



University of Iowa Health Care

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(70FR 75752)

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DOCKETED
USNRC

December 29, 2005 (11:41am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 29, 2005

RE: Docket No. PRM-35-18, Petition for rulemaking filed by Peter G. Crane

Dear sirs,

I respectfully request that you deny the petition for rulemaking filed by Peter G. Crane, specifically his request that the patient release rule be partially revoked to not allow patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine I-131 in their bodies.

I endorse the current patient release rule. I believe that the current rule adequately protects the public while minimizing high costs associated with inpatient hospitalization. Specific points relating to the reasonableness, appropriateness, and positive value of the current rule are as follow:

First, 10 CFR 35.75 "Release of individuals containing unsealed byproduct materials or implants containing byproduct material" does **not require** release of patients treated with I-131. Rather, it **allows** release, as stated in 35.75 (a) "A licensee may authorize the release...."

Inherent in performing patient-specific calculations upon which patient release may be authorized, per Regulatory Guide 8.39 "Release of Patients Administered Radioactive Materials," is consideration of co-existing medical conditions and patient behavior which may effect occupancy factors and/or ability of the patient to follow radiation protection instructions. Hence, patients with medical conditions that require extensive caretaking should not be released because high occupancy factors will result in calculations with lower activity levels allowed for release to assure that other individuals will likely be exposed to no more than 5 mSv. Also, patients with behavior such that they are unable or unwilling to follow radiation protection instructions should not be released because the requirement that other individuals will likely be exposed to no more than 5 mSv cannot be assured.

Purported instances of excessive radiation exposure to others could result from improper compliance with the rule vis-à-vis occupancy factors and/or patient behavior. Such instances, if substantiated, would suggest the possible need for enhanced education of licensees and/or more stringent enforcement of the existing rule, but do not suggest that the rule itself is flawed.

Second, release of patients treated with I-131 requires that radiation exposure to other individuals from the released individual is not likely to exceed 5 mSv. The limit of 5 mSv is consistent with NCRP recommendations for infrequent annual exposures (NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation," National Council on Radiation Protection and Measurements, 1987). NCRP states that radiation exposures in this

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range "need not be regarded as especially hazardous" and will fall in the range of comparable risks from other common sources.

Hence, compliance with the current rule will not result in unsafe or hazardous exposures to other individuals.

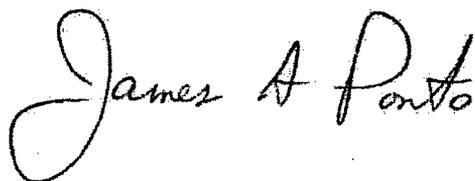
Third, the current rule [10 CFR 35.75 (b)] requires that the patient or the patient's parent or guardian receive instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv. Although the licensee cannot guarantee that the patient will follow these instructions, release is predicated, in part, on a judgment by the authorized user that the patient is willing and able to follow the instructions as discussed above.

Fourth, the guidance associated with the current rule is conservative in its assumptions and calculations; real-life exposures to individuals are typically much lower than the limit of 5 mSv. For example, Grigsby et al. found that household members received exposures of only 0.01 – 1.09 mSv (mean = 0.024 mSv) [Grigsby PW, Siegel BA, Baker S, Eichling JO. Radiation exposure from outpatient radioactive iodine (¹³¹I) therapy for thyroid carcinoma. JAMA 2000; 282:2272-2274.]

Fifth, release of treated patients in compliance with the current rule is, I believe, consistent with ALARA. 10 CFR 20 defines ALARA as "making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest." Clearly, economics is a key part of ALARA. The current rule is extremely helpful in minimizing healthcare costs (i.e., allowing release vs. isolative hospitalization for many patients saves overall healthcare costs), while not substantially increasing risk to others as described above. Moreover, release often results in more timely medical care, because scheduling of isolation hospital rooms can be problematic. For example, many hospitals have only one or two isolation rooms, and limited availability of those rooms frequently requires delay in treatment.

In summary, I believe that a large body of evidence exists supporting the reasonableness, appropriateness, and positive value of the current rule. Purported instances of excessive exposure to others are generally the result of non-compliance with the current rule and associated guidance, rather than a problem with the rule itself. Therefore, I urge the Commission to deny the cited petition.

Sincerely,

A handwritten signature in cursive script that reads "James A. Ponto". The signature is written in dark ink on a white background.

From: "Ponto, James" <james-ponto@uiowa.edu>
To: <SECY@nrc.gov>
Date: Thu, Dec 29, 2005 9:39 AM
Subject: PRM-35-18

Dear sirs,

I wish to comment on PRM-35-18, Petition for rule-making filed by Peter G. Crane. Please see my comments in the attached file.
Thank you. <<comments on patient release petition to NRC.doc>>

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Subject: PRM-35-18
Creation Date: Thu, Dec 29, 2005 9:39 AM
From: "Ponto, James" <james-ponto@uiowa.edu>

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MESSAGE	480	Thursday, December 29, 2005 9:39 AM
TEXT.htm	2487	
comments on patient release petition to NRC.doc	81920	
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Options

Expiration Date: None
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard