

From: "Collins, Steve" <Collins@idns.state.il.us>
To: "Walter, David" <dwalter@adph.state.al.us>, <bat@nrc.gov>
Date: 6/14/01 12:26PM
Subject: RE: STP-01-044

I like the idea of revisiting Part 20. Let us consider changing the dose limit for members of the public to 200 or 300 or 500 mrem per year (plus ALARA) and a lot of the non-health physics concerns will go away. A lot of the policy disagreement could also go away if EPA would change the federal guidance to match. We all know that 500 mrem plus ALARA resulted in almost the same level of protection of the public as 100 mrem has, but it cost a lot less.

-----Original Message-----

From: dwalter@adph.state.al.us [mailto:dwalter@adph.state.al.us]
Sent: Thursday, June 14, 2001 10:11 AM
To: bat@nrc.gov
Cc: phl@nrc.gov; lab@nrc.gov; rjd@nrc.gov; dsf1@nrc.gov; cxh@nrc.gov; mhoward@gw.odh.state.oh.us; pan@nrc.gov; mur@nrc.gov; TFY@nrc.gov
Subject: STP-01-044

Ms. Torres:

I would like to offer some comments regarding the proposed rule change to 35.75. I personally am against this proposed rule, as well as the new 5,000 mrem notification limit for the embryo/fetus or nursing child (35.3047).

Some questions immediately come to mind. Why is such a rule needed in the first place? Is there a problem with released patients exposing so many members of the public to greater than 500 mrem that the medical community needs such an exception? How many reports of exposures exceeding 500 mrem has the NRC received? If the number is few, then what is the need for such a rule? Let the 500 mrem limit of Part 20 be the reporting requirement. If there have been many reports of exposures exceeding 500 mrem, perhaps the answer lies not in changing the reporting limits, but in finding the root cause of these overexposures.

In my opinion, this change seems to muddy the waters even further. It makes no sense to have so many different exposure limits for the public, much less confusing the issue further by saying that if you exceed the specified limits, you don't need to report it to the NRC. It appears to trivialize your own limits, and says they are of no consequence. I can assure you that the licensee is going to worry more about the reporting level than the actual exposure limit. This is further compounded by making an apparent distinction between medical and non-medical exposures. It appears the NRC equates 5,000 mrem of gamma radiation exposure from a released patient to 100 mrem of gamma radiation exposure from an industrial gauge. We all know that this is not true, but

these medical exceptions are now the norm, and give that appearance.

Creating so many rules that are exceptions to the most basic exposure limits of Part 20 essentially questions the validity of these limits. Instead of the confusion of constant special exceptions, maybe the NRC should revisit Part 20

Thank you for this opportunity to comment on the proposed rule. Please feel free to contact me if you have any questions. If you wish to talk to me, I may be reached by phone at 334-206-5391.

David Walter

CC: "Lohaus, Paul" <phi@nrc.gov>, "Bolling, Lloyd" <lab@nrc.gov>, <rjd@nrc.gov>, <dsf1@nrc.gov>, <cxh@nrc.gov>, <mhoward@gw.odh.state.oh.us>, <pan@nrc.gov>, <mur@nrc.gov>, <TFY@nrc.gov>

Division of Environmental Safety, Health & Analytical Programs
Bureau of Environmental Radiation
Radioactive Materials Section
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Phone (609)-984-5462
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June 19, 2001

Dear Sir,

The following are the New Jersey State Department of Environmental Protection's comments on NRC's proposed rule 10 CFR 35.3075 for reporting excessive exposures to individuals as a result of patients released as per 10 CFR 35.75.

- 1 What was the rationale for selecting 5,000 mrem as the value for reporting exposure to individuals? This value is 50 times the "Dose Limits for Individual Members of the Public" listed in 10 CFR 20.1301, and 10 times the limiting value listed for "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants" listed in 10 CFR 35.75.
- 2 If NRC is attempting to use the reported information as feed back on their revised patient release limits and NRC only anticipates one reported event per year, then there will be very little information available. Perhaps NRC should have chosen a lower reporting value such as 1,000-2,000 mrem, which would not put the individual into the realm of the occupational radiation worker and would provide more feed back on the revised patient release limits. This would provide more useful feed back on the revised patient release limits. By having a reporting value of 5,000 mrem NRC may get a false sense that the revised rule is working, when in fact there may be many cases of individual members of the public being exposed beyond the 500-mrem limit.
- 3 After reviewing the Advisory Committee on Medical Uses of Isotopes concerns, one would have to realistically question whether licensees would take the time and make an effort to report such incidents? Additionally, how would the licensee ever become aware of circumstances that would lead to excessive exposures?
- 4 NRC's concerns for their rules to be less intrusive into the practice of nuclear medicine may result in them being more intrusive on the general public as a result of increased patient excreta contaminating trash which sets off radiation monitors at landfills and incinerators. Perhaps NRC should have reporting or records requirements for incidents

involving patient excreta contaminated trash which sets off radiation monitors as a means of providing feedback on the impact of their patient release rule.

- 5 Lastly, if licensees end up not being required to report such exposures, they should be required to keep a record of such exposures for review during an inspection.

Should you have any questions regarding the above comments, please call John Feeney (609) 984-5555.

Sincerely,

John Feeney, License Administrator
Radioactive Materials Section

Ms. Betty Ann Torres
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Ms. Torres:

Staff members of the Texas Department of Health, Bureau of Radiation Control have reviewed the predecisional draft proposed rule concerning a notification requirement associated with the patient release rule in 10 CFR 35.75. We offer the following comments for consideration.

The rule as written is not workable and is unenforceable. The only reporting that should be required in this situation, if any, would be in the instance where the exposure to a member of the public came from a mistake in calculation by the physician or physicist or wrong patient directions from the physician. It is highly unlikely that a patient will admit that he or she did not follow the direction of the physician, for example, that he or she decided to fly to Hawaii with a child on his or her lap. In this situation, the fault is not with the facility, but with the patient. Therefore, if a member of the public does receive a dose in excess of the limit, reporting of it should be limited to errors on the part of the licensee. Another issue that makes the rule difficult to enforce is the lack of actual data to support the overexposure without dose reconstruction (time/distance factors). The licensee would have to depend on the input of the released patient and/or the person exposed for verification of an estimated dose.

This requirement does not appear to be effective in reducing risk to members of the public, especially when compared to the added cost to the licensee. Therefore, it can be considered both burdensome and unnecessary.

We appreciate the opportunity to comment on the predecisional draft proposed rule. If you have any questions or need further information, please contact me at 512-834-6688 or E-mail address: richard.ratliff@tdh.state.tx.us

Sincerely,

Richard Ratliff, P.E., Chief
Bureau of Radiation Control

From: "Frazee, Terry" <Terry.Frazee@DOH.WA.GOV>
To: "bat@nrc.gov" <bat@nrc.gov>
Date: 7/11/01 9:04 PM
Subject: STP-01-044 (RE: 10 CFR 35.75)

I read with interest the comments from David Walter (sent via e-mail on June 14). I agree with Mr. Walter that the proposed rule is of questionable value and should not be promulgated. While I agree with NRC that there may be potential for members of the public to be "overexposed" due to patients released under 35.75, the root of the problem is not the rule but the Regulatory Guide.

NUREG 8.39 allows the licensee to "adjust" the assumptions made for determining the "activity" that may be contained in a patient at release (and presumably not cause an exposed individual to exceed the 5 rem dose limit). While the "baseline" used in setting up NUREG 8.39 is essentially the same as used for many years (the Iodine 131 release value in the table is 33 mCi instead of the previous 30 mCi release rule), the concern is that "occupancy" and other factors can be altered to allow patients to be released with hundreds of millicuries of residual activity! With this much activity, any deviation from the "expected behavior" can result in greater exposure to the public.

I believe the proper solution to the concern that NRC has expressed should be to re-evaluate NUREG 8.39 and set release values (in activity) for various radionuclides (and "chemical" forms) based on conservative assumptions, without allowing for "tweaking" by the licensee. Standardized patient instructions should be reviewed and set for the various treatment methods in current use. NRC should promptly update the NUREG when appropriate. This will simplify life for all parties involved.

As far as the proposed rule is concerned there are several problems: the first being the assumption this will be "minimal cost" to the licensee. Another problem is certain to be enforcement. The rule requires that the licensee "report any dose ... that an individual receives ... " Even though the notification requirement states that this is "after the licensee becomes aware ... " it is clear that every licensee will need to be diligent in talking with patients after treatment to assess how well they complied with instructions given by the licensee. If they do not make an attempt to assess this, they cannot report any dose "that an individual receives". This adds to the licensee's task for EVERY patient. "Time is money." The regulatory analysis on the cost of the rule is therefore totally inadequate and misleading. Finally, if the regulators don't ask about this area of regulation, and enforce licensee efforts to comply, then the rule should not exist. Only write rules we intend to enforce.

Thank you for the opportunity to comment.

"The Department of Health works to protect and improve the health of people

in Washington State."

~~This message from Terry C. Frazee~~
e-mail terry.frazee@doh.wa.gov

Quick ways to reach me:

Voice = 360-236-3221

FAX = 360-236-2255

Also, visit our Home Page at
<http://www.doh.wa.gov/ehp/rp>

CC: "Demaris, Curt" <Curt.Demaris@DOH.WA.GOV>, "Erickson, John (DOH)"
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George H. Ryan
Governor

Thomas W. Ortziger
Director

July 24, 2001

Betty Ann Torres
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Request for Comment on Predecisional Draft Amendment to 10 CFR 35.75
(STP-01-044)

Dear Ms. Torres:

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the predecisional draft amendment to 10 CFR 35.75. The letter requests comment on the development of a proposed "Patient Release Rule" which would require, among other things, notification of the NRC after a licensee becomes aware that an individual received or is estimated to have received a dose exceeding 5 rem from a patient who was released in accordance with 10 CFR 35.75. The Department's specific comments follow:

1. Since NRC now intends to make doses to the public from therapy patients reportable again, the reference for dose limits for individual members of the public in 10 CFR 20.1301(a)(1) that excludes "exposure from individuals administered radioactive material and released again in accordance with 10 CFR 35.75" should be moved to 10 CFR 20.1301(c). This would prevent the need for medical licensees to apply for a higher dose limit, and all the current reporting requirements already published in the regulations (10 CFR 20.2202 and 20.2203) would be enforceable again. This would obviate the need for another cumbersome reporting system strictly for medical treatments. In addition, the current reporting requirements of 10 CFR 20 have been effective for many years and are more appropriate for protecting public health and safety.
2. The content of the report to be filed does not need to be detailed by regulation to a greater degree than that already addressed in 10 CFR 20. The predecisional amendment requires a certification that the exposed individuals be notified. If it is not possible to specifically identify them or notify them, the licensee should be given the opportunity to explain such and not be held accountable for other portions of the reporting requirement.



3. The Department agrees with the ACMUI in that the licensee should not be held responsible for ensuring compliance by patients that have ignored those instructions specifically addressed by the licensee/physician. However, the licensee/physician should be held accountable for proper implementation of 10 CFR 35.75 in evaluating whether or not the patient is a viable candidate for release and for providing "reasonable" instruction and safety procedures. Towards that end, it may be beneficial to have the physician sign a patient evaluation form to certify that they are professionally satisfied that the patient is most likely to comply with the provided instructions and is suitable for release. Several tools are available and discussed in peer reviewed journals that include the use of Karnofsky scores to evaluate patient conditions and modeling of potential exposures to members of the public.
4. The Department agrees with the ACMUI that dose reconstruction and verification of estimated exposure can be difficult and can include a significant margin of error. However, this is nothing new. Every dose limit in 10 CFR 20 can be affected by contributing/mitigating factors based on individual circumstances, and these elements should be evaluated in conjunction with the regulatory agency to determine the extent of their significance. Similarly, if the licensee is in disagreement with how the information is handled or processed, there are avenues available to them for expressing their concerns and seeking immediate correction. Such is the case with any regulatory relationship regardless of the nature of the action taken by the agency's representatives.
5. The Department disagrees with the ACMUI that anonymity should be ensured for licensees under these circumstances. Any radiation safety program at a medical facility should currently have mechanisms in place to address public responses to these incidents. The medical community needs to review the risk vs. benefit of these treatments and take responsibility for decisions made under 10 CFR 20.110 and 35.75.
6. The Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility in the matter (as noted in this predecisional amendment). Our state has experienced this with an NRC licensee that disregarded certain requirements of 10 CFR 35.75, released the patient for additional medical care in our state and subsequently rebuffed our inquiries for further information about doses to the public. The NRC Regional office was ultimately notified to address the licensee's release criteria.

U.S. Nuclear Regulatory Commission

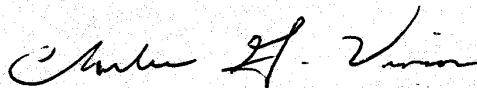
July 24, 2001

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The State of Illinois has not adopted the patient release language contained in 10 CFR 35 for the very reasons addressed by this predecisional draft along with other unresolved issues. Illinois is currently granting patient release under specific license conditions contained in a license amendment. The notifications mentioned are certainly part of our concern. Subsequent steps of addressing the concerns of the exposed members of the public and incidents beyond the control of the licensee have not been fully addressed by this proposal. In addition, as pointed out in the supporting information, the NRC is the responsible regulatory agency for only 1,655 medical licensees whereas there are 4,138 such licensees under the jurisdiction of Agreement States. Follow up actions by licensees and the states should be revisited for impact on resources if these changes become final. The impacts could be substantial for the Agreement States since we have responsibility for the majority of these licensees.

Thank you for the opportunity to comment. Please contact me at (217) 785-9947 if you have any questions.

Sincerely,



JGK Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:CGV:DMP

cc: James Lynch, NRC Region III