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POLICY ISSUE
(Information)

SECY-93-310

FOR: The Commissioners
FROM: James M. Taylor
Executive Director for Operations
SUBJECT: RESPONSE TO THE HEALTH PHYSICS SOCIETY
EDITORIAL

As the Commission knows, an editorial in the September 1993 edition of the Health Physics Society's Newsletter (Enclosure 1) focussed on a recent enforcement action involving a contamination incident where a researcher failed to conduct required surveys following laboratory work. The editorial and two followup letters to the editor that were published in the October 1993 Newsletter (Enclosure 2) criticized the NRC's enforcement approach and the use of escalated enforcement actions for licensee-reported violations of low safety significance. In a Staff Requirements Memorandum dated September 30, 1993, the Commission invited the staff to provide comments on the editorial and to provide other suggestions on ways to improve the resource expenditures for enforcement actions.

In view of some of the criticisms contained in the Health Physics Society Newsletter materials, the staff believes that it would be appropriate to address the issue of licensee reporting of violations. The enclosed draft letter (Enclosure 3) is a proposed response to the September editorial and the October letters. Unless directed otherwise by the Commission, the staff plans to submit the proposed response to the Health Physics Society Newsletter by November 20, 1993 so that it may be considered for publication in the December issue of the Newsletter.

The staff does not intend to address the specifics of the case since the licensee in this case, Mayo Clinic, has paid the civil penalty. In the staff's view, enforcement action was warranted notwithstanding the minimal safety significance resulting from a

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small amount of contamination offsite. The contamination was not significant from a health and safety perspective, but it was preventable and that was the primary concern of the staff. Further, the researcher was a post graduate student who was trained in the proper procedures and who was aware of the requirement to survey. The researcher, because he was in a hurry chose not to perform the survey when he recognized that the survey instrument batteries were low. In addition, he was also aware of another meter available in the next lab. This also happened again later that day and again the next day. The licensee did identify the failure of the researcher to perform surveys and some of the offsite contamination. However, it was NRC who discovered that the researcher knew of the availability of other instruments and that the contamination did go to other public areas. In this case, the civil penalty would have been higher had the licensee not identified some of the violations.

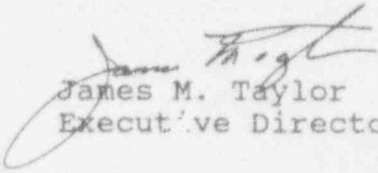
As to the Commission's inquiry regarding ways to improve the resource expenditures for enforcement actions, the staff is considering changes to the enforcement policy in the materials area to ensure that it continues to meet the primary objectives to promote and protect public health and safety and to ensure it is effective and resource efficient. OE has questioned the regions to determine what areas in the enforcement process cause a significant resource expenditure. The responses indicate that a significant portion of the resources expended on escalated enforcement actions involves the preparation of the inspection report. In addition, significant portions of the resources are expended on preparation for the enforcement conference and on formulation of the actual civil penalty based on the application of the escalation/mitigation factors.

Based on the regional responses, OE, in the future, will consider a proposal that would allow the regions to complete a form that summarizes the areas of noncompliance in lieu of the detailed and time-consuming preparation of an inspection report in materials cases. In addition, enforcement policy and practice currently allows the regions to forego an enforcement conference when the licensee identifies the violations and provides corrective actions, and when it is determined that no further information can be gained by conducting an enforcement conference. Telephone enforcement conferences are also becoming more useful and resource efficient for NRC and the licensees. With regard to the regions' difficulties in applying the escalation/mitigation factors, OE is considering reducing the levels of management involved in routine materials civil penalty actions, provided the enforcement factor application is simplified. OE, therefore, is considering the development of a proposal that would modify the escalation/mitigation factors in materials cases by instituting a simpler enforcement action matrix-type system based on the

The Commissioners

- 3 -

licensee's identification, corrective actions and past performance. The staff will submit any such proposals for the Commission's consideration prior to implementation.


James M. Taylor
Executive Director for Operations

Enclosures: As Stated

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EDITORIAL

Has Regulatory Enforcement Become Counterproductive?

Consider this scenario. An NRC licensee identifies a violation and reports it to the NRC in accordance with reporting requirements, or identifies these violations to an inspector who asks whether the licensee has self-discovered any violations. The inspector writes up the violation and notes any corrective actions taken by the licensee and any actions taken to prevent a recurrence.

Next, a Notice of Violation (NOV), and Proposed Imposition of Civil Penalty are issued against the licensee. Since the licensee self-identified the violation(s), the civil penalty is mitigated (reduced) in accordance with NRC Rules of Practice.

As a result, the NRC enhances its image in the eyes of the public and the licensee has saved face by self-identifying the violation. But does it really work that way? Do the civil penalty and the media coverage actually encourage other licensees to report self-identified violations?

There is speculation that some licensees fail to report a self-identified violation. If this is the case, we might ask why.

Consider the following. An NOV and Proposed Imposition of Civil Penalty were issued recently to a licensee after a researcher failed to perform contamination surveys of himself and tracked contamination off site.

The level of contamination, while low, required that a report be filed with the NRC. Even though the failure of the researcher to perform contamination surveys was self-identified and even though the NRC determined that the off-site contamination posed no health or safety problem, the failure to perform contamination surveys was considered as a willful violation.

In light of the December 1992 articles in the *Cleveland Plain Dealer* about radiation accidents and the hearings held by Senator John Glenn on these articles, one can wonder whether the motivation for characterizing this violation as willful was based on the need to demonstrate that the NRC was protecting the health and safety of the public through the issuance of an NOV.

The licensee issued a press release to inform the public about the contamination. Later, the NRC distributed a press release to announce the NOV and Proposed Imposition of Civil Penalty. The incident was reported regionally in numerous newspapers, on many radio stations and on several TV stations.

Could the accelerated enforcement by the NRC in this case—where there were no health and safety problems—actually have confused the public and discouraged some licensees from reporting self-identified violations?

Contemporary management models suggest that win-win solutions should be sought when two parties must take action to solve a conflict between them.

When a licensee has a problem, the NRC is obligated to assure that the problem is corrected. The health and safety of the public are guaranteed by correcting the problem whether or not an NOV is issued. The licensee benefits from a better understanding of its role.

Globally, the greatest benefit arises when problems of all licensees are identified and corrected. NOV's, civil penalties, and characterizations of willfulness intimidate licensees, discourage voluntary reporting, and consequently, fail to protect the pub-

[see EDITORIAL, page 3]

Enclosure 1

[EDITORIAL, continued from page 2]

lic. Swift, appropriate action should be taken in cases where licensee deficiencies threaten the health and safety of the public.

Establishing this level may not be easy, but the NRC would encourage licensee cooperation, optimize public health and safety, and enhance its own

image if its mission were directed toward the assurance of health and safety rather than looking for violators.

Contemporary management models also suggest that the success of an organization requires a positive, inspiring vision. The actions of an organization are a reflection of its vision. An emphasis on violations

rather than safety suggests that the NRC should examine its vision, instruct its staff in its vision for the safe and beneficial uses of radiation, and communicate that vision to licensees and the public to solicit their understanding, cooperation, and support.

That's one view. Let's hear yours.
Gen Roessler ■

From the President

I have been asked frequently what the Secretariat does for the Society and its members. The administrative and management support of Health Physics Society affairs is provided by Burk & Associates, Inc. in McLean, Virginia, under the able direction of Dick Burk, Executive Secretary of the Society. A listing of the support staff and their Society responsibilities is provided in the front of the membership directory.

Burk & Associates provides support to the Society in a number of different areas. Following is a brief listing of the kinds of services they provide. It is not an exhaustive list but should give you a sense of the depth and breadth of their support of the Society since 1974.

- **Administrative and Management Services:** Burk & Associates provides headquarters offices for continuity of programs and activities; provides adequate staff to perform clerical, administrative, secretarial and bookkeeping functions; provides mailing, copying and data base management services; maintains the permanent records and files of the Society; safeguards the Society's non-profit and corporate status; maintains the Society's accreditation and certification programs; assists the Society's chapters and sections; and assists the Society in government and public relations efforts.

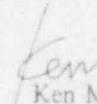
- **Financial Management Control Services:** The Secretariat prepares and issues annual dues and journal invoices; receives records, and deposits dues and journal payments, annual meeting income, etc.; administers the Society's investments and accounts; establishes and maintains necessary bank accounts; assists in the preparation of the annual budget of the Society; supervises the preparation of tax returns; and arranges for annual audits of financial records.

- **Membership Services:** The Secretariat maintains an accurate roster of members and prepares and issues a Membership Directory; responds to inquiries regarding membership and provides the Membership Committee all applications for membership; and actively participates in the development of membership recruitment and development programs.

- **Liaison Services:** The Secretariat provides various liaison activities for the Executive Committee, the Board of Directors, and the standing committees of the Board; executes contracts and commitments authorized by the Board; provides liaison and staff support to committee chairs and committees; serves as principal contact with the Society's legal counsel; and acts as business liaison with the Editors, Board of Directors and Publisher of all publications of the Society.

- **Meetings and Exhibitions:** The Secretariat assists and advises the Board of Directors of future annual and mid-year meeting sites; executes all hotel and service contracts; assists in the formulation of the annual and mid-year meeting budgets; assists the Program Committee in developing and implementing meeting programs; establishes, maintains and provides on-site management of our exhibition program; and provides management of pre-registration and on-site registration services.

The Society's Headquarters staff is under the direct control of the Society for the purpose of carrying out contracted services. The administrative supervision, ancillary services, staff, equipment and offices are supplied by Burk & Associates.



Ken Mossman

President, Health Physics Society

LETTERS TO THE EDITOR

September Editorial on Target

Name Withheld Upon Request

To the Editor:

Your editorial in the September issue of the *Newsletter* is certainly on target. For those of us who attend health physics meetings, the matter of regulatory enforcement is a constant source of speculation and discussion. My views on this issue are based on over 10 years experience as a "regulatee" at a large medical/research institution.

About 5 years ago, I would have to say that the NRC was in the business of "helping" licensees comply with the conditions of their licenses. At that time, I would never hesitate to contact our regional NRC office and request input on a situation which might cause regulatory problems. Escalated enforcement such as civil penalties, mandatory orders, etc. were basically issued to those licensees who had serious problems with the implementation of their radiation safety programs. Minor problems were not ignored; however, the NRC seemed to recognize, at that time, that situations arise which are beyond the institutions' control and that human nature in the form of poor judgement is a factor which could never be totally regulated.

Gradually, the NRC gravitated to a position that every deviation from the regulations of license requirements had a cause and the licensee should be required to implement specific changes to assure that the violation would never happen again. This has led to the increased utilization of escalated enforcement to assure that these "bad" licensees take such violations seriously. Thus, the NRC is now attempting to "make" (rather than help) licensees comply. Because of this change, I am very reluctant to call the NRC for advice or assistance. I would never fail to report a situation which is required to be reported; however, if there is some question as to the need to report such an incident, I am more inclined to rely on my past experiences as a guide rather than to seek NRC advice.

There is certainly a need for escalated enforcement in certain situations. When licensees fail to administer their radiation safety programs in such a way as to cause significant health risks, then escalated enforcement may need to be considered. If a licensee has been told a number of times to correct a problem within their program and fails to do so, possible escalated enforcement is again warranted. However, I and many of my colleagues operate under the simple philosophy of "Just tell us what we should do and we will do our best to see it through." That doesn't mean that we will always accept all of the NRC's suggestions; however, we will certainly work to come to a reasonable agreement on how to approach a given problem.

"Why has the regulatory climate changed?" Only the regulators know for sure, but I have some opinions. First of all, the media has not done the NRC any favors, particularly the *Cleveland Plain Dealer*. I certainly feel that the NRC was much maligned in those articles as well as in the follow-up coverage by the rest of the media. Unfortunately, Senator John Glenn apparently believes everything he reads in the newspaper and in doing so has added congressional pressure to the NRC. While I feel that the NRC has been unjustly chastised, the upper echelons of the NRC may need to take a more assertive approach with the media and Congress and "educate" them regarding the reality of certain radiation safety issues.

Another problem which I feel contributes to these enforcement issues and which carries over into other NRC activities is the lack of experienced health physicists at all levels of the NRC. While many NRC inspectors, license reviewers, section chiefs, etc. may have had some experience on our side of the regulatory fence, that experience is, many times, not in a radiation safety capacity. Rather, they may have had some interaction with the radiation safety program (e.g. a nuclear medicine technologist) but were not directly responsible for administering the same. These individuals ultimately end up "regulating" licensees and making decisions on issues with which they have had little previous experience. Recognizing the paucity of experienced health physicists, this is a situation which will not change in the foreseeable future. The NRC has used various seminars and other information exchange sessions in an effort to increase communications between themselves and licensees. Such efforts are certainly appreciated and should be continued.

It is my intent to present these views in a constructive manner and I would like to think that the NRC would consider them as such. Hopefully, the regulatory pendulum will begin to swing the other way and both the NRC and licensees can get on with their joint responsibilities of providing a safe environment for both radiation workers and the general public in a cooperative manner. ■

NRC/Licensee Relationship

Name Withheld Upon Request

To the Editor:

Your September editorial regarding the relationship of the NRC with its licensees has probably hit close to home with many licensees. As a Radiation Safety Officer for a number of years, I have seen the relationship go from

[see NRC, continued on page 6]

[NRC, continued from page 5]

one of cooperation and mutual goals (respect) to that which might be described by some as an adversarial relationship (fear).

In discussions with some of my colleagues, the consensus seems to indicate that most licensees want to comply with NRC regulations and license conditions (it's our job). In my view, enforcement conferences and escalated enforcement action are detrimental except in circumstances where serious repeat violations occur, actions are truly willful or in cases where there is a lack of management support for the program. All too often, licensees are summoned to regional offices where the details of an incident are rehashed without a significant benefit to either party. Just tell us what the violations are and we will work to ensure that it doesn't occur again. The time involved in the preparation of a response to a Notice of Violation and the explanation to management as to how and why it occurred is penalty enough for me.

As you mentioned, the public currently has enough fear and misunderstanding of radiation. Press releases, civil penalties and investigations by teams of licensee and Federal officials do not seem to be warranted in cases such as the one you described, where risk to the public is negligible. Was the total cost of the incident investigation (described in your editorial) by the NRC and the licensee consistent with ALARA cost/benefit analysis in terms of dose avoided in future incidents? I would imagine that the same level of remedial action would have been taken if this incident would have been handled as a Severity Level IV violation with no civil penalty.

I believe we need to allocate our dwindling resources to those issues that have the potential for significant exposure to licensee workers and the general public. Items which do not meet this criteria should be treated with less urgency and importance.

You Need to Ask People: "How Much Do You Value Your Life?"

H.L. Gjørup
Lyngby, Denmark

To the Editor:

Dr. Puskin's letter in the August 1993 issue (see *Newsletter*, August 1993, page 5) criticizing the Scientific and Public Issues Position Statement on "Radiation Dose Limits for the General Public" (see *Newsletter*, May 1993, pages 13-17) was very interesting.

I agree with Puskin that what we need to know is the maximum amount people are willing and able to pay to gain a health benefit—taking into account their preferences concerning health benefits and all other goods and benefits they crave for their well-being. The average amount

actually paid in specific cases is of no use as a guide to implementing the ALARA principle.

But Puskin's criticism is perhaps not the worst that can be leveled at the Position Statement. I think it is more confusing that a slip of the mind has apparently occurred in the reasoning in column 2 of page 15 where, it is argued, that the public is willing and able to spend approximately \$10 per statistical day of life.

The flaw is that the \$10 per day is actually the amount spent per day per individual among those now alive—and not, as implied, the amount equivalent to a statistical day of life gained. (The U.S. health expenditures in 1990 were \$666 billion [Hoffman, 1992] corresponding to \$7.3 per day per U.S. citizen now alive). Optimization is based on differential analysis of the distribution of costs of saving lives or years of life. The problem is that the information offered gives no indication of this distribution—not even of the number of lives or years of life saved.

To Puskin I would say this: if you want to know how much people are willing and able to pay to avoid a premature death, you have to ask them just that question and inform them fully—before you put the question—about things like latency delays and life expectancy at their actual age.

Asking questions like how much people are willing and able to pay for air bags in automobiles is useless because small probabilities are weighted heavily psychologically (Tversky, 1982), and because a small amount divided by a low probability is not the same as the benefit of not being killed: the value function is not linear but exhibits diminishing sensitivity with increasing gain (Tversky, 1991).

A Danish pilot investigation, asking people how much they were willing and able to pay for one extra year of life (an extra 1992), yielded surprisingly low amounts. The GNP per capita (human capital approach) does not necessarily underestimate the detriment from premature death because the individual's contribution to society is the GNP minus his consumption. Most people value safety by their aversion to death rather than because of concern for their future contribution to the national economy (ICRP, 1991).

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Ms. Genevieve S. Roessler, Editor
The Health Physics Society's Newsletter
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Elysian, MN 56028

Dear Ms. Roessler:

The purpose of this letter is to provide additional insight into discussions in the September editorial and October letters to the editor which suggest that NRC enforcement actions discourage reporting of violations. From an enforcement perspective and impact of providing information to NRC, it is clear that since 1987 NRC requirements in the medical area have become more encompassing and specific. Actions that would not have been violations in the past are now violations. As reflected in the Commission's enforcement policy, some of those violations result in escalated enforcement and civil penalties. The enforcement policy does attempt to encourage licensees to identify and report problems by providing mitigation for the licensee's own identification of issues. A civil penalty may be completely mitigated for licensee identified violations which are fully corrected. For less significant violations, formal citations are not issued if a licensee identifies and corrects the matter. We recognize the fact that a licensee may make inquiries on an issue which may result in inspection and investigation and may have the potential for a chilling effect if violations are then identified by the NRC. This is inevitable when communicating with a regulator in contrast to an educator. On the other hand, a licensee who makes a conscious decision to not report required information, including that required under 10 CFR 30.9(b), may be subject to criminal sanctions and application of the Deliberate Misconduct Rule. Thus, the staff believes there is an appropriate balance in encouraging licensees to be candid and NRC taking enforcement action only when warranted.

The exercise of enforcement authority can have negative implications, but it is the NRC's view that to avoid such negative implications, licensees should work to ensure compliance with Commission requirements. When noncompliances are identified, they should be immediately corrected and reports be made to NRC as required.

Sincerely,

Patricia Ann Elker-Santiago
Assistant Director for Materials
Office of Enforcement
U. S. Nuclear Regulatory Commission
301-504-3055

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