

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS ...

§ 2.108 Denial of application for failure to supply information.

(a) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, may deny an application if an applicant fails to respond to a request for additional information within thirty (30) days from the date of the request, or within such other time as may be specified.

(b) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will cause to be published in the **FEDERAL REGISTER** a notice of denial when notice of receipt of the application has previously been published, but no notice of hearing has yet been published. The notice of denial will provide that, within thirty (30) days after the date of publication in the **FEDERAL REGISTER** (1) the applicant may demand a hearing, and (2) any person whose interest may be affected by the proceeding may file a petition for leave to intervene.

(c) When both a notice of receipt of the application and a notice of hearing have been published, the presiding officer, upon a motion made by the staff pursuant to § 2.730, will rule whether an application should be denied by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, pursuant to paragraph (a).

§ 2.109 Effect of timely renewal application.

(a) Except for the renewal of an operating license for a nuclear power plant under 10 CFR 50.21(b) or 50.22, if, at least 30 days prior to the expiration of an existing license authorizing any activity of a continuing nature, the licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 50.22 files a sufficient application for renewal of an operating license at least 5 years prior to the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

§ 2.110 Filing and administrative action on submittals for design review or early review of site suitability issues.

(a)(1) A submittal pursuant to Appendix O of Part 52 of this chapter shall be subject to §§ 2.101(a) and 2.790 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of Appendix Q to Part 52 of this chapter, a submittal pursuant to Appendix Q shall be subject to § 2.101(a) (2) through (4) to the same extent as if it were an application for a permit or license.

(b) Upon initiation of review by the staff of a submittal of a type described in paragraph (a)(1) of this section, the Director of Nuclear Reactor Regulation shall publish in the **FEDERAL REGISTER** a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or such other time as may be specified, for consideration by the staff and ACRS in their review.

(c) Upon completion of review by the NRC staff and the ACRS of a submittal of the type described in paragraph (a)(1) of this section, the Director of the Office of Nuclear Reactor Regulation shall publish in the **Federal Register** a determination as to whether or not the design is acceptable, subject to conditions as may be appropriate, and shall make available at the NRC Web site, <http://www.nrc.gov>, a report that analyzes the design.

§ 2.111 Prohibition of sex discrimination.

No person shall on the ground of sex be excluded from participation in, be denied a license under, be denied the benefits of, or be subjected to discrimination under any program or activity carried on or receiving Federal assistance under the Act or the Energy Reorganization Act of 1974.

Subpart B—Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties

§ 2.200 Scope of subpart.

(a) This subpart prescribes the procedures in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, or to take other action as may be proper, against any person subject to the jurisdiction of the Commission. However, with regard to the holder of a part 76 certificate of compliance or compliance plan, except for civil penalty procedures in this subpart, the applicable procedures are set forth in § 76.70 of this chapter.

(b) This subpart also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to section 234 of the Act and section 206 of the Energy Reorganization Act of 1974.

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§ 2.201 Notice of violation.

(a) In response to an alleged violation of any provision of the Act or this chapter or the conditions of a license or an order issued by the Commission, the Commission may serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation; a separate notice may be omitted if an order pursuant to § 2.202 or demand for information pursuant to § 2.204 is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation and may require that the licensee or other person submit, within 20 days of the date of the notice or other specified time, a written explanation or statement in reply if the Commission believes that the licensee has not already addressed all the issues contained in the notice of violation, including:

- (1) Corrective steps which have been taken by the licensee or other person and the results achieved;
- (2) Corrective steps which will be taken; and
- (3) The date when full compliance will be achieved.

(b) The notice may require the licensee or other person subject to the jurisdiction of the Commission to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the Commission may issue an order or a demand for information as to why the license should not be modified, suspended or revoked or why such other action as may be proper should not be taken.

§ 2.202 Orders.

(a) The Commission may institute a proceeding to modify, suspend, or revoke a license or to take such other action as may be proper by serving on the licensee or other person subject to the jurisdiction of the Commission an order that will:

- (1) Allege the violations with which the licensee or other person subject to the Commission's jurisdiction is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the proposed action, and specify the action proposed;
- (2) Provide that the licensee or other person must file a written answer to the order under oath or affirmation within twenty (20) days of its date, or such other time as may be specified in the order;
- (3) Inform the licensee or any other person adversely affected by the order of his or her right, within twenty (20) days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the licensee or other person has consented in writing to the order;

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(4) Specify the issues for hearing; and
(5) State the effective date of the order; if the Commission finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

(b) A licensee or other person to whom the Commission has issued an order under this section must respond to the order by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order, and shall set forth the matters of fact and law on which the licensee or other person relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph (d) of this section, the answer may demand a hearing.

(c) If the answer demands a hearing, the Commission will issue an order designating the time and place of hearing.

(1) If the answer demands a hearing with respect to an immediately effective order, the hearing will be conducted expeditiously, giving due consideration to the rights of the parties.

(2) (i) The licensee or other person to whom the Commission has issued an immediately effective order may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the order on the ground that the order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. The motion must state with particularity the reasons why the order is not based on adequate evidence and must be accompanied by affidavits or other evidence relied on. The NRC staff shall respond within (5) days of the receipt of the motion. The motion must be decided by the presiding officer expeditiously. During the pendency of the motion or at any other time, the presiding officer may not stay the immediate effectiveness of the order, either on its own motion, or upon motion of the licensee or other person. The presiding officer will uphold the immediate effectiveness of the order if it finds that there is adequate evidence to support immediate effectiveness. An order upholding immediate effectiveness will constitute the final agency action on

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immediate effectiveness. An order setting aside immediate effectiveness will be referred promptly to the Commission itself and will not be effective pending further order of the Commission.

(ii) The presiding officer may, on motion by the staff or any other party to the proceeding, where good cause exists, delay the hearing on the immediately effective order at any time for such periods as are consistent with the due process rights of the licensee and other affected parties.

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(d) An answer may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the licensee or other person to whom the order has been issued to the entry of an order shall constitute a waiver by the licensee or other person of a hearing, findings of fact and conclusions of law, and of all right to seek Commission and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the Commission, and shall be effective as provided in the order.

(e) If the order involves the modification of a part 50 license and is a backfit, the requirements of § 50.109 of this chapter shall be followed, unless the licensee has consented to the action required.

38 FR 2330

§ 2.203 Settlement and compromise.

At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke a license or for other action, the staff and a licensee or other person may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the Chief Administrative Law Judge, according due weight to the position of the staff. The presiding officer, or if none has been designated, the Chief Administrative Law Judge, may order such adjudication of the issues as he may deem to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

§ 2.204 Demand for information.

(a) The Commission may issue to a licensee or other person subject to the jurisdiction of the Commission a demand for information for the purpose of determining whether an order under § 2.202 should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the licensee or other person is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the licensee must, or the other person may, file a written answer to the demand for information under oath or affirmation within twenty (20) days of its date, or such other time as may be specified in the demand for information.

(b) A licensee to whom the Commission has issued a demand for information under this section must respond to the demand by filing a written answer under oath or affirmation; any other person to whom the Commission has issued a demand for information may, in its discretion, respond to the demand by filing a written answer under oath or affirmation. The licensee's answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described

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above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

(c) Upon review of the answer filed pursuant to paragraph (a)(2) of this section, or if no answer is filed, the Commission may institute a proceeding pursuant to 10 CFR 2.202 to take such action as may be proper.

(d) An answer may consent to the entry of an order pursuant to § 2.202 in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in § 2.202(d).

§ 2.205 Civil penalties.

(a) Before instituting any proceeding to impose a civil penalty under section 234 of the Act, the Executive Director for Operations or the Executive Director's designee, as appropriate, shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to § 2.201 or § 76.70(d) of this chapter. The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, part 76 certificate of compliance or compliance plan, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Commission, if any, unless compromised, remitted, or mitigated, be collected by civil action, pursuant to Section 234c of the Act.

(b) Within twenty (20) days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

(c) If the person charged with violation fails to answer within the time specified in paragraph (b) of this section, an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in paragraph (a) of this section.

(d) If the person charged with violation files an answer to the notice of violation, the Executive Director for Operations or the Executive Director's designee, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within twenty (20) days of the date of the order or other time specified in the order, request a hearing.

(e) If the person charged with violation requests a hearing, the Commission will issue an order designating the time and place of hearing.

(f) If a hearing is held, an order will be issued after the hearing by the presiding officer or the Commission dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

(g) The Executive Director for Operations or the Executive Director's designee, as appropriate may compromise any civil penalty, subject to the provisions of § 2.203.

(h) If the civil penalty is not compromised, or is not remitted by the Executive Director for Operations or the Executive Director's designee, as appropriate, the presiding officer, or the Commission, and if payment is not made within ten (10) days following either the service of the order described in paragraph (c) or (f) of this section, or the expiration of the time for requesting a hearing described in paragraph (d) of this section, the Executive Director for Operations or the Executive Director's designee, as appropriate, may refer the matter to the Attorney General for collection.

(i) Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the United States, following reference of the matter to the Attorney General for collection, payment of civil penalties imposed under Section 234 of the Act are to be made payable to the U.S. Nuclear Regulatory Commission, in U.S. funds, by check, draft, money order, credit card, or electronic funds transfer such as Automated Clearing House (ACH) using Electronic Data Interchange (EDI). Federal agencies may also make payment by the On-Line Payment and Collections System (OPAC's). All payments are to be made in accordance with the specific payment instructions provided with Notices of Violation that propose civil penalties and Orders Imposing Civil Monetary Penalties.

(j) Amount. A civil monetary penalty imposed under Section 234 of the Atomic Energy Act of 1954, as amended, or any other statute within the jurisdiction of the Commission that provides for imposition of a civil penalty in an amount equal to the amount set forth in Section 234, may not exceed \$110,000 for each violation. If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty.

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62 FR 6664

36 FR 16894

52 FR 31601

62 FR 3664

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62 FR 6664

63 FR 31840

61 FR 53554

§ 2.206 Requests for action under this subpart.

64 FR 48942

➤ (a) Any person may file a request to institute a proceeding pursuant to § 2.202 to modify, suspend, or revoke a license, or for any other action as may be proper. Requests must be addressed to the Executive Director for Operations and must be filed either by delivery to the NRC Public Document Room at 2120 L Street, NW, Washington, DC, or by mail or telegram addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The request must specify the action requested and set forth the facts that constitute the basis for the request. The Executive Director for Operations will refer the request to the Director of the NRC office with responsibility for the subject matter of the request for appropriate action in accordance with paragraph (b) of this section.

53 FR 43419

(b) Within a reasonable time after a request pursuant to paragraph (a) of this section has been received, the Director of the NRC office with responsibility for the subject matter of the request shall either institute the requested proceeding in accordance with this subpart or shall advise the person who made the request in writing that no proceeding will be instituted in whole or in part, with respect to the request, and the reasons for the decision.

45 FR 74893

(c)(1) Director's decisions under this section will be filed with the Office of the Secretary. Within twenty-five (25) days after the date of the Director's decision under this section that no proceeding will be instituted or other action taken in whole or in part, the Commission may on its own motion review that decision, in whole or in part, to determine if the Director has abused his discretion. This review power does not limit in any way either the Commission's supervisory power over delegated staff actions or the Commission's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this section.

42 FR 36239

(2) No petition or other request for Commission review of a Director's decision under this section will be entertained by the Commission.

Subpart C [removed] 51 FR 7744

54 FR 15372

Subpart D—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Construct or Operate Nuclear Power Plants of Duplicate Design at Multiple Sites

§ 2.400 Scope of subpart.

This subpart describes procedures applicable to licensing proceedings which involve the consideration in hearings of a number of applications, filed by one or more applicants pursuant to Appendix N of Part 52 of this chapter, for licenses to construct and operate nuclear power reactors of essentially the same design to be located at different sites.

§ 2.401 Notice of hearing on applications pursuant to Appendix N of Part 52 for construction permits.

54 FR 15372

(a) In the case of applications pursuant to Appendix N of Part 52 of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 of this chapter, the Secretary will issue notices of hearing pursuant to § 2.104.

(b) The notice of hearing will also state the time and place of the hearings on any separate phase of the proceeding.

§ 2.402 Separate hearings on separate issues; consolidation of proceedings.

(a) In the case of applications pursuant to Appendix N of Part 52 of this chapter for construction permits for nuclear power reactors of a type described in § 50.22 of this chapter, the Commission or the presiding officer may order separate hearings on particular phases of the proceeding, such as matters related to the acceptability of the design of the reactor, in the context of the site parameters postulated for the design; environmental matters; or antitrust aspects of the application.

43 FR 17798

(b) If a separate hearing is held on a particular phase of the proceeding, the Commission or presiding officers of each affected proceeding may, pursuant to § 2.716, consolidate for hearing on that phase two or more proceedings to consider common issues relating to the applications involved in the proceedings, if it finds that such action will be conducive to the proper dispatch of its business and to the ends of justice. In fixing the place of any such consolidated hearing due regard will be given to the convenience and necessity of the parties, petitioners for leave to intervene or the attorneys or representatives of such persons, and the public interest.

§ 2.403 Notice of proposed action on applications for operating licenses pursuant to Appendix N of Part 52.

In the case of applications pursuant to Appendix N of Part 52 of this chapter for operating licenses for nuclear power reactors, if the Commission has not found that a hearing is in the public interest, the Director of Nuclear Reactor Regulation will, prior to acting thereon, cause to be published in the FEDERAL REGISTER, pursuant to § 2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

§ 2.404 Hearings on applications for operating licenses pursuant to Appendix N of Part 52.

54 FR 15372

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license pursuant to Appendix N of Part 52 of this chapter with respect to a specific reactor(s) at a specific site and the Commission or an atomic safety and licensing board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel has issued a notice of hearing or other appropriate order, the Commission or the atomic safety and licensing board may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in § 2.402.

§ 2.405 Initial decisions in consolidated hearings.

40 FR 2976

At the conclusion of any hearing held pursuant to this subpart, the presiding officer will render a partial initial decision which may be appealed pursuant to § 2.762. No construction permit or full power operating license will be issued until an initial decision has been issued on all phases of the hearing and all issues under the Act and the National Environmental Policy Act of 1969 appropriate to the proceeding have been resolved.

§ 2.406 Finality of decisions on separate issues.

54 FR 15372

Notwithstanding any other provision of this chapter, in a proceeding conducted pursuant to this subpart and Appendix N of Part 52 of this chapter, no matter which has been reserved for consideration in one phase of the hearing shall be considered at another phase of the hearing except on the basis of significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause.

§ 2.407 Applicability of other sections.

The provisions of Subparts A and G relating to construction permits and operating licenses apply, respectively, to construction permits and operating licenses subject to this subpart, except as qualified by the provisions of this subpart.

Subpart E—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Manufacture Nuclear Power Reactors To Be Operated at Sites Not Identified in the License Application and Related Licensing Proceedings

§ 2.500 Scope of subpart.

This subpart prescribes procedures, applicable to licensing proceedings which involve the consideration in separate hearings of an application for a license to manufacture nuclear power reactors pursuant to Appendix M of Part 52 of this chapter, and applications for construction permits and operating licenses for nuclear power reactors which have been the subject of such an application for a license to manufacture such facilities (manufacturing license).

§ 2.501 Notice of hearing on application pursuant to Appendix M of Part 52 for a license to manufacture nuclear power reactors.

(a) In the case of an application pursuant to Appendix M of Part 52 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the FEDERAL REGISTER at least thirty (30) days prior to the date set for hearing in the notice.¹ The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

- (1) The time, place, and nature of the hearing and/or the prehearing conference;
 - (2) The authority within which the hearing is to be held;
 - (3) The matters of fact and law to be considered; and
 - (4) The time within which answers to the notice shall be filed.
- (b) The issues stated in the notice of hearing pursuant to paragraph (a) of this section will not involve consideration of the particular sites at which any of the

¹The thirty (30) day requirement of this paragraph is not applicable to a notice of the time and place of hearing published by the presiding officer after the notice of hearing described in this section has been published.

nuclear power reactors to be manufactured will be located and operated. Except as the Commission determines otherwise, the notice of hearing will state:

(1) That, if the proceeding is a contested proceeding, the presiding officer will consider the following issues:²

- (i) Whether the applicant has described the proposed design of, and the site parameters postulated for, the reactor(s), including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;
- (ii) Whether such further technical

or design information as may be required to complete the design report and which can reasonably be left for later consideration, will be supplied in a supplement to the design report;

(iii) Whether safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted a research and development program reasonably designed to resolve any safety questions associated with such features or components;

(iv) Whether on the basis of the foregoing, there is reasonable assurance that (A) such safety questions will be satisfactorily resolved before any of the proposed nuclear power reactors are removed from the manufacturing site, and (B) taking into consideration the site criteria contained in Part 100 of this chapter, the proposed reactor(s) can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design of the reactor(s) without undue risk to the health and safety of the public;

(v) Whether the applicant is technically and financially qualified to design and manufacture the proposed reactor(s).

(vi) Whether the issuance of a license for manufacture of the reactor(s) will be inimical to the common defense and security or to the health and safety of the public; and

(vii) Whether, in accordance with the requirements of Subpart A of Part 51 and Appendix M of Part 52 of this chapter, the license should be issued as proposed.

²Issues (i) and (vi) are the issues pursuant to the Atomic Energy Act of 1954, as amended. Issue (vii) is the issue pursuant to the National Environmental Policy Act of 1969.

(2) That, if the proceeding is not a contested proceeding, the presiding officer will determine (i) without conducting a de novo evaluation of the application, whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's staff has been adequate to support affirmative findings on paragraphs (b)(1)(i) through (v) of this section and a negative finding on paragraph (b)(1)(vi) of this section proposed to be made and the issuance of the license to manufacture proposed by the Director of Nuclear Reactor Regulation, and (ii) whether the review conducted by the Commission pursuant to the National Environmental Policy Act (NEPA) has been adequate.

(3) That, regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with Subpart A of Part 51 and paragraph 3 of Appendix M of Part 52 of this chapter,

(i) Determine whether the requirements of section 102(2) (A), (C) and (E) of the National Environmental Policy Act and Subpart A of Part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and

(iii) Determine whether the manufacturing license should be issued, denied or appropriately conditioned to protect environmental values.

(c) The place of hearing on an application for a manufacturing license will be Washington, D.C., or such other location as the Commission deems appropriate.

§ 2.502 Notice of hearing on application for a permit to construct a nuclear power reactor manufactured pursuant to a Commission license issued pursuant to Appendix M of Part 52 of this chapter at the site at which the reactor is to be operated.

The issues stated for consideration in the notice of hearing on an application for a permit to construct a nuclear power reactor(s) which is the subject of an application for a manufacturing license pursuant to Appendix M of Part 52 of this chapter, will be those stated in § 2.104(b) and, in addition, whether the site on which the facility is to be operated falls within the postulated site parameters specified in the relevant application for a manufacturing license.