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Results of Regulatory Impact Survey of Industrial and Medical Materials Licensees of the Office of Nuclear Material Safety and Safeguards

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ABSTRACT

This report presents the findings of a regulatory impact survey of nuclear materials licensees of the United States Nuclear Regulatory Commission (NRC). Commissioners of the NRC directed staff to provide the Commission with first hand information from licensees that could be used to improve the overall regulatory program. A self-administered, mail-out survey questionnaire was used to collect data from a sample of licensees who had an interaction with the NRC during the previous 12 months. A total of 371 respondents of the 589 who were sent questionnaires returned completed surveys, for a response rate of 63%. The body of the report presents the findings of the survey including a brief introduction to the approach used, followed by survey findings regarding regulations, policies and regulatory guidance; experience with licensing applications, renewals and amendments; inspections; reporting requirements; and enforcement actions. The appendices of the report include a copy of the survey as administered to licensees, a fuller description of the survey design and data collection methods, and detailed graphic material describing survey responses.

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EXECUTIVE SUMMARY

This report presents the results of a regulatory impact survey of nuclear materials licensees of the United States Nuclear Regulatory Commission (NRC) which addressed regulations, policies and regulatory guidance and experience with licensing applications, renewals and amendments, inspections, reporting requirements and enforcement actions. This survey followed an earlier regulatory impact survey of materials and fuel cycle licensees based on interviews with individuals during on-site visits to nine large fuel cycle and materials licensees. The Commission directed staff to proceed with a second phase mail survey of materials licensees to provide the Commission with first hand information from a large number of licensees in order to improve the overall regulatory program.

A self-administered, mail-out survey questionnaire was used to collect data from a sample of licensees who had an interaction with the NRC during the previous 12 months. The sample of licensees was selected through a process that grouped license program codes together into categories of similar licensed activities. A sample of licensees was then selected randomly from the list of eligible facilities within each category. A total of 371 respondents of the 589 who were sent questionnaires returned completed surveys, for a response rate of 63%.

The key findings of the survey analysis and implications for NRC are described briefly below and in greater detail in the body of the report.

1 Regulations, Policies, and Regulatory Guides

In general, respondents reported their perceptions that both the cost of complying with and the number of NRC regulations have increased over the past three years. These results are coupled with respondents' perceptions that the costs of complying with several NRC regulations is high although these regulations make only a low or moderate contribution to safety. Exceptions in terms of regulations rated highly for their safety contribution are Part 20, Radiation Protection, Part 34, Radiography, Part 35, Medical Use, and Part 39, Well Logging. The major areas recommended for NRC attention regarding the number of and cost of complying with regulations include:

- reviewing the safety importance of regulations and identifying ways to increase licensees' awareness of how specific regulations are linked to safe operations;
- monitoring resource burdens on licensees due to multiple regulations;
- determining whether licensees are discriminating between more and less relevant information about regulations and policies.

2 Licensing

Overall, respondents reported positive perceptions about license reviewers' performance and competence. There appears to be general satisfaction with the quality of reviewers who respond to requests for new licenses, renewals, and amendments. Respondents expressed more concern about NRC's lack of timeliness in response to licensing action requests. However, most respondents indicated that delays caused by slow NRC response have led to no or only minor operational problems at their facilities. Most respondents reported that they understood the processes to issue, renew, or amend their license, although a sizable portion of respondents indicated that NRC guidance was not as helpful as it could be. Finally, a majority of respondents reported that they feel free to notify NRC management of disagreements over licensing actions, and report taking action when they have disagreed. However, about one quarter of respondents indicated they did not feel free to notify NRC of disagreements. The major areas recommended for NRC attention regarding licensing actions include:

- ways for enhancing reviewers' knowledge of specific operations and facilities;

- methods for improving the timeliness of response to requests for licensing actions;
- ways to further promote a climate open to licensee disagreements; and
- revised guidance regarding filing amendments, renewals, and applications.

3 Inspections

Overall, respondents also reported very positive perceptions about inspectors' abilities and inspection practices. Respondents indicated that they were generally satisfied with the frequency and length of inspections. Most respondents reported that they feel free to notify NRC management when they have disagreements about inspections, although about one quarter of respondents expressed reservations about challenging inspection results. Finally, many respondents indicated that inspection procedures could be improved, although specific improvements were suggested by only a few respondents. The major areas recommended for NRC attention in inspections include ways to create a climate in which licensees feel free to disagree with inspection results and methods to solicit information about specific inspection process improvements from licensees.

4 Reporting Requirements and Enforcement Processes

In general, respondents perceived Part 20, Radiation Protection, reporting requirements as very necessary and not very burdensome. While respondents considered most of the other specific reporting requirements necessary and not very burdensome, they also identified two reporting requirements (Part 35.645 teletherapy and Part 35.33(a)(2) misadministration) that they considered at least somewhat burdensome. Although many respondents have received a Notice of Violation at some point, very few have ever participated in an enforcement conference or received a penalty. Of those who have, many questioned the safety significance of the issues for which they were penalized. The recommended areas for NRC attention in enforcement actions are to review the safety importance of issues that lead to sanctions and to identify ways to increase licensees' understanding of how enforcement processes and sanctions for important safety concerns enhance the safe handling of nuclear materials.

5 Other Issues of Concern

Respondents also provided information about several issues through written comments in response to open-ended general questions. Two issues of considerable concern were 1) that costs were increasing significantly, both in terms of fees and regulatory compliance costs, and 2) that NRC reviewers and inspectors were taking increasingly adversarial positions. Respondents (N = 55) providing comments about NRC costs focused on rising annual fees for licensed activities, other rising fees including inspection and amendment fees, and costs of complying with NRC regulations including the cost of civil penalties. Other respondents (N = 42) described a sense of a change in the relationship between licensees and the NRC, from "helpmeet" (in the terms of one respondent) to "prosecutorial" (in the terms of another respondent). These respondents appeared to be concerned that the agency they had found helpful in managing nuclear materials at their facility was becoming less of a partner in creating safe workplaces. There appears to be a certain amount of good will, however, among these respondents toward the NRC as an agency that can help them meet their radiation safety obligations.

6 Conclusions

The survey provides NRC with a wealth of information about its licensees' current perceptions and recent experiences. The results of this survey can serve immediate organizational needs in targeting areas for assessment and improvement, as suggested in each section above and for planning for and monitoring future activities.

In the near term, the survey results also can be a valuable communication tool within NRC headquarters and regional offices to identify areas of licensee concern and areas of licensee satisfaction. The survey provides positive reinforcement for many efforts. NRC staff also can use the survey results to identify specific areas for change or improvement based

on their own or licensee concerns. The survey provides a good tool for communicating with licensees about NRC performance and efforts.

In the long term, the survey can serve as a benchmark of how licensees perceive NRC performance in certain areas. Periodic administration of the survey (or some version thereof) can serve to document performance trends. Questions for future surveys can be modified or added to capture additional information as needed.

Both NRC staff and licensees committed considerable resources to develop, complete, and analyze the survey. The results provide an abundance of information about both the strengths and limitations of current NRC practices. This information can be used effectively to reinforce those activities that contribute highly to safe operations at licensees' facilities and modify those that contribute little to safety.

ACKNOWLEDGEMENTS

We appreciate the important contributions of the almost 400 staff members of licensees who provided their comments and perceptions regarding NRC regulations and operations affecting their facilities. Several individuals in the Office of Nuclear Material Safety and Safeguards of the US Nuclear Regulatory Commission contributed valuable assistance to this project. Many thanks to Paul Goldberg, Patricia Rathbun and Carl Paperiello for the vision and wisdom of their contributions to the design and implementation of the survey. In addition, Paul Goldberg, Patricia Rathbun, George Pangburn, Carl Paperiello, William Brach, and Fred Combs of the NRC all carefully reviewed the analysis results and the manuscript and provided insightful comments that helped improve the final report. Donna Umbel did an excellent job of coordinating this project. We also appreciate the help of Maureen Moriarty and Jay Bradford in using the Licensee Tracking System and drawing the sample of licensees and Patricia Vacca and Sally Merchant for their comments and assistance regarding regulatory guides. And finally, Rob Baxter and Renee Petri at the Social and Economic Sciences Research Center (SESRC) at the University of Washington did a superb job of administering this large survey.

1 INTRODUCTION

The major objective of this project was to elicit views regarding the impact of NRC regulatory activities on operations from licensees representing the range of types of materials licensees that had a recent interaction with the NRC in the form of a licensing action or inspection. Topics addressed were related to the NRC's regulatory program including regulations, policies and regulatory guidance, the licensing process, the inspection process, reporting requirements, and enforcement processes.

1.1 Background

In 1993, the U.S. Nuclear Regulatory Commission (NRC) staff reported to the Commission on the first phase of a regulatory impact survey of materials and fuel cycle licensees, consisting of on-site visits to nine large fuel cycle and materials licensees (SECY-93-130). These visits surveyed the views of licensees on a number of topics related to NRC's regulations and policies, license reviews, inspections, enforcement and investigations, and costs. In response to the Phase I report, the Commission directed the staff to proceed with a second phase mail survey of materials licensees in accordance with a plan presented in SECY-93-268. The staff's plan suggested a mail survey administered to a random sample of 300-500 licensees. This survey was to provide the Commission with first hand information which could be used to make improvements to the overall regulatory program. Battelle's Pacific Northwest Laboratory (PNL) and Human Affairs Research Centers (HARC) worked with NRC staff in conducting this project.

1.2 Approach

A self-administered, mail-out survey questionnaire was used to collect the data from licensees. The questionnaire was based on the interview protocol originally used in Phase I of the project. The draft questionnaire was pretested with a small sample of licensees and with NRC staff to determine how long the survey would take to complete and to assess any problems in the survey design. The final questionnaire consisted of 46 open- and closed-ended questions (see Appendix A). The questionnaire was approved by the Office of Management and Budget for distribution to NRC licensees.

A stratified random sample design was selected to ensure that a wide range of licensee categories were sampled in order for the NRC to receive feedback from almost all licensee types. NRC staff combined program codes into 14 distinct "categories" of licensed facilities (see Table 1.1). The NRC contractor responsible for maintaining the Licensing Tracking System (LTS) used the stratified population of facilities to select a random sample of a specified number of licensees from each category. Because facilities may be listed in more than one category, depending on how many regulated activities they engage in, multiple selection of the same licensed facility was eliminated to avoid duplication of respondents. A total of 589 licensed facilities were selected to receive the questionnaire.

The surveys were administered confidentially, with only the survey administrator able to associate names with surveys. Neither the NRC nor the analysts knew who filled out each survey. A total of 371 respondents returned completed questionnaires for a response rate of 63%. The distribution of respondents appears to be representative of the NRC licensee categories (see Table 1.1). Most (about 80%) of the respondents served as the Radiation Safety Officer (RSO) at their facility. Ten percent of respondents reported that their facilities had full-time RSOs, while 89% had RSOs with additional job responsibilities. There was considerable variation in the number of individuals issued personal dosimetry monitoring devices at licensees' facilities. The range was from 0 to 3334, with 0 to 4 in the first quartile, 5 to 10 in the second, 11 to 40 in the third, and 41 to 3334 in the fourth quartile. However, only 10% of respondents reported more than 170 individuals had been issued personal dosimetry monitoring devices. Each respondent identified a specific licensed activity which best described the primary licensed activity at their facility. These self-selected licensee categories were used in the analyses for this report rather than the program code by which the original sample was drawn. The survey responses were considered to better reflect the respondents' primary licensee category than the licensee category based on one program code for sample selection purposes. (See Appendix B, Survey Methods, for a detailed discussion of the categories.)

Table 1.1: Sample and Response Pool Proportions and Rates by LTS-Assigned Licensee Type

Licensee Type	Percent in Sample %	N	Percent of Response %	N*	Response Rate
Academic	6.3%	37	6.6%	24	65%
Gauges	8.5%	50	7.7%	28	56%
Irradiators	5.9%	35	5.8%	21	60%
Medical Institutions	21.9%	129	21.4%	78	60%
Medical Other	10.9%	64	9.3%	34	53%
Manufacturing and Distribution	5.1%	30	3.6%	13	43%
Other Source	4.9%	29	3.6%	13	45%
Pharmacies, Medical Distribution	3.7%	22	4.7%	17	77%
Research and Development	9.2%	54	10.7%	39	72%
Radiography, fixed	3.4%	20	4.7%	17	85%
Radiography, temporary	5.9%	35	7.1%	26	74%
Services	5.1%	30	5.5%	20	67%
Special Nuclear Material	4.9%	29	5.0%	18	62%
Well-Logging	4.2%	25	4.4%	16	64%
Subtotal	100.0%	589	100.0%	364	62%
Category not known (ID number removed by respondent)	------	------	------	7	------
Total for All Respondents	------	589	------	371	63%

* Chi-Squared Analysis was run to test the response distribution by categories of licensees in the sample. This was done to determine if there was a significant difference in the response rates of the different licensee types. Based on the results of the analysis, the probability of a significant difference in response rates is only about 4%. (Analysis results: 13 degrees of freedom, Chi-squared value = 22.912, probability = 0.043)

The quantitative analysis of the data was conducted using computer software and is focused primarily on descriptive statistics including the distribution of responses by self-selected licensee categories. These quantitative results, as well as a content analysis of the open-ended questions, were used to form the basis of this report. The analyses are supported by illustrative materials including graphs, tables, and charts. A detailed explanation of the methods used in the survey design, administration, and analyses is included in Appendix B.

1.3 The Report

This document summarizes the results of the questionnaire survey. The main body of the report describes the results of each section of the survey. After reviewing licensees' responses regarding regulations, policies, and regulatory guidance (Chapter 2), the report describes the results about licensing (Chapter 3), inspections (Chapter 4), and reporting requirements and enforcement processes (Chapter 5). The final chapters review the comments provided by respondents to open-ended questions (Chapter 6) and provide conclusions (Chapter 7). Appendix A contains the questionnaire and distributions of responses to the survey questions; Appendix B details the methods used to design, administer, and analyze the survey; and Appendices C, D, and E contain additional graphic material presenting results of analyses.

2 REGULATIONS, POLICIES, AND REGULATORY GUIDANCE

The discussion in this section focuses on several key areas regarding the contribution to safety, the cost, and the usefulness of selected NRC regulations, policies, and regulatory guidance including:

- fifty percent or more of affected respondents identifying Part 20, Radiation Protection, Part 34, Radiography, Part 35, Medical Use, and Part 39, Well Logging, as contributing highly to safety, but lower percentages of respondents rating several other NRC regulations as making a high contribution to safe operations;
- the perception that the cost of complying with regulations in general, has increased over the past three years and costs of complying with many specific regulations are high; and
- respondents' indications of fairly high levels of both their knowledge of and the usefulness of non-specialized regulatory documents and guidance.

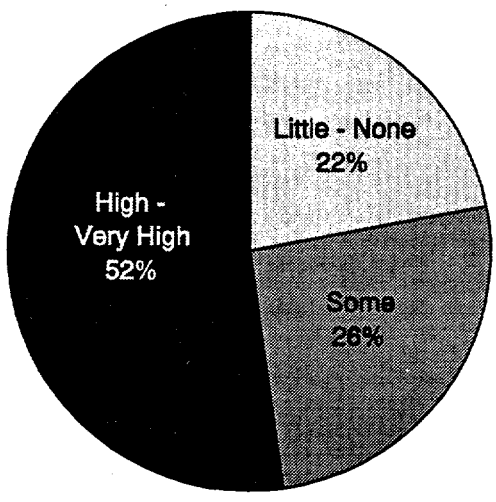
Analyses in this chapter are based on responses to both closed- and open-ended survey questions (or response categories). Quotations are taken directly from the written comments provided by respondents on the survey. Any modification of respondents' comments are noted. While direct statements are very powerful and evocative, they represent the perceptions of only a few respondents. The percentage distributions reflect more accurately the overall perceptions of the total group of respondents. The comments are selected as examples of licensees' responses and used to corroborate and illustrate the survey results.

2.1 Ratings of the Safety Contribution of Selected NRC Regulations

Respondents were asked to assess the extent to which eleven selected regulations contributed to the safe operation of facilities. The regulations selected include three that apply to all or most licensees: Part 19, Communication/Reports to Workers; Part 20, Radiation Protection; and Part 30, Byproduct Material Licensing. They also include eight regulations that apply only to specific groups of licensees based on particular licensed activities: Part 33, Broad Scope; Part 34, Radiography; Part 35, Medical Use; Part 36, Irradiators; Part 39, Well Logging; Part 40, Source Material; Part 70, Special Nuclear Material; and Part 71, Transportation. (The distribution of "not applicable" responses for each regulation is displayed in Figures C.1-C.11 in Appendix C).

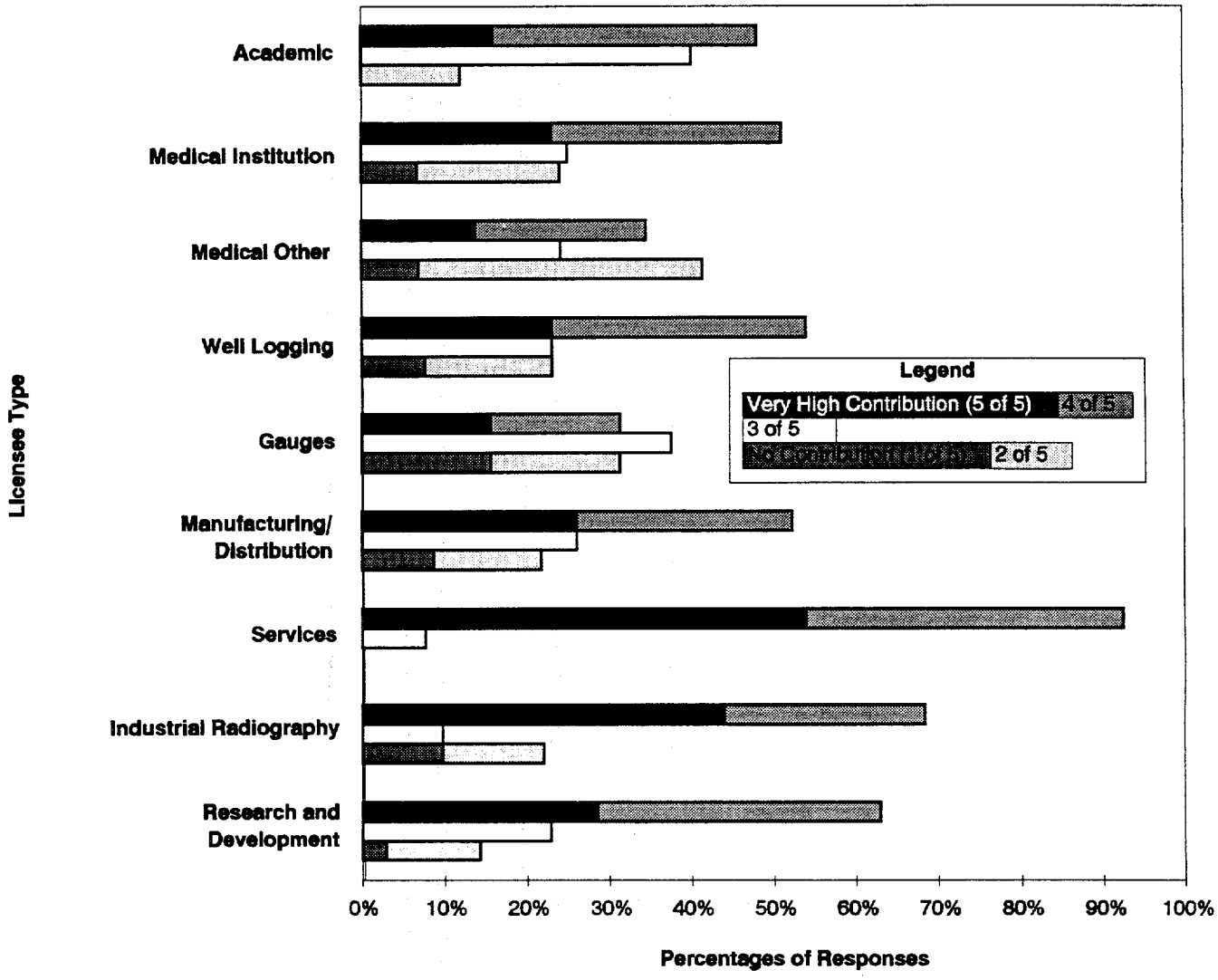
More than one-half of all respondents rated Part 20, Radiation Protection, as contributing highly to safety (see Figure 2.1). Approximately 50% to 60% of respondents in most licensee categories were likely to assess Part 20 as contributing highly to safety, as shown in Figure 2.2. In only two of the nine licensee categories did a lower percentage of respondents rate Part 20 as high in safety contribution--medical other (35%) and gauges (32%). About 15% to 25% of respondents in most categories thought Part 20 made little or no contribution to safety.

Figure 2.1: Perceived Contribution to Safety of Part 20, Radiation Protection (Question 5)



These results are corroborated and illustrated by written comments in response to an open-ended question asking if any of the eleven selected regulations were particularly effective at enhancing safe operations at the respondents' own facilities. Eighty-eight respondents (about one quarter of the total number of respondents) identified all or specific sections of Part 20 as particularly effective at enhancing safe operations. Several respondents noted the flexibility to design local programs as particularly effective. This flexibility is described cogently by one respondent: "Company program, tailored to our

Figure 2.2: Perceived Contribution to Safety of Part 20, Radiation Protection, by Licensee Type
(Question 5)



operation, takes unique situations and capabilities into account more effectively than 'shotgun' regulations." Other respondents identified the clarity of Part 20 as contributing to safe operations. One respondent described Part 20 as "provid[ing] simple, yet valuable, guidance." Part 20 was also described as effectively raising awareness of radiation safety: "[Part 20] has helped to ensure greatest employee (user) awareness. Through extensive documentation, it has been possible to involve both the management level and users. A better understanding of the [radiation] safety officer [RSO] duties by upper management was the most positive impact."

Several respondents (N = 24), however, identified Part 20 (or sections of Part 20) as counterproductive to safety in response to an open-ended question on this issue. These comments focused on very specific elements of the regulation, as illustrated in the following example: "Previous limit of 0.5 REM/year [compared to the new limit of 0.1 REM/year in 20.1301] allowed radiographers at temporary sites more control and less complications at multiple-visit sites, allowing them to concentrate on completing the job in a timely manner, maintain surveillance, and pay more attention to their own exposure/ALARA."

Figure 2.3: Perceived Contribution to Safety of Part 19, Communication/Reports to Workers (Question 5)

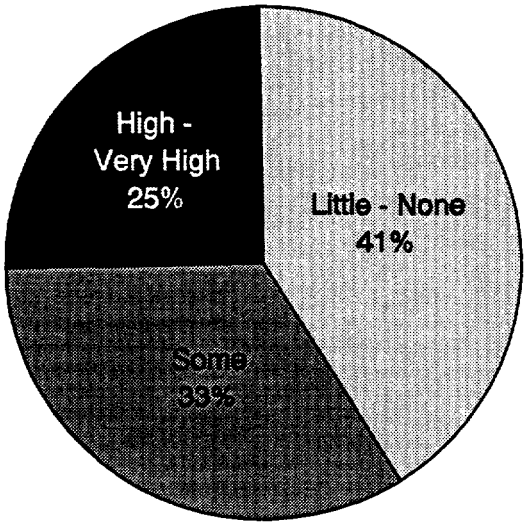
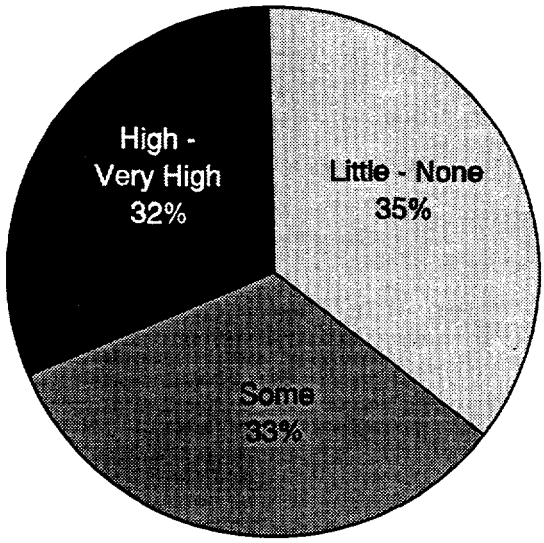


Figure 2.4: Perceived Contribution to Safety of Part 30, Byproduct Material Licensing (Question 5)

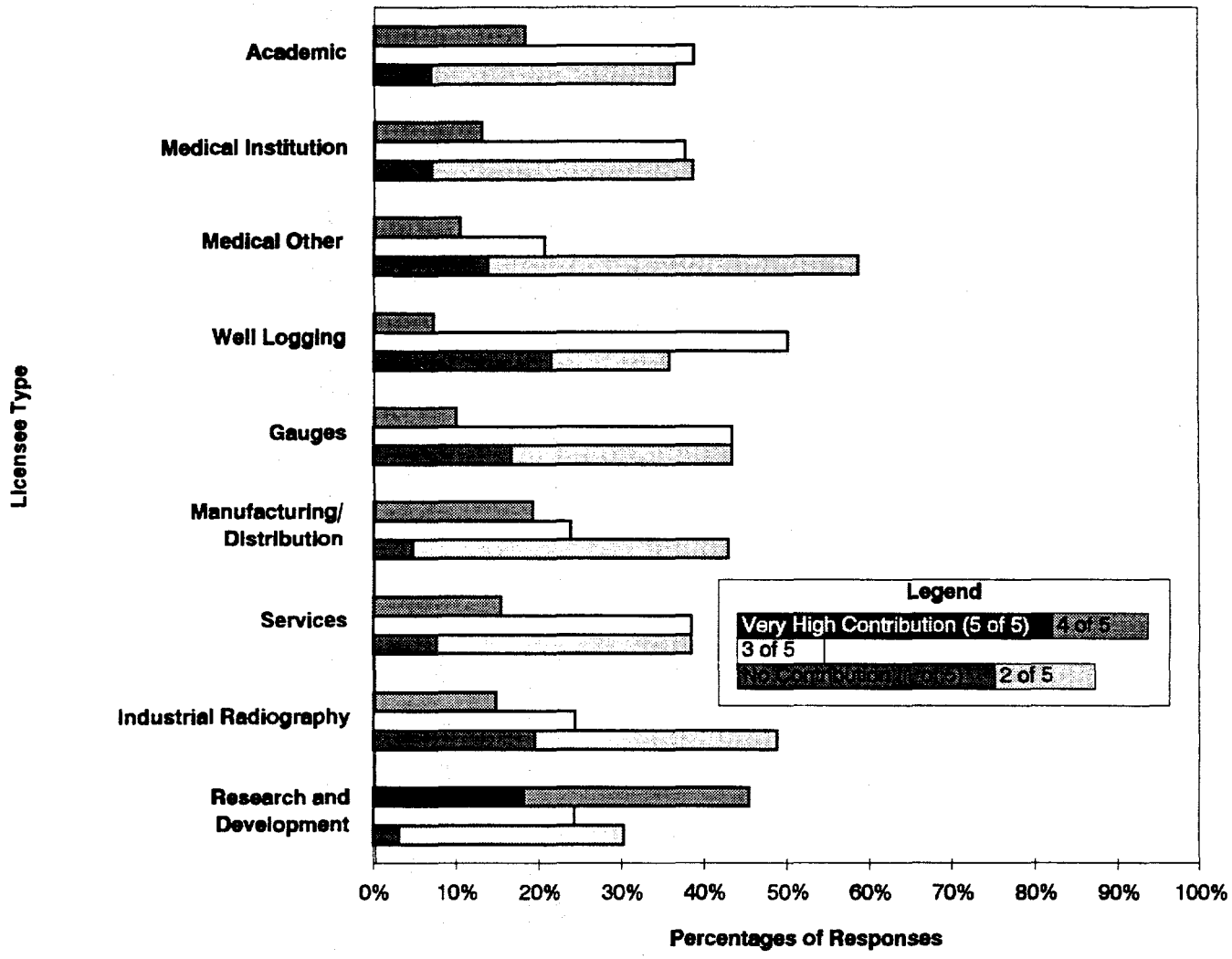


Overall findings for Part 19, Communication/Reports to Workers, and Part 30, Byproduct Material Licensing, are quite different from those regarding Part 20. Only about one-quarter of all respondents described Part 19 and one third described Part 30 as contributing highly to safe operations (as shown in Figures 2.3 and 2.4, respectively). A substantial percentage of respondents (averaging about 30%-35% in most licensee categories) perceived Parts 19 and 30 as contributing little if anything to safety (see Figures 2.5 and 2.6, respectively). Licensee respondents in research and development (45%) and manufacturing and distribution (32%) categories were most likely to identify Part 19, Communication/Reports to Workers, as contributing highly to safe operations, while well logging (15%) and gauges (12%) had the lowest percentages of respondents rating Part 19 high on safety. About one-quarter of respondents in each of the other categories identified Part 19 as contributing highly to safety. Research and development licensees (49%) had the highest percentage of respondents that identified Part 30, Byproduct Material Licensing, as contributing highly to safe operations while services (11%) and gauges (17%) had the lowest percentages. About one-third of respondents in each of the other licensee categories identified Part 30 as contributing highly to safety.

Regarding the eight more specialized regulations, most respondents in relevant licensee categories reported that Part 34, Radiography (about 70%), and Part 39, Well Logging (about 70%), contributed highly to safety and close to half of affected licensees indicated that Part 35, Medical Use, contributed highly to safety (see Figure 2.7). Smaller percentages of respondents in relevant licensee categories, however, identified other specific regulations as contributing to safety at their facility. For example, less than 40% of respondents in relevant categories perceived Part 33, Broad Scope, as contributing highly to safety, and less than 35% of respondents in relevant categories identified Part 40, Source Material, as contributing highly to safety (see Figure 2.7).

Overall, a majority of respondents consistently indicated that Part 20, Radiation Protection, contributed highly to safe operations at their facilities. Well logging (Part 39) and radiography (Part 34) regulations were perceived by most affected respondents and medical use (Part 35) was considered by close to half of affected respondents as contributing highly to safety. The remaining seven of the eleven regulations selected were viewed as having a moderate to low safety contribution at respondents' facilities. These results suggest that many licensee respondents do not see a link between certain NRC regulations and safe operations at their facilities.

Figure 2.5: Perceived Contribution to Safety of Part 19, Communication/Reports to Workers, by Licensee Type
(Question 5)

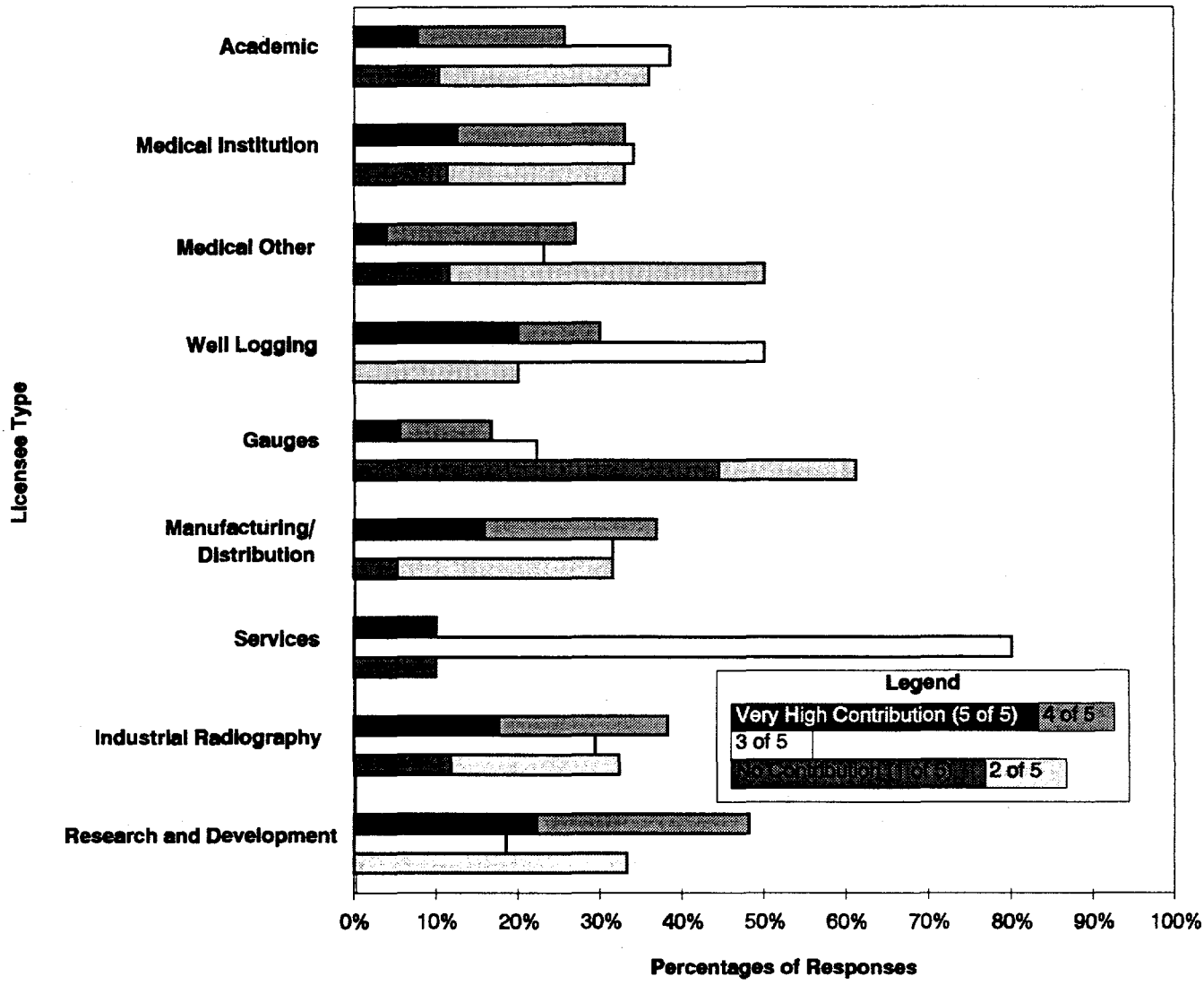


2.2 Cost of Complying with NRC Regulations

Respondents were asked to rate the cost of complying with the same set of eleven NRC regulations that they rated on safety contribution. In terms of the regulations that applied to almost all licensees, respondents were much more likely to describe the costs of complying with Part 20, Radiation Protection (about 45% to 50% overall), and Part 30, Byproduct Material Licensing (about 40%), as high than they were to describe the costs of complying with Part 19, Communication/ Reports to Workers (about 15%), as high.

Respondents reporting that the costs of complying with Part 20 were high ranged from 60% of academic licensees to 31% of services licensees, with other categories' response rates resting in-between. Respondents in the well logging (62%) and industrial radiography (60%) categories were most likely to indicate that complying with Part 30 was high although at least 40% of the respondents in each of the other licensee categories reported compliance costs as high.

Figure 2.6: Perceived Contribution to Safety of Part 30, Byproduct Material Licensing, by Licensee Type
(Question 5)



While respondents, in general, reported that Part 20, Radiation Protection, is a high-cost regulation, respondents also rated Part 20 as contributing highly to safety. Although Part 19, Communication/Reports to Workers, is not generally perceived as a high cost regulation, respondents also do not generally perceive it as contributing highly to safety. And, while Part 30, Byproduct Material Licensing, is generally perceived as a high cost regulation, it is generally regarded as not contributing highly to safety. Figures 2.8, 2.9, and 2.10 show the distribution of high ratings by licensee category for safety and cost for Parts 20, 19, and 30, respectively.

Among those regulations specific to certain licensee categories (see Figures 2.11, 2.12, and 2.13), almost 80% of industrial radiography respondents reported that compliance costs were high for Part 34, Radiography. More than 80% of academic respondents and almost 60% of medical institution respondents reported that Part 35, Medical Use, compliance costs were high. More than 70% of well logging respondents described cost of compliance with Part 39, Well Logging, as high. The percentage of respondents indicating that compliance costs for Part 71, Transportation, were high ranged from only about 5% of research and development respondents to 62% of well logging respondents. These results may reflect the relative differences in transportation requirements of the respondents.

Figure 2.7: Perceived Contribution to Safety of Selected Regulations, by Affected Licensee Type
(Question 5)

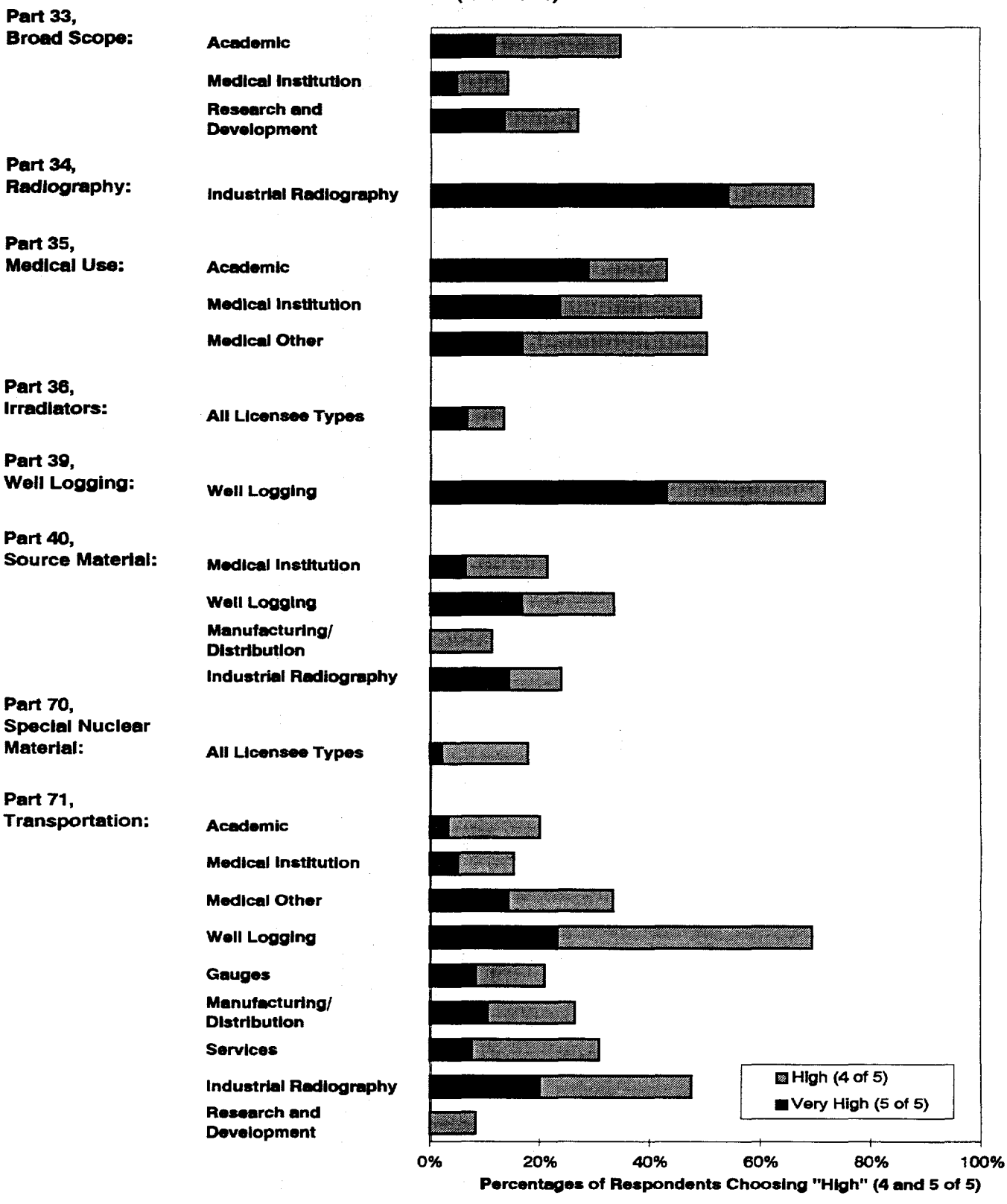


Figure 2.8: Percentage Saying Contribution to Safety of, and Cost of Complying with, Part 20, Radiation Protection, are High, by Licensee Type
(Questions 5 and 6)

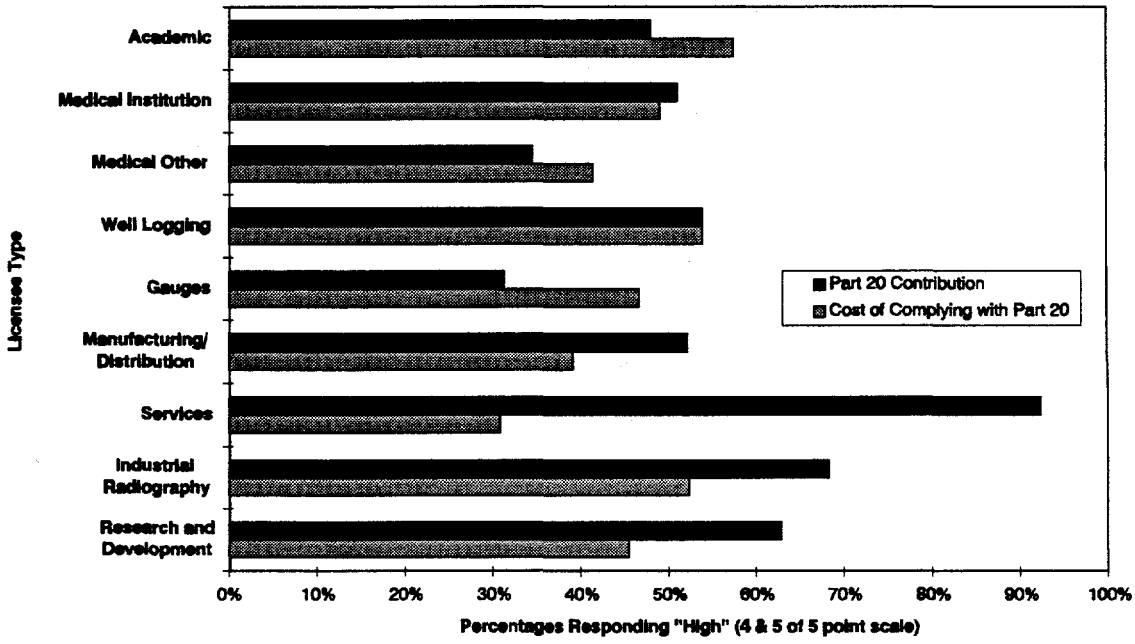


Figure 2.9: Percentage Saying Contribution to Safety of, and Cost of Complying with, Part 19, Communication/Reports to Workers, are High, by Licensee Type
(Questions 5 and 6)

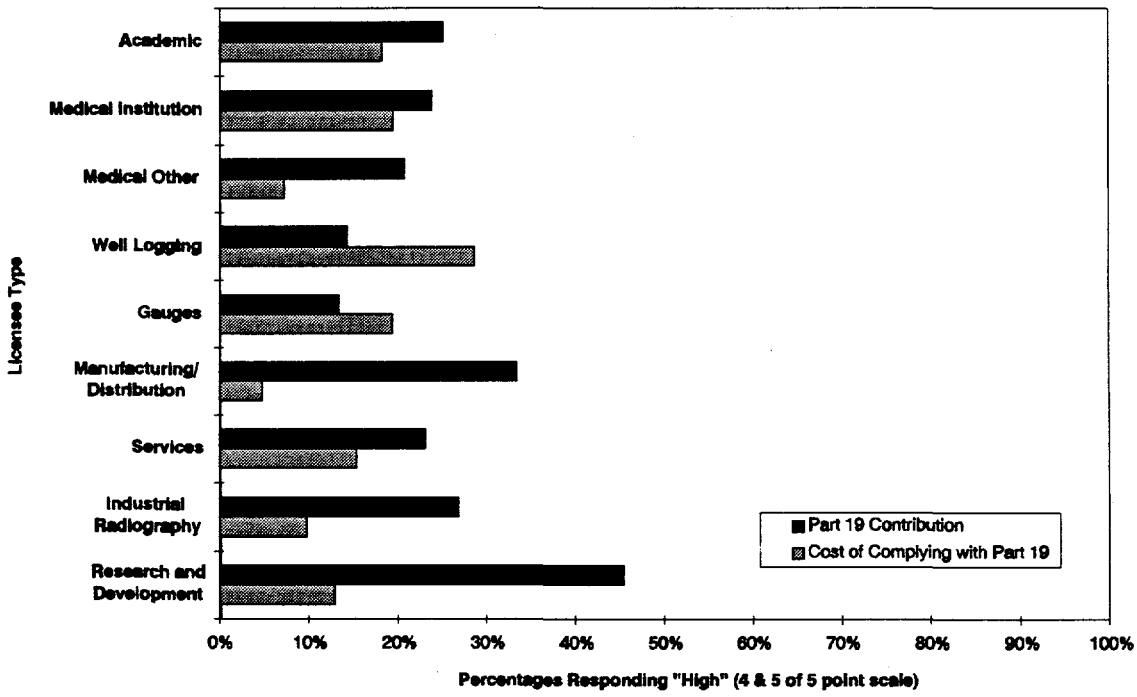
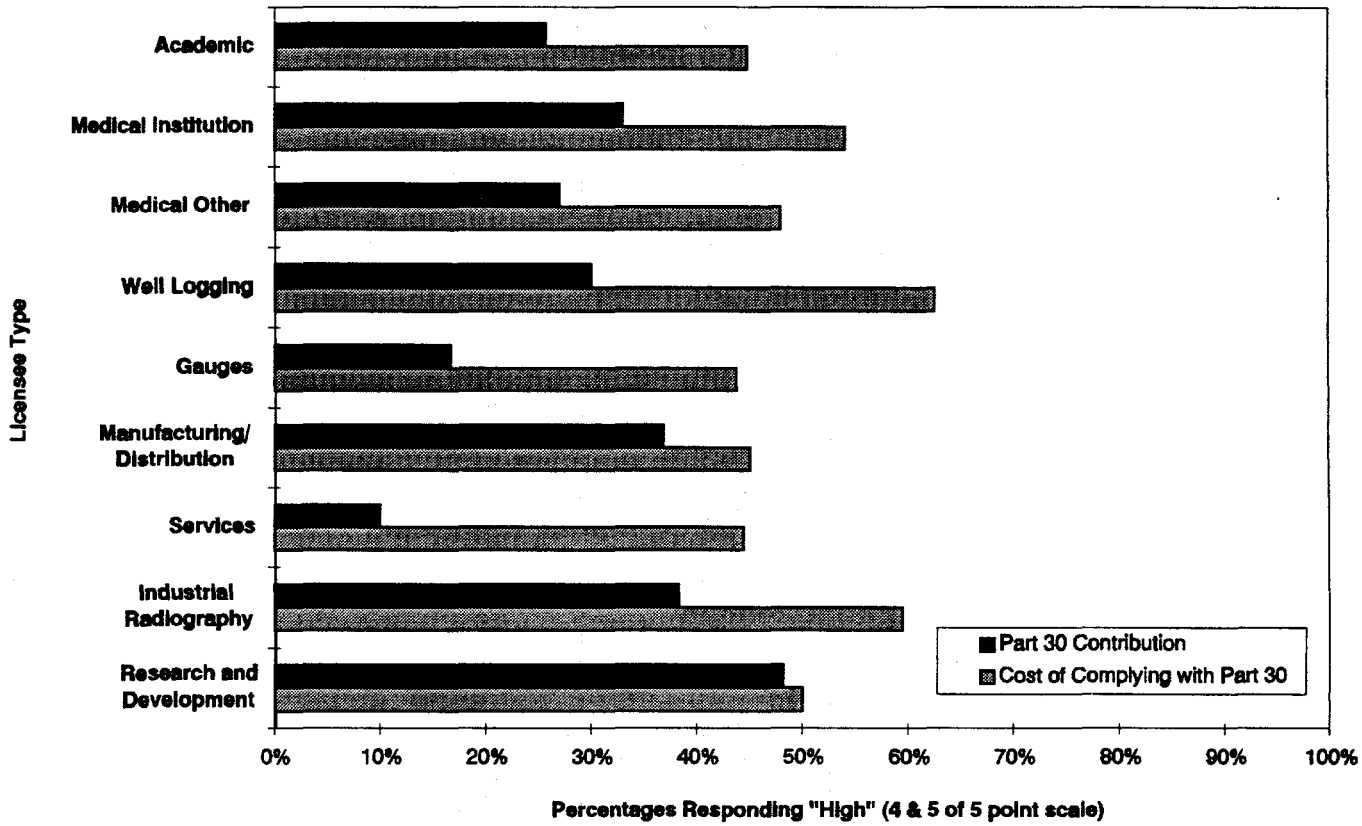


Figure 2.10: Percentage Saying Contribution to Safety of, and Cost of Complying with, Part 30, Byproduct Material Licensing, are High, by Licensee Type
(Questions 5 and 6)



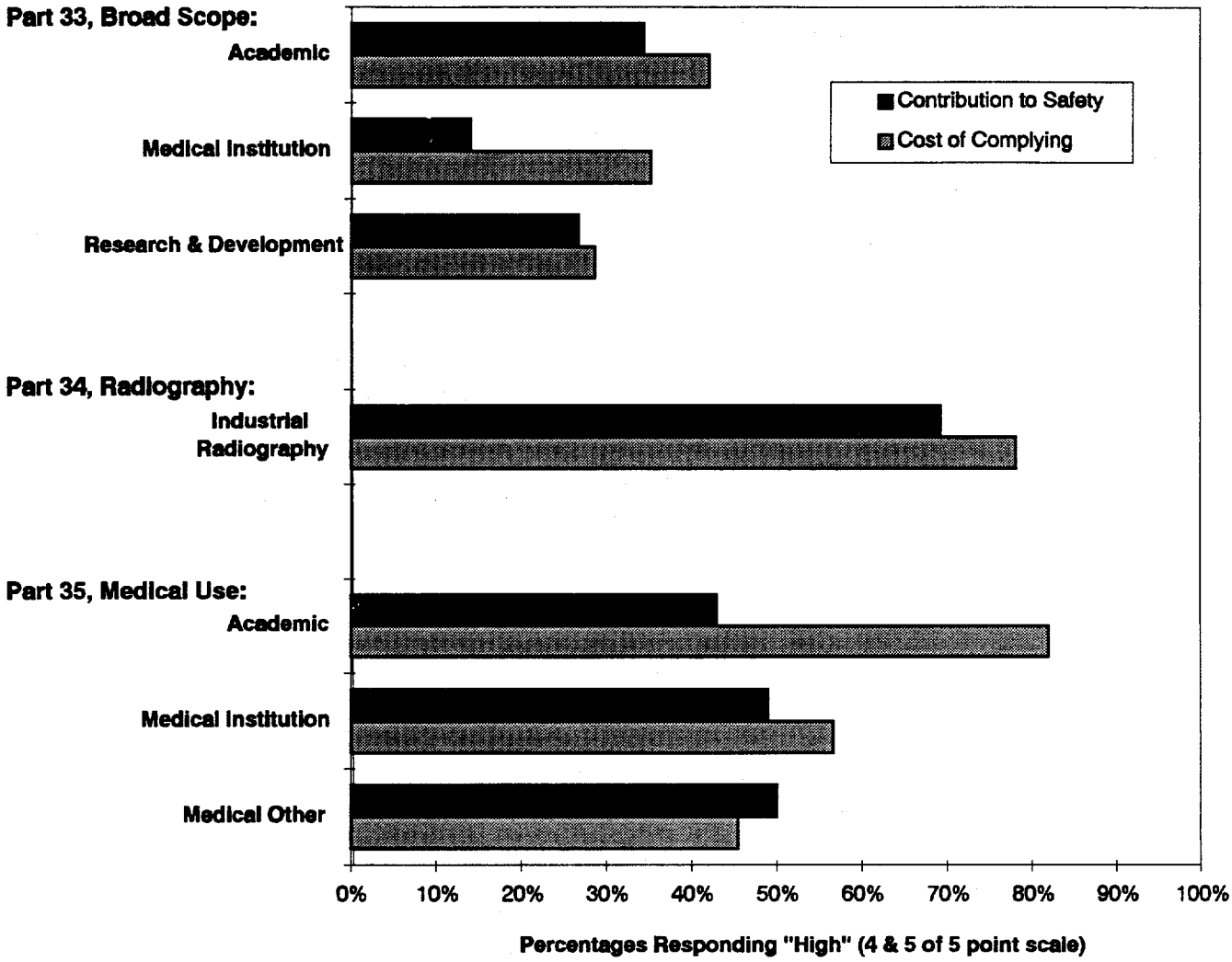
Among those regulations applicable to specific licensee categories, Parts 34, Radiography, 35, Medical Use, and 39, Well Logging, are generally perceived by respondents in relevant categories as high cost regulations, but also contributing highly to safety. Parts 33, Broad Scope, 36, Irradiators, 40, Source Material, and 70, Special Nuclear Material, are perceived by respondents in relevant licensee categories as generally low cost regulations but not high contributors to safe operations.

Respondents were asked to describe their overall perceptions of changes over the past three years in the cost of complying with NRC regulations. Most respondents (over 70%) from all but three licensee categories indicated that the cost of complying with NRC regulations has increased "significantly" (see Figure 2.14); the exceptions were academic (almost 40%), research and development (almost 45%) and gauges (close to 60%).

Many respondents also reported that the number of NRC regulations had increased over the past three years. As shown in Figure 2.15, 40% to 50% of respondents in academic, medical institution, medical other, and industrial radiography indicated that the number of NRC regulations has increased significantly over the past three years. Concern over the increasing number of regulations was addressed in written comments (N = 14) provided in response to the final open-ended question requesting additional information. One typical comment suggested: "The NRC has imposed too many regulations and a majority of them are unnecessary for the safety of the patient, public, or employees. NRC seems to feel that the imposition of regulations is the answer to safety. While, in reality, the answer is adequately educated and trained employees who understand radiation and radioactive material uses."

Respondents also described concerns about costs. While many respondents (N = 53) discussed the whole NRC fee structure (e.g., licenses, inspections, amendments, and fines) as problematic (described in Chapter 6), several, (N = 18)

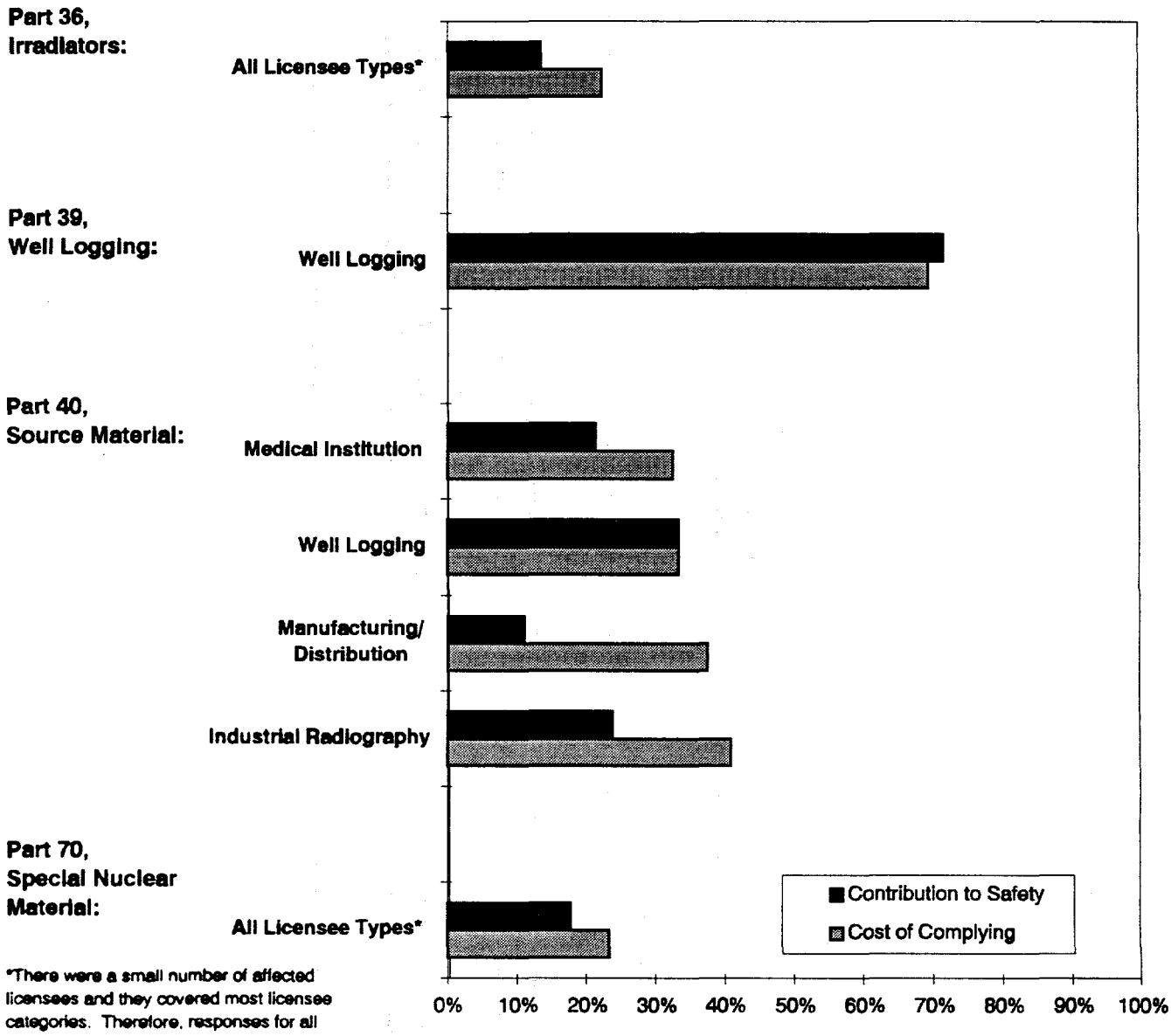
Figure 2.11: Percentage Saying Contribution to Safety of, and Cost of Complying with, Part 33, Broad Scope, Part 34, Radiography, and Part 35, Medical Use, are High, by Affected Licensee Type
(Questions 5 and 6)



focused solely on the costs of compliance with regulations. The following comment illustrates the major concern discussed by these respondents: "Excessive regulations increased staff requirements which increases the cost of health care with no documented increase in improvement of the health/welfare of U.S. citizens."

In general, respondents reported perceptions that the cost of complying with NRC regulations has increased over the past three years. Respondents in general identified the costs of complying with Parts 20, Radiation Protection, and 30, Byproduct Material Licensing, as high and Part 19, Communication/Reports to Workers, as low. Several specific regulations were identified as not having high compliance costs (e.g., Parts 33, Broad Scope, 36, Irradiators, 40, Source Material, and 70, Special Nuclear Material), although respondents also described a few regulations with high compliance costs (e.g., Parts 34, Radiography, 35, Medical Use, and 39, Well Logging). Perceptions about the cost of complying with NRC regulations appear to be driven by both the increased numbers of regulations as well as new high cost regulations such as Part 20. These findings suggest that NRC may wish to assess the resource burden of multiple regulations on licensed facilities.

Figure 2.12: Percentage Saying Contribution to Safety of, and Cost of Complying with, Part 36, Irradiators, Part 39, Well Logging, Part 40, Source Material, and Part 70, Special Nuclear Material, are High, by Affected Licensee Type
(Questions 5 and 6)



*There were a small number of affected licensees and they covered most licensee categories. Therefore, responses for all respondents who said this regulation was applicable to their facilities were grouped together

Figure 2.13: Percentage Saying Contribution to Safety of, and Cost of Complying with, Part 71, Transportation, are High, by Licensee Type
(Questions 5 and 6)

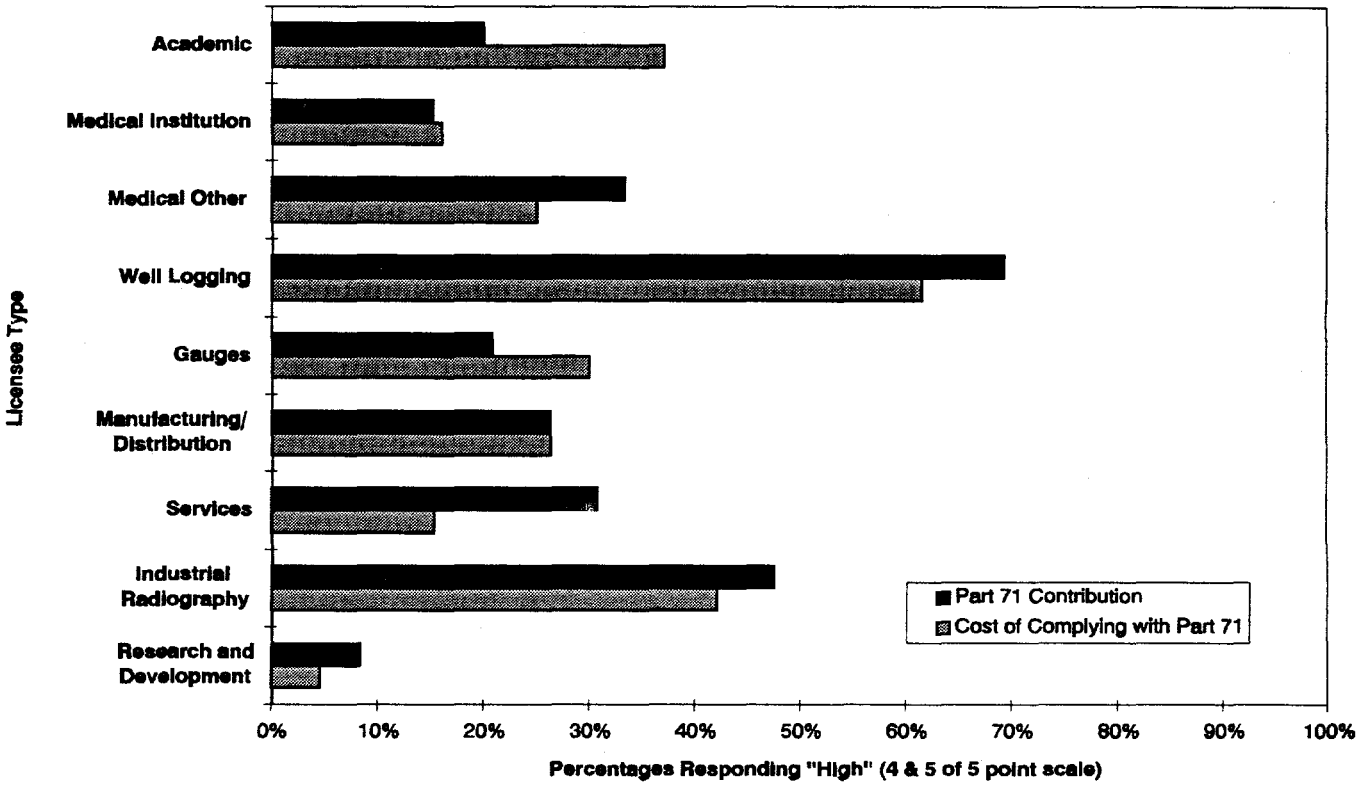


Figure 2.14: Percent Saying Cost of Complying with NRC Regulations Has Increased Significantly over the Past Three Years, by Licensee Type
(Question 4)

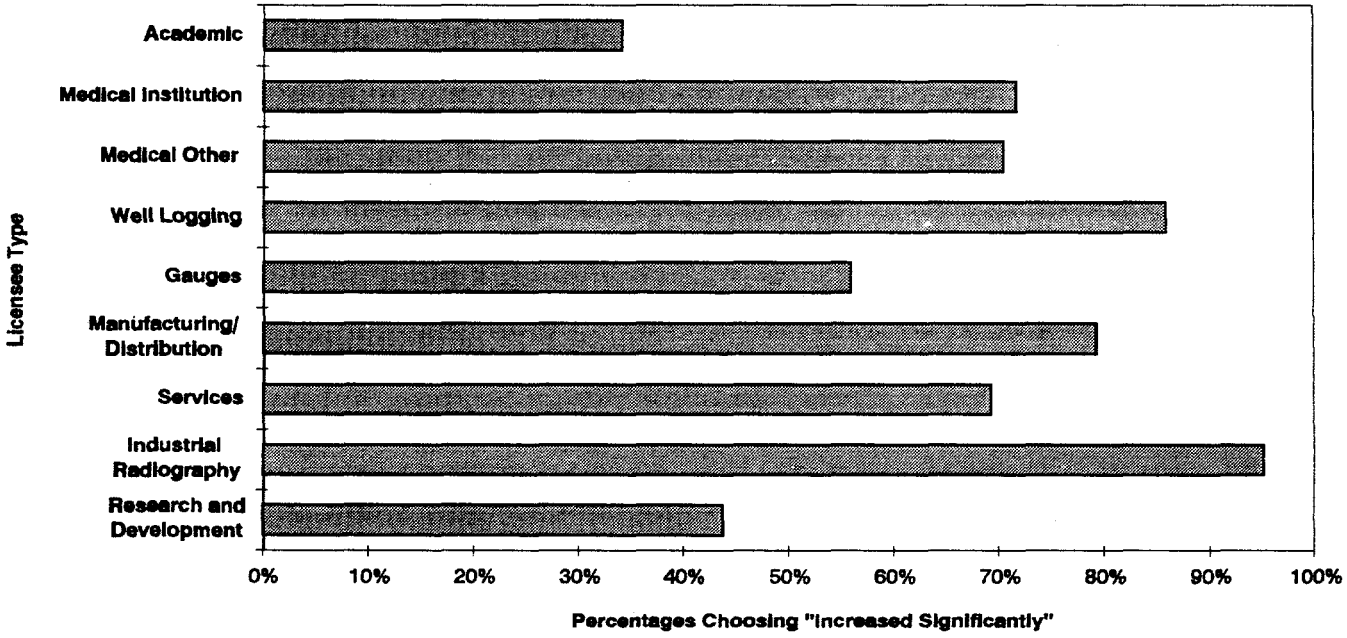
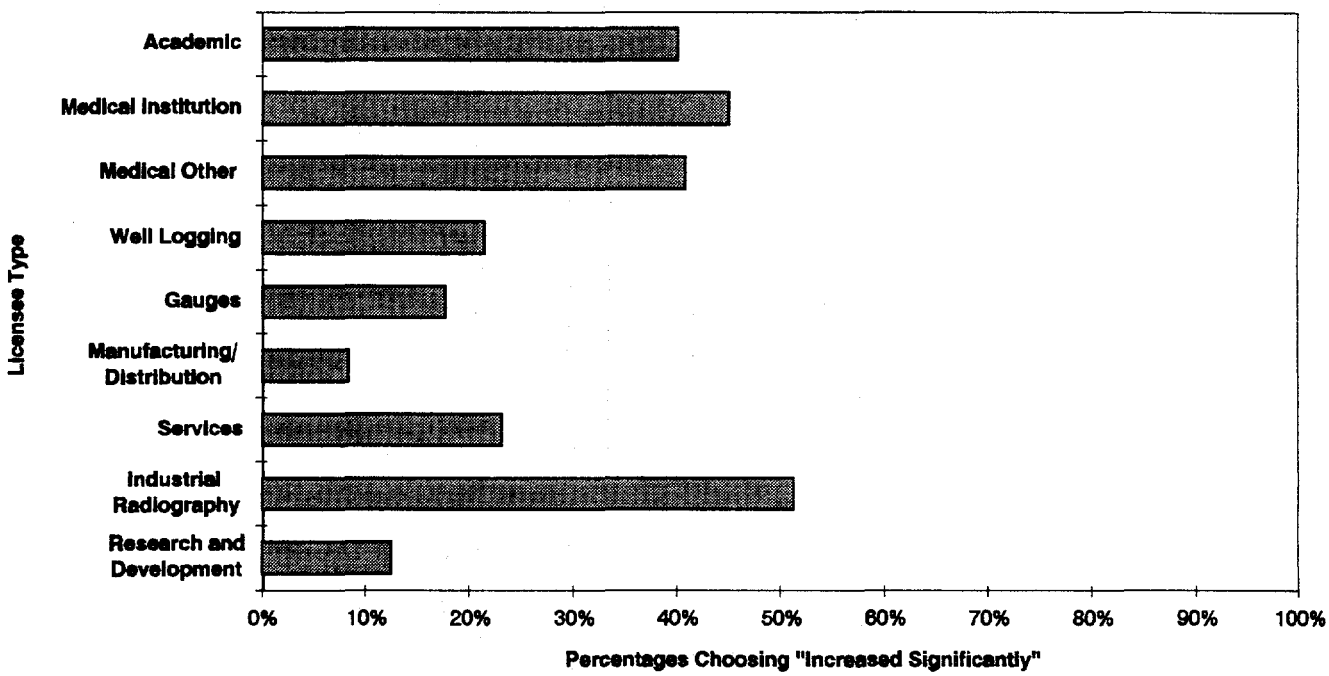


Figure 2.15: Percent Saying Number of Applicable NRC Regulations Has Increased Significantly over the Past Three Years, by Licensee Type
(Question 3)



2.3 Knowledge About and Usefulness of Regulatory Documents and Guides

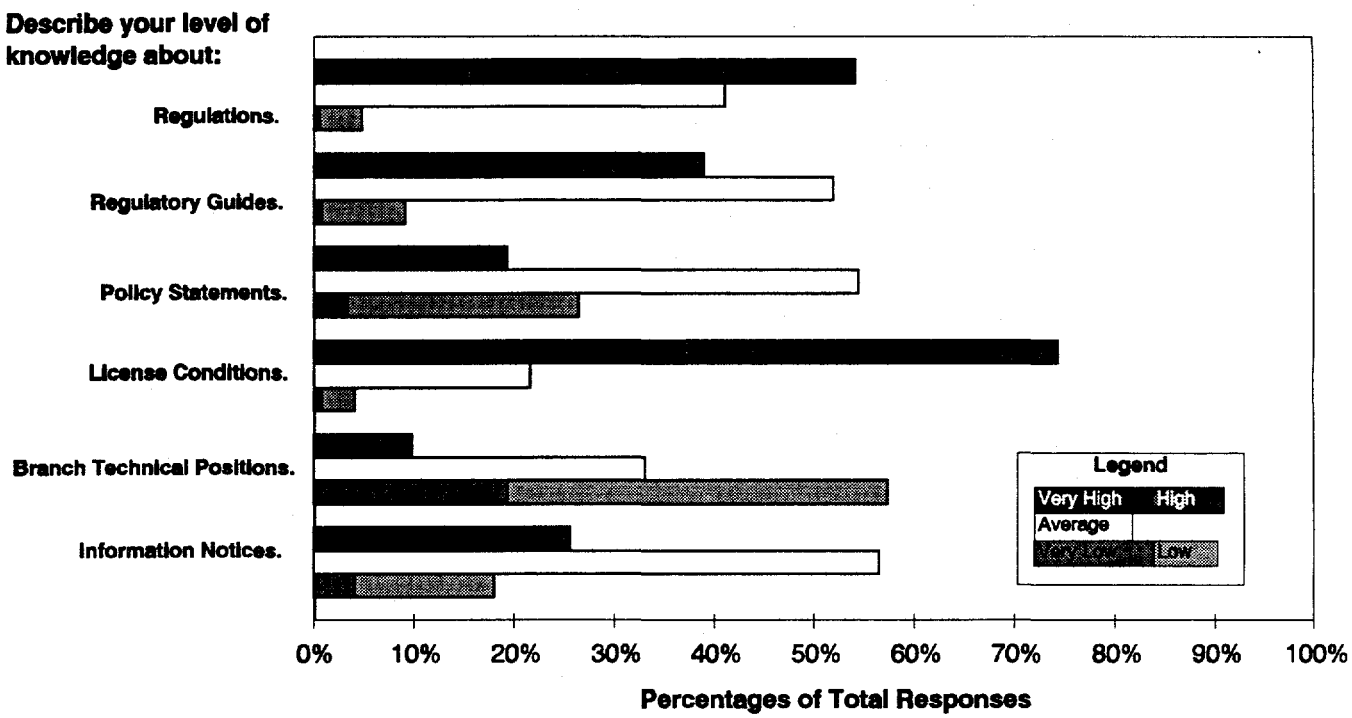
Respondents were asked to assess their level of knowledge about general NRC documents (see Figure 2.16). In general, respondents were most likely to describe their level of knowledge as high for "license conditions" (73%) and "regulations" (57%). They were least likely to describe high levels of knowledge about "branch technical positions" (10%) and "policy statements" (19%).

Respondents generally report higher levels of knowledge about NRC documents especially salient to the everyday operation of their facilities. Respondents are less knowledgeable about other types of documents.

Eight respondents provided comments that suggest that radiation safety officers (RSOs) may be having some difficulty sorting through NRC material to identify relevant information. They reported that they perceive much of the material they receive from NRC is extraneous to their own responsibilities and have difficulty determining important information. One respondent described this problem: "It would be very helpful if NRC sent me regulations that only pertain to my [operation]. . . . I'm sure I miss a lot because I have a hard time finding what pertains to my [operation]." Another respondent echoed this concern: "There should be a way to avoid receiving information that has no relevance to our situation--like information on nuclear plants." These results suggest that NRC may wish to assess whether licensees are correctly discriminating between more and less relevant information.

Respondents were also asked to rate the usefulness of selected regulatory guides on a five-point scale from "not useful" to "very useful." For guides applying to respondents in all licensee categories, guidance regarding the Preparation of Application for Licensed Activity and Prenatal Radiation Exposure were considered quite useful by 40% to 50% of respondents. About 30% to 35% rated Occupational Radiation Exposure Risk and Radiation Doses to Embryo/Fetus Guides as useful (see Figure 2.17). (Figure C.12 in Appendix C shows the perceived usefulness of eleven regulatory guides for all respondents.)

Figure 2.16: Self-Reported Levels of Knowledge
(Question 1)



In terms of specialized guides, about 40% of academic, medical other, manufacturing and distribution, and research and development respondents said that the Bioassay Program Regulatory Guide was quite useful compared to about 20% of medical institution and well logging respondents (see Figure 2.18). Only a small percentage (about 20%) of respondents in relevant licensee categories found the Quality Management Program Guide quite useful (See Figure 2.19). These results suggest that a sizable portion of NRC licensees could benefit from additional and/or different types of information in the various regulatory guides.

Figure 2.17: Perceived Usefulness of Selected Regulatory Guides
(Question 9)

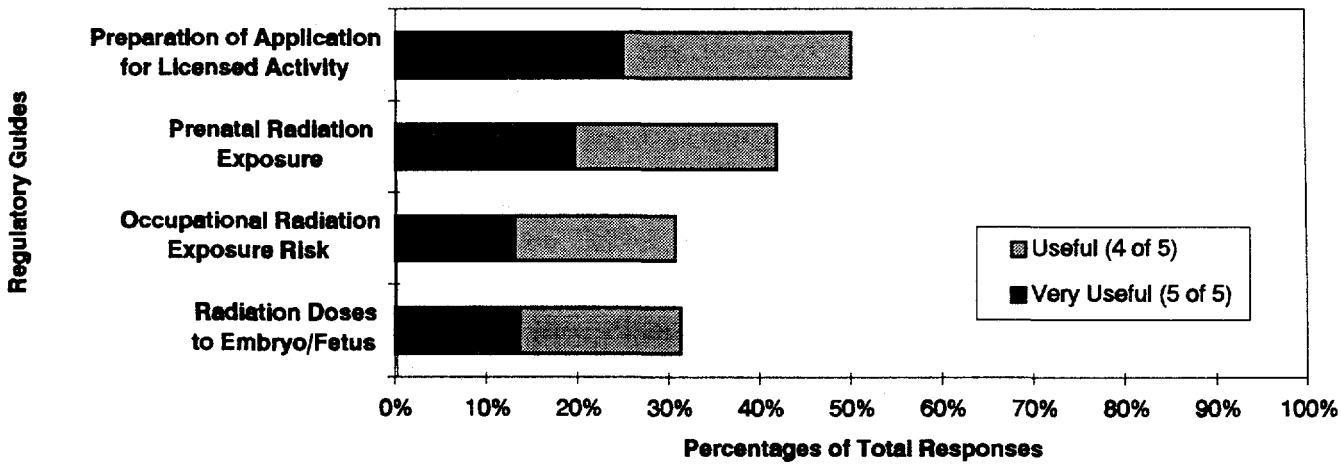


Figure 2.18: Perceived Usefulness of Bioassay Program Regulatory Guide, by Affected Licensee Type
(Question 9)

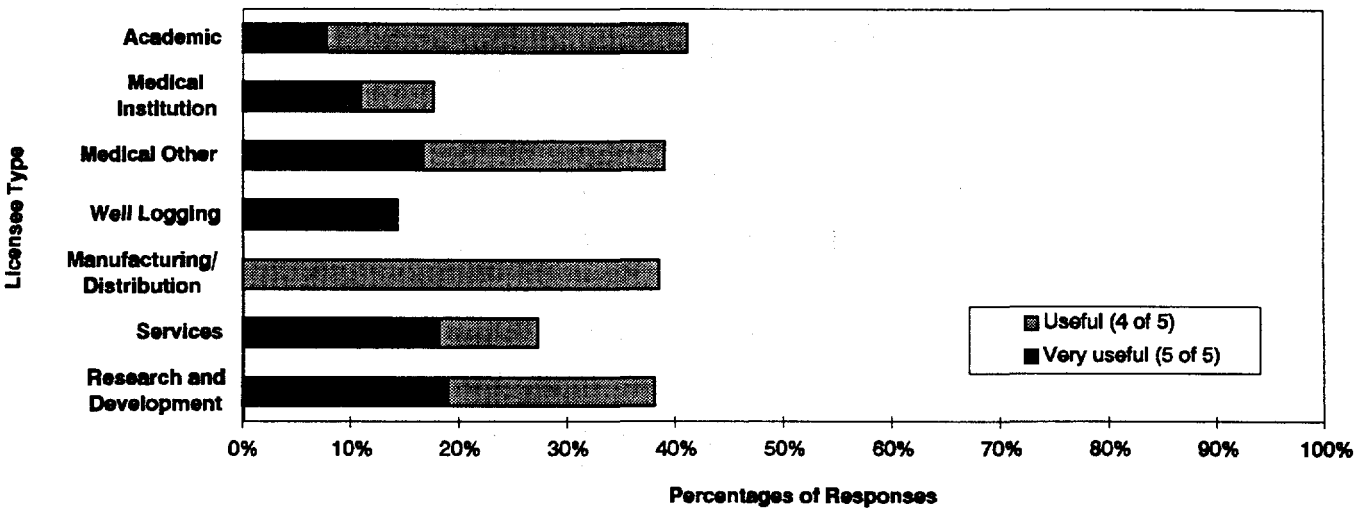
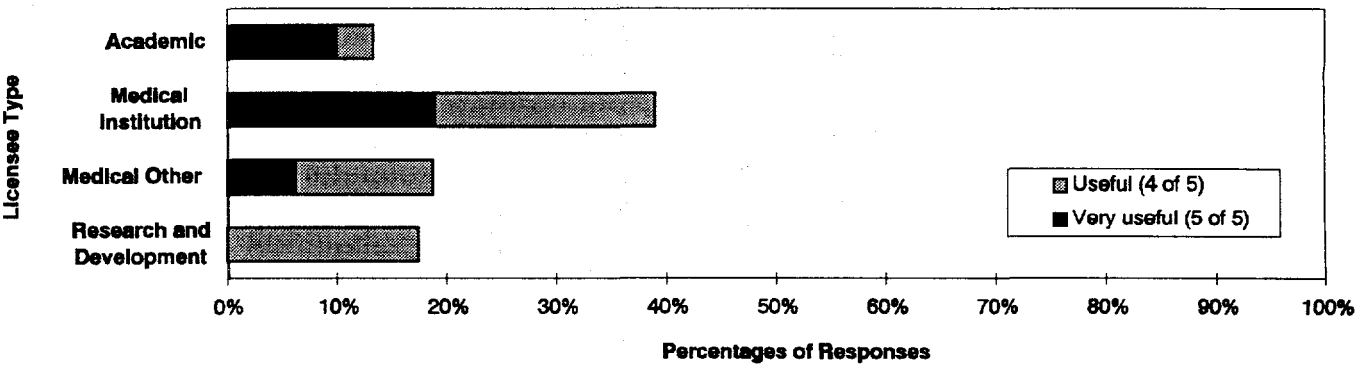


Figure 2.19: Perceived Usefulness of Quality Management Program Regulatory Guide, by Affected Licensee Type
(Question 9)



2.4 Summary

In general, respondents reported their perceptions that both the cost of complying with and the number of NRC regulations have increased substantially over the past three years. These results are coupled with respondents' perceptions that complying with several NRC regulations is high although these regulations make only a low to moderate contribution to safety. Exceptions in terms of regulations rated highly for their safety contribution are Part 20, Radiation Protection,

Part 34, Radiography, Part 35, Medical Use, and Part 39, Well Logging. The major areas that appear to warrant NRC attention in terms of the safety of and cost of complying with regulations (discussed above) include:

- reviewing the safety importance of regulations and identifying ways to increase licensees' awareness of how specific regulations are linked to safe operations;
- monitoring resource burdens of multiple regulations on licensees;
- determining whether licensees are discriminating between more and less relevant information about regulations and policies.

3 LICENSING

The discussion in this section focuses on several key areas regarding NRC licensing activities:

- favorable perceptions among respondents about license reviewer performance and competence;
- concerns about the timeliness of NRC response to requests;
- the relatively limited impact on operations of NRC delays in responding to licensing requests;
- the levels of understanding and perceived usefulness of NRC guidance on licensing actions; and
- issues concerning disagreements with NRC reviewers.

Analyses in this section are based on responses from the 88% of respondents who reported a licensing action in the prior twelve months, a total of 308 respondents. Information from both the survey responses to questions 12 through 18 and written comments provided by respondents are used in the analyses.

For most of the analysis of survey questions, the "medical institutions," "medical other," and "academic" licensee groups have been treated as discrete and separate licensee groups. However, many medical licensees report requesting license amendments[1] and to a lesser extent license renewals. Because the medical licensees taken together represent a large number of respondents (143), they were combined into a single "medical facilities" category in order to examine how medical licensees, as a group, perceived NRC licensing processes. The "medical institutions," "medical other," and the portion (approximately 20%) of "academic" licensees that carry out licensed medical activities comprise the "medical facilities" category. Their responses are discussed in some detail in each section below.

3.1 NRC License Reviewer Performance

Respondents were asked to assess license reviewers' performance on a number of review-related qualities. In general, respondents reported that NRC license reviewers performed well (see Figure 3.1). At least 50% of respondents agreed or strongly agreed that reviewers performed the selected job tasks well. For example, 75% of the respondents strongly agreed or agreed that reviewers were professional in their conduct and 65% indicated that reviewers were helpful. About 60% of the respondents agreed that reviewers were competent in relevant technical fields, applied regulations consistently with what NRC intended, and asked clear and reasonable questions. About half of the responding licensees agreed that reviewers asked only for relevant information and have sufficient knowledge of the respondents' operations to do their job adequately. As shown in Figure 3.1, on average only about 10% to 15% of respondents disagreed with positive statements about licensing reviews (approximately 25% to 30% of respondents were neutral on most statements).

A similar response pattern was observed in almost all instances when we examined the results by license category for each statement about reviewer performance.[2] Two exceptions were in responses in a couple of licensee categories to the statements: "Reviewers applied NRC regulations consistently with what I believe NRC intended" (Figure 3.2) and "Reviewers were competent in relevant technical fields" (Figure 3.3). On average, 60% to 70% of respondents in most

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[1] Nearly 60% of the respondents from this category reported amending their licenses. Only about 20% to 40% of the respondents from the other licensee groups reported amending their licenses. NRC may want to use its License Tracking System to verify this apparent pattern, then determine why more medical licensees are amending their licenses than other types of licensees.

[2] When these results were examined by NRC region, a similar response pattern was observed on almost all the statements about license reviewers. The majority of respondents from each region agreed with the statements in almost all instances. Please see Appendix D for the complete set of regional reviewer evaluations.

Figure 3.1: Experience with NRC Reviewers of License Applications, Amendments, and Renewals
(Question 14)

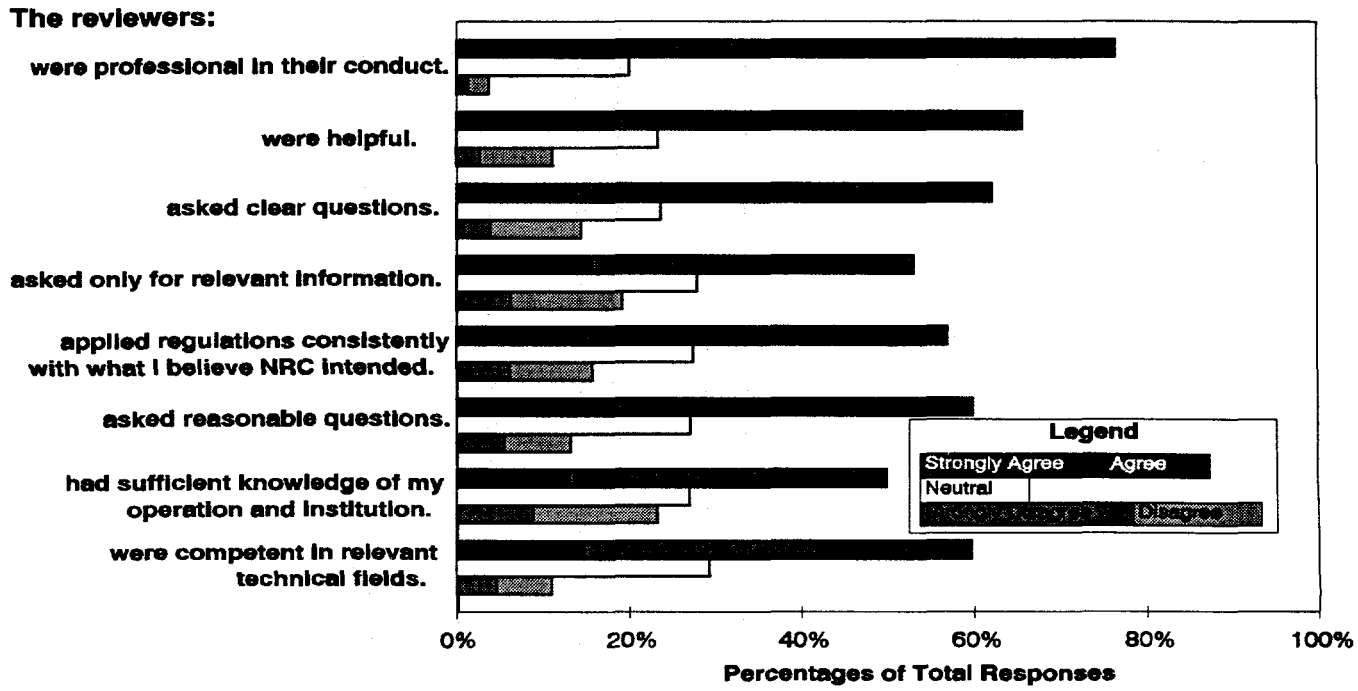


Figure 3.2: Percent Agreeing That Reviewers Applied Regulations Consistently with NRC Intent, by Licensee Type
(Question 14)

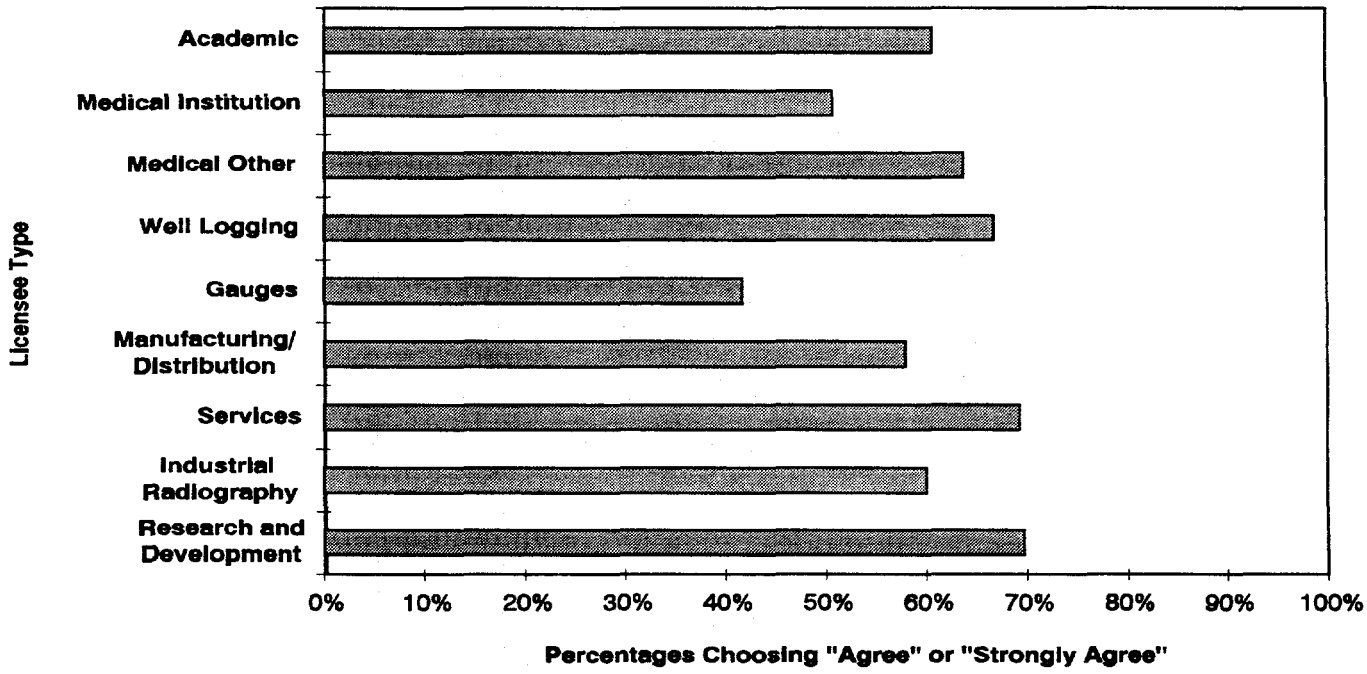
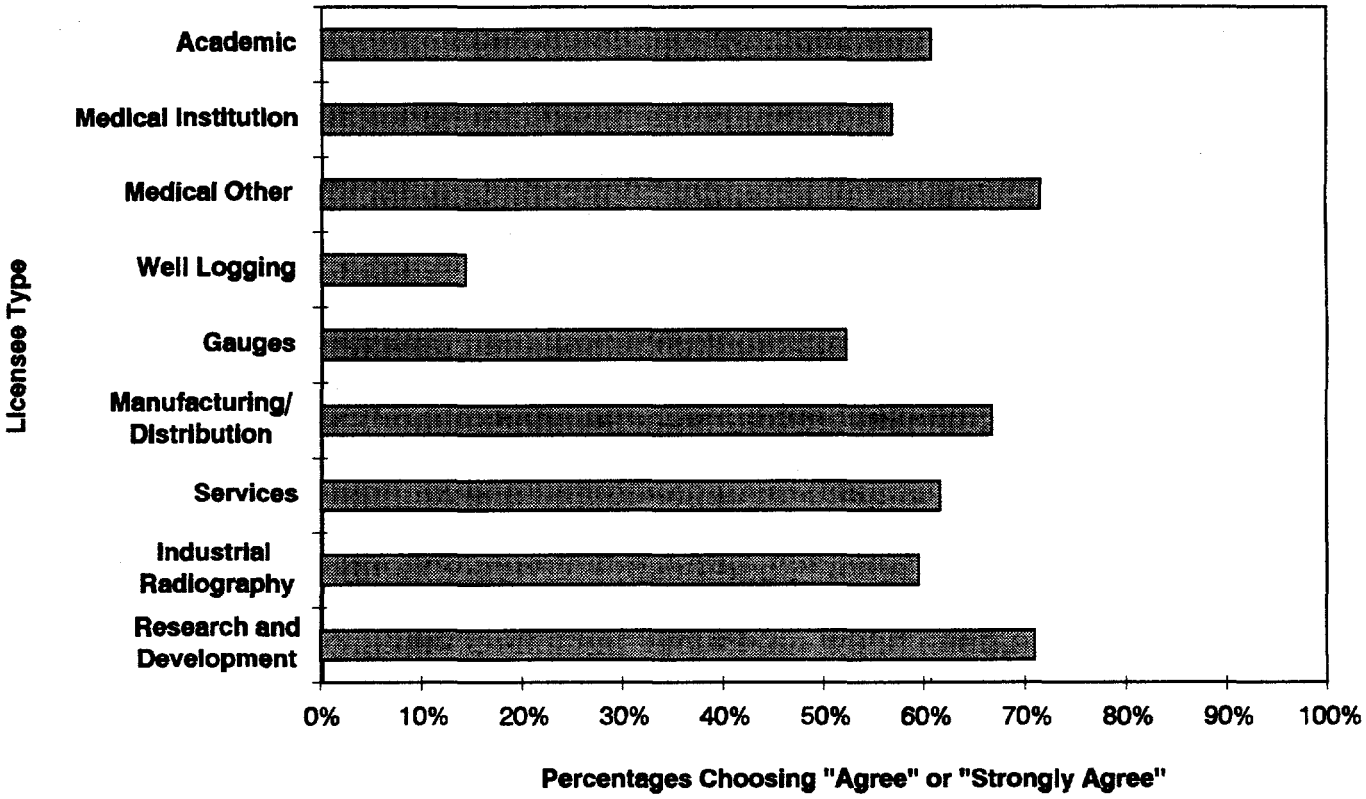


Figure 3.3: Percent Saying Reviewers Were Competent in Relevant Technical Fields, by Licensee Type
(Question 14)



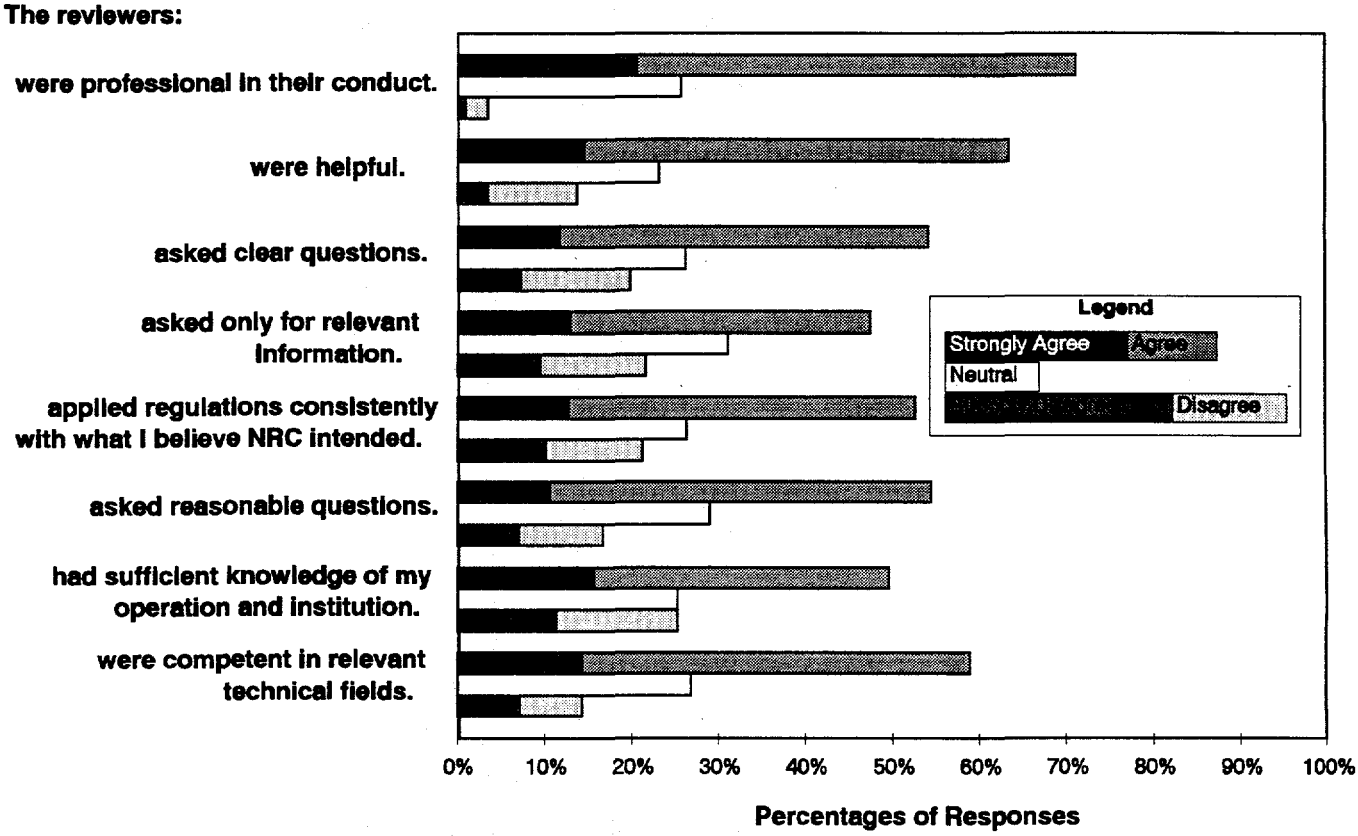
licensee categories agreed or strongly agreed that reviewers applied regulations consistently with NRC intent. The two license categories where fewer respondents agreed or strongly agreed about consistent application of regulations were gauges (about 45%) and medical institutions (about 50%). On the average, about 60% of respondents in almost all categories agreed or strongly agreed that reviewers were competent in relevant technical fields. The only significant exception was well logging licensees, where only 15% indicated that reviewers were competent in the relevant technical areas. (However, this is based on a very small number of respondents (7) who had been involved in a licensing action during the prior 12 months.)

The respondents in the combined medical facilities category provided responses about license reviewer performance similar to the overall responses reported above, but in a few instances tended to be slightly less positive than respondents in general (see Figure 3.4). For example, 47% of medical facilities respondents agreed or strongly agreed that reviewers asked only relevant information compared to 53% of all respondents who agreed or strongly agreed. This was the statement with the lowest percentage agreement of respondents in the "medical facilities" category.

Overall, respondents were positive about the way NRC reviewers carried out licensing reviews. Respondents agreed most frequently (75%) that reviewers were professional in their conduct. They agreed least frequently (50%) that reviewers asked only for relevant information or had sufficient knowledge of the respondents' own operations and institutions.

These results suggest that there is general confidence in the quality of NRC license reviewers' performance and competence. The exception to this general finding suggests that respondents in the combined medical facility category were not as confident as respondents in general that reviewers had sufficient knowledge of respondents' operations.

Figure 3.4: Experience with NRC Reviewers of License Applications, Amendments, and Renewals, by Medical Facilities
(Question 14)



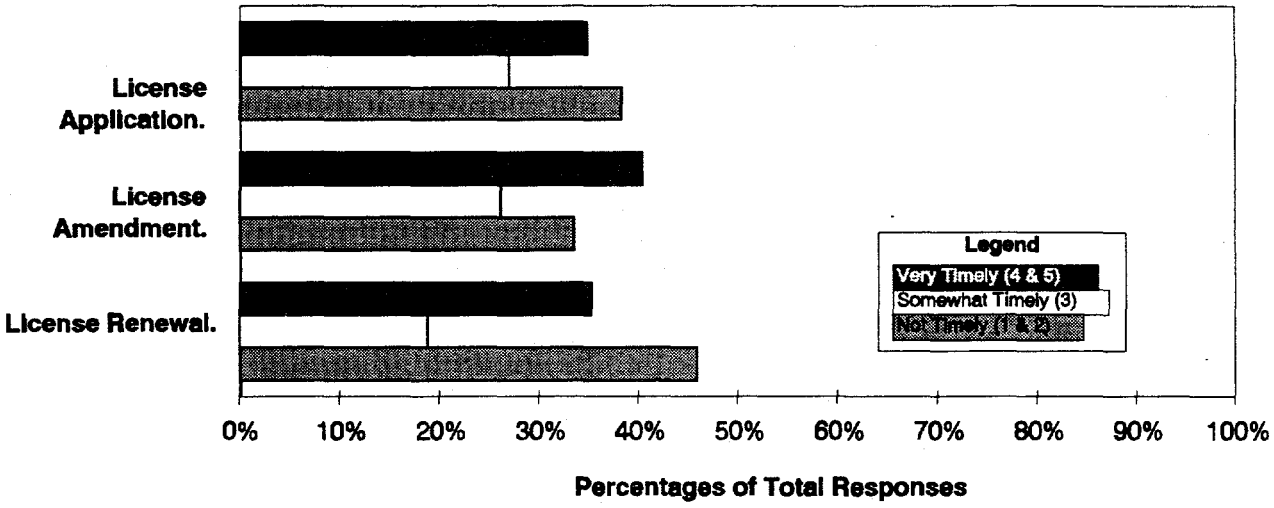
3.2 Timeliness of NRC Response to Licensing Requests

Respondents were asked to rate the timeliness of NRC response to license requests. Over 45% of respondents indicated that license renewal requests were *not* processed in a timely manner. In addition, 38% reported that responses to new license applications were untimely and 33% indicated that responses to amendment requests were not timely. Figure 3.5 displays the distribution of licensee perceptions about the timeliness of NRC response to licensing requests.

Respondents in the combined medical facilities category indicated similar patterns of perceptions of timeliness. Medical facilities respondents, for example, were only slightly more likely (51%) than respondents in general (46%) to report that NRC response to requests for license renewals were not timely. Medical facilities respondents were also slightly more likely to report that NRC response to requests for amendments were not timely (43%) than respondents in general (33%). The comparison between medical facility responses and respondents in general is displayed in Figure 3.6.

There is some variation among licensee groups in their perceptions of NRC timeliness in response to license requests (see Figure 3.7). For example, academic, well logging, and gauges licensees were more likely than other licensee respondents to perceive NRC response to amendment and renewal requests as timely. Medical institution licensees were least likely to perceive NRC responses as timely. The results also indicate that respondents had differing perceptions of NRC timeliness to different types of requests. For example, research and development licensees more frequently described responses to amendment requests as very timely (50%) than renewal requests as very timely (30%). Services licensees also were more likely to perceive NRC response to amendment requests as very timely (45%) than response to renewal requests (25%).

Figure 3.5: Reported Timeliness of NRC Responses to Requests for License Applications, Amendments and Renewals
(Question 15)



In general, while a majority of respondents perceived NRC response to requests for license application, amendment, or renewal as somewhat or very timely, a substantial portion of respondents (35-45%) reported that NRC response was not timely. Concerns about timeliness were also indicated by written comments provided by 37 respondents. One respondent wrote, "[The] renewal process is not timely. We are currently working under 'timely renewal' of our license which expired in 1989." Another respondent wrote, "the 30 day response time for NRC licensing actions is too short when NRC takes 6 months to 5 years to respond to applications for renewals and/or amendments."

With a few exceptions, more respondents across the various licensee categories perceived NRC response to amendment requests as timely than perceived responses to application or renewal requests as timely. However, these differences are not large. Given that over a third of respondents reported lack of timeliness, these results suggest that NRC assess its current application, renewal and amendment processes in order to identify ways to streamline its methods for responding to licensees.

Figure 3.6: Percentage of Respondents Indicating the NRC Response to License Requests was Not Timely
(Question 15)

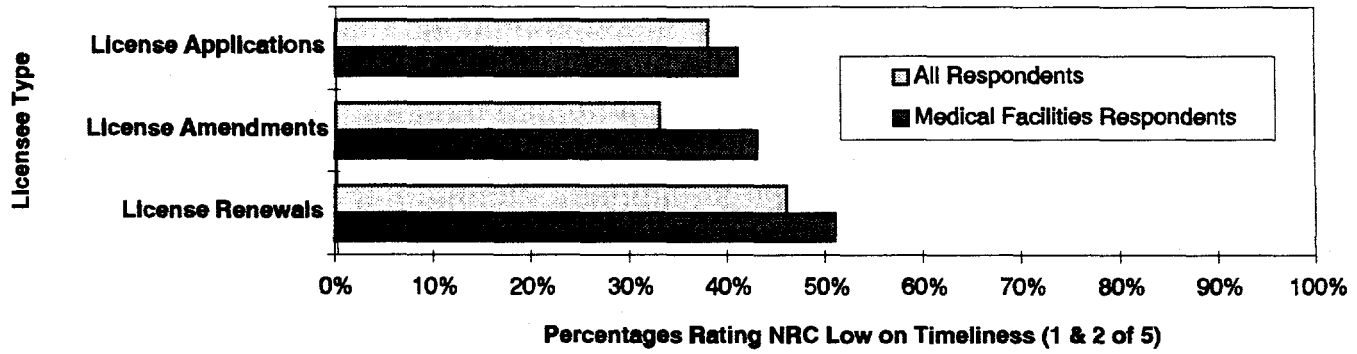
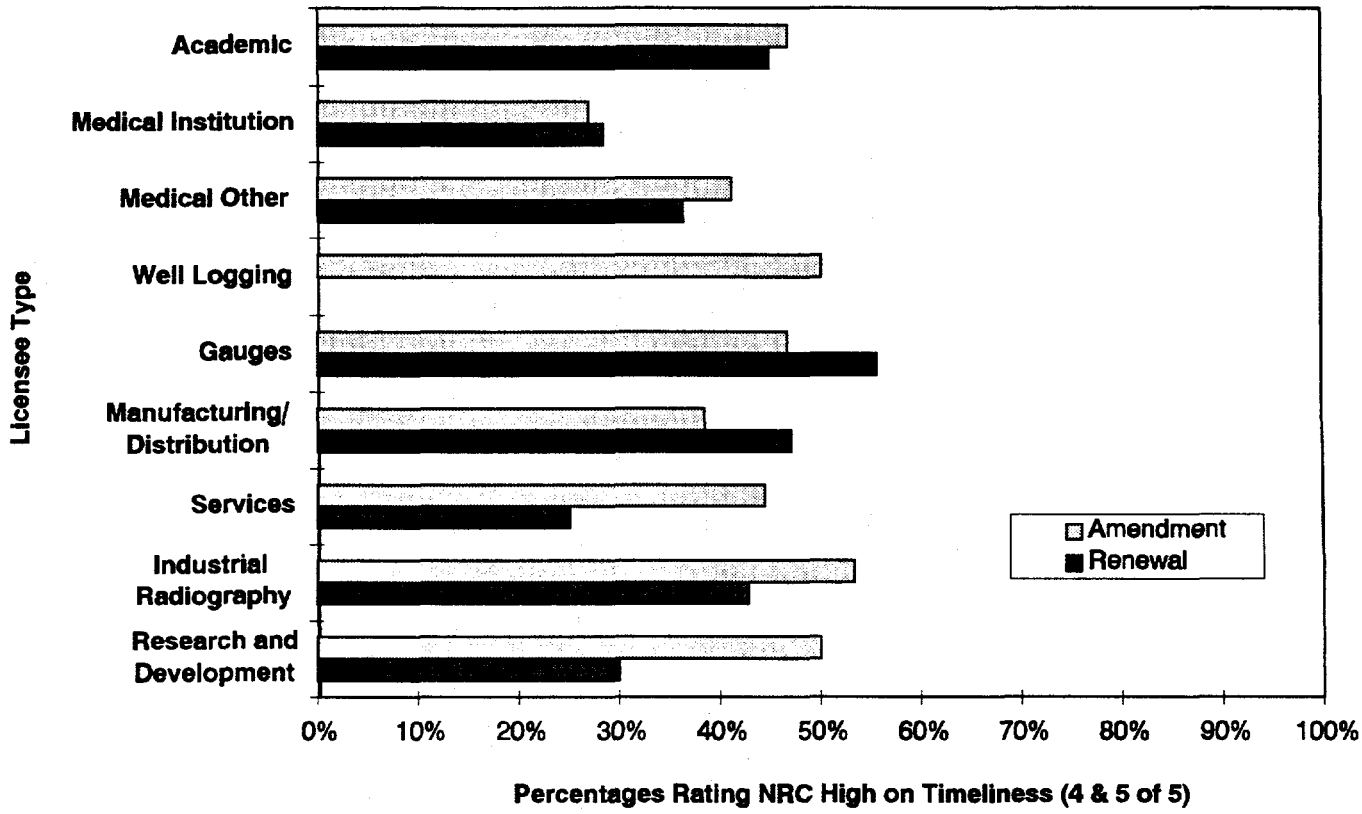


Figure 3.7: Percentages Rating NRC High on Timeliness of Amendment and Renewal Responses, by Licensee Type
(Question 15)



3.3 Impact of Delays in NRC Response to Licensing Requests

Respondents were asked to describe the effect of any experienced delay in NRC response to requests for a licensing action. While lack of timeliness in NRC response is of concern to respondents (as described above, in Section 3.2), delays in response to licensing requests did *not* typically lead to either moderate or serious operational problems (see Figure 3.8). Only 27% of respondents reported that they experienced serious or moderate operational problems due to delays in NRC response and about 22% reported experiencing minor operational problems. About 23% of respondents experienced delays, but incurred no operational problems and about 29% did not experience delays. Responses of the combined medical facilities group reveal similar levels of impact due to NRC response delay (see Figure 3.9). Slightly more medical facilities respondents (31%) than respondents in general (27%) reported serious or moderate operational problems due to NRC delays in response.

Examination of responses by licensee type does suggest some differences in the level of impact caused by NRC delay in response (see Figure 3.10). For example, medical other (40%) and research and development (35%) respondents were more likely than other licensees to report serious or moderate operational problems due to a delay in NRC response. Gauge respondents (15%) were less likely than other respondents to experience moderate or serious operations problems due to NRC delays. Gauges (70%), well logging (62%), and academic (57%) respondents were more likely than other respondents to report either no NRC delays or delays that did not lead to any operational problems.

Overall, most (about 3/4) of the respondents did not report experiencing serious or moderate operational problems due to NRC delays in responding to license requests, although more than one-third of "medical other" (broken out from the

Figure 3.8: Operational Problems due to Delays in NRC Response to Licensing Requests (All Licensee Types)

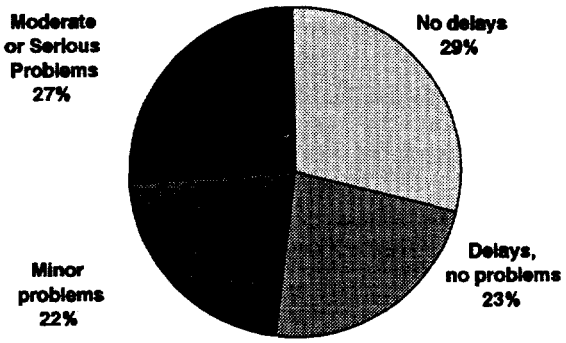
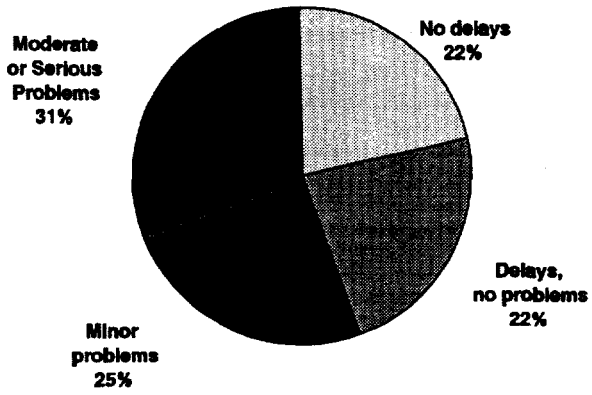
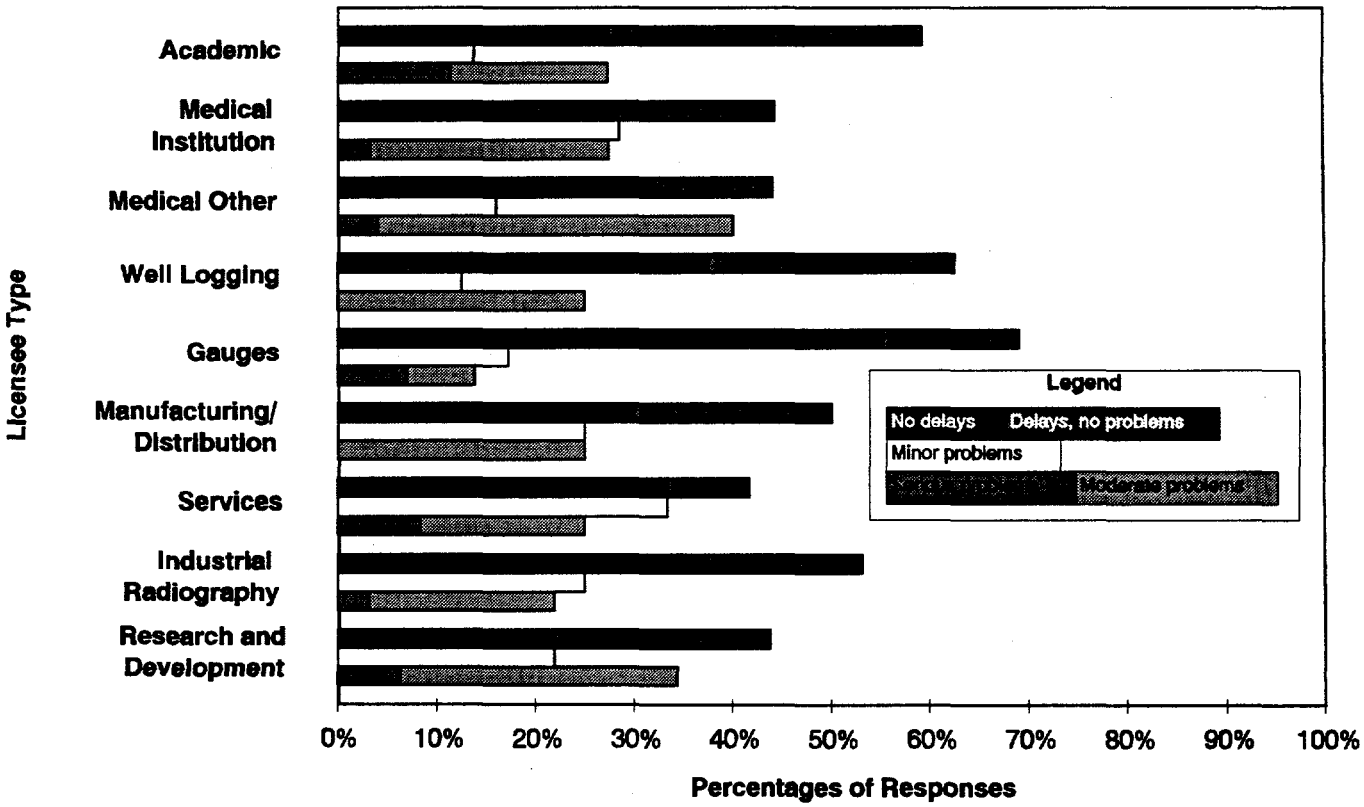


Figure 3.9: Operational Problems due to Delays in NRC Response to Licensing Requests (by Medical Facilities)



medical facilities category) and research and development respondents did report such levels of operational impact. As NRC develops methods for increasing the timeliness of its response to requests for licensing actions, operational problems experienced by licensees due to delays should be reduced.

Figure 3.10: Reported Impacts on Operational Problems due to Delays in NRC Response to Licensing Requests, by Licensee Type
(Question 16)



3.4 Licensing Process: Understanding, Guidance, and Disagreements

Respondents were asked to describe their level of understanding of NRC license review processes and guidance. At least 50% of all respondents reported understanding the processes required to issue, renew, or amend their license. Approximately 20% of respondents, however, indicated that they did not understand these processes (see Figure 3.11).

Respondents also were asked whether NRC guidance was helpful in filing license applications, amendments, and renewals. Slightly more respondents found amendment guidance helpful (52%) than found renewal guidance (48%) and application guidance (45%) helpful. About 45% of respondents reported that they were confident that NRC guidance helped them prepare license information that would be accepted by NRC; about 25% disagreed, and the remaining 30% were neutral (see Figure 3.12). Taken together, these results suggest that a sizable proportion of licensees could benefit from additional and/or different types of information from the NRC about technical and administrative aspects of licensing actions. This is an area recommended for NRC assessment and enhancement.

Respondents were asked to assess how free they felt to notify NRC management when they disagreed with a license reviewer's position. More than one-half of the respondents indicated that they feel free to take further action if they dispute a reviewer's findings. However, about 28% of respondents in general and 37% of medical institution respondents reported that they would not feel free to notify NRC management. Respondents were then asked to describe the actions they have taken to resolve any disputes with a license reviewer. Nearly two-thirds of the respondents indicated that they have disagreed with a reviewer's position on a license issue. Respondents were most likely to call the reviewer directly to discuss the disagreement (39%) or write a letter to the reviewer (23%). Few respondents reported that they ever met with a reviewer (5%) or contacted the reviewer's manager (6%). The results also indicated that only a small percentage of respondents (9%) took no action to resolve their disputes (see Figure 3.13). A few respondents provided written comments that provide some insight into why they may be reluctant to pursue a dispute with license reviewers. A typical written comment described a fear of retaliation during future interactions: "we were fearful that any disagreement would jeopardize our program or license." If the response categories represent a hierarchy of effective dispute escalation techniques, these results suggest that respondents find a phone discussion with, or a letter to, the reviewer most likely to be effective.

Figure 3.11: Understanding Regarding Issuing, Renewing and Amending Licenses (Question 12)

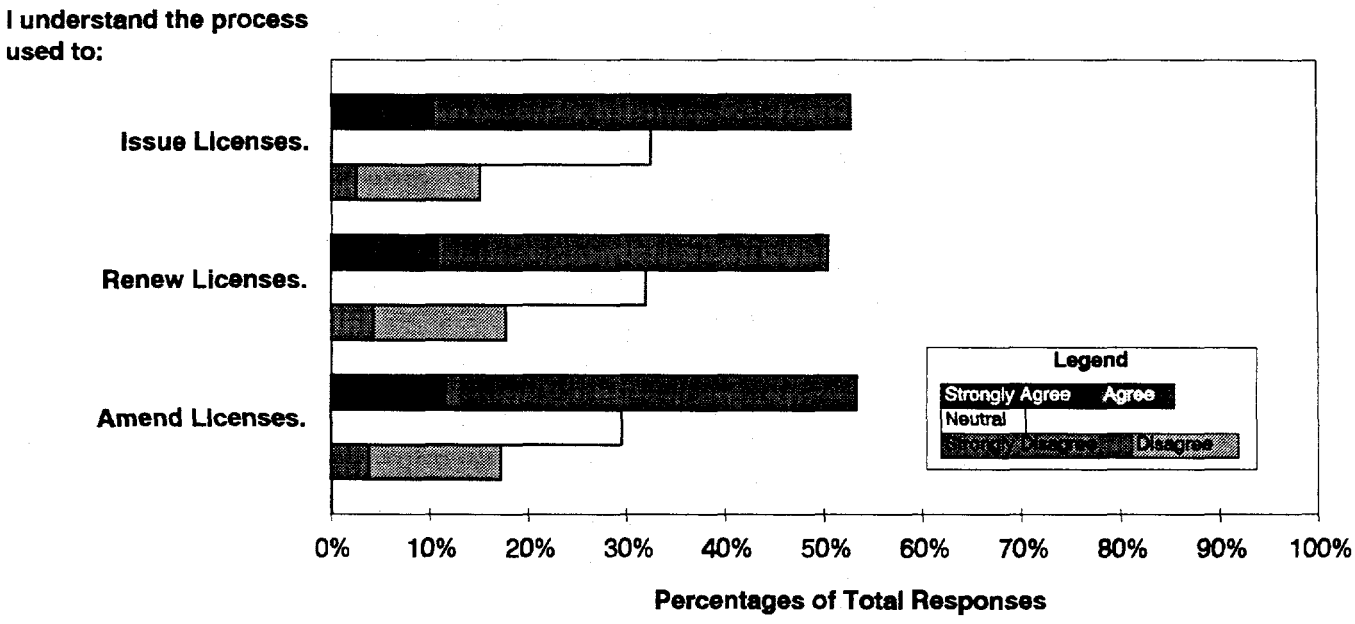


Figure 3.12: Guidance Regarding Issuing, Renewing and Amending Licenses
(Question 12)

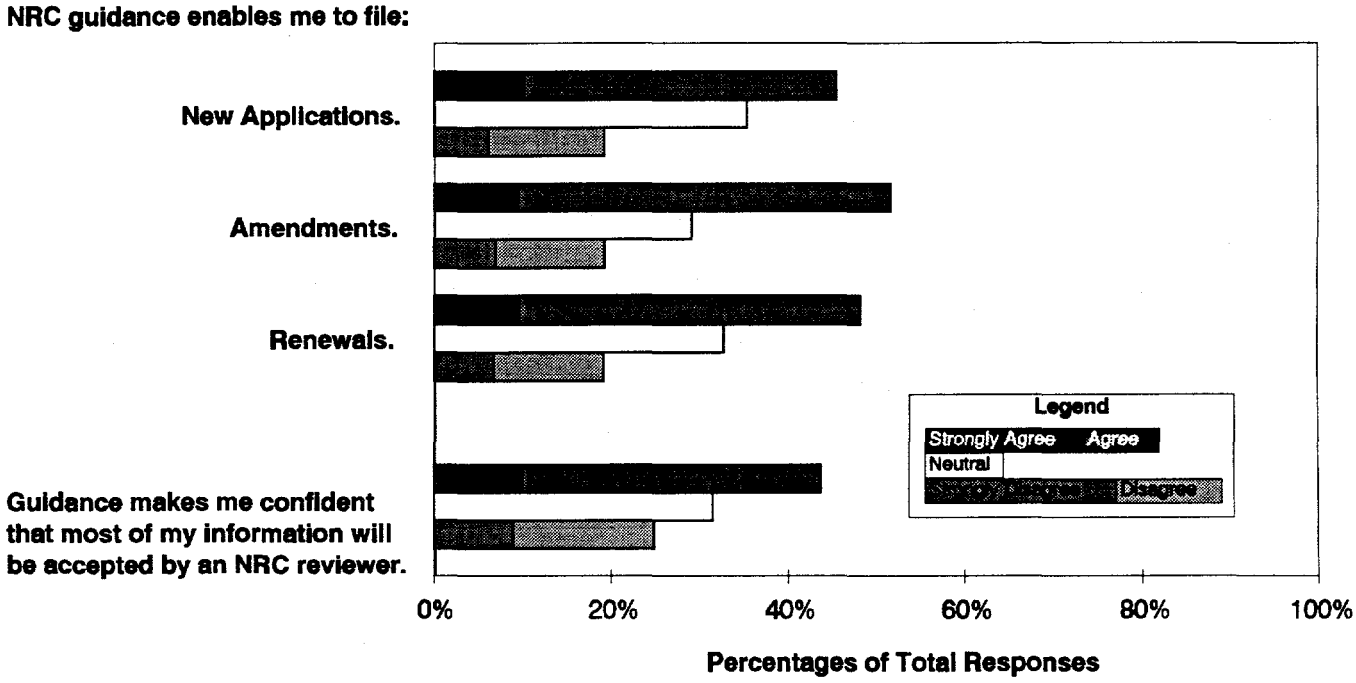
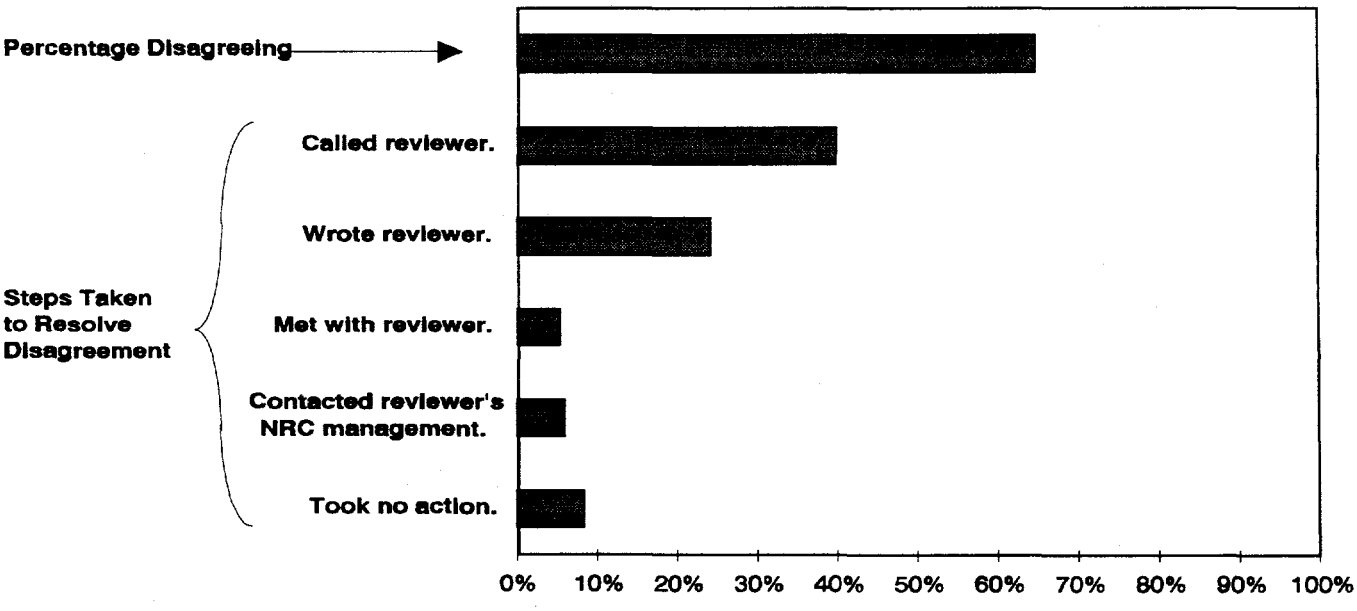


Figure 3.13: Reported Ways of Resolving Disagreements with a License Reviewer
(Question 17)*



* Totals are greater than 100% as multiple responses were allowed.

Overall, the results suggest that many respondents have pursued a dispute they had with a specific license reviewer. More than one-half of respondents indicated that they feel free to contact NRC management with a dispute. Respondents most often used the least confrontational methods to resolve their license disputes.

3.5 Summary

Overall, respondents reported positive perceptions about license reviewers' performance and competence. There appears to be general satisfaction with the quality of reviewers who respond to license requests for applications, renewals, and amendments. Respondents expressed more concern about the lack of timeliness of NRC response to licensing action requests. However, most respondents indicated that delays caused by slow NRC response have not led to moderate or serious operational problems at licensees' facilities. Most respondents reported that they understood the processes to issue, renew, or amend their license, although a sizable portion of respondents indicated that NRC guidance was not as helpful as it could be. Finally, a majority of respondents reported that they feel free to notify NRC management of disagreements over licensing actions although most reported taking less confrontational measures--phone discussions with or letters to the reviewer--to resolve any licensing disputes. A substantial minority of respondents, 28% overall and 37% in medical institutions, however, do not feel free to notify NRC of disagreements. The major areas recommended for NRC attention regarding licensing actions include:

- ways for enhancing reviewers' knowledge of specific operations and facilities;
- methods for improving the timeliness of response to requests for licensing actions;
- ways to further promote a climate open to licensee disagreements; and
- guidance regarding filing amendments, renewals, and applications.

4 INSPECTIONS

The discussion in this section focuses on several key areas regarding NRC inspection activities including:

- favorable perception of inspectors' abilities and performance;
- general willingness of a majority of respondents to pursue disagreements with NRC inspectors;
- overall satisfaction with the frequency and length of inspections; and
- agreement by most respondents that inspections could be improved.

Most of the analyses in this section were based on 70% of the licensees who had had an NRC inspection in the prior 12 months, a total of 241 respondents. Information from the responses to questions 19 through 27 and written comments were used in the analyses.

In this chapter, the respondents in "medical institutions," "medical other," and about 20% of the "academic" respondents whose facilities are licensed for medical activities are once again combined into a single "medical facilities" category in order to examine how they as a group evaluate NRC inspectors and inspections. Their responses are discussed in sections below as relevant.

4.1 NRC Inspector Performance

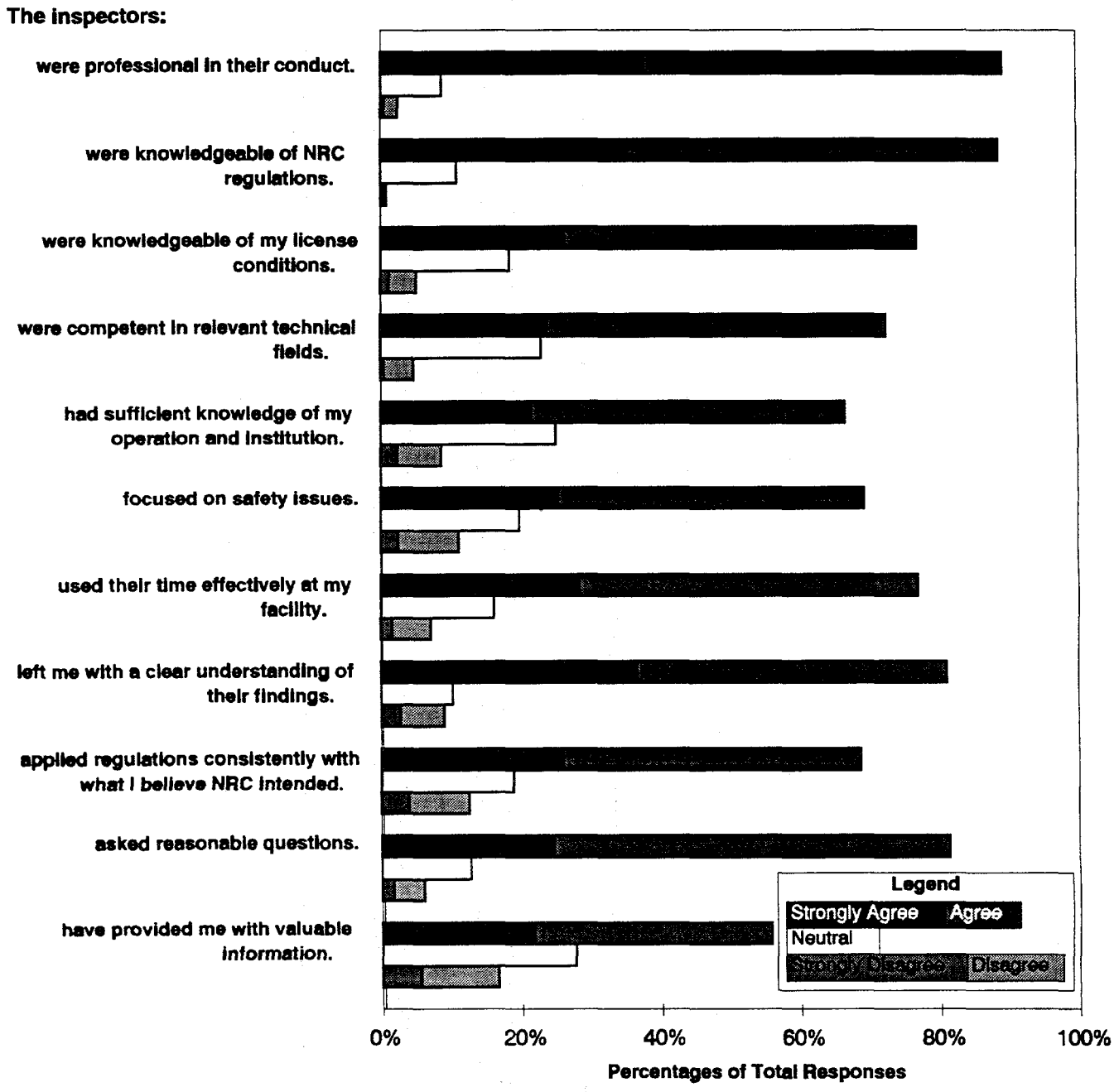
Respondents were asked to assess NRC inspectors' performance on a number of inspection-related qualities and practices. In general, respondents report very positive perceptions regarding the performance of the inspections (see Figure 4.1). Between 60-80% of the respondents agreed or strongly agreed with favorable statements describing inspectors' abilities or inspection practices. For example, more than 80% of the respondents reported that inspectors were professional in their conduct, knowledgeable of NRC regulations, asked reasonable questions, and provided clear descriptions of inspection findings. Only about 10% to 20% of respondents, on average, disagreed with positive statements about inspector quality (approximately 10% to 25% of the respondents were neutral on most statements).

A similar response pattern was observed on almost all the statements about inspectors when responses were examined by license category.[1] Differences from the overall results were usually confined to two or three licensee categories. Variation across licensee groups on three statements about inspectors' abilities or inspection practices: "The inspectors had sufficient knowledge of my license conditions;" "The inspectors focused on safety issues;" and "The inspectors applied regulations consistently with what I believe NRC intended" are shown in Figures 4.2, 4.3, and 4.4.

About 80% of the respondents in most licensee groups agreed or strongly agreed that inspectors had sufficient knowledge of license conditions, while only about 50% to 60% of the respondents in the services, gauges, and well logging licensee groups agreed with the statement (see Figure 4.2). The result for well logging licensees is based on a very small number of respondents (8) who had been involved in an inspection during the prior 12 months. A small number of respondents provided written comments that contradicted this general level of satisfaction with inspectors' experience or knowledge. One respondent sums up this different perspective: "Many NRC inspectors are not familiar with or have no actual work experience in the areas they are regulating. Example: inspectors who clearly don't know what iodination is. They often make unrealistic suggestions or try to impose unreasonable restrictions." In general, however, respondents in all license categories were very likely to describe inspectors as having sufficient knowledge of operations.

[1] When these results were examined by NRC region, a similar response pattern was observed on almost all the statements about inspectors. The majority of respondents agreed with the statements in almost all instances. See Appendix D for the complete set of responses by region.

Figure 4.1: Experience with NRC Inspectors
(Question 20)



Between 60% and 70% of the respondents in most of the licensee groups agreed that inspectors focused on safety issues during inspections (see Figure 4.3). The distribution of responses ranged from a high of over 80% of the industrial radiography respondents to a low of slightly over 50% of the academic respondents who agreed with the statement.

Most of the respondents (from about 65% to 80% in each licensee group) agreed with the statement that inspectors applied regulations consistently with what they believed NRC intended. Only about 50% of the well logging licensees

Figure 4.2: Extent of Agreement that Inspectors Were Knowledgeable of Specific License Conditions, by Licensee Type
(Question 20)

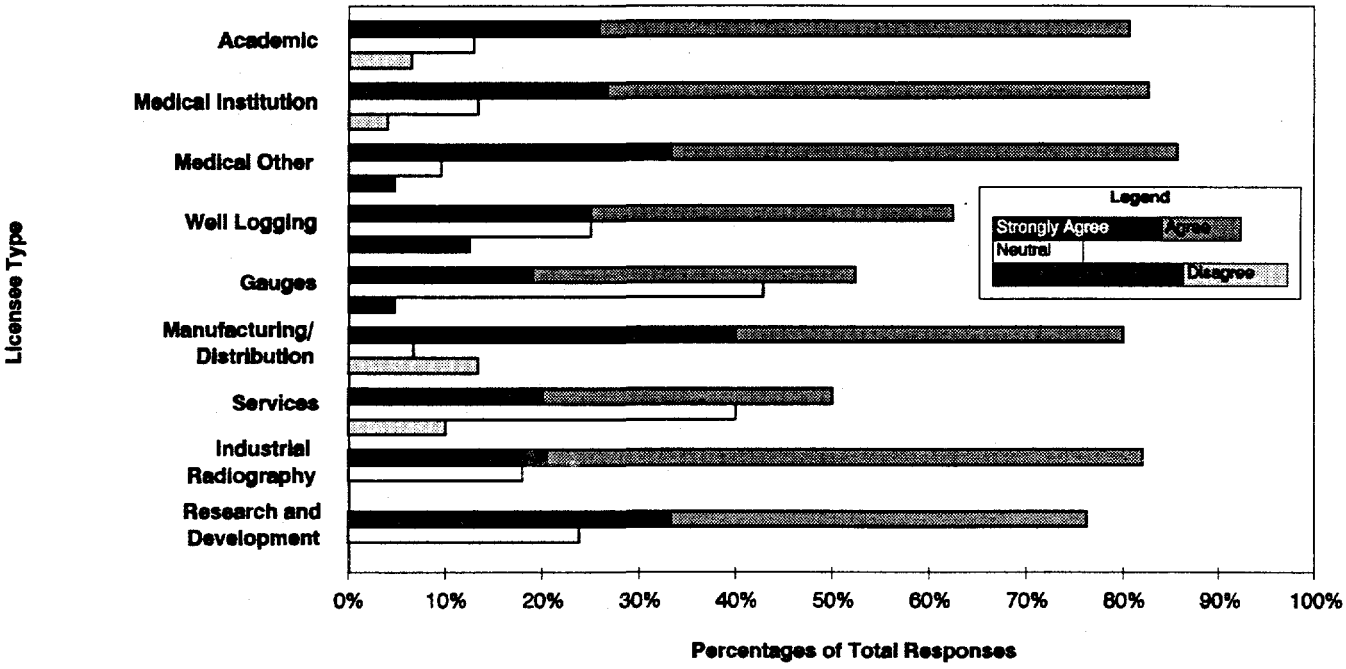


Figure 4.3: Extent of Agreement that Inspectors Focused on Safety, by Licensee Type
(Question 20)

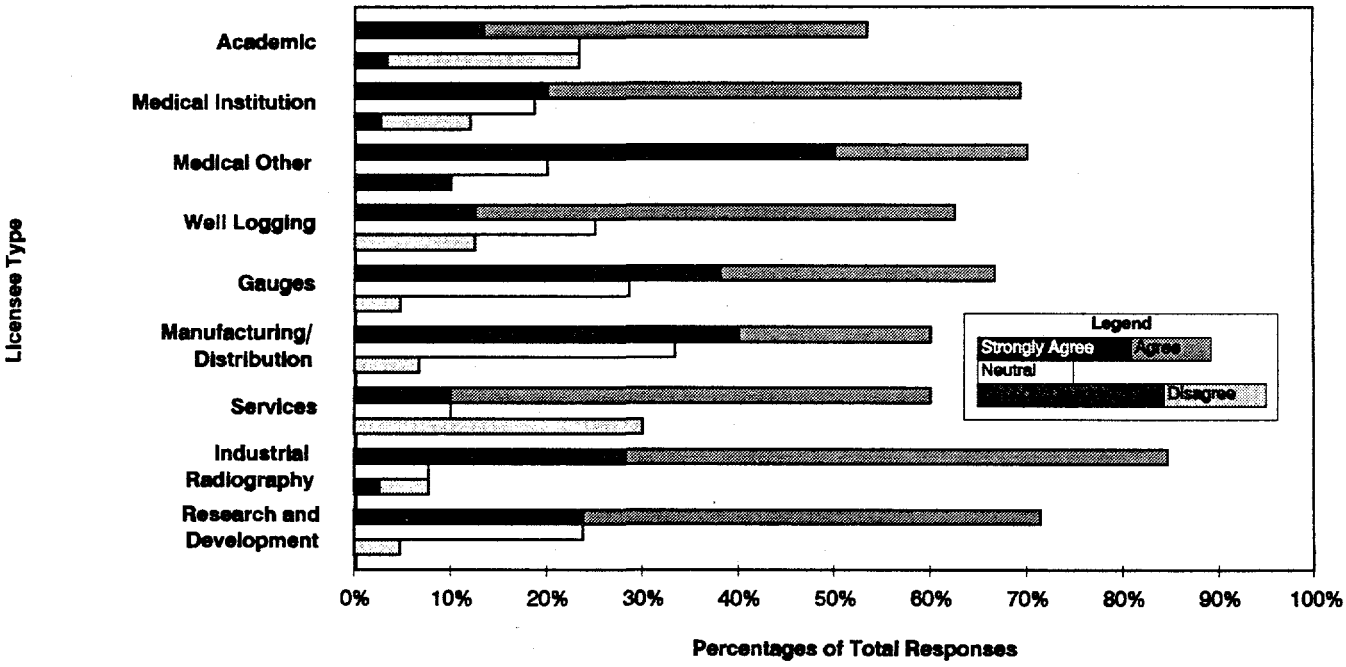
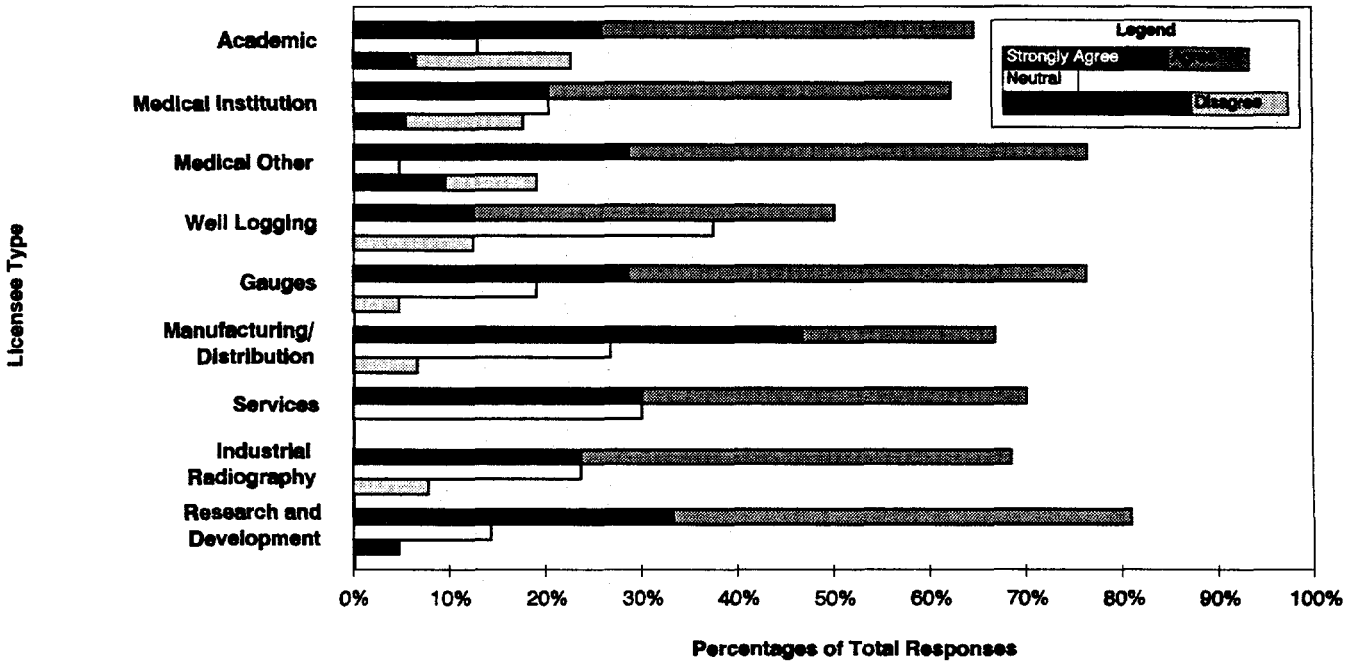


Figure 4.4: Extent of Agreement that Inspectors Applied Regulations Consistently with NRC Intent, by Licensee Type
(Question 20)

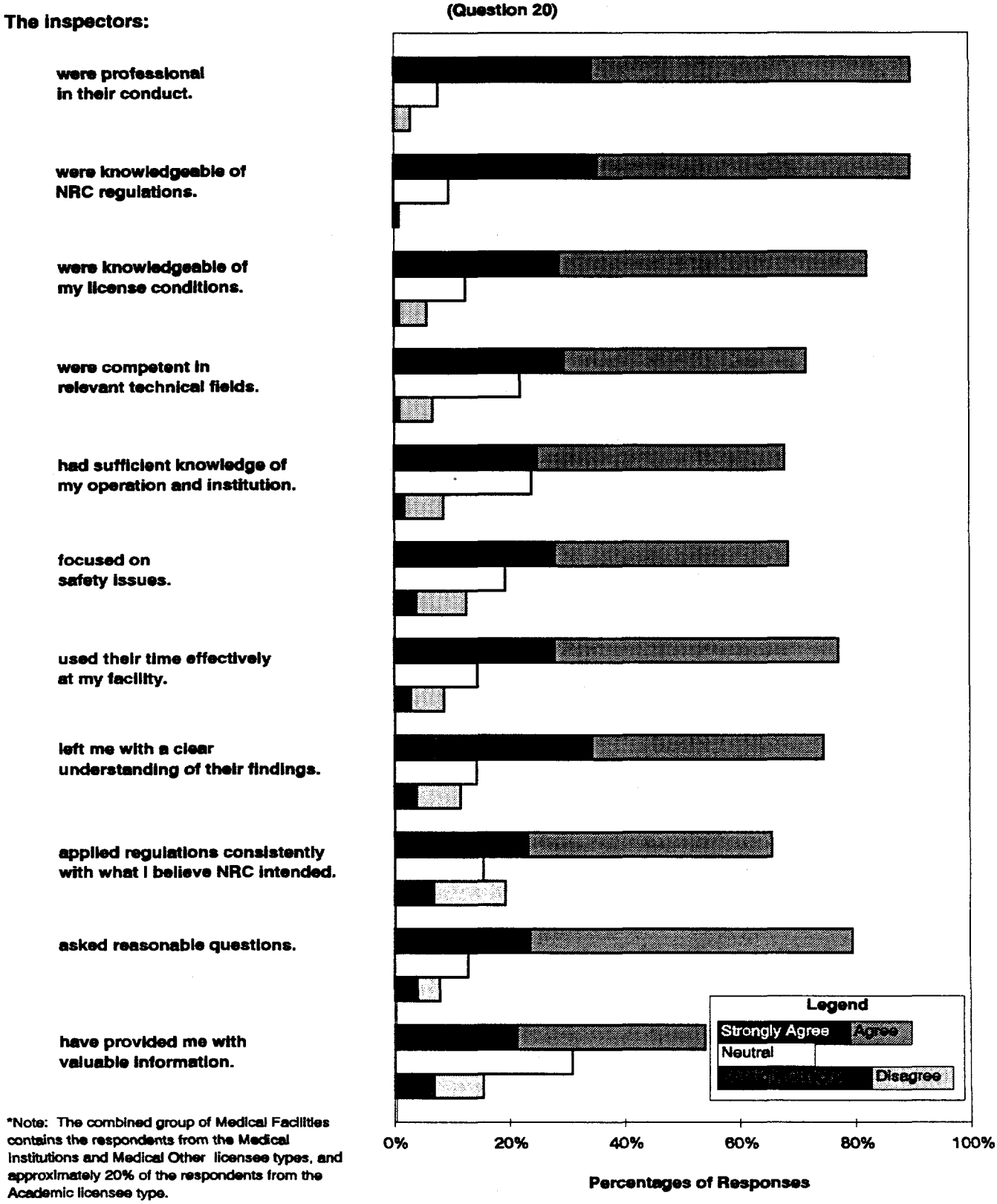


felt this way (see Figure 4.4). Again, the result for well logging licensees is based on only 8 respondents. A few (n=15) respondents, however, provided narratives about incidents where inspectors applied rules and regulations inconsistently. One respondent described inter-*inspector* as well as inter-*inspection* inconsistency: "What is told to us by one inspector is not what is okay by another. And, from inspection to inspection, we are unable to have confidence that our programs and operations will pass the muster." In general, however, respondents in all license categories were likely to indicate that inspectors applied rules and regulations consistently.

The respondents in the combined medical facilities category mirrored the responses about inspector performance from all respondents (see Figure 4.5). For example, 82% of the combined medical facilities respondents and 76% of all respondents agreed that inspectors were knowledgeable of their license conditions.

These results suggest that there is a high level of confidence among respondents in the abilities and inspection practices of NRC inspectors. Respondents are especially positive about inspectors' professional conduct, knowledge of NRC regulations, practice of asking reasonable questions, and ability to provide clear descriptions of inspection findings. The exceptions to these general findings are slight, but include less confidence among respondents in specific license categories that inspectors may not have sufficient knowledge of operations, do not concentrate on safety issues, and do not consistently apply regulations. Written comments provided by some respondents corroborate these concerns. While these concerns are voiced by a minority of respondents in certain license categories, they may suggest areas for improving NRC inspectors' abilities and inspection practices.

Figure 4.5: Experience with NRC Inspectors, by Medical Facilities*
(Question 20)



*Note: The combined group of Medical Facilities contains the respondents from the Medical Institutions and Medical Other licensee types, and approximately 20% of the respondents from the Academic licensee type.

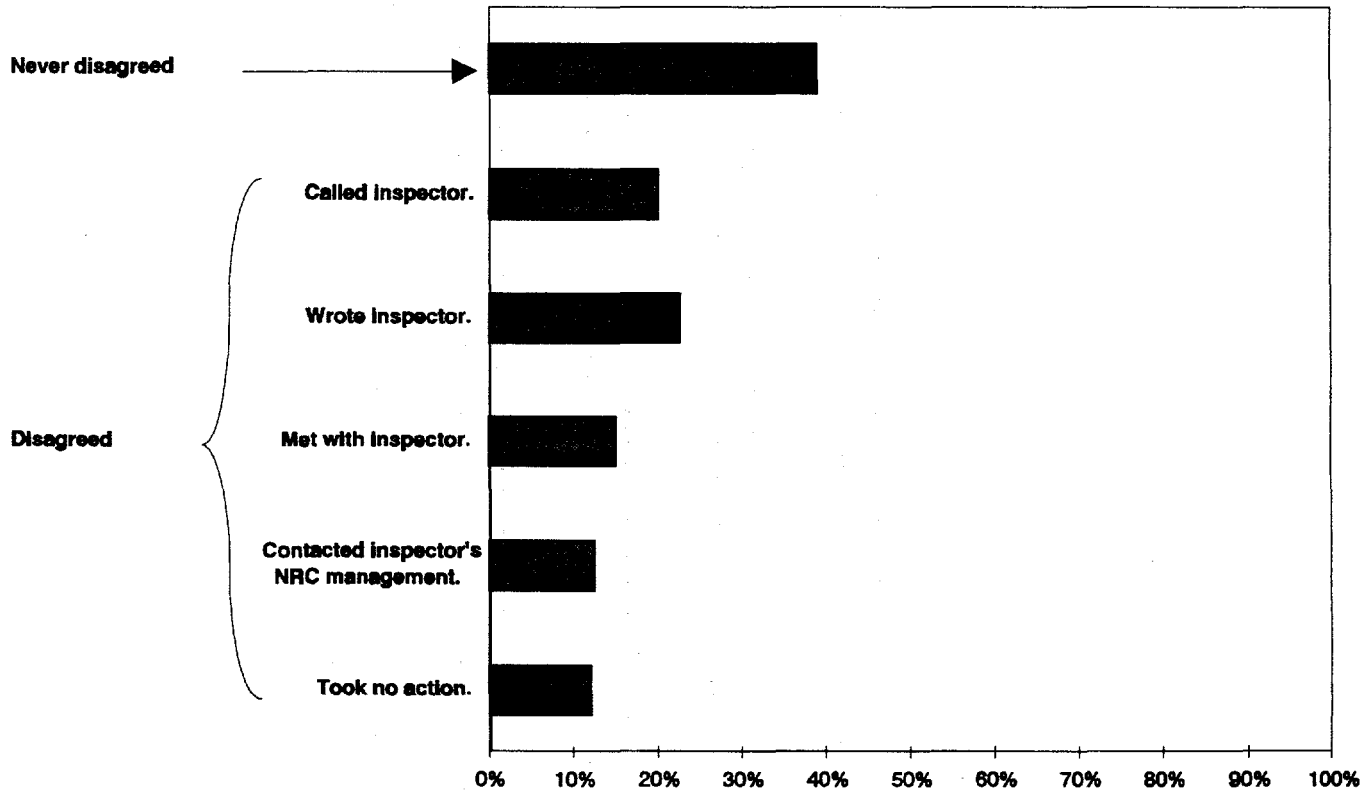
4.2 Actions Taken to Dispute Inspectors' Findings

Respondents were asked to assess how free they felt to notify NRC management if they disagreed with an inspector's findings. About 58% indicated that they felt very free, while 26% reported that did not feel free to notify NRC management. (About 16% of respondents indicated that they felt somewhat free.) Respondents in the well logging (50%) and medical institutions (36%) licensee groups were the least likely to feel free to notify NRC management when they disagreed with an inspector. (Again, the result for well logging licensees is based on a very small number of respondents (8) who had been involved in an inspection action during the prior 12 months.)

Respondents were also asked to describe the actions they have taken to resolve a disagreement when they disagree with an inspector's position on an issue (see Figure 4.6). Over 60% of the respondents had disagreed with an inspector's position on an inspection-related issue. Respondents were most likely to write a letter to the inspector regarding the disagreement (23%) or call the inspector (20%). Few respondents reported that they ever met with an inspector (15%) or contacted the inspector's manager (13%) to resolve a disagreement. The results also indicated that only a small percentage (12%) took no action to resolve their disagreements.

Sixteen respondents described in greater detail actions they had taken to resolve disagreements with an inspector's position on an issue. Five respondents reported taking an issue to a higher level than the inspector (e.g., a management review or a hearing). For example, one respondent reported: "[We] had a hearing before administrative judges - chief judge very incompetent." Another wrote: "[At the] NRC hearing [the] inspector grossly overstated [the] case. [The] inspector [was] not versed in [specific facility] operations." Four respondents said they took no action for fear of future

Figure 4.6: Reported Ways of Resolving Disagreements with an Inspector
(Question 23)*



* Totals are greater than 100% as multiple responses were allowed.

retaliation. One statement represents the others, "Kept my mouth shut, knowing to do otherwise would not be in my best interests."

Overall, the results suggest that the majority of respondents feel free to contact NRC management with a dispute and many respondents have actively pursued disputes with inspectors. When respondents do pursue disputes they most often use letters or phone calls to the inspectors to resolve disputes. Even though many licensees are willing to challenge an NRC inspector or inspection result, the freedom to disagree does appear to be an issue for a minority of respondents (26%), in particular, for respondents from medical institutions (36%).

4.3 Inspection Processes

When asked to describe perceptions of the frequency and length of NRC inspections, between 70% and 75% of respondents indicated that inspections occur as often as they should and take about the right amount of time (see Figure 4.7). Only about 30% of the respondents across most licensee groups reported that inspections were too frequent. One exception to these positive responses about inspection processes was that 55% of medical other respondents reported that inspections were too frequent.

Respondents across all license categories reported being familiar with NRC inspection processes (see Figure 4.8). Respondents tended to be more familiar with the inspection process than with the reporting requirements or enforcement policy. This may reflect the regularity and frequency of the inspection schedule as opposed to more intermittent contact with reporting requirements or enforcement policies.

Figure 4.7: Opinions Regarding Frequency and Length of Inspections
(Questions 26 and 27)

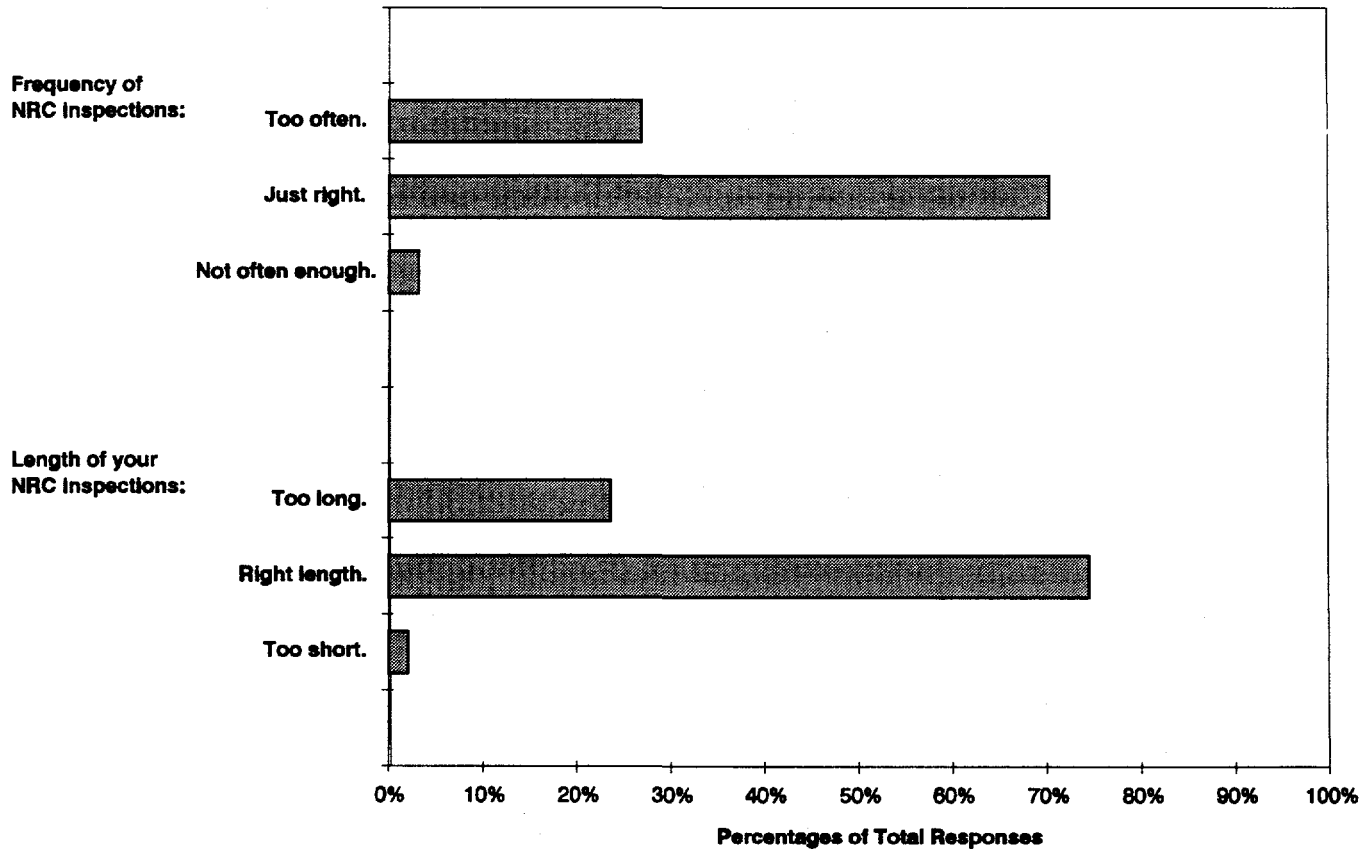
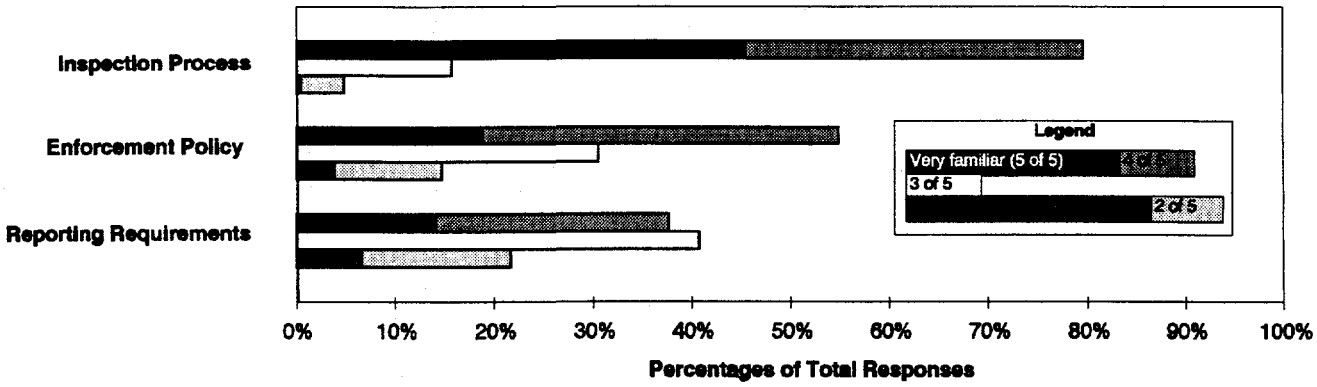


Figure 4.8: Familiarity with NRC Inspection Process, Reporting Requirements, and Enforcement Policy
(Questions 19, 28, and 35)



Overall, respondents reported general satisfaction with both the frequency and the length of NRC inspections. The single exception is reported by 55% of the medical other respondents who find the frequency of inspections too high. Respondents also appear to be familiar with inspection processes in general.

4.4 Respondents' Suggestions for Improvements in Inspections

Most respondents thought there were areas of inspections that could be cut without affecting safety (70%) and that safety areas were being ignored in inspections (90%). About one-fourth of respondents provided general suggestions or examples of areas to cut (N = 69) and a few identified safety areas that were being ignored (N = 21).

Even though many respondents reported that specific areas of inspections could be cut without affecting safety, only eleven provided examples of specific inspection cuts. Other respondents providing written comments focused on general ideas for improving inspections by:

- reducing the amount of time inspectors spend examining paperwork and records (20 comments);
- reducing the inspection schedule frequency or reducing the inspection content itself either by sampling activities to be inspected or basing inspection activities on specific licensee performance (16 comments); and
- improving inspection procedures such as using a clear-cut inspection checklist, communication of inspection results, and a focus on the total program rather than single behaviors (11 comments).

Specific inspection areas to cut included quality management programs, visits to field sites, lab security, equipment demonstrations, meter calibration surveys, rate alarm meters and inservice documentation.

Respondents' concerns about inspections are provided in written comments identifying areas that are ignored during inspections. One respondent wrote, "They are not looking at the whole program or personnel. They are looking to find errors in documentation." Another respondent provided a suggestion for helping interpret the results of an inspection: "The inspector could have a checklist of items to be reviewed and leave a copy when the inspection is completed. Thus, the radiation safety committee is aware that all areas are checked and whether or not they're in compliance." A respondent identified an ignored area of inspection that he or she was concerned could affect safety: "Inspectors do not address manpower issues. This area could have a major impact on safety at any institution." And another reported a related concern: "[The] work load of RSO--does he have the time to properly administer the license?"

Taken together, many respondents (70-90%) indicated that the inspection process could be improved either by cutting or adding areas to current inspection procedures. While most respondents did not follow-up with specific suggestions for improvements, a general sense among the written narratives was the perception that NRC inspections may be too focused on the details and not enough on the whole picture including the licensee's past history. These results suggest that respondents perceive many opportunities for inspection process improvements.

4.5 Summary

Overall, respondents reported very positive perceptions about inspectors' abilities and inspection practices. Respondents also indicated that they were generally satisfied with the frequency and length of inspections. Most respondents reported that they feel free to notify NRC management when they have disagreements about inspections, although about one-quarter still express reservations about challenging inspection results. Finally, many respondents suggested that inspection procedures could be improved, although not many provided specific examples. The major areas that appear to merit NRC attention regarding inspections include ways to create a climate in which more licensees feel free to disagree with inspection results and methods to solicit ideas about inspection process improvements from licensees.

5 REPORTING REQUIREMENTS AND ENFORCEMENT PROCESSES

This discussion focuses on two issues regarding the effectiveness of NRC reporting requirements and enforcement processes including:

- the generally favorable perception that reporting requirements are necessary and not very burdensome; and
- respondents' perceptions that issues giving rise to enforcement processes, including Notices of Violation, fines, and civil penalties, often do not represent significant safety issues.

5.1 Reporting Requirements

Respondents were asked to assess the necessity for and burden created by several specific reporting requirements. In general, respondents indicated that reporting requirements are necessary. For example, 70% or more of all respondents reported that the immediate, 24-hour, two week, and 30 day notification requirements in Part 20 Radiation Protection are all very necessary (see Figure 5.1). More than 60% of respondents indicated that the bankruptcy reporting requirements in Part 30 are very necessary and about 65% reported that teletherapy reporting requirements in Part 35.645 are very necessary. And finally, about 50% of respondents reported that the misadministration reporting requirements in Part 35.33(a)(2) are very necessary.

The positive nature of respondents' perceptions about the necessity of specific reporting requirements are strengthened by respondents' general assessment of the relatively low burden of most of the reporting requirements (see Figure 5.2). For example, less than 20% of respondents indicated that any of the Part 20 reporting requirements (immediate, 24-hour, two

Figure 5.1: Opinions Regarding Necessity of Selected Reporting Requirements
(Question 32)

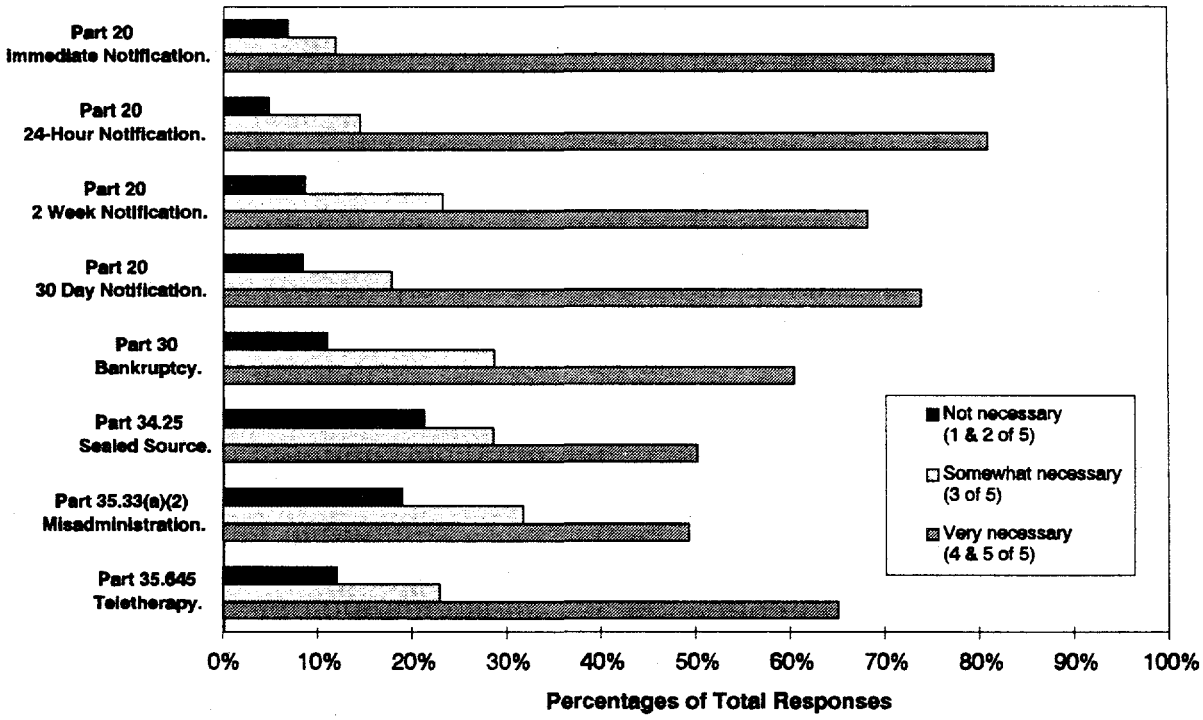
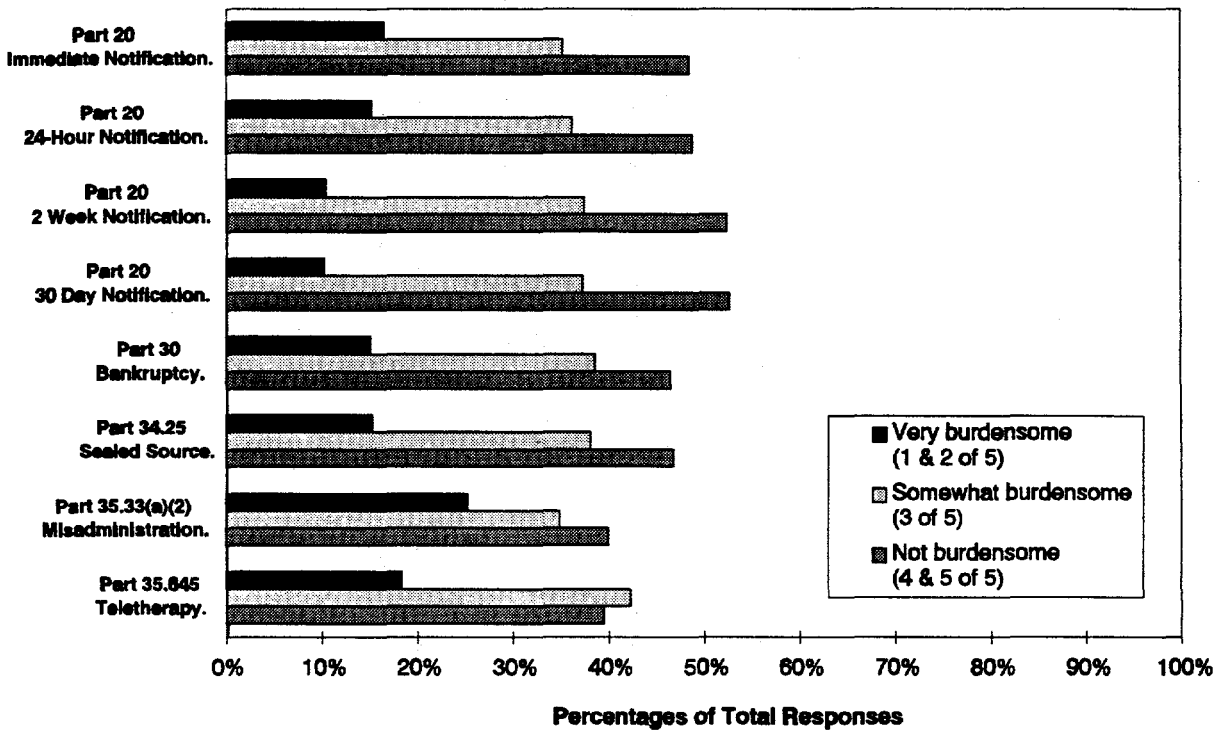


Figure 5.2: Opinions of Burden of Selected Reporting Requirements
(Question 33)



week, 30 day) was very burdensome. Only about 15% of respondents reported that the bankruptcy reporting requirements of Part 30 are very burdensome. However, about 25% indicated that the misadministration reporting requirements of Part 35.33(a)(1) were very burdensome and about 37% found them somewhat burdensome. Only about 18% of respondents suggested that the teletherapy reporting requirements of Part 35.645 were very burdensome, but fully 42% found them somewhat burdensome.

Generally, respondents find the reporting requirements of Part 20 Radiation Protection to be very necessary and not very burdensome. While most of the other reporting requirements are generally considered very necessary, there are differing perceptions of how burdensome the requirements are to licensees. Part 35.645 teletherapy and Part 35.33(a)(1) misadministration reporting requirements, in particular, are considered at least somewhat burdensome by the majority of respondents. These results suggest that NRC has found a good balance between the perceived usefulness and burden for many, although not all, reporting requirements.

5.2 Enforcement Processes

Respondents were asked to assess the safety significance of issues which resulted in enforcement actions. About 60% of respondents reported that they have received a Notice of Violation (NOV) and virtually all who have indicated that they know how to respond. Of those respondents who have received an NOV, less than 30% reported that the issue for which they received the notice represented a significant safety issue (see Figure 5.3). Respondents in academic, medical institutions, medical other, well logging, and gauges license categories were most likely to question the safety significance of their NOV (see Figure 5.4).

Very few respondents reported that they had participated in an enforcement conference (about 20%) or had received a fine or civil penalty (10%). Those respondents who had participated in an enforcement conference generally agreed with

Figure 5.3: Notices of Violation (NOVs)
(Question 36)

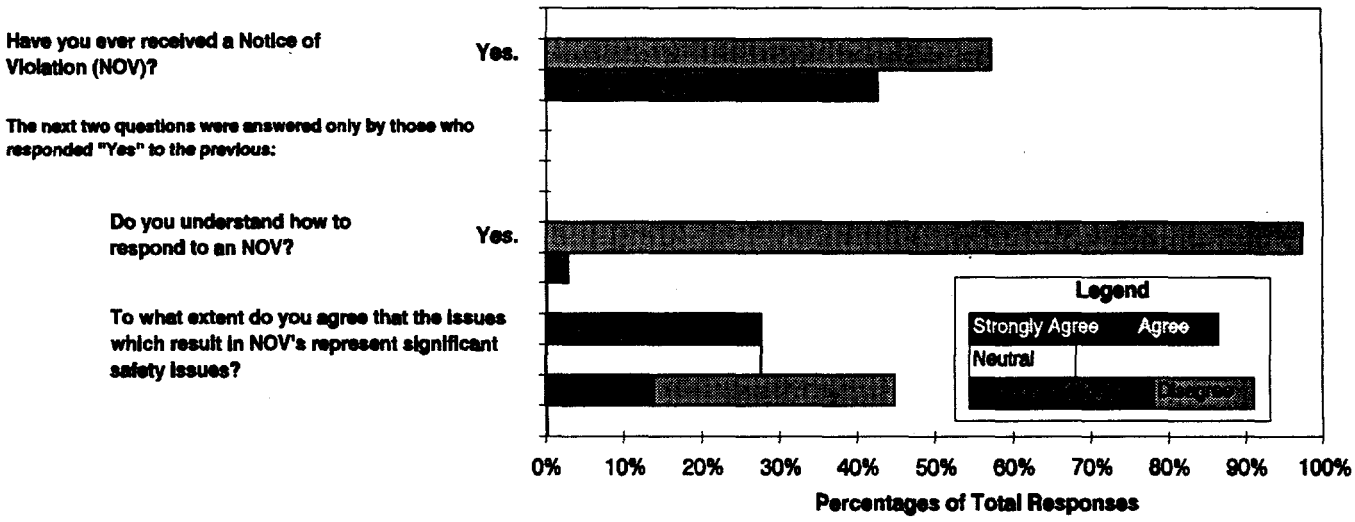
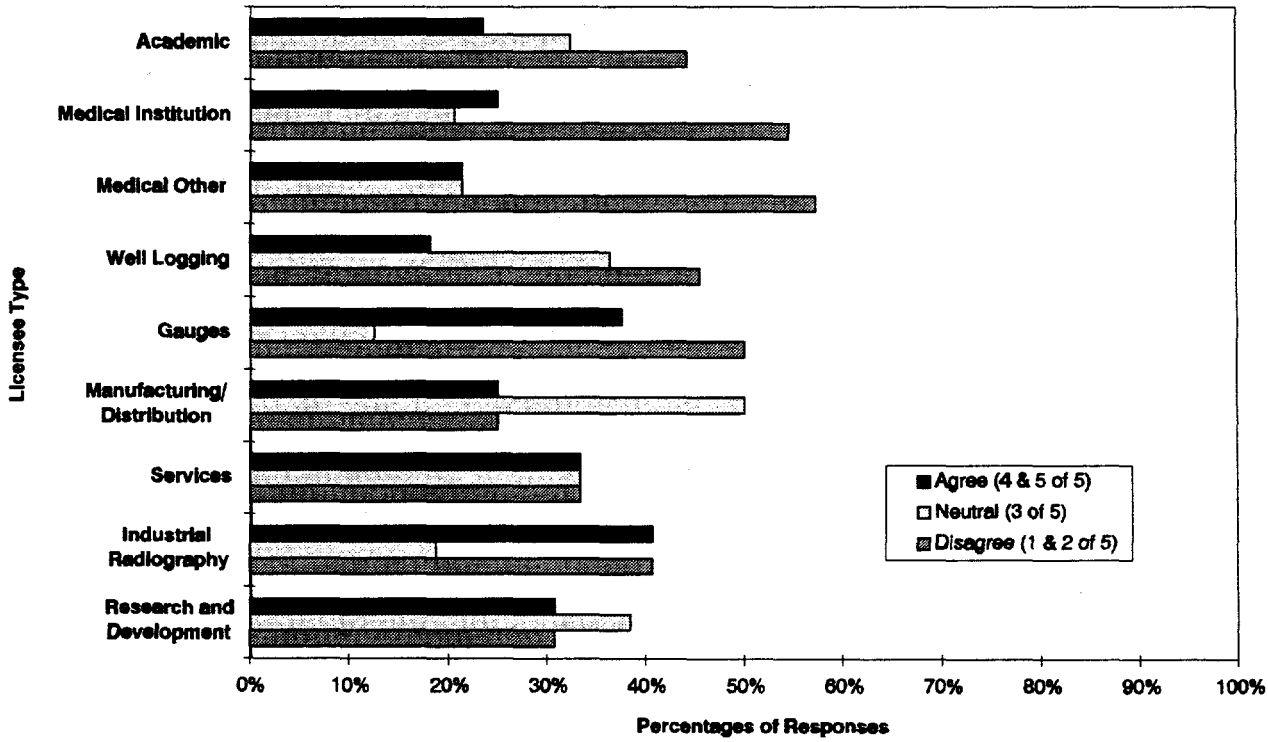


Figure 5.4: Extent of Agreement that Issues which Result in Notices of Violation (NOVs) Are Safety Significant, by Licensee Type
(Question 36)



the usefulness and fairness of the process (see Figure 5.5). However, almost 60% of the respondents who reported participating in an enforcement conference questioned the safety contribution of imposing civil penalties. More than half of those respondents who have received a fine or civil penalty question whether the issue for which they were fined was a significant safety concern (see Figure 5.6).

Receiving a Notice of Violation seems to be a common occurrence among respondents while participating in an enforcement conference or receiving a fine or civil penalty is relatively rare. Of those respondents receiving a Notice of Violation, fine, or civil penalty, virtually all know how to respond. Of those same respondents, many (45-60%) do not perceive these sanctions to be related to safety significant issues in their facilities. These results indicate that many respondents do not believe that NRC enforcement processes for civil penalties contribute to safe operations at their facility.

Figure 5.5: Opinions Regarding Enforcement Conferences
(Questions 37 and 38)

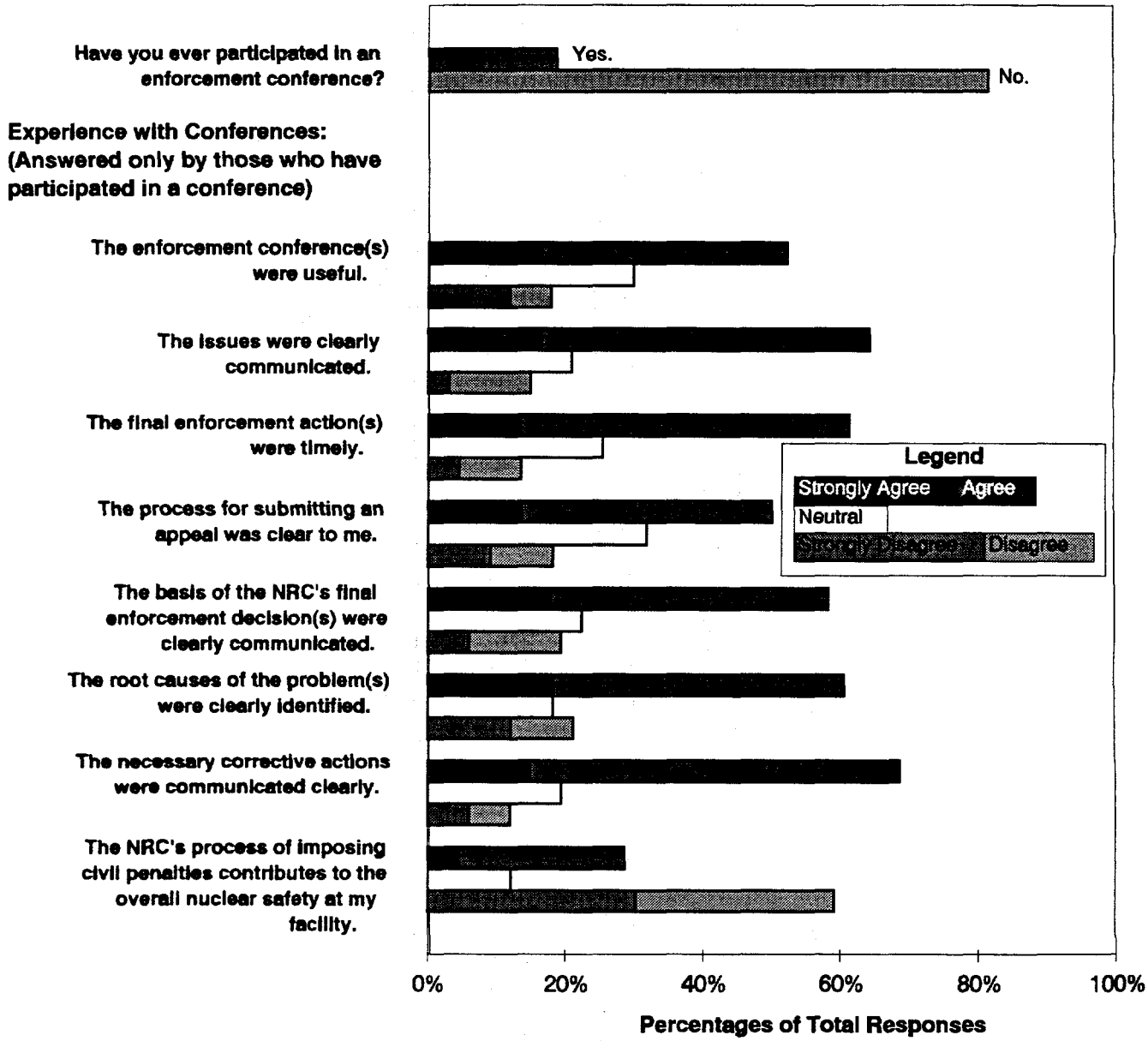
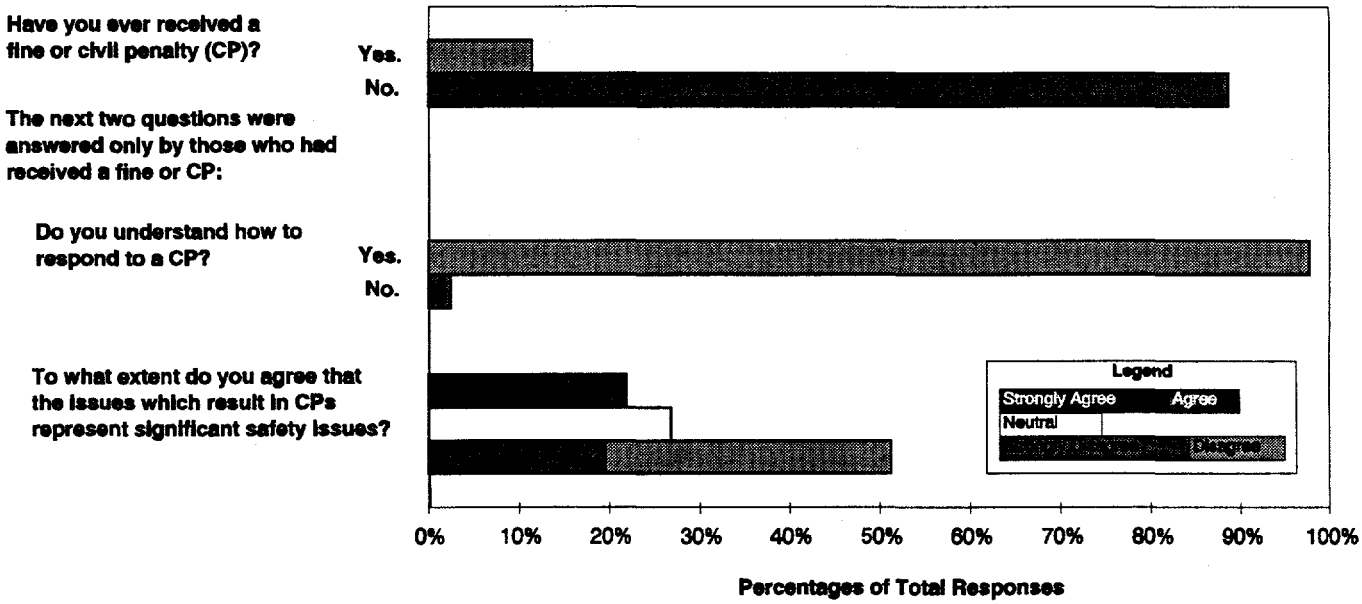


Figure 5.6: Experience with Fines and Civil Penalties
(Question 39)



5.3 Summary

In general, respondents perceive Part 20 Radiation Protection reporting requirements as very necessary and not very burdensome. While respondents consider most of the specific reporting requirements necessary and not very burdensome, they also identified two reporting requirements (Part 35.645 teletherapy and Part 35.33(a)(1) misadministration) that they consider at least somewhat burdensome. Although many respondents have received a Notice of Violation at some point, very few have ever participated in an enforcement conference or received a fine or penalty. Of those who have, many (45-60%) question the safety significance of the issues for which they were sanctioned. The recommended areas for NRC attention in enforcement actions are to review the safety importance of issues that lead to sanctions and to identify ways to increase licensees' understanding of how enforcement processes and sanctions for important safety concerns enhance the safe handling of nuclear materials at their facility.

6 OTHER ISSUES OF CONCERN

An impressive number of individuals took the time to provide written statements in the open-ended questions throughout the survey, including the final question requesting additional comments. In most instances, these comments provide concrete and powerful illustrations of the survey results and are used throughout the report to help the numbers of the analyses come alive with respondents' experiences. An analysis of the narrative comments shows that respondents in all licensee categories gave examples of their concerns and made suggestions about possible improvements. No one license category type dominated the open-ended responses.

170 respondents, 46% of the total sample, provided additional comments at the end of the survey in response to a general request (Question 46). Many respondents discussed several different issues in their written comments. Most of these comments have been integrated into the analyses and discussions in previous chapters including:

- 40 comments about the increasing costs of operating a licensed facility that were integrated into discussion of the cost of complying with NRC regulations (Question 4);

- 39 comments about specific regulations that have been integrated into discussions of sections of regulations that are particularly effective at enhancing safety (Question 7) and sections that are particularly counterproductive to safety (Question 8);

- 45 comments about NRC practices, including 37 comments about NRC response timeliness that were integrated into discussion of timeliness of response to licensing requests (Question 15); and

- 48 comments about inspections and inspectors that have been integrated into the discussions of areas for improvement in inspections (Questions 21 and 22).

Respondents also provided information in written comments, both in Question 46 and throughout the survey, about two additional issues: a concern voiced by 55 respondents that the NRC fee structure was rising precipitously and concerns expressed by 42 respondents about an increasingly adversarial position taken by NRC reviewers and inspectors.

Of the 55 respondents who provided comments about NRC fees, 31 focused primarily on annual fees for licensed activities, while 24 respondents added concerns about other rising fees including inspection and amendment fees. An additional 18 respondents discussed costs associated with complying with NRC regulations including the cost of civil penalties. (These concerns are discussed in more detail in Section 2.3 above). One respondent described concerns about fee increases without related safety increases: "I am sorry to say that NRC fines and regulations have skyrocketed lately with very little increase in safety. Is the NRC interested in safety or just in feathering their nest?" Several respondents listed all the fees they paid to NRC during the last year and others described the rate of increase over the past five years. One respondent expressed the opinion, "NRC activities and their related costs stifle innovation, degrade safety and increase costs." There is some indication that these self-selected respondents believe that the cost of NRC regulation has some negative impacts on the safe handling of nuclear materials.

Of the 42 respondents who indicated their concern about an increasingly adversarial relationship developing between licensees and NRC staff, 23 provided comments in response to Question 46 and 19 provided comments in response to a variety of other open-ended questions throughout the survey including Questions 10 (comments on NRC regulations), 17 (actions taken in dispute with reviewer), 21 (inspection areas that could be cut), 22 (inspection areas that are ignored), and 23 (actions taken in dispute with inspector). One respondent summed up these concerns, "I feel strongly that in the last ten years our interactions with the NRC have gone from cooperation to very adversarial." This sense of a change in the relationship, from "helpmeet" (in the terms of one respondent) to "prosecutorial" (in the terms of another respondent), runs through many of the written comments. Respondents appear to be concerned that the agency they found *helpful* in managing nuclear materials at their facility was becoming less of a partner in creating safe workplaces. (A few respondents provided written comments that described their perception and satisfaction with a cooperative NRC. These comments will be discussed in more detail below.) While only a small portion (about 10%) of respondents provided

comments about this changing relationship between licensees and the NRC, the results suggest a relatively strong underlying current of concern. There appears to be a certain amount of good will among these respondents toward the NRC as an agency that previously helped them meet their radiation safety obligations.

A few respondents had specific ideas for ways to improve their interactions with the NRC. These included training classes and/or modules for radiation safety officers as well as other staff who come in contact with nuclear material. Another respondent suggested a software program designed to help licensees track required items, including license renewals and inspections. And one respondent suggested a central contact number for inquiries into the status of NRC actions such as license reviews.

The survey was designed to evaluate the effectiveness of NRC regulations, inspections, licensing, reporting requirements, and enforcement processes and the body of this report discusses the results of those evaluations. However, twelve respondents took the opportunity provided by the survey to give unsolicited positive comments and praise for the NRC. In general, these respondents found the NRC to be much more helpful than other federal agencies with which they interact. One respondent describes this perception: "NRC has been reasonable in both inspections and conversations. They do a better job than other government agencies in keeping regulated industries informed about policies." Another respondent describes his satisfaction with the helpfulness of the NRC: "To date, I have found the NRC to have the right attitude and degree of cooperativeness [sic] to help us understand and meet regulatory requirements. I believe they deserve high marks for a regulatory agency."

7 CONCLUSION AND RECOMMENDATIONS

In this chapter we highlight key findings from the survey and indicate the areas recommended for NRC attention based on the survey results. The chapter concludes with a discussion of potential uses for the survey by NRC now and in the future.

7.1 Key Findings

A majority of affected respondents rated four of eleven selected regulations as contributing highly to the safe operation of the respondents' facilities. These regulations included: Part 20, Radiation Protection, Part 34, Radiography, Part 35, Medical Use, and Part 39, Well Logging. Respondents also indicated that these four regulations have high compliance costs.

In general, respondents reported that both the costs of compliance and the number of regulations have increased over the past three years. Respondents rated Part 30, Byproduct Material Licensing as high in compliance costs but low to moderate in terms of contribution to safety. Regulations considered low in compliance costs but also low to moderate in safety contribution included: Part 19, Communication/Reports to Workers, Part 33, Broad Scope, Part 36, Irradiators, Part 40, Source Material, and Part 70, Special Nuclear Material. A majority of respondents considered Part 71, Transportation, low to moderate in terms of both cost and safety contribution.

Overall, respondents reported positive perceptions of the performance and technical competence of NRC inspectors of licensed activities and reviewers of license applications, renewals and amendments. In general, respondents indicated that inspectors and reviewers were professional in their conduct, were competent in relevant technical fields, had sufficient knowledge of respondents' institutions and applied regulations consistently. Usually a higher percentage of respondents reported favorable perceptions of inspectors than of reviewers; while percentages of respondents agreeing with the above statements ranged from about 65% to 90% regarding inspectors, they ranged from about 50% to 75% for license reviewers.

Timeliness of NRC response to license applications, renewals and amendments was a concern of respondents, although most respondents indicated that delays had caused no or minor operational problems at their facilities. In terms of inspections, most respondents were satisfied with the frequency of inspections, about 70% saying the frequency was "just right" compared to close to 30% saying inspections were "too often," and less than 5% saying inspections were "not often enough."

Respondents reported very similar reactions to disagreements with findings of both NRC inspectors and license reviewers. The majority of respondents said they felt very free to notify NRC of disagreements with inspectors or reviewers. However, about 25% indicated they did not feel free to report disagreements. A larger percentage (about 35%) of respondents from medical institutions did not feel free to report disagreements to either inspectors or reviewers. About 65% of respondents said they had disagreed with a reviewer's findings and about 60% had disagreed with an inspector's findings. In most cases respondents had acted on these disagreements, by calling, writing or meeting with the inspector or reviewer. Very few took no action; 9% reported having disagreed with a reviewer and not having notified NRC and 12% of respondents had disagreed with an inspector and not notified NRC.

Most respondents, ranging from 60% to 80%, indicated that several specific reporting requirements are very necessary and generally, respondents also reported that these requirements are a relatively low burden. The reporting requirements include: Part 20, immediate, 24 hour, two-week and 30 day notification; Part 30, Bankruptcy; and Part 35.645, Teletherapy. About 50% of respondents considered Part 34.25, Sealed Source, and Part 35.33(a)(2), Misadministration requirements very necessary, and only 15% and 25%, respectively, found these requirements very burdensome.

Most respondents (about 80%) reported they were very familiar with NRC's inspection process, compared to about 55% who said they were very familiar with reporting requirements and 40% who said they were very familiar with

enforcement policy. Approximately 50% said they understood processes for issuing, renewing and amending licenses (about 20% indicated they did not understand these processes and 30% were in-between).

7.2 Recommendations

Several areas, listed below, are recommended for NRC attention based on the results of this survey.

Safety contribution and cost of complying with regulations:

- review of the safety importance of regulations and identification of ways to increase licensees' awareness of how specific regulations are linked to safe operations;
- monitoring resource burdens of multiple regulations on licensees; and
- determination of whether licensees are discriminating between more and less relevant information about regulations and policies.

Reviews of licensing applications, renewals, and amendments:

- identification of ways to enhance reviewers' knowledge of specific operations and facilities;
- development of methods to improve the timeliness of response to requests for licensing actions;
- identification of ways to further promote a climate open to licensee disagreements; and
- revision of guidance regarding filing amendments, renewals, and applications.

Inspections of licensed activities:

- identification of ways to create a climate in which more licensees feel free to disagree with inspection results; and
- soliciting ideas about inspection process improvements from licensees.

Enforcement actions and reporting requirements:

- review of the safety importance of issues that lead to sanctions; and
- identification of ways to increase licensees' understanding of how enforcement processes and sanctions for important safety concerns enhance safety.

7.3 Uses of the Survey

The survey provides NRC with a wealth of information about its licensees' current perceptions and recent experiences. The results of this survey can serve immediate organizational needs in targeting areas for assessment and improvement, as suggested in each section above and for planning for and monitoring future activities.

In the near term. the survey results also can be a valuable communication tool within NRC headquarters and regional offices to identify areas of licensee concern and areas of licensee satisfaction. The survey provides positive reinforcement for many efforts. NRC staff also can use the survey results to identify specific areas for change or improvement based on their own or licensee concerns. The survey provides a good tool for communicating with licensees about NRC performance and efforts.

In the long term, the survey can serve as a benchmark of how licensees perceive NRC performance in certain areas. Periodic administration of the survey (or some version thereof) can serve to document performance trends. Questions for future surveys can be modified or added to capture additional information as needed.

Both NRC staff and licensees committed considerable resources to develop, complete, and analyze the survey. The results provide an abundance of information about both the strengths and limitations of current NRC practices. This information can be used effectively to reinforce those activities that contribute highly to safe operations at licensees' facilities and modify those that contribute little to safety.

APPENDIX A QUESTIONNAIRE: DISTRIBUTION OF RESPONSES FROM ALL RESPONDENTS

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

TO: NRC Materials Licensees

FROM: Carl J. Paperiello, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

SUBJECT: REGULATORY IMPACT SURVEY

I need your help. Enclosed is a survey to determine your views on the impact of the Nuclear Regulatory Commission's regulatory activities on your licensed operation.

We will use the information from the survey to determine how we can minimize adverse impacts on licensees such as yourself, while still achieving our goal of safety. We are seeking your views on the value of our regulations and policies. We also want your views on the licensing process, the inspection process, reporting requirements and enforcement. Although the survey consists of a set of questions, space is provided for additional comments.

Since this survey is being sent to a random sample of licensees, your voluntary participation is very important to the success of this project. Your frank views are important. The survey is being administered for the NRC by Pacific Northwest Laboratory (PNL) under contract to the NRC. The questionnaire is designed so as not to reveal your identity and no one at the NRC will see any completed questionnaire. About 600 surveys are being conducted. Results will be published in the NMSS Licensee Newsletter.

We anticipate that it will take approximately 45 minutes to complete. If you have any questions regarding this questionnaire, please call Robin Conger or Mark Hattrup, PNL survey administrators, at (509) 372-4687.

Carl J. Paperiello

Carl J. Paperiello, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

Approved by OMB: No. 3150-0182 Expires: 7-31-97
ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST IS .75 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0182), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

CONFIDENTIALITY STATEMENT: THE RESULTS OF THIS SURVEY WILL BE USED TO ASSIST THE NRC IN BETTER DETERMINING THE EFFECT OF ITS REGULATORY PROGRAM ON NUCLEAR SAFETY. ALL INFORMATION PROVIDED WILL BE TREATED AS CONFIDENTIAL. ONLY MEMBERS OF THE SURVEY TEAM AND DESIGNATED ANALYSTS WILL BE PERMITTED ACCESS TO THE QUESTIONNAIRE DATA. YOUR RESPONSES WILL BE GROUPED WITH ALL OTHER RESPONDENTS FOR PURPOSES OF ANALYSIS AND WILL NOT BE REPORTED AS INDIVIDUAL ANSWERS.

REGULATIONS, POLICIES AND REGULATORY GUIDANCE

The purpose of this section of the survey is to obtain your perceptions regarding 1) the cost of NRC regulations, 2) the usefulness of NRC regulations, and 3) the safety impact of NRC regulations.

1. How would you describe your level of knowledge of each of the following NRC regulatory documents applicable to your licensed activities? *(Please circle one response per document type.)*

	Very Low	Low	Average	High	Very High
Regulations	1%	4%	41%	39%	15%
Regulatory Guides	1%	8%	52%	31%	8%
Policy Statements	3%	23%	54%	16%	4%
License Conditions	1%	3%	22%	37%	37%
Branch Technical Positions	19%	38%	33%	7%	3%
Information Notices	4%	14%	57%	18%	7%

2. During the past 2 years, how many times have you used outside consultants to assist you in each of the following areas? *(Please indicate the approximate number of times in the space provided; if you have not used a consultant, enter a "0".)*

Need for Consultants	Number of Times Used
To understand regulations	mean = 2
To understand the new 10 CFR Part 20	mean = 1
To conduct training	mean = 1
To conduct internal audits	mean = 2
To submit a license application	mean = 0
To submit a license amendment	mean = 0
To submit a license renewal request	mean = 0
Other (specify):	

3. Thinking back over the past 3 years, do you believe that the number of NRC regulations applicable to your licensed activity has... *(Please circle only one response.)*

1. increased significantly	34%
2. increased somewhat	46%
3. remained about the same	19%
4. decreased somewhat	0%
5. decreased significantly	0%

4. Thinking back over the past 3 years, do you believe the cost of complying with NRC regulations has... *(Please circle only one response.)*

1. increased significantly	65%
2. increased somewhat	25%
3. remained about the same	10%
4. decreased somewhat	0%
5. decreased significantly	0%

5. NRC is interested in obtaining your perceptions about the cost of complying with some specific NRC regulations versus the overall safety impact of those regulations on your facility.

To what extent does each of the regulations listed below contribute to the safe operation of your facility? *(Please circle the number that best represents your opinion. Use NA if the regulation does not apply to your licensed activity.)*

(Not Applicables deleted)	No Contribution	2	3	4	Very High Contribution
a. Part 19 - Communication/ Reports to Workers	10%	31%	34%	15%	11%
b. Part 20 - Radiation Protection (new Part 20)	6%	16%	25%	27%	26%
c. Part 30 - Byproduct Material Licensing	11%	24%	34%	19%	13%
d. Part 33 - Broad Scope	16%	32%	28%	14%	9%
e. Part 34 - Radiography	17%	23%	25%	14%	22%
f. Part 35 - Medical Use	8%	20%	26%	23%	23%
g. Part 36 - Irradiators	23%	26%	33%	6%	12%
h. Part 39 - Well Logging	35%	19%	19%	13%	15%
i. Part 40 - Source Material	23%	21%	38%	10%	7%
j. Part 70 - Special Nuclear Material	26%	24%	33%	15%	2%
k. Part 71 - Transportation	14%	25%	35%	17%	9%

6. **How would you rate the cost of complying with each of the NRC regulations listed below?** *(Please circle the number that best represents your opinion. Use NA if the regulation does not apply to your licensed activity.)*

(Not Applicables Deleted)	Low	2	3	4	High
a. Part 19 - Communication/ Reports to Workers	36%	23%	25%	10%	6%
b. Part 20 - Radiation Protection (new Part 20)	10%	13%	28%	30%	19%
c. Part 30 - Byproduct Material Licensing	9%	11%	28%	20%	31%
d. Part 33 - Broad Scope	16%	20%	31%	15%	19%
e. Part 34 - Radiography	14%	16%	28%	14%	28%
f. Part 35 - Medical Use	9%	11%	25%	25%	30%
g. Part 36 - Irradiators	30%	16%	30%	12%	12%
h. Part 39 - Well Logging	24%	18%	21%	13%	24%
i. Part 40 - Source Material	23%	20%	28%	10%	19%
j. Part 70 - Special Nuclear Material	30%	20%	28%	8%	14%
k. Part 71 - Transportation	23%	18%	31%	15%	13%

7. **Are there any sections within the regulations listed in the previous table that you believe are particularly effective at <u>enhancing</u> the safe operation of your facility?** *(Please identify the sections (e.g., <u>19.13(d)</u>, <u>20.1601</u>, <u>35.1-35.10</u>) and explain in the space provided.)*

8. **Are there any sections within the regulations listed in the previous table that you believe are <u>counterproductive</u> to the safe operation of your facility?** *(Please identify the sections (e.g., <u>19.13(d)</u>, <u>20.1601</u>, <u>35.1-35.10</u>) and explain in the space provided.)*

9. **How useful is each of the regulatory guides listed below?** *(Please circle the number that best represents your opinion. Use NA if the regulatory guide does not apply to your licensed activity.)*

(Not Applicables deleted)	Not Useful	2	3	4	Very Useful
a. Bioassay Program (8.9)	13%	22%	37%	17%	11%
b. Prenatal Radiation Exposure (8.13)	7%	19%	33%	22%	20%
c. Radiation Safety Survey at Medical Institutions (8.23)	8%	16%	33%	28%	15%
d. Calibration of Air Sampling Instruments (8.25)	18%	24%	41%	9%	8%
e. Occupational Radiation Exposure Risk (8.29)	9%	18%	42%	18%	13%
f. Tritium Bioassay Program (8.32)	18%	20%	34%	20%	8%
g. Quality Management Program (8.33)	15%	21%	38%	13%	12%
h. Occupational Radiation Dose Calculation (8.34)	13%	25%	34%	19%	9%
i. Radiation Doses to Embryo/ Fetus (8.36)	11%	23%	35%	18%	14%
j. ALARA Levels of Effluents (8.37)	15%	24%	38%	16%	8%
k. Preparation of Application for Licensed Activity (Division 10 Guides)	8%	9%	33%	25%	25%
l. Other					

10. **Have you ever provided comments on proposed NRC regulations or guidance documents?** *(Please circle all that apply for each document type.)**

	Regulations	Guidance Document
yes	29%	11%
no, because the process is too time consuming	24%	24%
no, because the process is too expensive	4%	3%
no, because my input will have no impact	17%	14%
no, because the process is too difficult to understand	14%	13%
no, because I was not aware of them in time to comment	11%	11%
no, because I had no comments to make	33%	32%
no, other (please specify):	6%	6%

* Totals are greater than 100% due to multiple responses representing reasons why no comments were made.

11. **How valuable is the NMSS newsletter to you?** *(Please circle only one.)*

1. very valuable	30%
2. somewhat valuable	47%
3. not very valuable	15%
4. no value	4%
5. do not receive it	4%

LICENSING

The purpose of the next set of questions is to determine how effectively and efficiently the NRC performs its licensing functions.

12. Based on your licensing action(s) in the past 12 months (e.g., issuance, renewal, amendment), to what extent do you agree with each of the statements in the table below? *(Please circle one response per line.)* **If you have not had a licensing action in the last 12 months, please skip to Question 19.**

(Not Applicables Deleted)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a. I understand the review process the NRC uses to:					
issue a license	3%	13%	32%	42%	10%
renew a license	4%	13%	32%	39%	11%
amend a license	4%	13%	29%	42%	12%
b. The guidance provided by the NRC enables me to file the following in an efficient manner:					
new applications	6%	13%	35%	35%	10%
amendments	7%	12%	29%	42%	9%
renewals	7%	13%	33%	39%	10%
c. The guidance provided by the NRC enables me to feel confident that most information I provide will be accepted by an NRC license reviewer.	9%	16%	31%	34%	10%

13. What was the last type of licensing action you had with the NRC? *(Please circle only one.)*

1. license issuance	6%
2. license renewal	49%
3. license amendment	45%

14. Thinking back to that last licensing action, to what extent do you agree with each of the statements in the table below? *(Please circle only one response per statement.)*

(Not Applicables Deleted)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a. The reviewers were professional in their conduct	1%	2%	20%	51%	25%
b. The reviewers were helpful.	3%	8%	23%	47%	19%
c. The reviewers asked clear questions.	4%	11%	24%	48%	14%
d. The reviewers asked only for relevant information.	6%	13%	28%	37%	16%
e. The reviewers applied regulations consistently with what I believe NRC intended.	6%	10%	27%	42%	15%
f. The reviewers asked reasonable questions.	6%	8%	27%	47%	13%
g. The reviewers had sufficient knowledge of my operation and institution to do their job adequately.	9%	14%	27%	37%	13%
h. The reviewers were competent in relevant technical fields.	5%	6%	29%	45%	15%

15. How timely was the NRC response to any license applications, amendments, and/or renewal requests you made in the last twelve months? *(Please circle one response for each type of licensing action.)*

(Not Applicables Deleted)	Not at all Timely	2	3	4	Very Timely
Application	16%	22%	27%	21%	13%
Amendment	18%	16%	26%	28%	12%
Renewal	28%	18%	19%	21%	14%

16. If you have experienced delays in NRC responses to license amendments or other licensing requests, how have they affected your facility? *(Please circle only one response.)*

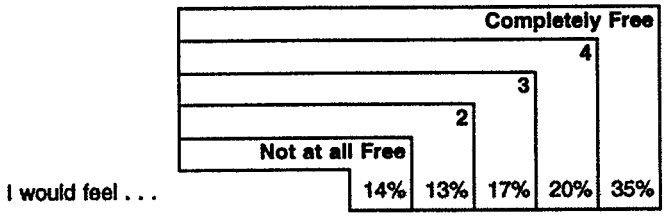
1. haven't experienced any delays	29%
2. delays created serious operational problems	5%
3. delays created moderate operational problems	21%
4. delays created minor operational problems	22%
5. delays created no operational problems	23%

17. If you have ever disagreed with a license reviewer's position on an issue, what did you do to resolve it? *(Please circle all that apply.)**

1. never disagreed with a reviewer's position	35%
2. called the reviewer	40%
3. wrote a letter to the reviewer	24%
4. met with the reviewer	5%
5. contacted the reviewer's management at NRC	6%
6. took no action	8%
7. other:	6%

* The total is greater than 100% due to multiple responses representing actions taken to resolve disagreement.

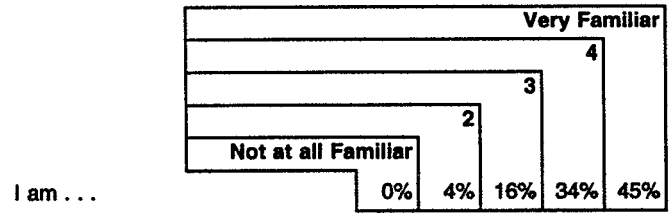
18. How free would you feel to notify NRC management if you disagreed with a license reviewer's position? *(Please circle only one response.)*



INSPECTIONS

The purpose of this part of the questionnaire is to determine how effectively and efficiently the NRC conducts its inspection activities.

19. How familiar are you with the NRC's inspection process? *(Please circle only one response.) If you have not been inspected in the last 12 months, please skip to Question 28.)*



20. Thinking back to the last inspection you've had, to what extent do you agree with the following statements? *(Please use the scale provided and circle the appropriate response.)*

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a. The inspectors were professional in their conduct.	0%	2%	9%	51%	38%
b. The inspectors were knowledgeable of NRC regulations.	0%	0%	11%	53%	35%
c. The inspectors were knowledgeable of my license conditions.	1%	4%	18%	50%	26%
d. The inspectors were competent in relevant technical fields.	0%	4%	23%	49%	24%
e. The inspectors had sufficient knowledge of my operation and institution to do their job adequately.	2%	6%	25%	45%	21%
f. The inspectors focused on safety issues.	2%	9%	20%	44%	25%
g. The inspectors used their time effectively at my facility.	2%	6%	16%	48%	28%
h. The inspectors left me with a clear understanding of their findings.	3%	6%	10%	44%	36%
i. The inspectors applied regulations consistently with what I believe NRC intended.	4%	9%	19%	43%	26%
j. The inspectors asked reasonable questions.	2%	4%	13%	57%	25%
k. Inspectors have provided me with valuable information.	6%	11%	28%	34%	22%

21. Are there areas of inspections that could be cut and that would have little or no effect on the safe operation of your facility? *(Please circle your response.)*

1. No.	30%
2. Yes (please describe)	70%

22. Are there areas that are being ignored by inspectors that you believe are important to the safe operation of your facility? *(Please circle your response.)*

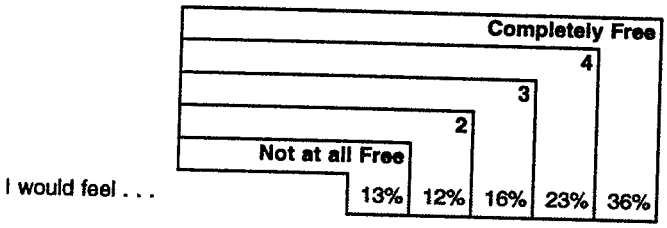
1. No.	9%
2. Yes (please describe)	91%

23. If you have ever disagreed with an inspector's position on an issue, what did you do to resolve it? *(Please circle all that apply.)**

1. never disagreed with a inspector's position	38%
2. called the inspector	20%
3. wrote a letter to the inspector	23%
4. met with the inspector	16%
5. contacted the inspector's management at NRC	13%
6. took no action	12%
7. other (please specify):	7%

* The total is greater than 100% due to multiple responses representing actions taken to resolve disagreement.

24. How free would you feel to notify NRC management if you disagreed with an inspector's findings? *(Please circle only one response.)*



25. Has an inspector's supervisor or manager ever participated in an inspection at your facility? *(Please circle only one response.)*

1. yes	28%
2. no	54%
3. Do not know.	18%

26. How would you describe the frequency of NRC inspections? *(Please circle only one response.)*

1. NRC inspections occur too often.	27%
2. NRC inspections occur about as often as they should.	70%
3. NRC inspections don't occur often enough.	3%

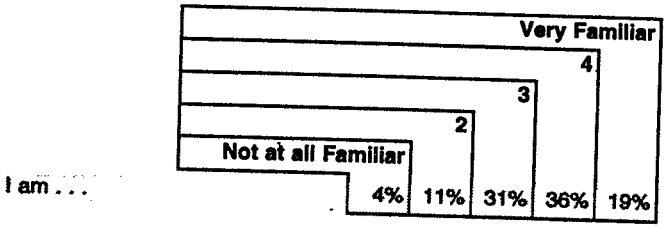
27. How would you describe the length of your NRC inspections? *(Please circle only one response.)*

1. NRC inspections take too long.	24%
2. NRC inspections take about the right amount of time.	74%
3. NRC inspections should take longer than they do.	2%

REPORTING REQUIREMENTS

The purpose of these questions is to determine your views regarding the effectiveness of NRC reporting requirements.

28. How familiar are you with the NRC's reporting requirements? *(Please circle only one response.)*



29. Has your facility been cited by the NRC for failing to make a required report? *(Please circle as many as apply.)**

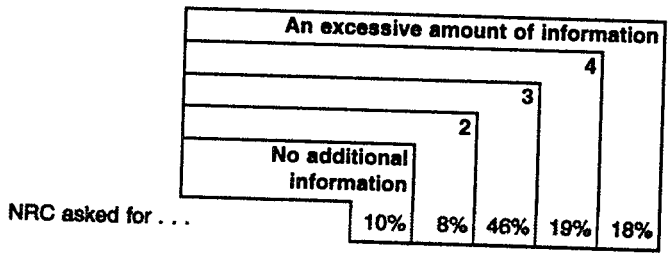
1. My facility has never been cited for failing to make a required report.	82%
2. My facility was cited because I, or someone at my facility, misinterpreted the requirement.	8%
3. My facility was cited because a report was made in an incorrect manner.	2%
4. My facility was cited because a report was not made on time.	4%
5. My facility was cited because a required report was not filed.	3%
6. Other (please describe)	3%

* Multiple responses representing reasons for citation were allowed.

30. Have you ever made a telephone report of a significant event to the NRC? *(Please circle only one.)*

1. Yes	23%
2. No	77%

If yes, how would you describe NRC's requests for additional information? *(Please circle only one.)*



31. How courteously are you treated when you make a telephone report to the NRC? *(Please circle only one.)*

1. I am always treated courteously.	31%
2. I am usually treated courteously.	17%
3. I am occasionally treated courteously.	2%
4. I am rarely treated courteously.	1%
5. I am never treated courteously.	0%
6. I have never made a telephone report.	49%

32. In your opinion, how necessary is each of the reporting requirements listed below? *(Please circle one response for each reporting requirement. If the reporting requirement is not applicable to your licensed activity, please circle "NA".)*

(Not Applicables deleted)	Not at all Necessary	2	3	4	Very Necessary
Part 20 - Immediate Notification for lost, stolen or missing licensed material or overexposure or excessive releases [20.2201(a)(1)(i) and 20.2202(a)]	2%	4%	12%	22%	59%
Part 20 - 24-Hour Notification for lost, stolen or missing licensed material or overexposure or excessive releases [20.2202(b)]	1%	4%	14%	25%	56%
Part 20 - 30 Day Notification for lost, stolen or missing licensed material or overexposure or excessive releases [20.2201(a), 20.2201(b), 20.2201(d), 20.2203(a)]	2%	6%	18%	27%	46%
Part 20 - 2 Week Notification for lost, stolen or missing licensed material or overexposure or excessive releases [Appendix F III.E.2.]	2%	6%	23%	29%	39%
Part 30 - Bankruptcy, request for termination of license, notification of event that prevents immediate protective actions	3%	8%	29%	25%	35%
Part 34.25 - Sealed source leak test results	6%	15%	29%	23%	28%
Part 35.33(a)(2) - Misadministration report	7%	12%	32%	24%	25%
Part 35.645 - Teletherapy facility safety checks	4%	8%	23%	22%	43%
Other Reporting Requirements (please specify)					

33. In your opinion, how burdensome is each of the reporting requirements listed below? *(Please circle one response for each reporting requirement. If the reporting requirement is not applicable to your licensed activity, please circle "NA".)*

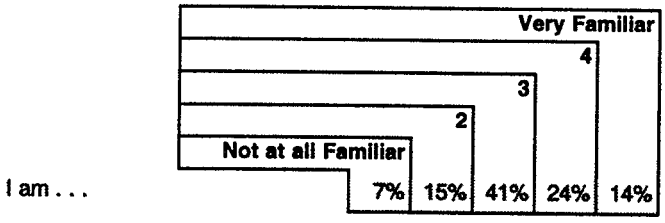
(Not Applicables deleted)	Very Burdensome	2	3	4	Not at all Burdensome
Part 20 - Immediate Notification for lost, stolen or missing licensed material or overexposure or excessive releases [20.2201(a)(1)(i) and 20.2202(a)]	6%	10%	35%	20%	28%
Part 20 - 24-Hour Notification for lost, stolen or missing licensed material or overexposure or excessive releases [20.2202(b)]	4%	11%	36%	22%	27%
Part 20 - 30 Day Notification for lost, stolen or missing licensed material or overexposure or excessive releases [20.2201(a), 20.2201(b), 20.2201(d), 20.2203(a)]	2%	8%	37%	25%	28%
Part 20 - 2 Week Notification for lost, stolen or missing licensed material or overexposure or excessive releases [Appendix F III.E.2.]	2%	7%	37%	26%	26%
Part 30 - Bankruptcy, request for termination of license, notification of event that prevents immediate protective actions	4%	11%	38%	17%	30%
Part 34.25 - Sealed source leak test results	5%	11%	38%	21%	26%
Part 35.33(a)(2) - Misadministration report	10%	16%	35%	20%	20%
Part 35.645 - Teletherapy facility safety checks	6%	13%	42%	15%	24%
Other Reporting Requirements (please specify)					

34. Are there any changes you would recommend in NRC reporting requirements? *(Please identify the reporting requirement and explain in the space provided.)*

ENFORCEMENT

The purpose of this section is to determine the effectiveness of the NRC's enforcement process in promoting safety and safeguards.

35. How familiar are you with the NRC's Enforcement Policy? *(Please circle only one response.)*



36. Have you ever received a Notice of Violation (NOV)? *(Please circle only one response.)*

1. yes	57%
2. no (skip to Question 37.)	43%

Do you understand how to respond to an NOV? *(Please circle only one response.)*

1. yes	97%
2. no	3%

To what extent do you agree that the issues which result in NOV's represent significant safety issues? *(Please circle only one response.)*

1. strongly disagree	14%
2. disagree	31%
3. neutral	28%
4. agree	24%
5. strongly agree	4%

37. Have you ever participated in an enforcement conference? *(Please circle only one response.)*

1. yes	19%
2. no (Please skip to Question 39.)	81%

38. Based on your participation in enforcement conferences, to what extent do you agree with the statements in the table? *(Please circle one response for each statement.)*

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The enforcement conference(s) were useful.	12%	6%	30%	36%	16%
The issues were clearly communicated.	3%	12%	21%	48%	16%
The final enforcement action(s) were timely.	4%	9%	25%	48%	13%
The process for submitting an appeal was clear to me.	9%	9%	32%	36%	14%
The basis of the NRC's final enforcement decision(s) were clearly communicated.	6%	13%	22%	40%	18%
The root causes of the problem(s) were clearly identified.	12%	9%	18%	42%	18%
The necessary corrective actions were communicated clearly.	6%	6%	19%	54%	15%
The NRC process of imposing civil penalties contributes to the overall nuclear safety at my facility.	30%	29%	12%	24%	5%

39. Have you ever received a fine or civil penalty (CP)? *(Please circle only one response.)*

1. yes	11%
2.no (skip to Question 40.)	89%

Do you understand how to respond to a CP? *(Please circle only one response.)*

1. yes	98%
2. no	2%

To what extent do you agree that the issues which result in CP's represent significant safety issues? *(Please circle only one response.)*

1. strongly disagree	20%
2. disagree	32%
3. neutral	27%
4. agree	20%
5. strongly agree	2%

LICENSEE CHARACTERISTICS

The following questions will allow us to categorize the responses you have provided so that the information can be reported in summary form.

40. Which of the following best describes your licensed activity? *(Please circle only one response.)*

1.	academic	11%
2.	medical/academic	2%
3.	medical institution (hospital, medical center, etc.)	30%
4.	medical other	5%
5.	pharmacy/medical distribution only	3%
6.	well logging	4%
7.	gauges (measuring systems)	9%
8.	manufacturing and distribution	7%
9.	services (laundry, decon., calibration, disposal, leak test)	4%
10.	industrial radiography	12%
11.	irradiators	1%
12.	research & development	10%
13.	other source	2%
14.	special nuclear material (1 out of 363 responses)	0%

41. How many individuals have been issued personal dosimetry monitoring devices for your NRC licensed activities? *(Please write the number in the space provided.)*

Quartiles Mean = 85

1: 0 to 4
2: 5 to 10
3: 11 to 40
4: 41 to 3334 (only 10% reported more than 170)

42. In what state is your licensed facility located? *(Please write the state in the space provided.)*

_____

43. What is your job title? *(Please write your title in the space provided.)*

_____

44. Do you serve as the Radiation Safety Officer (RSO) for your facility? *(Please circle only one response.)*

1.	yes	82%
2.	no	18%

45. Is the RSO position at your facility a full-time RSO dedicated position, or does the RSO also have other job responsibilities? *(Please circle only one response.)*

1.	Full-time RSO responsibilities	10%
2.	RSO also has other job responsibilities	89%
3.	No RSO at this facility	1%

46. Please provide any other comments that you wish to make regarding NRC regulations, policies, regulatory guidance, licensing activities, inspections, reporting requirements, and/or enforcement actions.

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APPENDIX B SURVEY METHODS

B.1 Survey Sample Design

NRC-NMSS staff conducted a series of face-to-face interviews in 1993 with staff and management at nine licensed facilities to gather information about regulations, policies and regulatory guidance, the licensing and inspection processes, investigations, and fees. These interviews collected a wealth of rich data that were analyzed and reported in NRC document SECY-93-130. The results suggested that further information about how licensees perceived the impact of NRC regulations could help NRC find ways to facilitate licensees' compliance.

Continuing to interview licensee representatives in person could provide such information, but only at the high costs associated with collection and analysis of interview data. A survey can collect information from the population of interest more efficiently than face-to-face interviews and with a carefully selected sample can produce accurate information. It was determined to design and administer a mail-out self-administered survey to a selection of licensed facilities. Battelle's Pacific Northwest Laboratory (PNL) and Human Affairs Research Centers (HARC) worked with NRC staff in conducting this project. The survey design, administration, and analytic methods used in this study are reviewed below.

B.1.1 Population, Unit of Analysis, and Sampling Frame

The population for this sample, or all eligible respondents, was created from NRC's licensing tracking system (LTS) of licensed facilities. Each facility applies for a license for any regulated activity it engages in. Facilities, therefore, may hold more than one NRC license. The NRC maintains a record of each licensed facility in its licensee tracking system, sorting the licenses by program codes.

For the purposes of this survey, the population included all those licensed facilities having an interaction with the NRC during the past twelve months. It was believed that these more recent experiences would be easier for respondents to recall and assess in the survey. The resulting eligible population consisted of 3,276 licenses held by an unknown number of licensees, each having some licensing or inspection interaction during the past twelve months. The licensed facility, not the individual respondent, is the unit of analysis for this survey.

NRC staff combined program codes into 14 distinct "categories" of licensed facilities and provided a list of the eligible licensees (those with an interaction within the past 12 months). This list became the "sampling frame" from which the sample of respondents was to be selected.

B.1.2 Questionnaire Design

The protocol used in the face-to-face interviews conducted by NRC staff was reviewed prior to designing the questionnaire. It was determined to focus the mail survey on questions about the impact on licensees of regulations and policies, regulatory guidance, and the licensing and inspection processes. Questions from the interview protocol were re-formatted for use in a self-administered mail survey. New questions and alternative answer formats were also developed.

The survey was pre-tested with a small number of licensees. It was also reviewed by NRC staff familiar with the licensed facilities and/or survey research. This combination of licensee pre-test and expert review provided information that was used to modify the draft questionnaire. The draft survey was cleared by the Office of Management and Budget (OMB) without requiring additional modification.

The survey as administered consists of 46 questions in five sections including licensee characteristics which were used to sort responses. Both closed- and open-ended question formats were used to elicit information from respondents. Frequently, respondents were asked to provide answers on a five point Likert-type scale (strongly agree to strongly disagree, very useful to not useful). The survey as distributed to respondents is contained in Appendix A.

B.1.3 Sampling Design

A sampling design is the plan for how respondents are to be selected to receive the survey. The essential characteristic of a sampling design is to ensure that all respondents have a known probability of being included in the sample, usually by using a random selection method. A stratified random sample design was selected for this survey to ensure that the widest range of licensee categories were sampled in order for NRC to receive feedback from the full range of licensee types. It is usually desirable to have a minimum group size of about 20 in order to avoid the category being represented by only a few respondents. Using a simple random sample could not guarantee that enough licensees from the smallest categories (e.g., well logging or radiography) would be selected. The stratification process ensured that a certain number of licensees from each identified category would be selected.

In a stratified random sample plan, the population is first subdivided into two or more mutually exclusive segments. For this survey, the categories designed by the NRC for the sampling frame were also used as the 14 strata for the sample. Using results of the earlier interview survey as well as prior experience, NRC staff determined the number of respondents to sample in each licensee category. Respondents selected through this stratification process are representative of each licensee category, not of the total licensee population.

A random sample of 600 licensees was pulled sequentially from the list of eligible licensees provided by the licensee tracking system. Because facilities may be listed in more than one category (depending on how many regulated activities they engage in), as a licensee was selected it was eliminated from any other category in which it was listed. In this way, duplication of respondents could be avoided. In the final sample, eleven duplications were found and eliminated, reducing the final total sample to 589. Table B.1 shows the licensee population, the eligible population, and the number selected by category.

B.1.4 Survey Administration

Social and Economic Sciences Research Center (SESRC), a survey research center located at Washington State University, was responsible for administering the survey. Each of the 589 sampled licensees received a copy of the survey accompanied by a cover letter from the Director of the Division of Industrial and Medical Nuclear Safety. The cover letter outlined the objectives of the survey and also stressed the confidential nature of the responses (see Appendix A).

The "Total Design Method"[1] was used to plan delivery of the surveys. Key elements of the method include the personalization of all mailings to respondents and the use of follow-up mailings, both of which have been shown to increase response rates. Three rounds of mailings were used for this survey. The initial mailing was sent to all 589 sampled licensees. Two weeks later, a postcard reminder was sent to all licensees requesting that they complete the questionnaire and return it if they hadn't already done so. A final mailing was sent to nonrespondents with a cover letter, replacement questionnaire, and pre-stamped return envelope. Respondents were also encouraged to contact survey administrators directly if they had any questions or concerns about the survey.

A total of 371 respondents returned their completed questionnaires for a response rate of 63%. Seven of the 371 respondents removed the identification numbers used to track responses. Response rate by licensee category ranged from 85% of radiography fixed licensees to 43% of manufacturing and distributing licensees (see Table B.2). The distribution of respondents appears to be representative of all NRC licensees. Table B.3 describes the distribution of respondents by NRC region and illustrates another dimension of similarity (location) between the respondents and NRC licensees in general.

All surveys returned to SESRC by the cut-off date (10/17/94) were coded and submitted for data entry and verification. SESRC staff reviewed each questionnaire and resolved any coding discrepancies prior to data entry. All responses were keypunched directly into a computer system and 100% data verified. The resulting data set of responses to both closed-

[1] Dillman, Don A. 1978. *Mail and Telephone Surveys: The Total Design Method.* NY: John Wiley and Sons.

Table B.1: Population and Sample Size By Category

Population Category	Program Codes	Total # of Licensees	Eligible Licensees*	Number Selected	Number of Respondents
Academic	01100-01200	84	56	37	24
Medical Institution	02120-02121	1,437	788	129	78
Medical Other	02200-02410	747	483	64	34
Pharmacies, Medical Distribution	02500-02513	76	23	22	17
Well-Logging	03110-03113	67	37	25	16
Gauges (Measuring Systems)	03120-03124	2,453	926	50	28
Manufacturing and Distribution	03211-03214	144	83	30	13
Services	03218-03238	183	97	30	20
Radiography, fixed	03310	47	24	20	17
Radiography, temporary	03320	153	124	35	26
Irradiators	03510-03521	228	117	35	21
Research and Development	03610-03620	655	361	54	39
Other source	11200-11300, 11400-11500	154	56	29	13
Special Nuclear Material	21130-21300	244	101	29	18
Category not known (ID# removed by respondent)	———	———	———	———	7
Totals		6,672	3,276	589	371

* Last interaction within 12 months (on or after August 1993).

and open-ended questions was then available for analysis.

B.2 Data Analysis

Before the data analysis could begin, it was necessary to review the overall distribution of response. As discussed above, each sampled respondent was selected based on one licensee category even though the facility may have multiple licenses. For example, a facility could be selected for its special nuclear material license even though it also had a medical institution (or other) license(s). Question 40 of the survey asked respondents to select a category that best described its activity. It is likely that respondents selected that category which best represented its main or major activities and it is also likely that respondents answered survey questions based on that activity. Respondents were sorted on their self-selected primary activity, rather than the program code used for sampling, because survey responses are likely to be a better representation of respondents in the primary activity licensee category than in the program code licensee category.

This sorting by self-identified category, however, resulted in small numbers of respondents in certain categories. Similar licensee categories were combined to create fewer licensee categories, each with a relatively large number of respondents. Respondents who self-selected academic and medical academic licensee categories were combined into a single academic category. Medical other and pharmacy licensees were combined into a single medical other category. The self-selected categories of irradiators (N=5), other source (N=7), and special nuclear material (N=1) were eliminated as separate categories. These categories were not included in the analyses as separate licensee groups because of the small number

Table B.2: Sample and Response Pool Proportions and Rates by LTS-Assigned Licensee Type

Licensee Type	Percent in Sample %	N	Percent of Response %	N*	Response Rate
Academic	6.3%	37	6.6%	24	65%
Gauges	8.5%	50	7.7%	28	56%
Irradiators	5.9%	35	5.8%	21	60%
Medical Institutions	21.9%	129	21.4%	78	60%
Medical Other	10.9%	64	9.3%	34	53%
Manufacturing and Distribution	5.1%	30	3.6%	13	43%
Other Source	4.9%	29	3.6%	13	45%
Pharmacies, Medical Distribution	3.7%	22	4.7%	17	77%
Research and Development	9.2%	54	10.7%	39	72%
Radiography, fixed	3.4%	20	4.7%	17	85%
Radiography, temporary	5.9%	35	7.1%	26	74%
Services	5.1%	30	5.5%	20	67%
Special Nuclear Material	4.9%	29	5.0%	18	62%
Well-Logging	4.2%	25	4.4%	16	64%
Subtotal	100.0%	589	100.0%	364	62%
Category not known (ID number removed by respondent)	------	------	------	7	------
Total for All Respondents	------	589	------	371	63%

* Chi-Squared Analysis was run to test the response distribution by categories of licensees in the sample. This was done to determine if there was a significant difference in the response rates of the different licensee types. Based on the results of the analysis, the probability of a significant difference in response rates is only about 4%. (Analysis results: 13 degrees of freedom, Chi-squared value = 22.912, probability = 0.043)

of respondents in each category but were included in analyses of the group as a whole. In addition, eight respondents did not self select a licensee category but are included in the total group analyses. Table B.4 displays the distribution of respondents by self-selected and re-combined categories.

Table B.3: Sample and Response Pool Proportions and Rates, by Region

License Region	Percent of Sample	Percent of Respondents	Response Rate
Region 0	1.2%	1.4%	71%
Region 1	43.0%	39.0%	56%
Region 2	9.8%	9.9%	62%
Region 3	32.5%	33.5%	64%
Region 4	13.4%	16.2%	75%

Table B.4: Distribution of Respondents by Self-Identified License Activity

Licensed Activity	Number	Percent of Respondents
• Academic (including Medical/ Academic)	50	13.5%
• Medical Institution	109	29.4%
• Medical Other (including Pharmacy/ Medical Distribution)	29	7.8%
• Well Logging	14	3.8%
• Gauges	34	9.2%
• Manufacturing and Distribution	24	6.5%
• Services	13	3.5%
• Industrial Radiography	42	11.3%
• Research and Development	35	9.4%
• Irradiators*	5	1.4%
• Other Source*	7	1.9%
• Special Nuclear Material*	1	0.3%
Subtotal	363	97.8%
Missing Responses	8	2.2%
Total	371	100.0%

* Not included as separate licensee categories in the analysis.

For most of the survey analyses, the medical institution and medical other respondents were considered as discrete and separate licensee categories. Many medical licensee respondents, however, reported that they were currently involved in license amendments, and to a lesser extent renewals. Because the medical licensees taken together represent a large number of respondents, they were combined into a single medical facilities category in order to examine how medical licensees, as a group, perceived NRC licensing processes. The medical institutions, medical other, and the portion of academic licensees (approximately 20%) that carry out licensed medical activities constitute the combined medical facilities category. This category was used to analyze survey questions regarding licensing actions and inspections (see Chapters 3 and 4).

B.2.1 Quantitative Data Analysis

The quantitative analysis of the data was conducted using SAS[2] software. The analysis is limited primarily to descriptive statistics including the distribution of responses by licensee types. For those questions providing a "not applicable" response category, distribution of responses was calculated without the "not applicable" category. For example, if 10% of

[2] Copyright 1990 by SAS Institute Inc., Cary, North Carolina, USA.

the respondents indicated that the question was not applicable, the distribution across the other response categories was considered to be 100% of the responses (not 90%).

The distribution of responses to each response category were typically examined first for the respondents as a whole group and then broken down by licensee category. For example, Question 14 of the survey asked respondents to describe their level of agreement on a five-point scale from "strongly agree" to "strongly disagree" with a statement about reviewers' conduct. First, the distribution of responses across the five-point scale, for each of the selected performance qualities was analyzed. This suggested that, in general, respondents agreed or strongly agreed that license reviewers performed well on the selected qualities (see Figure 3.1). Then, the responses were analyzed by licensee category to determine whether there were any licensee categories that did not agree with this general trend. For example, respondents in the gauges licensee category were less likely than respondents in the other licensee categories to "agree" or "strongly agree" that "reviewers applied regulations consistently with NRC intent" (see Figure 3.2).

These two levels of analysis were conducted for each question as necessary and are accompanied in the report by a brief interpretive narrative. In addition, graphic materials (figures and tables) were constructed to display the responses for easy reference and are included throughout the report.

B.2.2 Qualitative Data Analysis

Responses to the open-ended questions were also entered into the database by SESRC and used to analyze results of the survey. A technique, drawing on traditional tools of qualitative content analysis, was used to analyze the written comments provided by respondents. Content analysis is the objective, systematic, and quantitative description of the content of communication (i.e., the written responses). Content analysis is objective in the sense that it examines what is said, not the implied meaning behind what is said. Content analysis is systematic in that it involves identification of domains of inquiry (in this case categories of responses) and the attributes that signal differences in respondents' experiences. Content analysis is quantitative in that the coding involves looking for the presence or absence of certain items of content, their frequency, and their degree of intensity.

Responses to the open-ended questions were first coded for content. This typically involved examining all the answers to identify types of comments that respondents were providing. For example, Question 22 asked respondents to identify any areas that they felt were important to safety but being ignored during inspections. After reading through the comments, it appeared that responses were of three general types: (1) concerns about specific equipment; (2) concerns about inspector practices; and (3) concerns about organizational procedures (either the NRC's or the licensees' own) that appear to hinder a complete inspection. After these categories were constructed, the responses were coded. A single respondent could, and often did, provide comments about different types of concerns.

After the responses were coded, they were "counted" and sorted. First, it was determined how many responses were in each category. This can provide a rough estimate of how salient an issue is for respondents. For example, 37 respondents suggested that NRC timeliness in responding to requests from respondents could be improved while eight respondents suggested that NRC provides information to licensees that may or may not apply to their category. This suggests that NRC timeliness is more likely to be a licensee concern than superfluous information. Answers to the open-ended questions were then sorted by licensee category to determine whether any specific licensee category respondents were consistently providing similar comments.

Both the descriptive information about the open-ended responses and the comments themselves were used throughout the report to corroborate, illustrate, and provide supporting evidence for the quantitative results. For example, while a majority of respondents reported that NRC response to requests for license actions were "somewhat" or "very timely," a substantial portion (35-45%) reported otherwise. These concerns were corroborated by the written comments provided by 37 respondents and several of their statements were used to illustrate the concerns of respondents regarding NRC timeliness. These individual remarks cannot replace the distribution of responses in the quantitative analyses, but they can provide powerful illustrations of the respondents' concerns.

APPENDIX C FIGURES ON REGULATIONS, POLICIES, AND REGULATORY GUIDANCE

Figure C.1: Percentage Saying Part 19, Communication/Reports to Workers, is Not Applicable, by Licensee Type
(from Questions 5--Contribution to Safety, and 6--Cost of Complying)

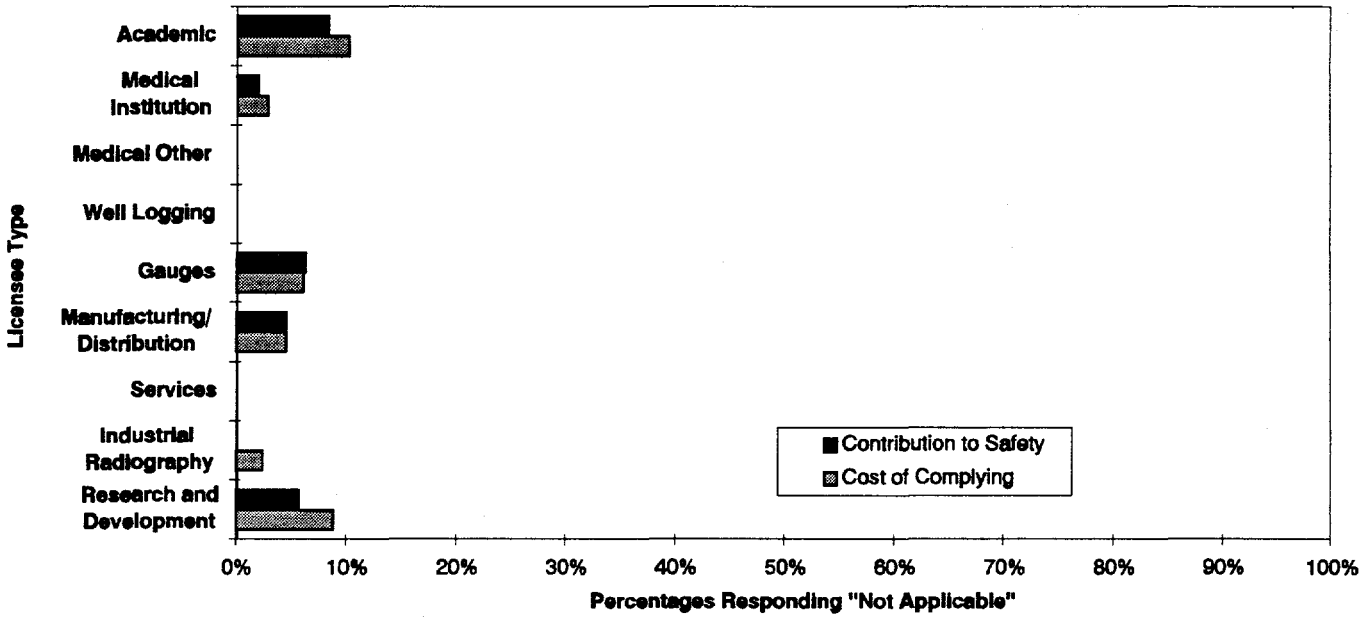


Figure C.2: Percentage Saying Part 20, Radiation Protection, is Not Applicable, by Licensee Type
(from Questions 5--Contribution to Safety, and 6--Cost of Complying)

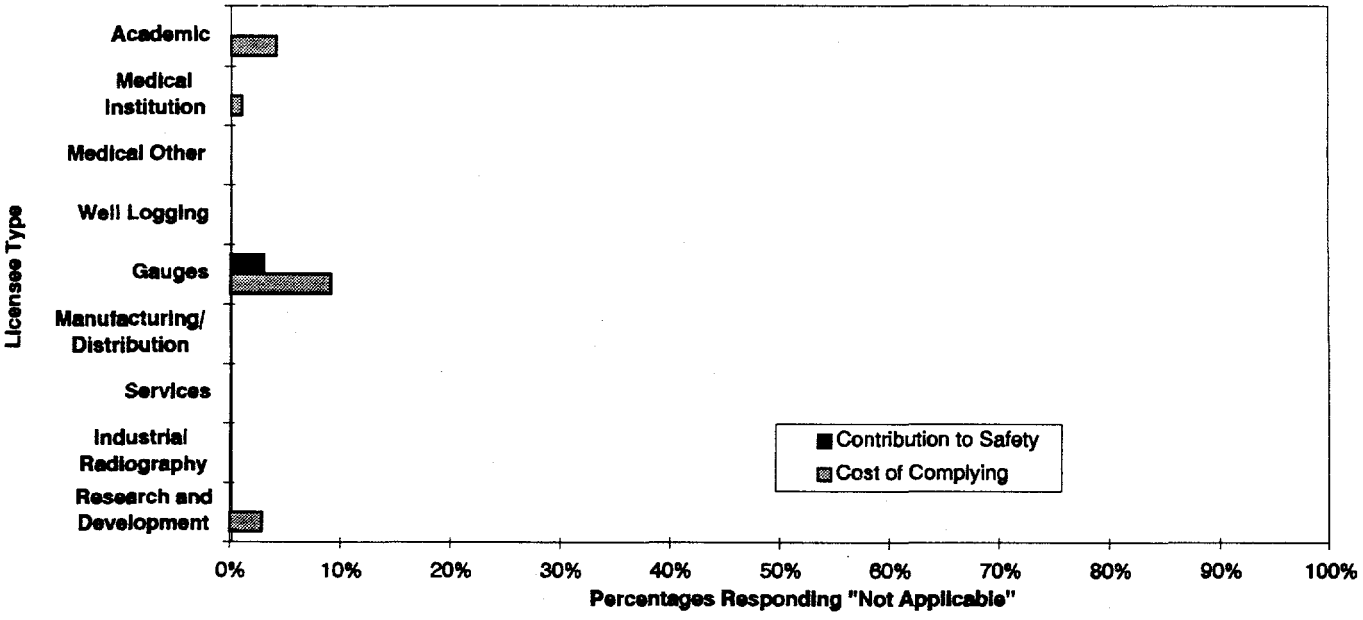


Figure C.3: Percentage Saying Part 30, Byproduct Material Licensing, is Not Applicable, by Licensee Type
(from Questions 5--Contribution to Safety, and 6--Cost of Complying)

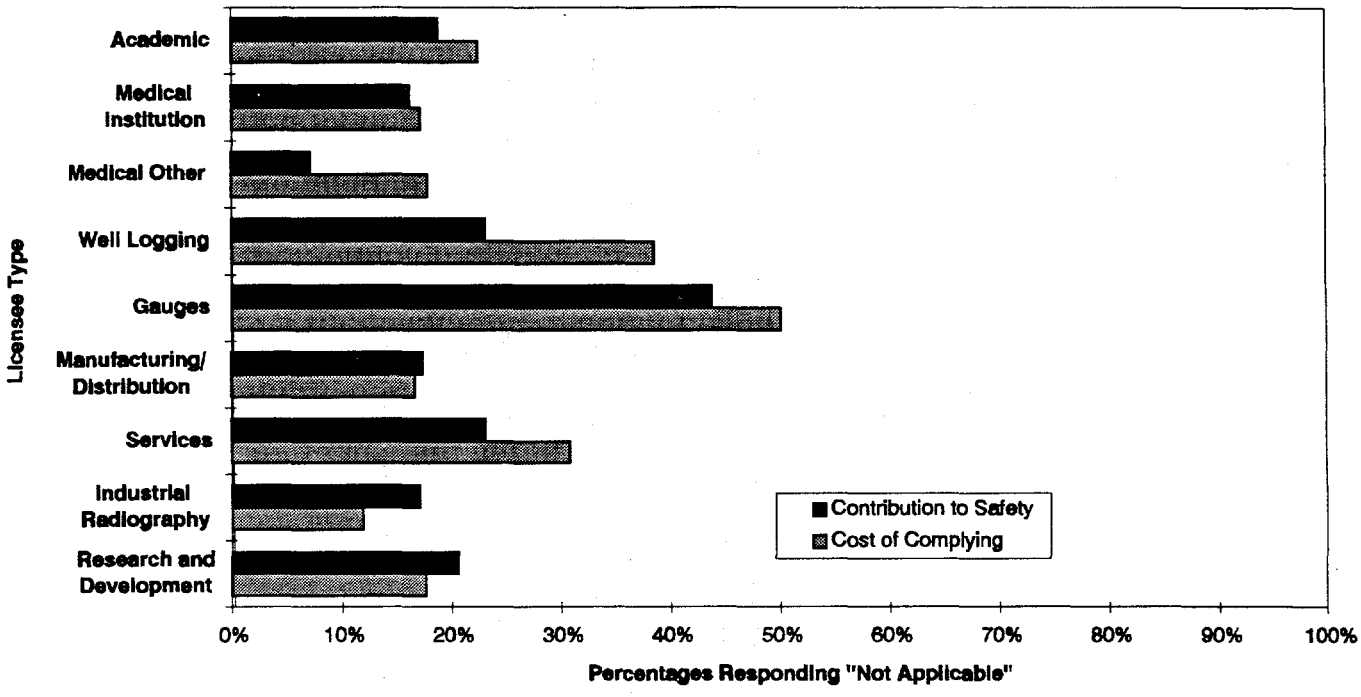


Figure C.4: Percentage Saying Part 33, Broad Scope, is Not Applicable, by Licensee Type
(from Questions 5--Contribution to Safety, and 6--Cost of Complying)

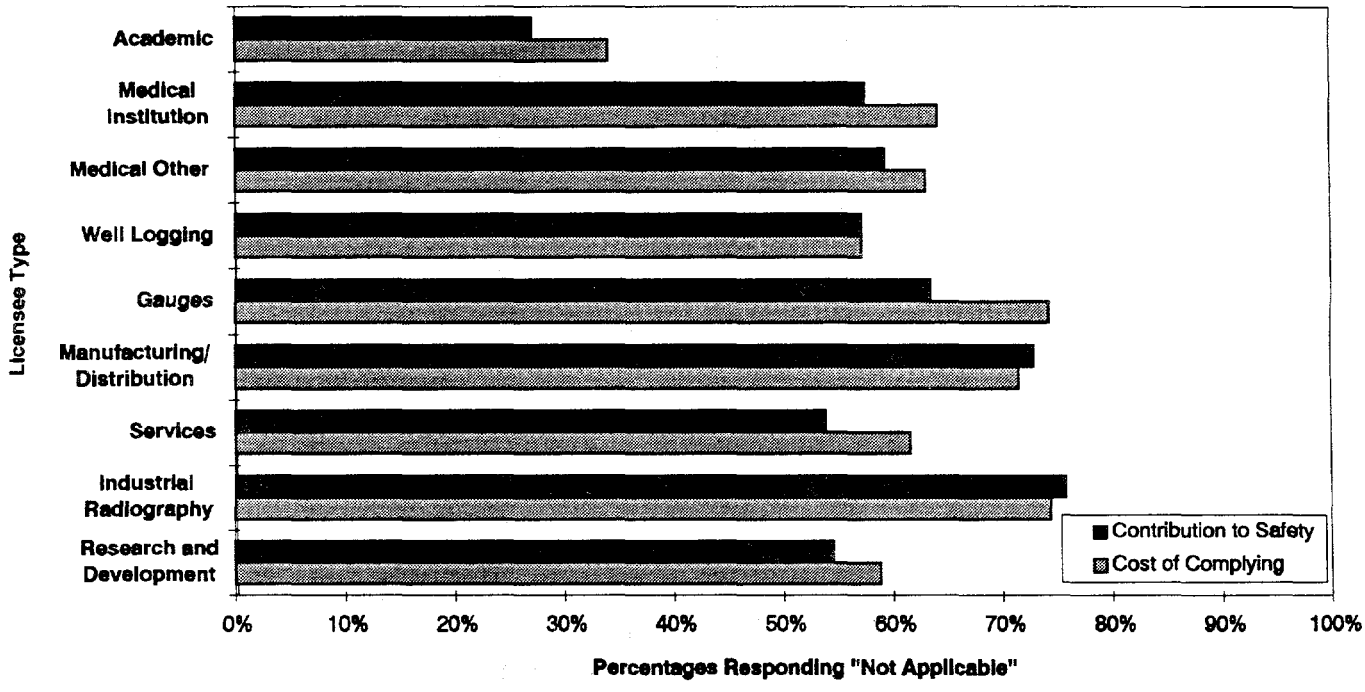


Figure C.5: Percentage Saying Part 34, Radiography, is Not Applicable, by Licensee Type

(from Questions 5–Contribution to Safety, and 6–Cost of Complying)

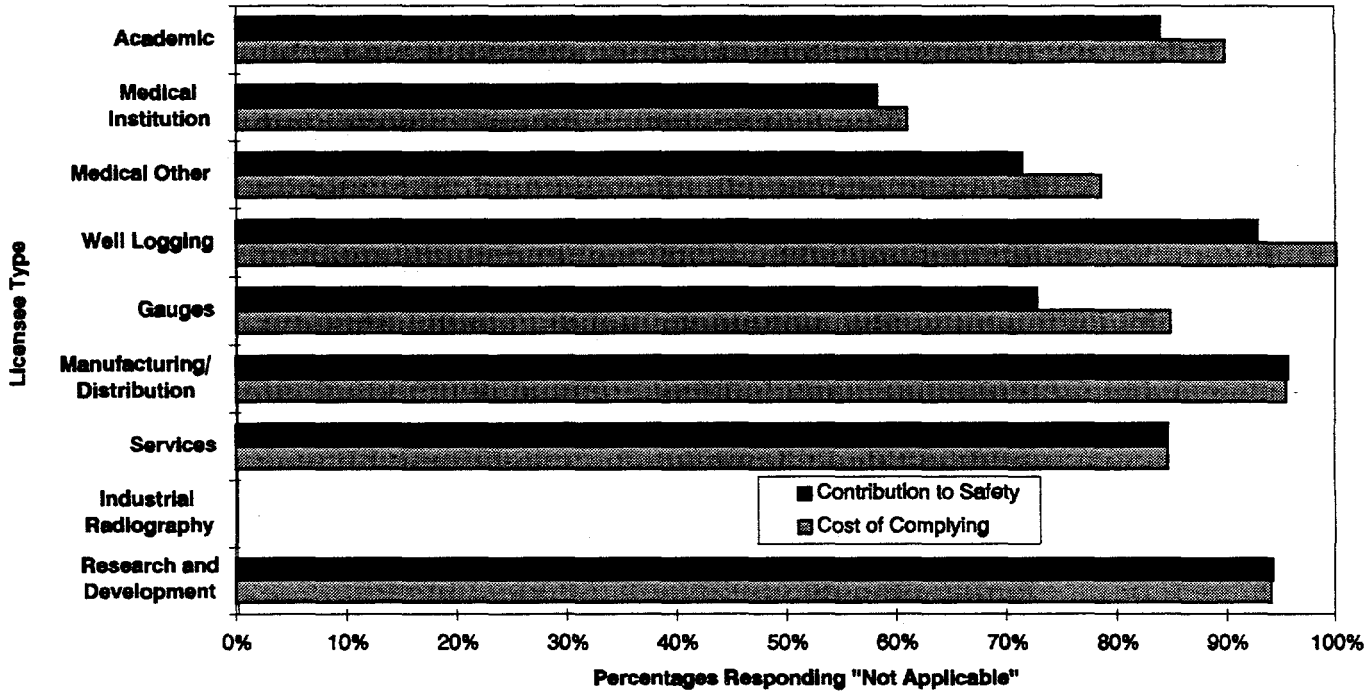


Figure C.6: Percentage Saying Part 35, Medical Use, is Not Applicable, by Licensee Type

(from Questions 5–Contribution to Safety, and 6–Cost of Complying)

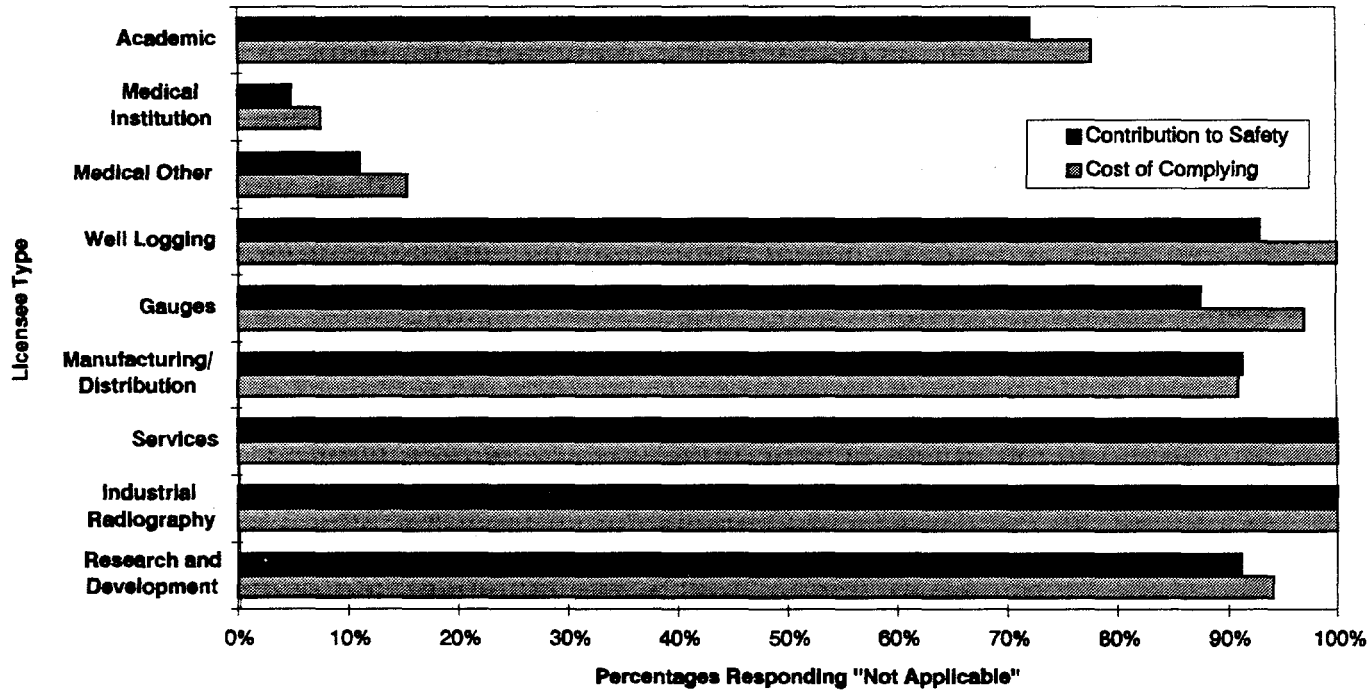


Figure C.7: Percentage Saying Part 36, Irradiators, is Not Applicable, by Licensee Type
(from Questions 5–Contribution to Safety, and 6–Cost of Complying)

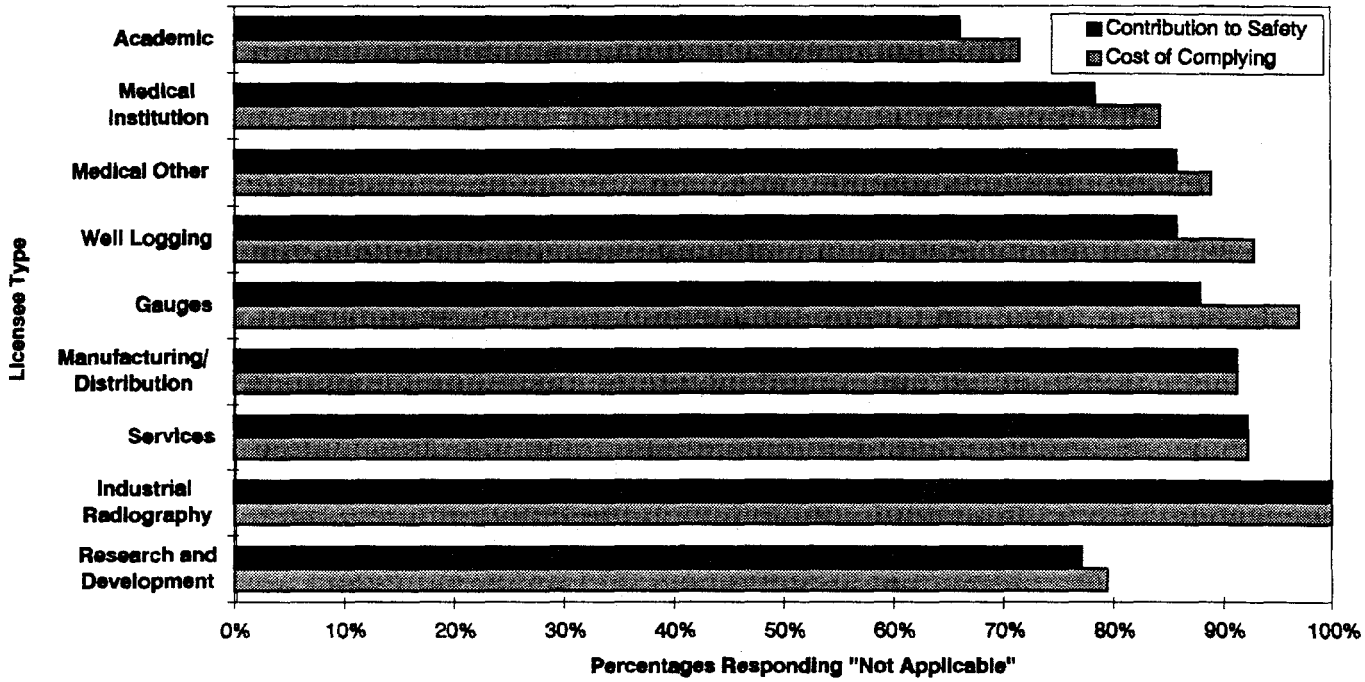


Figure C.8: Percentage Saying Part 39, Well Logging, is Not Applicable, by Licensee Type
(from Questions 5–Contribution to Safety, and 6–Cost of Complying)

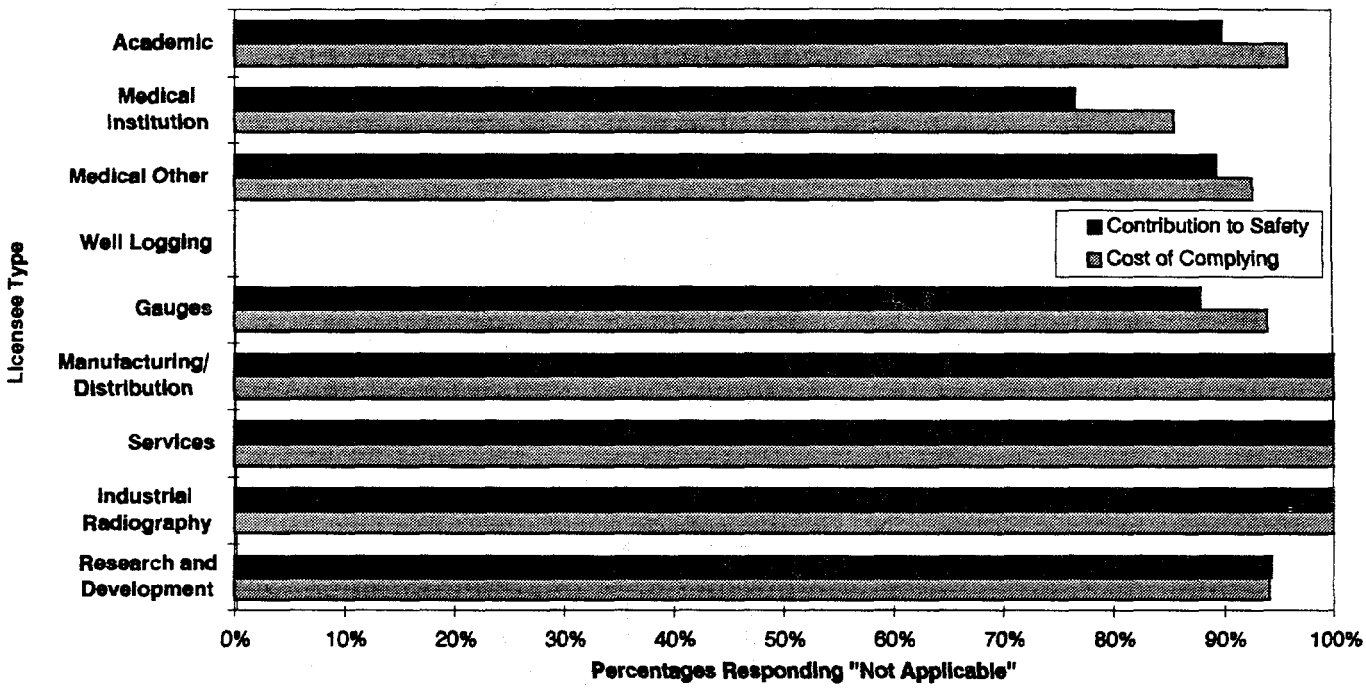


Figure C.9: Percentage Saying Part 40, Source Material, is Not Applicable, by Licensee Type
(from Questions 5--Contribution to Safety, and 6--Cost of Complying)

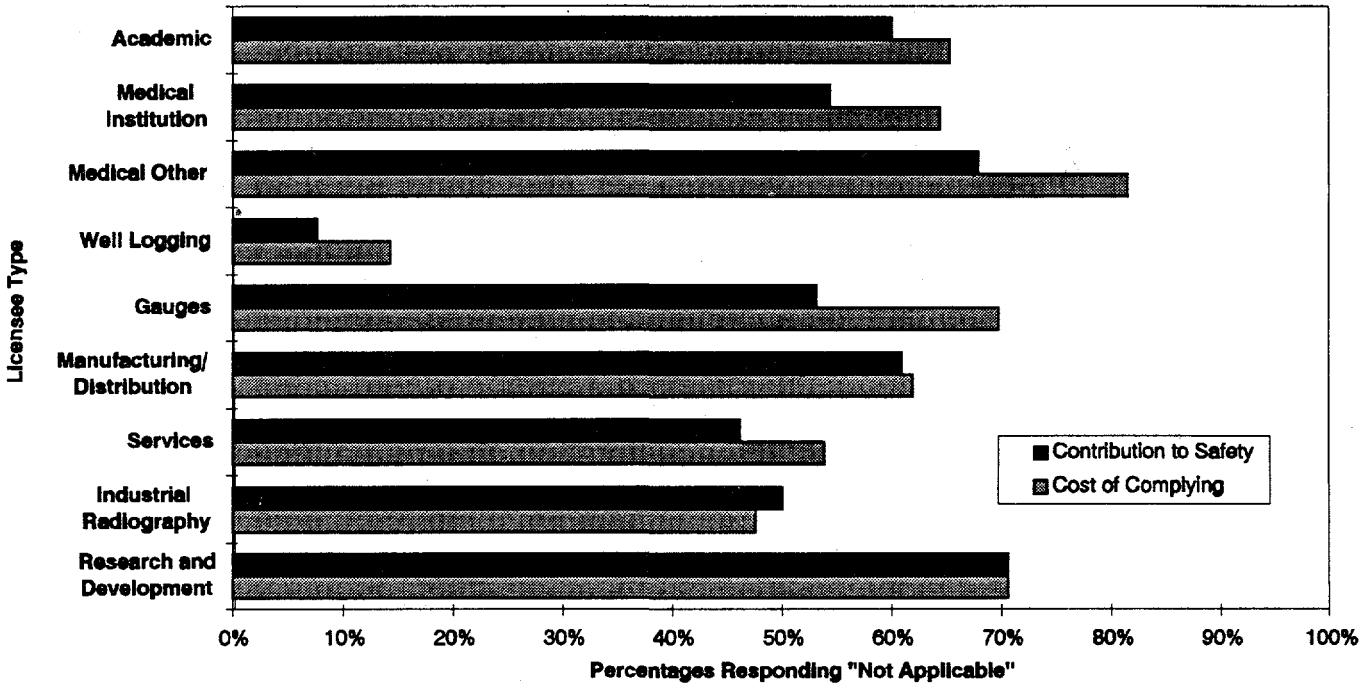


Figure C.10: Percentage Saying Part 70, Special Nuclear Material, is Not Applicable, by Licensee Type
(from Questions 5--Contribution to Safety, and 6--Cost of Complying)

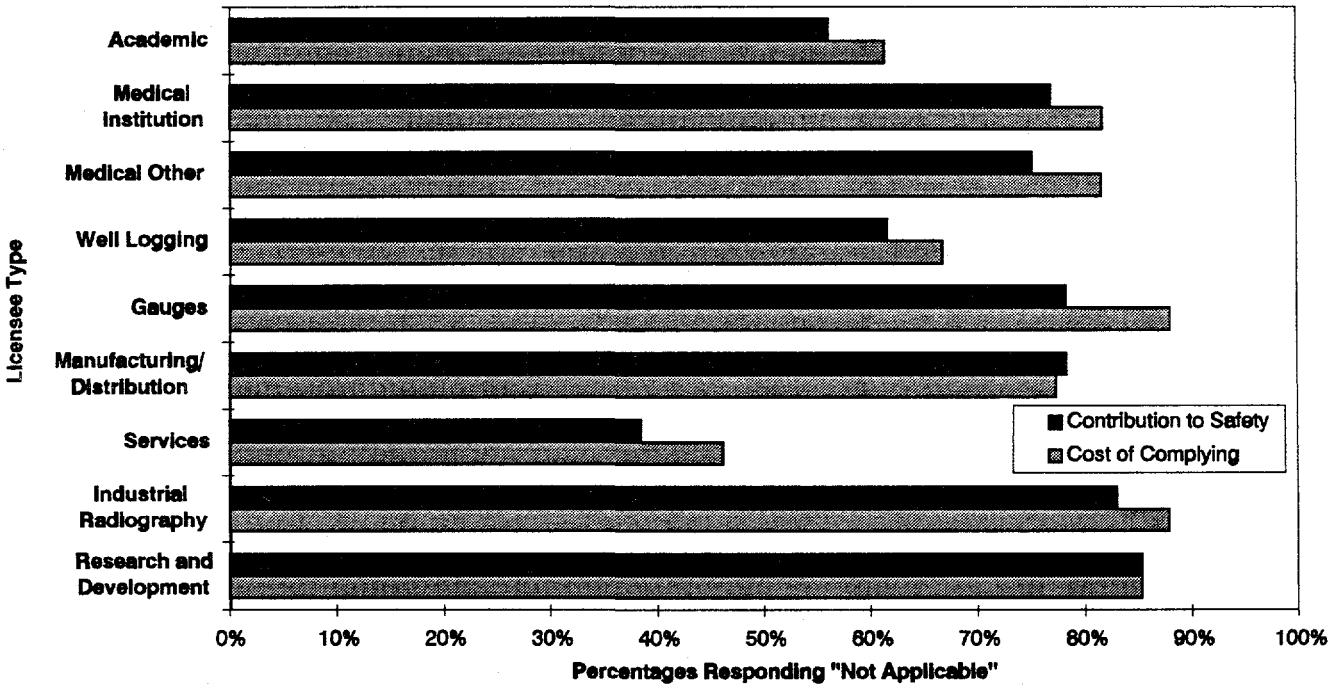


Figure C.11: Percentage Saying Part 71, Transportation, is Not Applicable, by Licensee Type

(from Questions 5–Contribution to Safety, and 6–Cost of Complying)

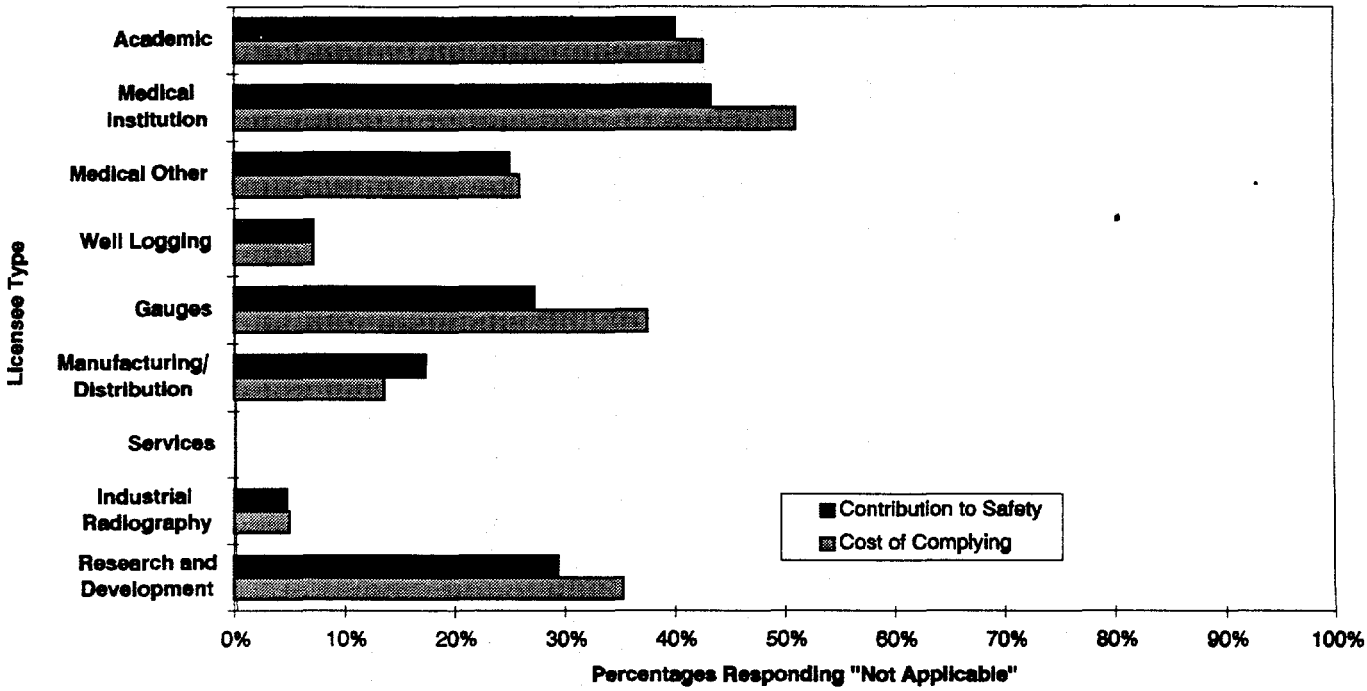
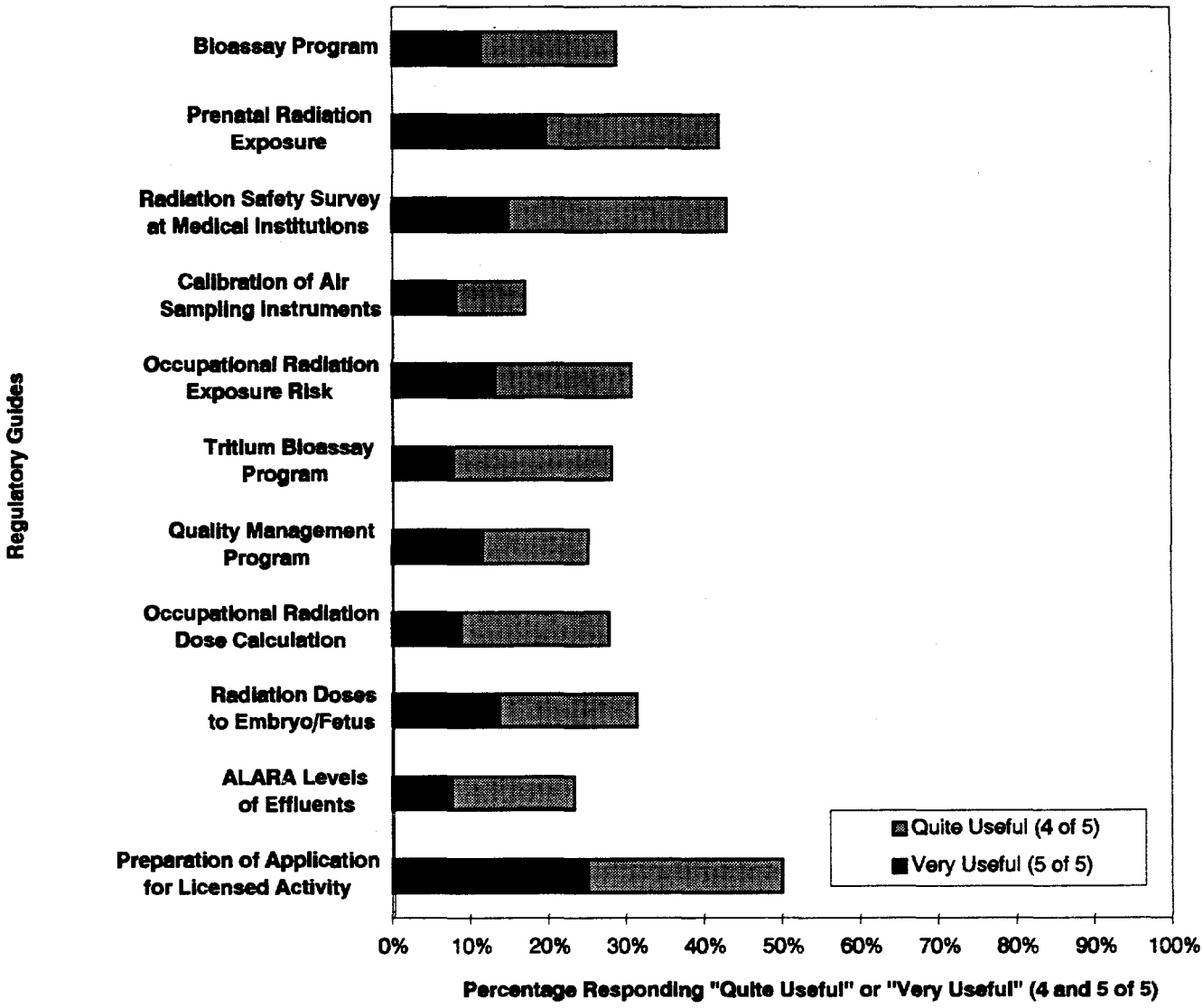


Figure C.12: Perceived Usefulness of Regulatory Guides
(Question 9)



APPENDIX D TABLES OF RESPONSES BY REGION TO QUESTION 14--EXPERIENCE WITH LAST LICENSING ACTION

Table D.1: Agreement that Reviewers were Professional in their Conduct--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	77%	84%	78%	68%
Neutral	20%	16%	19%	23%
Disagree or Strongly Disagree	2%	0%	3%	9%

Table D.2: Agreement that Reviewers were Helpful--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	59%	85%	73%	59%
Neutral	30%	12%	20%	18%
Disagree or Strongly Disagree	11%	4%	6%	23%

Table D.3: Agreement that Reviewers Asked Clear Questions--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	61%	79%	62%	56%
Neutral	23%	17%	28%	20%
Disagree or Strongly Disagree	17%	4%	10%	24%

Table D.4: Agreement that Reviewers Asked Only for Relevant Information--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	52%	64%	54%	48%
Neutral	28%	24%	28%	26%
Disagree or Strongly Disagree	20%	12%	18%	26%

Table D.5: Agreement that Reviewers Applied Regulations Consistently with NRC Intent--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	56%	72%	57%	52%
Neutral	26%	24%	34%	20%
Disagree or Strongly Disagree	18%	4%	9%	27%

Table D.6: Agreement that Reviewers Asked Reasonable Questions--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	54%	72%	65%	56%
Neutral	32%	16%	23%	30%
Disagree or Strongly Disagree	14%	12%	13%	14%

Table D.7: Agreement that Reviewers had Sufficient Knowledge of Licensees' Operations and Institutions--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	47%	54%	52%	46%
Neutral	31%	25%	24%	26%
Disagree or Strongly Disagree	22%	21%	24%	28%

Table D.8: Agreement that Reviewers were Competent in Relevant Technical Fields--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	60%	76%	58%	50%
Neutral	29%	14%	31%	36%
Disagree or Strongly Disagree	11%	10%	11%	14%

APPENDIX E TABLES OF RESPONSES BY REGION TO QUESTION 20--EXPERIENCE WITH LAST INSPECTION

Table E.1: Agreement that Inspectors were Professional in their Conduct--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	88%	96%	94%	80%
Neutral	11%	4%	2%	16%
Disagree or Strongly Disagree	1%	0%	4%	4%

Table E.2: Agreement that Inspectors were Knowledgeable of NRC Regulations--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	86%	96%	92%	84%
Neutral	13%	4%	8%	13%
Disagree or Strongly Disagree	1%	0%	0%	2%

Table E.3: Agreement that Inspectors were Knowledgeable of Licensees' License Conditions--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	73%	84%	81%	73%
Neutral	20%	12%	15%	22%
Disagree or Strongly Disagree	7%	4%	4%	4%

Table E.4: Agreement that Inspectors were Competent in Relevant Technical Fields--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	75%	88%	74%	58%
Neutral	20%	12%	22%	33%
Disagree or Strongly Disagree	5%	0%	4%	9%

Table E.5: Agreement that Inspectors had Sufficient Knowledge of Licensees' Operations and Institutions--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	68%	72%	68%	53%
Neutral	24%	16%	26%	33%
Disagree or Strongly Disagree	7%	12%	6%	13%

Table E.6: Agreement that Inspectors Focused on Safety Issues--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	69%	83%	71%	60%
Neutral	20%	9%	22%	22%
Disagree or Strongly Disagree	11%	9%	7%	18%

Table E.7: Agreement that Inspectors Used their Time Effectively at Licensees' Facilities--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	83%	88%	78%	60%
Neutral	14%	8%	13%	24%
Disagree or Strongly Disagree	3%	4%	8%	16%

Table E.8: Agreement that Inspectors Left Licensees a Clear Understanding of their Findings--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	83%	84%	80%	76%
Neutral	6%	12%	11%	9%
Disagree or Strongly Disagree	11%	4%	10%	16%

Table E.9: Agreement that Inspectors Applied Regulations Consistently with NRC Intent--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	71%	68%	70%	60%
Neutral	19%	24%	15%	22%
Disagree or Strongly Disagree	10%	8%	14%	18%

Table E.10: Agreement that Inspectors Asked Reasonable Questions--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	81%	92%	89%	67%
Neutral	14%	4%	7%	22%
Disagree or Strongly Disagree	5%	4%	4%	11%

Table E.11: Agreement that Inspectors Provided Licensees with Valuable Information--Percent Distribution

	Region I	Region II	Region III	Region IV
Agree or Strongly Agree	48%	68%	68%	41%
Neutral	34%	20%	21%	30%
Disagree or Strongly Disagree	17%	12%	11%	30%

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

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10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

This report presents the findings of a regulatory impact survey of nuclear materials licensees of the United States Nuclear Regulatory Commission (NRC). Commissioners of the NRC directed staff to provide the Commission with first hand information from licensees that could be used to improve the overall regulatory program. A self-administered, mail-out survey questionnaire was used to collect data from a sample of licensees who had interaction with the NRC during the previous 12 months. A total of 371 respondents of the 589 who were sent questionnaires returned completed surveys, for a response rate of 63%. The body of the report presents the findings of the survey including a brief introduction to the approach used, followed by survey findings regarding regulations, policies and regulatory guidance; experience with licensing applications, renewals and amendments; inspections; reporting requirements; and enforcement actions. The appendices of the report include a copy of the survey as administered to licensees, a fuller description of the survey design and data collection methods, and detailed graphic material describing survey responses.

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