DS09

Bill Morris
57FR53794
11/12/92

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

BERKELEY · DAVIS · IRVINE · LOS ANGELES · RIVERSIDE · SAN DIEGO · SAN FRANCISCO SANTA BARBARA · SANTA CRUZ



(2)

UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

December 10, 1992

Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: DG-8013, "ALARA Levels for Effluents from Materials Facilities"; FR 57(219): 53794-5, 12 Nov. 92.

Dear Mr. Morris:

These comments are being submitted in response to your comment request regarding your draft regulatory guide, "ALARA Levels for Effluents from Materials Facilities". These comments pertain to nuclear medicine facilities.

THE ALARA CONCEPT

The concept underlying ALARA existed long before the acronym was coined, and has long been part of the education of those who use radioactive materials and radiation-producing machines. However, ALARA makes sense only to the point that radiation levels are associated with measurable harm. It is not sensible to make any effort to decrease radiation levels to more and more minuscule levels when there is no evidence of measurable risk at the present levels. We have spent nearly a century studying radiation biology, and have been interested in low level effects for perhaps 75 years. The overwhelming scientific experience shows that low levels of radiation are harmless or even beneficial. There is no compelling evidence of hazard at low levels. As most nuclear medicine activities involve low levels of radiation to workers and very low levels to members of the general public, the whole concept of a written "ALARA Program" was unnecessary from the start. Any thought of increasing the requirements now, out of lack of substantial understanding of nuclear medicine procedures or to appease EPA, is without valid scientific basis.

Nuclear medicine activities that could result in extra rem are few and are well-recognized and controlled. NRC has therefore focussed on millirem, microrem, nanorem and lately even picorem levels (the 15 Sept. 92 P-32 spill in a research laboratory at the U. of Michigan would have resulted in 10 picorem to 7.5 nanorem had it not been cleaned up). If NRC wishes to waste its

regulatory efforts and our User Fees on such questionable past-times, this is bad enough. To expect us to pretend to respect this by concocting extensive "ALARA Programs" to avoid these tiny radiation absorbed doses is unacceptable. The "radioactive effluents" of clinical nuclear medicine are extremely small to virtually nonexistent.

## NRC'S UNDERSTANDING OF AIRBORNE EMISSIONS

NRC/AEC has been inspecting nuclear medicine facilities for nearly 40 years, and this includes evaluation of airborne emissions of radionuclides and compliance with 10 CFR Part 20. Why, then, did NRC fail to give EPA any useful information about our airborne emissions? Why did EPA have to repeatedly claim to us that NRC could not give it any data? Why, when a number of offers were made to NRC by nuclear medicine professionals to teach NRC about our airborne emissions did NRC refuse to use us as a resource? Why has NRC not challenged EPA's Radionuclide NESHAPS on pure scientific grounds? After all, although the models are standard, the actual values for the parameters that EPA (or its contractor) used for the calculations were often not based on best available data but on oversimplification and wildly conservative guesses. EPA's COMPLY Program likewise uses wild "guestimates" for actual values and is, in my opinion, absolutely worthless. The NESHAPS value for I-131 is at least three orders of magnitude too conservative, and the volatility coefficient for I-131 in the COMPLY Program is three orders of magnitude greater than the repeatedly measured volatility coefficients. The EPA is therefore at least a million times too conservative; surely NRC might have spoken up? When EPA complained that NRC's Part 20 standards used only the inhalation pathway and that other pathways were important for certain radionuclides, why didn't NRC fix its calculations and deprive EPA of any basis for scientific criticism?

EPA is very proud of its "models". For radiopharmaceutical preparation, EPA used the "open cauldron" or "witches brew" model, vented directly into a stack with a member of the public's lips essentially sealed around the stack opening. After 40 years of watching radiopharmaceuticals made almost entirely under closed conditions (the "sterility model"), couldn't NRC have pointed out that EPA's model is inaccurate? With all the collected thyroid bioassay data for I-131 in medical institutions, couldn't NRC have shared it? Why does NRC want it if it doesn't feel an obligation to use it?

When we finally realized the degree of NRC's scientific reticence in this area we began communicating directly with EPA. However, EPA insisted on doggedly sticking to its bad science, and would not consider a "second opinion" on the NESHAPS standards or the COMPLY Program.

One thing that is truly ALARA about radionuclide airborne emissions is the scientific performance of both EPA and NRC thus far.

## THE MOU WITH EPA AND NRC'S ALARA REGULATORY GUIDE

Now we see that NRC has totally capitulated to EPA without a shadow of an intellectual fight, and NRC has transferred this ALARA mess to us. It is almost as though the "L" in "ALARA" stands for "loud". That is, if NRC makes enough noise about ALARA, maybe EPA will go away.

This is not appropriate. NRC must learn about our airborne emissions and put ALARA Programs into scientific perspective. I propose that NRC finally educate itself by having a meeting with a subcommittee of the ACMUI (Siegel, Marcus, Briner, Webster) and some other knowledgeable scientists of the ACMUI's choosing. We can then present our data and discuss the very limited situations in which ALARA Programs could possibly serve some usefulness. For almost all nuclear medicine programs, WE ARE AS ALARA AS WE NEED TO BE AND WE DON'T NEED TO GET ANY MORESO.

## THE PATIENT AS A SOURCE OF AIRBORNE EMISSIONS

The only significant source of airborne emissions in clinical nuclear medicine is the patient given large activities of therapeutic NaI-131. Fortunately, the EPA has stated verbally that it does not regulate this source.

There remains little else to be concerned with except research-type activities such as iodinating proteins, or large radiopharmacy operations that stabilize and dispense NaI-131. However, these licensees generally have very good programs, and NRC has presented no evidence that their emissions levels need to be lower.

## CONCLUSION

Before this contest between NRC and EPA escalates any further into absurdity, may the nuclear medicine community have an opportunity to teach NRC about its airborne emissions, current controls, and the radiation exposure of members of the general

public due to nuclear medicine activities? This would help put "ALARA Programs" into better perspective.

Thank you for your attention and consideration.

Sincerely,

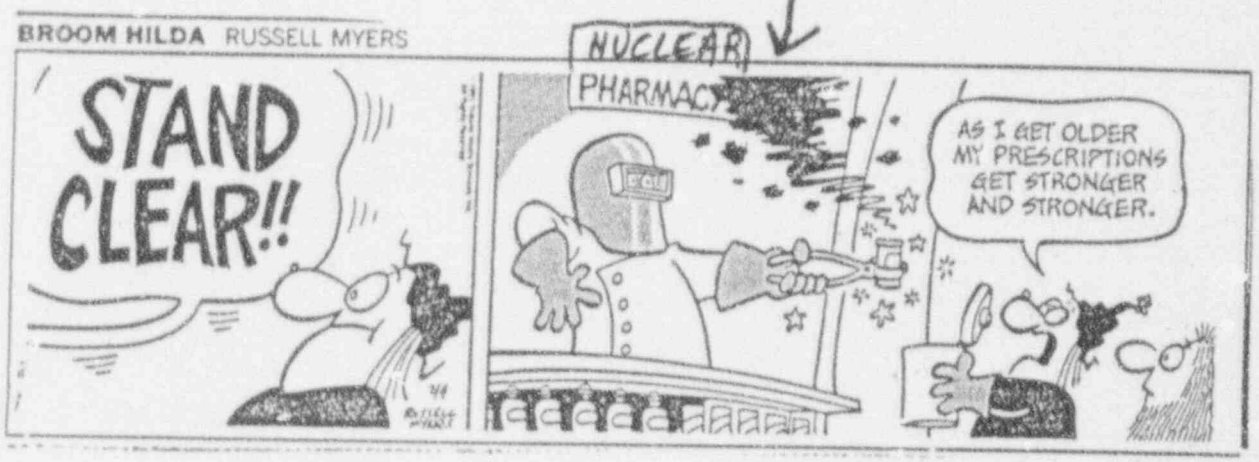
Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

cc: Regulatory Publications Branch
Division of Freedom of Information
and Publications Services
Office of Administration
USNRC
Washington, DC 20555

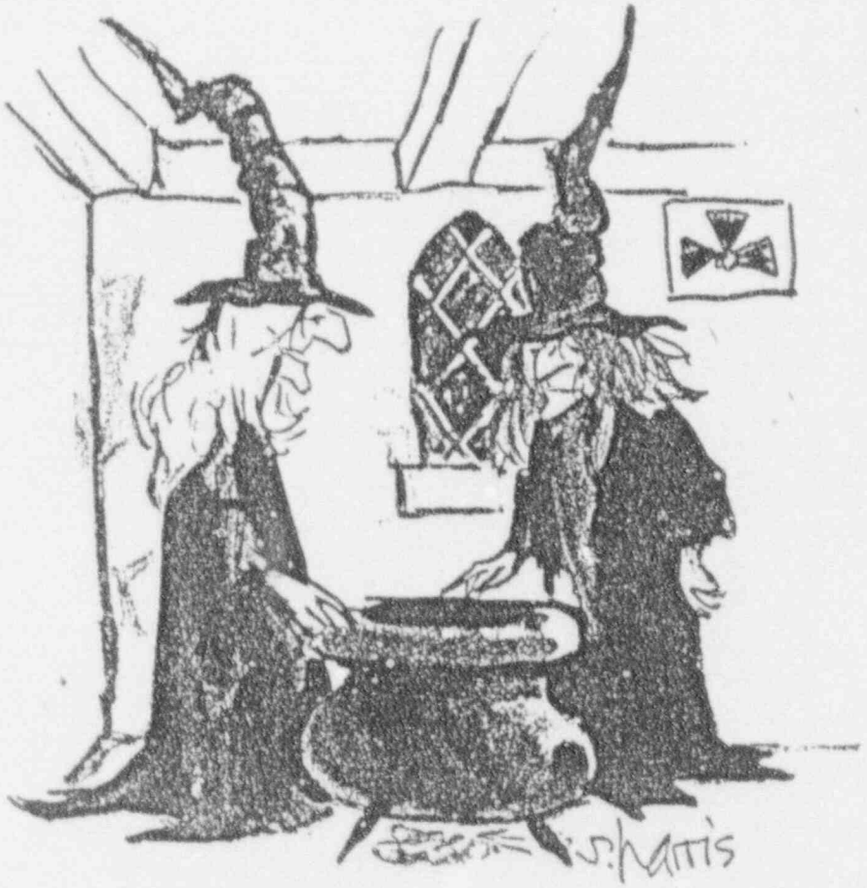
Chairman, Ivan Selin, Ph.D.
Commissioner E. Gail de Planque, Ph.D.
Hugh L.Thompson, Jr.
Richard E. Cunningham
John E. Glenn, Ph.D.
Kristen W. Morris
Barry A. Siegel, M.D.

CSM:sfd

NRC's CONCEPT OF OUR AIRBORNE EMISSIONS:



EPA's CONCEPT OF OUR AIRBORNE EMISSIONS.....



"I don't use it anymore, since I got my ~~microwave oven.~~" NESHAPS violation.

"IT IS DISGRACEFUL IN EVERY ART, AND MORE ESPECIALLY IN MEDICINE, AFTER MUCH TROUBLE, MUCH DISPLAY, AND MUCH TALK TO DO NO GOOD AFTER ALL."

— HIPPOCRATES

SCIENCE

Publisher: Richard S. Nicholson
Editor: Daniel E. Koshland, Jr.
Deputy Editor: Ellis Rubinstein
Managing Editor: Monica M. Bradford
Deputy Editors: Philip H. Abelson *(Engineering and Applied Sciences)*; John I. Brauman *(Physical Sciences)*; Thomas R. Cech *(Biological Sciences)*

Editorial Staff
Assistant Managing Editor: Dawn Bennett
Senior Editors: Eleanore Butz, R. Brooks Hanson, Barbara Jasny, Katrina L. Kelner, Linda J. Miller, Phillip D. Szuromi, David F. Voss
Associate Editors: Gilbert J. Chin, Pamela J. Hines, Paula A. Kiberstis, Suki Parks, L. Bryan Ray
Letters: Christine Gilbert, *Editor*; Steven S. Lapham
Book Reviews: Katherine Livingston, *Editor*
Contributing Editor: Lawrence I. Grossman
Chief Production Editor: Ellen E. Murphy
Editing Department: Lois Schmitt, *Senior Copy Editor*; Douglas B. Casey, Valerie Jablow, Harry Jach
Copy Desk: Joi S. Granger, Beverly Shields, Kirsten L. Wall
Editorial Support: Sherryf Farmer, *Supervisor*; Carolyn Kyle, Michele Listisard, Diane Long, Patricia M. Moore, Melissa Quackenbos, Kameaka Williams
Administrative Support: Sylvia Kihara, Jeanette Prastein

News Staff
Managing News Editor: Colin Norman
Deputy News Editors: Tim Appenzeller, John M. Benditt, Jean Marx
News and Comment/Research News: Ivan Amato, Faye Flam, Troy Gately (copy), Ann Gibbons, Constance Holden, Richard A. Kerr, Eliot Marshall, Leslie Roberts, Richard Stone, Dawn Levy (intern)
Bureaus: Peter Aldhous (London), Marcia Barinaga (West Coast), John Travis (Northeast), Anne Simon Moffat (Midwest)
Contributing Correspondents: Joseph Alper, Barry A. Cipra, Jon Cohen, Robert Crease, Elizabeth Culotta, Robert Pool, M. Mitchell Waldrop
Administrative Support: Fannie Groom

Art & Production Staff
Production: James Landry, *Director*; Wendy K. Shank, *Manager*; Catherine S. Siskos, *Assistant Manager*; Scherraine Mack, *Associate*; Linda C. Owens, Macintosh *Operator*
Art: Amy Decker Henry, *Director*; C. [illegible] Smith, *Associate Director*; Diana DeFrancesco, *Technical Illustrator*; Holly Bishop, *Graphics Assistant*
Administrative Support: Leslie Blizard

Associate Publisher: Beth Rosner
Circulation Director: Michael Spinella
See Letters page for additional Advertising and Circulation Staff

Science Editorial Board
Charles J. Arntzen, Elizabeth E. Bailey, David Baltimore, William F. Brinkman, E. Margaret Burbidge, Pierre-Gilles de Gennes, Joseph L. Goldstein, Mary L. Good, Harry B. Gray, John J. Hopfield, F. Clark Howell, Paul A. Marks, Yasutomi Nishizuka, Helen M. Ranney, Robert M. Solow, Edward C. Stone, James D. Watson

# EDITORIAL

## A Campaign for Science

*Science*. Dr. Noitall, you are one of the international experts on election campaigns, the man who managed Harry Truman's campaign, the man who arranged the Lincoln-Douglas debates, and the man who got Moses all that favorable publicity in the Bible.

*Noitall*. A vast understatement of my true worth.

*Science*. Are there any lessons from the recent campaign that might be transferred to science and science publishing?

*Noitall*. Of course there are. For example, politicians have learned the advantage of double, triple, and quadruple publication. None of this nonsense of one paper in one journal only. You repeat your message in Boston, Dallas, Terre Haute, and Sacramento until everyone gets so bored with it that they think it's a fact.

*Science*. That might cause some problems for scientific publication.

*Noitall*. That's your typical stodgy response that will prevent science from ever being in prime time. A second innovation would be references. You will note that news stories of the election all reported information from "insiders," "foreign policy experts," "economic experts," or, in cases of extreme importance, "a high official." This kind of uncheckable reference has great advantages over the mind-numbing data of modern science.

*Science*. Did you notice any novel ideas on the moral front?

*Noitall*. Science should, of course, come out for something like "traditional science values," which would solve a lot of the debate over ethical issues. Traditional science values should be defined as those principles on which all scientists agree, and any deviation from those principles will be considered to be unacceptable and morally corrupt.

*Science*. What do you mean by deviations?

*Noitall*. Good examples of deviation from accepted values are fraud, plagiarism, and highly original ideas.

*Science*. And do you have any ideas for improvement in scientific publication?

*Noitall*. The anchors on television are a close analog to the editors of scientific publications. And you will note that they never let presidential or other candidates finish a speech, or even a sentence, before they explain to the audience what the poor idiot is trying to say and whether he or she is sincere or just trying to get the Oklahoma vote. Editors should be allowed to insert sentences of clarification within authors' articles and to write little introductions and conclusions on the sincerity of the authors. That is more readable than scientific details.

*Science*. What about plans for the future?

*Noitall*. Plans for the future are "pie-in-the-sky" if it's an unlikeable author and "sticking to the issues" if it's a likeable author. A lot of wasted time on data and experiments could be eliminated if authors were allowed to say what they intend to do and wrote results they thought were likely, rather than bothering to go through all the experiments. Authors would be allowed to promise that if they get published, they are planning to get the data for a Higgs' boson or a cure for cancer. Good intentions should be considered far better than past history, such as experiments.

*Science*. What kinds of behavior should disqualify authors?

*Noitall*. Clearly, any past character deficiencies or guilts by association should be enough to disqualify an author. It is of course disgraceful that the entropy of the universe has been increasing for years without any imaginative ideas on how to decrease it. And the second law of thermodynamics by preventing perpetual motion machines has an abominably regressive effect on growth. Anyone identified with these notions should not be allowed to publish. Scientists who change their minds are reprehensible. Sticking to one's old ideas regardless of new facts shows steadfastness of character. Change for change's sake is also highly desirable. These principles are somewhat contradictory when expressed together but are very valuable for decision-making if considered one at a time. Selective use of mutually exclusive moral positions allows one to publish nice authors and reject unpleasant authors on principle.

*Science*. Do you think these campaign ideas will actually help scientific publication?

*Noitall*. Eliminating references and data will, of course, decrease the difficulty of publishing scientific research, which should mean that the literature will increase astronomically, giving the illusion of productivity. Of course, what is published won't amount to much, but it won't require a tax increase either.

Daniel E. Koshland, Jr.