VOLUME 2: Appendix D

RISK INFORMING THE MATERIALS AND WASTE ARENAS:

A Case Study on the Regulation of Fixed Gauges

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ABSTRACT

In striving toward risk-informed regulation in the nuclear material and waste arenas, the staff of the U. S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards identified candidate regulatory applications as subjects of case studies to test screening criteria and develop safety goals. Among these cases, the NMSS staff studied the regulation of fixed gauges to illustrate what has been done and what could be done to risk-inform the regulatory approach . The study follows the outline provided in the “Plan for Using Risk Information in the Materials and Waste Arenas,” that was developed by the NMSS Risk Task Group. This report presents information regarding the use of risk information in this activity, as well as preliminary responses to the draft screening criteria and the draft questions for case studies.

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CONTENTS

ABSTRACT i

ACKNOWLEDGMENT ii

1. INTRODUCTION 1
   1.1 Objectives and Approach 1
   1.2 Scope of the Case Study 2
   1.3 Organization of the Report 2

2. BACKGROUND 3

3. CASE STUDY APPROACH 7

4. RESPONSES TO DRAFT QUESTIONS 8
   4.1 Screening Criteria Analysis/Risk Analysis Questions 8
   4.2 Safety Goal Analysis Questions 12
   4.3 Questions upon Developing Draft Safety Goals 16

5. Draft Screening Criteria 18
   5.1 Application of the Draft Screening Criteria to Fixed Gauges 18
   5.2 Outcome of Applying Draft Screening Criteria 20

6. SUMMARY AND CONCLUSIONS 21

7. REFERENCES 22

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, 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. 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 fixed gauges, 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 of the Case Study

The regulation of fixed gauges is one of the eight general areas from which case studies were selected. These eight areas were selected to represent the wide spectrum of activities, materials, and devices within the regulatory scope of NMSS. Fixed gauges use sealed sources of radioactive material for a variety of uses, such as monitoring a production process or ensuring quality control. The fixed gauges case study is focused on generally licensed fixed gauge users under Title 10, Section 31.5 of the *Code of Federal Regulations* (10 CFR 31.5), as well as specifically licensed users under 10 CFR 30, and manufacturers under 10 CFR 32.51. The case study does not address the regulations of Agreement States regarding fixed gauges.

1.3 Organization of the Report

The report is organized into seven sections. Section 2 presents a general description of the regulatory scheme for fixed gauges, including requirements for users and manufacturers, along with some of the ways that the regulations present a unique situation for fixed gauges. Section 3 introduces the approach used to conduct the case study. Section 4 presents the responses to the draft questions in the case study plan, including the screening criteria analysis/risk analysis questions and the safety goal analysis questions. Section 5 discusses the application of the draft screening criteria questions to fixed gauges. Section 6 summarizes and discusses future work, and Section 7 lists the references used in conducting this case study.

2. BACKGROUND

General Description

Fixed gauges are usually used to monitor a production process and ensure quality control. There are many types of fixed gauges, including those that measure thickness, density, level, and volumetric flow, and most contain either gamma or beta radiation sources. Most of these "fixed gauges" are indeed gauges that are installed at a specific location. However, the definition of this category of devices has sometimes been expanded to include "movable fixed gauges," which are mounted or affixed to a vehicle or other transportation device (such as a cart) and moved from place to place as the need arises. These moveable devices present some unique risks that more traditional fixed gauges do not, because of the need for a higher degree of direct interaction between workers and gauges.

Most fixed gauges fall into the category of transmission gauges, and can be used in a variety of applications such as measuring bulk density or weight, monitoring moisture content or tank level, or measuring thicknesses of material. Transmission gauges all work on the same principle:

(1) Radiation is absorbed to some extent by all matter.
(2) The denser the material or the greater the amount of material present, the more radiation that will be absorbed.
(3) The amount of radiation absorbed can be related to the density or amount of material present.

Bulk density and weight measuring gauges are used to a large extent in mining operations for measuring and controlling slurry and sludge on conveyor belts, pipelines, and in storage tanks. In these applications a gamma or beta source is mounted on one side of the belt, pipeline or tank and a detector is mounted on the other. As material passes through the radiation beam, the detector measures the amount of radiation which is not absorbed and compares this reading to a standard. The amount of radiation absorbed by the material is converted into a reading of density or weight.

Level gauges are typically mounted to storage tanks and give either a single reading (ex. full/not full) or a variable reading (percent full) of tank contents for liquids or bulk material. These gauges work on the principle that if a detector receives any amount of radiation less than maximum, then there is material present up to the level of the tank where the detector is located. Variable reading gauges have a series of detectors mounted along the length of one side of the tank and a source housing located at the level of the highest detector on the other side of the tank. The source housing collimates the radiation so that a beam is directed at all the detectors simultaneously. As material enters the tank and reaches the level of a detector, the radiation beam received by that detector is reduced. The gauge then indicates that the tank level has reached the level of the detector.

Thickness gauges are often mounted on conveyor belts; and material which is required to be within a certain range of thickness, such as paper or steel plate, is passed through the gauge's radiation beam. If too little or too much radiation is detected, the material is not of the correct thickness.

Fixed gauges have most often been the subject of public attention when they find their way into the metals industry as a result of loss, theft, or improper disposal. Radioactive sources from these gauges have been found in scrap yards and have contaminated steel mills. More and more metals facilities have installed radiation detectors to protect themselves, but not all have done so.

Regulatory Framework

Fixed gauges are subject to a perplexing regulatory scheme. Many fixed gauges can be used under the authority of either a specific or general license depending on the desires of the end user, while some are specifically licensed only, and some are generally licensed only. The category that a particular gauge falls into is not always determined by the type of gauge, or the risk it presents, but is determined by the desires of the manufacturer, and the interpretation of regulations and policy by the regulator. The regulations for generally licensed fixed gauges can be separated into two distinct areas, one that applies to users of gauges (10 CFR 31.5), and one that applies to manufacturers (10 CFR 32.51). Manufacturers must have their device design approved by a sealed source and device (SS&D) review in accordance with 10 CFR 32.51. For specifically licensed gauges, users are regulated under 10 CFR 30, and manufacturers must have their device design approved by a sealed source and device review (SS&D) in accordance with 10 CFR 32.210.

General licensees who use fixed gauges are subject to the regulations of 10 CFR 31.5 “Certain Measuring, Gauging, or Controlling Devices.” The regulations require general licensees to appoint a responsible individual and to register the device with NRC if the device contains at least the following amounts of radioactive material: 10 mCi of Cs-137, 1 mCi Co-60, 1 mCi Am-241 or any other transuranic, or 0.1 mCi Sr-90. The licensee must also comply with some other basic requirements such as following instructions on the device label, periodic leak testing, and transfer restrictions. The licensee must also, according to 31.5(c)(10) “ . . Comply with the provisions of 20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21, of this chapter.”

Users of specifically licensed gauges are required to obtain a license from NRC in accordance with 10 CFR 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material.” All specific licensees are required to follow the regulations in Parts 19, 20, and 21. The licensee is bound by the regulations, the license conditions, and the commitments made in letters during the license application process that are referenced in the license. Inspections of specific licensees occur at a prescribed frequency. In general, specific licensees who possess fixed gauges are required to have a radiation safety officer, provide training in radiation safety if workers are likely to receive doses of radiation in excess of 100 mrem/year, implement a radiation safety program, have adequate facilities and equipment, among other requirements.

Manufacturers of generally licensed fixed gauges are subject to the design criteria for devices given in 10 CFR 32.51 “Byproduct material contained in devices for use under 31.5; requirements for license to manufacture, or initially transfer.” Specifically licensed devices must meet requirements in 10 CFR 32.210, “Registration of Product Information.” NRC reviewers conduct a sealed source and device review in accordance with the applicable regulations to ensure that gauges meet the regulatory requirements before they are approved for distribution

to either general or specific licensees, or both. A sealed source and device registration certificate is then issued which contains sections on “Conditions of Normal Use” and “Limitations and Other Considerations of Use.” These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, the working life of the device, or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by NRC, licensees are required to use gauges according to their respective SS&D registration certificates.

Both specifically and generally licensed devices are reviewed for criteria such as the intended use of the product, prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, quality assurance, quality control, and leak testing requirements. There is no limit on the quantity of radioactive material that can be contained in a device, provided it can meet the design requirements. For generally licensed devices, the basic design requirements in addition to those of specifically licensed devices are:

- The device can be safely operated be persons without 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, and it is unlikely that any person will receive in 1 year a dose in excess of the annual limits specified in 10 CFR 20.1201(a).

- Under accident conditions (such as fire and 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 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 averaged over areas no larger than 1 square centimeter; and 50 rem to any other organs.

The manufacturer’s design dose criteria found in 10 CFR 32.51 were not updated when 10 CFR 20 was revised in 1991 to reflect ICRP 26 guidelines. Currently, manufacturers are allowed to design gauges that could expose general licensees using their devices under ordinary conditions of handling, storage, and use, to radiation doses up to 10% of the annual limits specified in 20.1201(a), with no training in radiological protection. When that criteria in 10 CFR 32 was written, the public dose limit was 10% of the annual dose limit allowed for workers. Currently, the public dose limit is 100 mrem, which is 2% of the annual dose allowed for workers. If a specific licensee’s workers are expected to exceed 100 mrem in a year, they are required under 10 CFR 19.12 “Instructions to workers” to receive training in radiological protection. However, because general licensees under 10 CFR 32.51 are exempt from parts 19 and 20, they are not required to receive this training.

Types of Risk

The types of risk associated with fixed gauges includes occupational radiation doses incurred by workers routinely, radiation doses incurred by workers during accident conditions, and radiation doses to members of the public who encounter fixed gauges after they have been lost, stolen, or improperly disposed. Risks from contamination of metals facilities, and disposal of

radioactive waste produced during cleanup of these facilities is also an issue. Also, since fixed gauges are sometimes used in areas that would be inhospitable to humans, such as in tanks, or other dangerous locations or environments, they may reduce the immediate safety risk to workers at the facility by performing a function that would otherwise expose the worker to a dangerous environment.

3. CASE STUDY APPROACH

In the course of conducting the fixed gauges case study, many sources of data were consulted, including: the Nuclear Material Events Database (NMED), SS&D Registry information, SS & D application reviewers, license reviewers, a gauge user at a manufacturing facility, members of the public, and gauge manufacturers. Risk studies were also reviewed including, NUREG/CR-6642, “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems”, NUREG-1669 “Risk Analysis of Fixed Nuclear Gauges”, NUREG-1551 “Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices”, “Improper Transfer and Disposal Scenarios for General Licensed Devices”, and PNNL-11905 “Technical Letter Report: Task 7, Final Review of the 1987 Report by Oak Ridge Associated Universities, Improper Transfer/Disposal Scenarios for Generally Licensed Devices”. Other documents utilized include:, NUREG-1188 “The Auburn Steel Company Radioactive Contamination Incident”, SECY 98-117 “Shelwell Services Inc., Risk Assessment”, NUREG-1556 Vol. 3, 4, and 16 “Consolidated Guidance About Materials Licenses”, and SECY 00-0137 “Response to Staff Requirements Memorandum Dated December 21, 1998 -- SECY-98-232 -- Seaman Nuclear’s Application to Distribute Portable Gauges to General Licensees”. References to these documents are given at the end of the report.

After review of the applicable documents, answers were prepared to the questions found in the case study plan. Section four documents the responses to the Screening Criteria Analysis/Risk Analysis Questions, and the Safety Goal Analysis Questions. In order to test the draft screening criteria, the screening criteria questions were applied as if the decision to risk-inform fixed gauges were being proposed now. This is documented in Section five of the report.

The NMSS staff then presented its preliminary responses to the standard case study questions at a public meeting held at NRC Headquarters in Rockville, Maryland on February 9, 2001. This report was then modified so that responses to certain questions addressed input provided at that public meeting.

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?)

- NUREG/CR-6642 "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" System 22 and System 23. System 22 contains generic risk information for the receipt, storage, maintenance, operation, and disposal of fixed gauges which contain gamma sources such as C0-60, Cs-137, and Am-241. System 23 provides similar information about fixed gauges that contain beta sources such as Kr-85, Sr-90, Pm-147, and Tl-204.

- NUREG-1669, "Risk Analysis of Fixed Nuclear Gauges," focuses on gauges containing Cs-137, Co-60, and Am-241 in the scrap/recycling stream only.

- NUREG-1551, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices" -- Although not specifically a risk study, the report contains information on proposed solutions to improve licensee's control over and accountability for fixed gauges and other devices.

- "Improper Transfer and Disposal Scenarios for General Licensed Devices," Oak Ridge Associated Universities, April 1987.

- PNNL-11905, "Technical Letter Report: Task 7, Final Review of the 1987 Report by Oak Ridge Associated Universities, Improper Transfer/Disposal Scenarios for Generally Licensed Devices", Strom et al., June 3, 1994. This report details strengths and weaknesses of the 1987 Oak Ridge report. The authors conclude that the 1987 report is outdated and inadequate to provide a basis for decision making. The report also provides the authors opinions as to what would be necessary to create a risk study of sufficient quality to support decision making.

- NUREG-1188, "The Auburn Steel Company Radioactive Contamination Incident", 1983, provides details of an accidental source melt involving a large cobalt-60 source.

- SECY-98-117, "Shelwell Services, Inc., Risk Assessment", May 1998, details a risk assessment for an event involving a 2-curie cesium-137 sealed source used for well logging in which the source encapsulation was breached.

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

- NUREG-1669 states that "an accurate assessment of risk was precluded by a paucity of data for the elements of risk . . . to quantify risk, information from surveys about licensees and the steel industry is needed." The surveys forms were completed for this effort, but were never sent to licensees. The study does not address the aspect of risk to workers and the public at facilities where gauges are used, and is not sufficient, on its own, to support decision making. The study does, however, focus on gauges containing Cs-137, Co-60, and Am-241 in the scrap/recycling stream, and provides useful insights which could be used in combination with other risk assessments to produce practical decisions.

- NUREG/CR-6642 calculated doses to workers and the public for both specifically licensed and generally licensed fixed gauges. For fixed gamma gauges they considered the isotopes Am-241, Co-60, and Cs-137, and calculated doses based on an "average" source strength. The study resulted in the following conclusion:

  > "... while the normal risks are larger than the accident risk, the accident risk for the Am-241 device under task 22-4b, operation at a remote site, for both specifically and generally licensed devices could yield a maximum dose such that significant adverse health effects would be expected. This is because of the high radiological effect of Am-241 and an assumed relatively high release fraction if the source encapsulation is crushed while used at a temporary work site. Even though this scenario has a high total dose, the occurrences of the event are very infrequent. The estimated accident dose, given that an accident occurs, is however, high enough to lead to serious chronic health effects."

  The study further states that the evaluation of these events is based on extremely limited data. There is at least an order of magnitude overall uncertainty in the accident results. The risks to the public probably have an uncertainty of two orders of magnitude. For fixed beta gauges, the study considered Kr-85, Sr-90, Pm-147, and Tl-204, and calculated doses based on average source strengths. The risks to workers and members of the public from fixed beta gauges are seen to be very small. Specifically licensed devices have a higher risk due to their higher source activities, but the doses are below those for which a significant adverse health effect would be expected to either the worker or the public.

  The study was the subject of a peer review conducted by Dr. Charles B. Meinhold, President of the National Council on Radiation Protection and Measurement. Dr. Meinhold found that the study "provides an important step in developing the data and an approach to reducing the regulatory burden while ensuring the safety of the worker and the public are ensured. In summary, an excellent approach and a report which provides the detail necessary for the Commission to begin the process of extending this work in a manner that will ensure the overall objectives of reducing the burden and still ensuring the health of the worker and the public."

- NUREG-1551 outlines the basis for the General License Tracking System -- a registration program for a subset of generally licensed devices, that are thought to pose a higher risk to workers, the public, and the environment. Devices that contain sources with activities equal to or greater than a certain criterion at the time of manufacture are subject to registration. These levels were derived on the basis of professional judgement of the working group, with input from vendors, device users, and other health physicists. They took into consideration (1) the hazard from external and internal exposure, (2) the typical quantity of isotope contained in a device, (3) costs and availability for disposal of the device, (4) the half-life of the isotope, and (5) the cost associated with clean-up and disposal from accidents resulting from loss of the device. They also considered levels that were 1000 times the exempt quantity specified in 10 CFR 30.71, appendix B. The registration program has been incorporated into 10 CFR part 31 through a recent rulemaking effort.

- "Improper Transfer and Disposal Scenarios for General Licensed Devices," Oak Ridge Associated Universities, April 1987. This report is outdated and is not sufficient to support decision making.

- PNNL-11905, "Technical Letter Report: Task 7, Final Review of the 1987 Report by Oak Ridge Associated Universities, Improper Transfer/Disposal Scenarios for Generally Licensed Devices", Strom et al., June 3, 1994. This report alone is not sufficient to support decision making.

- NUREG-1188 "The Auburn Steel Company Radioactive Contamination Incident". This report gives the details of a 1983 incident in which workers at the Auburn Steel Company discovered that about 120 tons on steel had become contaminated with approximately 25 curies of Cobalt-60. Decontamination and disposal cost in excess of $2,200,000. The report documents the discovery of the contamination, decontamination of the plant, and disposal of the contamination. The study provides relevant information that could be combined with other risk studies to better understand the impacts of source melts.

  While the source of contamination in the Auburn Steel case was not known to be a fixed gauge, the report does give information on clean-up costs and other issues involved in source melt incidents. The author of the report also suggests that sources contained in generally licensed devices should be limited to 1 curie. The basis for this suggestion is the fact that "at 50 tons of steel per melt, a 1-curie Cobalt-60, Cesium-137, or Strontium-90 source would not pose an unacceptable risk at specific activities of 22 nanocuries per gram."

- SECY-98-117, "Shelwell Services, Inc., Risk Assessment", This study was the result of the staffs efforts to assess residual contamination at the Shelwell Services site in Columbus, Ohio. In 1983 the licensee accidently drilled into a 2 curie Cesium-137 sealed source used for well logging. The study provides relevant information which could be used in conjunction with other studies to better define the consequences of breaching a large Cesium source. This information could be useful when considering impacts on metals facilities, which often use shredding and cutting equipment to process scrap.

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

The information contained in the database which accompanies NUREG-6642 could be used to calculate doses/risks from a more representative population of gauges. The information currently in the database is based on calculations which were made using a mathematical average of the wide variety of source strengths found in fixed gauges. One plausible exposure scenario that was not evaluated in the NUREG is the case in which a person finds a radioactive source and places that source in their pocket. Calculations for this scenario should be completed. The costs to complete the necessary calculations are estimated to be minimal.

The PNNL report states that "there is a need for detailed data on numbers of devices by source type, isotopes, activities, and design," this data could be obtained from the General License Tracking System.

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

In general, risk information is just beginning to be used by the NRC for fixed gauges. The new registration requirements in 10 CFR 32, which are based on the recommendations of the General License (GL) working group, were developed using consequence based information and professional judgement, and are a beginning in the use of risk information for these devices. NRC has attempted to reduce the probability of higher activity devices being lost or discarded by implementing the GL registration program.

The use of risk information in determining which gauges should be generally licensed has been very limited in the past. Generally licensed devices are required to meet 32.51(a)(2)(iii) which states: "under accident conditions (such as fire and 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 the table in 32.24." The probability for failure that should be assigned to "unlikely" is not clear. In the past, "unlikely" has been judged only in qualitative terms, and has never been defined.

The doses listed in column IV of the table correspond to those which should be negligible "in use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product . . " How these doses were or should be applied to generally licensed devices is unclear.

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

Fixed gauges are used in many industries to improve the quality and lower the costs of products for industrial, commercial, and private uses. They are most often used as a way of monitoring a production process and ensuring quality control. They serve such purposes as controlling thickness, density of coal, and monitoring and controlling liquid levels in tanks, among others.

Some fixed gauges are able to be used in areas that would be inhospitable to humans, such as in tanks, or other dangerous locations. Use of fixed gauges in these locations may reduce the immediate safety risk to workers at the facility by performing a function that would otherwise expose the workers to a dangerous environment. In the Auburn Steel incident, detailed in NUREG-1188, fixed gauges in use by the licensee to indicate the height of steel in molds alerted workers at the facility to the presence of Cobalt-60 in the steel when they gave a higher than expected reading. When the workers investigated the cause of the high reading, they discovered that the gauges were not malfunctioning, but were responding to the presence of radioactivity in the steel. Without those gauges, the Auburn workers would not have known that they were being exposed to radiation.

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

The public is generally unaware of these devices, and the fact that they contain radioactive material. However, the public is becoming much more aware of radioactive materials in recycled metals, therefore, an accidental melting of a large fixed gauge source by a metal recycling facility could generate an adverse reaction by the public.

(7) What was the outcome when this application was put through the draft screening criteria? Did this application pass any of the screening criteria? Does the outcome seem reasonable? Why or why not?

This application passed the draft screening criteria. The outcome seems reasonable, especially in light of the fact that fixed gauges have been the subject of many risk studies and there is a clear desire on the part of both regulators and stakeholders to begin assigning gauges to licensing categories commensurate with their risk.

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 regulations for generally licensed fixed gauges can be separated into two distinct areas, one that applies to users of gauges (10 CFR 31.5), and one that applies to manufacturers (10 CFR 32.51). Specifically licensed gauges are regulated under 10 CFR 30.32(g), and 10 CFR 32.210.

10 CFR 31.5

In response to increasing event reports regarding lost devices, and radioactive sources being discovered in scrap yards, as well as steel industry outcry, the staff of the NRC acknowledged that licensees were having problems maintaining control over, and accountability for their devices. In June 1995, a joint NRC-Agreement State working group was formed to evaluate the problem and propose solutions. In 1996, the recommendations of the group were published as NUREG-1551, and at Commission direction work began on a rulemaking to incorporate changes recommended by the group into 10 CFR 31.5. Effective February 16, 2001, 10 CFR 31.5 was revised to include a registration requirement for devices which contain at least 10 mCi of Cs-137, 0.1 mCi Sr-90, 1 mCi Co-60, or 1 mCi Am-241 or any other transuranic. The revision also requires that the licensee appoint a responsible individual who is aware of the requirements of the general license.

10 CFR 32.51

The basis for the dose and probability requirements in 32.51 is largely unknown. The statements of consideration contain no insights into why or how the various requirements were chosen. An example of this is 32.51(a)(2)(iii), the allowable doses for accident conditions. The section states that it should be “unlikely” that any person would receive a dose in excess of those specified in column IV of the table in 32.24. Prior to 1975, there was no explicit requirement for consideration of accident doses. In a 1974 rulemaking effort, the paragraph was inserted into the regulation, but there is no documentation to address why these values were chosen, or why the Commission chose to address accident conditions when previously it had not.

(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 qualitative safety goals in 32.51, to the extent that we have been approving gauges for distribution if they meet the safety requirements, i.e. they are safe enough. These requirements are that (1) the device can be safely operated by persons not having training in radiological protection; (2) that under ordinary conditions of handling, storage, and use, it is unlikely that any person will receive a dose in excess of 10 percent of the annual limits specified in 20.1201(a); and (3) that under accident conditions it is unlikely that any person would receive a dose in excess of the dose specified in Column IV of the table in 32.24. However, the term unlikely is open to interpretation by the reviewer, and it is left to the individual reviewer to decide what accident scenarios to accept. Whether the dose numbers given in these limits are appropriate as safety goals is not clear at this time, but the idea of considering dose in both normal and accident conditions is consistent with a safety goal.

(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 first four of the factors considered in the screening criteria, are the performance goals in the NRC Strategic Plan for the Materials Arena. These are: maintain safety, improve efficiency, reduce burden, and increase public confidence. Safety goals for fixed gauges would have a positive effect on all of these.

(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?

SECY-00-0137, "Response to Staff Requirements Memorandum Dated December 21, 1998 -- SECY-98-232 -- Seaman Nuclear's Application to Distribute Portable Gauges to General Licensees", documents the staff's use of risk information in deciding the appropriate licensing category for a portable gauge. The staff reviewed NUREG-6642, as well as documented data on events involving portable nuclear gauges, and made a risk informed decision to deny Seaman's application to distribute their gauge as a generally licensed device. While the device in this case was not a fixed gauge, the case does provide an example of what risk the staff felt was acceptable, and what types of accident scenarios need to be evaluated.

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

Any safety goals developed for fixed gauges would most likely apply to a broader category of devices, which could include all generally or specifically licensed devices, or devices used under 10 CFR 31.5 or 10 CFR 30. Depending on the nature of the proposed safety goal, the data listed previously in question 1 of the Screening Criteria Analysis/Risk Analysis questions would be available for measurement, as well as reports from the Nuclear Material Events Database.

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

Populations at risk from the use of fixed gauges include workers in facilities that use fixed gauges, members of the public who may find a lost, stolen, or improperly disposed of gauge, including workers in scrap yards and other metals recycling facilities, manufacturers and repair workers, individuals involved in transportation or the sources and devices, and those involved in disposal activities. The environment and metals facilities are also at risk for property damage and environmental contamination.

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

Radioactive sources that have been accidently melted by the metals industry have caused millions of dollars in damages and lost production time to those facilities. In

addition, unshielded sources have been found at scrap yards. One such incident in Illinois, where a 370 millicurie cesium source was discovered in backfill used to re-grade the site, resulted in dose rates of 145 millirem/hour at 3 feet. There is no way of knowing how long the source had been on the site or whether it may have been exposing workers and other individuals prior to being discovered. Cesium sources in the tens of milicurie range, if placed in a persons pocket, could produce a dose such that deterministic effects including skin burns could occur in a relatively short period of time. Acute whole body radiation effects could be a concern with some fixed gauges under accident conditions, and cancer or other effects could be noted through routine exposure.

(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?

In general, safety goals for generally licensed fixed gauges should not differentiate between workers and the public. 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 measures. Safety goals should address accident conditions as well as normal conditions, since the available risk information indicates that accident conditions can pose significant additional risks. Safety goals should also reflect protection of the environment and property, in terms of containment of the isotope within the sealed source, and control and accountability measures, among others. A safety goal for prevention of deterministic injury, such as skin burns, should also be considered.

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

Yes, development of safety goals for fixed gauges is feasible based on the technical information, although what makes a safety goal appropriate is largely a policy decision.

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

Depending on the use of a particular device, the same methods, data results, and regulatory requirements could be applicable. Currently, 10 CFR 32.51 applies not only to fixed gauges, but to other “measuring, gauging, or controlling devices” as well. In a similar manner, 10 CFR 30.32(g) applies to an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains sealed sources. The safety goal considerations should be generally applicable to other similar 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 fixed gauges 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 objective of the draft goals? Would major changes be required?

The regulations for fixed gauges do not completely address the environmental and property damage aspects of the goals. The regulations require that the devices undergo a sealed

source and device review that addresses such things as sealed source integrity, leak testing requirements, and labeling. All of these things are considerations for limiting environmental and property damage, however, since there is no limit on the amount of radioactive material that can be contained in a fixed gauge, the risk from an accidental source melt at a metals facility is not addressed.

2. Would the regulations need to be tightened?

If the environmental and property damage goal is adopted, the regulations may need to be further developed to reflect this objective.

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

No, the regulations governing fixed gauges provide sufficient flexibility.

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

The goals would 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 fixed gauges.

5.1 Application of the Draft Screening Criteria to Fixed Gauges

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

Yes. Fixed gauges, and other devices which contain similar sealed sources, can become problems when they are lost, stolen, or improperly disposed of. Accidental source melts by steel mills have caused both financial losses to the mills, and an increase in radioactive waste. A risk-informed approach could implement a scheme wherein devices which are expected to produce higher exposures would be subjected to greater restrictions. We can use risk information to change the way devices are licensed by identifying devices which are suitable for general licensing as the program exists now, and those which require more control. We can also use risk information to determine what those controls should be. A risk-informed approach would also help to provide a more consistent licensing scheme between the Agreement States and NRC.

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

A risk-informed approach in this area could improve the effectiveness of the NRC regulatory process by providing a greater degree of consistency as to how fixed gauges are licensed. If safety goals were developed, license and device reviewers would have a better understanding of where individual gauges belong in the regulatory categories. Currently, manufacturers can designate whether they want to distribute their gauge as specifically licensed or generally licensed, providing it can meet the minimum requirements. Some devices which could meet the general license requirements are distributed as specifically licensed devices due to the manufacturers desire. This practice increases the NRC resources needed to oversee the specifically licensed end users of the devices. If risk information were used to help assign gauges to license categories based on the hazard of the device, regulatory resources could be focused on devices which truly require additional oversight.

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

A risk-informed approach could allow fixed gauges which do not present an undue hazard to remain generally licensed, and could increase requirements on more hazardous devices without arbitrarily assigning them to a more restrictive licensing category. For example, a risk-informed licensing scheme could be developed in which generally licensed gauges in the highest risk categories could be removed from the traditional

general license, and put into a new category of license. This category could have requirements commensurate with the hazard of the device, but might not include all of the conditions which are currently required of specific licensees. Similarly, specifically licensed gauges which represent a lower hazard could be put into a less restrictive licensing category commensurate with the hazard.

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

A risk-informed approach could allow for a better understanding of how decisions regarding licensing of fixed gauges are made.

(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?

Risk-informing fixed gauges could be accomplished through existing studies and techniques.

(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.)

Yes. The benefit gained by both the licensee and NRC would outweigh the costs associated with development of a new licensing and inspection scheme. Currently, decisions about whether a device should be generally or specifically licensed are made on an individual basis. The development and implementation of a risk-informed approach could benefit licensees, the public, and NRC in the following ways:

<u>Licensee</u>

Gauge manufacturers could be given clear and understandable technical criteria for gauge design, which would save them time and money when submitting a package for review. Under the current system, there is sometimes a lengthy process of review and policy decision making when a new type of device is proposed, or when a current design is evaluated for a different type of license category. A risk-informed approach could shorten this process by giving manufacturers a sense of whether their design is likely to be approved before hand.

<u>Public</u>

Implementation of a risk-informed approach would provide better protection for the public by providing greater controls on devices which are more likely to cause harm. The approach would also allow resources to be focused in proportion to the risk a device presents.

NRC

Implementation of a risk-informed approach would aid NRC by giving the staff the tools to make a clear safety argument for their licensing and inspection decisions. Efficiency and effectiveness would be improved by reducing the review time necessary for special cases in licensing and device approvals.

One example of how a risk-informed approach could benefit licensees, the public, and NRC is the case of using shielding to reduce exposure to persons during routine use of gauges. Some manufacturers add additional shielding to specifically licensed gauge designs which are intended for distribution to general licensees. Others do not, and there is no regulatory requirement for them to do so. Use of a risk-informed approach would give NRC a clear basis for requirements in this area, benefitting licensees, the public, and NRC.

(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. The stakeholders present at the initial public meeting held on this case study were in favor of using risk information in the licensing and regulation of fixed gauges. One stakeholder commented "I think a lot of us who represent manufacturers really like the idea of there being more attention paid to the risk. Because it's been obvious that some of the problems that we see are because things have been put in categories and it doesn't necessarily relate to risk. . .I've often thought that some of the requirements that have come down is because there are some devices, perhaps that have been put in the general license category that never belonged there in the first place. And it's sort of like it's tainted the license category and made things stricter when it would have been better just to remove that group of things . .I think I speak for a lot of us that we kind of welcome this, more let's take a step back, let's look at the risk, let's sort this out. I think that's a very good approach. "

5.2 Outcome of Applying Draft Screening Criteria

This application passes all of the screening criteria. The screening criteria were useful for providing a path to follow when attempting to make a decision about whether risk-informing fixed gauges is feasible and desirable. Guidance on some questions, especially number 5, would be useful for the staff when applying the criteria to other future decisions.

6. SUMMARY AND CONCLUSIONS

The conclusions are organized 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?

As stated above, the draft screening criteria appear to contain all the relevant considerations for making decisions as to whether to pursue risk-informing a proposed regulatory action.

2. What insights did the case study provide about the current and potential value of using risk information?

This case study demonstrated that the use of risk information can provide burden reduction and improved efficiency in decision making. It can also point out where consideration of an increase in regulatory oversight might be warranted.

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

This case demonstrated that safety goals for fixed gauges would be beneficial. They would enable the staff to making licensing and inspection decisions which are consistent and defensible. The manufactures design dose criteria found in 10 CFR 32.51 are elements of safety goals. The staff decisions found in the Shelwell and Seaman Nuclear cases provide reference points for safety goals on accident risks. If safety goals had existed prior to these cases, both the licensees and NRC would have benefitted from a reduced decision making time frame, and from reduced uncertainty in the acceptability of the final decision. From the information considered in this case study, there appears to be no reason why safety goals could not be developed for occupational exposure and accident risks.

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 in other similar regulatory areas?

This case highlighted the fact that several risk studies have been done in the area of fixed gauges, and other devices which use similar sealed sources of radioactivity. During the course of conducting the study, it became apparent that while not every study considered in this report is specifically for fixed gauges, certain insights can be applied to risk-informing fixed gauges due to the similarities in the types of sealed sources. It may be necessary, in risk-informing other regulatory areas, to consider studies that are of a similar nature to the area under consideration, rather than to conduct specific studies for individual device types. Guidance in this area could be beneficial to staff who will be using this approach in the future.

7. REFERENCES

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