclear Reactor Regulation, U.S. Regulatory Commission, at 301-415-3173 or by e-mail at jfc@nrc.gov. The Commission requests public comment on the regulatory analysis. Comments on the analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this

proposed rule; therefore, a backfit analysis is not required for this proposed rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in Part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Part 55.

PART 55—OPERATOR'S LICENSES

1. The authority citation for Part 55 continues to read as follows:

Authority: Secs. 107, 161, 182, 68 Stat. 939, 948, 953, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2137, 2201, 2232, 2282); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Sections 55.41, 55.43, 55.45, and 55.59 also issued under sec. 306, Pub. L. 97-425, 96 Stat. 2262 (42 U.S.C. 10226). Section 55.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237).

2. In § 55.4, the terms "Performance testing," "Plant-referenced simulator," and "Simulation facility," are revised to read as follows:

§ 55.4 Definitions.

* * * * *

Performance testing means validation, scenario-based, or operability testing conducted to verify a simulation facility's performance as compared to actual or predicted reference plant performance.

* * * * *

Plant-referenced simulator means a simulator modeling the systems of the reference plant with which the operator interfaces in the control room, including operating consoles, and which permits use of the reference plant's procedures. A plant-referenced simulator demonstrates expected plant response to operator input, and to normal, transient, and accident conditions to which the simulator has been designed to respond. A plant-referenced simulator is designed and implemented such that it:

(1) Is sufficient in scope and fidelity to allow conduct of the evolutions listed in §§ 55.45(a)(1) through (13), and 55.59(c)(3)(i)(A) through (AA), as applicable to the design of the reference unit, and

(2) Allows for the completion of on-the-job training experience prerequisites for licensed operator applicant eligibility consistent with § 55.45(b)(3)(i).

* * * * *

Simulation facility means one or more of the following components, alone or in combination, used for the partial conduct of operating tests for operators, senior operators, and license applicants, or to establish on-the-job training experience prerequisites for operator license eligibility:

- (1) The plant;
- (2) A plant-referenced simulator;
- (3) A Commission-approved simulator in accordance with § 55.45(b)(2); and
- (4) Another simulation device, including part-task and limited scope simulation devices.

* * * * *

3. In § 55.8, paragraphs (c)(3) and (c)(4) are removed and paragraph (b) is revised to read as follows:

§ 55.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 55.11, 55.23, 55.25, 55.27, 55.31, 55.35, 55.40, 55.41, 55.43, 55.45, 55.47, 55.53, 55.57, and 55.59.

* * * * *

4. In § 55.31, paragraph (a)(5) is revised to read as follows:

§ 55.31 How to apply.

(a) * * *

(5) Provide evidence that the applicant, as a trainee, has successfully manipulated the controls of the facility for which a license is sought. At a minimum, five significant control manipulations must be performed that affect reactivity or power level. Evidence of satisfactory performance of control manipulations may be demonstrated on a plant-referenced simulator that meets the requirements of § 55.45(b)(3). Control manipulations performed on the simulator may be chosen from a representative sampling of the control manipulations and plant evolutions described in § 55.59(c)(3)(A-F), (R), (T), (W), and (X) of this part, as applicable to the design of the plant for which the license application is submitted. For licensed operators applying for a senior operator license, certification that the operator has successfully operated the controls of the facility as a licensed operator shall be accepted; and

* * * * *

5. In § 55.45, paragraph (b) is revised to read as follows:

§ 55.45 Operating tests.

* * * * *

(b) *Implementation*—(1)

Administration. The operating test will be administered in a plant walkthrough and in either—

(i) A simulation facility which the Commission has approved for use after application has been made by the facility licensee; or

(ii) A plant-referenced simulator as defined in § 55.4.

(2) *Commission-approved simulation facilities.* (i) Facility licensees who

propose to use a simulation facility in the administration of the operating test in accordance with paragraph (b)(1)(i) of this section, shall submit an application for approval of the simulation facility to the Commission. This application must include:

(A) A description of the components of the simulation facility that are intended to be used for each part of the operating test, unless previously approved;

(B) A description of the performance tests as part of the application, and the results of these tests; and

(C) A description of the procedures for maintaining examination and test integrity consistent with the requirements of § 55.49.

(ii) The Commission will approve a simulation facility if it finds that the simulation facility and its proposed use are suitable for the conduct of operating tests for the facility licensee's reference plant under paragraph (a) of this section.

(3) *Plant-referenced simulators.* (i) Facility licensees which propose to use a plant-referenced simulator to meet the experience requirements in § 55.31(a)(5) must ensure that:

(A) The plant-referenced simulator uses models relating to nuclear and thermal-hydraulic characteristics that replicate the core load that exists in the nuclear power unit for which a license is being sought at the time of the applicant's operating test; and

(B) Simulator fidelity has been demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(ii) If the Commission determines that a simulation facility consisting solely of a plant-referenced simulator does not meet either the definition of a plant-referenced simulator as defined in § 55.4, or the criteria in § 55.45(b)(4)(A) and (D), the Commission will not accept

the plant-referenced simulator for conducting operating tests as described in § 55.45(b)(1) of this part, requalification training as described in § 55.59(c)(3) of this part, or performing control manipulations that affect reactivity to establish eligibility for an operator's license as described in § 55.31(a)(5).

(4) *Continued assurance of simulator fidelity.* Facility licensees that maintain a simulation facility shall:

(A) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to assure that the criteria of paragraphs 55.45(b)(4)(C) and 55.45(b)(3)(i)(B) as applicable, are met. The results of performance tests must be retained for four years after the completion of each performance test or until superseded by updated test results;

(B) Correct scenario validation, performance test, modeling, and hardware discrepancies;

(C) Make available for NRC review, before or concurrent with preparations for each operator licensing operating test or requalification program inspection, results of any uncorrected performance test failures that may exist at the time of the operating test or requalification program inspection; and

(D) Maintain the provisions for examination and test integrity consistent with § 55.49.

* * * * *

6. In § 55.59, paragraph (c)(4)(iv) is revised to read as follows:

§ 55.59 Requalification.

* * * * *

(c) * * *

(4) * * *

(iv) Simulation of emergency or abnormal conditions that may be accomplished by using the control panel of the facility involved or by using a simulator. Where the control panel of the facility is used for simulation, the actions taken or to be taken for the emergency or abnormal condition must be discussed; actual manipulation of the plant controls is not required. If a simulator is used in meeting the requirements of paragraph (c)(4)(iii) of this section, it must accurately reproduce the operating characteristics of the facility involved and the arrangement of the instrumentation and controls of the simulator must closely parallel that of the facility involved. After the provisions of § 55.45(b) have been implemented at a facility, the simulation facility must be used to comply with this paragraph.

* * * * *

Dated at Rockville, Maryland, this 27th day of June, 2000.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 00-16751 Filed 6-30-00; 8:45 am]

BILLING CODE 7590-01-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00N-1351]

Food Labeling; Use of the Term "Fresh" for Foods Processed With Alternative Nonthermal Technologies; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the use of the term "fresh" in the labeling of foods processed with alternative nonthermal technologies. The purpose of the meeting is to determine whether the use of the term "fresh" is truthful and not misleading on foods processed with these alternative technologies and to determine what type of criteria FDA should use when considering the use of the term with future technologies.

DATES: The public meeting will be held on July 21, 2000, from 8:30 a.m. to 4 p.m. Please preregister by July 14, 2000. Late registrations will be accepted contingent on space availability. Comments must be submitted no later than August 21, 2000.

ADDRESSES: The meeting will be held at the Holiday Inn City Centre, 300 East Ohio St., Chicago, IL, 312-787-6100.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or on the FDA website at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

FOR FURTHER INFORMATION CONTACT:

For registration: Kimberly Phillips or Darlene M. Bailey, Office of Public Affairs (HFR-CE645), Food and Drug Administration, 300 South Riverside Plaza, suite 550 South, Chicago, IL 60606, 312-353-7126 or FAX 312-886-3280.