**VOLUME 2: APPENDIX B**

# RISK INFORMING THE NUCLEAR MATERIALS AND WASTE ARENAS:

## A Case Study on the Regulation of Gas Chromatographs

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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 gas chromatographs 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 Case Study . . . . . 2
1.3 Organization of the Report . . . . . 2

2 BACKGROUND . . . . . 3

3 CASE STUDY APPROACH . . . . . 5

4 RESPONSES TO DRAFT QUESTIONS . . . . . 6
4.1 Screening Criteria Analysis/ Risk Analysis Questions . . . . . 6
4.2 Safety Goal Analysis Questions . . . . . 8
4.3 Questions upon Developing Draft Safety Goals . . . . . 13

5 DRAFT SCREENING CRITERIA . . . . . 15
5.1 Application of Draft Screening Criteria to Gas Chromatographs . . . . . 15
5.2 Outcome of Applying Draft Screening Criteria . . . . . 16

6 SUMMARY AND CONCLUSIONS . . . . . 17

7 REFERENCES . . . . . 19

# 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 gas chromatographs, 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 staff 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 Case Study

One of the activities chosen for the case studies is NRC's regulation of commercial uses of radioactive material in gas chromatographs. Gas chromatographs are used in industrial and laboratory settings to detect small quantities of organic compounds. Modified versions of this device known as chemical agent monitors are used by the military to detect poisonous chemical gases in the field, and other versions are being developed to assist forensic investigators in determining a persons time and cause of death. This case study focuses on the regulation of gas chromatographs by NRC under the requirements specified in 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." The case study also considers the risk studies available for gas chromatographs, including NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," and NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," as well as individual sealed source and device evaluations.

## 1.3 Organization of the Report

The report is organized into seven sections. Section 2 presents a general description of the regulatory scheme for gas chromatographs, including requirements for users and manufacturers. 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 gas chromatographs. Section 6 summarizes and discusses future work, and Section 7 lists the references used in conducting this case study.

## 2. BACKGROUND

Gas chromatographs are used to separate a gas mixture in order to identify its various components and their concentrations. Electron capture detectors (ECD) are used to enhance sensitivity and thus further refine the analysis of molecules in the effluent stream from gas chromatographs. The electrons are typically provided by low-energy beta particles from tritium (H-3) sources containing about11 giga becquerels (300 milli curies) or nickel-63 (Ni-63) sources containing about 0.74 giga becquerels (20 milli curies). The analyte, in a carrier gas such as helium, argon, or nitrogen is passed through the ECD. The electrons are thermalized in the carrier gas, and produce negative ions of the analyte at a rate that depends on the electron capture cross-section for the different molecules or molecular subunits. The change in electron current while passing through the gas stream is monitored, and a variety of signal processing techniques can be used to detect extremely small concentrations of analyte in the carrier gas. The few molecular compounds that react rapidly with thermalized electrons are mostly compounds that are either highly toxic or otherwise environmentally objectionable (e.g., pesticides, nitro compounds, chlorofluorocarbons). Thus, such high sensitivities make the combination of a gas chromatograph and ECD important in environmental sampling for very small amounts of pollutants.

The radioactive sources usually consist of either H-3 in the form of titanium tritide, or of Ni-63 on a metallic foil in the form of a cylindrical sleeve through which the gas stream flows. The foils are mounted in solid cylindrical containers with small inlet and outlet holes or tubes for the analyte. The unit holding the radioactive source has a stainless steel body, plastic parts for insulation between the metal components, and ceramic parts for electrical leads. The components of the device are assembled by the manufacturer using special securing screws or other techniques to eliminate easy access to the radioactive source. The ECD has no moving parts that might damage the foil or require frequent servicing.

The wall materials surrounding the radioactive source foils are generally thick enough to stop all beta particles from H-3 or Ni-63, since the range of the beta particles is less than 0.1 mm in plastic. In addition, these beta particles are not energetic enough to contribute to the shallow-dose equivalent (dose equivalent at 0.007 cm in skin), even if a person was in close proximity to the source. Bremsstrahlung created by the interaction of the beta particles and the detector housing is shielded by the external case of the detector, and various other components, reducing the dose rate on the outside of the gas chromatograph to essentially zero.

Gas Chromatographs are used under the authority of either a general or specific license. A general license is granted in 10 CFR 31.5 to acquire, possess, use, or transfer byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. Included in the general license are requirements for labeling, leak testing, and proper storage or disposition of the device. The licensee is also subject to 10 CFR 20.2201 and 20.2202 for reporting theft or loss of licensed material.

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 gas chromatographs 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 gas chromatographs 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 the devices 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; 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 or other environmental conditions may be specified. Except as specifically approved by NRC, licensees are required to use devices 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.

## 3. CASE STUDY APPROACH

The case study approach consisted primarily of reviewing applicable documents, searching the internet for information on gas chromatographs and their regulation, and interviewing NRC personnel involved with licensing devices which contain byproduct material. Risk studies were also reviewed including, NUREG/CR-6642, “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems,” and NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials.” Other documents utilized include NUREG/CP-001, “Radioactivity in Consumer Products,” which provides the policy background for exempt products. References to these documents are given at the end of the report.

The case study followed the outline provided in the Case Study Plan that was developed by NRC’s Office of Nuclear Materials Safety and Safeguards, Risk Task Group. The use of gas chromatographs by licensees, as well as NRC’s regulation of gas chromatographs was evaluated against questions in three categories: screening criteria analysis/risk analysis, safety goal analysis, and 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.

The 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 the 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 6642, *Risk Analysis And Evaluation of Regulatory Options for Nuclear Byproduct Material Systems*, is the most current risk analysis for gas chromatographs. System 27 of the study contains generic risk information for the receipt, storage, maintenance, use, and disposal of the most common forms of gas chromatographs, that is, those using tritium (H-3) and nickel-63 (Ni-63). Gas Chromatographs are used under the authority of general licenses granted by the NRC in accordance with 10 CFR 31.5, or under specific licenses issued under 10 CFR Part 30.

- NUREG 1717, *Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials*, is an assessment of potential radiation doses associated with the current exemptions for byproduct and source material. Radiological assessments of five generally licensed applications, including gas chromatographs, were included in the study because they had previously been identified by NMSS staff as potential candidates for exemption.

- Since the regulations which govern gas chromatographs require that they be evaluated in a Sealed Source and Device (SS & D) review in accordance with either 10 CFR 32.210 for specifically licensed devices, or 32.51 for generally licensed devices, there is detailed information about each type of gas chromatograph available in the SS & D registry.

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

- NUREG-6642 calculated doses to workers and the public for both generally licensed and specifically licensed gas chromatographs. They considered the most common gas chromatograph isotopes H-3, and Ni-63, and calculated doses based on an “average” source strength for both normal and accident conditions. The study concludes that for all risks to workers or public, the maximum dose is well below that for which significant adverse health effects would be expected. The study acknowledges that uncertainty exists within the study, but that the likelihood of doses which could lead to health effects is quite low.

- NUREG-6642 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-1717 calculated doses to workers and members of the public for a variety of scenarios, including: distribution and transport, routine use, sample analysis, transport, source replacement, disposal, accidents, and misuse. The study considered sources that are typical of generally licensed gas chromatographs, and concludes that the details of the design are important to ensure control of exposure. The authors further conclude that for the radiation doses resulting under an exemption of the devices to be comparable to those estimated, similar controls over the distributors would be necessary to ensure that the designs of the devices are comparable in minimizing exposures to users and members of the public. The NUREG has been used in its draft state by the Commission to make decisions with respect to the disposal of 40.13(a) materials.

  Use of NUREG-6642 in combination with NUREG-1717 should provide sufficient information on which to base decisions

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

The existing studies appear sufficient to support decision making. However, decision makers should note that the dose calculations are based on specific source strengths, and that additional calculations should be completed if the device in question exceeds this source strength.

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

Manufacturers of gas chromatographs must submit information about the device in order for NRC to conduct a SS & D review. This information includes dose estimates and information related to product integrity and accessibility of the radioactive material. Currently, this information from the SS&D review is used to determine that the sources and devices are manufactured in such a manner that the they pose very little risk to members of the public, or occupationally exposed individuals under both normal and accident conditions.

If gas chromatographs are considered for distribution to persons exempt from licensing, a new category may need to be created within the regulations which allows distribution of such a product. In this case, an environmental assessment would have to be completed in support of the rulemaking effort. In addition, the individual types of gas chromatographs would undergo a SS & D review to ensure that they are able to meet the manufacturing standards for exempt products.

NUREG 1717, *Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials*, is an assessment of potential radiation doses associated with the current exemptions for byproduct and source material. Radiological assessments of five

generally licensed applications, including gas chromatographs, were conducted in the study because they had previously been identified by NMSS staff as potential candidates for exemption. This information, combined with the information from NUREG-6642, was used by the Phase II, Byproduct Material Review Team to provide a basis for recommending that the level of regulatory oversight for gas chromatographs be reduced, due to the low probability of health consequences in both accident and normal conditions.

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

These devices are used in industrial and laboratory settings to detect small quantities of organic compounds. Modified portable versions of this device known as Chemical Agent Monitors are used by the military to detect poisonous and explosive chemical gases in the field. Other versions are being developed to assist forensic investigators in determining the time and cause of a persons death. Gas chromatographs and ECD's are particularly useful for detecting highly toxic or objectional compounds such as pesticides, nitro compounds, and chloroflorocarbons.

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

The public is largely unaware of these devices and the fact that they contain radioactive material. However, some members of the public are concerned about the possibility of additional products moving into the category of exempt distribution, even though they represent a very small radiological risk.

**(7) What is 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?**

The application passes all of the screening criteria with the possible exception of Question 7. There is not sufficient information available to determine whether adverse stakeholder reaction would result if efforts to move gas chromatographs into an exempt distribution category were initiated.

## 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 Atomic Energy Commission published criteria in 1965 that set forth the essential terms of the policy currently used by the NRC with respect to approval of consumer (exempt) products. The criteria state that approval of a proposed product will depend on two factors: the radiation exposures that will be associated with the product and the product's apparent usefulness. The criteria state that risks of exposure to radiation will generally be considered acceptable if it is unlikely that the individuals in the population will receive no more than a few hundredths of the individual dose limits recommended by the International Council of Radiation Protection and Measurements.

NRC's policy on exempt products states that there are three major areas of concern: (1) the radiation safety of workers; (2) the radiation safety of the general public, including both users and non-users; and (3) long-term contamination of the environment. It further states that the radiation exposure of workers in licensed facilities must be kept below the limits of 5 rems per year; and further, should be kept as far below those limits as is reasonably achievable. Radiation exposure of individuals in the general public as a result of the distribution, marketing, installation, repair, and use of consumer (exempt) products must be kept at even lower levels. The calculated doses must include contributions from normal use and from misuse or accidents. In general, risks of exposure to radiation will be considered acceptable when the individual dose is less than a small fraction of the recommended dose limits. Further, the probability of individual doses approaching any of the specified limits must be negligibly small. The potential cumulative dose from the use of multiple products and from other sources must also be taken into account. Finally, NRC considers the benefit to be derived by the public from the use of the product.

If the product is found acceptable after an assessment of its environmental and safety impact, the regulations can be amended to allow the exemption under appropriate standards. In a separate action, the manufacturer or initial distributor must demonstrate to NRC that its product is designed and will be manufactured to meet those specific standards before it can be licensed to manufacture the product for distribution.

**(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 acceptance of a regulatory exemption based in part on a risk analysis and the outcome)?**

Products intended to be distributed to persons exempt from licensing (e.g. the general public) must meet specific safety requirements. These specific requirements could be seen as safety goals for these products. The requirements which pertain to smoke detectors, and other gas and aerosol detectors are found in 10 CFR 32.26, this is the category that is most similar to gas chromatographs. These regulations contain safety criteria that the device must meet which include:

1) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column 1 of the table in § 32.28 (below).

| Part of Body | Column I (rem) | Column II (rem) | Column III (rem) |
|---|---|---|---|
| Whole body; head and trunk; active blood forming organs; gonads; or lens of eye | 0.005 | 0.5 | 15 |
| Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter | 0.075 | 7.5 | 200 |
| Other organs | 0.015 | 1.5 | 50 |

2) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

3) In use and disposal of a single exempt unit and 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, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment excess of the dose to the appropriate organ as specified in Column II of the table in §32.28, and the probability is negligible that a person would receive and external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in §32.28.

In addition, the table contains the following explanatory footnote: “It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low – not more than one such failure per year for each 10,000 exempt units distributed.

Negligible – not more than one such failure per year for each one million exempt units distributed.”

Thus, for products intended for exempt distribution, there are elements of both quantitative and qualitative safety goals.

**(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 gas chromatographs 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?**

There is a fair amount of documentation on the approval of consumer products available in NRC records. Since approval of a new category of exempt distribution products generally requires a rulemaking effort and an environmental assessment, there is information available within the statements of consideration for the appropriate regulations. However, since the approval policy for exempt products contains implicit safety goals, most recent product approvals will not contain new safety goal insights.

**(5) If safety goals are developed in this area. Would tools/data be available for measurement?**

Any safety goals developed for gas chromatographs would most likely apply to a broader category of devices, which would include, for example, all exempt products or generally licensed devices for use under 31.5. Depending on the nature of the proposed safety goal, the data listed previously in question 1 of the screening criterial/risk analysis questions would be available for measurement, as well as reports from the Nuclear Material Events Database which describes incidence of leaking sources and other events for the past eight years. With the information relative to the radiological hazards from these incidents, along with the methodologies in NUREG-6642 and the radiological assessments in NUREG-1717, the magnitude of the risk could be ascertained for decision making purposes.

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

There are currently, approximately 120,000 of these devices in use in the United States. Of these, there are approximately 160 specific licenses under NRC regulatory authority for the possession and use of gas chromatographs, the rest are general licensees. The populations at risk include the owners of these devices, their employees, the manufacturers and servicers of the sources and devices, the individuals involved in transport of the device, and those involved in the disposal of the device. Based on the dose assessments and scenarios from the risk studies, a change in the licensing program to generally license the160 specific licenses or exempt from licensing the entire 120,000 devices, would not result in a significant increase in risk to the population.

**(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 very small. Under accident conditions, NUREG-6642 calculated that the largest dose for gas chromatographs (System 27) as 12 mrem, for several low probability accidents. NUREG-1717 also assessed the radiological consequences for accidents and misuse scenarios. According to their assessment, the worst case consequence from highly unlikely events, would result in a dose of 200 mrem for users of H-3 devices, and 300 mrem for users of Ni-63 devices. These assessments assumed very conservative leakage rates -- up to 10 times the rate normally experienced in a leaking source. More realistic estimates of expected doses under leakage conditions would be less than 100 mrem.

**(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 or exempt gas chromatographs 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 additional risks. Safety goals should also reflect protection of the environment and property, in terms of containment of the isotope within the sealed source.

**(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 generally licensed or exempt gas chromatographs is feasible based on the available technical information.

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

A review of the remaining four generally licensed systems considered for exempt distribution included in NUREG 1717, and further analyzed using NUREG-6642 methodologies, would provide a similar set of consequences and probabilities for consideration of acceptability. The same methods, data results, and regulatory requirements would most likely be applicable to these other systems, since the requirements for exempt distribution of products are based on design features, performance testing (i.e. leak testing) and control and accountability.

## 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 current regulations provide sufficient to ensure that the manufacture and use of these devices do constitute a significant risk.

**(2) Would the regulations need to be tightened?**

No.

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

The Regulations are not overly conservative, but due to the nature of the design and function of these devices, changes in the regulations are not likely to affect the overall risk these devices pose to society.

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

Again, since these devices are inherently safe, the regulations placed on these devices do not affect the overall risk associated with them. However, the regulations may make the use of these devices tolerable to the general public from the point of view of ALARA. I,e., in that, our ability to engineer risks down to infinitesimal levels, exceeds the practical need to provide that level of safety.

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

Depending upon the political and regulatory climate at the time, the majority of the public would likely accept these goals. However, there is likely to be small minority of the public who will not accept these goals, regardless of the level of tolerable risk associated with them.

## 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 gas chromatographs.

### 5.1 Application of Draft Screening Criteria to Gas Chromatographs

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

Yes, a risk informed approach could be used to maintain the safety of gas chromatographs. A risk-informed approach, focusing on consequences and probability, would show that NRC's resources are not effectively used in overseeing these devices at the current level. A reduction in their oversight would not reduce the level of safety below an adequate level, and would free resources to reduce risks and increase overall safety in other, more risky materials applications.

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

Yes, by reducing the regulatory burden associated with gas chromatographs to a level commensurate with the risk they present, resources spent on the oversight of these devices could contribute to maintaining safety of other higher risk materials licensees, without adversely affecting safety.

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

Yes, burden in the form of the preparation of licensing applications and payment of fees for the 160 NRC specific licensees, along with elimination or reduction of inspection, would reduce the monetary burden on these licensees without adding a substantial reduction in safety to the population at risk.

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

Based upon the comments of some stakeholders from the February 9, 2001 meeting, regarding consideration of exempt distribution for these devices, any amount of increase in risk would appear to be unacceptable to some members of the public. Therefore, it is not clear that further clarification or bounding of the low levels of risk associated with this device would meet with the general approval of the public. However, a risk-informed approach could allow for a better understanding of how decisions regarding licensing of gas chromatographs are made.

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

Yes, studies currently exist that are of sufficient quality to determine the possible consequences, and their probabilities. These studies could be used to make a decision as to whether regulatory oversight of these devices could be reduced commensurate with their risk. Further studies would not by likely to provide significant additional insights or risk information for these devices.

**(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, sufficient studies have been performed to determine the possible consequences and their probabilities to make a decision as to whether regulatory oversight these devices could be reduced commensurate with their risk. Further studies would not add anymore insights or risk information for these devices. However, a determination of societal tolerance of the low probability, low consequences associated with these devices based on the existing studies is a large unknown.

**(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?**

There is not sufficient information available to determine whether adverse stakeholder reaction would result if efforts to exempt users of gas chromatographs from regulatory oversight were initiated. However, based upon comments received at the February 9, 2001 public meeting, some members of the public are concerned about exempting the distribution of additional products from regulatory oversight.

## 5.2 Outcome of Applying Draft Screening Criteria

The application passes all of the screening criteria with the possible exception of Question 7. There is not sufficient information available to determine whether adverse stakeholder reaction would result if efforts to exempt users of gas chromatographs from regulatory oversight were initiated.

## 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?

The case study indicated that the screening criteria may be useful in the future in deciding whether to use risk information in regulatory activities; however, questions related to public acceptance of the use of this information can only be guessed a priori. Therefore, use of this as a criteria may be questionable since at least some public objection may be inevitable among some stakeholders. Instead this criteria should be used as a consideration to be taken by risk managers when determining whether to pursue the use of risk information in making regulatory decisions on a case by case basis.

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

The case study demonstrated that the use of risk information can provide burden reduction and improved efficiency in decision making, without a reduction in safety.

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

The case study indicated that safety goals for gas chromatographs would be beneficial. They would enable the licensing and inspection staff to make decisions that are consistent and defensible. There are implicit qualitative safety goals for exempt distribution products within the approval policy for consumer products. The policy states that risks of exposure to radiation will generally be considered acceptable if it is unlikely that the individuals in the population will receive no more than a few hundredths of the individual dose limits recommended by the International Council of Radiation Protection and Measurements. The policy further states that there are three major areas of concern: (1) the radiation safety of workers; (2) the radiation safety of the general public, including both users and non-users; and (3) long-term contamination of the environment. These things can all be seen as qualitative safety goals. These have been translated into quantitative requirements via the table in 10 CFR 32.28, and its accompanying explanatory footnote.

By comparison of the exposure levels for gas chromatographs given in NUREG-1717 with the dose criteria given in the table of 10 CFR 32.28, it can be demonstrated that these devices meet the implicit safety goals, and are likely to also meet any reasonable explicit quantitative or qualitative safety goal that may be developed in the future.

**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?**

The case study demonstrated that adequate risk studies have been performed to allow a risk-informed regulatory approach to be used with gas chromatographs. The study also demonstrated that guidance is needed for the application of the screening criteria, since they seem to be subjective in nature.

## 7. REFERENCES


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