



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 11, 2011

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-11-0032

TITLE: CONSIDERATION OF THE CUMULATIVE EFFECTS OF
REGULATION IN THE RULEMAKING PROCESS

The Commission (with Commissioners Svinicki, Apostolakis, Magwood and Ostendorff agreeing and Chairman Jaczko agreeing in part) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of October 11, 2011.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-11-0032

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACZKO	X	X			X	8/29/11
COMR. SVINICKI	X				X	8/23/11
COMR. APOSTOLAKIS	X				X	8/16/11
COMR. MAGWOOD	X				X	7/12/11
COMR. OSTENDORFF	X				X	8/16/11

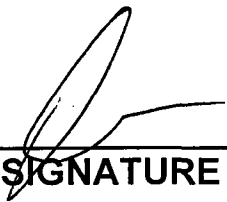
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Chairman Gregory B. Jaczko
SUBJECT: SECY-11-0032- CONSIDERATION OF THE
CUMULATIVE EFFECTS OF REGULATION IN THE
RULEMAKING PROCESS

Approved in Part X Disapproved in Part X Abstain
Not Participating

COMMENTS: Below Attached X None



SIGNATURE
8/29/11

DATE

Entered on "STARS" Yes X No

Chairman Jaczko's Comments on
SECY-11-0032, "Consideration of the Cumulative Effects of Regulations in the Rulemaking
Process"

I approve in part and disapprove in part the actions described by the NRC staff in SECY-11-0032. I support the actions described in the SECY paper associated with interaction with external stakeholders during the development of regulatory basis, interaction with external stakeholders during the development of draft guidance, publication of draft guidance with proposed rules, publication of final guidance with final rule, interaction with external stakeholders on implementation of the final rule, and revision of the common prioritization of NRC's rulemaking activities. These actions are good practices that should enhance the openness and transparency of the regulatory process. In addition these actions will enhance the ability of external stakeholders to more fully participate in the rulemaking process.

I do not support any of the other actions associated with "cumulative effects," with the exception of soliciting targeted comments during the proposed rule stage on implementation date and regulatory analysis. In addition, the staff should take appropriate steps to encourage comments in these targeted areas. Meaningful comments from external stakeholders, especially from licensees, applicants, States governments, local governments, and tribal governments that may be effected by the proposed regulation, in these targeted areas will ensure new regulations are coherent, logical, and practical. With publication of any associated guidance along with a proposed rule, stakeholders should have a more complete understanding of a new regulation and will be better positioned to provide meaningful comments on implementation and the regulatory analysis. I agree with Commissioners Apostolakis and Magwood that exceptions to publishing rules and guidance at the same time should be very limited. Also, I agree with Commissioner Ostendorff that the EDO should inform the Commission of any instance, and the associated reasons, where a proposed rule package will be provided to the Commission without having completed the draft guidance.

At repeated points throughout the NRC's history, the industry has asked, encouraged, and pressured, in one form or another, the Agency to broadly and explicitly consider costs, which is a plain English descriptor for "cumulative effects" or "aggregate impact." In the course of the congressional debate that culminated in the creation of the NRC as an independent agency in 1974, the industry urged Congress that "the time is ripe to reassess the regulatory process and in fact, probably have an impact statement of changes that are required for safety to show that the added safety is worth the costs in delay and money."¹

After the NRC was created and for the past thirty-six years, the industry has continued to seek a greater considerations of costs. As the attached speech by former NRC Chairman Hendrie recounts, giving greater consideration to the cost (or "cumulative effects") of regulation was a topic of interest for the industry before the Three Mile Island accident, and remained so after the accident. There are a number of thoughtful points in former Chairman Hendrie's speech. The two points that resonates most with me are his statements that:

¹ III Legislative History of the Energy Reorganization Act of 1974, at 2238 (1974), quoted in Union of Concerned Scientists, et al., *Petitioners v. U.S. Nuclear Regulatory Commission and the United States Of America*, 824 F.2d 108, 115 (D.C. Cir. 1987).

“We regulate on the basis of protecting the public health and safety. In setting the standards for that protection, we can take some limited account of the costs but it is the protection that is important and not the costs.”

and

“When we find that changes are needed to maintain the protection we had previously thought was in place, or when we identify new measures that provide substantial additional protection and are necessary for safety, they must be made.”


Industry's efforts in the 1980s led to the revision of the backfit rule (i.e., §10 CFR 50.109), which in its original form was struck down by the D.C. Circuit Court of Appeal for inappropriately introducing the consideration of costs into providing adequate protection to the public. At the DC Circuits' direction, the Commission had to revise its policy to make explicit that costs are not to be considered either when backfitting is necessary to ensure adequate protection of public health and safety or when the Commission defines or redefines what is needed for adequate protection.

The NRC cannot consider costs when issuing rules and regulations that are necessary to ensure adequate protection of public health and safety, or common defense and security. Because they are so essential to safety, there is no wiggle room in our statute for reducing these requirements on the basis of cumulative effects. As the bedrock of our safety efforts, our adequate protection rules represent the bulk of the requirements that we impose on our licensees.

The NRC does consider cost in an appropriate, limited, and legally permissible manner, and I fully support the current practice for the consideration of costs. It is important to recognize that - in the limited circumstances where the agency does consider cost – the NRC already has processes in place to address the impact of regulations on licensees: solicitation of public comments and regulatory analyses. The most significant is the solicitation of public comments, which is built into our rulemaking activities. In the past, licensees have primarily raised issues specific to the rule under consideration, rather than concerns about cumulative effects. But that has been a matter of choice. The NRC has not precluded licensees from raising these kinds of issues. Licensees should take full advantage of the opportunities the Agency provides during our rulemakings to raise any concerns that they have about implementation, including timing and costs. That is the appropriate time – not after the final rule has been adopted.

There is another factor that contributes to the aggregate impact of new or revised requirements or the enforcement of existing requirements. This factor can be easily illustrated with two rulemakings cited by the industry to illustrate their concern with the aggregate impact of regulations: recently revised Part 26, “Fitness for Duty Programs” and Part 73, “Physical Protection of Plants and Materials.” Because of repeated delays in the completion of Part 26, these two large rulemakings ended up being completed and implemented in the same timeframe. If Part 26 had been completed on its original timetable, this situation could have been avoided. The inability to complete rulemakings and resolve longstanding regulatory issues in timely manner contributes to cumulative effects. Repeated delays in resolving long standing safety issue such as the pressurized water reactor sump blockage issue and fire protection are ongoing examples of needed regulatory actions will contribute to perceived cumulative effects

because of protracted delays in their completion. The best way to avoid this type of impact is for both the NRC and licensees to move forward on timely schedules without unwarranted delays so that resources can be freed up to address other important issues.



Gregory B. Jaczko

06/29/11

Date

Chairman Joseph M. Hendrie
U.S. Nuclear Regulatory Commission
Speech before the Atomic Industrial Forum's¹
International Conference on Financing Nuclear Power
Copenhagen, Denmark
September 24, 1979

RECONCILING REGULATION AND COSTS

It was the first month of this year - - January 4, to be exact - - that I received the invitation to meet with you today and discuss the relation between costs and regulation. I accepted the invitation and the topic at that time on the speculation that I could say something useful on the subject. Of course I am still interested in your theme and your concerns, and I am pleased to have the chance to address them here today. But I have to say that my interest back in January was not quite the same as my interest now is in September, because nothing in the world of nuclear power generation is the same as it was before March 28, 1979.

A watershed event for nuclear power has taken place. Its implications for the future of nuclear power in the United States, in Europe, and throughout the world are only just beginning to emerge. In the next few months, several full-scale reports on the Three Mile Island accident will be forthcoming. These studies, which include those being carried out by the industry itself, will prove invaluable and, I expect, critical to the future of nuclear power in the U.S.

I would propose at the outset that we meet to talk about costs at a time when it is hard to think of the cost of thorough, rigorous and effective regulation as excessive. It has always been true - - though never before so unmistakably true - - that your investment in prevention and protection is an investment with high return. The true value of effective regulation can only be measured in terms of the sole available alternative... the end of the nuclear power industry.

The invitation of last January proposed that I speak of the reconciliation of costs and regulation. The question, I take it, is do we regulators give sufficient consideration to the financial impact of the regulations we impose? It is a question upon which reasonable people can differ, and generally do.

Let me give a short answer to the cost question. We regulate on the basis of protecting the public health and safety. In setting the standards for that protection, we can take some limited account of the costs but it is the protection that is important and not the costs. And any safety measure that prevents even a minor plant upset will have paid for itself many times over.

I should note that my remarks here are limited to the regulation of U.S. commercial nuclear plants, with no implications for import-export matters. I realize we have an international audience here today and some of you may have particular interest in the costs of export licensing, but that is a labyrinth I would prefer not to enter.

¹ This speech was retyped from a microfiche printout. The typist was unable to discern two of the words in the last paragraph of the speech.

Enclosure

The argument is often made that the law under which the NRC operates requires that we look to the effect of our actions on the general public welfare in framing regulations for nuclear power. Under this construction of the law, the NRC must seek to protect the public not only from undue hazards related to nuclear power but also from undue expense associated with regulatory requirements. There is indeed some language in the Atomic Energy Act, the law which provides for regulation of civilian nuclear activities, that the control of this energy resource shall be exercised "so as to make the maximum contribution to the general welfare," and again, to "improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise."

Despite this preamble, the Atomic Energy Act, in setting out the aims and standards related to the issuance of licenses and the regulation of licensees, concentrates on the protection of the public health and safety and the common defense and security. Thus the Act says that the commission is prohibited from issuing any special nuclear material licenses if it finds that such action would be "inimical to the common defense and security or would constitute an unreasonable risk to the health and safety of the public." Again, the Commission is authorized to establish such standards regarding the possession and use of nuclear materials as the Commission "deems necessary or desirable to promote the common defense or to protect health or to minimize danger to life or property." And in issuing an operating license, the Commission must find that the nuclear facility "will provide adequate protection to the health and safety of the public."

What is important here for our discussion of the costs of regulation is that the main thrust of the law is that we are to protect the public health and safety, both the legislative and judicial history of the Atomic Energy Act corroborate the conclusion that for the NRC, protection of the public health and safety - - and not enhancement of the general public welfare - - is the decisive criterion in determining the appropriateness of a regulation. But neither the Atomic Energy Act nor decisions of the courts shed light on the exact nature of that protection, or identify the factors or characteristics whose presence signifies proper protection of the public and whose absence denotes unreasonable risk. The discretionary authority of the Commission in this regard is very extensive. Adequate protection means what the Commission says it means, and we mean it to require a very high level of safety.

Now where does all of this leave us with regard to the costs of regulatory requirements?

The Commission in effect defines the necessary level of protection through the regulations that set various requirements for nuclear plants. We can and do consider costs and related factors in our rulemaking, either explicitly through value-impact analyses, or implicitly in the individual judgments of the Commissioners. But it is the improvement in safety that must be the dominant element in our considerations. In a similar way the NRC Staff, in considering new generic requirements to implement the regulations, will generally make a value-impact analysis. So we do take costs in account, at least in a limited way, in setting the general requirements to obtain a high safety level.

But when we come to apply these general requirements to a specific matter, on a specific plant, costs and related factors do not count for much. Each plant must meet those general requirements in order to be allowed to operate. Our purpose, after all, is to reduce the risk to the public, by appropriate regulation, to as low a level as we can reasonably achieve at the time a facility is designed and constructed and to keep it there during operation. That requires adherence to the body of regulations with which all licensed plants must comply. The regulations are not totally inflexible. Exemptions can be granted where it can be shown that the

necessary level of safety can be maintained by some other means. But in general, a plant that does not meet the regulations cannot operate, and costs and other factors don't have much to do with it.

You may recall that earlier this year, before Three Mile Island, the Commission shut down five plants because we had good reason to believe they were in violation of our requirements for protection against earthquakes. These shutdowns were very costly to consumers in terms of the electricity the plants would otherwise have produced, and the shutdowns came in the middle of an acute oil and gasoline shortage. I subsequently was lectured at length in numerous hearings before Congress on how high those costs were and on reducing oil consumption. But I thought it was the right decision then, and I still think so. I don't believe we should relax safety standards simply because the costs or other effects of maintaining those standards are significant.

No discussion of the costs of regulation would be complete without mention of ratcheting -- that is, the regulators' inclination to impose successively more stringent safety requirements on new plants -- and of backfitting of new requirements to operating plants. If we consider that the plants now operating meet current regulations, and thus, as a group, in principle represent the required level of safety that is defined by the regulations, why do we have ratcheting and backfitting? I would hope the answer is obvious to all of us. We are still learning things about nuclear power technology, from the experience with operating plants and from safety research. It would be entirely inconsistent with the purposes of regulation to pretend that there are no new developments and improvements to be incorporated into the design and construction of newer facilities over a period of time. It would be irrational to ignore the opportunities to raise the levels of safety as they are presented by new construction and to hold to an original standard that never changes. Hence we occasionally find it necessary to ratchet new projects.

The same considerations apply to backfitting new safety requirements on operating plants. When we find that changes are needed to maintain the protection we had previously thought was in place, or when we identify new measures that provide substantial additional protection and are necessary for safety, they must be made. We take into account the costs involved in such changes and we try to look carefully to see that the additional protection from a backfitting action is real and worthwhile. Having done so, where we find backfitting is appropriate, it must be done, and the costs will have to be born.

There have already been a number of backfitting actions required with regard to both equipment and operating procedures as a result of the Three Mile Island accident. I can assure you that there will be many more. I am sure that some of those changes will be regarded with dismay in some quarters. But consider. Suppose that a year or so ago we had been bright enough, as we should have been, to recognize the potential problem in allowing the frequent lifting of the primary relief valves in the Babcock and Wilcox plants. And suppose we had then required the changes we have, in fact, required since Three Mile Island. These include eliminating the lifting of these relief valves during secondary system transients, retraining PWR operators to recognize the meaning of saturation conditions for pressurizer level, and all the other changes that have been required to date. There certainly would have been additional costs involved in those changes, and I would not have been able to point to a major accident to prove that the changes were necessary. But what a bargain it would have been.

Given the limited framework within which we can consider the costs of regulation, what can we do to improve the effectiveness of the process? Certainly we can improve the quality of our value-impact analyses. A clearer and more specific enunciation of the safety benefits of

proposed change in regulations or staff positions, together with a more realistic cost estimate would improve the decision-making process in general. However, I doubt that this kind of improvement could ever reach the point of producing uniform satisfaction for all parties. I suspect there would be a general tendency of the regulators to see more safety benefits and smaller costs in proposed changes, and an equal and opposite tendency of licensees and applicants to see smaller safety benefits and larger costs for the same changes.

More generally, it is fair to recognize that the present framework of regulation is a difficult one within which to achieve a fully efficient assignment of costs and safety benefits. We have, over the years, evolved a set of regulations. We modify them and add new regulations pretty much on a one-at-a-time basis. The same is true of NRC staff positions and guidance documents implementing the regulations. Taken as a set the regulations and staff documents attempt to define a very high safety level for nuclear plants and a correspondingly low risk to the public. That certainly was the underlying thought as each regulation was adopted. But for any given regulation or staff position, it may be hard to assess with any great precision the overall increase in safety margins achieved thereby. The result is that we probably have a less than optimum cost structure associated with the required safety level. That is, we get the required safety, or try to, but we may occasionally overshoot and cause larger costs than are really necessary.

Optimization of the process, to obtain the required very low risk at the least cost, requires that we have a method of quantitatively determining risk levels, both incrementally for a proposed modification and overall for a complete plant. With such a method in hand, one could express the aim of very low risk to the public in numerical terms and evaluate proposed changes against that model. It would also help us to identify and remedy any weak points in plant designs and operation. Overall, it would be a more efficient basis for regulation, and probably a more clearly understood one. Before we can move in that direction, however, we need a risk assessment methodology that is well understood and generally accepted, and a set of data bases that are adequate for the purpose. It will be a while before that is the case, but it is an objective worth working toward.

Let me turn briefly at this point to the subject of the Three Mile Island accident, a matter of most serious interest to us all. A number of investigations are still under way, as you know. The Presidential Commission is scheduled to issue its findings late next month, several Congressional inquiries are in progress, your industry is examining major aspects of the accident, and the NRC has instituted a special inquiry, under independent leadership, to explore the matter. The findings and recommendations of that group are due for issuance about the end of this year.

It is not my intention to predict the results of any of these efforts, but I don't think we need to wait for the results of all of the investigations to be able to identify some of the key elements and lessons of Three Mile Island. In brief, the accident was a small-break loss-of-coolant accident brought about by the failure of a relief valve to close and the failure of the operators on the scene to realize that it was open. Being unaware of the true nature of the problem they were dealing with - - that it was a small loss of coolant accident - - the operators turned off the high-pressure injection. This subsequently led to overheating, the formation of steam voids, periods when the core was uncovered and extensive damage occurred, the famous hydrogen bubble, and so on. The operators' problems were compounded by instrument failures and idiosyncrasies, by some elements of the design of the plant, and by deficiencies in their training.

There were other things that happened, not as crucial, but disturbing and revealing. It was some time after the onset of the accident before the operators realized that water in the containment sump was being pumped to the auxiliary building and overflowing the tankage there and it was some hours before the containment was fully isolated. And the auxiliary feedwater block valves were closed at the onset of the accident. That's a fact that apparently did not have much to do with the severity of subsequent events, but it was a flat violation of the license conditions for that plant to be in operation with those block valves closed.

An important lesson is that operator training has not been sufficiently rigorous with respect to transient or off-normal situations. Operators, of course, are licensed by the NRC and a good bit of training and testing takes place before a license is granted. But I think we have simply failed to recognize that the operators' readiness to deal with the unusual, and a frequent reinforcement of that readiness by training with the reactor simulators, are essential elements in the process. A substantial upgrading in operator training requirements and in frequent retraining and requalification is necessary.

A second lesson in this same area is the need to reassess the makeup of operator teams or shifts and the backup engineering capability of licensee companies. One of the disturbing problems emerging in the decisive early stages of the accident is that the small operating staff on that dawn shift became prisoners of the control panel. They were instantly riveted to the switches and the gauges and no one stood back, to take in the overall situation and comprehend what was taking place. It is clear that some enlargement of control room staffing should go along with improvements in operator training.

A related area has to do with control room arrangements and instrumentation. The most highly skilled and trained operators are likely to make errors in a fast-moving situations if their instrument readings are ambiguous, or if the instrument displays are not quickly and easily understood. Finding better ways to integrate and display the data that give the operators a clear understanding of the plant condition is an important step in assuring that operators will respond correctly to abnormal situations. We are moving toward an upgrading in this whole area, including improvements in water-level instrumentation, direct indication of relief valve positions, diverse containment isolation, and a number of other items.

The next key lesson is that we must understand and use the operating experience of these plants much more effectively. There were several precursor events to the Three Mile Island accident that should have alerted all of us to the sensitivity of that design to feedwater transients. One of these events was almost a trial run for the Three Mile Island accident. This is an especially frustrating aspect of the matter because it involved an activity which I thought NRC was doing well. As you know, we have long required the extensive reporting of every sort of occurrence from licensed facilities. Our staff make a selection of the more significant items and reports them in a publication that goes to the licensees. It happens that a couple of the precursor events I speak of made their way into this publication, but we did not understand them well enough and we did not sit down with the operators of these plants to make sure they understood them as well. We are establishing a group of experienced staff members to understand the lessons in those experiences, and to make sure that the plant operators understand them and take all necessary steps.

The final lesson I will note here is the need for substantial work to be done in the area of emergency planning, particularly with respect to off-site preparations for the aftermath of an accident. Federal, state, and local government agencies are involved in this effort. Soon after the accident I wrote to the governors of states having nuclear plant sites and urged speedy and

determined action to bring their planning up to date. There is now a considerably enhanced spirit of urgency and cooperation in this area.

There are a number of other actions that are being taken as a result of the Three Mile Island accident and I would not want you to regard my list here as exhaustive. Some of these actions relate to plant design features and others to the extent and emphasis of our safety analyses and the way in which we review application and inspect the plants, and, of course, the results of the major independent investigations, with their recommendations, are still to come.

To conclude these remarks, let me make two points. The first has to do with my nominal subject - - costs and regulation. It is simply that these plants must operate safely and that safe and reliable operation is the most cost effective condition you can achieve for them. Safe operation is a "best buy" from all standpoints.

The second point is that safe and reliable operation results much more from all elements of the nuclear industry than just passive acceptance of whatever we regulators _____ that you do. It requires an alert, a vigorous, and a continuing effort by the nuclear industry to improve safety _____ the line, from design to operation. I am very much encouraged in this regard by the recent announcement of the efforts to form the Institute of Nuclear Power Operations, and of the formation and work to date of the Nuclear Safety Analysis Center of the Electric Power Research Institute. These efforts also are going to be "best buys" for the nuclear industry.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER SVINICKI
SUBJECT: SECY-11-0032- CONSIDERATION OF THE
CUMULATIVE EFFECTS OF REGULATION IN THE
RULEMAKING PROCESS

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___



SIGNATURE

08/23/11

DATE

Entered on "STARS" Yes No ___

Commissioner Svinicki's Comments on SECY-11-0032
Consideration of the Cumulative Effects of Regulation in the Rulemaking Process

I thank Commissioner Magwood for his conversion of this paper into a voting matter for the Commission. I agree with his thoughtful framing of the issues contained in the paper, as well as some issues that were not addressed by the staff, for the consideration of his colleagues. I approve the specific actions related to the explicit consideration of cumulative effects of regulation in the rulemaking process, which have been laid out in SECY-11-0032, with the additions and modifications contained in this vote.

While not applying directly to independent regulatory agencies like the NRC, Executive Order 13563, "Improving Regulation and Regulatory Review," dated January 18, 2011 [which reaffirms and supplements Executive Order 12866, issued by President Clinton in 1993] states that our regulatory system "must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements."

I support these goals.

In Executive Order 13579, "Regulation and Independent Regulatory Agencies," and the accompanying Memorandum, both dated July 11, 2011, President Obama went further and asked - to the extent permitted by law - that independent regulatory agencies "join in this review and produce your own plans to reassess and streamline regulations. For rules going forward, I am also asking you to follow the key cost-saving, burden-reducing principles outlined in the January Executive Order." The policy statement contained in the order posits that wise regulatory decisions depend on public participation and on careful analysis of the likely consequences of regulation; that such decisions are informed and improved by allowing interested members of the public a meaningful opportunity to participate in rulemaking.

The Commission should endorse not only the spirit of these executive orders, but should direct the staff's response to Executive Order 13579 as a matter for Commission review and approval to capture the opportunity this Executive Order provides. I believe this is an opportunity to engage more fully with external stakeholders on the question of cumulative impacts, to sharpen our regulatory analyses, and perhaps, more importantly, to understand better the answer to the questions framed by Commissioner Magwood in his vote: "How can we measure the efficiency of our safety oversight if we have no objective way to measure its overall impact on licensees? When regulatory impacts are viewed in aggregate, how can we ensure the 'balance' inherent in our mandate?"

The actions requested in Executive Order 13579 are not new ground for the NRC. The NRC's Principles of Good Regulation already direct us as follows. Under the Principle of "Independence" we state: "[I]ndependence does not imply isolation. All available facts and opinions must be sought openly from licensees and other interested members of the public. . . . Final decisions must be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated." Under the Principle of "Openness" we state:

"The public must be informed about and have the opportunity to participate in the regulatory process as required by law." Under the Principle of "Efficiency" we state: "Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted."

In my view, the proposals put forward by the NRC staff in SECY-11-0032 advance the regulatory objectives of these Executive Orders, as well as aligning strongly with the NRC's Principles of Good Regulation. Consequently, I approve the staff's proposals to 1) increase interaction with external stakeholders throughout the rulemaking process, 2) issue draft and final supporting guidance with the proposed and final rules (and I agree that any exemptions to the achievement of this goal should be approved by the Commission), and 3) request stakeholder feedback as part of the rulemaking process so that cumulative effects of regulation can be addressed, when warranted. Staff's final strategy to implement the proposed process changes should be submitted to the Commission for review and approval as a notation vote paper within 12 months of the staff requirements memorandum (SRM) resulting from SECY-11-0032.

The NRC has previously recognized the value in the issuance of draft guidance and final supporting guidance with the proposed and final rules. Some of this history is worth revisiting here.

In SECY-07-0134, the staff provided an assessment of rulemaking process improvements. In the area of guidance documents, staff concluded the following:

"Developing implementation guidance concurrent with the rulemaking can reveal problems with proposed rule language, such as where it would be impractical or not feasible to implement and enforce proposed requirements. Implementation guidance can identify where proposed provisions would not achieve the desired objective, and provide no added value, or cause conflict with other requirements. . . . Feedback from stakeholders at the proposed rule stage based on insights from draft implementation guidance can also enable the staff to correct problems, improve the final rule and supporting statement of consideration (SOC), and avoid situations that call into question whether a final rule is within the logical outgrowth of the proposed rule. . . . Development of implementation guidance requires a thorough understanding of the new requirements, which in turn is directly related to a sound understanding of the technical basis for the new requirements.

"The development of implementation guidance concurrently with the proposed rule does require increased resources initially, and can result in an extended schedule to publish a proposed rule. However, for technically complex rules where regulatory guidance is crucial to proper implementation of the rule requirements, the effort to develop the regulatory guidance is better spent during the proposed rule development stage where the benefits noted above can inform the proposed rule language, the technical basis, and the supporting SOC. To the extent that the development of implementation guidance during the proposed rule portion of the rulemaking process reveals issues that can be corrected in both the guidance and the proposed rule language, the net result should be a reduced expenditure of effort to revise the technical basis, implementation guidance and rule language in response to public comments. As a result, the net total resources spent for the rulemaking should be reduced."

Based on this assessment, in its SRM on SECY-07-0134, the Commission directed an increased emphasis on issuing draft implementation guidance in conjunction with the issuance of proposed rules for public comment.

I also approve an approach that will apply risk insights to prioritize regulatory actions; as has been proposed in the votes of some of my colleagues. As part of the broader strategy paper for the consideration of cumulative effects, the staff should propose how such a prioritization might be pursued. I also agree that regulatory impacts do not result solely from rulemaking. Any review of cumulative effects should include other regulatory instruments such as generic communications, changes to guidance documents and supporting processes, license amendment requests, and inspection findings of a generic nature.

I also wish to note how impressed I was with the passion and thoughtfulness of the NRC staff who briefed me on their efforts, both in development of this paper and their overall efforts to improve the consideration of aggregate impacts between offices and across the agency. It was very heartening to engage with them in a discussion about their efforts. One aspect we discussed was the Common Prioritization of Rulemaking (CPR) and the potential for this process to provide better scrutability for the Commission regarding agency rulemaking priorities and a more risk-informed application of agency resources. The staff should provide the results of its revised CPR process to the Commission, when they are available.

In an editorial for the Wall Street Journal (published January 18, 2011, coincident with issuance of Executive Order 13563), President Obama wrote, "This is the lesson of our history: Our economy is not a zero-sum game. Regulations do have costs; often, as a country, we have to make tough decisions about whether these costs are necessary. But what is clear is that we can strike the right balance." Under the rubric of the Executive Order, the staff's proposed actions in SECY-11-0032, if implemented with consideration of the expanded aspects Commissioner Magwood outlined in his vote, provide us with the opportunity to advance the development of our regulatory tools for the measurement and evaluation of cumulative effects while making a lasting contribution to the effectiveness of our regulatory actions.



Kristine L. Svinicki

08/23/11

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Apostolakis
SUBJECT: SECY-11-0032- CONSIDERATION OF THE CUMULATIVE EFFECTS OF REGULATION IN THE RULEMAKING PROCESS

Approved X Disapproved _____ Abstain _____

Not Participating _____

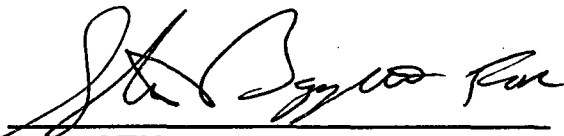
COMMENTS: Below X Attached _____ None _____

I approve staff's plans to further enhance the rulemaking process and increase consideration of potential means of mitigating the cumulative effects of regulations. I agree with Commissioner Magwood that the sources of cumulative effects are not comprised solely of rulemaking activities. I strongly encourage staff to consider significant non-rulemaking activities in its determination of cumulative effects. Therefore, staff's office-specific procedures should include provisions to account for regulatory actions (e.g. orders or generic requirements) that may influence implementation dates for new rule requirements.

I support the staff's plan to issue draft and final supporting guidance with the proposed and final rulemakings, respectively. I agree with Commissioner Magwood that exceptions to this approach should be very limited.

I support Commission Magwood's proposal that the staff should apply risk insights to prioritize regulatory actions. I acknowledge that it may be challenging for staff to develop a fully integrated risk-informed approach, but the use of risk insights should be an important consideration in the CER decision-making strategy.

Addressing the wide range of rulemaking activities by using office specific-procedures has merit. As staff develops the office specific-procedures, it should ensure uniform adoption of the rulemaking process enhancements to the extent practicable.



SIGNATURE

8/16/2011

DATE

Entered on "STARS" Yes No _____

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary


FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-11-0032-- CONSIDERATION OF THE
CUMULATIVE EFFECTS OF REGULATION IN THE
RULEMAKING PROCESS

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached None _____



SIGNATURE

12 July 2011

DATE

Entered on "STARS" Yes No _____

**Commissioner Magwood's Comments on SECY-11-0032:
"Consideration of the Cumulative Effects
of Regulation in the Rulemaking Process"**

I appreciate the staff's attempt to grapple with this complex issue. While the general question of "how much regulation is too much" has been the subject of active debate in this country since the founding of the Republic, the consideration of what is now known as the "cumulative effects of regulation" (CER) with the respect to the NRC traces back to 2002. At that time, the NRC's regulations and practices were assessed to determine whether they presented an "unnecessary regulatory burden." This discussion raises both very practical issues regarding how regulations are implemented as well as more far-reaching policy issues associated with the appropriate role of a safety regulator.

As has been observed many times over the years, the safest nuclear activities are those that have been regulated out of existence. While there are stakeholders who may find this outcome acceptable, the clear intent of Congress as reflected in both the Atomic Energy Act, the Energy Reorganization Act, and other established law is that nuclear activities be allowed to proceed in the United States under a regulatory regime that allows the commercial application of nuclear technologies while protecting public health, safety, and security. It is, therefore, the principle role of the Commission to determine the appropriate balance.

It has been my observation, however, that the Commission rarely, if ever, has sufficient information to determine that balance.

As I consider the staff's paper, I find that there are three aspects of this issue. Each aspect is a difficult matter in its own right, but each in its own way speaks to the larger issue of how the Commission determines the balance necessary to assure that the NRC is performing its mission in an appropriate manner.

First is a very pragmatic component of this issue. Stakeholders have often raised the concern that NRC's process for scheduling the implementation of new requirements were not considered in light of the impact of concurrent regulatory actions. As we have learned, licensees can face significant challenges when attempting to simultaneously implement multiple actions stemming from diverse requirements, within a limited schedule and with limited resources. This diversion of resources has the potential to distract licensee staff from executing their primary responsibility of safe operation. While we should always be prepared to require licensees to take prompt action when it is necessary, it does not as a general matter advance the cause of safety to inundate licensee staffs with multiple actions when a more thoughtful process might achieve the agency's safety goals without straining licensee resources.

With this perspective in mind, staff has engaged external stakeholders to develop a common perspective on CER as well as a path forward. The outcome of this process

comprises the substance of SECY-11- 0032, which highlights a range of rulemaking process changes intended to address CER as it pertains to the pursuit of specific rulemaking activities. Salient among the staff's proposed process changes are three items: establishment of a "Regulatory Basis Development Interaction" with stakeholders, "Draft Guidance Interaction," and the "Revised Common Prioritization of Rulemaking (CPR) Process. Subject to the following comments, I support the staff's proposed changes and approve its proposed schedule to complete work on the proposed process revision within 12 months (of the SRM for SECY-11- 0032):

- Regarding the Regulatory Basis Development Interaction for each rule, I believe that it is important that the Commission be informed as to the outcome of these interactions as the staff is able to draw conclusions. Staff should, therefore, provide the Commission with its general conclusions based on these interactions via a CA note for each rulemaking as soon as practical. This practice could, for example, prove very important in assuring the optimum implementation of any new requirements arising from the agency's response to the events surrounding Japan's Fukushima nuclear plant. Ideally, the output of the agency's task force could serve as an early application of Regulatory Basis Development Interaction.
- I fully support the development of draft guidance in concert with draft rulemakings; in fact, I recommend that the inclusion of such draft guidance be required for Commission consideration of all rules—unless the Commission (rather than the EDO as suggested in the paper) provides an exemption.
- Further, while I provide no specific approval for its unfortunate acronym, I further recommend that the staff provide the Commission the results of its Revised CPR Process as they become available. This should also be provided via CA notes and provided on a periodic basis. I leave it to the staff to propose an appropriate interval.
- I also note that regulatory impacts are not comprised solely of rulemaking activities. CER includes other regulatory actions such as generic communications, changes to guidance documents and supporting processes, license amendment requests, and inspection findings of a generic nature. I believe that an effective CER review must consider the entire suite of concurrent requirements and, therefore, propose that staff expand its vista to develop an integrated consideration of all regulatory requirements.
- Finally, SECY-11- 0032 highlights stakeholder comments that suggest this revised process should apply risk insights to prioritize regulatory actions. This avenue was not discussed substantively in the staff paper. The Commission would benefit from the staff's consideration of whether such a prioritization is practical and if so, how it might be pursued. Staff's review of this issue should be reflected in its CER strategy.

As suggested by the paper, staff's final strategy to implement the proposed process changes should be submitted to the Commission for review and approval within 12 months.

While I recognize that the proposed process changes are likely to impact the schedules for future rulemakings, no aspect of the proposed process revisions should inhibit staff's efforts to propose, pursue, and implement rules, guidance, or other regulatory tools that address issues of safety significance. If implemented as planned, the approach anticipated by SECY-11-0032 should assist the agency in mitigating unintended impacts on licensees and improve the implementation of needed regulatory actions.

While beneficial, these changes, however, reflect only the interaction of new regulatory activities. As mentioned above, I believe there are two other aspects of CER—neither of which are considered in the staff's paper, but both of which involve the aggregate effect of existing and new regulatory guidance.

To begin, the agency has heard the anecdotal vexations of some licensees about the mounting financial cost of regulatory actions and their proposition that some nuclear plants may become too burdened by regulatory costs to remain economically viable. On a first order, this assertion is not compelling. If the NRC is performing as it should, regulatory requirements are necessary for safety and such requirements cost what they cost and no nuclear safety regulator should base its decisions on cost.

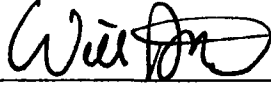
Nevertheless, it is fair to ask whether the agency is implementing its safety responsibilities efficiently. Put another way, are all NRC requirements placed on a given licensee necessary for safety? Is it possible that various requirements overlap in a manner such that an "unnecessary burden" is created? I am not confident that we are in a position to answer these questions on a plant-by-plant basis. As the agency enters its fifth decade, it has built a complex and evolving framework of regulatory actions to assure the safe and secure use of nuclear materials. How can we measure the efficiency of our safety oversight if we have no objective way to measure its overall impact on licensees? When regulatory impacts are viewed in aggregate, how can we ensure the "balance" inherent in our mandate?

This line of thought leads to a corollary question which encapsulates the third aspect of CER; a question which has been raised by groups such as the Union of Concerned Scientists: How can we measure the *effectiveness* of our safety oversight if we have no objective way to measure its overall impact on *risk*? How can we be certain that the complex web of regulations, orders, exemptions, and other guidance interact in a manner that assures the adequate protection of the public?

The central issue of the cumulative effects of regulation is, therefore, the need to understand the aggregate impact of all the agency's actions—both in terms of the regulatory burden on licensees and the assurance of safety. An aggregate regulatory burden that is larger than is needed to achieve a given level of safety does not well

serve the assurance of safety. It may, in fact, distract from safety by inadvertently substituting regulatory "quantity" for regulatory "quality."

I recommend that staff consider the need to quantify the cumulative impacts of regulation in the strategy paper due to the Commission in 12 months or in a new decision paper. If staff determines that a new paper is appropriate, it should propose a schedule of work for Commission consideration. Either way, staff should provide the Commission with its views as to how the agency might develop a measurement and evaluation approach that will inform both future and current regulatory activities.

 7/12/11

William D. Magwood, IV Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER OSTENDORFF
SUBJECT: SECY-11-0032

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached X None

WCO Ostendorff
SIGNATURE

8/16/11
DATE

Entered on "STARS" Yes X No

Commissioner Ostendorff's Comments on SECY-11-0032
Consideration of the Cumulative Effects of Regulation in the Rulemaking Process

I approve the staff's plans for process changes as presented in SECY-11-0032 to address the cumulative effects of regulation in the rulemaking process. I appreciate the staff's efforts to consider and take actions to address this issue, and I thank Commissioner Magwood for framing this issue for collegial review by the Commission.

I agree with Commissioner Magwood that the development of regulatory guidance should be developed in concert with proposed rules. As an alternative approach to Commissioner Magwood's proposal in this area, I suggest that the EDO promptly inform the Commission of any instances, and the associated reasons, where a proposed rule package will be provided to the Commission without having completed the draft guidance.

I believe that licensee and NRC management can only effectively focus on a handful of important issues at any given time. In my vote on the Japan Task Force report in SECY-11-0093, I supported an integrated, prioritized assessment of the Task Force recommendations as a necessary step prior to Commission decision making on individual recommendations. In that same vein, I support the effort for a "Revised Common Prioritization of Rulemaking Process" that seeks to prioritize rulemaking activities on a common basis agency wide, rather than just within a given office. The new process should be reflected in the 2012 Rulemaking Activity Plan.

The staff should include status updates of its overall progress in this area in future annual Rulemaking Activity Plans. In addition, the staff should consider the July 11, 2011 Executive Order on Regulation and Independent Regulatory Agencies (E.O. 13579) as it works to improve our regulatory processes.