



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
BOLLING AFB DC 20532-6188

25 JAN 1990

REPLY TO
ATTN OF: SGP

SUBJECT: Reply to a Notice of Violation; License No. 42-23539-01AF, Docket No.
030-28641/EA 89-230

TO: U.S. Nuclear Regulatory Commission
(ATTN: Document Control Desk)
Washington, DC 20555

1. Attached is the Air Force response to a Notice of Violation (NOV) issued for unauthorized incineration of In-Vitro radioimmunoassay test kit wastes containing Iodine-125 at USAF Medical Center Keesler, Keesler AFB, MS.
2. The following corrections to the NOV correspondence are not germane to the substance of the NOV or response, but are important as a matter of clarification for future readers:

a. References to the "Base Radiation Safety Officer (RSO)" in paragraph 2 of the cover letter and to "Keesler's Radiation Safety Officer" in paragraph 2 of the Synopsis are incorrect. The RSO involved was not the Base RSO, but the Medical Center permit RSO.

b. The references in the Synopsis to the "Brooks AFB" authority to grant a permit and to the "Brooks AFB Radioisotope Committee" should be to the "USAF Radioisotope Committee Secretariat" to avoid confusion with the Base Isotope and Radiation Sources Committee.

Ken Maffet

CHARLES K. MAFFET, Col, USAF, MC
Deputy Director, Professional Affairs
and Quality Assurance
Office of the Surgeon General

1 Atch
Reply to Notice of Violation w/App
cc: Regional Administrator, USNRC
Region IV
Mississippi Radiation Control
Program Director

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Reply to Notice of Violation

A. Reason for Violation:

1. USAF Medical Center Keesler personnel did incinerate wastes from In-Vitro radioimmunoassay (RIA) test kits which contained Iodine-125 (I-125) without prior Nuclear Regulatory Commission (NRC) authorization. The decision was documented in the 18 December 1985 minutes of the Medical Center Radiation Safety Committee (RSC).

2. As best we can determine, the decision was made by the RSC based on the recommendation of the radiation safety officer (RSO) named on the Medical Center's nuclear medicine permit, an experienced, Ph.D., board certified, medical physicist using the rationale that:

a. The radiological hazard of the I-125 contaminant in wastes from the RIA kits was judged to be less than the biological hazard of any pathogenic organisms present. This was based on the absence of NRC restrictions on disposal of RIA wastes by facilities using kits within the limits specified in the NRC General License of 10 CFR 31.11 of 10 microcuries (uCi) per kit not to exceed 200 uCi total at any one time. The hazardous biological materials required disposal by incineration. Extended storage of the wastes for radioactive decay increased the potential for an incident which could result in contamination or infection of personnel by a pathogenic organism with possibly fatal results.

b. The Medical Center was authorized a total possession limit of 3000 uCi of I-125 for In-Vitro testing with no single kit to exceed the 10 uCi limit in 10 CFR 31.11. However, the actual possession and use rate was much lower (300 uCi per month was the basis for calculations submitted in the Center's application for incineration). The authorized possession limit allowed for variables in procuring and delivering kits by the Center's medical supply system. The radioactive wastes generated were conservatively judged to be no more than could have been disposed of in an uncontrolled manner had the Center been using RIA kits within the total possession limits of 10 CFR 31.11. Calculated I-125 activity in incinerated wastes was approximately 2 uCi per week. The limits for RIA materials given in 10 CFR 31.11 are specified only in terms of individual kit activity and total possessed activity; there is no limit specified on use rate. In fact, uncontrolled disposal of up to 200 uCi per day is possible as long as the total possession limit is not exceeded.

c. The I-125 activity released by incineration was calculated to be well below NRC limits for unrestricted release given in 10 CFR 20, Appendix B, Table II.

d. Based upon the above, there was good reason to believe the NRC would approve a request for incineration.

3. Review of the RSC minutes documenting the decision to remain in noncompliance with NRC regulations by Medical Center executive management and Major Air Command staff officials was either inadequate to identify this inappropriate decision, or the reviewers did not understand the seriousness of the decision.

4. The USAF Radioisotope Committee (RIC) executive secretariat staff did not adequately document either its telephonic disapproval to the Medical Center RSO when the RSC minutes were reviewed at the secretariat, or follow-up to ensure incineration did not continue. The RIC was not informed by the secretariat of the problem at that time. Factors contributing to the secretariat's actions were:

a. Secretariat staff and the RIC were still relatively inexperienced, individually and corporately, with managing the expanded oversight and enforcement functions delegated by NRC as part of the Master License.

b. At the time, the RIC secretariat was focused on resolving an issue with another medical permittee which had far more serious potential for harm to an individual.

c. The RIC secretariat staff had a high degree of confidence that Medical Center RSOs would be responsive to verbal disapproval by the secretariat of an action, at least to the extent of suspending any controversial or noncompliant activity, pending resolution by higher Command authorities.

5. We differ with NRC Office of Investigation's implication that no verbal notification was made by a member of the secretariat staff to the Medical Center RSO. We recognize that supporting documentation that would give conclusive evidence is lacking. However, based upon the medical permit reviewer's brief annotation on the secretariat's file copy of the RSC minutes, and that individual's performance on other issues of compliance with NRC regulations, both preceding and following December 1985, we conclude that the call was made and that the medical reviewer did not have a "careless disregard" for NRC regulations. No detailed Air Force procedures existed at the time specifying how the secretariat would administratively manage such issues. Practice was to correct errors or resolve problems in the simplest manner judged to be effective. Procedures contained in RIC Operating Instruction (OI) 161-18, USAF Master Materials License Compliance Enforcement, originally published 17 November 1987, were developed in response to this and other events. The OI was previously provided to NRC Region IV. (See Atch 7 to HQ AFOMS/SGPR Ltr, Information on Inspection Frequencies, 24 November 1987).

B. Corrective Steps Taken and Results Achieved:

1. The RIC secretariat issued verbal and written direction to the Medical Center to cease incineration of radioactive materials not specifically authorized by permit immediately upon recognizing that unauthorized incineration of RIA wastes had continued. (See HQ AFOMS/SGPR message, 2 June 1987, previously provided NRC Region IV as Atch 2 to HQ AFOMS/SGPR Ltr, USAF Medical Center Keesler Incident, 9 June 1987.) The Medical Center had halted all incinerations of radiologically contaminated wastes on 1 June 1987.

2. In addition to ceasing planned incineration of radiologically contaminated wastes, Medical Center corrective actions to minimize the likelihood of inadvertent incineration or other improper disposal of radiological wastes included:

a. Educating the facilities management section concerning radioactive waste disposal requirements applicable to Medical Center radiological wastes. This was completed 13 July 1987.

b. Reviewing and modifying, as needed, Operating Instructions for each department in the Medical Center using or handling radioactive materials to ensure they contained clear guidance on radioisotope transfer and disposal requirements. This was completed 1 November 1988.

c. Conducting annual radiation safety training to workers reemphasizing restrictions on transfer and disposal of radiologically active contaminated wastes. This was accomplished in the 1987 to 1988 training cycle.

d. Submitting an amendment request to allow incineration of I-125 contaminated RIA wastes for NRC consideration on 28 May 1986. NRC approval was received on 1 July 1987. However, no incineration has occurred since 1 June 1987 because State Air Quality regulations established under the Clean Air Act prohibit radionuclide incineration.

e. Appointing the base environmental coordinator as a nonvoting member of the Medical Center RSC effective 12 August 1987, to ensure better coordination of Medical Center radioisotope activities with base environmental protection activities, especially in those instances where state or local permits may be required.

3. The USAF Radioisotope Committee sent a notice to all Air Force medical permittees outlining and reemphasizing NRC regulations governing use and disposal of radioactive materials used in In-Vitro radioimmunoassay, and other, radiopharmaceuticals. This was further amplified by the Medical Center's own Major Air Command, Air Training Command (ATC), in a cover letter to all ATC medical facilities. (See HQ AFOMS/SGPR Ltr, Management of Biohazardous Wastes Containing Radioisotopes, 11 June 1987, and HQ ATC Ltr, Management of Biohazardous Wastes Contaminated with Radioactive Materials, 22 June 1987, previously provided NRC Region IV as Atch 5 to HQ AFOMS/SGPR Ltr, Transfer and Incineration of Radiological Wastes, USAF Medical Center, Keesler, Permit No. 23-010020-2AFP, Docket No. 030-02260, 25 June 1987.)

4. The Medical Center RSO involved separated from service in May 1987.

5. The Air Force Inspection and Safety Center conducted a formal inquiry at the express request of the Air Force Deputy Surgeon General. He subsequently provided the results of the inquiry to Major Air Command Surgeons for their action and distribution to all Air Force medical treatment facilities. A copy of the transmittal letter emphasizing the importance of compliance with NRC regulations and commander's responsibilities for enforcement is attached. Additionally, the Air Force Assistant Vice Chief of Staff emphasized the need for compliance by all organizations using radioactive materials in a letter to all Major Air Commands. [See Atch 2 to HQ AFOMS/SGPR Ltr, Incorrect Radioactive Waste Shipments, Kelly and Whiteman AFBs (License No. 42-23539-01AF, Docket No. 03-28641), 4 May 1988.

C. Corrective Steps Which Will Be Taken to Avoid Further Violations:

None. See above; corrective actions completed.

D. Date When Full Compliance Will Be Achieved:

Full compliance achieved 1 June 1987.

1 Appendix

HQ USAF/SG Ltr, 27 Feb 89



DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE

BOLLING AFB DC 20332-6188

27 FEB 1989

REPLY TO
ATTN OF: SG

SUBJECT: Responsibilities for Managing USAF Radioactive Material Permits (CTRL #89-021)

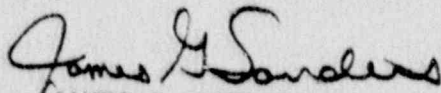
TO: ALMAJCOM/SG HQ USAFA/SG HQ AFISC/SG

1. I am concerned that medical facility commanders and major command (MAJCOM) surgeons' staff are not aware of their responsibilities for providing stringent oversight of USAF Radioactive Material Permits. As the attached report of inquiry shows, this allowed deliberate disregard for federal regulations at one Air Force medical treatment facility which resulted in unauthorized incineration of radioactive waste, unauthorized transfer of radioactive materials to civilian medical institutions, and across state lines, and violation of state air pollution laws. I am providing a copy of the report of inquiry for your use in learning from the mistakes of others. Please distribute the report to medical facilities throughout your command.

2. The report recommends that commanders of medical facilities be reminded of the seriousness of their responsibilities regarding radioactive material permits. The report also recommends that MAJCOM surgeons' staff address radioactive material compliance during periodic staff assistance visits, improve their review of radiation safety committee meeting minutes, and ensure correspondence between the medical facility and the USAF Radioisotope Committee is routed through the command surgeon's office. I fully endorse these recommendations and urge their immediate implementation.

3. These events are the subject of an ongoing investigation by the Nuclear Regulatory Commission (NRC) that could result in the assessment of a penalty on the Air Force. This is clearly unacceptable. The matter of proper control of radioactive materials, and adherence to federal regulations, has been the cause for much concern since the Air Force Master Materials License was issued by the NRC. All of us must be fully informed of our responsibilities. If we are not, serious consequences for Air Force operations may result. We cannot allow that to happen.

4. The Air Staff point of contact is Col David R. Case, HQ USAF/SCPA, AUTOVON 297-0621.


JAMES G. SANDERS
Major General, USAF, MC
Deputy Surgeon General

1 Atch
Report of Inquiry, 10 Jan 89

cc: HQ USEUCOM/ECMD