



THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

VIA TELECOPY AND OVERNIGHT DELIVERY

March 7, 1997

Mr. Michael M. LaFranzo
Radiation Specialist
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532

RE: The Cleveland Clinic Foundation
License No. 34-00466-01

Dear Mr. LaFranzo:

As requested by the NRC, the Cleveland Clinic Foundation ("the Foundation") has performed an evaluation regarding the solubility of licensed material discharged to the sewer from January 1994 to June 1996. During this period, the Foundation had practices and procedures in place providing that its scientists and researchers were to make solubility determinations for discharges of licensed material to the sink based on widely accepted scientific principles. Further, the Foundation believes that its past sink disposal procedures were consistent with the solubility requirement in 10 C.F.R. § 20.2003.¹

Like other medical research institutions, the use of radioactive materials within the Foundation is typically by scientists and their research personnel performing biological research. These scientists and researchers assess the solubility of both the licensed material that they receive and the compounds produced through their experimentation as an underlying and important part of their research. In addition, through the Foundation's Radiation Safety Program, scientists and researchers are kept apprised of regulatory requirements. As a result of this program, scientists and researchers were made aware of the requirement that licensed material discharged to the sink must be soluble. Information regarding past practices and

¹ "Solubility" as used herein, refers to both elements in § 20.2003 -- "soluble" and "dispersible biological material."

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procedures gathered from scientists and authorized users reflect that scientists and researchers made solubility assessments for the compounds they used and produced and, although not documented, that they applied those decisions in their sink disposal practices.

I. THE FOUNDATION'S SOLUBILITY EVALUATION OF PAST DISCHARGES

In response to the NRC's request, members of Radiation Safety, the Radioisotope and Radiation Safety Committee (RRSC) and the Office of Clinical Effectiveness have undertaken an evaluation of the practices and procedures regarding solubility determinations and sink disposal practices for the period from January 1994 to June 1996. Specifically, the Foundation gathered information from representatives of Radiation Safety and the Research Institute regarding how scientists and researchers were assessing solubility of licensed material during this period. Based upon this evaluation, the Foundation concludes that there were practices and procedures in place to effect the following: (1) an understanding by the scientists and researchers that they were required to make scientific judgments as to the solubility of licensed material that they discharged to the sink, (2) the use of widely accepted scientific principles for those solubility assessments, and (3) the application of these assessments by scientists and researchers in their sink disposal practices. These three conclusions are discussed more fully below.

A. Scientists and Researchers Were Aware of the Solubility Requirement

Policies and practices of the Foundation's Radiation Safety Program during the relevant time period were aimed at making the scientists and researchers aware of the requirement that all material disposed via the sink must be soluble. The Foundation follows a thorough evaluation procedure for authorization of new users. All new scientists who propose to use licensed materials must request authorization for such use from the RRSC. The proposed user is first required to complete an Application for Authorized Use. This Application requires the individual to include, for each radionuclide that he or she proposes to use, a statement as to whether radioactive waste will be generated during the experimentation, and whether the waste will be soluble liquid, insoluble liquid and/or a dry solid. Once the Application is received, Radiation Safety interviews the proposed user, and through this procedure, evaluates the information provided and resolves use issues, including methods for disposal. The Radiation Safety Officer also provides in-person training for each proposed user.

After this review, the authorized user's request is presented to the RRSC for approval. As part of this procedure, the proposed user must appear before the RRSC and attest to his or her understanding of NRC requirements, including requirements on waste disposal. The proposed users are again subject to questioning regarding material use, including inquiry as to the proper method of waste disposal. During the relevant time period (as well as today), proper waste disposal and associated issues were given high priority by members of the RRSC, especially those representatives of the Research Institute. Also, each

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user approved by the RRSC ("authorized user") must sign a statement in which he or she accepts certain responsibilities, including the proper disposal of waste.

Researchers other than authorized users also were made aware of the waste disposal requirements. All research personnel who would handle licensed material are provided orientation. Radiation Safety provides new-hire training to review regulations, policies and other principles of safe use of licensed materials. Also, specially-trained Radiation Safety contacts train new personnel on laboratory-specific procedures. Proper waste disposal has been fully incorporated into this training. In addition, all new personnel are required to become familiar with the Radiation Safety Manual as part of new-hire training. During the relevant time period, and at all times thereafter, the Radiation Safety Manual included guidelines on radioactive waste disposal which specified that liquid waste must be soluble or dispersible in water for it to be discharged to the sewer system.

B. Scientists and Researchers Conducted Solubility Evaluations

As supported by information gathered from the Foundation's scientists and authorized users regarding past practices and procedures, its scientists and researchers made solubility assessments for licensed material. Scientists and researchers need to know the solubility of the parent compound in order to conduct most experiments. In addition, the scientists and researchers need to know the solubility of compounds produced by chemical reaction during the experiment ("daughter" compounds) in order to analyze their results. In contrast perhaps to operators in an industrial process, scientists are trained to perform solubility assessments for the research itself, in addition to proper waste disposal. The Foundation found that the fact that these scientists and researchers did not record a calculation or cite a reference book to support their solubility determination does not mean that a determination was not made.

These solubility assessments were based on widely accepted scientific principles applied to the scientists' underlying knowledge of the chemical form and molecular structure of the compounds being produced during their experimentation. The NRC issued guidance for solubility determinations in its November, 1994 Information Notice 94-07 (which has not been subject to formal rulemaking procedures) ("NRC Guidance"). The NRC Guidance is based on similar principles, such as reference to the literature, including *Handbook of Chemistry and Physics*, *Lange's Handbook of Chemistry*, and the *Merck Index*, as outlined in Section 1(a) of the NRC Guidance.

Notably, the NRC Guidance expressly recognizes that "there are many approaches that may be used to determine a chemical compound's solubility in water." The NRC Guidance provides "two of the more common approaches" for determining solubility which it acknowledges are only "suggestions" or "recommendations," not requirements.

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C. Evaluation of Available Documentation Regarding Sink Disposal Practices

At the time the NRC requested the Foundation to review its past sink disposal practices (at the close of the Pre-decisional Enforcement Conference held on October 22, 1996), there was no discussion of the scope or method for the requested evaluation. You later informed Radiation Safety that the NRC is seeking the following information: (1) radionuclide; (2) activity; (3) chemical name; (4) basis for determining compliance with 10 C.F.R. 20.2003 (e.g., water soluble or biological dispersible); and (5) the methodology used to arrive at the basis for determining compliance with 10 C.F.R. 20.2003.

As requested, the Foundation is providing a summary of the radionuclides that were discharged to the sink and their activity. This information is documented in Exhibit A. The radionuclide/activity information is provided in a summary to provide the information in a more easily reviewable form.

This summary is derived from past sink disposal forms which recorded the identity of the radionuclide and the activity of the material at the time of discharge for each sink discharge. The daily discharges are summarized and evaluated by Radiation Safety to evaluate compliance with Sections § 20.2003(a)(3) and (4) of the NRC regulations which impose limits on the concentrations and total activity discharged to the sewer on a monthly and annual basis. The summary illustrates that the Foundation's monthly and annual sink discharges have been well below the regulatory limits -- ranging between only 11% to 22% of the limits -- and that sink discharges of licensed material have steadily decreased.

As the NRC knows by virtue of its December 20, 1996 administrative action, however, the past sink disposal forms did not record the chemical name of the material actually discharged nor did they record the associated method(s) for solubility determinations. Without the chemical name for each material produced by the experiments and subsequently discharged, it is not possible to provide the NRC with definitive information. Simply stated, given the numerous isotopes used, the variety of experiments conducted, and the numerous different compounds produced during experimentation, a discharge-by-discharge solubility evaluation is not feasible. The NRC Guidance expressly recognizes this fact -- a direct solubility determination based on solubility class, formal solubility, or solubility product is applicable only when there is sufficient knowledge of "the chemical form of all materials contained in the liquid effluent *at the point of release*." (Emphasis added).

The Foundation attempted, although unsuccessfully, to compile this missing data from other sources. Specifically, based on direction from the NRC, the Foundation initiated a review of the shipping records for the parent compounds received by authorized users for use in their experiments to evaluate the solubility of the materials actually discharged.

However, it was quickly learned that the chemical form and name of the parent compound cannot predict (without other information), the chemical name(s) and form(s) of

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the resulting daughter compounds. The parent compound used by the scientist typically is reacted during the experiments and as a result is transformed into many additional or different compounds, depending upon the processes involved in the experiment. Due to the reaction, the compounds change, as can the solubility properties of the resulting compounds (either enhancing or decreasing solubility). This is true whether the parent compound is soluble or insoluble.

In sum, the Foundation does not have the documentation that would allow it to conclusively identify the chemical name of each licensed material which was discharged to the sink from January 1994 through June 1996, and thus, cannot provide further solubility information on a discharge-by-discharge basis. However, even in light of this, the Foundation believes that its past practices and procedures were protective of the solubility requirement, as detailed above.

II. CURRENT PRACTICES AND FUTURE COMPLIANCE

The Foundation is in the process of implementing numerous improvements to its licensed program, including its solubility surveys for licensed materials discharged to the sink. Through these measures, solubility of licensed material discharged to the sink will be fully documented.

Specifically, Radiation Safety has enhanced its practices and procedures for solubility determinations and for documentation of the solubility of liquid waste containing licensed material prior to sink discharge. On December 5, 1996, all authorized users were informed of these enhancements. In that communication, the methodologies set forth in the NRC Guidance were given to authorized users as a reference. To implement these enhanced procedures, Radiation Safety has developed a new sink disposal form which requires identification of the chemical form and the method used to determine solubility, in addition to the information previously required.

The current waste disposal practices and procedures continue to be refined and improved as part of the development of a formal policy on sink disposal, to be approved by the Director of the Office of Clinical Effectiveness, the Chairman of the RRSC, and the RSO. In addition to the documentation requirements and suggested methodologies, the policy will emphasize that the disposal of any insoluble material via the sink is cause for corrective action as determined by the RRSC, which could include suspension of the user's authorization to handle radioactive material. In addition, the policy will stress that, for any material for which solubility is unknown or has not been definitively determined, the material is to be disposed of by a method other than sink disposal.

In addition, as previously explained, Radiation Safety is developing an audit program focussed on waste disposal documentation which will be conducted during 1997 and thereafter. The Foundation believes that the audit program will be effective in continuing to

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educate scientists and researchers on waste disposal issues and in enhancing understanding of these issues through increased interface with Radiation Safety.

The Foundation is committed to enhancing its overall Radiation Safety program above and beyond that dictated by law. As part of these efforts, the Foundation has established a new office which will be directly responsible for ensuring regulatory compliance and safety at the Foundation, including radiation safety. Stuart Kline, formerly of Purdue University, will head this department as the Director of Environmental Health and Safety. Mr. Kline is scheduled to assume the position on April 1, 1997. Top priority is being assigned to radiation safety, including review and improvement, where appropriate, of the Foundation's policy on sink disposal, as well as any procedures that may be advantageous for monitoring compliance with the adopted practices and procedures. The Foundation is confident that this dedicated oversight will move the Foundation's licensed program toward its ultimate goal. In addition, the Foundation's Corporate Compliance Program, administered by the Office of General Counsel, will provide another layer of input and oversight for Radiation Safety and move the Foundation closer to this goal.

If you have any further questions or comments, please contact me directly at (216) 444-2348.

Sincerely,



Lynn S. Berner, J.D., MPH
Corporate Compliance Representative

Enclosure

cc: Floyd Loop, M.D.
Edgar Achkar, M.D.
Xiaowei Zhu

Sanitary Sewer Disposal for January 1, 1994 through December 31, 1994

Radionuclide	Jan. 1994 (mCi)	Feb. 1994 (mCi)	Mar. 1994 (mCi)	Apr. 1994 (mCi)	May 1994 (mCi)	Jun. 1994 (mCi)	Jul. 1994 (mCi)	Aug. 1994 (mCi)	Sep. 1994 (mCi)	Oct. 1994 (mCi)	Nov. 1994 (mCi)	Dec. 1994 (mCi)	1994 YTD (mCi)
H-3	8.967	8.281	8.897	11.357	9.371	8.313	8.937	12.027	11.182	13.334	13.191	12.330	126.187
C-14	0.073	0.055	0.059	0.029	0.051	0.039	0.104	0.178	0.124	0.057	0.066	0.080	0.915
P-32	11.259	16.135	17.673	9.391	12.518	17.198	11.439	10.218	9.468	10.253	11.597	7.187	144.336
P-33	0.000	0.000	0.000	0.000	0.120	0.040	0.000	0.000	0.000	0.000	0.000	0.000	0.160
S-35	2.305	1.625	2.283	0.880	1.218	2.372	1.810	3.177	2.540	1.900	3.684	1.650	24.46
Ca-45	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Cr-51	1.960	0.781	0.691	0.676	0.317	1.382	0.060	1.492	2.400	1.485	0.125	0.000	0.000
Mn-54	0.000	0.010	0.000	0.000	0.000	0.000	0.001	0.000	0.000	0.000	0.000	0.000	0.000
Fe-55	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Co-57	0.042	0.072	0.096	0.320	0.010	0.008	0.004	0.024	0.003	0.026	0.009	0.004	0.618
Fe-59	0.038	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.038
Ni-63	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Cu-67	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Se-75	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Y-90	0.000	0.000	0.000	0.000	0.000	0.000	0.010	0.000	0.000	0.000	0.000	0.000	0.010
Nb-95	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001
Tc-99m	0.001	0.000	0.006	0.029	0.000	0.029	0.000	0.000	0.023	0.021	0.021	0.000	0.130
Ru-103	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001
In-111	0.000	0.000	0.000	0.000	0.000	0.000	0.010	0.000	0.000	0.000	0.000	0.000	0.010
I-123	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I-125	2.417	1.204	5.287	1.297	1.604	3.655	3.985	3.096	4.149	3.278	3.368	2.865	36.205
I-131	0.000	0.000	0.019	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.019
Ce-141	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001
Re-186	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Total excluding H-3 & C-14	18.022	19.827	26.055	12.593	15.787	24.684	17.319	18.007	18.583	16.963	18.804	11.711	218.355

Sanitary Sewer Disposal for January 1, 1995 through December 31, 1995

Radionuclide	Jan. 1995 (mCi)	Feb. 1995 (mCi)	Mar. 1995 (mCi)	Apr. 1995 (mCi)	May 1995 (mCi)	Jun. 1995 (mCi)	Jul. 1995 (mCi)	Aug. 1995 (mCi)	Sep. 1995 (mCi)	Oct. 1995 (mCi)	Nov. 1995 (mCi)	Dec. 1995 (mCi)	1995 YTD (mCi)
H-3	12.189	12.041	13.954	9.200	16.500	16.004	14.193	13.400	10.337	11.370	11.505	8.806	149.499
C-14	0.068	0.321	0.073	0.019	0.145	0.148	0.120	0.166	0.046	0.134	0.045	0.032	1.317
P-32	7.579	7.429	10.278	9.949	9.551	9.965	6.766	10.693	8.516	9.013	8.874	8.236	106.849
P-33	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
S-35	1.402	1.501	2.798	1.933	2.286	1.218	2.558	4.068	2.046	2.751	5.087	3.017	30.665
Ca-45	0.000	0.000	0.000	0.000	0.000	0.000	0.013	0.000	0.000	0.000	0.039	0.000	0.052
Cr-51	0.152	0.000	0.066	0.000	0.082	0.000	0.000	0.190	0.000	0.000	0.561	0.000	1.051
Mn-54	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Fe-55	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Co-57	0.008	1.012	0.004	0.004	0.002	0.009	0.000	0.000	0.000	0.008	0.000	0.002	1.049
Fe-59	0.000	0.000	0.000	0.000	0.000	0.070	0.000	0.000	0.000	0.000	0.000	0.000	0.070
Ni-63	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Cu-67	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Se-75	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Y-90	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Nb-95	0.004	0.005	0.007	0.000	0.000	0.000	0.000	0.000	0.006	0.014	0.000	0.000	0.036
Tc99m	0.000	0.000	0.000	0.000	0.000	0.000	0.010	0.000	0.000	0.025	0.000	0.000	0.035
Ru-103	0.004	0.005	0.006	0.000	0.000	0.000	0.000	0.000	0.007	0.013	0.000	0.000	0.035
In-111	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I-123	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I-125	2.777	1.811	2.764	2.168	2.235	1.550	2.130	1.901	1.137	1.204	1.565	0.827	22.069
I-131	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Ce-141	0.004	0.005	0.006	0.000	0.000	0.000	0.000	0.000	0.007	0.012	0.000	0.000	0.034
Re-186	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.005	0.005	0.010
Tl-201	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Total excluding H-3 & C-14	11.930	11.768	15.929	14.054	14.156	12.812	11.477	16.852	11.719	13.040	16.131	12.087	161.955

Sanitary Sewer Disposal for January 1, 1996 through December 31, 1996

Radionuclide	Jan. 1996 (mCi)	Feb. 1996 (mCi)	Mar. 1996 (mCi)	Apr. 1996 (mCi)	May 1996 (mCi)	Jun. 1996 (mCi)	Jul. 1996 (mCi)	Aug. 1996 (mCi)	Sep. 1996 (mCi)	Oct. 1996 (mCi)	Nov. 1996 (mCi)	Dec. 1996 (mCi)	1996 YTD (mCi)
H-3	9.625	10.282	6.852	8.975	10.503	6.316	4.516	5.607	5.796	10.688	5.327	2.556	87.033
C-14	0.169	0.071	0.159	0.088	0.185	0.127	0.085	0.275	0.212	1.389	0.448	0.306	3.514
P-32	6.466	9.008	10.258	9.016	10.840	5.287	4.237	6.339	5.678	8.670	7.577	6.407	89.783
P-33	0.004	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.004
S-35	1.519	2.468	1.744	1.849	3.089	0.903	1.852	0.554	0.387	0.415	1.039	0.661	16.480
Ca-45	0.000	0.000	0.015	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.015
Cr-51	0.000	0.000	0.222	0.000	0.005	0.017	0.000	0.005	0.582	0.082	0.056	0.000	0.969
Mn-54	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Fe-55	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.117	0.260	0.000	0.377
Co-57	0.000	0.006	0.000	0.003	0.003	0.000	0.003	0.006	0.003	0.000	0.000	0.000	0.024
Fe-59	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Ni-63	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Cu-67	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Se-75	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Y-90	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Nb-95	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Tc-99m	0.000	0.029	0.030	0.000	0.022	0.000	0.014	0.001	0.027	0.005	0.000	0.025	0.153
Ru-103	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.004	0.008
In-111	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I-123	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I-125	0.600	0.928	0.505	0.779	1.083	0.949	0.793	0.438	0.233	0.252	0.333	0.420	7.313
I-131	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Ce-141	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Re-186	0.005	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.007
Ti-201	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.006
Total excluding H-3 & C-14	8.594	12.440	12.774	11.647	15.042	7.156	6.899	7.344	6.911	9.546	9.272	7.525	115.150