VOLUME 2: APPENDIX C

RISK INFORMING THE MATERIALS AND WASTE ARENAS:

A Case Study on the Regulation of Static Eliminators

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ABSTRACT

In Commission Paper SECY-99-100, “Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards,” dated March 31, 1999, the staff of the U.S. Nuclear Regulatory Commission (NRC) proposed a framework for risk-informed regulation in the nuclear materials and waste arenas. The Commission approved the staff’s proposal and directed the staff to develop appropriate safety goals for these arenas and to use an enhanced participatory process. As part of this effort, the NRC staff is conducting case studies on a spectrum of activities in the nuclear materials and waste arenas. The objectives of these case studies are to (1) develop screening criteria for identifying regulatory applications where risk-informed approaches would add value; (2) determine the feasibility of safety goals; (3) illustrate how the staff can apply risk information to improve regulatory processes in the materials and waste arenas; and (4) identify the methods, data, and guidance needed to implement a risk-informed regulatory approach.

One of the activities chosen for the case studies is the NRC’s regulation of the use of radioactive material in static eliminators. Static eliminators are devices that contain a sealed source of radioactive material to reduce the buildup of electric charge on equipment and materials that are used in consumer and commercial applications.

The NRC currently regulates the use of static eliminators under the requirements specified in Title 10, Part 30, of the *Code of Federal Regulations* (10 CFR Part 30), “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and 10 CFR Part 31, “General Domestic Licenses for Byproduct Material.” In addition, the NRC regulates manufacturing and initial distribution of these devices under 10 CFR Part 30 and 10 CFR Part 32, “Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material.”

The general risks associated with the use of static eliminators have been evaluated and documented in several reports. In addition, sealed sources and devices, including most static eliminators, are registered in accordance with 10 CFR 32.210. The individual registration certificates provide an evaluation of risks associated with the specific devices. The available risk assessments and evaluations may support modifying the regulatory requirements for these static eliminators.

The static eliminator case study consisted of reviewing applicable documents and interviewing NRC personnel involved with licensing byproduct material devices. The case study followed the outline provided in the “Plan for Using Risk Information in the Materials and Waste Arenas” that was developed by the Risk Task Group in the NRC’s Office of Nuclear Materials Safety and Safeguards. The use and regulation of static eliminators were evaluated against questions in three categories, including (1) screening criteria analysis/risk analysis questions, (2) safety goal analysis questions, and (3) questions upon developing draft safety goals. These questions were designed to meet objectives related to the effectiveness of the draft screening criteria, the current and potential value of risk information, the feasibility and utility of safety goals, and the information needed for a risk-informed regulatory approach.

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1. INTRODUCTION

In Commission Paper SECY-99-100, “Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards,” dated March 31, 1999 [1], the staff of the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards (NMSS), proposed a framework for risk-informed regulation in the nuclear materials and waste arenas. The Commission approved the staff's proposal and directed the staff to develop appropriate safety goals for these arenas, and to use an enhanced participatory process that includes regular public meetings with all stakeholders who are involved in or affected by regulation of these arenas [2].

At the first such meeting, the NRC staff suggested that screening criteria were needed to identify issues for which risk information would be productive. The staff further suggested that the development of safety goals and screening criteria would be enhanced by studying actual regulatory cases in the materials and waste arenas, to see how risk information was, or could have been, used. The NMSS staff adopted this suggestion and, as part of the overall risk-informing effort, is conducting case studies of a spectrum of activities in the nuclear materials and waste arenas, including the transportation of radioactive materials. The regulation of the use of static eliminators, the subject of this report, is one of these case studies.

1.1 Objectives and Approach

The NMSS staff will consolidate the results of this case study with those from the other case studies to further the following objectives:

(1) Produce final screening criteria for the materials and waste arenas.

(2) Illustrate how the application of risk information has improved or could improve particular areas of the regulatory process in the materials and waste arenas.

(3) Determine the feasibility of safety goals in the particular areas studied. If feasible, develop safety goal parameters and a first draft of safety goals. Otherwise, document the reasons why this is infeasible.

(4) Identify methods, data, and guidance needed to implement a risk-informed regulatory approach.

It is not an objective of this or any other case study to reconsider the regulatory actions that the NRC took in the case being studied. The objectives are strictly those listed above.

The NMSS is conducting all of its case studies using a standardized approach. The case studies are largely retrospective; that is, they involve regulatory and physical actions that the NRC has already taken. Each case is studied by a member of the NMSS Risk Task Group or a contractor with risk expertise. Advisors include subject matter experts from the NRC staff who have knowledge of the particular case. The reviewers also consult with licensees and other stakeholders having knowledge of the particular case.

The basis for each case study is the review of information from NRC and licensee source documentation, through which the staff answers a standardized list of questions that address

aspects of the four objectives listed above. After the investigative phase of the study, the NMSS staff generates a set of preliminary conclusions on the basis of the answers to these questions. The staff then presents its preliminary conclusions at a public meeting in which all stakeholders are invited to participate. After incorporating information and ideas that emerge from this meeting, the NMSS staff produces a report documenting the case study. This document is one such case study report. In addition, the NMSS staff will consolidate the results from all of the case studies to prepare a final summary report.

1.2 Scope

Static eliminators are devices that contain a sealed source of radioactive material to reduce the buildup of electric charge on equipment and materials that are used in consumer and commercial applications. The radiation from the radioactive source produces ions in air that neutralize the static charges in their vicinity.

The NRC currently regulates the use, manufacturing, and initial distribution (transfer) of static eliminators under Title 10 of the *Code of Federal Regulations* (10 CFR), Parts 30 through 32. Sealed sources and devices containing them may be used under a general license or a specific license, or may be exempt from licensing requirements. Specifically, 10 CFR Part 31 indicates that a static eliminator device may be used under a general license if certain conditions are met; otherwise, use of the device would be governed by a specific license. Static eliminators are not included in the set of exempt devices.

1.3 Organization of the Report

In addition to this introduction (Section 1), this report consists of six sections. Section 2 gives background information on the design, use, and regulation of static eliminators. Section 3 discusses the specific approach and actions taken for this case study, including the sources of information considered. Sections 4 and 5 provide the results in the form of answers to the standardized risk questions, and the draft screening criteria that the NMSS generated. Section 6 summarizes the staff's conclusions regarding the use of risk information in the nuclear materials and waste arenas. Finally, Section 7 lists the references used in conducting this case study.

2. BACKGROUND

As stated in Section 1.2, static eliminators are devices that contain a sealed source of byproduct material to reduce the buildup of electric charge on equipment and materials that are used in consumer and commercial applications. Static electric charges may develop when different materials are in close contact. If the materials are nonconducting, the static charge will remain, and the presence of this static charge can lead to various problems. To combat this situation, the radiation from the static eliminator source produces ions in air, that neutralize the static charges in their vicinity.

As consumer products, the use of static eliminators is generally limited to eliminating static charges on photographic film and lenses, as well as those that can hinder the delicate operation of precision balances. As commercial products, static eliminators are used to reduce (1) the risk of fire or explosion that might result from the buildup and discharge of static charges in volatile and explosive environments (e.g., paint shops), (2) the buildup of static charges that can damage electronic circuits and hard drives during assembly and repair of personal computers, (3) the buildup of dust on surfaces to be electroplated or painted, and (4) the static cling of processed material on sheet-fed webs and rollers (e.g., print shops).

The NRC currently regulates the use, manufacturing, and initial distribution (transfer) of static eliminators under 10 CFR Parts 30, 31, and 32:

- 10 CFR Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material
- 10 CFR Part 31 - General Domestic Licenses for Byproduct Material
- 10 CFR Part 32 - Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material

In general, static eliminators may be used under a general license or a specific license. Specifically, 10 CFR Part 31 allows a static eliminator to be used under a general license if certain conditions are met; otherwise, use of the device would require a specific license. The manufacturing and initial transfer of a static eliminator requires a specific license.

2.1 Static Eliminators Used Under a 10 CFR 31.3 General License

Under 10 CFR 31.3, the NRC issues a general license to transfer, receive, acquire, own, possess, and use a static elimination device containing as a sealed source no more than 500 microcuries of polonium-210 (Po-210), as long as the device is manufactured, tested, and labeled by the manufacturer under a specific license. Po-210 is an alpha emitter and a weak gamma emitter, with a half life of 138 days. These devices may be used in both consumer and commercial applications. The general license issued under 10 CFR 31.3 to use static eliminators is subject to the provisions of 10 CFR Part 30 that are applicable to general licensees, including requirements and restrictions on transferring the devices, reporting to the NRC, recordkeeping, inspection, testing, and enforcement.

The specific license to manufacture a 10 CFR 31.3 generally licensed static eliminator is issued pursuant to 10 CFR Part 30. 10 CFR Part 30 places requirements on the specifically licensed manufacturer regarding labeling and transfer (distribution) of the devices, reporting to the NRC,

recordkeeping, inspection, testing, and enforcement. There are approximately 30,000 of these devices distributed for use each year.

A safety evaluation and registration (discussed below) are not required as a prerequisite to distributing or using devices that are licensed under 10 CFR 31.3. Similarly, there are no explicit requirements for the design, leak testing, installation, or servicing of static eliminators that are generally licensed for use under the 10 CFR 31.3. However, the sealed source used in manufacturing the devices is specifically licensed, and is subject to the safety evaluation and registration requirements.

2.2 Static Eliminators Used Under a 10 CFR 31.5 General License

Under 10 CFR 31.5, the NRC issues a general license to transfer, acquire, receive, possess, or use certain devices, including devices for producing an ionized atmosphere (e.g., static elimination devices), as long as the devices are manufactured or initially transferred and labeled in accordance with the specifications of a specific license issued pursuant to 10 CFR Parts 30 and 32. The general license issued under 10 CFR 31.5 is explicitly limited to commercial and industrial firms; research, educational, and medical institutions; individuals in the conduct of their business; and Federal, State, or local government agencies.

10 CFR 31.5 identifies the requirements that apply to the general license holder with regard to labeling, leak testing, recordkeeping, servicing, failure reporting, abandonment, transfer, and disposal. The general license holder is also subject to the provisions of 10 CFR Part 30 that are applicable to other general licensees, including requirements and restrictions on transferring the devices, reporting to the NRC, recordkeeping, inspection, testing, and enforcement.

Manufacturing and initially transferring any 10 CFR 31.5 generally licensed static eliminator requires a specific license issued pursuant to 10 CFR Parts 30 and 32, specifically 10 CFR, Sections 32.51 and 32.52. 10 CFR 32.51 requires an applicant to submit an application containing information related to the design, manufacture, prototype testing, quality control, labeling, proposed leak testing, operating and safety instructions, and potential hazards of the device. The information provided by the manufacturer must be sufficient to provide reasonable assurance that the device meets the following criteria:

- The device can be safely operated by persons who do not have training in radiological protection.

- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device.

- Under ordinary conditions of handling, storage, and use of the device, it is unlikely that any person will receive in 1 year a dose that exceeds 10% of the annual limits specified in 10 CFR 20.1201(a) (the occupational dose limits for adults).

- Under accident conditions (such as fire or explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment that exceeds the dose to the appropriate organ as specified in Column IV of 10 CFR 32.24 (15 rem to the whole body, head and trunk, active blood-

forming organs, gonads, or lens of the eye; 200 rem to the hands and forearms, feet and ankles, or localized areas of skin; 50 rem to other organs).

In addition, 10 CFR 32.51 specifies labeling, leak testing, installation, and servicing requirements for generally licensed 10 CFR 31.5 devices, as well as other general requirements that apply to the specifically licensed manufacturer's facility and operations. 10 CFR 32.52 specifies material transfer reporting and recordkeeping requirements for 10 CFR 31.5 devices applicable to the manufacturer.

Specific static eliminators that may be used under a general license pursuant to 10 CFR 31.5 are described in Section 2.6.

2.3 Static Eliminators Used Under a Specific License

A static eliminator may also be used under a specific license issued pursuant to 10 CFR Part 30. To obtain a specific license, a person must submit an application to the NRC or Agreement State (discussed below) that satisfies the requirements of 10 CFR 30.32. If a specific license is issued, the licensee is subject to specific terms and conditions of the license, as well as the other applicable requirements of 10 CFR Part 30, until the license is terminated.

Under 10 CFR 30.32(g), an application for a specific license to use a static eliminator must either (1) identify the device by manufacturer and model number as registered with the NRC (under 10 CFR 32.210) or with an Agreement State, or (2) contain the information identified in 10 CFR 32.210. The registration of static eliminators and other sealed sources and devices is discussed in Section 2.4.

Specific static eliminator devices requiring a specific license for use are described in Section 2.6.

2.4 Device Registration

10 CFR 32.210 allows manufacturers and initial distributors of specifically licensed sealed sources and devices to submit and register the radiation safety information that is needed to perform an independent safety evaluation. Applicants for a specific license to use a particular source or device may then reference the registration, rather than individually providing the safety information in their applications, to satisfy the requirements of 10 CFR 30.32(g).

According to 10 CFR 32.210(c), the request for evaluation and registration must include information regarding the source and device design, manufacture, prototype testing, quality control, labeling, proposed uses, and leak testing. In addition, for a device, the request must include information regarding installation, service, and maintenance; operating and safety instructions; and the potential hazards associated with the device. The information must be sufficient to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

According to 10 CFR 32.210(d), the safety of a sealed source or device will be evaluated on the basis of radiation safety criteria in accepted industry standards. If standards and criteria do not readily apply to a particular case, the NRC will formulate reasonable standards and criteria that will be sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

While 10 CFR 30.32(g) and 10 CFR 32.210 explicitly applies to sealed sources and devices that are used under a specific license, the NRC has determined that registration is necessary for certain exempt and generally licensed devices, including those that are used under the general license pursuant to 10 CFR 31.5. Therefore, manufacturers and initial distributors of static eliminators generally licensed under 10 CFR 31.5 submit a request for evaluation of radiation safety information, and for registration of that information, according to 10 CFR 32.210.

2.5 Agreement States

Agreements States have the authority to perform safety evaluations and to register byproduct materials that are used, possessed, or distributed by persons within their borders. An applicant located in an Agreement State that is seeking a safety evaluation and registration of a sealed source or device applies to the authority within that Agreement State. Agreement States forward copies of their registration certificates to the NRC for administrative review. Copies are then forwarded to the NRC regions, all Agreement States, and appropriate Federal and international agencies. Any administrative problems or omissions are resolved directly with the Agreement State.

The NRC may determine that a sealed source or device that is registered by an Agreement State does not meet the regulations required of an NRC licensee, or may identify significant safety concerns regarding a sealed source or device that has been evaluated by an Agreement State. In such instances, the NRC will attach a cover letter to the registration certificate, indicating why the sealed source or device is not approved for use by NRC licensees. The NRC will raise the safety issues with the Agreement State that issued the registration certificate, as well as the vendor that manufactured of the source or device.

2.6 Sealed Source and Device Registry (SSDR)

The NRC maintains a registry of radiation safety information on sealed sources and devices that contain byproduct material for which the NRC or an Agreement State issued registration certificates. A search of the SSDR indicates that there are currently eight active registration certificates for static eliminator devices that are intended for use under a general license. Of these certificates, seven reference Po-210 as the radiation. The remaining certificate references krypton-85 (Kr-85) as the source.

The registered Po-210 devices include bars and disks onto which the sealed source is mounted and protected by a tamper-resistant housing and screen. These bars and disks are then installed in proximity to the application. The devices also include air blowers, as well as cartridges and air guns through which compressed air is blown. The activity of Po-210 in these devices ranges from 5 millicuries to 324 millicuries.

The 20 registered Po-210 devices employ 3 different registered sealed sources. One of these sealed sources is Model PDM.1001, which is manufactured and distributed by AEA Technology QSA Inc. This foil source consists of polonium chromate dispersed in a matrix of silver. According to the registry certificate, the radioactive component is a layer approximately 1 micrometer thick, sandwiched between a 0.2-millimeter silver backing and a 3-micrometer thick cover layer of palladium gold alloy. The finished foil strip is 20 millimeters wide, with the Po-210 source limited to the center 10 millimeters. The foil source is cut to the length determined by the eliminator design, the cut ends are protected with silver end caps, and the foil segment is

electroplated 1 micrometer thick with nickel. The source concentration is 0.8 millicurie per centimeter length. The registration certificate for the device in which this foil source is used indicates that the dose rate at the surface of the device does not exceed 0.75 millirem per hour.

A second referenced Po-210 source, Model PDM.1002, is also manufactured and distributed by AEA Technology QSA Inc., and is very similar to PDM.1001. This is also a foil source, consisting of Po-210 oxide dispersed in a gold matrix. The source layer is sandwiched between a silver-coated copper base and a copper cover layer. The finished foil strip is 20 millimeters wide, with the Po-210 source limited to the center 11 millimeters. The source concentration is 1.25 millicurie per centimeter length. The registration certificate for the devices in which this foil source is used indicates that dose rates are less than 1 millirem per hour at 5 centimeters from the surface of the devices, and are less than 0.05 millirem per hour at 30 centimeters from the surface of the devices

The third Po-210 sealed source, Model P-001, is a foil source manufactured by NRD, Inc. The source consists of the gold-Po-210 active layer, sandwiched between a gold overcoat and undercoat, all of which is supported by a thicker silver backing. This laminated foil is sealed with gold through electroplating. The maximum activity reported for the source ranges between 5 millicurie and 324 millicurie, depending on the length of the foil strip. The registration certificates for devices in which this foil source is used indicate that exposure rates are less than 0.2 milliroentgens per hour at the surface of the devices.

In addition to the seven active registration certificates that reference Po-210 as the radiation source, one active registration certificate for a generally licensed static eliminator employs Kr-85 as a source. This registration covers five different devices manufactured by TSI Incorporated. For each of these devices, the krypton gas is sealed within a stainless steel tube, which is then mounted inside a stainless steel or aluminum tubular housing, ranging from 15 to 50 centimeters in length and 4 to 9 centimeters in diameter. The housing is then typically plumbed into a flow system, and is used to eliminate static charges on solid particles in the flow stream. The activity of Kr-85 in the sealed source ranges from 1 to 10 millicuries, depending on the device. For the 10-millicurie device, the registration certificate indicates that the dose rate on the surface of the device is 13.1 millirem per hour.

The SSDR also shows three registration certificates for static eliminators that may be used only under a specific license. Two of the registration certificates are for static eliminators that employ americium-241 (Am-241). The third registration certificate describes a static elimination application that was discontinued in the 1970s, according to the licensee.

One of the specifically licensed static eliminators that uses Am-241 is a laser transceiver manufactured and distributed through Lockheed Martin Corporation. This device is used for laser target range and designation onboard aircraft. Contained in the device are two 4.5-microcurie Amersham Model AMM Am-241 foil sources. The AMM foil source is a gold-americium oxide mixture contained between a 0.006-millimeter thick silver backing and a 0.002 millimeter face of gold or gold and palladium. The AMM foil source is also included in the SSDR.

The other specifically licensed static eliminator that uses Am-241 is the Ionotron model manufactured and distributed by NRD, Inc. The device consists of a foil source mounted in an aluminum housing and protected by a stainless steel grid. The grid allows alpha particles to be freely emitted to ionize the ambient atmosphere. The foil source, Model A-001, is also

manufactured by NRD, Inc., and is comprised of a gold or silver overcoat and undercoat, an active layer of gold or silver and Am-241 oxide, and a silver or gold backing, all of which are welded and rolled to completely seal the source. The foil unit is then gold-plated. Depending on the application, the Am-241 content in the source may range from 0.4 microcuries per linear inch to 8350 microcuries per linear inch.

3. CASE STUDY APPROACH

In studying this case, the NMSS staff reviewed existing and applicable documentation and databases, held discussions with NRC staff involved with registering and tracking static eliminators and other sealed source devices, and conducted an interim stakeholder workshop to solicit input on preliminary findings. The workshop was held on February 9, 2001, and was documented through an official transcript [3].

The NMSS staff began by reviewing 10 CFR Parts 30, 31, and 32, which apply to the licensing of byproduct material and, specifically, sealed sources and devices, as well as 10 CFR Part 20, which contains regulations applicable to existing dose limits. In addition, the NMSS staff reviewed the guidance for implementing these regulations, with respect to sealed sources and devices, as provided in NUREG-1556, Volume 3, “Consolidated Guidance About Materials Licenses -- Applications for Sealed Source and Device Evaluation and Registration” [4].

The NMSS staff also queried several databases maintained by the NRC to identify records that apply to static eliminators. Specifically, the staff searched the SSDR to retrieve, categorize, and review the registration certificates for all static eliminator sources and devices. For completeness, the staff included both active and inactive registration certificates for both generally and specifically licensed sources and devices. The staff also searched the Nuclear Material Events Database (NMED) to retrieve records pertaining to events involving static eliminators. Finally, the staff queried the General License Tracking System (GLST) for information related to the distribution of static eliminators.

On the basis of an Internet search and a search of internal NRC records, the NMSS staff then retrieved and reviewed several studies related to dose and risk assessments of static eliminators. In addition, on the basis of input received during the interim public stakeholder workshop, the NMSS staff searched NRC records for documents related to a specific event involving the recall of static eliminators manufactured by the Minnesota Mining and Manufacturing Company (3M). (The recall event is discussed in Section 4.2.)

Finally, the NMSS staff consulted with other NRC staff involved with regulating byproduct materials. This consultation included discussions with staff associated with the safety evaluation and registration of sealed sources and devices, and others responsible for maintaining the databases mentioned above.

After reviewing all available information, the NMSS staff focused the case study on answering the three sets of questions in the Case Study Plan [5]. (Section 4 of this report presents the answers to these questions.) The NMSS staff then evaluated the regulation of static eliminators against the draft screening criteria defined in the Case Study Plan. Although these criteria are intended for use in determining if a particular regulatory application would be amenable to, and would benefit from, the use of risk information, in the case studies, the intent was to evaluate the applicability and usefulness of the draft screening criteria themselves, before they are finalized. (Section 5 of this report discusses the application of the screening criteria in this case study.)

4. RESPONSES TO DRAFT QUESTIONS

This section presents answers to three sets of questions identified in the Case Study Plan. The NMSS staff developed the answers based on the information collected and reviewed through the case study process.

4.1 Screening Criteria Analysis/Risk Analysis Questions

(1) What risk information is currently available in this area? (Have any specific risk studies been done?)

The existing information includes several documented, general risk-related studies that consider the risks associated with static eliminators. These studies express risks in terms of radiation doses under normal and off-normal (e.g., accident, misuse) conditions.

Two early studies (listed and discussed below) considered only static eliminators that were intended for consumer use, containing sealed sources of Po-210 with activities of no more than 500 microcuries. (These would be devices that were generally licensed for use under 10 CFR 31.3.) Both studies considered the Po-210 source in the form of microspheres, a form that is no longer used.

- NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material" [6]

  NUREG/CR-1775 assessed the impact on people and the environment, which may result from the use of radioactive materials in consumer products. The study focused on the benefits and risks associated with presently distributed consumer products, and was intended to provide a source of information for a future generic environmental impact statement on consumer products. Specifically, this study defined 'consumer products' as products, commodities, and materials that are available in the marketplace as 'off-the-shelf' items intended for personal and household use by the general public. Hence, the study considered static eliminators that were intended for consumer use, but did not consider products that were intended solely for industrial and medical use.

  At the time the study was conducted, consumers primarily used static eliminators in photographic and high-fidelity (phonographic) applications. Consequently, the devices were marketed through photographic and audio component stores. The report states that only one line of static eliminators containing radioactive material was manufactured in the United States for consumer use. That line included two available sizes, one containing nominally 200 microcuries of Po-210 and another containing nominally 500 microcuries of Po-210. The Po-210 was fixed in ceramic microspheres, which were resin-bonded to an aluminum backing. Up to the time of the report, the maximum quantities of 200-microcurie and 500-microcurie units distributed in a year was 50,000 and 20,000, respectively. NUREG/CR-1775 evaluated the radiological health impacts (committed organ doses) during normal manufacturing and distribution, use, and disposal, as well as during accident conditions (residential and warehouse fires) and misuse.

- "NCRP Report No. 95, Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources" [7]

  In 1987, the National Council on Radiation Protection (NCRP) published a report documenting the estimated dose equivalents received by members of the public from consumer products containing radioactive material. For each source category, the study attempted to provide data on the number of products currently in use, the rate at which the usage was changing, and the range of typical dose equivalents received by the general public. Among the various source categories, the study included static eliminators that were used in consumer applications. The estimated dose equivalents reported in the NCRP report were determined using the organ-dose calculations in NUREG/CR-1775. Specifically, the NCRP report assumed that 37,600 units were distributed annually with an initial source strength of 500 microcuries. Given these assumptions, the NCRP estimated the annual collective effective population dose equivalent and the average annual effective dose equivalent to the exposed population during normal use and disposal. The NCRP also estimated the effective dose equivalent to a firefighter during accident conditions (a fire in a warehouse); however, the NCRP based the estimate on the organ dose calculations reported in NUREG/CR-1775, and did not account for respiratory protection worn by firefighters.

Two more recent risk-related studies (listed and discussed below) considered static eliminators that are intended for consumer use (under 10 CFR 31.3) and commercial use (under 10 CFR 31.5). Both assumed Po-210 as the source, and both assumed that the sealed source was in the form of a laminated foil, the form that is currently used.

- NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" [8]

  NUREG-1717 documents an assessment of potential radiological impacts on the public associated with the present regulatory exemptions for source and byproduct materials. Such exemptions have generally been issued on the basis of a determination by the Atomic Energy Commission (AEC), prior to 1974, or NRC, since 1974, that the possession, use, and transfer of the exempted materials would not constitute an unreasonable risk to public health and safety. However, the exemptions were issued over many years, some as early as the 1940s when AEC regulations did not yet include radiation protection standards for the public, and methods for quantitative assessment of dose to the public had not yet been developed. Therefore, approaches used by the AEC and NRC in assessing radiological impacts on the public in support of establishing the exemptions have varied widely. In addition, for exposures involving ingestion or inhalation of radionuclides, assessments were often based on internal dosimetry models and databases that, although representative of the state-of-the-art at the time, have since been superseded and are no longer used by Federal agencies. Therefore, NUREG-1717 addressed the need to reevaluate the current exemptions for source and byproduct materials to determine the potential radiological impacts on the public.

  In addition, some items generally licensed under 10 CFR Part 31, that contain small quantities of byproduct material, are considered potential candidates for exemption from licensing requirements. As part of the study, the NRC assessed of the potential radiological impacts on the public associated with five generally licensed items containing byproduct material, including static eliminators. Specifically, NUREG-1717

evaluated individual and collective doses associated with the distribution, routine use, disposal as ordinary trash, and misuse (and accidents) of both commercial and consumer static eliminator devices.

NUREG-1717 evaluated a source consisting of a composite foil of gold and Po-210 pressure-welded onto a silver backing plate, and gold-plated to encapsulate the source. For the consumer units, the study assumed that 30,000 units are distributed annually, each with an initial polonium source of 500 microcuries. For the commercial units, the study assumed a source of 200 millicuries as the basis for estimating the maximum dose to an individual user, and a source of 50 millicuries and an annual distribution of 10,000 units as the basis for estimating the collective radiation dose to the public. The study estimated doses resulting from normal distribution, consumer and commercial use, and disposal. The study also considered misuse and accident conditions.

During distribution, the study estimated that a single driver picking up all 40,000 consumer and commercial units distributed in a single year would receive an annual effective dose equivalent of approximately 2 millirem. Individual doses received during normal consumer and commercial use and disposal through landfill and incineration were all estimated to be much less than 1 millirem. For misuse, the study assumed that a unit was carried in an individual's pocket for 2,000 hours during the year. For a consumer unit, this resulted in an estimated annual effective dose equivalent of 0.2 millirem to the whole body and a dose equivalent of 20 millirem to a small area of the skin. For a commercial unit, this resulted in an estimated annual effective dose equivalent of 80 millirem to the whole body and a dose equivalent of 8 rem to a small area of the skin. The accidents evaluated included a residential fire, a truck fire while transporting the units from the manufacturer for distribution, and a warehouse fire. The effective dose equivalent to an individual involved in a residential fire, without respiratory protection, was estimated to be 2 millirem. A firefighter (with respiratory protection) at a truck fire was estimated to receive an effective dose equivalent of 20 millirem, and an individual (without respiratory protection) involved in the cleanup after a fire was estimated to receive an effective dose equivalent of 200 millirem. A firefighter (with respiratory protection) at a warehouse fire was estimated to receive an effective dose equivalent of 20 millirem, and an individual (without respiratory protection) involved in the cleanup after a fire was estimated to receive an effective dose equivalent of 100 millirem.

- NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" [9]

  NUREG/CR-6642 documents a project directed by the NRC staff to identify regulatory options for byproduct material (including static eliminators) that are risk-informed (that is, options that are formulated in light of insights obtained from risk analysis). The specific objectives of the project were to (1) use qualitative and, to the extent possible and reasonable, quantitative and probabilistic tools to identify and evaluate the risks associated with nuclear byproduct materials systems, (2) develop and apply a radiation risk evaluation system to categorize each of those systems, and (3) develop and evaluate options for regulatory approaches and their associated costs and benefits.

  The analysis grouped the full set of byproduct material licenses in a manner that was conducive to a systematic analysis. Licensees' activities and devices were organized

into 40 systems, each with unique features (i.e., radionuclides, source form, nature of use, etc.) necessary to achieve the objectives of the study. Static eliminators were grouped into a 'system' with other small sealed sources (e.g., check sources, calibration sources, scintillation detectors, Mossbauer sources, radioluminescent light sources).

Each system was described in terms of tasks, hazards, barriers, and receptors. Tasks included receipt and storage, installation and maintenance, use, and disposal of the devices. Barriers (both physical and administrative) limit the doses to both the worker and the public during tasks. A barrier structure was developed according to current regulations, guides and good practice. Development of the barrier structure development was guided by four fundamental safety functions that serve to minimize the exposure dose, including shielding from radionuclides, confinement of radionuclides, the source strength of radionuclides, and access to radionuclides. A radiation risk assessment was performed for each of the 40 byproduct material systems, determining both the normal operation and accident risk for the worker and the public. Doses (consequences) and risks (consequences and associated frequencies) were quantified for several event sequences that occur (or can possibly occur) for several tasks associated with a given system. The risks were tallied to assess those that apply to each system task and those that apply to the system as a whole. This risk information was then used to provide a risk (dose consequence and frequency) perspective for consideration of regulatory options.

The study considered static eliminator units that are intended for both consumer and commercial use. Po-210 source strengths for consumer units were assumed to range from 200 to 500 microcuries, with 30,000 units in use. Source strengths for commercial units were assumed to range from 10 to 50 millicuries, with 10,000 to 150,000 units in use. On the basis of this information, the evaluation of static eliminators assumed 75,000 commercial units, each with a Po-210 source strength of 50 millicuries.

The study reports risks as very low (much less than 1 millirem per year) on a per-unit basis, under normal conditions. For a fire, with failure to follow good radiation practices, the dose to a worker is 'higher, but well under 500 mrem.' The maximum public dose resulting from a fire is reported as 'less than 500 mrem.'

In addition to these four general risk-related studies, all devices that are distributed for use under a 10 CFR 31.5 general license or a specific license undergo a device-specific independent safety evaluation and are registered. The safety evaluation determines whether the device meets the applicable safety criteria, including the dose limits discussed in Section 2 of this report.

(2) What is the quality of the study? (Is it of sufficient quality to support decisionmaking?)

NUREG/CR-1775 laid the groundwork for future studies, but should be considered outdated for the following reasons:

- The source described (ceramic microspheres) is reportedly no longer in use.
- The study was based on consumer applications that may no longer be appropriate (e.g., phonographic applications).

- The study was based on dosimetry models that are no longer current (doses calculated and reported as organ doses rather than effective dose equivalents).

- The study did not consider commercial devices or applications.

NCRP Report No. 95 was based on the information available in NUREG/CR-1775, with respect to the physical and radiological characteristics of the consumer static eliminator, its applications, and the estimated doses to the consumer; therefore, this study shares the limitations and shortcomings of NUREG/CR-1775. However, the NCRP study did convert organ doses to effective dose equivalents, and it provided a relative ranking of consumer products containing radioactive material, on the basis of the dose to an individual and the collective population dose. This ranking provides useful insight on relative risks.

The NUREG-1717 study provides useful summary information based on evaluation of a number of scenarios regarding the estimated doses from both consumer and commercial static eliminators. However, the current use of static eliminators, in terms of the number and types of devices and the specific consumer and commercial applications, should be verified. The report indicates that doses incurred through normal use are minimal. Significant doses are estimated only for accident scenarios; however, the accident scenarios are based on conservative, bounding parameter assumptions. The report does not discuss the likelihood of the accident scenario, or the uncertainty in the results.

NUREG/CR-6642 explicitly discusses the limitations of the underlying study and the uncertainty in the reported results. The report states that the schedule and resource limitations of the study precluded extensive research. Data were reportedly gathered from six sources, including (1) contractor staff and consultants, (2) the NRC staff, (3) the open literature, (4) the licensees (but only in a limited fashion, with appropriate guidance from the staff to avoid conflict of interest and avoid imposing a data-gathering burden on licensees), (5) public comments, and (6) publicly accessible databases. However, it appears that data pertinent to static eliminators, regarding source characteristics, device design, and the number of devices in use, was obtained from NUREG-1717.

In NUREG/CR-6642, the reporting of detailed results specific to static eliminators was precluded by grouping the evaluation of static eliminators in a system with other small sealed sources. The report states that, in general, the risk results have large uncertainties. In most cases, the results are reported with an uncertainty of at least an order of magnitude, with normal risk having a smaller uncertainty and accident risks a larger uncertainty. The uncertainties arise as a result of a lack of data in some circumstances, and a lack of completeness and detail resulting from the scoping nature of the study. Whereas the large uncertainties in the absolute values must be recognized, the relative risk values have considerable usefulness for comparing one system risk to another. The robustness of the relative comparisons stems from the consistency in the risk methodology and implementation of that methodology from one system to another.

In developing NUREG/CR-6642, the NRC staff requested Mr. Charles B. Meinhold, President of the NCRP, to perform a peer review of the methodology and its application, as described in a draft version of the report. Mr. Meinhold documented the results of his peer review in a letter that is included in Appendix B of NUREG/CR-6642. Mr. Meinhold found that “the approach taken in [the study] exceeds admirably in developing an engineering based approach to evaluating the appropriate level of regulatory oversight based primarily on the radionuclides

used, the quantities involved, together with all of the radiological engineering and radiological protection elements used to limit exposure to these materials."

Mr. Meinhold further stated that "the methodology and assumptions needed to calculate the myriad scenarios are given in general terms...but the effected communities (the regulators, the licensees, the workers and members of the public) need to have access to the detailed information...."

None of the four general studies considers the risks associated with static eliminators employing a source other than Po-210. While the source in static eliminators generally licensed under 10 CFR 31.3 is limited to 500 microcuries of Po-210, there is no isotope or activity restriction specified for the static eliminators that are generally licensed for use under 10 CFR 31.5. In fact, static eliminators using Kr-85 are currently registered. However, the safety evaluations performed in registering the devices do consider isotopes other than Po-210 on a case-by-case basis.

(3) What additional studies would be needed to support decisionmaking and at what cost?

To support generally applicable regulatory decisions regarding static eliminators, the NRC needs definitive and current information regarding their physical and radiological characteristics, and their distribution and use. This information is currently available to the NRC through several registration, reporting and tracking systems. For example, since manufacturers are all specific licensees, the NRC is able to obtain definitive descriptions of the static eliminators that they currently manufacture. The SSDR and the General License Tracking System provide this information.

Also, the NRC needs general risk assessments of static eliminators with sources other than Po-210, such as Kr-85 and Am-241, to support regulatory decisions that are generally applicable to static eliminators.

(4) How is/was risk information used and considered by the NRC and licensee(s) in this area?

As discussed, the use of static eliminators in consumer and commercial applications is specifically licensed under 10 CFR Part 30, or generally licensed under 10 CFR 31.3 (consumer products) and 10 CFR 31.5 (commercial products). As such, manufacturers submit risk information, in terms of dose estimates, for specifically licensed static eliminators and for static eliminators that will be used under a 10 CFR 31.5 general license. Regulatory authorities (at the NRC or in Agreement States) perform an independent safety evaluation to ensure that the device will meet the regulatory dose limits, before certifying the device for use.

Regulatory authorities do not perform independent safety evaluations for devices that are generally licensed under 10 CFR 31.3. However, the regulations limit the isotopes and activity that may be used in these devices, and the two recent risk studies of byproduct materials have addressed the general risks associated with these devices.

(5) What is the societal benefit of this regulated activity?

As consumer products, the use of static eliminators is generally limited to eliminating static charges on photographic film and lenses, as well as those that can hinder the delicate operation of precision balances. As commercial products, static eliminators are used to reduce (1) the risk of fire or explosion that might result from the buildup and discharge of static charge in volatile and explosive environments (e.g., paint shops), (2) the buildup of static charges that can damage electronic circuits and hard drives during assembly and repair of personal computers, (3) the buildup of dust on surfaces to be electroplated or painted, (4) the static cling of processed material on sheet-fed webs and rollers (e.g., print shops), and (5) static charge on filters used in industrial-hygiene monitoring applications.

The nature of the devices permits their use in industrial settings and configurations that may not be feasible for other non-radioactive devices, for physical or safety reasons (e.g., in the presence of combustibles). Thus, the use of static eliminators results in a direct economic and safety benefit to society.

(6) What is the public perception/acceptance of risk in this area?

On the basis of the information considered during this case study, public perception and acceptance of risk associated with the use of static eliminators in consumer and commercial applications may be considered to be comparable to the perception and acceptance associated with the use of exempt devices. Approximately 30,000 of the generally licensed devices are used by the general public each year, and all of the generally licensed devices distributed each year are used by individuals with no required radiological training.

During the public workshop in February 2001, a few stakeholders expressed concern with reducing the regulation of static eliminators. However, no definitive information regarding the public perception or acceptance of risk is available.

4.2 Safety Goal Analysis Questions

(1) What is the basis for the current regulations in this area (e.g., legislative requirements, international compatibility, historical events, public confidence, undetermined, etc.)?

The use of static eliminators in consumer and commercial applications is permitted under general licenses that are issued pursuant to 10 CFR 31.3 and 31.5. This authorization dates back to before June 26, 1965, when the regulations pertaining to the licensing of byproduct material were recodified (30 FR 8189). The use of static eliminators may also be authorized under the more rigorous requirements of a specific license, pursuant to 10 CFR Part 30.

Use of static eliminators under a general license reflects the risks associated with the device relative to other uses of byproduct materials and the widespread use of the devices in consumer and commercial applications. The general license requirement allows control, traceability, and performance verification of the devices that would not be possible if the devices were exempt from licensing requirements.

Conversely, use under a specific license would require each user of a static eliminator containing byproduct material to prepare and submit a license application to the NRC or Agreement State. Such applications would require review and approval, and the regulatory authority would issue a specific license to the applicant. Given that there are tens of thousands of static eliminators in use, this would require thousands of license applications and reviews. This would likely be an impossible task and, more importantly, it would draw resources away from higher-risk activities without yielding a commensurate reduction in risk.

(2) Are there any explicit safety goals or implicit safety goals embedded in the regulations, statements of consideration, or other documents (an example would be the acceptance of a regulatory exemption based in part on a risk analysis and the outcome)?

There are both explicit and implicit safety goals embedded in the regulations, guidance documents, and sealed source and device registration certificates. These goals are both quantitative and qualitative.

Static eliminators containing a sealed source of no more than 500 microcuries of Po-210 may be used in both consumer and commercial applications under a 10 CFR 31.3 general license. The device must be manufactured, tested, and labeled by the manufacturer in accordance with the specifications of a specific license. This implies that an acceptable level of safety is provided by the quantity of the particular radionuclide, together with the physical properties of the sealed source and device. The general license issued under 10 CFR 31.3 to use static eliminators is subject to the provisions of 10 CFR Part 30 that are applicable to general licensees, including requirements and restrictions on transferring the devices, reporting to the NRC, recordkeeping, inspection, testing, and enforcement.

Static eliminators may also be used in the commercial sector pursuant to 10 CFR 31.5. The regulations and the individual sealed source and device registration certificates for these devices identify several quantitative safety goals. According to 10 CFR 32.51, an applicant for a specific license to manufacture a 10 CFR 31.5 device must submit information that is sufficient to provide reasonable assurance that, under ordinary conditions of handling, storage,

and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device (i.e., zero release). This is quantified in the regulations through the specific leak test threshold of 0.005 microcuries of removable contamination. Also, the manufacturer must demonstrate that, under ordinary conditions, it is unlikely that any person will receive in 1 year a dose that exceeds 10% of the annual occupational dose limits for adults specified in 10 CFR 20.1201(a).

Additionally, 10 CFR 32.51 requires that, under accident conditions (such as fire or explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of 10 CFR 32.24 (15 rem to the whole body, head and trunk, active blood-forming organs, gonads, or lens of the eye; 200 rem to the hands and forearms, feet and ankles, or localized areas of skin; 50 rem to other organs). A review of the registration certificates for these devices indicates that the reviewer's safety evaluation of each device is based on the applicant's ability to demonstrate conformance to these requirements.

Several qualitative safety goals may also be identified. Review of the registration certificates indicates that the devices should be designed so that the user of the device will not come into direct contact with the sealed source. Also, the registration certificates indicate that the devices should only be used in environments that will not lead to degradation of the containment capability of the sealed source. Additionally, distributors and users of 10 CFR 31.5 devices are required to demonstrate control of the devices, through reporting to the regulatory authorities.

(3) What was the basis for the development of the strategic goals, performance goals, measures, and metrics? How are they relevant/applicable to the area being studied, and how do they relate/compare with the regulatory requirements? How would they relate to safety goals in this area?

The strategic goal for the NRC's nuclear materials safety arena is to "prevent radiation-related deaths and illnesses, promote the common defense and security, and protect the environment in the use of source, byproduct, and special nuclear material." This strategic goal is supported by four performance goals, and subordinate strategies, measures, and metrics. These are presented in the agency's Strategic Plan [10].

The regulation of byproduct material in static eliminators relates to all four of the performance goals. The devices are regulated to adequately maintain the safety of workers and the public, to protect the environment, and to ensure public confidence in this regulation. This is balanced by the goals to make the agency's activities and decisions effective, efficient, and realistic, and to reduce unnecessary regulatory burden on stakeholders.

(4) Are there any safety goals, limits, or other criteria implied by decisions or evaluations that have been made that are relevant to this area?

As previously discussed in this report, applicants that intend to distribute a static eliminator under the general license provisions of 10 CFR 31.5 are required to submit safety-related information to regulatory authorities, who then conduct a safety evaluation to determine whether the device will meet the applicable regulatory requirements during its use. The decision to issue a registration certificate documents the determination on the part of the regulatory authority that the device meets the applicable safety requirements.

In 1988, the NRC issued a series of orders to a particular manufacturer and distributor of static eliminators, Minnesota Mining and Manufacturing Company (3M). The orders required 3M to suspend distribution and to recall static eliminators employing Po-210 in the form of "microspheres" as the source. These devices were being used in commercial manufacturing applications. Evidence indicated that the sealed sources were failing and the microspheres were being released from the devices, thereby resulting in contamination of the manufacturing environment, workers and other individuals in the manufacturing environment, and possibly the manufactured products.

A review of the agency's records indicates that the decision to issue the recall orders was based on the evidence of release of the radioactive material from the sealed source device, and the subsequent contamination of the immediate environment, workers and others in the environment, and the products being manufactured. While the risks associated with the contamination are not evident, the chronic failure of the devices and the resulting contamination were sufficient to support the recall orders. A safety goal of zero release from a sealed source may, therefore, be inferred from this decision.

(5) If safety goals were to be developed in this area, would tools/data be available for measurement?

At least four potential safety goals may be identified:

- doses should be only a small fraction of the limits currently existing in the regulations, applicable to normal and accident conditions
- no direct contact with the sealed source contained within the device
- zero release from the sealed source (i.e., complete containment of the byproduct material)
- control and accountability for the byproduct material contained within the devices

The existing regulatory requirements provide the tools and data necessary to evaluate the extent to which these safety goals are met. Rigorous tracking of the devices and the requirements for returning the devices to the manufacture would facilitate measurement against the second, third, and fourth goals. Upon receipt, manufacturers would be able to verify that the device is intact and that the sealed source within the device has not been contacted. Current requirements for leak testing upon return would allow verification of complete containment of the source. Given that there has been no direct contact with the source and no release from the sealed source, compliance with the first goal may be inferred. The fourth goal would allow different accounting requirements for different isotopes, based on their respective half-lives. Accounting requirements may be less stringent for isotopes with relatively short half-lives, such as Po-210, given that the devices would be self-extinguishing after a relatively short time.

(6) Who are/were the populations at risk?

The populations at risk under normal use are those in close contact with the devices. These are the consumers using devices licensed under 10 CFR 31.3, and the workers in proximity to the devices used in commercial applications under 10 CFR 31.5. Also at risk are the individuals who transport the devices between the manufacturers and the users.

Populations at risk under accident conditions are varied. These include the individuals responding to an accident, such as firefighters and other emergency response personnel. In the case of misuse, such as tampering with the device, individuals at risk would include those doing the tampering, as well as those coming into contact with the device after tampering.

Loss of control of the devices places other populations at risk. For lost devices or devices that are disposed of improperly, this would include members of the general public who find or come in contact with the devices.

(7) What are/were, and what could be/have been, the various consequences to the populations at risk?

The consequences to the populations at risk under normal use are generally low. Consequences from the sealed source are limited to external exposure, which is minimal, as demonstrated in the general risk studies and safety evaluations discussed above.

Under accident or off-normal conditions, the consequences may be more significant. For static eliminators using Po-210 as the source, these consequences are estimated in the general risk studies discussed above (NUREG-1717 and NUREG/CR-6642), and are dominated by the inhalation and ingestion of the air-borne alpha-emitting radionuclides. Consequences associated with accident and off-normal conditions for static eliminators using other isotopic sources have not been evaluated.

(8) What parameters should be considered for the safety goals (e.g., workers vs. public, individual vs. societal, accidents vs. normal operations, acute vs. latent fatality or serious injury, environmental and property damage)?

Several possible safety goals are discussed above. In general, safety goals for generally licensed static eliminators should not differentiate between workers and the public, since the regulations state that the use of the device should not presume any special training in radiological protection. The goals should also reflect protection of the individual through the design of the sealed source and device, and protection of the population through control and accountability. Safety goals should address accident conditions, as well as normal conditions, since the available risk information indicates that accident conditions can pose significant risks. Safety goals should also reflect protection of the environment and property, in terms of containment of the isotope within the sealed source. Safety goals for specifically licensed static eliminators may differentiate between workers, who may have radiation protection training, and the general public, who would not.

(9) On the basis of the answers to the questions above, would it be feasible to develop safety goals in this regulatory area?

Development of safety goals for the use of static eliminators is feasible, as evidenced by the preceding discussions.

(10) What methods, data results, safety goals, or regulatory requirements would be necessary to make it possible to risk-inform similar cases?

This case study focused on static eliminators containing byproduct material, used under a general license or specific license. However, much of the discussion is applicable to other devices that use byproduct material in the form of sealed sources. Requirements regarding design features, performance testing (i.e., leak testing), and control and accountability are generally applicable.

The risk insights gained through this case study may be applicable to sealed sources and devices used under a general license and employing similar isotopes and quantities. Similar cases would require isotope-specific assessments, because of the relatively short half-life of Po-210. Otherwise, the discussion of safety goal development should be generally applicable to other generally licensed devices.

4.3 Questions upon Developing Draft Safety Goals

The Commission established two qualitative safety goals applicable to the reactor safety strategic arena (51 FR 30028):

- Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.

- Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

Subsequently, the Commission directed the staff to develop safety goals for the nuclear materials and waste strategic arenas analogous to the reactor safety goals (SECY-99-100).

As stated, one of the objectives of the case studies is to determine the feasibility of safety goals and, if feasible, develop safety goal parameters and a first draft of safety goals. The previous set of ten questions, and the following set of five questions, address this objective. In answering the previous set of questions (specifically, question 2 of the Safety Goal Analysis Questions), implicit and explicit safety goals were identified. These goals were embedded in regulations and other documents specific to static eliminators and other sealed sources. However, they seem to fall into a general set of qualitative safety goals which have broader materials and waste applications:

- Nuclear materials use and disposal should not pose a significant additional risk to life and health of individual members of the public, and to workers associated with these activities.

- Societal risks to life and health from nuclear materials use and disposal should not be a significant addition to other societal risks.

- Nuclear materials use and disposal should not result in environmental or property damage in excess of other means of achieving a similar end objective that is deemed beneficial to society.

Thus, for the purpose of answering the following set of five questions, these preliminary draft qualitative safety goals were considered. These preliminary draft safety goals are generally analogous to the reactor safety goals, but have been developed to include worker safety, and protection of the environment. It is stressed that these draft safety goals are preliminary and will likely be modified in the near future, but are presented to focus attention and prepare answers to the set of case study questions that follows.

(1) Are the current regulations sufficient in that they reflect the objectives of the draft goals? Would major changes be required?

The draft safety goals address risk to individuals, societal risks, and damage to the environment or property. The existing regulations sufficiently reflect the objective of the individual-risk safety goal for normal conditions, but not for accident conditions. Under normal conditions, the regulations limit the consequence (dose) to an individual from a sealed source or device to a fraction of the allowable public dose limit specified in 10 CFR Part 20. This would not likely pose significant additional risks to the life and health of individual members of the public or to workers associated with the use and disposal of these devices. The regulatory dose limit under accident conditions is much greater (15 rem to the whole body, head and trunk, active blood-forming organs, gonads, or lens of the eye; 200 rem to the hands and forearms, feet and ankles, or localized areas of skin; 50 rem to other organs.) The regulation, however, does not address the likelihood of the accident occurring.

The existing regulations do not sufficiently reflect the objective of the societal-risk safety goal for either normal or accident conditions. The regulations do not address the size of the population that may be exposed to risk.

The environmental and property protection safety goal is reflected in the regulations. The regulations specifically address control and accountability of the devices, and zero release of radioactive material from the device.

(2) Would the regulations need to be tightened?

To address individual risk under accident conditions, the regulations should discuss the likelihood of accident scenarios as well as the consequences. To address the societal risk safety goal, the regulations could be expanded to address risk from the use and disposal of the devices integrated over the populations incurring the risk.

(3) Are the regulations overly conservative and/or too prescriptive with respect to the goals?

The dose limits and leakage limits of the regulations do not seem overly conservative. Specific requirements pertaining to control and disposal of devices may be overly conservative and prescriptive, depending on the half-life of the particular radionuclide used in the device.

(4) If these were the safety goals, what decisions would be made?

Decisions would not necessarily be very different from those currently being made. As stated above, the regulations do not seem overly conservative. The exception may be static eliminators using polonium-210 as the source, where regulations may currently be overly prescriptive. In general, the goals may be helpful to the staff in making decisions that are consistent and commensurate with the risk the device presents.

(5) Would these goals be acceptable to the public?

At the Stakeholders Meeting held on October 25, 2001, there was general agreement by the stakeholders that NRC should proceed with development of safety goals in the nuclear materials and waste arenas. The goals presented in this section are cast in a framework similar to the one that has been in existence for over 15 years for nuclear power plants.

5. DRAFT SCREENING CRITERIA

One of the stated objectives of the case studies is to develop screening criteria for identifying regulatory applications where risk-informed approaches would add value. Draft screening criteria were identified in the case study plan, and the information obtained through the individual case studies is used to evaluate the adequacy and applicability of the draft screening criteria. The following discusses the application of the draft screening criteria to the regulation of static eliminators.

(1) Would a risk-informed regulatory approach help to resolve a question with respect to maintaining or improving the activity's safety?

A risk-informed regulatory approach *would* help to resolve questions with respect to maintaining or improving the safety of static eliminators. Use of static eliminators is currently regulated under one of two types of general license or under a specific license. Quantifying the risks associated with the various types of static eliminators would allow a review of licensing requirements to identify where the use of static eliminators may be over- or under-regulated, relative to the potential risks (e.g., whether certain generally licensed static eliminators may be moved to exempt status). It also allows applicants, licensees, regulators, and other stakeholders to make regulatory decisions on a case-by-case basis, while ensuring that safety is maintained. With respect to specific events involving static eliminators and other devices, risk information will allow a response to the events in a manner that is commensurate with maintaining safety.

(2) Could a risk-informed regulatory approach improve the efficiency or effectiveness of the NRC's regulatory process?

A risk-informed regulatory approach in the nuclear materials and waste arenas *would* improve the efficiency and effectiveness of the NRC's regulatory process by providing a greater degree of consistency in the way static eliminators are licensed, relative to other generally licensed devices and activities and exemptions for byproduct and source materials. For example, classifying some static eliminators as exempt, consistent with the associated risk, may modestly increase the resources available to regulate generally licensed devices and applications that pose more significant risks to workers, the public, and the environment. (Currently, the NRC expends very little resources on the regulation of static eliminators.) Alternatively, taking a broader perspective across sealed sources of byproduct material, modifying the requirements imposed on devices that use short-lived isotopes, such as Po-210, based on risk information, may more significantly increase efficiency and effectiveness through resource allocation.

(3) Could a risk-informed regulatory approach reduce unnecessary regulatory burden for the applicant or licensee?

A risk-informed regulatory approach *would* reduce unnecessary regulatory burden on *both* applicants and licensees. Manufacturers of static eliminators would be relieved of some of the requirements specified in 10 CFR Parts 30 and 32, to the extent that the regulations apply to manufacturers and distributors of exempt devices. Commercial users of static eliminators would be relieved of the testing, reporting and disposal requirements specified in 10 CFR 31.5. While consumer users of static eliminators are generally licensed under 10 CFR 31.3, this regulation does not impose any specific requirements on the licensee. None the less, the burden on consumer users would also be reduced in that they would no longer be directed by

manufacturers (through labeling and instructions accompanying the devices) to return the expired devices to the manufacturer.

(4) Would a risk-informed approach help to effectively communicate a regulatory decision or situation?

A risk-informed regulatory approach *would* help to effectively communicate regulatory decisions or situations. Any changes to the regulatory requirements imposed on general licensees would be proposed for comment before they were implemented. Using risk information to support any regulatory changes would allow the agency to communicate to stakeholders and other interested parties the impact of the change with respect to safety. Similarly, risk information would allow the agency to communicate the basis for its response to events involving byproduct materials.

(5) Do information (data) and analytical models exist that are of sufficient quality, or could they be reasonably developed to support risk-informing a regulatory activity?

The information and analytical models needed to support risk-informed regulation in the nuclear materials and waste arenas either exists or could reasonably be developed. The available risk information, its limitations and applicability, and additional data needs are discussed in Section 4 of this case study report.

(6) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit? The net benefit will be considered to apply to the public, the applicant or licensee, and the NRC. The benefit to be considered can be improvement of public health and safety, improved protection of the environment, improved regulatory efficiency and effectiveness, improved communication to the public, and/or reduced regulatory burden (which translates to reduced cost to the public.)

This case study did not yield a clear answer to this question. The NUREG/CR-6642 study, discussed in Section 4, provides a foundation for risk-informing the byproduct materials program. Additionally, specific risk assessments may be required to supplement this study. It is possible that any regulatory changes that would affect static eliminators, based on risk information, would involve changing distribution and reporting requirements for manufactures and licensees. This would require rulemaking. Also, such a change would likely involve thousands of licensees. However, without identifying a specific regulatory change, the total cost cannot be determined.

(7) Do other factors exist (e.g., legislative, judicial, adverse stakeholder reaction) which would preclude changing the regulatory approach in an area, and therefore, limit the utility of implementing a risk-informed approach?

No known factors specifically related to static eliminators would preclude or limit the usefulness of a risk-informed regulatory approach in the nuclear materials and waste arenas. Many different types of devices containing byproduct material are currently used under general and specific licenses, and some devices are exempt from licensing altogether. There are presently

numerous devices within each category, demonstrating that the use of byproduct materials under significantly different licensing frameworks is possible and accepted. A few stakeholders indicated during the stakeholder workshop, however, that any changes that result in additional exempt devices may raise concerns with the public.

6. SUMMARY AND CONCLUSIONS

This section organizes the staff's conclusions to address the four objectives of the case studies, as numbered below.

1. What did the case study say about the effectiveness of the screening criteria?

The first four draft screening criteria are based on the four performance goals for the nuclear material safety arena, identified in the NRC's Strategic Plan. These four draft screening criteria are adequate to demonstrate that increasing the use of risk information in the regulation of static eliminators would support the agency's strategic and performance goals for the nuclear materials safety arena.

The remaining three screening criteria adequately support the assessment of feasibility. One addresses technical feasibility, the next evaluates whether there would be a net benefit, and the last addresses any other significant obstacles or considerations that may preclude regulatory actions. The case study indicates that risk-informing the regulation of static eliminators would be technically feasible; however; it is not clear whether there would be a significant net benefit, in terms of increased efficiency and effectiveness in the NRC's regulatory process, or reduced burden on the stakeholders (licensed manufacturers and users).

2. What insights did the case study provide about the current and potential value of using risk-information? What process improvements could be made to facilitate applying risk information in similar situations?

This case study showed that risk information may have the potential to reduce regulatory burden and improve the staff's efficiency in making decisions, without increasing risk. The extent to which there may be a net benefit, however, is undetermined.

The case study indicated that, while there are two generic risk studies addressing static eliminators, the risks associated with individual models of static eliminators are evaluated on a case-by-case basis through the sealed source and device registration process. There may be potential for increasing the efficiency of the regulatory process by making more general regulatory decisions based on isotope and activity, or sealed source and device design. Also, the regulation under 10 CFR 31.3 may be better integrated with the static eliminator regulation under 10 CFR 31.5, and some devices may be suitable for exempt status.

Risk insights may be used to make the regulation of static eliminators more consistent with other generally licensed, specifically licensed, and exempt devices, from a risk perspective, thus increasing regulatory effectiveness and efficiency and reducing unnecessary regulatory burden, while maintaining health and safety.

3. What did the case study say about the feasibility and utility of safety goals? What were the implicit/explicit safety goals or elements?

The case study indicates that it would be feasible to develop safety goals for the regulation of sealed sources and devices, and specifically static eliminators. The case study identified several explicit and implicit quantitative and qualitative safety goals in the existing regulatory framework. These included the dose limits for normal and accident conditions, the requirement for complete containment of byproduct material within the sealed source, the prevention of

direct contact with the sealed source through the design of the device, and control and accountability of the byproduct material during distribution, use, and disposal.

4. What insights did the case study provide on the information, tools, methods, and guidance needed for a risk-informed regulatory approach in this specific case study area and (if possible) in other similar regulatory areas?

A review of the existing studies and databases indicated that a significant amount of risk information exists for static eliminators and other sealed sources and devices. For static eliminators, the generic risk studies focus only on generally licensed devices that use Po-210. The generic studies do not address generally licensed or specifically licensed static eliminators that use other isotopes, such as Kr-85 or Am-241. However, all the devices currently registered for use have undergone an independent safety evaluation.

7. REFERENCES

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