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Mr. John C. Hoyle, Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
ATTN: Chief of Docketing and Services Branch  
Washington, DC 20555-0001



Dear Mr. Hoyle,

Please accept these comments on the Direction Setting Issue (DSI) papers issued by the Nuclear Regulatory Commission (NRC) as part of the Strategic Planning initiative. These comments have been prepared by myself and my staff, and do not necessarily represent the views of everyone within New Jersey.

**Overall comments**

At various nuclear power plants, NRC has supported a cultural shift, from a culture that permits workarounds and other short cuts, to a culture that emphasizes safety, doing things right the first time, fixing things for the long term. As I see the NRC's Strategic Assessment and Rebaselining Project, it is part of a cultural shift for the agency. Instead of the ego centric philosophy that NRC has held in the past, there seems to be a shift to a more inclusive environment, where stakeholders can make a contribution to the direction of the agency. Rather than simply operating in a reactive mode, there appears to be an opportunity to lead the agency into taking proactive stands on current issues. Focussing on those activities which have the most risk to the public rather than those activities which cause the public concern are part of the long term thinking that is changing the NRC's culture. This is an exciting moment in the NRC's history.

The options identified in the DSIs were creative, and showed some "out of the box" thinking. However, the Commission chose the "status quo" option in almost every case. While dramatic changes at the federal level would probably cause some trauma to the states, and I do not recommend precipitous changes without lots of stakeholder discussion, it seems that at the very least, NRC is ready to show some leadership and advocate for radiation protection. Notice I did not say advocate

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for nuclear power, but advocate for radiation protection. This seems to be a part of the NRC's organizational values of "Commitment to protecting public health and safety" and "Service to the public". The public expects its servants to frame issues for them in terms they can understand. They have a fear of radiation, but not much knowledge about it. It is time for NRC to embark on an educational effort to put some of the risks into perspective, and to describe the cost of regulation in areas of very small risks and in areas of potentially large risks.

It seems that embracing the risk-informed, performance based regulations in the materials area as well as the reactor area will mean some changes for the agency. This regulatory paradigm shift is good, but needs to be preceded by an aggressive public education program, so that the public will understand that there will be tradeoffs in what government regulates. If the public is serious about decreasing the size of government (and I am including state as well as federal) there will be some services which will no longer be available.

There may be strategies for protecting public health which are more effective than the traditional "licence, inspect, and enforce". Since no regulatory agency can inspect everywhere at once, there is a certain amount of trust that licensees will follow regulations even if someone is not checking on them all the time. This is explicit in NRC's regulatory philosophy of licensee responsibility. It is common knowledge that a well run nuclear power plant will have an emphasis on safety, and will actually increase its productivity. Analogous statements can be made for all radiation source users. It is possible to leave some control to peer pressure groups, such as medical boards, to enforce good practices which are protective of public health and safety. Other pressure groups, such as consumer groups, can educate the public to look for certain indications of good practice and bring any doubts to the attention of the regulators. In effect, the entire public is deputized to assist in public health protection. The media also plays a role in bringing attention to sloppy operations.

The DSI on public communication initiatives should support Option 3 (increased NRC involvement). If NRC is moving toward a risk-based prioritization for regulatory matters, (and the Environmental Protection Agency, too, if the Interagency Steering Committee on Radiation Standards is any indication), then they must work to increase public understanding of risk within the radiation area and outside of it, too. The cost/ benefit ratios must be publicized so that as NRC changes to regulating the most risky practices rather than what the Congress has demanded in the past, there will be public support, rather than opposition. A paragraph in the DSI on Enhancing Regulatory Excellence gives voice to the concern that initiatives associated with downsizing the organization and reducing regulatory burdens could be misinterpreted as a relaxation of safety vigilance. It is essential that the changes within the NRC are made concurrently with a coherent outreach programs which describes their enhancement of effectiveness.

Comments on specific DSI's follow.



### **Oversight of the Department of Energy (DOE)**

There is another possible option: NRC could operate in the limited role of providing technical assistance to DOE on issues related to site clean-up. No evidence is presented that DOE is failing to comply with their voluntary standards for occupational exposure. However, it is in the area of site clean-up that expensive blunders are occurring. While the site clean-ups are not the highest risk to the public or workers, they are the most expensive to fix. When there are examples such as the soil washing project in Hanford where the detector used to determine success could not detect the radionuclides which were the contaminants, and millions of taxpayers dollars were misspent, it appears there is a clear role for NRC to provide expertise. It is not oversight of the entire DOE program, but it is a quality assurance check that the technology selected for site clean up is technically feasible and defensible. It is a role that fits with the NRC values of integrity, excellence, and service to the public. By assessing whether DOE has based their conclusions on sound science, and weeding out expensive solutions that won't work, NRC could reduce the cost burden for the taxpayers. While some state programs can handle the DOE, most states don't have the resources or the clout to argue effectively with the DOE. By relying on the radiation control expertise of the NRC, if there were some discrepancy between the DOE and NRC, the two federal giants could face off, and they would at least be using sound science.

### **Agreement State**

It is appalling to me, as a non-agreement state, that the entire DSI on Agreement State is focussed on funding issues, and in particular, about \$500,000 for support to states so that they can get some training. There was not even a mention of public health and safety. None of the principles of good regulation - independence, openness, efficiency, clarity, and reliability - were discussed with regard to agreement state regulation. The NRC organizational values of integrity, excellence, service, respect, cooperation, commitment, and openness were not mentioned.

There is no question that shrinking resources are going to be the driving force on whether a state becomes an agreement state. But in the options, there was no mention of having a discussion with Congress on the best level of government to regulate these sources, and the best way to pay for that regulation. If training funds are a problem, why not approach Congress and ask that the costs for training be funded by appropriation, rather than fees? Then there would be a tangible benefit to seeking Agreement State status, and NRC could comfortably shrink its materials staff. Agreement states should be able to act as contractors to the NRC and perform inspections on behalf of the NRC at federal facilities (such as Veterans Administration hospitals) as well as at neighboring state licensees, if some assistance is needed.

Notably absent from the DSI was a discussion of the benefits of centralized training with a mix of attendees from both state and federal government. Training is more than just transferring facts from a teacher's brain to those of the students. Each student brings a different perspective to the class, and the diversity can lead to some pretty exciting new ideas. Respect and openness are born in the comfortable setting of a training classroom and can lead to life long friendships and



cooperation. Standardized training can bring every inspector the same core principles to use when performing an inspection, which can lead to a more predictable environment for the regulated community. Training is too important to quibble about who pays.

### **Low level radioactive waste**

Option 1 (Leadership role) should not be pursued. It is not appropriate for the regulator to become a proponent. As another agency within the same administration, the NRC will not be able to influence the Department of Interior to transfer Ward Valley. The obstacles in the way of land transfer are political, not substantive, and the NRC is in no position to change the political philosophy of the administration.

Option 4 (Recognize Progress and Reduce Program) should be renamed as "Recognize the Futility of LLRWPA and Reduce the program". The LLRWPA has been a complete failure:

- o fewer disposal options exist now than when the LLRWPA was enacted;
- o the LLRWPA has not resulted in any new disposal capacity;
- o access to existing disposal facilities is more tenuous now than when LLRWPA was enacted;
- o the prospect for developing new disposal facilities is distant in most state and compacts; and
- o those compacts closest to developing new disposal facilities (TX and CA) are Agreement States.

Some resources should be devoted to Option 6 ( Assured storage) to provide some guidance and, if necessary, regulation. It does not make sense to apply the NRC's philosophy on short-term storage to a facility designed to safely isolate LLRW for hundreds of years. At the same time, it also does not make sense to apply NRC's philosophy of disposal to an accessible facility that will remain under close observation and maintenance. While it is possible that the concept of assured storage will not have an advantage over a disposal facility in terms of public acceptance, adequate consideration of this alternative can only enhance our credibility with the public. Rejecting it without a full understanding of the issues is short-sighted.

Whatever option NRC selects to pursue, one activity that should definitely be retained is rulemakings. Specifically, it is important to finish revisions to Part 61 to conform to the effective dose equivalent requirements of Part 20.

### **High level radioactive waste**

One of the most difficult questions posed to a low level radioactive waste (LLRW) siting board is why independent spent fuel storage is permitted at a nuclear power plant site, but a LLRW facility on site is discouraged. Assured Storage, as a concept for managing LLRW is not even fully



explored, but ISFSIs are permitted. This seems contradictory. If the Commission chooses Option 5 (Take a position on the Storage of Spent Fuel) and advocates at-reactor storage these apparent contradictions will have to be explained.

As frustrating as it is to watch the Department of Energy's slow progress toward establishing a national repository, for the NRC to assume a leadership role as in Option 1 (approach Congress and the administration to refocus the national program) would mean that the agency had crossed the line from regulator to proponent.

The key specific barriers to the HLW programs success range from technical issues, political issues, public mistrust, and budgetary constraints. The NRC can work to help resolve the technical issues, and should be proactive in providing public education to overcome misinformation. However, it should not enter into the political arena to advocate for the HLW program. That can only lead to increased mistrust on the part of the public. As for interceding on the budgetary constraints put on the HLW program, it appears that all interested parties could use some help in putting risks and costs in perspective. Examining the costs of the HLW program and the radiation risks from the spent fuel, and comparing these risks and costs to other regulatory programs, such as the regulation of radioactive materials in medicine, LLRW, nuclear power plants, x-ray machines, and radon should help to frame the issue for the decision makers - the general public and Congress.

### **Materials/ Medical Oversight**

There are currently 29 agreement states that are presently regulating medical uses of byproduct materials. That leaves 21 states who will have to take on these activities within a very short period of time if the recommendations of the IOM committee are taken literally. It is unrealistic to think that all 21 states will be able to establish and implement a regulatory program to appropriately regulate these activities in less than 5 years. There are a few states that have been taking measures to become agreement states for almost 5 years now and they still have another year or so to go. Presumably those states which are seeking to become agreement states are well motivated to take over the regulatory program. For those states forced into taking on this regulatory responsibility, perhaps harboring resentment over yet another unfunded mandate, there may be additional time necessary to get up to speed. Some of the state effort could even be spent in fighting the decision in court.

It seems naive to believe that all 50 states will be able to effectively maintain congruent regulations and procedures on a voluntary basis, especially when budgets for state programs are being cut and many states are cutting programs and staff. It appears that most of the comments in favor of the IOM recommendations were from individuals and organizations that are associated with providing nuclear medicine services and would prefer to be able to operate with little or no controls.

The criticism of the NRC as being too prescriptive in their regulations seems a bit ironic, when regulators are usually criticized for being arbitrary and capricious. Our legal support group advises that our regulations should be more exact (i.e. more prescriptive) to avoid the criticism. More exact



well-written regulations puts limitations on the regulators as well on the regulated. The over zealous inspector is limited in his ability to "interpret" a regulation if it is prescriptive.

The problem really stems from a concern that the regulations, as written, are sort of a "one size fits all" regulation, and the don't really address the differences in risk from a diagnostic dose of a radionuclide versus a therapy dose. If there is a problem with a regulation, fix it. Your first step has to be in regulatory reform. It seems that you should be able to construct a matrix of various medical uses of isotopes, and their inherent risk, probability of mishap, consequences to patients, workers, the public, and the environment. Then various regulatory schemes, with their associated cost, can be applied to the matrix items to determine the most cost-effective regulatory action.

The NRC has accumulated hundreds of work years of experience in regulating medical uses of byproduct materials to ensure that members of the public receive adequate radiation protection during medical procedures without undue interference in the practice of medicine. This is not an easy task. There is no other Federal agency with the vast knowledge and experience to replace the NRC as the agency responsible for medical uses of byproduct materials. However, I believe there is even greater expertise among many other interested "stakeholders" than at the NRC. I realize that the NRC has their Advisory Committee structure to provide input, but perhaps it is time to change to a process more like the enhanced participatory rulemaking. Work hand in hand with groups like pharmaceutical companies to make sure that the regulations not only address those nuclear medicines which are currently on the market, but those in the process of becoming available. Work with public interest and advocacy groups such as those representing patients to keep health care costs low, services available, and delivery systems responsive. And of course, work with peer pressure groups such as medical boards to enhance physician expertise in nuclear medicine and place sanctions on those who do ignore the rules of good practice. Providing good basic information to patients involved in nuclear medicine procedures can also enhance the credibility of the NRC, and engage the patients in advocating for their own health care. Regulatory reform is best when all stakeholders are engaged.

Part of the regulatory reform group's work should be to establish a consistent and unified national program to establish basic standards for all uses of ionizing radiation, both radioactive material and machine sources. This, combined with a commitment to risk-based regulations and programs, would ensure greater consistency of regulation of those sources. To devise this type of regulatory reform, states must be at the table. And this type of regulatory reform will only be acceptable to the public if there is a concurrent effort at public education in risk assessment and risk management.

The Commission's preliminary view combining Option 2 and 3 could be enhanced with additional stakeholder input as described above. In a discussion with the New Jersey chapter of the Health Physics Society, the membership suggested that New Jersey consider agreement state status for medical use only, since the expertise for medical use regulation already existed within the program. The suggestion was noted, but no further investigation of the feasibility has taken place.



### **Decommissioning - Non-reactor facilities**

In a complete departure from their record of supporting the maintenance of the existing programs, the Commission's preliminary views were not just to maintain status quo, but to take a little from each of four options. It is a confusing position, and does not really spell out a strategic plan for dealing with these facilities. It is not clear why Option 3 was not selected among those that the Commission favored. For various reasons, it looks like a very good option. Particularly with the emphasis on "brownfield" development, in land use planning, having the option to use deed restrictions seems like a way to make a contaminated site economically desirable. Much more thought should be given to this option before dismissing it.

One problem not really addressed is the potential for recycle of material. Both for discrete sources such as Co, Am/Be, Cs, Am/Pu, etc., and for contaminated or activated metal, disposal is not a good option. Disposal takes up land, and the sources and metals are potentially valuable for other things. However, there are no standards which encourage recycling. This is an area for NRC to research.

### **Risk-Informed, Performance-Based Regulation**

In decreasing the oversight of "low risk activities" care must be taken that it does not result in an increase of radioactive material incidents involving lost, stolen, or discarded radioactive items.

### **Role of Industry**

It is not clear why the Commission's preliminary views did not support Option 3 (Increase Accreditation and Certification of Licensee Activities), because other regulatory agencies are considering this approach. With certifications such as ISO 9000 and ISO 14000 available to proactive facilities, this bears further investigation. From the state point of view, in the area of mammography, those facilities which voluntarily participated in the American College of Radiology (ACR) accreditation process, were at a distinct advantage in complying with the Mammography Quality Standards Act requirements. Participation in the ACR process directly contributed to the improvement in health care in terms of better diagnostic capabilities of facilities performing mammography. Of course, in this instance, the voluntary program was so successful, it pointed out the need for better regulation of those facilities which did not participate, and regulations were passed to make it mandatory. It is true that the best performing facilities are the ones to participate in voluntary programs, and there will always be some facilities which will not do something necessary for safety until it is mandated, and even then they only comply just before an inspection. But perhaps credit could be given for participation in an accreditation program, and that could lengthen the time between inspections and shorten the actual inspection time which would free up resources for both the regulator and regulatee. This option should be more fully explored.

Industry participation in accreditation and certification programs set up by professional societies will promote standardization and consistency in training and operations, and the NRC should



encourage these programs. Such professional activities on the part of licensees and individuals would likely result in better radiation safety programs.

Option 5 (Designated Industry Representative) is an interesting idea. We are considering allowing physicists on staff at hospitals perform the annual x-ray machine inspection using state protocols, and then send the inspection report to the state. The state inspectors would then recheck 10% of the x-ray machines to ensure that the physicists really did the work. If we try this, it would be a pilot program, and the success would be assessed in a year. One of the big questions is whether the physicists will have some conflict of interest. After all, they get paid by the hospital. The hospital administrator is looking at the bottom line. If they find a problem with an x-ray machine, will it get fixed? This particular option is one which is part of the move to privatize government. It would be useful to get a group of regulators from different agencies and different levels of government together to work on a task force. What do you think?

In the medical arena, technology is so fast moving that it is essential that the regulators and the inventors work together. Otherwise, it takes years to get the regulations in place to deal with the new technology, and by then, even newer technology is out. I know that the NRC is proactive in following developments with new nuclear power plants. Do you have the staff to follow developments in nuclear medicine as well?

### **Public Communication Issues**

Many of the options in the other DSIs have a public communication component. This issue could have been subsumed in the discussion on other options, but it is noteworthy that it was considered important enough to be dealt with individually. This is an area ripe for a self-assessment. What are the goals of a public communication effort? Are they to obtain agreement for a course of action that the NRC has already defined? Or are they to really identify additional issues for consideration? If NRC has not always been "right" in the past, can a program of public interaction help to improve regulatory excellence? Can public discussion of risk help to provide a sound foundation to make resource decisions? Can better understanding of the trade-offs involved in regulation help NRC regain public confidence? Is the public affairs program only to assist the public in making informed judgements regarding NRC activities, or is it to influence the NRC's activities?

If NRC is to regain public credibility, it needs to find grass roots support for its mission. It is not enough to provide information to those who ask for it, or those who take the time to go to a public document room and search for it. You have to first capture the interest of a largely disinterested public. The most effective public communication strategy for regaining credibility is positive visibility. This could be as simple as providing informational materials at local community sponsored events to educate state, county, and local officials as well as the general public. Forming a partnership with local concerned citizens could lead to a better strategy for cleaning up a contaminated site, for instance. It is important not to just identify public concerns and address them, but to allow public input to help to shape the final outcome of a project. Option 3 (Place a Priority on Expanding General Public Outreach) is the only option that actually begins to engage the public



The NRC has relied on conducting open meetings to discuss various issues. The traditional public meeting format may be intimidating. People will be put off enough by the technical terminology and the endless acronyms. If they are expected to speak into a microphone and have their comments recorded by a stenographer, they could be even further alienated. There are other options for public meetings. These should be explored.

To begin to overcome the skepticism and mistrust of the NRC by the media and the public, there needs to be better public understanding of the NRC's role, philosophy, and regulatory programs. Utilizing retired NRC employees to give educational seminars at various venues would be an inexpensive and advantageous educational method of overcoming mistrust. Some likely audiences might be League of Municipality conferences, League of Mayor conferences, universities, community colleges, etc. It is important that the NRC ensure the presenters are aware of their audiences. This means not using technical jargon or speaking over the heads of those listening. People tend to lose interest. Simplifying the presentation, empathetically listening to what people have to say, and thoughtfully responding are all important skills for the presenters.

The NRC would be missing the opportunity to effectively implement the programs in the other DSIs if they only concentrate on Option 2 (Early Identification of Public Concerns). Even if public concerns could be anticipated, as a situation evolves, concerns can also evolve. A skeptical public will keep finding "concerns" rather than moving on to action unless they can learn to trust a public agency. It is the long term, general public communication and education that will pay off in the future. The NRC should be providing the leadership in education of the public about radiation protection in a general sense, and then showing how they are applying it in a specific instance. Anything less will only increase mistrust.

### **Fees**

The NRC does indeed have a public health and safety mission. NRC activities serve a broader need than just providing a service to a licensee. They must provide leadership in radiation protection. They have to build public confidence in the safe use of radioactive materials. The foundation for NRC decision making should be the pursuit of that mission, not who will pay for it. Fee allocation should be as fair and equitable as possible, but programmatic decisions should not be fee driven.

### **Research**

The Commission's preliminary view of Option 4 (conduct both confirmatory and exploratory research) is the best option. However, the option should have the flexibility to move away from the present approximate 80/20 allocation of research funds to confirmatory / exploratory research as the need arises. This flexibility would balance the research needs related to current licensing issues and permit response to programmatic needs as well as anticipation of future needs. It is important for NRC to maintain an active and independent research program so that they do not have to rely solely on the industry's technical research and an independent assessment can be conducted on the adequacy of safety issues. It is also prudent that the Commission maintain its university based resources and



participation in international safety programs if possible.

### **Enhancing Regulatory Excellence**

Reading this DSI struck a chord with me as a state regulator. Many of the same principles which the NRC used to describe their aspirations are ones which the state strives for. Terms such as "regulatory effectiveness, regulatory efficiency, technically sound regulations, flexibility, consistency in the enforcement of areas of non-compliance, credibility, avoidance of overregulation" are concepts for all regulators to try to use when we write regulations.

The paper discusses the importance of self-assessment in ensuring that regulations meet current technology. One phrase that I like in the description of the NRC is that the NRC is a "learning organization." It appears that this self-assessment has resulted in improvement in the effectiveness of NRC's regulatory framework.

For a self-assessment to be effective, the people doing the assessing must be able to be critical of their own operations, and not be afraid that they will lose their jobs as a result of eliminating non-productive activities. In Option 2, the use of a senior management review group seems to be able to take a step back from the day-to-day operations and attempt to critically appraise the elements of regulation. However, when you recommend cutting programs you are still telling people that what they did in the past is no longer necessary and by inference, never was necessary. The effect on morale cannot be dismissed. And when the message is delivered by their own senior management, it is even more distressing. If the staff is involved in the decision making and the conclusion was reached amicably, staff may feel they still have some control over the regulatory process, as well as their own careers. It would be even better if they could identify a new role for themselves that would enhance regulatory excellence and preserve their own contribution to public health and safety.

The current system of review and assessment used by the NRC is reactive. The NRC revises procedures and practices as deficiencies in the process become apparent through a sequence of events at some facility within the regulated industry. The proposition of a comprehensive review and strategic analysis of NRC's entire regulatory process would most likely result in a more effective regulatory body. One deterrent to such a proactive program is clearly identified - it would be costly, particularly if the NRC undertakes it alone.

Neither option includes a significant role for the regulated community, even though the external economic environment is a driving force to improve regulatory effectiveness. Licensees would like to reduce their direct and indirect costs, and lessen the need for NRC inspections. It would seem that they may have some ideas for demonstration of voluntary compliance, perhaps through compliance with industry established standards such as ISO standards that the same health and safety goals could be realized. I would strongly advise that NRC include some representatives of the regulated community on their assessment groups, as well as members of consumer groups and other advocates for the public. Including stakeholders in the assessments may increase the time to get consensus, but will increase the commitment to whatever solution is forthcoming. Many states



have already started these processes, with their "Performance Partnerships", and you could learn from the states.

As an example, NRC adopted the NUMARC methodology for developing Emergency Action Levels. The net result of this regulatory action was a decrease in report ability of events from nuclear facilities and a relaxation of the regulatory requirements placed on nuclear facilities. The NRC believed that the changes that resulted from the adoption of their methodology did not compromise the ability of the plant to protect the health and safety of the public. In fact, it could enhance public health and safety by allowing licensees as well as governmental agencies to focus on only highly significant events. However, a comprehensive review by New Jersey of draft EALs submitted by PSE&G raised some significant safety concerns and revisions were made to the EAL document. This example points out the need for some sort of external review group. Internal audits of the regulatory process may miss important issues. All of the NRC's customers should be represented on a review group to provide oversight for the protection of the public's interests.

As a state, we struggle to have our regs reflect current technology but as a result of shortfalls in staffing, regulations can't be revised quickly enough to meet the accelerated change particularly in the medical field. One alternative to ensure public and worker safety in the face of technological change could be to use mutually agreeable standards. A partnership could be formed to have staff learn from industry about anticipated advances in the technology, so that they could work together on the most effective ways to ensure that the new technology functions appropriately without any degradation to public health and safety. Old methods of regulating are not always appropriate for new technology, and it takes so long to change regulations, that even newer technology is available before the regs are changed. Let's acknowledge this dilemma, and work together to address it.

### **Decommissioning - Power Reactors**

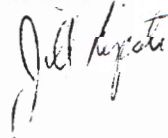
While the Commission's preliminary view selecting Option 1 (Continue the current direction and approach) seems on the surface to be supporting status quo, the examples of innovative regulatory approaches that the Commission suggest could change the direction dramatically. The states would like to be brought into the discussion now, to contribute ideas about what a regulatory program for a shut-down and defueled reactor site should look like. If the Commission wants the staff to consider transfer of a nuclear power plant to state control with the fuel still on site, but put into dry storage, there are many implications for state resources. The option for NRC to reduce oversight and just perform a radiological assessment of the site when it is ready to be released is interesting, but has some implications for a state's emergency planning about what to do in the case of an offsite release.

The Commission should be able to shift into Option 2 (Pursue current direction and approaches more aggressively) if there are more plants which are shut down prematurely as a result of deregulation. States are particularly concerned about a shortfall of decommissioning funds.



Thank you for preparing this comprehensive document and for giving us the opportunity to comment. My staff and I enjoyed preparing these comments, and you provided us with a number of stimulating issues for discussion. I would be happy to answer any questions you may have as you read my letter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jill Lipoti".

Jill Lipoti, Ph.D.,  
Assistant Director