Regulatory Flexibility Analysis

The NRC is required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. This paper describes the assessment of the small entity impacts expected to be incurred by 10 CFR Part 35 licensees as a result of the comprehensive revisions to Part 35.

This analysis describes (1) the NRC's definition of "small entities," including "small businesses," "small governmental jurisdictions," and "small organizations;" (2) what number constitutes a "substantial number" of these entities; (3) whether "significant impacts" will be incurred by licensees under the rule; and (4) the measures that NRC has adopted in the rule to mitigate impacts on small entities.

1.1 Defining "Small Entities" Affected by the Rule

The NRC has established size standards that it uses to determine which NRC licensees qualify as small entities (60 FR 18344; April 11, 1995). These size standards are codified in 10 CFR 2.810. The size standards pertinent to Part 35 licensees include the following:

Under 10 CFR 2.810 (a)(1), a small business is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average annual gross receipts of $5 million or less over its last 3 completed fiscal years. (The Small Business Administration size standards for the "health services" category, including "offices and clinics of doctors of medicine" and all other health services subcategories also establish $5 million as the cut off point for "small entities.")

Under 10 CFR 2.810 (b), a small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $5 million or less.

Under 10 CFR 2.810(c), a small governmental jurisdiction is a government or a city, county, town, township, village, school district or special district with a population of fewer than 50,000 persons.

Under 10 CFR 2.810(d), a small educational institution is one that is (1) supported by a qualifying small governmental institution; or (2) not State or publicly supported and has 500 or fewer employees.

For purposes of this analysis, therefore, "small entity" refers to any specific medical licensee under 10 CFR Part 35 with annual gross receipts of $5 million or less, or a government medical institution licensee serving a population of less than 50,000.

The rule would affect about 1688 NRC licensees. These licenses are issued principally to medical institutions, with at least 1015 of the Part 35 licensees classified as medical institutions (codes 2110, 2120, and 2121 in NRC's licensee tracking system).

In 1998, NRC performed an analysis that indicated that, at most, eight of these medical institutions had operating revenues of less than $5 million in 1996 (the most recent year for which all necessary data were available). First, all hospitals in States in which Part 35 licensees are regulated by NRC first were screened for revenues (because annual gross receipts data were not available), using data obtained from Profiles of U.S. Hospitals, 1996, HCIA Inc. HCIA collects, analyzes, and publishes data on hospitals, based on financial submissions to the Health Care Financing Administration (HCFA). Revenues were measured as operating revenue, which is the sum of net patient revenue and other operating revenue, such as revenue from sources such as cafeterias and parking facilities, but which does not include revenue from non-operating sources such as investment income or donations. Operating revenue therefore is a less inclusive measure of revenues than gross revenues or annual gross receipts. All hospitals identified as having operating revenues less than $5 million then were checked against the NRC License Tracking System to identify those medical institutions that both had operating revenues less than $5 million and were regulated by NRC under Part 35. Of the eight institutions that were identified as meeting both criteria, three had operating revenues above $4.4 million, and therefore may have annual gross receipts above $5 million. They were, however, included in the group of institutions with less than $5 million in revenues for this analysis. Available data indicate substantial growth in annual receipts for hospitals between 1996 and 1997 (U.S. Census Bureau, Statistical Abstract of the United States, 1999, Table 192. Annual Receipts/Revenue for the Health Service Industries: 1990 to 1997), suggesting that this result overstates the number of NRC licensed medical institutions with annual gross receipts below $5 million.

Because NRC licensees that are government organizations serving populations of less than 50,000 pay reduced fees (64 FR 31448, June 10, 1999), the NRC has data on the number of Part 35 licensees who certified that they qualified as small entities for reduced fee purposes between 5/01/99 and 4/30/00. Based on self-certification by such entities, a substantially higher estimate was obtained of medical institutions that can be classified as small government entities on the basis of the population that they serve. Sixty-seven such licensees were identified.

The balance of the licenses, approximately 673 licenses, are issued principally to physicians in private practice. Information on annual gross receipts is not available, but information is available on annual revenues for such physicians.

First, data from the AMA's Socioeconomic Monitoring System, provided in Physician Socioeconomic Statistics 1999-2000 Edition: Profiles for Detailed Specialties, Selected States and Practice Arrangements, Center for Health Policy Research, American Medical Association, provides data from the AMA's Socioeconomic Monitoring System. Table 45, "Practice Revenue per Self-employed Physician, 1997 (in thousands of dollars)" indicates that at the 75th percentile only one physician specialty (Cardiovascular Diseases), and no geographic area, or practice arrangement exceeded $1 million in annual revenues. These results were based on a survey of 1,189 physicians, including physicians from over 20 different specialties. Therefore, a relatively small part of the sample is likely to be representative of Part 35 licensees. Data from the Physician Compensation and Production Survey: 1996 Report Based on 1995 Data, Medical Group Management Association, are similar. The median for "production," defined as gross charges, for all physicians was $422,937 in 1995 (p. 10). Although "production" generally is larger for specialists than all physicians, the difference is too small to place specialists above the $5 million criterion.

Because NRC licensees with annual gross receipts below $5 million pay reduced fees (64 FR 31448, June 10, 1999), NRC has data on the number of Part 35 licensees who certified that they qualified as small entities for reduced fee purposes between 5/01/99 and 4/30/00. A total of 334 Part 35 licensees reported that their annual gross receipts were below $5 million (236 below $5 million plus 97 below $350,000).

In total, therefore, the proportion of all NRC Part 35 licensees that are small entities could be as high as 44 percent (67 licensees in categories 2110, 2120, and 2131 and 673 in the remaining Part 35 categories, for a total of 740 out of 1688) or as low as 20 percent (334 out of 1688, based on self-reported data).

1.2 Determining What Number Constitutes a Substantial Number

NRC has not established a quantitative definition of the number or proportion of licensees that constitutes a substantial number. Even relying on the low estimate, however, it appears that over 300 licensees or 20 percent of all licensees constitutes a "substantial number" of small entities likely to be impacted by this rule. A substantial number of both of the two categories of licensees considered, medical institutions and individual private medical practitioners, are impacted by the rule.

1.3 Measuring "Significant Impacts"

To evaluate the impact that a small entity is expected to incur as a result of the rule, the ratio of annualized compliance costs was calculated as a percentage of gross receipts. Although NRC has not established a quantitative cutoff for "significant impact," entities were classified as facing potentially "significant" impacts if the ratio of annualized compliance costs to annual gross receipts exceeds one percent.

Determining annual compliance costs for this rule is complicated by the fact that the Part 35 rule comprehensively addresses a wide variety of uses of byproduct materials in medicine. The entities likely to be most affected by the rule are broad scope medical institutions with a large number of different modalities and conducting a large number of medical procedures involving byproduct material or radiation therefrom. However, the preceding analysis indicated that, at most, very few broad scope licensees are small entities. The costs attributable to Part 35 compliance for such broad scope licensees will be substantially greater than the annual compliance costs likely to be incurred by those licensees most likely to be small entities (i.e., single private practice physicians performing diagnostic procedures).

An additional complicating factor in calculating annual compliance costs likely to be incurred by licensees is that the Part 35 rule addresses contingent actions as well as actions that must be carried out by all licensees. In particular, the lower risk posed by diagnostic procedures reduces the likelihood that private practice physicians performing diagnostic procedures will experience medical events involving costs of reporting and followup. Licensees using unsealed byproduct material for uptake, dilution, and excretion studies or for imaging and localization studies are not required to prepare a written directive if they meet the criteria of Subpart D. Certain licensees may rely on a decay correction to determine the dosage of unsealed byproduct material for medical use, based on the activity or activity concentration determined by a manufacturer or preparer or an NRC or Agreement State licensee. Other contingencies include whether a licensee

is authorized for two or more different types of uses of byproduct material under Subparts E, F, and H or two or more types of units under Subpart H. Only such licensees are required to establish a Radiation Safety Committee.

All licensees will incur annual compliance costs for general administrative and technical requirements established by Part 35, although the level of such compliance costs will vary significantly depending on the activities being performed by the licensee and other contingencies, such as those described above. Annual compliance costs for licensees are expected, in all cases, to involve compliance with requirements to establish and maintain a radiation safety program and compliance with those requirements pertinent to the modality or modalities used by the licensee. NRC estimates that annual compliance costs for a licensee will in all cases exceed 80 hours annually at $100 per hour, or $8,000.

Assuming annual revenues of $244,000 for a single private practitioner subject to Part 35,[1] or alternatively average annual "production" of $422,000, annual compliance costs as low as $8,000 per year exceed the one percent criterion for "significant impacts." Therefore, the proposed rule appears to affect a substantial number of licensees that are small entities, and to have a significant economic impact on those small entities.

1.4 *Steps taken to Mitigate Economic Impacts on Small Entities*

NRC has taken a number of actions in this rule to ensure that the selected alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. As the Regulatory Analysis prepared for this rule demonstrates, the total annual cost to licensees (of both NRC and Agreement States) of compliance with the amended rule would be over $10.7 million less than the cost of compliance with the current rule. This is equivalent to savings of approximately $1,800 per licensee. (NRC notes that such savings will not necessarily be reflected in lower fees to licensees, because they are derived from lower costs of compliance due to the less prescriptive nature of the revised Part 35 regulations.) Although savings to small licensees can be expected to be proportionately less than savings to licensees with more extensive operations, smaller licensees also can be expected to incur smaller compliance costs.

In order to assist small licensees, the NRC has sought to eliminate prescriptive requirements wherever possible, and to allow for much greater flexibility in compliance. Such flexibility is particularly helpful to small licensees in reducing their cost of compliance, because it will enable them to avoid the costs of radiation safety measures, such as the detailed requirements for Radiation Safety Committees, that were especially oriented toward larger licensees with numerous modalities and activities in the same institution. NRC has reduced the training and experience requirements applicable to the diagnostic use of byproduct material by focusing those requirements on radiation safety and by reducing the number of hours of training required. NRC also has sought to reduce the prescriptive nature of requirements for testing and calibration, and to reduce reporting and recordkeeping burdens, which can have an especially strong impact on small entities.

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[1] Socioeconomic Characteristics of Medical Practice, 1997, American Medical Association, Center for Health Policy Research, Table 43."Mean Physician Net Income (in thousands of dollars) after Expenses before Taxes, 1995," indicates $244.4 thousand as the net income for "all physicians-rad." This is a very conservative surrogate for gross revenues, however.

Finally, the program for revising Part 35 and the associated guidance documents has involved numerous interactions and consultations with potentially affected parties (the medical community and the public, including representatives of small licensees) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public comment through documents published in the Federal Register; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; convening public workshops, both before and after the publication of the proposed rule; and extending the public comment period on the proposed rule.