

October 1, 1996

John E. Lindsey
Newark Metrology Center
Wyle Laboratories
813 Irving-Wick Drive West
Newark, OH 43507

Subject: Notice of Denial of Exemption Request

Dear Mr. Lindsey:

This refers to your letter dated June 25, 1996 (enclosed), and to several telephone conversations between members of our organizations regarding your request for certain exemptions from the requirements in 10 CFR Part 36. These conversations resulted in the issuance of a license on July 24, 1996, which limited the use of a radiation survey meter calibrator pending the completion of our technical review. We have completed our review and concluded that we cannot grant your request. In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, this letter constitutes denial of your request to be exempted from the requirements of 10 CFR 36.23 for the reasons stated below.

Your request was based upon a view that the costs associated with the alterations necessary to bring the facility into compliance with the regulations would not result in added safety to the facility. Additionally, you noted that the facility is only accessible by employees of the facility; therefore, the facility's non-compliance would not endanger members of the public.

The basis for the denial is that compliance with NRC regulations do require some expenditure of capital to purchase and install safety devices required by regulations. The NRC considers this during the rulemaking process, and only those requirements which the NRC views as necessary to protect health and safety are included within the regulations. Therefore, your objection, the cost associated with compliance, is not adequate justification to warrant granting the exemption requests.

Additionally, the NRC notes that all overexposures at irradiator facilities have historically involved employees, not members of the public. Therefore, the fact that members of the public do not have access to the facility, does not lessen the need for compliance with 10 CFR Part 36.

Specifically, your letter requested several exemptions. The requirement, your facility description, and your justification for the exemption from the requirement and our responses are discussed in detail in Enclosure 1 to this letter.

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As provided in Section 2.103 of 10 CFR Part 2, enclosed, you have the right to request a hearing concerning this denial. If you wish to request a hearing, you must submit it within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Assistant General Counsel for Hearings and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The request should reference this letter and Docket Number 030-34085.

If you have any questions or require clarification on any of the information stated above, you may contact John R. Madera of my staff at (630) 829-9887.

Sincerely,

Original Signed By
A. Bill Beach
Regional Administrator

Enclosures:

1. Ltr dated 6/25/96
2. Enclosure 1, Details of Denial
3. 10 CFR Part 2

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Enclosure 1
Details of Denial

Your letter dated June 25, 1996, requested the following exemptions. The requirement, your facility description and justification for the exemption from the requirement and our responses are as follows:

- A. 36.23(a) The personnel entrance door or barrier must have a lock operated by the same key used to move the sources.

Justification: "The personnel entrance door does not require a key different from the key used to move the source. The door is operated with an interlock which does not require a key. If the door opens while the source is opened the interlock pins will release and cause the source to immediately return to the shielded position."

Response: Currently, your irradiation facility lacks a locked door at the entrance to the radiation room. The regulation clearly requires the presence of primary and backup access control barriers and clearly requires the entrance door to have a lock. These barriers are designed to prevent inadvertent entry into the irradiator facility when the source is exposed. The locked door to the irradiator is necessary as a primary barrier to prevent inadvertent entry into the irradiator facility during source exposure. The interlock system functions as a redundant control. If the interlock system fails, an unlocked door will not prevent inadvertent entry; therefore, the system you now have does not have both primary and backup access controls. The request for an exemption is denied.

Therefore, to achieve compliance, you must install a lock on the door and the key must be the same key that is used to operate the source. Be advised that you must comply with all provisions of 10 CFR 36.23. For example, the locked door or barrier must not prevent any individual in the radiation room from leaving.

- B. 36.23(b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry.

Justification: "There are numerous visible indications (lights) which activate when the source is exposed. One black and white lighted caution light goes on over the entrance door, another identical black and white caution

light goes on inside the range. The light inside the range can be seen from the shielded viewing window outside the range. Also, the red indicator lights on the source controller indicate "source moving" and "source exposed."

"Although there is no audible or visible alarm specifically tied to an individual entering the range, the interlock system is designed to return the source to the shielded position immediately should the door open. There is no other way into the range other than the one interlocking door. All RADIAC workers are trained in the workings of the visible and audible alarm systems."

Response: Currently, your facility does not have an entry detection system that activates a visible and audible alarm upon entry into the irradiation room when sources are exposed. The purpose of such an alarm system is to detect an entry, shut down the source, and to make the individual entering the room aware of the hazard. With your current system, visible alarms only are initiated when the source is exposed and they are constantly flashing while the source is exposed whether or not an entry has been made. The visible alarm is not connected in a way that gives a separate warning to someone who has inadvertently entered the irradiation room. In addition, your system does not have audible alarms that activate when an individual enters the room when the source is exposed.

The statements of consideration for this requirement state the following:

"This section also requires an independent backup access control system on panoramic irradiators. The purpose of the backup system is to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of failure of the interlocks on the door or barrier combined with a failure to follow operating procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the source to return to their shielded position. The system must also alert another person of the entry."

Therefore, your justification does not meet the intent of the regulation and the exemption request is denied.

To achieve compliance, you must install a system in which visible and audible alarms are activated when a person entering the irradiation room breaks the door interlock when the source is exposed. In addition, the alarm must also alert at least one other individual who is onsite of the entry.

- C. 36.23(c) The radiation monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the radiation monitor measures high radiation levels, must activate the alarm described in paragraph(b) of this section.

Justification: "There is a range monitor that detects the radiation levels in the range. When high levels of radiation are detected an alarm will sound. Although there is no integration between the door interlocks and the radiation source-- the instant the door opens the radiation source would be returned to the shielded position."

Response: The statements of consideration regarding this requirement state the following:

"The purpose is to provide an additional level of protection in case of some failure of the source movement mechanism combined with a failure of the operator to make the required radiation survey upon entry into the radiation room."

Under your current system, it appears that the radiation monitor alarms only when abnormally high radiation levels are detected. Conversely, it does not alarm when the source is exposed and the resulting radiation levels are within normal operating parameters. The intent of the regulation is for the monitor to detect any exposure of the source, not just abnormal operating levels. Therefore, you must assure that the alarm levels of the monitor are set so that it activates the interlock and alarms whenever the source is in the exposed position.

In addition, the monitor must communicate with the door interlock so that when the source is exposed, the interlock is active. When interrupted, a visible and audible alarm sounds so that the alarms make a person entering the room aware that the source is not retracted. However, your monitor is not coordinated with the door interlock. The regulation requires that the radiation monitor detect an exposed source (it may be stuck or not fully retracted), detect an entry, and warn a person of the radiation hazard upon entry. When the radiation monitor detects an exposed source, the door interlock must be active and when it is interrupted, the visible and audible alarms must activate. Your monitor is not coordinated with the door interlock and you do not have visible and audible alarms that are activated when someone attempts entry when the source is exposed.

With your current system, if the source fails to retract, the radiation monitor may not detect it, the door interlock may not be active, and the alarms will not activate when a person entering the room breaks the interlock.

Therefore, your justification does not meet the intent of the regulation and the exemption request is denied.

- D. 36.23(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the operator will move the sources from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

Justification: "There is an audible alarm that sounds for 10 seconds before the source is to be opened. There are visible alarms in the range and outside the range which activate at the time the source is being moved from the shielded position. With the size of the range, 10 seconds is adequate time for an individual inadvertently remaining within the range to exit the range before the source would leave its shielded position.

"There are numerous visible indications (lights) which activate when the source is exposed. One black-and-white light goes on over the entrance door, another identical black-and-white caution light goes on inside the range. The light inside the range can be seen from the shielded viewing window outside the range. Also, the red indicator lights on the source controller indicate "source moving" and "source exposed.""

"The operating technician would have to be outside the range to use the key to move the source from the shielded position."

Response: It appears that your current system may fulfill the requirement for sounding an audible alarm before the source is opened. However, we question whether activating the visible alarms at the time the source is exposed allows individuals sufficient time to leave the room. In addition, the regulation clearly states that the visible alarms must activate before the source moves from the shielded position. The fact that the visible alarms (lighted signs and lights) are activated only after the operator exposes the source, does not meet the intent of the regulation. Therefore, your exemption request is denied.

- E. 36.23(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the operator has activated the control and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

Justification: "The ON-OFF switch on the source itself must be in the correct position, the source controller outside the range must be activated, and the door must be in the closed position before the Cobalt-60 source can be moved from the shielded position. Therefore, the preset time referred to above is zero or negative for this system, because the door to the radiation room must have been closed before activation of the control."

Response: The NRC intends the requirement to assure that the door be closed shortly after a check of the room has been completed to assure no one is in the room. The preset time prevents the door from staying open after the operator has activated the in-room control and prevents individuals from inadvertently entering the open door to the radiation room without the operator's knowledge.

With your current system, it is possible for the ON-OFF switch to always be in the ON position. This means that the operator can simply close the door and activate the source without first entering the room to initiate the start up sequence and without assuring that everyone is out of the room. Therefore, your system does not meet the intent of the regulation and the exemption request is denied.