NUCLEAR REGULATORY COMMISSION '88 AUG 30 P2:24

10 CFR Part 35

Control of Aerosols and Gases

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the medical uses of byproduct material by removing the requirement that radioactive aerosols be administered to patients only in rooms that are at negative pressure relative to surrounding rooms. The rule, developed in response to PRM-35-6, allows the use of radioactive aerosols in locations such as intensive care units, critical care units, and patients' rooms. Evaluation of potential radiation hazards to hospital personnel showed minimal risk when a radioactive aerosol is used with a closed, shielded system either vented to the outside atmosphere through an air exhaust or a system which provides for collection and disposal of the aerosol. The rule allows physicians greater latitude in administering necessary clinical procedures to their patients. The safety requirement that certain diagnostic medical procedures be performed only in rooms at negative pressure relative to surrounding rooms continues to apply to the use of radioactive gases.

EFFECTIVE DATE: AUG 22 1988

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 492-3740.

SUPPLEMENTARY INFORMATION:

## Background

In 1983, NRC began authorizing medical licensees to administer radioactive aerosols by inhalation (see 48 FR 5217; February 4, 1983) to patients for diagnosing lung disease. The only safety measure required specific to this clinical procedure was that the licensee had to administer the radioactive aerosol "with a closed, shielded system that either is vented to the outside atmosphere through an air exhaust or provides for collection and disposal of the aerosol," (see 10 CFR 35.14(b)(8)). In a complete revision of 10 CFR Part 35, effective April 1, 1987, NRC added the requirement that aerosols be administered only in rooms that are at negative pressure (see § 35.205(b), 51 FR 36932; October 16, 1986). In response to a letter received in February 1987 that stated that application of the requirement would have a negative impact on health care delivery, medical licensees were temporarily exempted from the requirement in § 35.205(b) (see 52 FR 9292; March 24, 1987).

## Petition for Rulemaking

On March 9, 1987, Mallinckrodt, Inc., submitted a petition for rulemaking which was docketed PRM-35-6 on March 11, 1987. A copy of the

petition may be obtained from the Regulatory Publications Branch, Division of Freedom of Information and Publication Service, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The petitioner requested that the Commission remove the requirement that radioactive aerosols be administered only in rooms that are at negative pressure relative to surrounding rooms.

The petitioner submitted literature showing that, for many hospitals, TC-99m DTPA aerosol is the preferred lung ventilation imaging procedure. For critically ill patients who cannot be moved, it has been the only lung imaging technique available. If use of aerosols is restricted to negative pressure rooms, these patients would be deprived of the benefits of lung imaging.

The petitioner described a typical radioactive aerosol delivery system. Because the only radiation safety hazard is leakage of the aerosol, three potential leakage points external to the shield were identified in drawings. Two leakage points require patient compliance for safety; the frequencies of patient non-compliance based on clinical experience were 10% and 5%. Corresponding durations of leakage were 2-3 exhalations and 1-2 exhalations. These numbers were used to calculate the average administration loss per patient. This quantity was used to calculate the maximum number of clinical procedures that could be performed in an average room per week without exceeding the maximum permissible concentration for Tc-99m in an unrestricted area. The very large number (238) of diagnostic procedures possible before exceeding the maximum permissible concentration greatly exceeds the busiest work load of 30 studies per week in a large hospital. The third potential leakage point is the junction between the manifold and the plastic patient

breathing tube. Leakage has been found to be negligible during routine, proper use.

The NRC examined Mallinckrodt's petition and supporting information and made a determination to grant the petition. The requirement for administering radioactive aerosols in rooms at negative pressure relative to their surroundings may adversely affect the public health and safety. Some patients requiring the clinical procedure cannot be moved safely to an appropriate room or another hospital that has the required facilities. These patients would not be able to be treated unless the restriction on the negative pressure is removed. Calculations show that worker health and safety does not require negative pressure rooms for administration of radioaerosols. This final rule completes the action necessary to grant PRM-35-6 and also completes action on the petition for rulemaking.

## Public Comments

A notice of proposed rulemaking was published in the Federal Register on December 16, 1987 (52 FR 47726). Four letters of public comment were received and docketed in the NRC public docketing facilities. Georgetown University Hospital supported the rulemaking unequivocally. An E.I. DuPont DeNemours & Co. spokesperson had no objection to the amendment but requested a copy of the petition for rulemaking which was provided.

Representatives of the Bureau of Environmental Health of the State of Iowa, and the University of Washington commented that the rule was too broad, that it might permit the use of other radioisotopes in aerosol form which could pose a serious public health problem, and that the need for negative pressure or supplemental ventilation should be addressed on an individual basis. Given that this amendment addresses the use of

radioisotopes in aerosol form, administered by inhalation for diagnostic purposes, the Commission rejected these comments for the following reasons:

Although it is possible that some radioisotope other than Tc-99m might be developed in aerosol form for inhalation diagnostic studies, it is not likely that it would be in a different hazard classification. Considerations of patient dose would restrict half-life and decay mode. Future imaging techniques would require photon energies comparable to Tc-99m. Because imaging equipment detection sensitivities are high, total administered radioactivity for any new clinical diagnostic procedures would not need to be higher than current methods. Additionally, any new diagnostic radiopharmaceutical would be evaluated by the Food and Drug Administration prior to approval for use based on these considerations.

The clinical requirements for aerosol particle size and other physical properties are expected to remain constant so that the risk form dispersion of any aerosol lost during patient administration would be minimal. All devices currently used for aerosol administration include exhalant trapping, and the current requirements for using collection or atmospheric venting systems remain unchanged.

The NRC notes that relief from the negative pressure requirement of § 35.205(b) does not relieve licensees from the requirements to comply with other NRC regulations, orders, or license conditions limiting maximum permissible air concentrations in controlled and uncontrolled areas.

Finding of No Significant

Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. In a revision to 10 CFR Part 35, effective April 1, 1987, the NRC added a requirement that radioactive aerosols be administered only in rooms that are at negative pressure. This was in addition to existing requirements that radioactive aerosols were to be administered "with a closed, shielded system that either is vented to the outside atmosphere through an air exhaust or provides for collection and disposal of the aerosol." In response to a letter stating that the negative pressure requirement would have a negative impact on health care delivery, medical licensees were temporarily exempted from the requirement in March 1987, before the rule became effective. This action removes the requirement in 10 CFR Part 35 to use negative pressure rooms for the administration of radioactive aerosols, which requirement was never in fact implemented. The remaining requirements, a closed system either vented to the atmosphere or provided with collection and disposal, remain in effect, and were found when promulgated in February 1983 (48 FR 5217) to have no significant environmental impact. This action, removing a safety requirement for negative pressure rooms, which in fact was not implemented, has no significant environmental impact. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC

Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the environmental assessment and the finding of no significant impact are available from Alan K. Roecklein, USNRC, Washington, DC 20555, (301)492-3740.

## Paperwork Reduction Act Statement

The final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0010.

## Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, DC.

Removing the requirement to use Tc-99m DTPA and other aerosols only in rooms kept at negative pressure will eliminate an unnecessary safety measure for medical licensees and will avoid depriving patients of a necessary clinical diagnostic procedure. No adverse impact on public or worker health and safety will result.

## Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule removes a restriction imposed on many of the NRC's 2500 medical licensees that administer radioactive aerosols by inhalation for diagnostic purposes. The NRC has adopted size standards that classify a hospital as a small entity if its annual gross receipts do not exceed $3.5 million, and a private practice physician as a small entity if the physician's annual gross receipts are $1 million or less (50 FR 50241; December 9, 1985). Although some NRC medical licensees could be considered "small entities," the number that would fall into this category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The effect of the regulation is to remove a restriction applicable to the administration of radioactive aerosols. This will benefit all medical licensees but will provide special benefits for smaller institutions by allowing the continued use of a clinical diagnostic procedure without imposing the requirement of constructing additional facilities or modifying existing facilities.

## Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109 does not apply to this final rule, and therefore, that a backfit analysis is not required for this rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR PAkT 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendment to 10 CFR Part 35.

PART 35 -- MEDICAL USES OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20(a) and (b), 35.21(a) and (b), 35.22, 35.23, 35.25, 35.27(a), (c) and (d), 35.31(a), 35.49, 35.50(a)-(d), 35.51(a)-(c), 35.53(a) and (b), 35.59(a)-(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70(a)-(f), 35.75, 35.80(a)-(e), 35.90, 35.92(a), 35.120, 35.200(b), 35.204(a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406(a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610(a) and (b), 35.615, 35.620, 35.630(a) and (b),

35.632(a)-(f), 35.633(a)-(i), 35.636(a) and (b), 35.641(a) and (b), 35.643(a) and (b), 35.645(a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27(a) and (c), 35.29(b), 35.33(a)-(d), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406(b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(j), 35.636(c), 35.641(c), 35.643(c) 35.645, and 35.647(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

2. In § 35.205, paragraphs (b) and (e) are revised to read as follows:

§ 35.205 Control of aerosols and gases.

* * * * *

(b) A licensee shall administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

* * * * *

(e) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months.

Dated at Rockville, Maryland, this 20th day of June, 1988.

For the Nuclear Regulatory Commission.

James M. Taylor, Acting
Executive Director for Operations.