UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Before the Commission

In the Matter of	)	Docket Nos. 110-05896 (Import)
	)	110-05897 (Export)
ENERGY*SOLUTIONS*	)	
	)	
(Radioactive Waste Import/Export Licenses)	)	January 10, 2011

ENERGY*SOLUTIONS'* RESPONSE TO PETITIONERS' WAIVER REQUEST

In accordance with 10 CFR 110.111(d), Energy*Solutions* hereby files this timely Response to the waiver request included in the Hearing Request and Petition to Intervene ("Hearing Request")[1] filed by the Tennessee Environmental Council, the Oak Ridge Environmental Peace Alliance, and Citizens to End Nuclear Dumping in Tennessee (collectively, "Petitioners").[2] Petitioners' Hearing Request asks for an "examination of the premise that the business of world-wide radioactive waste management is good for the people of the USA." In seeking this examination, Petitioners ask the Commission to waive its regulation in 10 CFR 51.22(c)(15), which categorically excludes the import licenses under 10 CFR Part 110 from environmental review.[3] Petitioners are asking the Commission to conduct an environmental assessment under circumstances where the Commission has already determined that such an assessment is not needed based upon sound policy decisions that have already been made in a

[1] Dated December 30, 2010.

[2] In accordance with 10 CFR 110.83(a), Energy*Solutions* will separately file its Answer to the Hearing Request in a timely manner.

[3] Hearing Request at 8. Though not styled as such, the Petitioners' request for waiver of 10 CFR 51.22(c)(15) would presumably be treated as a petition for waiver of an NRC regulation pursuant to 10 CFR 110.111(a).

prior rulemaking proceeding. For the reasons set forth below, the waiver request should be denied.

The waiver request should be denied because, contrary to 10 CFR 110.111, it fails to show that special circumstances exist, such that the application of 10 CFR 51.22(c)(15) would not serve the purposes for which it was adopted. In addition, the policy "examination" Petitioners seek is unnecessary. Rather, the categorical exclusion in 10 CFR 51.22(c)(15) that is applicable to the proposed import license is consistent with sound public policy and in the interest of global public health and safety. The low-level radioactive waste ("LLRW") proposed to be imported under the above-captioned license application is primarily medical waste, from hospitals, research facilities, and other technical facilities.[4] Effective management of such LLRW is important to global public health, because nuclear medicine provides life saving treatments and non-invasive diagnostic procedures. Global public health interests mandate the need to assure that these treatments and procedures are available to populations around the world. This is particularly compelling in the broader context of the many countries around the globe that need access to nuclear medicine, but may lack adequate waste management capabilities or capacity.

Moreover, proper waste management in the U.S. reduces the global environmental risk that could arise if countries (for example, in the developing parts of the world) become desperate to provide nuclear medicine without having adequate waste management resources of their own. Thus, the United States has policy and legal interests in the safe disposal of radioactive waste

[4] Application for Specific License to Import Radioactive Material (from Germany), Lic. No. IW029 (Aug. 27, 2010), *available at* ADAMS Accession No. ML103090582 ("Import Application").

that is generated throughout the world, and these interests are properly reflected in the existing rules.[5] No new public policy examination is appropriate or warranted.

I. BACKGROUND

On November 3, 2010, the NRC received Energy*Solutions'* application for a license to import up to 1,000 tons of LLRW into the United States from Germany under the provisions of 10 CFR Part 110. The LLRW is to be imported for the purpose of volume reduction through incineration at the Energy*Solutions* Bear Creek Facility in Oak Ridge, Tennessee (the "Bear Creek Facility").

Energy*Solutions* applied for the import license to support a routine commercial transaction. The company provides LLRW services to the commercial nuclear sector and many other nuclear users, including hospitals, research facilities, the Tennessee Valley Authority, and the U.S. Departments of Energy and Defense. Energy*Solutions* is authorized to possess radioactive material in accordance with a Tennessee license held by its subsidiary, Duratek Services, Inc. ("Duratek"). The radionuclides in the LLRW will meet the possession criteria in Duratek's Tennessee licenses[6] throughout the duration of the proposed import and export. Thus, the German material to be imported under the proposed import license would be, from a public health and safety perspective, indistinguishable from the domestic and other international LLRW that Energy*Solutions* routinely receives, processes, and dispositions at its facilities.

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[5] Having ratified the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management ("Joint Convention"), the United States has an obligation to "achieve and maintain a high level of safety worldwide in . . . radioactive waste management, through the enhancement of national measures and international cooperation." Int'l Atomic Energy Agency, Joint Convention, Art. 1(i), IAEA Doc. INFCIRC/546 (Sept. 5, 1997), *available at* http://www.iaea.org/Publications/Documents/Infcircs/1997/infcirc546.pdf.

[6] Tennessee licenses R-73008 and R-73016.

As noted above, included in Petitioners' Hearing Request is a request to waive 10 CFR 51.22(c)(15), a regulation that categorically excludes the import licenses under 10 CFR Part 110 from environmental review. According to Petitioners:

> Import licenses were excluded from environmental review because an import license does not itself permit the use of radioactive materials in the United States. 45 Fed. Reg. 13,739, 13,748 (Mar. 3, 1980). In this case, however, the issuance of an import license is the key federal action that will allow the incineration of foreign--made radioactive waste in a Tennessee incinerator.[7]

Petitioners fail to acknowledge the role of other federal licensing actions and licensing actions by agreement states that otherwise control radioactive waste. In creating the Section 51.22(c)(15) exclusion, the Commission concluded that "issuance, amendment or renewal of licenses for import of nuclear facilities and material pursuant to Part 110 . . . comprises a category of actions which do not individually or cumulatively have a significant effect on the human environment."[8] The Commission instead appropriately relied on the fact that facilities receiving material are otherwise licensed themselves and thereby subject to environmental review regarding the activities of such facilities. In this instance, NRC is implicitly relying upon the program established by the State of Tennessee to provide for control of radiation hazards and adequate protection of the public health and safety.[9] To argue that approval of the import license is the regulatory action authorizing the incineration of waste is to ignore the regulatory program otherwise applicable to the facility licensed to receive the material. In this instance, Petitioners ignore the interdependency between the NRC and agreement states in the national regulatory scheme.

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[7] Hearing Request at 8-9.

[8] Environmental Protection Regulations for Domestic Licensing, Proposed Rule, 45 Fed. Reg. 13,739, 13,748 (Mar. 3, 1980).

[9] *See id*. at 13,743 (the Atomic Energy Act authorizes the Commission to relinquish "certain defined areas of regulatory authority over source, byproduct, and special nuclear material" to individual States).

II. LEGAL STANDARDS

As a general matter, a contention that challenges an NRC rule is outside the scope of the proceeding because, absent a waiver, no rule or regulation of the Commission is subject to attack in any adjudicatory proceeding.[10] Requests for the Commission to waive a rule or regulation in this proceeding are governed by 10 CFR 110.111:

> (a) A participant may petition that a Commission rule or regulation be waived with respect to the license application under consideration.
>
> (b) The sole ground for a waiver shall be that, because of special circumstances concerning the subject of the hearing, application of a rule or regulation would not serve the purposes for which it was adopted.
>
> (c) Waiver petition shall specify why application of the rule or regulation would not serve the purposes for which it was adopted.

The Commission has previously denied a 10 CFR 110.111 waiver request, where it "[did] not find that special circumstances exist that would result in the rule not serving the purpose for which it was adopted."[11] In the *Plutonium Export License* proceeding, the Commission rejected the petitioner's invitation (through a waiver request) to "upgrade" its regulatory standard for maintaining security in the export of materials to foreign countries in response to the events of September 11, 2001.[12] Rather, the Commission reaffirmed its existing regulations and found no special circumstances to support the granting of the requested waiver.[13] This precedent suggests

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[10] *See* 10 CFR 2.335(a).

[11] *U.S. Dep't of Energy* (Plutonium Export License), CLI-04-17, 59 NRC 357, 376 (2004).

[12] *See id*. at 362, 376.

[13] *See id*. at 376-77.

that, consistent with NRC practice in other areas, there is a significant threshold for demonstrating special circumstances under 10 CFR 110.111.

In Part 2 proceedings, a request for a waiver "can be granted only in unusual and compelling circumstances."[14] The legal standard set forth in 10 CFR 110.111 is essentially the same as that applied in Part 2 proceedings, under 10 CFR 2.335. Under Section 2.335, just as under Section 110.111, waiver of a rule or regulation in a proceeding is based upon the following standard:

> [T]he sole ground for petition or waiver or exception is that special circumstances with respect to the subject matter of the particular proceeding are such that the application of the rule or regulation (or provision of it) would not serve the purposes for which the rule or regulation was adopted.[15]

Given the similarity in legal standards and the lack of case law specifically interpreting Section 110.111, it is appropriate to look to the legal principle as it is applied by the Commission to 10 CFR Part 2 to evaluate Petitioners' waiver request.

To obtain a waiver, a petitioner must demonstrate that it satisfies each of the following criteria:

> (i) the rule's strict application "would not serve the purposes for which [it] was adopted"; (ii) the movant has alleged "special circumstances" that were "not considered, either explicitly or by necessary implication, in the rulemaking proceeding leading to the rule sought to be waived"; (iii) those circumstances are "unique" to the facility rather than "common to a large class of facilities"; and

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[14] *Pub. Serv. Co. of N.H.* (Seabrook Station, Units 1 & 2), ALAB-895, 28 NRC 7, 16 (*citing Northern. States Power Co*. (Monticello Nuclear Generating Plant, Unit 1), CLI-72-31, 5 AEC 25, 26 (1972)), *aff'd*, CLI-88-10, 28 NRC 573 (1988), *recons. denied*, CLI-89-3, 29 NRC 234 (1989).

[15] 10 CFR 2.335(b).

(iv) a waiver of the regulation is necessary to reach a "significant safety problem."[16]

In analyzing the fourth factor, the Commission explained that "[i]t would not be consistent with the Commission's statutorily mandated responsibilities to spend time and resources on matters that are of no substantive regulatory significance."[17] The Commission has also stated "[t]he use of 'and' in this list of requirements is both intentional and significant. For a waiver request to be granted, *all four* factors must be met."[18] If the petitioner fails to satisfy any of these requirements, then the waiver should not be granted.[19]

III. ARGUMENT

A. Petitioners Do Not Show Special Circumstances Required for a Waiver

1. *Petitioners Do Not Show that the Categorical Exclusion Would Not Serve the Purposes for Which It Was Adopted.*

Petitioners note that "[i]mport licenses were excluded from environmental review because an import license does not itself permit the use of radioactive material in the United States,"[20] but suggest that this import license application somehow involves an exception to this rule. Contrary to the requirements of 10 CFR 110.111(b), Petitioners fail to show that application of the regulation would not serve the purposes for which it was adopted. The categorical exclusion in 10 CFR 51.22(c)(15) was adopted as part of NRC's effort to reach an accommodation between its independent regulatory responsibilities and the Council on

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16 *Dominion Nuclear Conn., Inc.* (Millstone Nuclear Power Station Units 2 & 3), CLI-05-24, 62 NRC 551, 559-60 (2005) (alternation in the original) (*citing Seabrook*, CLI-89-20, 30 NRC at 235; *Seabrook*, CLI-88-10, 28 NRC at 597).

17 *Seabrook*, CLI-88-10, 28 NRC at 597.

18 *Millstone*, CLI-05-24, 62 NRC at 560 (citations omitted).

19 *See id*.

20 Hearing Request at 8 (*citing* Environmental Protection Regulations for Domestic Licensing, Proposed Rule, 45 Fed. Reg. at 13,748).

Environmental Quality's ("CEQ") objectives of establishing uniform NEPA procedures.[21] In doing so, the NRC indicated that it wanted to limit the preparation of environmental assessments to "those types of actions for which they are really needed."[22]

Petitioners assert that issuance of an import license "is the key federal action that will allow the incineration of foreign-made radioactive waste in a Tennessee incinerator."[23] However, NRC determined in the rulemaking history that "[i]mport licenses issued pursuant to 10 CFR Part 110 merely authorize import into the United States and do not authorize any person to possess, use, or transfer the facilities or materials within the United States."[24] Though the Hearing Request acknowledges this conclusion,[25] it ignores the logical implications. The NRC effectively determined in the rulemaking that the authorization of possession, use or transfer of materials in the United States is subject to separate regulatory action (by NRC or a state) that governs the actual activity involving such materials within U.S. borders. As such, NRC need not conduct duplicative environmental reviews in connection with an import license, because any subsequent U.S. activity is already subject to review. Therefore, the categorical exclusion serves the purpose for which it was adopted, which is to avoid an environmental assessment when it is not really needed.

2. *Petitioners Have Not Established Special Circumstances.*

Petitioners do not allege special circumstances that were not considered, either explicitly or by necessary implication, in the rulemaking proceeding leading to the rule sought to be waived. In suggesting "the issuance of an import license is the key federal action" allowing the

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[21] Environmental Protection Regulations for Domestic Licensing, Proposed Rule, 45 Fed. Reg. at 13,739.

[22] *Id.* at 13,740.

[23] Hearing Request at 9.

[24] Environmental Protection Regulations for Domestic Licensing, Proposed Rule, 45 Fed. Reg. at 13,748.

[25] Hearing Request at 8.

processing of foreign-origin material, Petitioners ignore the role of federal and state regulatory programs governing facilities that receive LLRW. Here, this ignores the regulatory authority of the State of Tennessee under the NRC's agreement state program. As described in the Statements of Consideration that accompany the proposed rule establishing 10 CFR 51.22(c)(15), Section 274 of the Atomic Energy Act authorizes the Commission to relinquish certain defined areas of regulatory authority to individual States.[26] Moreover, "in order to make sure the health and safety of the public will continue to be adequately protected, . . . certain conditions . . . must be met before an agreement can be entered into."[27]

The Commission recognized the interplay between itself and agreement states when 10 CFR 51.22(c)(15) was promulgated. In determining that import licenses do not authorize any person to possess, use, transfer, or transport materials within the United States, the Commission relies on other regulations, whether state or federal, to provide those authorizations. Petitioners' assertion that Energy*Solutions* should provide information "to assure the affected public that the waste to be shipped will conform to the specifications of the incinerator"[28] confuses the requirements for an import license with the requirements of the required licenses to possess, use, transfer, or transport.

Moreover, Section 51.22 contemplates exceptions to the numerous categorical exclusions from environmental review, including import applications under Part 110, when special circumstances exist "where the proposed action involves unresolved conflicts concerning alternative uses of available resources."[29] Petitioners allege no such problem here.

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[26] Environmental Protection Regulations for Domestic Licensing, Proposed Rule, 45 Fed. Reg. at 13,743.

[27] *Id*.

[28] Hearing Request at 9.

[29] 10 CFR § 51.22(b).

3. *The Factual Circumstances Are Not Unique.*

The third prong of the special circumstances analysis requires that the factual circumstances in the proceeding be unique. "Special circumstances are present only if the petition properly pleads one or more facts, not common to a large class of applications or facilities, that were not considered either explicitly or by necessary implication in the proceeding leading to the rule sought to be waived."[30] The circumstances that Petitioners complain about are not unique to this project or the Energy*Solutions*' Bear Creek facility. 10 CFR 51.22(c)(15) applies to any license to import material pursuant to 10 CFR 110 other than spent nuclear fuel from power reactors. For any material imported into an agreement state under Part 110, authority to possess, use, transfer, or transport the materials is controlled by state regulations. Therefore, the facts of this license application are not unique and do not support a waiver under Section 110.111.

4. *Petitioners Have Not Established that a Waiver of the Regulation is Necessary to Reach a "Significant Safety Problem."*

Petitioners have not shown, and cannot show, that waiver of the categorical exclusion from environmental review for import licenses presents a "significant" safety problem, as required by the fourth prong. The safety issues associated with any possession, use or transfer of the materials subject to the import license are addressed by licensing actions and ongoing regulation that govern these activities within U.S. borders. For example, the "national origin" of material processed by the Bear Creek Facility not only does not create a significant safety problem, but it does not create any unique safety issue. The licensed activities involving non-U.S. origin material are indistinguishable from licensed activities involving U.S.-origin

[30] *Seabrook*, CLI-88-10, 28 NRC at 597.

material. As such, there is no significant safety problem that needs to be addressed by the Commission.

* * *

The Petitioners' request for waiver of the application of 10 CFR 51.22(c)(15) should be denied, because Petitioners have failed to demonstrate that any single prong of the applicable tests has been met, let alone all four prongs as would be required under NRC precedent applicable to requests under 10 CFR Part 2. Simply stated, there are no special circumstances that make it appropriate to grant a waiver of the NRC's regulation in this instance.

B. <u>Global Health and Safety Implications of Petitioners' Desired Policy Changes</u>

Petitioners seek a waiver of the existing regulatory requirements for purposes of conducting an "examination of the premise that the business of world-wide radioactive waste management is good for the people of the USA."[31] For the reasons already discussed no such waiver is appropriate. Moreover, no such waiver or new policy "examination" is warranted, because the existing rules are founded in sound public policy. The United States has policy and legal interests in the promotion of global public health and safety through the safe management of radioactive waste that is generated throughout the world from nuclear medicine and the research and development activities that make it possible. In addition, global environmental issues could arise, if countries were to choose to accept the risk of poor waste management practices, for example, as a "trade-off" for the benefits of nuclear medicine. As such, the United States has good reason to promote sound waste management practices in a global commercial marketplace.

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[31] Hearing Request at 8.

Nuclear medicine and the research and development activities that make it possible provide life-saving treatments and non-invasive diagnostic procedures. According to the IAEA, there are over 100 radiopharmaceuticals which are used for diagnosis of or treatment of diseases.[32] In the United States alone, an estimated 16 million nuclear medicine diagnostic and therapeutic procedures are performed each year. A prerequisite for the responsible use of nuclear medicine is sound management of the radioactive waste that is necessarily generated, including waste generated through research and development activities. Thus, nuclear medical procedures could become unavailable to populations living in countries that lack a cost-effective method of managing the waste responsibly. By facilitating the responsible management of waste, the United States is able to help support the use of nuclear medicine for the benefit of populations in other countries.

It is important to acknowledge that U.S. citizens also benefit from the global marketplace, because the United States imports radio-pharmaceutical products that are produced by other countries. In these instances, other countries absorb the burden of waste management required throughout the "front-end" of the production cycle. For example, when radio-pharmaceutical products are produced in a reactor in another country, the host country typically has the responsibility for managing and disposing the spent nuclear fuel and other radiological hazards associated with the reactor operations. Thus, U.S. citizens simply benefit from their access to these radio-pharmaceutical products without assuming the associated waste management burden that can be traced to the production of the materials that are exported to the United States.

Restraining the availability of sound waste management practices in the global marketplace not only presents a potential global public health risk, but also increases global

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[32] Int'l Atomic Energy Agency, *Radiopharmaceuticals: Production and Availability* at 2 (2007), *available at* http://www.iaea.org/About/Policy/GC/GC51/GC51InfDocuments/English/gc51inf-3-att2_en.pdf.

environmental risk. Presumably, countries that have adequate technical or financial resources to manage waste are likely to use nuclear medicine responsibly, *i.e.*, they will either assure adequate domestic capacity to manage waste effectively, or they will restrict the availability of nuclear medicine. However, many countries lack the technical or financial resources to manage their own medical waste, and these countries may become willing to compromise environmental safety in exchange for obtaining the benefits of nuclear medicine. In such extreme cases, the viable options for such a country may be to either deprive the domestic population of desirable medical procedures, or accept the risk of suboptimal waste management. Constraining the global ability to provide proper waste management techniques may therefore result in adverse environmental consequences.

While all countries that have produced radioactive waste must ultimately take responsibility for seeing that it is dealt with safely and securely, this should not preclude utilizing facilities or expertise in other countries that can greatly assist in this process. In the case at hand, Energy*Solutions* has such specialized facilities and expertise at Bear Creek, Tennessee. This facility is able to process a range of wastes in a far more cost-effective and efficient manner than elsewhere around the world. Thus, Energy*Solutions* has the capabilities to help other nations solve their problems, and we should use them. Doing so makes an important contribution to a global enterprise from which U.S. citizens clearly benefit.

IV. CONCLUSION

For the foregoing reasons, Energy*Solutions* respectfully requests that the waiver request be denied in its entirety.

Respectfully submitted,

Signed (electronically) by Raphael P. Kuyler

John E. Matthews
Raphael P. Kuyler
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, DC 20004
Phone: 202-739-5524
Email: jmatthews@morganlewis.com

Brett Hickman
Energy*Solution*s, Inc.
423 West 300 South
Suite 200
Salt Lake City, UT 84101
Phone: 801-244-8438
Email: bahickman@energysolutions.com

Counsel for Energy*Solutions*

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CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing ENERGY*SOLUTIONS'* RESPONSE TO PETITIONERS' WAIVER REQUEST has been served upon the following persons on January 10, 2011 through the Electronic Information Exchange. Participants who are not registered with EIE were served via e-mail and U.S. Mail in accordance with 10 CFR 110.89(c)(3) and are indicated with an asterisk. Other persons who have been granted an extension of time for requesting a hearing and/or submitting public comments were provided a courtesy copy via e-mail and/or U.S. Mail and are indicated with two asterisks.

U.S. Nuclear Regulatory Commission
Office of the Secretary of the Commission
Mail Stop O-16C1
Washington, DC 20555-0001

OCAAMAIL
E-mail: OCAAMAIL@nrc.gov

Hearing Docket
E-mail: hearingdocket@nrc.gov
Evangeline S. Ngbea
E-mail: evangeline.ngbea@nrc.gov

OGCMailCenter
Kristy Remsburg
E-mail: ogcmailcenter@nrc.gov

Diane D'Arrigo
E-mail: dianed@nirs.org

Kathleen Ferris, Co-Founder
Citizens to End Nuclear Dumping in Tennessee
E-mail: k.r.ferris@comcast.net

Franz Raetzer
E-mail: fraetzer@icx.net

Donald Safer
Tennessee Environmental Council
E-mail: dsafer@comast.net

Marcia C. Free**
E-mail: marciafree@comcast.net

Norman A. Mulvenon*
Chair, LOC Citizens' Advisory Panel
102 Robertsville Rd., Suite B
Oak Ridge, TN 37830
E-mail: loc@icx.net

James B. Steinberg*
Deputy Secretary of State
2201 C Street NW
Washington DC 20520
E-mail: updegrovell@state.gov

Kennedy Ferris**
Dr. Norman B. Ferris**
3210 E. Compton Rd.
Murfreesboro, TN 37130

Anita Feldman**
63 Avenue A, Apt. 21E
New York, NY 10009

Rev. Neal W. Ferris**
24 Woodridge Rd.
Durham, NH 03824

Christopher Thomas, Executive Director**
HEAL Utah
E-mail: christopher@healutah.org

Douglas Kiker**
Kaye Kiker, Organizer**
Citizens Task Force
P.O. Box 504
Mentone, AL 35984
E-mail: khkiker@farmerstel.com

Jimmie Hays**
1509 Grady Ave.
Charlottesville, VA 22903

Aaron T. Cerutti**
Chloe L. Cerutti**
2841 Vicwood Dr.
Murfreesboro, TN 37128

Allison Pierce**
2927 Regenwood Dr.
Murfreesboro, TN 37129

Patricia P. Sanders**
P.O. Box 1275
Murfreesboro, TN 37133

Robert L. Taylor**
1107 Whitehall Rd.
Murfreesboro, TN 37130

Paul Wulfsberg**
366 Highland Ave., Apt. 3
Somerville, MA 02144

Marlys Wulfsberg**
1503 Maymont Dr.
Murfreesboro, TN 37130-2318

Joanna Wulfsberg**
2020 Beech Ave., Apt. A9
Nashville, TN 37204

W. R. C. Smith**
729 Skyline Dr.
Lewisburg, TN 37091

Respectfully submitted,

Signed (electronically) by Raphael P. Kuyler

Raphael P. Kuyler