DOCKET NUMBER
PETITION RULE PRM 35-18
(70 FR 75752)

341 Winthrop Street
Taunton, Massachusetts
March 2, 2006

(28)

DOCKETED
USNRC

March 2, 2006 (2:10pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: Docket Number PRM-35-18

Dear Secretary:

Thank you for the opportunity to provide commentary concerning the appropriateness of the rulemaking change permitting the immediate release of individuals who have received specifically Iodine-131 radiopharmaceutical therapy at medical use facilities under licensing authority of the U.S. Nuclear Regulatory Commission or Agreement States. I am writing to you as a private citizen and neither as a representative of the Massachusetts Department of Public Health nor as an employee of the Massachusetts Agreement State program for which I work.

I concur with the petitioner that the patient release rule should be partially revoked to not allow patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine-131 in their bodies.

I am unfamiliar with the appropriateness of the steps that led to this open-ended policy change back in 1997, so it would be improper for me to comment on those 'legal' and 'policy' grounds. However, since this matter has been opened to review and scrutiny, I hope the matter is thoroughly examined and re-evaluated. If the release rule is to be revised or rewritten, the rationale and the criteria for the rule should be based on sound health and safety considerations, not only ALARA for the medical use facilities. The problems authored by the current rule are distributed without ALARA considerations to private industries, such as the waste handlers and haulers, "trash to energy" power plants, sanitation workers of towns and cities, and to other interfacing governmental bodies such as boards of health and States' responders to unexpected radioactivity found in the public domain.

The current release rule relies in the 'deregulation' of ingested Iodine-131 after the radiopharmaceutical is administered to the human. Consequentially, after the patient or human research subject leaves the licensed medical use facility, any misdirected, radioactively-contaminated "medical use fallout" has been deemed as collateral radioactivity introduced into the natural background The unrealistic expectation seems to be that all these medically treated individuals will always and exclusively shed their body fluids and excreta into the sanitary sewerage system. This is totally unrealistic. Sweat and breath from the human body account for a portion of the 'insensible' loss of water, and therefore radioactive iodine, from the body. In Massachusetts, many therapy patients are now routinely profiled for out-patient status and have received from one hundred to two hundred millicuries and in one case, reportedly, "as high a dose as is legally allowed". Furthermore, while people in the United States have access to a

Template=SECY-067

SECY-02

sewage or septic system, not all individuals in need of Iodine-131 therapy have access to a sanitary 'sewerage' system. Sewage and septic systems can fail, pollute and spread iodine-131 across one's property. Only in a perfect world will all body fluids from therapy patients be disposed of via the toilet connected to a sanitary sewerage system. Is the U.S. Nuclear Regulatory Commission concerned or surprised that out-patients may be contaminating their household solid waste or overflowing sewage systems on a routine basis in cities and towns across Massachusetts and in other states? Is the U.S. Nuclear Regulatory Commission concerned that this waste is transported by households to local transfer stations or offered for curbside pick-up and commingled with other wastes sent to trash to energy power plants for immediate incineration? This is institutionally preventable and had been conventionally avoidable until this rule. Now, in Massachusetts, an increasing number of waste transfer stations, trash to energy power plants and landfill operators are painstakingly monitoring for radioactive contaminated municipal solid waste so that they can reject it and return it to the point of origin. These conscientious stakeholders want to protect their facilities, their employees and their environment, as well as their reputations, from the effects of radiation from orphan sources by rejecting "medical use fallout", MUF.

From a public health standpoint and in order to abate the MUF problem, it might be prudent to reconsider the threshold for therapy patient release based upon future case-control studies. This would take time. It would be necessary to evaluate the doses and ages of patients as variables. Perhaps at sometime in the future the threshold could be increased, but the rulemaking body or panel to render any future determination for rulemaking should include input from those impacted beyond the "medical use" advisors. Members of the solid waste industry, the trash to energy facility operators and State constituencies are important stakeholders that deserve more consideration.

Furthermore, but allied to MUF, is the advent of "veterinary use fallout" (hereafter called "VUF") which is currently impacting the same waste streams, industries and government agencies. It is disingenuous to examine the human patient release rule without simultaneously studying and evaluating how the waste from felines undergoing Iodine-131 therapy can be uniformly and appropriately controlled.

For the Agreement State in which I work, we spend an increasing amount of time each year deal with this surmounting problem foisted upon us by this rule. Each year we receive scores of notifications of municipal solid waste rejections. Like others employed by the Massachusetts' Radiation Control Program, I may be assigned to assist in documenting the legal disposition of the MUF and VUF. These activities may include providing advisory information by telephone and fax, but sometimes the MUF and VUF must be hand separated with the supervision of skilled and trained 'agency' professionals or consultants, so one must proceed to oversee and/or to do the unthinkable 'dumpster diving'. These on-sight responses may result in unexpected contamination so one may need to decontaminate oneself by sequestering any contaminated gear and boots for months. Given the current release rule, this burgeoning problem is becoming an endless drain of our energy and limited resources.

Lastly, the costs associated with MUF and VUF have all been transferred disproportionately to

the stakeholders in the solid waste industry and, in part, to States at the convenience of the medical or veterinary use facilities. It is essential that there be some 'across the board' accountability of all the parties involved in this waste steam dilemma and in the waste stream resolution. No resolution will be perfect or without costs, but the 'use' facilities should become aware and mindful of the expense and inconveniences to others from the "fallout" resulting from the discovery of radioactive materials where it is objectionable and where it does not belong.

The willingness to quietly and conventionally contain and to minimalize this very costly "fallout" problem from medical and veterinary use must end. The public, the therapy patients, industry, and States deserve a better, cleaner rule from the U.S. Nuclear Regulatory Commission.

Respectfully submitted,

J. Thomas Coulombe

Nota bene: the signed, hard copy of this letter has been placed in the U. S. Mail today.

From: "Coulombe, Tom (DPH)" <Tom.Coulombe@state.ma.us>
To: "'SECY@nrc.gov'" <SECY@nrc.gov>
Date: Thu, Mar 2, 2006 12:54 PM
Subject: Docket Number PRM-35-18

<<Docket Number PRM-35-18.wpd>>

Docket Number PRM-35-18.wpd

Mail Envelope Properties (4407315E.904 : 14 : 6404)

Subject:	Docket Number PRM-35-18
Creation Date:	Thu, Mar 2, 2006 12:59 PM
From:	"Coulombe, Tom (DPH)" <Tom.Coulombe@state.ma.us>
Created By:	Tom.Coulombe@state.ma.us

Recipients
nrc.gov
owf5_po.OWFN_DO
SECY ('SECY@nrc.gov' SECY)

Post Office	**Route**
owf5_po.OWFN_DO	nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	67	Thursday, March 2, 2006 12:59 PM
Docket Number PRM-35-18.wpd	10282	
Mime.822	16286	

Options

Expiration Date:	None
Priority:	Standard
Reply Requested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard