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STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 457
State Office Building Campus
Albany, NY 12240

October 23, 1996

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTN: Chief of Docketing & Services Branch

Dear Mr. Hoyle:

Enclosed please find the New York State Department of Labor's comments on three of the Direction Setting Issues Papers (DSI's) included in the NRC's strategic assessment and rebaselining initiative (DSI 4, DSI 7, and DSI 21).

Sincerely,

Rita Aldrich

Rita Aldrich
Principal Radiophysicist

RA:jmp
enclosure

Acknowledged by card 10/31/96

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NYSDOL COMMENTS ON
DIRECTION SETTING ISSUE PAPER #7
(DSI 7)
"MATERIALS/MEDICAL OVERSIGHT"

In keeping with our comments on Direction Setting Issue 4 (NRC's Relationship with Agreement States), we strongly recommend adoption of Option 5, turning over all regulatory authority for Atomic Energy Act (AEA) materials to the states, which could be preceded by Option 3 during a transition period.

Option 5 is in accordance with the recommendations of the NRC National Performance Review Steering Committee, and in accordance with the National Academy of Sciences Institute of Medicine recommendations for NRC's medical regulation program.

We would also emphasize again (as in our comments on DSI 4), the economics of the situation. Option 5 is the only reasonable hope that NRC licensees have to contain or reduce their fees, since the other options would make only trivial differences. Eliminating 50% of NRC's remaining licensees, for example, would only eliminate 50 staff positions according to this paper. However, there is no estimate of the effect that this would have on fees for the remaining 50% -- perhaps they would increase due to the smaller licensee base.

We also note that this paper expresses a concern that turning over all regulatory authority for AEA materials to the states could be considered an "Unfunded Mandate," and viewed as subject to the Unfunded Mandate legislation. This is presented as an argument against Option 5. Strangely enough, concern over unfunded mandates didn't enter into the discussion in DSI 4 of the Commission's possible recommendation that OBRA-90 be modified so that NRC could charge Agreement States to recover its "oversight" costs.

So on the one hand, it is argued that states should not be burdened by the unfunded mandate of the NRC's turning its materials program over to them, while on the other hand, Agreement States, which have voluntarily accepted an unfunded mandate, will only be considered co-regulators and equals if they paid part of the expenses of the federal agency whose work they have taken over!

Two strong themes running throughout many of the NRC "Direction Setting Issue" papers are its shrinking licensee base and money. The themes are inexorably linked since NRC is required to recover all operating costs from licensees. As the number of licensees declines, fees rise and this accelerates the decline by causing licensees to give up their licenses or even relocate to Agreement States. This should be seen as a natural process driven by Section 274 of the Atomic Energy Act, which created the Agreement States program. The more successful the Agreement States program is (i.e., the more states that accept responsibility for "Agreement" materials and add them to their radiological health programs), the more marginal NRC's program becomes and the more difficult to support. Since states now regulate 70% of "Agreement" materials licensees, and will soon regulate 80%, it is rapidly becoming impossible for NRC to support its program by fees imposed on such a small number of licensees.

There are ways in which NRC could reduce its operating costs, such as eliminating its costly and extensive practice of contracting out work that could be done by its own technical staff, and reducing its research and rulemaking activities to those that are truly necessary to protect health and safety.

They could also save substantial amounts by adopting rules already developed by Agreement States (such as Industrial Radiography and Well Logging regulations) and adopting cost-effective practices already used by Agreement States to expedite licensing and inspection activities. Instead, NRC chose to discontinue the training it formerly offered to Agreement States, at a trivial savings of one-half million to one million dollars a year.

However, although such cost containment actions should certainly be undertaken as interim measures, they are not the solution. The solution is for NRC to recognize that what is happening is the desired outcome for the Agreement States program: the successful transfer of regulatory responsibility for Atomic Energy Act Section 274 materials from NRC to the states. Having achieved that goal, there should be no question that Section 274(a)(6) of the Act must now be implemented. That provision states that "as the states improve their capabilities to regulate effectively such materials, additional legislation may be desirable." This legislation would properly be to amend the AEA to withdraw the federal preemption of AEA materials, and restore them to the universe of radiation sources already regulated by the states.

Unfortunately, as in the DSI 4 paper, the Commission's preliminary views are basically to maintain the status quo with some decreased oversight over "low-risk" activities. Aside from the arguments we have already made against what amounts to a "no-action" option, this begs the question of who will pay for NRC's program if they insist on continuing it. There is no question in our minds that the states will not.

In regard to NRC's proposal to decrease oversight of "low-risk" activities we have the following comments:

- While the wording used in regard to defining "low-risk" is vague, we hope (and strongly recommend) that this will involve a risk-based reevaluation of all existing generally licensed and exempted radioactive materials in NRC regulations. The results of such a global reevaluation should be used to redefine and restructure these regulations, not just to move currently defined generally licensed and exempted materials from one category to another.

  We strongly recommend that this reevaluation include elimination of the general license given in 10 CFR Part 31, section 31.5, and reallocation of these devices to exempt or specific license status.

- The proposal to transfer some current specific licenses to general licenses appears to be an attempt at an ill-considered "quick fix" to reduce NRC's workload. We have submitted comments to NRC elsewhere (see attached July 29, 1996 letter from Rita Aldrich to Carl Paperiello) on the problems inherent in "general" licenses which have resulted in accidents requiring millions of dollars to be spent in remediation. Our letter suggested more innovative ways of shifting resources to reduce burdens on both regulatory agencies and regulated parties.

  Also, even though this proposal is planned to reduce 50% of NRC's current specific licensees to general license status, with a drastic reduction in oversight of these programs, only 50 NRC staff are expected to be eliminated as a result. We believe strongly that this proposal would result in a significantly increased risk to health, safety and property while producing negligible savings.

- NRC should begin an immediate review of all of its regulations for AEA materials, with the objective of eliminating as many prescriptive requirements as possible. For example, although every licensee needs to implement a radiation protection program, the existing requirement to perform an annual audit of the program, and of the conduct of the radiation safety officer, is reasonable only for larger, more sophisticated programs. However, NRC's guidance for portable gauge licensees (one of the categories it now apparently wants to relegate to general license status) contains a four and a half page form to be used for such audits. This combination of a needless regulatory requirement, made even more onerous through "guidance" is not unusual. Therefore, instead of seeking quick and easy fixes that may degrade the current level of safety, NRC should perform a thoughtful review of its regulations -- Part 35 in particular -- and its guidance documents for the expressed purpose of reducing regulatory burdens on itself and its licensees.

This regulatory reevaluation should be conducted concurrently with the implementation of Option 2 under DSI 4, since simplifying regulations, and making them performance-based and easier to implement, should in itself attract states to Agreement State status. The reevaluation should of course be conducted in close consultation with the Agreement States, as NRC also works on implementation of Option 5.

RA:jmp
10/16/96

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STATE OF NEW YORK
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DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
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July 29, 1996

Mr. Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards
USNRC
Washington, D.C. 20555

Dear Mr. Paperiello

On July 5, 1996, I received a copy of the "Final Working Group Recommendations & Report" on the regulation of general- and specific-licensed devices (GL's and SL's).

Since I am listed as a member (alternate) of the working group, and since I did not receive a draft of the report for comment before it was finalized, I am sending my comments directly to you and to the Commission.

Also, since the report does not mention the approach that New York is taking to the problem of improving control over GL's and SL's, while conserving precious resources, I am including a discussion of our initiative also.

I agree with some of the intermediate conclusions of the working group, but disagree strongly with the regulatory construct that the group derived from them.

Background

To begin with, the Agreement States have been objecting to the existing GL system for as long as I have been a supervisor of a radioactive materials program (since 1985), and probably long before that. It should be noted here that the SL/GL devices at issue were, and are, fixed radioactive gauges. One early request from the Agreement States to the NRC on this subject was mentioned by Joel Lubenau at a working group meeting, and a copy of a 1981 NRC memo concerning it is enclosed. It does not complain about control over SL's, only GL's, and there are good reasons for this.

If a regulatory agency has a problem with a class of specific licensees, it can address the problem with a license amendment. The license is a vehicle for control: it must be issued before sources can be acquired; it must be amended if the person responsible for

radiation safety (radiation safety officer or RSO) changes; it must be periodically renewed; proper control over and disposal of sources are the subject of periodic inspection, and proper disposal of all sources must be proved before the license can eventually be terminated.

The philosophy behind regulation of GL's is entirely different: sources can be acquired with no prior approval by a regulatory agency, by any person or company that can afford them. Therefore, there is no prior designation of a radiation safety officer, no licensing document that can be used to enhance control, no periodic license renewal process to refresh consciousness of regulatory control, no periodic inspections and almost complete reliance on source vendors for records of receipt and disposal.

One could argue that a regulatory agency could inspect GL's if it chose. However, since this system was set up as completely separate from the SL system, when NRC and the Agreement States set up their fee programs they applied only to SL's. As a result, since no fees were paid, no inspections could be supported.

There are many basic inequities in the GL vs. SL systems. For example, SL's are subject to all code requirements (whether they make sense for a simple gauge licensee or not), while GL's are exempt from everything except the few requirements in their segregated part of the regulations, plus disposal requirements. SL's have to submit license applications (with fees) describing a radiation protection program, and they have to renew their licenses at specified intervals. Finally, SL's are supposed to be inspected on a regular basis. In New York, they are inspected every three years. However, NRC representatives stated at working group meetings that their SL's, which are nominally due for inspection every five years, are in fact never inspected. These inequities persist even though the sources distributed as GL's are often identical, except for a label designation, to SL's.

To many observers the GL system was an accident waiting to happen -- and happen they did. Therefore, over the years the Agreement States regularly expressed their dissatisfaction with the system and requested that it be changed at the federal level, since these were the regulations the states had used as a pattern for their own. Also, over time, several states made regulatory and administrative changes in the regulation of these sources on their own. NRC, however, proposed no changes until recent protests by the steel mill industry about uncontrolled sources being found in scrap or being melted in mills.

Since a New York mill has experienced two such accidents (in 1983 and 1993), resulting in very expensive remediation efforts, I was very interested in being on the working group which NRC set up to address this longstanding problem.

Discussion

I sent Joel Lubenau my summary view of the problem, and a preferred solution, early

in the process and a copy is attached. Basically, it said that the current GL system included sources of vastly dissimilar hazard under one set of regulations, which underregulated some and overregulated others. The proposed solution was to move the hazardous sources needing better regulation to SL status, and to exempt the others since we were not really regulating them now anyway, nor did we need to.

When I attended a working group meeting, however, I found that the problem under discussion was not the problem which I thought the working group had been assigned, and/or that certain constraints had already been imposed on the group's considerations.

The problem had apparently been redefined as improving control over all sources, whether GL's or SL's . When I questioned this, I was told that apart from the longstanding GL controversy, NRC had no confidence that SL sources (not just gauges but all sealed sources) were adequately controlled. This was reportedly based on two observations:

1) since NRC did not inspect its' SL gauge licensees, they had no knowledge of, or confidence in, their performance; and

2) that since some identifiable SL sources had turned up in scrap, this meant that they were no better controlled than GL's.

I would submit that these observations do not even remotely support the contention that our current control over all SL sealed sources is inadequate. Also, although NRC has no experience base for its SL fixed-gauge licensee, we do. Our experience shows that these licensees perform as well as any other SL (sealed source or loose material), as long as the same degree of regulatory oversight is exercised. Also, even though some SL sources may have been found in scrap (portable moisture-density gauges for example), the reasons for this type of loss of control are entirely different from those for fixed gauges, and so would the solutions be. Our SL portable gauge licensees lose gauges because they are stolen, not because they are inadvertently (or otherwise) discarded with scrap by the licensee. Therefore, combining these licensees with fixed gauge licensees in seeking "control" improvements is not logical. It also ignores the additional regulatory controls that portable gauge and other SL's are already subject to, such as maintenance of daily use logs, six month inventories, more frequent inspections, etc. The recent Texas incident involving loss of control over radiography sources, for example, would not have been prevented by the actions being recommended by the working group. The incident does, however, raise complicated questions about a company's continued possession of sources which they are not authorized to use.

The working group was also advised of certain constraints on its deliberations. These were that any proposed solution could not be a drain on NRC resources, and, by extension, that there would not be any serious consideration of "specifically" licensing current GL devices. No explanation was given for this limitation, despite the fact that it foreclosed the

most common recommendation that has been made on this subject.

Given all of the above and the compressed time schedule for developing recommendations, the conclusions reached by the working group were almost foreordained, and permitted no revisiting of basic assumptions. For example, after having decided to divide GL's into two hazard categories and to impose additional requirements only on the more hazardous devices, there was no reconsideration of the resources needed to specifically license only that sub-group. Section 5.9 of the final report simply states that specific-licensing would not "prevent" loss of sources (no solution would absolutely prevent all losses); and that since the problem is caused by a small subset of GL's, it would "impose unnecessary burdens" to specifically license all GL's.

Also, it is highly unlikely that the recommendations in the final report will achieve effective control of the problem, since they continue the current GL regulatory approach, with some enhancements. In fact, since all SL sources are illogically folded into the proposed solution, one startling possibility is that NRC may even propose adopting a GL regulatory approach for sources which are currently specifically-licensed!

I would suggest an opposite approach, and would view this as an opportunity to re-baseline our regulatory programs for the general-and specific-licensed gauges of interest. First of all, no portable gauges (gauges used at field sites) can be obtained under general license in New York State, and we would strongly recommend NRC adoption of the same policy. The problems we have experienced with gauges used at stationary sites are bad enough. However, permitting individuals and companies that have no approved plans for use, control, transport and incident response for radioactive sources which can be used anywhere, even in residences, does not adequately protect health and safety.

Primarily, however, we need to reexamine how our resources, and our licensees' resources are being spent to regulate section 31.5 GL devices, versus similar (or identical) devices that are specific-licensed. Our conclusion in New York is that we are underregulating the GL's and overregulating the SL's. Our experience demonstrates that this has resulted in very good control of SL's, but that this control results from a few basic concepts:

1) requiring a licensee commitment to oversight of sources and proper eventual disposal, before sources are allowed to be acquired;

2) requiring licensees to maintain good records of receipt and disposal of sources, and of current source inventory;

3) requiring prompt notification to this Department of loss of control of a source;

4) regularly scheduled inspections to reinforce these requirements; and

5) regular license renewals to reinforce licensee commitments.

Therefore, we have begun a regulatory initiative to create equity between the regulation of GL's and SL's. This will improve control over GL's, while conserving both our resources and our licensees'. It will also assist licensees that have acquired sources under both SL and GL, in establishing one integrated program for equal oversight of all of their sources.

Recommendations

This involves creating a subset of GL's that will require a specific license to possess in the future. We would differ from the working group in recommending that one simple activity limit be used to define this subset (1 millicurie). It also involves relieving SL gauge licensees from the same code sections that GL's are currently exempt from.

As a part of this initiative we have:

1) Created a seven page combination licensing guide and application form, which explains the applicants' responsibilities (including the conditions that will be on the pre-formatted license we will issue), and only requires six items of information to be submitted. In signing the form the applicant commits to implementation of the contents. We guarantee license issuance within 10 days after receipt of the application, so there will be no adverse impact on companies that would formerly have obtained GL's with no license document.

2) Created a "blended" pre-formatted license which authorizes acquisition of any GL or SL gauge authorized for distribution in a license issued by an Agreement State or NRC. Whether the device is GL or SL the licensee will only be responsible for the requirements contained in the license. One of these requirements is performance of six month inventories and submission of annual inventories. You will note that the license has no "tie-down" condition because we feel that none is needed, and this minimizes the need for future amendments.

3) Created a form transmittal letter for these licenses, which informs the licensee of both the flexibility built into the license, and their responsibilities for control and accountability of sources.

4) Created a brief form for the inspection of these and gas chromatograph licensees.

5) Created a day-glow-red self-stick label to distribute to licensees for use on devices put into storage, or left unused on a process line, pending disposal. The label is adapted from one developed by a licensee for this purpose, which we thought was an excellent idea, and which should help prevent inadvertent disposal.

We have begun this initiative with renewal and issuance of SL gauge licenses, and are using it to combine a company's SL gauges and GL gauges in one regulatory document. Prior to this, separate registration files were kept for the GL's.

A tickler system is also being set up to ensure that we receive annual inventories from each of these licensees.

We strongly recommend that NRC consider this "resource shift" approach to the control problem. If, as one NRC staff person has told me, it would be impossible for NRC to give ten day turnaround on our mini-application, a contractor could be retained to do it.

I have enclosed copies of all documents referred to in this letter, along with staff memos on their use and implementation. I would be happy to discuss any and all of these with NRC staff.

If the working group's report is to be published as a NUREG, I would like to have my comments included as a separate statement, as was done in the IOM report.

Sincerely,

Rita Aldrich
Principal Radiophysicist

RA:jmp
enclosures
cc: Shirley Ann Jackson, Ph.D., Chairman