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April 8, 1991

MEMORANDUM FOR: James M. Taylor
Executive Director
for Operations

FROM: Peter G. Crane

SUBJECT: SECY-91-079

I believe that those who forwarded SECY-91-079 to you for your signature did you a serious disservice. That paper was prepared in response to a November 15, 1990 Staff Requirements Memo, COMKC-90-21, entitled "Proposed Response to Office of the Inspector General (OIG) Investigation Regarding a Medical Misadministration at the University of Cincinnati Hospital." The SRM asked the staff to "conduct a 'lessons-learned' assessment based on the University of Cincinnati misadministration." It stated that the assessment should focus on two specific topics: the types of questions to be asked and information to be collected, and the process for resolving differences of views on regulatory interpretations. For the reasons set forth below, I believe that SECY-91-079 is almost wholly unresponsive to COMKC-90-21.

The point of lessons-learned assessments, obviously enough, is to learn from mistakes in order not to repeat them. Yet this staff paper is not only devoid of any suggestion that the staff's handling of the matter was less than 100% commendable, it does not discuss the Cincinnati incident at all, other than in a one-paragraph "Background" section that describes only the misadministration itself, not the staff's handling of it. Enclosure 3, to be sure, describes procedures which a reader familiar with the Cincinnati case will recognize as designed to prevent a repetitition of what went wrong in that case; but the Commission is given no explanation of the link between those procedures and the facts as described in the OIG report.

How can there be a lessons-learned assessment that does not discuss what happened in the incident supposedly learned from? The Commission's request did not seem ambiguous; the Commission's SRM asked for "a 'lessons-learned' assessment based on the University of Cincinnati Hospital misadministration." It said, "The assessment should include a review of past misadministrations and inspection practices to determine information needs." Yet SECY-91-079 seems to say, on page 1, that the only "past misadministrations" it reviewed were therapy events occurring in 1989 and 1990, years after the 1984 Cincinnati misadministration. The memorandum neither agrees nor disagrees with the OIG report on the Cincinnati incident; it simply does not mention it at all.

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To make clear what a lessons-learned assessment might profitably have focused on, it may be useful to examine what actually happened in the Cincinnati case. Let us look in turn at the two issues about which the Commission asked, information gathering and resolution of differing views.

In October 1984, some weeks after the misadministration, the staff conducted an inspection at the hospital in which it neglected to ask for the patient's chart or for the hospital's records of the event. Instead, the staff relied on oral discussions with hospital personnel and a chronology drawn up after the event by the licensee. As a result, the staff was in error, among other things, as to (1) when the patient's doctors decided (to the extent they decided at all) that the potentially leaking seeds should remain in the patient; (2) the degree to which the hospital was aware that the seeds were leaking; (3) when the patient was released from the hospital; and (4) the identity of all persons irradiated in the incident. Thus the staff did not learn until five years after the event (and only because I insisted that the records be consulted) that the hospital's failure to isolate the patient led to the irradiation of her 5-year-old daughter.

OIG's report wrote:

"The investigation revealed that the staff failed to question the hospital regarding the specific events and actions undertaken during the incident. The staff assumed that the hospital made a medical decision based on the knowledge that a sealed source was leaking inside the patient. Yet, the hospital subsequently maintained that they did not definitely know, but rather only suspected the seeds were leaking inside the patient."

The report also stated that the OIG investigation had determined "that staff did not adequately review the incident and made an error in accepting the hospital's representations."

These deficiencies found by OIG in the 1984 investigation of the incident are not insignificant. In mitigation of those deficiencies, it could perhaps be argued that in 1984, the staff had no reason to doubt the licensee's account, and that its failure to "question the plausibility" of that account, as OIG puts it, was therefore excusable. But no such excuse applies to the staff's 1986 reinvestigation of the issue, for by then, it was on actual notice that the 1984 account was implausible. The OIG report makes clear that in 1986, the then EDO, responding to my charge that the 1984 staff account was inaccurate, sent the Commission a second inaccurate account, and at the same time urged in strong terms that the investigation initiated by the Commission be terminated at once. It is only because the Commission declined to accept the EDO's request for an end to the

investigation that the inaccuracy of the staff's versions of the event was ultimately confirmed.

To recall, when I learned of the incident in 1986, two years after it happened, I wrote a memo, dated August 27, 1986, asserting that the events could not have occurred as reported by the licensee and the staff, because the actions of the doctors were inconsistent with actual knowledge of a leaking seed. Notably, (1) no immediate urine test was run and (2) a thyroid blocker was not administered. This took no great clairvoyance on my part; anyone familiar with the respect with which radioiodine is handled in nuclear medicine departments might have had similar suspicions. Later, we also learned: (3) the patient was not sequestered, (4) nurses were not warned of the potential for their contamination, (5) the doctor scheduled to perform the explant was not informed, and (6) no notation of a suspected leaking seed was made in the patient's chart or other hospital records.

In response to my memo, the then EDO responded with a memo, dated November 28, 1986, that purported to be a true account of the facts, as confirmed in a November 24, 1986 telephone call with the licensee. OIG has this to say about the EDO's November 1986 memo and a briefing paper that followed it:

"The investigation also disclosed that the November 1986 memorandum ... and the December 1986 briefing paper to the Commissioners' Assistants did not identify the correct date and circumstances surrounding the hospital's medical decision. Because the staff failed to adequately review the incident, it incorporated inaccurate information which the hospital had provided in 1984."

I would also point out that the call of November 24, 1986 to the hospital had the effect, inevitably, of putting the licensee on notice of the Commission's renewed interest in the 1984 event, and thus may have crippled the investigation before it even began. OIG, which took three and a half years to conduct its investigation, was unable to determine who in the staff made the November 24 call or what was said. Perhaps the former EDO might have known; perhaps the responsible Division Director would have known; but OIG, for reasons best known to itself, appears not to have interviewed either.

Let us turn from the question of information-gathering to the question of "resolution of differences between regional staff and OGC staff," referred to in the Commission's SRM. What the Commission is referring to it the fact that in the Cincinnati case, the staff reported what it had learned to Tom Dorian, a lawyer in ELD (as it then was), was advised that the event constituted a misadministration, and nevertheless determined that the event was <u>not</u> a misadministration.

The staff based its non-misadministration finding on a conversation with hospital personnel on October 30, 1984. In 1989, two sets of handwritten notes on that conversation were found in the files of hospital personnel. Those notes show the NRC staff telling the hospital what it should report to NRC (a "medical decision"), and declaring that NRC will find that no misadministration has occurred. OIG has this to say about the notes: "Although [name deleted]'s handwritten notes of October 30, 1984, may suggest possible collusion, they are not conclusive proof." The OIG report inexplicably does not mention that the notes reveal that the NRC staff person on the line asked that the call not be tape-recorded -- which may suggest that he did not feel altogether comfortable about the propriety of the discussion.

What does SECY-91-079 have to say about the process by which Dorian's views were overridden and the decision made to find the event a non-misadministration? Nothing at all: just a general statement that individuals have a responsibility to make their best professional judgments known, and that new guidance for obtaining interpretations of NRC regulations "should reduce future internal conflicts such as those associated with the Cincinnati case."

And what is the result of the staff's actions toward the University of Cincinnati Hospital in 1984 and 1986? One possible interpretation, as one examines the record of the actions of the licensee and the staff since 1984, is that the licensee reached the not unreasonable conclusion that it had nothing to fear from the NRC, and no reason to be in a hurry to clean up its act. The record includes the following:

-- In 1984, the leaking seed incident led to a finding of two regulatory violations, but no civil penalty was assessed.

-- In 1986, the staff admitted that the 1984 event should have been called a misadministration, and the event was so reported to the Congress in a 1987 Abnormal Occurrence Report, which was also published in the Federal Register. But in May 1989, the head of the hospital's Radiation Safety Committee objected to questions about the 1984 "misadministration" on the grounds that no one at the NRC had ever advised the hospital that the event was a misadministration. (Of course, we have only his word for this.)

-- In 1989, acting on numerous allegations it had received, the staff found a management breakdown at the University of Cincinnati, with some 30 violations found. Though the staff rated the failure as Severity Level II (see SECY-90-198), no civil penalty was assessed.

-- In 1990, the staff went back to Cincinnati, and this time found some 22 violations, including two cases of failure to account properly for Iodine-125 seeds.

-- In 1991, the latest draft Abnormal Occurrence report begins with another misadministration at the University of Cincinnati Medical Center, again involving I-125 seeds.

This record does not speak well for the licensee, but neither is it testimony to the effectiveness of NRC regulation. Can it come as a surprise that NRC goes on having serious problems with a licensee, if the statutory finding of an Abnormal Occurrence is shared with the Congress and the readers of the Federal Register but -- allegedly -- not communicated to the licensee itself?

In sum, we have a case in which the inadequacy of the NRC-staff's information-gathering process caused five years to elapse before the agency learned of the wholly unnecessary exposure to radiation of a 5-year-old child. We have a case in which the staff provided erroneous information to the Commission not once but twice. We have a case in which the EDO himself, in an effort to halt an investigation initiated by the Commission, provided the Commission with inaccurate information, based on supposed verification with the licensee which no one is now willing to admit having conducted. We have a case in which the staff disregarded legal advice and exculpated a licensee in circumstances which, according to OIG, "may suggest possible collusion" between the staff and the licensee. And yet we have a staff paper, SECY-91-079, that seems to say to the Commission, "The premise of your SRM seems to be that the staff's actions in the Cincinnati case were deficient, and because we reject that premise, we reject your request for an assessment of the incident."

I cannot believe, after your response to the Pilgrim case, that you would regard the staff's handling of the Cincinnati case as representing acceptable performance. Nor can I believe that you would have approved SECY-91-079 if you had been made aware how far short it fell of being a true lessons-learned assessment of the incident.

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
The General Counsel
The Inspector General

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December 10, 1992

MEMORANDUM FOR: Martin G. Malsch
Deputy General Counsel

FROM: Peter G. Crane

SUBJECT: STAFF PAPER ON PATIENT [illegible]HS
ATTRIBUTED TO MISADMIN[illegible]IONS

At your request, I am providing comments on the staff paper that you received at the pre-briefing this afternoon. These comments are my own personal views, and they are written at home on my own time.

In a nutshell, I think that the staff paper, notwith[illegible]ing the disclaimer that it has not been reviewed by senior staff, is capable of doing serious damage to the Commission, since it seems to take a complacent and head-in-sand attitude toward events that are likely to horrify and anger the public. This evening I called Hugh Thompson, an old and close friend, to express my concerns, hoping that there might be a way to recall the paper. He said that the paper will not be recalled, but that the slides for the Chairman's December 11 briefing will be changed [illegible]ake clear that the staff's way of investigating events has c[illegible]ged since 1975 in the direction of greater thoroughness. I must say that I am greatly surprised that the senior staff should be so trusting of the staff in the medical area as to forward to the Commission a memorandum on this most sensitive of topics without even having read it through.

The crux of the staff's answer to the Plain Dealer's charge that many more deaths occurred at Riverside than NRC acknowledges is that the NRC does not know because the NRC did not need or care to know. Why not? Unapologetically, the staff explains that once it knew that the incident was serious -- and at Riverside, it knew after Dr. Saenger documented two deaths that the error was serious -- there was no need to go further and find out how many other people died. (This statement cannot be reconciled with the July 14, 1977 Preliminary Notification on the Riverside incident, which said that the coroner's office had identified radiation as a major contributor to two deaths, and that "the NRC medical consultant's evaluation of other deceased patients involved is continuing.") The clear implication is that the NRC still h[illegible]lds this attitude. See, for example, the answer to question [illegible]nich includes the following: "NRC does not regulate iss[illegible] regarding the quality of medical care given to individual pa[illegible]ents. NRC collects sufficient patient specific information in each case to determine the appropriateness of the actions taken by the licensee in response to the event."

I read that as saying that once we determine that a

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teletherapy machine has killed one patient because of a miscalibration, we have all the evidence we need to correct the problem, and it is a matter of indifference to us whether scores more people were also killed. Leaving aside for a moment the common-sense objection that an agency whose responsibility is the protection of public health and safety ought to care whether an event kills two people or 26 people, I do not see how this approach can be squared with our obligation to report abnormal occurrences accurately to the Congress, or with our declared policy, set forth in the Supplementary Information to the misadministration reporting rule, that individual patients have a right to know when they have been misadministered.

The staff's reticence about finding out the full dimensions of incidents explains why it emphasizes, in these answers, the small number of "confirmed" deaths. The line that I suspect will be quoted in every news story and in every outraged Congressman's public statement appears in the answer to the first of the list of expected questions: "[I]ssues such as cause of death are the responsibility of other federal, state or local organizations."

The staff's approach, which apparently has been applied consistently since the mid-1970's, may explains why it ignored the November 1986 SRM from the Commission that directed it to discuss, in its next paper to the Commission, creation of a mechanism to follow up on patients who have been misadministered. To do so would have meant being willing to learn who had been misadministered in the first place.

One piece of information that struck me as a bombshell, because it was the first I had heard of it, is the revelation that 20 or more people may have died at Sacred Heart Hospital in Cumberland, Maryland, in 1987-88 because someone forgot to insert into the computer program governing teletherapy procedures the fact that a new cobalt-60 source had been installed. (Appendix D, Item 52.) Hugh told me tonight that last week, the staff asked the State of Maryland for information on the incident. Apparently in response to the event, the NRC issued Information Notice 88-93 to all NRC medical licensees; I would be curious to know whether that notice mentioned that as of October 1988, 20 patients had died either during treatments or thereafter.

Overall, looking at this paper and at the totality of the problems facing the Commission in the medical area, I think that there is evidence of a chronic failure, going back to the agency's earliest days, to inform the Congress fully and accurately about misadministrations. In addition, there has been a failure of the agency to meet its obligation, declared in 1980, to assure that patients are informed when they are the victims of misadministrations. Both these problems stem from the fact that the staff has consistently disregarded Commission direction and has just as consistently been allowed to get away with it. If I

were the Commissioners, I would want to get out front, quickly, with a commitment to look at every misadministration, going back to the creation of the NRC in 1975 (that is long enough ago to include Riverside); to identify every victim; to follow up on every victim; to make sure that patients and family members have been notified; and, if it turns out that redress has been denied to anyone through the passage of time, to make recommendations to Congress for corrective action. This kind of project could not, of course, be done in-house, nor should it be.

The following are specific comments about the staff paper.

Enclosure 2, "Major Steps by NRC to Improve the Medical Use Program," has some problems. The description of the 1980 misadministration reporting requirement leaves out all mention of the patient's right to know as one of the bases of the rule. (The staff has been adamantly opposed to patient notification from the time the rule was instituted, seeing it as an invitation to malpractice suits.) The discussion of the 1987 final rule on 10 CFR Part 35 contains the truthful statement that the new Part 35 "modified the misadministration reporting requirements." Unfortunately, the staff paper that sent the proposal to the Commission stated explicitly that it was leaving the misadministration reporting requirements untouched, and the Commission so advised the public in its Federal Register notice. Thus the Commission was induced to change its misadministration reporting requirements -- those dealing with patient notification -- without knowing that it was doing so, and with the public equally misled. The effect of the change, in my view, is to make it more difficult ever to find that a licensee failed to notify a patient of a misadministration. (I would argue that the rule change was invalid for lack of notice.)

Appendix D lists 98 misadministrations culled from abnormal occurrence reports. I have comments and questions about some of them, as follows.

14. Hospital of St. Raphael, New Haven, Connecticut (1984): The summary says that the consultant offers a prognosis slightly more favorable than that of the licensee, on this 25-fold overdose of I-131, but does not say what either one predicted.

24. Robert Packer Hospital and Guthrie Clinic, Sayre, Pennsylvania (1986): There is no estimate of dosage to the thyroid from this event in which the patient got 10 mci of I-131 instead of technetium. (Probable dosage is 10,000-12,000 rads.) The summary says that an NRC consultant "concluded that there was a probability of inducing hypothyroidism." I would think it was a certainty; I believe that the therapeutic dose given President Bush to knock out his thyroid was 8 mci.

27. University of Cincinnati Medical Center, Cincinnati, Ohio

(1984): The summary, like the 1986 abnormal occurrence report, does not mention (probably because in 1986 the staff did not know) that the patient's 5-year-old daughter also received a measurable dose of I-125. As I recall, contamination was not confined to the brachytherapy storage room, as the summary states, but was carried elsewhere in the hospital by the air conditioning system. It is interesting that unlike the abnormal occurrence report, which said that on explant, the seeds were "confirmed" to be leaking -- a statement which implied that they were suspected to be leaking at the time -- there is no suggestion in this summary that anyone was aware that the seeds were leaking until they were removed from the patient.

29. Cleveland Clinic, Cleveland, Ohio (1986): The summary is misleading. It says, "The patient was discharged on October 10 [after radiation treatment], was readmitted on October 20 for symptoms believed to result from the radiation exposure, discharged, and readmitted on November 10 to another facility with skin burns." Would you know from this that on October 20, 10 days after her discharge, she was returned to the hospital for treatment of massive burns? For three weeks her condition declined, until it was necessary to move her to a hospital specializing in treatment of burns. Only at the time that they were transferring her -- supposedly -- did it occur to the Cleveland Clinic that her radiation treatments might be responsible, and only then did they consult her records and discover that she had been misadministered. This was the case where the staff wanted to use Dr. Eugene L. Saenger of the University of Cincinnati as its consultant, notwithstanding that the Commission had just ordered an investigation of the Cincinnati hospital. I am surprised to learn that even though the patient received a 67% overdose of radiation, her skin burns were found by the panel of consultants not to be attributable to the radiation. I would be very interested to see who made up the panel and what their findings were. I would also like to see what the coroner reported as cause of death, just to ensure that the two sets of findings are consistent.

31. Toledo Hospital, Toledo, Ohio (1986): The patient received 20 mci of iodine-131 instead of 20 mci of technetium-99m MDP. The summary says that the nuclear medicine personnel thought that the request was for a thyroid metastatic disease scan: "This procedure is usually performed on patients that have had their thyroid surgically removed." While it is true that I-131 is used to look for metastases in thyroid cancer patients whose thyroids have been removed, I have never heard of diagnostic doses in excess of 10 mci. This suggests to me that the error was less explicable than the summary indicates.

34. University of Massachusetts Medical Center, Worcester, Massachusetts (1987): This is yet another case of someone reading a prescription for microcuries and giving the patient

millicuries, a thousand-fold overdose. (I wish one of the two could be given a different name, because these events happen with sickening frequency. Incidentally, at George Washington University Hospital, the nuclear medicine department will not allow any administration of I-131 except to patients with a definite diagnosis of thyroid carcinoma, because the risk of harm to a healthy thyroid is so great.) My problem with this account is the extimated dose to the thyroid. I-131 results in a dose to the thyroid of 1000 to 1200 rads per millicurie; I don't see how 5.5 mci of I-131 could produce a dose of only 730 rad. Nor do I understand, from this account, why I-131 was administered "for the convenience of the patient."

40. Northern Westchester Medical Center, Westchester County, New York (1987): This report is extremely vague about an event in which numerous patients were overdosed in therapeutic administrations. One patient received a dose 204 times what was prescribed. But what happened to the patients? We know that "some patients which [sic] had received overexposures had exhibited physical symptoms apparently due to the exposures." "Physical symptoms" could mean anything from reddening of the skin to severe burns and death. I would like to know more.

44. St. Joseph's Hospital, Milwaukee, Wisconsin (1988): This event, in which the patient was irradiated in the wrong hip, was the subject of an abnormal occurrence report which was unusual in that it included the licensee's suggestion that the patient might have had cancer in both hips, in which case the misadministration should be regarded as beneficial rather than harmful.

48. West Houston Medical Center, Houston, Texas (1988): Another 1000-fold misadministration of I-131, this time with 30 mci, resulting in an estimated thyroid dose of 30,000 to 34,000 rads. Nothing is said about the consequences to the patient of this dose, which is sufficient to ablate a normal thyroid.

58. Worcester City Hospital, Worcester, Massachusetts (1989): This was a case in which the technologists decided that some freckles on the patient's lower back were the marks at which the teletherapy unit should aim. The patient protested that his problem was in his upper chest, not his lower back, but the technologists went ahead and irradiated his back.

60. Monongahela Valley Hospital, Monongahela, Pennsylvania (1990): This is a malfunction of a remote afterloading brachytherapy irradiator. How similar is it to the device used in Indiana, Pennsylvania? Should it have alerted NRC to problems with these devices?

70. Tripler Army Medical Center, Tripler AMC, Honolulu, Hawaii (1990): The summary is correct in saying that the root cause was the failure of licensee personnel to confirm that the

patient was not breastfeeding. More specifically, they had a list of questions to ask and skipped a number of them because they were in a hurry. The patient was from Truk, to be sure, but Tripler has a long (and admirable) history of serving patients from Micronesia, so there was no excuse for the failure to ask the question. This was the case, incidentally, where the NRC's consultant, Dr. Carol Marcus, in an extremely unusual report (e.g., "the fickle finger of fate came up Tripler") put the blame on the patient, and made repeated derogatory references to the fact that the child was born out of wedlock. (Her theory was that the patient hid the fact of the child's existence because of shame at its illegitimacy.)

78. University of Cincinnati, Cincinnati, Ohio (1990): Another misadministration at this hospital, with 15,000 rads to the tissue surrounding the patient's prostate and almost none to the prostate itself. The summary does not indicate that a consultant was called in. Why not?

81. Hutzel Hospital, Detroit, Michigan (1991): A 100-fold overdose of I-131, again to a nursing mother. Did they know she was nursing? Did the baby get a dose? The summary does not say.

93. Baystate Medical Center, Springfield, Massachusetts (1992): Another I-131 error, this time with 4.1 millicuries instead of 16 microcuries. This was the abnormal occurrence report which the NRC's consultant, Dr. Carol Marcus, bitterly protested in a November 1992 letter to Chairman Selin. Again, Dr. Marcus blamed the patient, who supposedly became impatient with the long wait for her diagnostic procedure. The summary states that the licensee's corrective action includes following the patient's progress "once every six weeks for three months." That strikes me as wholly inadequate followup, whether the dose to the thyroid was 14,300 rad, as calculated by the licensee, or a significantly lower figure, as calculated by Dr. Marcus. (My guess is that Dr. Marcus's figure is closer to the mark, given that only 4.1 mci were administered.)

94. The Christ Hospital, Cincinnati, Ohio (1992): Whom did we use as our consultant in this case?

96. St. Joseph's Medical Center, Paterson, New Jersey (1992): A high dose remote afterloading device using iridium; again, how similar is this to the event in Indiana, Pennsylvania?

As a general matter, I cannot figure out from these summaries what criteria the staff uses in deciding whether a consultant is needed. I might be useful to know who the consultant was on each case.