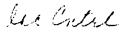
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WASHINGTON, D.C. 20655-0001

February 25, 1998

The Honorable Rob Portman United States House of Representatives Washington, DC 20515

Dear Congressman Portman:

I am responding to your letter, dated February 13, 1998, to Linda E. Portner, Associate Director for Congressional Affairs, U.S. Nuclear Regulatory Commission (NRC). In your letter, you request Ms. Portner's assistance regarding a letter you received from Dean Kereiakes, M.D., of The Lindner Center for Clinical Research, Cincinnati, Ohio. Dr. Kereiakes expressed concern about several amendment requests related to the use of intracoronary irradiation therapy.

The amendment requests in question involve the use of iridium-192 seeds in nylon ribbon for the use of intravascular brachytherapy, under a U.S. Department of Health and Human Services, Food and Drug Administration (FDA), Investigational Device Exemption. This procedure is currently conducted as human research and the FDA has not approved the source nor its proposed usage for routine use.

All sealed sources must undergo a sealed source review, in accordance with 10 CFR 35.49, before routine use. There are two pathways for obtaining review and approval for use of this source. First, a licensee authorized under a specific license of broad scope, such as a large medical or academic institution, may use the source, provided its radiation safety committee has reviewed and approved its use. The second pathway is to have the source reviewed and approved by NRC or an Agreement State. This pathway is required for a specific license of limited scope, such as a community hospital or clinic, to use the source. The second pathway is the approach applicable to your constituent. The information submitted in support of this review must include sufficient information about the design, manufacture, quality control program, prototype testings, and proposed uses to provide reasonable assurance that the radiation safety properties of the source are adequate to protect health and minimize danger to life and property.

The review for this source was completed, and the source approved for the proposed use, in January 1998. Until this approval, NRC could not approve these amendment requests. The use of this source will also require an exemption from 10 CFR 35.400, which currently does not authorize the use of this source for intravascular brachytherapy. The remaining steps in this



process will be a review of this exemption, followed by the issuance of the amendment by our Region III Office granting authorization to perform the requested procedure.

Our objective is to complete the licensing action, by April 30, 1998.

I trust this responds to your concern.

Sincerely,

L. Joseph Callan Executive Director for Operations



WASHINGTON, D.C. 2006-0001

September 1, 1999

The Honorable James M. Inhole, Chairman Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety Committee on Environment and Public Works United States Senate Washington, D. C. 20510

Dear Mr. Chairman:

We are pleased to inform the Subcommittee that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohlo program, was published in the Federal Register for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the Ohlo program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 574 ficensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversight of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear meterial. In addition, NRC will retain jurisdiction over the gaseous diffusion. plant in Portsmouth and two nuclear power plants near Toledo and Painesville.

Sincerely,

Dennis K. Rathbun, Director Office of Congressional Affairs

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OSP BACKGROUND MATERIAL

LETTERS SENT TO:

The Honorable James M. Inhofe, Chairman Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety Committee on Environment and Public Works United States Senate Washington, D. C. 20510

cc: Senator Bob Graham

The Honorable Joe Barton, Chairman Subcommittee on Energy and Power Committee on Commerce United States House of Representatives Washington, D. C. 20515

cc: Representative Ralph M. Hall

Ohio Congressional Delegation

Senators

The Honorable Mike DeWine
The Honr rable George V. Volnovich

Representatives

The Honorable Steve Chabot The Honorable Rob Portman The Honorable Tony P. Hall The Honorable Michael G. Oxley The Honorable Paul E. Gillmor The Honorable Ted Strickland The Honorable David L. Hobson The Honorable John A. Boehner The Honorable Marcy Kaptur The Honorable Dennis J. Kucinich The Honorable Stephanie Tubbs Jones The Honorable John R. Kasich The Honorable Sherrod Brown The Honorable Thomas C. Sawyer The Honorable Deborah Pryce The Honorable Ralph Regula The Honorable James A. Traficant, Jr. The Honorable Robert W. Ney The Honorable Steven C. LaTourette



WASHINGTON, D.C. 20865-0001

September 1, 1999

The Honorable Joe Barton, Chairman Subcommittee on Energy and Power Committee on Commerce United States House of Representatives Washington, D. C. 20515

Dear Mr. Chairman:

We are pleased to inform the Subcommittee that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely.

Dennis K. Rathbun, Director

Office of Congressional Affairs



WASHINGTON, D.C. 20685-0001

September 1, 1999

The Honorable Mike DeWine United States Senate Washington, DC 20510

Dear Senator DeWine:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20066-0001

September 1, 1999

The Honorable George V. Voinovich United States Senate Washington, DC 20510

Dear Senator Volnovich:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

In your June 22, 1998 request that the Commission enter into an Agreement, you, as Governor, certified that Ohio has a program for the control of the radiation hazards associated with the materials covered by the Agreement which is adequate to protect public health and safety. You further certified that the State desires to assume the regulatory responsibility for such materials.

The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

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Sincerely,



WASHINGTON, D.C. 20656-0001

September 1, 1999

The Honorable Steve Chabot United States House of Representatives Washington, DC 20515

Dear Congressman Chabot:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20555-0001

September 1, 1999

The Honorable Rob Portman
United States House of Representatives
Washington, DC 20515

Dear Congressman Portman:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20665-0001

September 1, 1999

The Honorable Tony P. Hall United States House of Representatives Washington, DC 20515

Dear Congressman Hall:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20668-0001

September 1, 1999

The Honorable Michael G. Oxley United States House of Representatives Washington, DC 20515

Dear Congressman Oxley:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume cortain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20555-0001

September 1, 1999

The Honorable Paul E. Gillmor
United States House of Representatives
Washington, DC 20515

Dear Congressman Gillmor:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely.



WASHINGTON, D.C. 20665-0001

September 1, 1999

The Honorable Ted Strickland United States House of Representatives Washington, DC 20515

Dear Congressman Strickland:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20668-0001

September 1, 1999

The Honorable David L. Hobson United States House of Representatives Washington, DC 20515

Dear Congressman Hobson:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20066-0001

September 1, 1999

The Honorable John A. Boehner United States House of Representatives Washington, DC 20515

Dear Congressman Boehner:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20005-0001

September 1, 1999

The Honorable Marcy Kaptur
United States House of Representatives
Washington, DC 20515

Dear Congresswoman Kaptur:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely,



WASHINGTON, D.C. 20005-0001

September 1, 1999

The Honorable Dennis J. Kucinich United States House of Representatives Washington, DC 20515

Dear Congressman Kucinich:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Sincerely.



WASHINGTON, D.C. 2008-0001

September 1, 1999

The Honorable Stephanie Tubbs Jones United States House of Representatives Washington, DC 20515

Dear Congresswoman Tubbs:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

In his June 22, 1998 request that the Commission enter into an Agreement, then Governor George V. Voinovich certified that Ohio has a program for the control of the radiation hazards associated with the materials covered by the Agreement which is adequate to protect public health and safety. Governor Voinovich further certified that the State desires to assume the regulatory responsibility for such materials.

The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 574 licensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversight of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear material. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth and two nuclear power plants near Toledo and Painesville.

Sincerely,



WASHINGTON, D.C. 2004-0001

September 1, 1999

The Honorable John R. Kasich
United States House of Representatives
Washington, DC 20515

Dear Congressman Kasich:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 574 licensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversight of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear material. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth and two nuclear power plants near Toledo and Painesville.

Sincerely.



WASHINGTON, D.C. 2006-0001

September 1, 1999

The Honorable She rod Brown
United States House of Representatives
Washington, DC 20515

Dear Congressman Brown:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 574 licensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversight of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear material. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth and two nuclear power plants near Toledo and Painesville.

Sincerety,



WASHINGTON, D.C. 20008-0091

September 1, 1999

The Honorable Thomas C. Sawyer United States House of Representatives Washington, DC 20515

Dear Congressman Sawyer.

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 574 ficensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversight of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear material. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth and two nuclear power plants near Toledo and Palnesville.

Sincerely.



WASHINGTON, D.C. SOSS-COOL

September 1, 1999

The Honorable Deborah Pryce United States House of Representatives Washington, DC 20515

Dear Congresswoman Pryce:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Soction 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 574 licensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversight of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear material. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth and two nuclear power plants near Toledo and Painesville.

Sincerely,



WASHINGTON, D.C. 20200-0001

September 1, 1999

The Honorable Raiph Regula United States House of Representatives Washington, DC 20515

Dear Congressman Regula:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the <u>Federal Register</u> for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Floom.

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff has identified 5.74 licensees that will be transferred to Ohio in whole or in part and continues to work with representatives of the Ohio program to ensure a smooth transition for both the regulator and its licensees, consistent with the agency's oversignt of the Agreement State program. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met. NRC will retain jurisdiction over 19 materials licensees, including certain Federal facilities, exempt distribution, and two licensees authorized to possess special nuclear material. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth and two nuclear power plants near Toledo and Painesville.

Sincerely.



WASHINGTON, B.C. SHIS-GOV September 1, 1999

The Honorable James A. Traficant, Jr. United States House of Representatives Washington, DC 20515

Dear Congressmen Traficant:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Bincerety

Dennis K. Rathbiun, Director Othice of Congressional Alters



WARRINGTON, S.C. SERIG-GERT

September 1, 1999

The Hunorable Robert W. Ney United States House of Representatives Washington, DC 20515

Deer Congressmen Ney:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e (1) and Section 11e (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

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Bincerety.



WASHINGTON, D.C. 20008-0001

September 1, 1999

The Honorable Steven C. LaTourette United States House of Representatives Washington, DC 20515

Dear Congressman LaTourette:

We are pleased to inform you that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitiod "Cooperation With States," the Commission on August 4, 1999 approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials received from other persons.

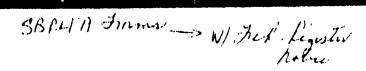
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Sincerely.





Submission of Federal Rules Under the Congressional Review Act

President of the Senate	□ Speaker of the House of Representatives □ GAO
Please fill the circles electronically or with black pe	n or #2 pencil.
Name of Department or Agency U.S. Nuclear Regulatory Commission	Subdivision or Office Office of State Programs
3. Rule Title Agreement with the State of Ohio	
Regulation Identifier Number (RIN) or Other Unio N/A	que Identifier (if applicable)
5. Major Rule ○ Non-major Rule ●	
6. Final Rule ● Other O	
7. With respect to this rule, did your agency solict	public comments? Yes ● No O N/A O
8. Priority of Regulation (fill in one) © Economically Significant; Significant, or Substantive, Nonsignificant	informational/Administrative/Other
9. Effective Date (if applicable) August 31, 19	99
10. Concise Summary of Rule (fill in one or both)	attached ● stated in rule O
Submitted by: Dennis K. Rathbun. Title: Director, Office of Congressi	
For Congressional Use Only:	
Date Received:	
Committee of Jurisdiction:	



Submission of Federal Rules Under the Congressional Review Act

President of the Senate	Speaker of the House of Representatives LIGAU
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1. Name of Department or Agency U.S. Nuclear Regulatory Commission	Subdivision or Office Office of State Programs
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Regulation Identifier Number (RIN) or Other Unique Iden N/A	ntifier (if applicable)
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6. Final Rule ● Other O	
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8. Priority of Regulation (fill in one)	
O Economically Significant; or Significant; or Substantive, Nonsignificant	 Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)
9. Effective Date (if applicable) August 31, 1999	
10. Concise Summary of Rule (fill in one or both)	attached ● stated in rule ○
Submitted by: Dernis K. Rathbun Name: Dennis K. Rathbun	(signature)
Title: Director, Office of Congressional /	Affairs 9/1/99
For Congressional Use Only:	
Date Received:	·
Committee of Jurisdiction:	



Committee of Jurisdiction.

Submission of Federal Rules Under the Congressional Review Act

☐ President of the Senate	☐ Speaker of the House of Representatives ■ GAO
Please fill the circles electronically or with black pen o	r #2 pencil
Name of Department or Agency U.S. Nuclear Regulatory Commission	Subdivision or Office Office of State Programs
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Regulation Identifier Number (RIN) or Other Unique N/A	Identifier (if applicable)
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6. Final Rule ● Other ○	
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Submitted by Dennis K. Rathbun Tide: Director, Office of Congression	(signeture) al Affairs 9/1/99
For Congressional Use Only: Date Received:	

U. S. MUCLEAR REGULATORY COMMISSION

State of Ohio: Discontinuance of Certain Commission Regulatory Authority Within the State.

AGENCY: U. S. Nuclear Regulatory Commission.

ACTION: Notice of Agreement with the State of Ohio.

SUMMARY: On August 11, 1999, Greta J. Dicus, Chalman of the U. S. Nuclear Regulatory Commission (NRC) and on August 18, 1999, Governor Bob Taft of the State of Ohio signed an Agreement as authorized by Section 274b of the Atomic Energy Act. The Agreement provides for the Commission to discontinue its regulatory authority over source, byproduct and special nuclear materials (in quantities not sufficient to form a critical mass) in the State of Ohio, and for Ohio to assume the regulatory authority.

Under the Agreement, a person in Ohio presessing these materials its exempt from certain Commission regulations. The exemptions have been previously published in the <u>Federal</u> <u>Begister</u> and are codified in the Commission's regulations as 10 CFR Part 150. The Agreement is published here as required by Section 274e of the Act.

FOR FURTIVER INFORMATION CONTACT: Richard L. Blanton, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 418-2322 or e-mail RLB@NRC.GOV.

The draft Agreement was published in the <u>Federal Register</u> for comment once a week for four consecutive weeks (see, e.g. 64 FR 12187, March 11, 1999) as required by the Act. The public comment period ended on April 12, 1999. A total of 25 comment letters were received and were considered by the NRC staff. After considering the comments, the request for an Agreement by the Governor of Ohio, the supporting documentation submitted with the request for an Agreement, and its interactions with the staff of the Ohio Department of Health, Bureau of Radiological Health, the NRC staff completed an assessment of the Ohio program. Based on the staff's assessment, the Commission determined on August 4, 1999, that the proposed Ohio program for the control of radiation hazards is adequate to protect public health and safety and compatible with the Commission's program. NRC will retain jurisdiction over 19 materials itsensees including certain Federal facilities and exempt distribution. In addition, NRC will retain jurisdiction over the gaseous diffusion plant in Portsmouth, Ohio and two nuclear power plants near Totado and Painesville.

Copies of the comment analysis by the NRC staff, the staff assessment, and the Commission's decision may be viewed at the NRC website, http://www.nrc.gov. To view the documents, click on the "News and Information" icon, then select "Staff Papers" under the "Commission" heading. The documents are contained in the Commission paper numbered SECY-99-179.

AN AGREEMENT

BETWEEN

THE UNITED STATES NUCLEAR REGULATORY COMMISSION

AND

THE STATE OF OHIO

FOR THE

DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY AND RESPONSIBILITY WITHIN THE STATE PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

Whereas, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuarize of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

Whereas, The Governor of the State of Ohio is authorized under Chapter 3748, of the Ohio Revised Code to enter into this Agreement with the Commission; and,

Whereas, The Governor of the State of Ohio certified on June 22, 1998, that the State of Ohio (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the health and safety of the public and to protect the environment with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

Whereas, The Commission found on August 4, 1999 that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

Whereas. The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

Whereas, The Commission and the State recognize the desirability of reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

Whereas, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended:

Now Therefore, it is hereby agreed between the Commission and the Governor of the State of Ohio, acting on behalf of the State, as follows:

Article I

Subject to the exceptions provided in Articles II, III, and IV, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- A. Byproduct materials as defined in Section 11e.(1) of the Act;
- B. Byproduct materials as defined in Section 11e.(2) of the Act;
- C. Source materials;
- D. Special nuclear materials in quantities not sufficient to form a critical mass;

E.The regulation of the land disposal of byproduct, source, or special nuclear waste materials received from other persons; and,

F.The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

Article II

- A. This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:
 - 1. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
 - 2. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
 - 3. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in the regulations or orders of the

Commission;

- The regulation of the disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed without a license from the Commission.
- B. Notwithstanding this Agreement, the Commission retains the following authorities pertaining to byproduct material as defined in Section 11e.(2) of the Atomic Energy Act:
 - 1. Prior to the termination of a State license for such byproduct material, or for any activity that results in the production of such material, the Commission shall have made a determination that all applicable standards and requirements pertaining to such material have been met.
 - 2. The Commission reserves the authority to establish minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of such byproduct material and of land used as a disposal site for such material.

Such reserved authority includes:

a. The authority to establish terms and conditions as the Commission determines necessary to assure that, prior to termination of any license for such byproduct material, or for any activity that results in the production of such material, the licensee shall comply with decontamination, decommissioning, and reclamation standards prescribed by the Commission; and with ownership requirements for such

materials and its disposal site;

- b. The authority to require that prior to termination of any license for such byproduct material or for any activity that results in the production of such material, title to such byproduct material and its disposal site be transferred to the United States or the State at the option of the State (provided such option is exercised prior to termination of the license);
- c. The authority to permit use of the surface or subsurface estates, or both, of the land transferred to the United States or a State pursuant to paragraph 2.b. in this section in a manner consistent with the provisions of the Uranium Mill Tailings Radiation Control Act of 1978, provided that the Commission determines that such use would not endanger public health, safety, welfare, or the environment;
- d. The authority to require, in the case of a license (if any) for any activity that produces such byproduct material (which license was in effect on November 8, 1981), transfer of land and material pursuant to paragraph 2.b. in this section, taking into consideration the status of such material and land and interests therein, and the ability of the licensee to transfer title and custody thereof to the United States or the State;
- e. The authority to require the Secretary of the Department of Energy, other Federal agency, or State, whichever has custody of such byproduct material and its disposal site, to undertake such monitoring, maintenance, and emergency measures as are necessary to protect public health and safety, and other actions as the Commission deems necessary; and

f. The authority to enter into arrangements as may be appropriate to assure Federal long-term surveillance or maintenance of such byproduct material and its disposal site on land held in trust by the United States for any Indian Tribe or land owned by an Indian Tribe and subject to a restriction against alienation imposed by the United States.

Article III

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

Article IV

This Agreement shall not affect the authority of the Commission under Subsection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

Article V

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory

programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

Article VI

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State. Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

Article VII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this Agreement If, in the judgement of the Commission, an

emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

Article VIII

In the licensing and regulation of byproduct material as defined in Section 11e.(2) of the Act, or of any activity which results in production of such material, the State shall comply with the provisions of Section 2740 of the Act. If in such licensing and regulation, the State requires financial surety arrangements for reclamation or long-term surveillance and maintenance of such material.

- A. The total amount of funds the State collects for such purposes shall be transferred to the United States if custody of such material and its disposal site is transferred to the United States upon termination of the State license for such material or any activity which results in the production of such material. Such funds include, but are not limited to, sums collected for long-term surveillance or maintenance. Such funds do not, however, include monies held as surety where no default has occurred and the reclamation or other bonded activity has been performed; and
- B. Such surety or other financial requirements must be sufficient to ensure compliance with those standards established by the Commission pertaining to bonds, sureties, and financial arrangements to ensure adequate reclamation and long-term management of such byproduct material and its disposal site.

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This Agreement	shall become el	fective on August 3	1, 1999,	and shall	remain in	effect ur	iless
and until such ti	me as it is termir	nated pursuant to Ar	ticle VII.				

Done at Rockville, Maryland, in triplicate, this 11th day of August, 1999.

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

/S/ Greta Joy Dicus
Greta Joy Dicus, Chalman

Done at Columbus, Ohio, in triplicate, this 18th day of August, 1999.

FOR THE STATE OF OHIO

/S/ Bob Taft
Bob Taft, Governor

Dated at Rockville, Maryland, this _____ day of _____, 1999.

For the U. S. Nuclear Regulatory Commission.

Annette L. Vietti-Cook
Secretary of the Commission