FROEDTERT
Memorial Lutheran Hospital

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Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

January 23, 1997

Dear Director:

Subject: REPLY TO A NOTICE OF VIOLATION
(NRC DOCKET NOS. 030-03444; 030-11119)

Enclosed is our reply to the NRC Inspection and Notice of Violation as directed by your letter of November 27, 1996.

Regarding the NRC's concerns involving the incinerator, in the letter dated November 27, 1996, the NRC states that the secondary "ash" chamber "contains low levels of hydrogen-3". The letter refers to, what is in actuality, the secondary burn chamber as a "secondary ash chamber". Additionally, there is no documentation that the residue in the secondary burn chamber contains hydrogen-3. If the NRC is basing it's supposition on Froedtert's correspondence of October 25, 1996, the supposition is likely not correct. As stated in the letter, dated October 25, 1996, the physical appearance of the "ash" in the secondary burn chamber is identical to firebrick. Firebrick contains radioactive thorium. We are in the process of submitting samples of the residue from the primary and secondary burn chambers for independent analysis. If at that time it is determined that there is hydrogen-3 and or carbon-14 in the residue, then we will address the NRC's concerns in the Notice of Violation letter. Upon receipt of the analytical report of the independent analysis, we will provide a copy of said report as additional information to your letter of November 27, 1996.

If you require additional information or need assistance regarding this correspondence, please contact Ralph Grunewald, Ph.D., Radiation Safety Officer at (414) 257-6540.

Sincerely,

Charles W. Runge
Vice President, Clinical Support Services

cc: Regional Administrator, U.S.N.R.C., Region III
J. Frank Wilson, M.D.
B. David Collier, M.D.

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Reply to a Notice of Violation

Froedtert Memorial Lutheran Hospital
Milwaukee, Wisconsin

License Nos. 48-04193-01;
48-04193-03
Docket Nos. 030-03444;
030-11119

I, Charles W. Runge having been duly sworn state as follows:

Violation I.

The violation did, in part, occur. Specifically, the overall treatment period was not written on the teletherapy written directive. However, we deny the part of the alleged violation regarding the total dose not being on the written directive for high-dose-rate (HDR) remote afterloading brachytherapy procedures.

1. The reason for the violation of the overall treatment period not being on the teletherapy written directive is that at the beginning of the teletherapy treatment sequence, it is not possible for the authorized user to know with certainty, due to patient tolerance, the overall treatment period. Froedtert's use of cobalt-60 teletherapy machine is unique in that the *only* patient use is for semi-continuous low dose rate treatments (SCLDR) for patients with advanced recurrent primary brain tumors. Under the SCLDR protocol, the same patient is treated for 6 to 8 hours per day to a total daily dose of 3 Gy with a total dose of 30 Gy in 10 fractions. This information is clearly stated in the patient's treatment chart. These patients are closely monitored by the authorized user and the support staff. Frequently, these patients are not able to tolerate the entire daily treatment, and as a result, the overall treatment period is modified to allow the patient to recover. Thus, it is not possible to state the overall treatment period in advance. As a result, multiple modifications of the written directive may lead to confusion and may also produce an unauditable document. The added burden on the authorized user of continuous modification of the written directive based on the patients condition, when this condition is clearly documented in the patient's treatment record, becomes a paperwork exercise and can be easily overlooked. Each patient's treatment chart contains a record of the patient's condition on a daily basis and instructions to allied health personnel relative to the patient's treatment.

   The basis for our contesting the alleged violation of not including the total dose is that the dose to be delivered by each fraction is the total dose and was written on the written directive. HDR treatment procedures involve patients being treated over a period of time receiving radiation doses on a fractionated schedule. The "total dose" for a HDR procedure is prescribed as the dose per fraction. The emphasis on the part of the radiation oncologist and the support staff is on the dose to be delivered in a specific fraction. The radiation oncologist and the support staff are greatly concerned that if emphasis is placed on the sum of the

fractionated doses as the "total dose", confusion may arise between the daily fractionated dose and the sum of the doses, and this confusion has the potential to lead to a misadministration.

2. Corrective action taken regarding the "treatment period" for cobalt-60 teletherapy treatments is to include the patient's treatment chart as part of the written directive. The patient treatment chart will contain the required total dose, dose per fraction, treatment site and overall treatment period as well as medical decisions which are made on a continuing basis during the course of treatment. Based on the patient's condition, medical decisions are the determining factors in changes made in the patient treatment, including the overall treatment period. The result of the corrective action is that the overall treatment period and other such changes in the patient treatment will not be inadvertently omitted.

   Even though the second part of the violation is denied, a change has been instituted in our HDR procedure for fractionated brachytherapy. We now complete a written directive for each fraction. Thus, there will be multiple written directives for each patient. This approach is being adopted to avoid confusion and minimize the potential for misadministration by having the emphasis placed on an inappropriate dose number. It is the opinion of qualified experts in radiation oncology that the "total dose" criteria, which is being required by the NRC, increases substantially the risk of a misadministration by emphasizing the wrong number. In fractionated brachytherapy, the number of fractions, the time interval between the fractions and the dose per fraction are the parameters prescribed by the authorized user physician.

3. Corrective steps that will be taken in the future include modification of our QMP program to specifically state the above actions and to amend our license to allow exception for the SCLDR protocol in 10 CFR 35.2 definition of a written directive requiring overall treatment period.

4. Full compliance will be achieved upon NRC receipt of the modifications to the QMP and approval of a license amendment. An evaluation of these modifications will be made to determine the effectiveness prior to submission to the NRC.

Violation 2.

The violation did occur.

1. The reason the violation occurred is that part of the survey was omitted because it was not known by the surveyors to be a strict license condition. The initial survey that was conducted when the HDR was installed monitored all accessible adjacent areas. Since the initial survey, when sources have been changed, a survey has been performed at specified locations, which met the intent of the license condition, to verify that the radiation levels did comply with 10 CFR 20

limits. These survey results were compared to previous surveys, and if the results were consistent with previous survey results, the survey was concluded. If the survey results had not been consistent, an investigation would have been initiated. All survey results have been consistent with previous survey results. Additionally, the installed source always has the same nominal source strength, of 10 curies or less, as directed by our license, therefore the dose rates in adjacent areas will never exceed those recorded at the initial survey, which complied with 10 CFR 20 limits.

2. The corrective action taken is to inform personnel that until further notice they are to resume the surveys of all accessible adjacent areas to the treatment room to ensure compliance with 10 CFR 20 limits each time a source is changed. The results achieved are that the surveys now reduces staff efficiency with no difference between the anticipated and measured results.

3. Corrective steps to be taken in the future are (1) to have management periodically check the survey records to ensure compliance; and (2) to amend our license to change license condition 27 to the performance of surveys that are meaningful and practical.

4. Full compliance will be achieved when our license is amended. License condition 27 of our license states "All areas adjacent..." and does not allow for exceptions for lack of accessibility. Therefore, full compliance with condition 27 of our license is not achievable until the license is amended as we have no practical way of monitoring the unexcavated earth area which is adjacent to part of the north wall or the unexcavated earth area which is adjacent below the treatment room.

Violation 3.

The violation occurred.

1. The reason the violation occurred is that historically we have only monitored accessible adjacent areas where there was reasonable potential for measurable radiation exposure. Prior to patient rooms being used for therapies in compliance with 10 CFR 35.75, a survey is performed of the accessible contiguous areas using a radioactive sealed source, generally a brachytherapy cesium-137 source. Although the specific patient room may not be surveyed, consideration is taken of the thicknesses and construction materials of the floors, ceilings and walls. Attenuation of cesium-137 radiation through the floors, ceilings and exterior walls range from 3 HVL to greater than 6 HVL. Unless the patient survey indicated, the complete survey was thought to be unnecessary and an unproductive use of personnel based on the attenuation factors of the walls and floors. The surveys performed met the intent of the regulations of complying with 10 CFR 20 limits.

2. The corrective action taken was to add the contiguous laboratory space below to the survey form. However, we did not add the contiguous open space area above and the contiguous area to the west as we have no practical means for surveying these areas to comply with 10 CFR 35.315 (a)(4). The results achieved are that the surveys now reduces staff efficiency with no difference between the anticipated and measured results.

3. Corrective steps to be taken are to request that the NRC amend our license to allow meaningful and practical surveys to comply with 10 CFR 35.315 (a)(4) to ensure compliance with 10 CFR 20 limits. 10 CFR 35.315 (a)(4) states, in part, to "measure the dose rates in contiguous restricted and unrestricted areas" and does not take into consideration lack of accessibility. As stated, measurement of dose rates in contiguous restricted and unrestricted areas was not performed below the patient rooms stated in the notice of violation, but neither were surveys performed in other contiguous areas to the west and above the patient rooms as required by 10 CFR 35.315 (a)(4). The regulation dose not differentiate between areas such as the contiguous laboratory space below where routine clinical laboratory procedures are performed and to the contiguous open air area above and the contiguous open air area west of the patient room.

4. Full compliance will be achieved when our license is amended to substitute practical surveys for the surveys required by 10 CFR 35.315 (a)(4) which does not allow for exception for lack of accessibility or practicality.

Violation 4.

The violation occurred.

1. The reason the violation occurred is that historically we have only monitored accessible adjacent areas where there was reasonable potential for measurable radiation exposure. Prior to patient rooms being used for therapies in compliance with 10 CFR 35.75, a survey is performed of the accessible contiguous areas using a radioactive sealed source, generally a brachytherapy cesium-137 source. Although the specific patient room may not be surveyed, consideration is taken of the thicknesses and construction materials of the floors, ceilings and walls. Attenuation of cesium-137 radiation through the floors, ceilings and exterior walls range from 3 HVL to greater than 6 HVL. Unless the patient survey indicated, the complete survey was thought to be unnecessary and an unproductive use of personnel based on the attenuation factors *of the walls and floors*. The surveys performed met the intent of the regulations of complying with 10 CFR 20 limits.

2. The corrective action taken was to add the contiguous laboratory space below to the survey form. However, we did not add the contiguous open space area above and the contiguous area to the west as we have no practical means for surveying these areas to comply with 10 CFR 35.415 (a)(4). The results achieved are that the surveys now reduces staff efficiency with no difference between the

anticipated and measured results.

3. Corrective steps to be taken are to request that the NRC amend our license to allow meaningful and practical surveys to comply with 10 CFR 35.415 (a)(4) to ensure compliance with 10 CFR 20 limits. 10 CFR 35.415 (a)(4) states, in part, to "measure the dose rates in contiguous restricted and unrestricted areas" and does not take into consideration lack of accessibility. As stated, measurement of dose rates in contiguous restricted and unrestricted areas was not performed below the patient rooms stated in the notice of violation, but neither were surveys performed in other contiguous areas to the west and above the patient rooms as required by 10 CFR 35.415 (a)(4). The regulation dose not differentiate between areas such as the contiguous laboratory space below where routine clinical laboratory procedures are performed and to the contiguous open air area above and the contiguous open air area west of the patient room.

4. Full compliance will be achieved when our license is amended to substitute practical surveys for the surveys required by 10 CFR 35.415 (a)(4) which does not allow for exception for lack of accessibility or practicality.

Charles W. Runge
Vice President of Clinical & Support Services

State of Wisconsin
County of Milwaukee

Subscribed and sworn to before me this 24th day of January, 1997.

Notary Public
State of Wisconsin
My commission ~~expires~~ is permanent.