



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

**SAFETY EVALUATION REPORT FOR
NATIONAL INSTITUTES OF HEALTH EXEMPTION
DOCKET NO. 30-08478**

SUMMARY

By application dated January 19, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17306A532), as supplemented on September 11, 2017 (ADAMS Accession No. ML17306A533), November 1, 2017 (ADAMS Accession No. ML17319A116), and November 15, 2017 (ADAMS Accession No. ML17320A867), the National Institutes of Health (NIH or the applicant) requested an exemption from the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 71.5. Specifically, NIH requested exemption from the U. S. Department of Transportation (DOT) regulations incorporated into the NRC transportation requirements in 10 CFR 71.5. This exemption is necessary for NIH to obtain NRC approval, via NIH's specific license, to perform a one-time movement of an irradiator. NIH proposes to move the irradiator in its current configuration (i.e., without disassembling the irradiator) 0.3 miles from one NIH building through an NIH parking lot, across a public road, and through another NIH parking lot to another NIH building.

Since the one-time movement by NIH will be accomplished using a motor vehicle operated by a Federal government employee solely for noncommercial Federal government purposes, the movement is not subject to the DOT's hazardous material regulations. 49 CFR 171.1(d)(5). However, since NIH will be moving NRC licensed material on a public highway, NIH is subject to 10 CFR 71.5, "Transportation of licensed material." The regulation in 10 CFR 71.5(b) states that "If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations." The DOT regulations referenced in 10 CFR 71.5(a) are (i) Packaging—49 CFR Part 173: subparts A, B, and I, (ii) Marking and labeling—49 CFR Part 172: subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of subpart E, (iii) Placarding—49 CFR Part 172: subpart F, especially §§ 172.500 through 172.519 and 172.556; and appendices B and C. (iv) Accident reporting—49 CFR Part 171: §§ 171.15 and 171.16, (v) Shipping papers and emergency information—49 CFR Part 172: subparts C and G, (vi) Hazardous material employee training—49 CFR Part 172: subpart H, and (vii) Security plans—49 CFR part 172: subpart I.

The DOT regulations in 49 CFR Part 172, Subpart B, "Table of Hazardous Materials and Special Provisions" lists and classifies those materials which the DOT has designated as hazardous materials, and prescribes the requirements for packaging, package marking and labeling, transport vehicle placarding, accident reporting, shipping papers and emergency response information, hazardous material employee training, security planning, hazardous material shipper/carrier registration, and requirements for transport on a public highway that are applicable to the shipment and transportation of class 7 hazardous materials. Radioactive material (Class 7 in DOT regulations) is just one of the classes of hazardous materials to which these regulations are applicable.

While the exemption would exempt NIH from all DOT regulations incorporated in 10 CFR 71.5(a), this evaluation discusses only those that would apply to the move proposed by NIH

absent the exemption. The DOT regulations that would otherwise be applicable are: packaging (49 CFR Part 173: Subparts A, B, and I), marking and labeling (49 CFR Part 172: Subpart D; and Subpart E , specifically, 49 CFR 172.400 through 172.407 and 49 CFR 172.436 through 172.441), placarding (49 CFR Part 172: Subpart F, especially 49 CFR 172.500 through 172.519 and 172.556; and appendices B and C), accident reporting (49 CFR Part 171, specifically 49 CFR 171.15 and 171.16), shipping papers and emergency information (49 CFR Part 172: Subparts C and G), hazardous material employee training (49 CFR Part 172: Subpart H), security plans (49 CFR Part 172: Subpart I), and the Federal Motor Carrier Safety Administration (FMCSA) requirements for transport on a public highway (49 CFR Part 177 and Parts 390 through 397). The hazardous material shipper/carrier registration requirements in 49 CFR Part 107, Subpart G only apply to a shipment of a highway route controlled quantity of radioactive material (as defined in 49 CFR 173.403). The quantity of radioactive material in the NIH movement does not meet the DOT definition of highway route controlled quantity.

In making its decision, the Commission has determined that, pursuant to 10 CFR 71.12, the exemption is authorized by law and will not endanger life or property nor the common defense and security. The Commission has also determined that the movement will not adversely impact the environment (83 FR 8302 February 26, 2018).

A. Authorized by Law

The regulations in 10 CFR 71.5(b) state “A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.” Since the regulation itself allows a licensee to request an exemption, issuing an exemption from 10 CFR 71.5 is authorized by law.

B. Will Not Endanger Life or Property

Staff reviewed NIH’s application, as supplemented, and concludes, as discussed below, that the operational and administrative controls that will be imposed on this movement provide reasonable assurance that the irradiator can be moved, as proposed by NIH, and will not endanger life or property.

1.0 GENERAL INFORMATION

NIH is proposing to move a Mark – 1 Series self-shielded irradiator containing a Type B quantity of radioactive material. NIH proposed using a forklift rated at 10,000 pounds to lift the irradiator from below and move it 0.3 miles between two NIH buildings. The movement between buildings will cross through 2 NIH parking lots that are separated by a public road. The irradiator will be secured to the forklift using two ratchet straps (one above and one below the irradiator’s vertical center of gravity). The DOT regulations in 49 CFR 173.413 require the use of a Type B package for shipments of radioactive materials that exceed specified values. Shipments of radioactive materials that do not exceed those values may be made in a Type A package. The material in the NIH move would normally require a Type B package that meets higher standards because of the larger quantity of radioactive material. DOT regulations in 49 CFR 173.416 specify the authorized Type B packages for transport of a Type B quantity of material. This exemption eliminates the need for NIH to complete the movement using a Type B package as required by DOT regulations.

The Mark – 1 irradiator is used to irradiate biological, horticultural, and chemical samples in a laboratory environment. The Mark – 1 irradiator consists of an irradiation chamber with a door on the front side; one or two cylindrical sealed source(s) attached to the end of a source rod, which can be moved vertically, and shielding around the sources and irradiation chamber, including the walls and door of the irradiation chamber. In the highest position the source is located at the back of the irradiation chamber; in the lowest position the irradiation chamber is shielded from the sources. The irradiator will be moved as-is with its shielded housing intact and the source rods will be secured in the lowest position to prevent the sources from relocating during the movement. Each irradiator contains more than 5 inches of lead shielding on all sides and is designed so that radiation levels cannot exceed 0.2 mR/h at 1 meter from the surface of the device for each 1,000 curies of Cs-137 installed in the device. The safety evaluation of the device is documented in the Registry of Radioactive Sealed Sources and Devices, No. CA0598D104S.

The irradiator is designed to meet the specifications for a DOT Specification 7A packaging requirements (see 49 CFR 178.350), which means it is designed to retain the integrity of containment and shielding under conditions of normal transport as demonstrated by the Type A packaging tests set forth in 49 CFR 173.465. These tests include a water spray test that simulates exposure to rainfall of 2 inches per hour for 1 hour; a free drop test through a distance of 4 feet; a stacking test which subjects the package to a compressive load equivalent to 5 times the mass of the actual package; and a penetration test directed to the weakest part of the package.

2.0 USE OF A TYPE B PACKAGE

2.1 STRUCTURAL EVALUATION

In lieu of using a Type B package, the applicant has proposed controls over the movement to ensure that the movement can be accomplished safely and will not endanger life and property. The applicant evaluated the tip over and a drop of the irradiator from the forklift.

Since the irradiator weighs 6,000 pounds, NIH proposed using a forklift rated at 10,000 pounds. NIH provided the manufacturer's forklift specification, which lists the rated capacity as 10,000 pounds, as determined using the American National Standards Institute/Industrial Truck Standards Development Foundation B56.1, "Safety Standard for Low Lift and High Lift Trucks." In addition to this standard, using the U. S. Department of Labor, Occupational Safety & Health Administration, Powered Industrial Trucks (Forklift) Load Composition guide, NIH determined that a 10,000 pound forklift is sufficient to carry the 6,000 pound irradiator. The NRC has reviewed and determined that a forklift rated at 10,000 pounds, that has been evaluated using this national standard and the Department of Labor guide, is sufficient to lift and move the irradiator.

The applicant stated that the forklift will raise the irradiator vertically from below and that the irradiator's 6,000 pound load will be distributed over the two forks and cradled between the two lifting masts of the forklift. The forklift's load center distance rating is 24 inches. The diameter of the irradiator is 32 inches. The center distance is 16 inches, which is less than the 24 inches. Thus the rated capacity of the forklift is more than sufficient for lifting and moving the 6,000 pound irradiator and the center of the load is well within the load center rating. Therefore, there is reasonable assurance that the load will not drop or tip over during the one-time movement.

NIH stated that the maximum calculated side load at the irradiator center of gravity is 4,000 pounds. NIH will use two ratchet straps, each rated at 5,000 pounds, to secure the irradiator to the forklift. Each strap will be secured to the masts of the forklift to restrain the irradiator at the top and bottom to prevent the irradiator from shifting during the movement. Given the calculated side load of 4,000 pounds and the combined ratchet strap capacity of 10,000 pounds, the safety factor for the ratchet straps is 2.5. In addition, the NRC staff determined that under a 4,000 pound side load the forklift itself would remain stable. NRC has reviewed and determined that using two ratchet straps, one above and one below the irradiator's center-of-gravity, each rated at 5,000 pounds is sufficient to ensure that the irradiator will remain secured to the forklift during the movement.

To minimize the potential for inadvertent activation of the forklift's lifting mechanism during the movement, NIH will secure the lift mechanism will be temporarily rendered inoperable, and the forklift operator will be instructed not to operate the lifting mechanism until the forklift is across the public road. In addition, NIH stated that the government employee driver will have a valid forklift driver's license and will be up-to-date on forklift training provided by the Division of Occupational Health and Safety at NIH. The NRC has reviewed and determined that the measures regarding the lifting mechanism and the forklift operator's training is sufficient to minimize inadvertent lifting or lowering of the irradiator while it is moving across the road.

The NRC staff reviewed the applicant's evaluation and confirms that the evaluation, including the items proposed by NIH, provides reasonable assurance that the forklift can adequately carry the load, will not tip over during the move, and that the ratchet straps can adequately secure the irradiator to the forklift so it will not fall and therefore will not endanger life or property.

2.2 Dose Rates

NIH provided dose rate measurements which demonstrate that the shielding of the irradiator, as it is currently configured and will be moved, provides similar radiation protection to that which would be provided if the sources were placed into a Type B package and evaluated for the normal conditions of transport that are specified in 10 CFR 71.71. NIH measured the radiation dose rates around the irradiator with the sources in the secured position, as it will be during the one-time movement. The maximum dose rate on contact at the rear base of the housing is <0.1 mrem/hr, which is much less than the dose rate requirement in 10 CFR 71.47(a) of 200 mrem/hr on the external surface of a package for Type B packages. The NRC reviewed and determined that as long as the irradiator is not lifted to a height which is greater than it was evaluated (4 feet) the irradiator will meet the dose rates in 10 CFR 71.47(a) and will not endanger life or property.

NIH also stated that the sources meet the additional testing requirements in 10 CFR 71.75 for special form sources, thus providing additional assurance that no radiological release would occur in the event of an accident. As defined in 10 CFR Part 71, a special form source is one that is "either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule." The special form source tests required by NRC and DOT regulations (49 CFR 173.469) are designed to ensure, in the event of an accident, the source will not break open, shatter, melt or disperse.

3.0 Communications Requirements

In its "[Radioactive Material Regulations Review](#)," (also known as the RAMREG), the DOT states that the requirements in 49 CFR Part 172 pertaining to shipments of hazardous material, which

include marking and labeling, placarding, shipping papers, and emergency response information are communication requirements that are designed to complement the basic safety requirements for package activity limits and package integrity. By using items such as shipping papers, package marking and labeling, and vehicle placarding, the appropriate information about the packaging being used, contents, and hazard class, emergency response information, that is typically is communicated between the shipper, carrier, and the consignor, as well as emergency responders in the event of an accident or unanticipated occurrence. This one-time movement of radioactive material will involve movement by a forklift only a short distance on a public road (approximately 60 feet). During the movement, the road will be closed to traffic by the Montgomery County Police Department (MCPD). Given that NIH will be the shipper, carrier, and consignor for this movement, and that NIH stated that the MCPD will be present for the shipment, much of the information that would typically be communicated via shipping papers and other related communications between parties involved in a transport will be known by all parties involved about the movement, including first responders.

Absent the exemption, NIH would be required to comply with DOT regulations requiring marking and labeling, shipping papers and emergency response information. These measures are imposed to ensure that emergency responders are notified, when appropriate, and are able to identify the contents of the package and provide appropriate response for a given shipment of radioactive material. In lieu of those requirements, NIH proposed the following measures to inform emergency responders what is being moved and how to respond in the event of an incident during the one-time movement:

- NIH Radiation Safety personnel and armed MCPD Special Operations Division Officers will escort the irradiator with a leading and trailing vehicle during the one-time movement, will maintain constant surveillance, and have direct line-of-sight of the irradiator from the time the irradiator is moved out of the current building until the irradiator is in its destination;
- The irradiator housing will be stamped with a “USA 7A Type A Radioactive Material” marking and a “RADIOACTIVE WHITE-I” label;
- A United Nations Committee of Experts on the Transport of Dangerous Goods (UN) identification number “3332” will be affixed to the irradiator housing during the one-time movement; and
- A transfer document, including emergency response information, will be present during the one-time movement and will be maintained by a MCPD officer. The emergency response information will include Guide number 164 from the 2016 Emergency Response Guidebook, which is for UN3332 material.

The NRC has reviewed and determined that the proposed controls listed above are sufficient to ensure that, in the event of an emergency, first responders will have basic information available to aid them as they assess how to respond and are sufficient to protect public health and safety. Provided those measures are in place during the movement of the irradiator, the failure to comply with the DOT regulations regarding shipping papers, package marking, labeling and vehicle placarding would not result in any increased risk of endangering life or property.

4.0 EMPLOYEE TRAINING

The DOT regulations for hazardous material employee training in 49 CFR 172, Subpart H, “Training,” ensure that individuals are provided with a program to familiarize the workers with the general provisions of 49 CFR Part 172; including identification and recognition of hazardous materials; knowledge of specific requirements of 49 CFR Part 172 which are applicable to the

workers' functions; knowledge of emergency response information; self-protection measures; and accident prevention methods and procedures. NIH has said that the workers involved in the movement of the irradiator have attended multiple sessions of a training course on irradiator security emergency response, sponsored by the National Nuclear Security Agency. Additionally, NIH Radiation Safety health physicists have conducted many joint training exercises with MCPD on radiological security using actual radioactive sources. Since the NRC action is to exempt the NIH from the DOT requirements, and the movement will occur with trained health physicists, who are also familiar with the emergency response actions needed for the irradiator, exempting NIH from the DOT training requirements will not endanger life or property.

5.0 MODE-SPECIFIC REQUIREMENTS FOR TRAVEL ON PUBLIC ROAD

The DOT also imposes mode-specific requirements for transportation of radioactive material on a public highway in 49 CFR Part 177, "Carriage by Public Highway" and in the FMCSA requirements placed on the carrier (49 CFR parts 390 through 397). To the extent that the regulations apply, the requirements in 49 CFR 177.804 also require compliance with the FMCSA requirements in 49 CFR 383, in addition to those listed above.

5.1 Carriage by Public Highway

The requirements in 49 CFR Part 177 that would be applicable to this movement without the exemption include general requirements for all hazard classes (subpart A), specific requirements for loading and unloading (subpart B), segregation and separation of hazardous materials (subpart C), and requirements for packages and vehicles in the event of an accident while in transit (subpart D).

The regulations in 49 CFR Part 177, Subpart A include requirements for driver training (§177.816), shipping papers (§177.817), and movement of motor vehicles in the event of an emergency situation (§177.823). The driver training requirements in 49 CFR 177.816(a) and (b) cover a number of subjects that will not pertain to this one-time movement over a very short distance on a flat straight road. For example, the training requirements include dangers associated with maneuvering through curves, tunnels, bridges and railroad crossings. Given the limited hazards that could be encountered in this move, the fact that the forklift operator will have a valid forklift driver's license, be up-to-date on forklift training as provided by the NIH's Division of Occupational Health and Safety, and will have specific instructions for this movement, which will be escorted by both NIH personnel who are knowledgeable about the specific material being moved and how to handle the irradiator's material and MCPD who are trained in responding to emergency situations, the forklift driver training is sufficient to protect the public health and the environment. According to the regulations in 49 CFR 177.823, a carrier may not move a vehicle containing hazardous material unless it is properly placarded and marked in accordance with 49 CFR part 172 or, in the event of an emergency the vehicle is escorted by a representative of a state or local government. The NRC has reviewed the proposed controls listed above in section 3.0 and has determined they are sufficient to ensure that, in the event of an emergency, first responders will have basic information available to aid them as they assess how to respond, and are sufficient to protect public health and safety. The MCPD, a representative of a local government, will be escorting this movement and will be able to give direction in the event of an emergency situation. Provided those measures are in place during the movement of the irradiator, authorizing an exemption from the applicable DOT regulations regarding shipping papers, package marking, labeling and vehicle placarding in 49 CFR 172.200 – 172.204, 49 CFR 172.300 – 172.338, 49 CFR 172.400 -172.407 and 49 CFR

172.436 - 172.441, 49 CFR 172.500 - 172.519 and 172.556; 49 CFR 172 Appendices B and C, and 49 CFR 177.817 would not result in any increased risk of endangering life or property.

The requirements in 49 CFR 177, Subpart B that are applicable to this movement include the general requirements in 49 CFR 177.834 and certain requirements in 49 CFR 177.842. The specific requirements in 49 CFR 177.834 that would apply to this movement without the exemption are 177.834(a), which requires that the package is secured from shifting, 177.834(e) which requires that the vehicle's handbrake is engaged during loading, and 177.834(f) which prohibits the use of tools during loading or unloading that are likely to damage the effectiveness of any package or the use of any Class 1 (explosive material or other dangerous article. The structural evaluation in section 2.1, above determined that once the irradiator is strapped to the forklift it will not move or tip over. The requirement for the handbrake to be engaged prior to loading hazardous material into or on a commercial vehicle is not applicable in this movement since the forklift will be actively used to move towards, load and secure the irradiator, and lift and move the irradiator. The NRC is unaware of any tools that will be used that could damage the irradiator, given that the irradiator is a Type A package that is able to withstand a 4 foot drop and meet the dose rate requirements in DOT regulations.

The DOT requirements 49 CFR 177.842(a) and (b) are not applicable to this movement since they are only applicable to transport of multiple items or those packages that require use of a "RADIOACTIVE YELLOW-II" or "RADIOACTIVE YELLOW-III" label. In addition 49 CFR 177.842(c) is not applicable to this movement since it is not a movement of low specific activity or a surface contaminated objects, as defined in both NRC and DOT regulations. The requirements in 177.842 that would be applicable to this movement without the exemption is the requirement in subsection (d) requiring packages to be blocked and braced so that they cannot change position during conditions normally incident to transport and subsection (e) prohibiting persons from remaining unnecessarily in a vehicle containing Class 7 material. As discussed in Section 2.1, above, utilizing the ratchet straps to brace the irradiator, NIH has demonstrated that the irradiator will not shift or drop during the movement, once it is secured to the forklift. The movement will be escorted by NIH radiation safety personnel and pursuant to 10 CFR 30.3, NIH is required to meet dose requirements in Part 20, and therefore, will ensure that the driver of the forklift, as well as other personnel involved in the move, do not unnecessarily remain by the irradiator. Subsections (f) and (g) are not applicable to this movement since it does not contain fissile material and the dose rates on the surface of the package do not exceed the dose rates in 49 CFR 173.441(a) for non-exclusive use shipment.

5.2 Federal Motor Carrier Safety Administration Requirements

The FMCSA requirements in 49 CFR Chapter III, Subchapter B include Parts 350 to 399. DOT's regulations in 49 CFR 390.3(a) specifies that the general applicability of these regulations are to "...all employers, employees, and commercial motor vehicles that transport property or passengers in interstate commerce." The movement of this irradiator will not cross state lines and therefore is intrastate movement. DOT's regulations in 49 CFR 390.3(g) does require that carriers who transport hazardous materials in intrastate commerce follow the FMCSA requirements in 49 CFR Part 386, "Rules of Practice for Motor Carrier, Intermodal Equipment Provider, Broker, Freight Forwarder, and Hazardous Materials Proceedings;" 49 CFR Part 387, Minimum Levels of Financial Responsibility for Motor Carriers", and, as stated in §390.3(g), for those carriers subject to the requirements of 49 CFR 385.403, the carriers must also comply with 49 CFR Part 385, subparts A and E, "General," and "Hazardous Materials Safety Permits," respectively; 49 CFR Part 177, Subpart E, "Unified Registration System;" 49 CFR 390.19T, "Motor carrier identification report;" and §390.21T, "Marking of CMVs

[commercial motor vehicle].” However, these requirements only apply to highway route controlled quantities of Class 7 material in intrastate transport; therefore, these requirements do not apply to this movement, and would not apply, even if NRC did not grant the exemption to 10 CFR 71.5.

5.3 Conclusions

For the reasons discussed above, the NRC has determined that exempting NIH from the DOT regulations incorporated in 10 CFR 71.5 for the one-time movement of the irradiator will not endanger life or property.

C. Will Not Endanger the Common Defense and Security

The exemption will also exempt NIH from the security plan required by DOT regulations (49 CFR part 172, subpart I). NIH will comply, however, with the security requirements in 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.” The provisions of 10 CFR Part 37 Subpart D, specifically sections 37.71, 37.73, 37.75, 37.77, and 37.79, impose requirements concerning : personnel security, controlled access, and personnel access authorization. Security during the movement shall be maintained as described in 10 CFR 37.79 “Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.” Preplanning requirements are imposed in 10 CFR 37.75, “Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.” The NRC security requirements in 10 CFR Part 37 meet or exceed those in DOT regulations, including the preplanning requirements in 49 CFR 172.802(b) and (c). Since NIH will comply with the security requirements governing transportation of category 2 sources, the one-time movement of the irradiator will not endanger the common defense and security.

CONDITIONS

This exemption is subject to the following conditions:

1. The lowest point of the irradiator shall not be lifted higher than 4 ft.
2. The forklift shall have a minimum rating of 10,000 pounds, as determined using the American National Standards Institute/Industrial Truck Standards Development Foundation B56.1 "Safety Standard for Low Lift and High Lift Trucks."
3. The irradiator shall be secured to the masts of the forklift using two ratchet straps, with one above and one below the irradiator's center-of-gravity. Each ratchet strap shall have a minimum rating of 5,000 pounds.
4. Once the irradiator is lifted, the lift mechanism on the forklift shall be will be temporarily rendered inoperable, and the forklift operator shall be instructed not to operate the lifting mechanism until the forklift and irradiator are across the public road.
5. The forklift driver shall have a valid forklift driver's license and must be up-to-date on forklift training as provided by the NIH's Division of Occupational Health and Safety.
6. During the movement across the public road, the road shall be closed by the Montgomery County Police Department to other vehicular traffic.
7. NIH Radiation Safety personnel and armed Montgomery County Police Department Special Operations Division Officers will escort the irradiator with a leading and trailing vehicle during the one-time movement, will maintain constant surveillance, and have direct line-of-sight of the irradiator from the time the irradiator is moved out of the current building until the irradiator is in its destination.

8. The irradiator housing will be stamped with a "USA 7A Type A Radioactive Material" marking and a "RADIOACTIVE WHITE-I" label.
9. A United Nations Committee of Experts on the Transport of Dangerous Goods (UN) identification number "3332" will be affixed to the irradiator housing during the one-time movement.
10. A transfer document, including emergency response information, will be present during the one-time movement and will be maintained by a Montgomery County Police Department officer. The emergency response information will include Guide number 164 from the 2016 Emergency Response Guidebook, which is for UN3332 material.
11. This authorization expires on July 31, 2018.

CONCLUSION

The NRC staff has reviewed the NIH application, as supplemented, and concludes that the operational and administrative controls that will be imposed on this one-time movement provide reasonable assurance that the proposed movement of a Mark-1 irradiator will not endanger life or property nor the common defense and security. Considering the statements and representations contained in the application, as supplemented, the conditions listed above and in the approval letter, and for the reasons listed above, the NRC staff concludes that the exemption meets the requirements of 10 CFR 71.12.