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May 9, 2001

VIA HAND DELIVERY

Mr. Mark J. Langer, Clerk
United States Court of Appeals
for the District of Columbia Circuit
U.S. Courthouse, Room 5423
333 Constitution Avenue, N.W.
Washington, DC 20001

Re: Novoste Corporation v. U.S. Nuclear Regulatory Commission
and United States of America, No. 01-1162

Dear Mr. Langer:

Enclosed for filing in the above-referenced proceeding, please find an original and four copies of the following documents on behalf of Petitioner Novoste Corporation:

- (1) Docketing Statement;
- (2) Non-Binding Statement of Issues;
- (3) Provisional Certificate of Counsel As to Parties, Rulings and Related Cases;
- (4) Statement Regarding Use of Deferred Appendix; and
- (5) Certificate of Service.

Also enclosed are two additional copies of the above-mentioned documents for date and time stamping to be returned via our courier.

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Mr. Mark J. Langer, Clerk
May 9, 2001
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With regard to procedural motions which could affect the calendaring of this case, reference is made to "Petitioner's Motion to Hold Judicial Review Proceeding in Abeyance Pending Further Action by the U.S. Nuclear Regulatory Commission," filed April 6, 2001.

Very truly yours,

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

Martin G. Malsch

Attorney for Petitioner Novoste Corporation

Enclosures

cc (w/encl.): John F. Cordes, Jr., Esq.
John Aschroft, Esq.

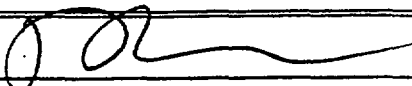
United States Court of Appeals

District of Columbia Circuit

DOCKETING STATEMENT

Administrative Agency Review Proceedings (To be completed by appellant/petitioner)

1. CASE NO. 01-1162 2. DATE DOCKETED April 6, 2001
3. CASE NAME Novoste Corporation v. U.S. Nuclear Regulatory Commission
(lead parties only)
4. TYPE OF CASE: ☒ Review ☐ Appeal ☐ Enforcement ☐ Complaint ☐ Tax Court
5. IS THIS CASE REQUIRED BY STATUTE TO BE EXPEDITED? YES ☐ NO ☒ X
If YES, cite statute: _____
6. CASE INFORMATION:
- a. Identify agency whose order is to be reviewed: U.S. Nuclear Regulatory Commission (NRC)
- b. Give agency docket or order number(s): None
- c. Give date(s) of order(s): February 5, 2001
- d. Has a request for rehearing or reconsideration been filed at the agency? YES ☐ NO ☒ X*
If so, when was it filed? _____ By whom? _____
Has the agency acted? YES ☐ NO ☐ If so, when? _____
- e. Are any other cases involving the same underlying agency order pending in this Court or in any other Court?
YES ☐ NO ☒ X If YES, identify case name(s), docket number(s), and court(s): _____
- f. Are any other cases, to counsel's knowledge, pending before the agency, this Court, another Circuit Court, or the Supreme Court which involve substantially the same issues as the instant case presents?
YES ☒ X NO ☐ If YES, give case name(s) and number(s) of these cases and identify court/agency:
Petitioner asked NRC to amend the order subject to review. **
- g. Have the parties attempted to resolve the issues in this case through arbitration, mediation, or any other alternative for dispute resolution? YES ☐ NO ☒ X If so, provide the name of the program and the dates of participation. _____

Signature  Date 5/9/01

Name of Party (Print) Novoste Corporation

Name of Counsel for Appellant/Petitioner (Print) Martin G. Malsch LeBoeuf, Lamb, Greene & MacRae, LLP

Address 1875 Connecticut Avenue, N.W., Suite 1200
Washington, DC 20009-5728

Phone (202) 986-8059 Fax No. (202) 986-8059

* See item 6f. below.

ATTACH A CERTIFICATE OF SERVICE

Note: If counsel for any other party believes that the information submitted is inaccurate or incomplete, counsel may so advise the Clerk within 10 days by letter, with copies to all other parties, specifically referring to the challenged statement. An original and three copies of such letter should be submitted.

** See Petitioner's Motion to Hold Judicial Review Proceeding in Abeyance Pending Further Action by the U.S. Nuclear Regulatory Commission, filed April 16, 2001.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION,

Petitioner,

v.

U.S. NUCLEAR REGULATORY COMMISSION and
UNITED STATES OF AMERICA,

Respondents.

No. 01-1162

**NON-BINDING STATEMENT OF ISSUES
NOVOSTE CORPORATION**

Pursuant to the Court's Order dated April 9, 2001, Novoste Corporation hereby submits its Statement of Issues as follows:

1. Whether the U.S. Nuclear Regulatory Commission's "GENERIC INSTRUCTIONS FOR LICENSING THE NOVOSTE BETACATH SYSTEM FOR INTRAVASCULAR BRACHYTHERAPY TREATMENTS IN RESPONSE TO A TECHNICAL ASSISTANCE REQUEST FROM REGION IV," "Generic Use February 5, 2001," constitutes a final, substantive, legislative rule subject to the informal rule making requirements of section 4 of the Administrative Procedure Act of 1946 ("APA"), 5 U.S.C. § 553, and section 189 of the Atomic Energy Act of 1954, as amended, ("AEA"), 42 U.S.C. § 2239.


2. Whether NRC violated section 4 of the APA by promulgating a final, substantive, legislative rule for licensing of Petitioner's Beta-Cath device without disclosing the safety basis for the rule.

3. Whether NRC violated section 4 of the APA and section 189 of the AEA by promulgating a final, substantive, legislative rule for licensing of Petitioner's Beta-Cath device without affording Petitioner an adequate opportunity to comment on the safety basis for the proposed rule.

4. Whether the NRC's rule imposing requirements on the licensing of Petitioner's Beta-Cath device is arbitrary and capricious because, contrary to prior NRC decisions and without adequate explanation, it intrudes into the practice of medicine by preventing qualified physicians from exercising their best medical judgment about how individual patients should be treated.

5. Whether the requirements in the rule for licensing of Petitioner's Beta-Cath device related to maximum source activity, verifying source strength, source transport blockage, depletion of the source transport fluid, and training and education, are arbitrary and capricious because they have no reasonable safety basis, and depart from prior NRC decisions without any explanation.

Respectfully submitted,



Martin G. Malsch
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(202) 986-8000 (Telephone)
(202) 986-8102 (Facsimile)

Attorney for Petitioner Novoste Corporation

May 9, 2001

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION,)	
)	
<u>Petitioner,</u>)	
)	
v.)	No. 01-1162
)	
U.S. NUCLEAR REGULATORY COMMISSION and)	
UNITED STATES OF AMERICA,)	
)	
<u>Respondents.</u>)	
)	

**PROVISIONAL CERTIFICATE OF COUNSEL
AS TO PARTIES, RULINGS, AND RELATED CASES
PURSUANT TO LOCAL RULES 15(c)(3) AND 28(a)(1)
OF NOVOSTE CORPORATION**

In accordance with Circuit Rules 15(c)(3) and 28(a)(1), Novoste Corporation hereby provides the following:

A. Parties and Amici. All persons who are parties, intervenors, or amici are: Novoste Corporation, Petitioner; U.S. Nuclear Regulatory Commission ("NRC") and United States of America, Respondents.

B. Rulings Under Review.

Petitioner Novoste Corporation seeks review of an NRC document entitled "Generic Instructions For Licensing the Novoste Betacath System For Intravascular Brachytherapy Treatments In Response to a Technical Assistance Request From Region IV," "Generic Use February 5, 2001." This document has no docket number or other citation.

C. Related Cases.

In counsel's judgment, there are no related cases.

Respectfully submitted,

A handwritten signature in black ink, consisting of a stylized 'M' followed by a horizontal line.

Martin G. Malsch
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Attorney for Petitioner Novoste Corporation

May 9, 2001

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION,

Petitioner,

v.

No. 01-1162

U.S. NUCLEAR REGULATORY COMMISSION and
UNITED STATES OF AMERICA,

Respondents.

**STATEMENT REGARDING USE OF
DEFERRED APPENDIX OF NOVOSTE CORPORATION**

Pursuant to this Court's order of April 9, 2001, Petitioner Novoste Corporation hereby states that it intends to utilize a deferred appendix as provided under Federal Rules of Appellate Procedure 30(c).

Respectfully submitted,



Martin G. Malsch
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Washington, DC 20009
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Attorney for Petitioner Novoste Corporation

May 9, 2001

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION,

Petitioner,

v.

U.S. NUCLEAR REGULATORY COMMISSION and
UNITED STATES OF AMERICA,

Respondents.

No. 01-1162

CERTIFICATE OF SERVICE

I hereby certify that I have served on this 9th day of May, 2001, a copy of Petitioner's Non-Binding Statement of Issues, Provisional Certificate of Counsel As to Parties, Rulings, and Related Cases Pursuant to Local Rules 15(c)(3) and 28 (s)(1), and Statement Regarding Use of Deferred Appendix by first-class mail, postage prepaid, upon the following:

John F. Cordes, Jr., Esq.
Solicitor
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852

John Aschroft, Esq.
Attorney General
U.S. Department of Justice
10th Street and Constitution Ave., NW
Washington, D.C. 20530


Martin G. Malsch