Radiation Protection and Health Effects

Research Program Plan

Radiation Protection, Environmental Risk & Waste Management Branch
Division of Systems Analysis and Regulatory Effectiveness
Office of Nuclear Regulatory Research

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1. Introduction

Since the NRC's primary mission is to protect public health and safety, and the environment from the effects of radiation from licensed activities, the NRC staff needs to have access to the best scientific information in order to make informed regulatory decisions. An effective research program will seek out answers to these questions.

Over the next few years, the Commission will be faced with a major challenge in radiation protection. The International Commission on Radiological Protection (ICRP) is proposing a new series of recommendations outlining a simplified system of radiation protection. These recommendations, when issued for public review in mid-2004, may significantly affect NRC regulations, policies and guidance. To effectively support the NRC mission, the Office of Nuclear Regulatory Research (RES) will participate in national and international activities to review and revise radiation protection recommendations and guidance. These proposals will need to be evaluated to ensure that there is a sound and robust technical basis for the Commission's consideration whether to adopt these recommendations. If the Commission were to adopt the new recommendations, research would be needed to develop the technical basis to revise our regulations (e.g., Parts 20 and 30) and to develop supporting guidance.

In addition, there will likely continue to be emerging radiation protection and health effects issues (e.g., material security) where research is needed to support NRC staff evaluations. For example, existing internal dose assessment models were developed during the 1970s and 1980s. However, new biophysical models were developed and adopted by the international community during the 1990's. These models have not yet been adopted by the NRC. If the NRC adopts the newer biophysical models, existing health physics codes and tools will need to be revised or developed.

2. Radiation Protection and Health Effects (RPHE) Research Plan Objective

The plan's basic research objective is to support the Offices of Nuclear Materials Safety and Safeguards (NMSS), Nuclear Reactor Regulation (NRR), and Nuclear Security and Incident Response (NSIR) by developing the technical basis for agency requirements and guidance in the area of radiation protection. In addition, the research program should develop information to better understand how NRC-licensed materials interact with biological systems and the environment, so that exposures to these materials can be accurately characterized and the health consequences realistically estimated for occupational workers and members of the public.

3. Establishing the Content of the Research Plan

As part of the development of this plan, user office review will be sought both to assess the content of the research program and to identify additional issues or questions to be addressed. While responses to user needs currently form the core of the RPHE research program, another important component will address future research needs anticipated by RES. This plan identifies ongoing and proposed research activities for the next 3-5 years. Research activities that address the movement of radioactive material through the environment are discussed

briefly here. A more complete description of these activities appear in another research plan, "Radionuclide Transport in the Environment."

4. RPHE Research Program Goals

The goals of the RPHE can be described as follows:

RPHE Goal No. 1: Maintain and Improve NRC's Knowledge of Radiation Health Effects - Evaluate data and information on health effects attributed to radiation exposure in order to serve as a technical information resource. Ensure that NRC has the most up-to-date information in order to make realistic estimates of radiation health effects.

RPHE Goal No. 2: Support Development of Radiation Protection Standards and Implementation - Develop and enhance methodologies for radiation detection, measurement, monitoring, and dose assessment to provide technical information with greater accuracy and less uncertainty in order to enhance the effectiveness and efficiency of regulatory decisions. Promote consistency in the development of radiation protection standards by evaluating the impact and relevance of new technical and scientific developments on the NRC regulatory program and actively participating in the development of radiation protection recommendations to ensure that they are based on sound and logical scientific principles.

RPHE Goal No. 3: Support Radiation Protection Rationales and Technical Bases - Provide models that support realistic decision making in radiation protection. The NRC needs up-to-date information to accurately assess the impact on public health and safety in developing new regulations and reviewing licensed activities.

RPHE Goal No. 4: Develop Technical Basis for Risk-Informing Materials Applications through Analysis of Operational Experience - Develop information to support regulatory decision-making on risks associated with the use of radioactive materials. By accurately assessing the risks associated with expected or accidental exposures to radioactive sources, the staff will be better able to risk-inform NRC regulations on byproduct and source material.

5. Implementation of the RPHE Program Goals

This section provides a listing of current and proposed research projects that support the RPHE program goals. The proposed projects have not yet been prioritized or rank ordered. However, the proposed projects will be rank ordered using the RES prioritization process and funded on the basis of their ranking. The level-of-effort estimates described below include both staff and contractor resources estimated for each project on project level or yearly basis, as appropriate for the activity.

A. Goal No. 1: Maintain and Improve NRC's Knowledge of Radiation Health Effects

Issue: NRC uses radiation risk estimates to set regulatory requirements and assess the effects of agency actions. A key goal of the research program is to ensure that NRC has the best information available to make realistic estimates of radiation health effects. Having this

information will enable NRC to effectively participate in national and international activities to develop or revise radiation protection recommendations. Proposed topics to accomplish this goal include:

1. Title: Basic Radiation Biology

Background: Epidemiological studies of human exposure to radiation currently provide the technical basis for radiation risk assessment. However, these studies are insensitive to the very small exposures that often are of regulatory concern. Consequently, the data on health effects observed after large radiation exposures are linearly extrapolated to low dose exposures. This technique assumes that each unit of radiation, no matter how small, can cause cancer. As a result, radiation-induced cancer is predicted from low doses of radiation for which it has not been possible to directly demonstrate cancer induction. Additional health effects information is needed to establish a sound, technical basis for low dose risk assessments.

Objective: Actively monitor new developments in radiation effects research to maintain knowledge of the state-of-the-art to inform NRC's regulatory process. This will include participating in the Department of Energy Low Dose Radiation Research Program and other national and international activities designed to assess health effects at low doses, such as work being completed by the National Academies committee on the Biological Effects of Ionizing Radiation (BEIR VII) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). RES will evaluate all of the available information and provide it to the user offices for possible incorporation into NRC regulatory activities, policies and regulations (e.g., Part 20).

Application: The information generated by BEIR VII and UNSCEAR may be useful in updating the current estimates used to assess radiation risk. If successful, the long term study currently being funded by DOE may shed additional light on radiation risk at low doses.

Period of performance: ongoing - annual level of staff effort = 0.2 FTE

2. Title: Studies of Radiation Epidemiology on Exposed Populations

Background: Epidemiological studies of populations exposed to radiation can be useful tools to estimate radiation risk. To date, Japanese atomic bomb survivors have been the major source of information on radiation health effects. As this population ages, more information on cancer incidence is becoming available. These and other data may lead to a better understanding of radiation risk.

Objective: Evaluate existing data and information to see whether there are any trends that could shed light on the question of radiation risk at low doses. RES would use all available data and reports to address this question. For example, the International Agency for Research on Cancer (IARC) is completing an epidemiological review of nuclear power plant worker health from 17 countries. The IARC review should be

completed and published in 2005 and will be reviewed by RES to assess whether this information can be used to inform our regulatory processes.

In addition, RES staff will continue to participate in the review and evaluation of epidemiology projects funded by DOE such as the Radiation Effects Research Foundation looking at cancer incidence in the Japanese atomic bomb survivors and, under the auspices of the Joint Coordinating Committee on Radiation Effects Research (JCCRER), cancer incidence among Russian Federation workers at the Mayak Production Association and residents living along the Techa River.

Application: Studies of populations such as these may be valuable for developing more realistic radiation risk estimates. The results will provide information useful in informing NRC's current knowledge of radiation risk at low doses.

Period of performance: ongoing - annual staff level of effort= 0.1 FTE

3. Title: Medical Countermeasures

Background: In the U.S., 104 commercial nuclear power reactors are licensed to operate at 65 sites in 31 states. For each of these facilities, there are onsite and offsite emergency plans to ensure that adequate protective measures are taken to protect the public in the event of a radiological emergency. The NRC revised a portion of its emergency response regulations on April 19, 2001, to require that consideration be given to including potassium iodide (KI) as a protective measure for the general public. Since September 2001, NRC's review of potential radiological emergencies has been expanded to include devises designed to disperse radioactive materials in an uncontrolled manner. With the formation of the Department of Homeland Security, additional counter measures are being developed that can be used to reduce radiation health effects.

Objective: Monitor the development and evaluation of new medical countermeasures that are designed to minimize, reverse, or ameliorate symptoms associated with radiation exposure. Investigational New Drug (IND) protocols have been developed for calcium and zinc diethylenetriaminepentaacetic acid (DTPA) chelation therapy for cases of plutonium, californium, americium or curium ingestion. Prussian Blue (ferric hexacyanoferrate), a drug that enhances the excretion of isotopes of cesium and thallium, also has been approved for IND status by FDA. RES staff will monitor additional efforts to improve protocols for existing agents or to improve chelators. In addition, RES staff will monitor national and international programs designed to develop new techniques to quickly assess radiation exposure using either bioassay methods or cytogenetics (i.e., biological dosimetry).

Application: As new countermeasures are approved by FDA for human use to treat radiation exposure, this information would assist NRC program offices in developing or revising emergency planning guidance. Biological dosimetry techniques are intended to assist emergency responders with the confirmation of external radiation exposure and as a tool to assist with triaging radiation casualties.

Period of performance: proposed - annual staff level of effort = 0.2 FTE

B. Goal No. 2: Support Development of Radiation Protection Standards and Implementation

Issue: NRC needs realistic tools to calculate internal and external doses and assess emerging technologies. The areas of interest include: internal and external dosimetry, bioassay measurements, radiation detection devices, and radio-analytical methods. A goal of the RPHE research program is to evaluate existing and new technologies to ensure that staff has access to the best scientific tools to accomplish its mission. In addition, this research will support the updating of radiation protection regulations in Parts 19 and 20. In many cases, this information will require updating of regulatory guidance. Proposed topics to accomplish this goal include the following:

1. Title: Development of Radiation Protection Recommendations

Background: The ICRP provides recommendations and guidance on protection against risks associated with ionizing radiation and is currently engaged in a process of developing new recommendations. As new information is developed, it is disseminated publicly for comment. NRC can most effectively engage in this process through active participation.

Objective: Participate in cooperative activities with international organizations during the development or revision of future consensus guidance and standards for radiation protection. RES staff will accomplish this by evaluating all draft ICRP publications to ensure that the scientific basis is sound and to assess any potential implications for NRC's regulatory program. In addition, RES will support the activities of the ICRP main Commission, and provide comments on proposed ICRP activities. RES staff also will continue to participate in IAEA and Nuclear Energy Agency (NEA) expert groups as another mechanism to provide input to ICRP and understand regulatory perspectives from other countries.

Application: Participation in such international activities should enable the NRC to effectively influence the development of radiation protection recommendations.

Period of performance: ongoing - annual staff level of effort = 0.2 FTE

2. Title: Assessment of Regulatory Impact

Background: Adoption of ICRP recommendations or revision of the IAEA Basic Safety Standards for Protection Against Ionizing Radiation could result in new or additional burdens for the NRC and its licensees without tangibly improving the health and safety of the public or occupational workers.

Objective: Evaluate the impact of any new ICRP recommendations by studying the potential impact such changes would have on NRR and NMSS regulatory programs and

current licensee practices. RES staff will assess the implications of future ICRP recommendations on NRC regulations as well as the cost potentially borne by the NRC, Agreement States, and NRC licensees to implement any new recommendations. A review of lessons learned from countries that have adopted ICRP 60 recommendations (i.e., France, United Kingdom) would be included. A NUREG report will be prepared describing the results of this review.

Application: This information would be useful to the staff and the Commission in making decisions on whether to adopt any new radiation protection recommendations.

Period of performance: proposed - staff level of effort = 0.1 FTE and $100K in contractor costs.

3. Title: Updating of Division 8 (Occupational Health) Regulatory Guides

Background: NRC Regulatory Guides describe methods acceptable to the NRC staff for implementing NRC regulations. Division 8 Regulatory Guides are used by licensees to implement radiation protection programs. Much of this guidance was published in the 1970s and 1980s and no longer reflects the latest technologies in use by licensees today.

Objective: Review the existing guides for applicability to the methodologies in use today and determine whether additional research may be needed to support updated guidance. As research is completed the results obtained will be evaluated to ascertain whether there is a need to revise any of the Division 8 Regulatory Guides. This may include new information on dosimetry instruments or dose assessment techniques. Information will be provided to the licensing offices to assist in these updates.

Application: This information will be useful to the staff and NRC licensees in implementing NRC regulations.

Period of Performance: ongoing - annual staff level of effort = 0.2 FTE

4. Title: Dose Coefficient Uncertainty and Human Variation Quantification Feasibility Study

Background: Current dose coefficients are presented by the ICRP and in other sources as values with no uncertainties, when, in fact, the reliability of the primary data and biokinetic models on which they are based varies enormously. The dose coefficients for some radionuclides are relatively well known, while others are based on analogies to animal or in vitro data–not human data or not direct animal data. Internal dose and, in turn, risk can vary considerably according to such factors as age, gender, size, diet, and state of health. Dosimetry for acute exposures to radionuclides, such as from accidents and terrorist events, and partial-body exposures is not well-known. Accurate dosimetry for the early time frame is needed when the dose effects of concern are short-term.

Objective: Demonstrate the feasibility of pursuing a project to quantitatively evaluate the uncertainties on radiation dosimetry including the effects of human variation. This feasibility demonstration will assess the accuracy, uncertainty, and robustness of current radiation dosimetry information. The project will assess the strengths and weaknesses of the primary data used as inputs to biokinetic models; the quantitative effects of variability among humans; and the fundamental structure of the models, including the ability of the models to predict biometric data (for example, excretion of radionuclides or effective treatments). A NUREG report describing the results of this review will be prepared.

Application: This work will assess the feasibility of updating this information to support calculations of internal and external radiation dose. If feasible, a longer-term project would be proposed for making more accurate predictions of radiation exposures.

Period of performance: ongoing - total staff level of effort = 0.2 FTE and $150K in contractor costs (The feasibility study will be initiated in FY04 and completed in FY05.)

5. Title: Articulating Phantom

Background: The mathematical phantom now used by NRC in conjunction with the MCNP code for dosimetry calculations is the MIRD phantom, which has been in use for many years. NRC has made attempts to update this phantom by incorporating the most recent anatomical information, such as masses and location of the various organs. However, the phantom suffers from several restrictions that prevent accurate calculation of dose in many situations. These restrictions arise from the fact that the phantom is rigid, and models only a person with legs outstretched. The arms are integral with the torso, and although the hand bones are modeled, the hands cannot be moved away from the body. However, many exposures occur when the involved people are not in this configuration, and in such cases only very approximate estimates of dose can be obtained, even using Monte Carlo techniques.

Objective: Develop a computer code to represent the human body (phantom) with the capability to establish accurate exposure geometry. The phantom will be capable of being positioned accurately to represent the exposed person's configuration with respect to the radiation field, and will also be capable of size scaling to better represent persons of different build and of different ages. This phantom will be used to interface with a new Monte Carlo code, to enable dose and shielding calculations.

Application: This project will provide the NRC staff with an easy-to-use code with a visual user interface that will permit more flexible and accurate dose calculations than is currently possible without the use of very complex codes. The ability of the NRC staff to perform accurate and reliable dose calculations will thereby be considerably enhanced. This type of model would be useful for more robust evaluations of exposure situations like that which occurred at St. Joseph Mercy Hospital.

Period of performance: This project is expected to take about 2 years to complete. (proposed - total staff level of effort= 0.1 FTE and contractor costs of $250K)

6. Title: Radiation Protection Databases

Background: The NRC staff are frequently required to perform calculations to assess radiation dose, shielding, environmental impacts, and exposures to support emergency response as well as licensing and inspection activities. Currently, individuals involved in performing these calculations use various reference documents in order to obtain the required information which is impractical and inefficient.

Objective: Develop and maintain a database management framework (referred to as a Radiological Toolbox) that includes various radiation protection databases necessary to perform radiological assessments and support inspection and licensing decisions. Examples include: tables of dose conversion factors for internal and external exposure; attenuation, absorption and other interaction coefficients for photons; stopping power for charged particles; kerma factors for neutrons; and ICRP tabulations of dose coefficients for various exposure situations. As additional data sources are developed they will be considered for inclusion in the toolbox.

Application: The toolbox will constitute a comprehensive electronic reference library to support regulatory reviews. Additional versions will be released when revised/new material becomes available. For example, information contained in the NRC emergency response manual RTM-96 can be added to the toolbox. Revisions to NUREG/CR-4884, which provides methods for interpreting methodologies, will be included in the next version of the toolbox.) It will be available to the staff on the NRC/RES website and can be installed on laptop computers for field use. The computer files will serve as a repository of important data bases that are essential for a variety of applications in both materials and reactor radiation protection.

Period of performance: ongoing - annual staff level of effort = 0.1 FTE with contractor costs of $100K per year (The prototype toolbox was completed in January 2004.)

C. Goal No. 3: Support Radiation Protection Rationales and Technical Bases

Issue: NRC needs accurate information to develop realistic radiation protection standards and regulatory requirements. The goal of this research is to provide data and tools necessary to support the development of realistic radiation protection standards and guidance. To accomplish this goal the following projects are proposed:

1. Title: Modeling to Support Waste and Decommissioning Decisions

Background: Many regulatory decisions are based on estimations of the movement of radioactive contaminants that have been released into the environment through NRC licensed activities. These decisions include decommissioning of licensed facilities, and the licensing of waste disposal facilities. The NRC staff employs models of varying complexity to represent the processes that may convey these materials from the point of release through environmental systems to locations where humans may be exposed. Traditional analyses have employed “conservative” assumptions and “bounding” analyses. A central need of the licensing staff is more realistic models of the natural

processes and systems that ultimately determine the potential exposures of members of the public to releases from NRC licensed activities. A separate, more detailed discussion of this research can be found in a separate document, "Radionuclide Transport in the Environment Research Program Plan, March 2002." The three major components of this plan will be briefly described here: the treatment of parameter, conceptual model, and scenario uncertainties; the effect of reactive transport processes; and the development and use of system models.

Objective 1.1: Develop effective methods to provide more realistic treatment of the uncertainties in multimedia environmental models related to measurement error, natural variability, data interpretation, and possible deviation from the predicted system performance over time. Parameter uncertainty, conceptual model uncertainty and techniques for establishing the appropriate level of complexity to be incorporated in each aspect of a system model have been addressed. The next step is the integration of these techniques. A NUREG report will be prepared describing these techniques. The design and implementation of effective confirmation programs (monitoring systems) based on both system description (site characterization) and predicted system evolution (performance assessment models) are also topics for research.

Application: These techniques and the supporting data will be incorporated in the models routinely used by licensing staff to provide more realistic analyses of proposed licensing actions. They will also provide information for staff use in assessing long term performance (monitoring) at sites when the potential impact on the public may warrant such attention.

Period of Performance:

Work on integration of uncertainty techniques and consideration of scenario uncertainty will be completed in FY06. (ongoing - total staff level of effort = 0.2 FTE and contractor costs of $500K.)

Work to develop a methodology for performance confirmation which takes into account both site characterization and performance assessment calculations will continue through FY06. (ongoing - total staff level of effort = 0.2 FTE and contractor costs of $800K.)

Objective 1.2: Develop data and realistic models to address the effects of reactive transport processes on the movement of radionuclides through the environment. The effect of processes which increase or decrease radionuclide mobility in environmental systems have traditionally been treated with crude, unrealistic assumptions to allow computational efficiency in complex system models. Ongoing work is addressing the fundamental basis (i.e. molecular modeling of contaminant interaction with mineral surfaces) for this modeling approach. A NUREG report will be prepared describing the results of this research. Another effort is extending the models to more radionuclides through additional field experiments. Through an interagency effort the general subject of the status of reactive transport process models will be addressed.

Application: More realistic reactive transport models will be incorporated into the modeling platform used to develop performance assessment models for sites with complex source terms and complex geochemical environments. This will allow NRC staff to both assess the effects of chemical processes and evaluate the use of reactive barriers to isolate contaminants and reduce the likelihood of public exposures.

Period of Performance:

Work to provide the fundamental basis for the semi-empirical surface complexation models will be completed in FY05. (ongoing - total staff level of effort = 0.1 FTE and contractor costs of $400K.)

Field experiments at contaminated sites designed to test reactive transport models will be completed in FY06. (ongoing - total staff level of effort = 0.1 FTE and contractor costs of $400K.)

Objective 1.3: Provide a range of computational tools to allow licensing staff to apply the appropriate level of realism to dose assessment of licensing actions. This includes tools for relatively simple sites that are currently assessed using the RESRAD family of codes. RESRAD improvement is an ongoing interagency effort being jointly funded by the Department of Energy. For more difficult licensing cases involving contamination over a significant area and sites with complex hydrogeology and geochemistry, more sophisticated models are needed. NRC, EPA and the Corps of Engineers are supporting development of the FRAMES platform under the MOU on Research and Development of Multimedia Environmental Models.

Application: Licensing decisions on both routine and complex sites need information from more realistic models to perform realistic dose estimates. Probabilistic versions of RESRAD are used by the staff to assess offsite movement of radionuclides and exposures of the public and non-human species. More sophisticated modeling systems will be needed to support licensing decisions for complex sites with extensive contamination. Updated pathway models will be employed for both the simple and complex sites to more realistically assess doses from the environmental contaminants.

Period of Performance:

Ongoing development and maintenance of RESRAD, in cooperation with the DOE, will continue through at least FY06. (ongoing - total staff level of effort = 0.2 FTE and contractor costs of $300K.)

Ongoing multi-agency work to enhance the FRAMES modeling platform will continue through FY06. (ongoing - total staff level of effort = 0.2 FTE and contractor costs of $500K.)

Ongoing work on updating pathway models and their supporting data will continue through FY07. (ongoing - total staff level of effort = 0.2 FTE and contractor costs of $500K.)

2. Title: Off-site Consequence Code Development

Background: NRC uses a code for evaluating off-site consequences for planning purposes (MACCS2). It accepts source term, weather, and other inputs and estimates doses to populations, early health effects, latent health effects, and economic consequences, including the pathways of cloudshine, groundshine, inhalation, and the food chain. The code is versatile, with models that may be chosen or omitted by the user, and user input to control the execution of the chosen models.

Objective: Provide short- and intermediate-term improvements in the capability to more realistically estimate off-site consequences. The economic and food pathway models will be reviewed and revised if necessary. Further, as a long-term effort, the code will be reviewed to decide if it should be modernized, incorporated into another code, or if a new code should be developed. Examples of some of the planned improvements include: a user-input threshold below which latent cancer effects are not generated, simplified models for explosive dispersal, urban effects and UF_6 dispersion. In addition the code will be transformed to a windows environment, through the addition of pre- and post-processing codes.

Application: The regulatory use of this work is for planning, cost-benefit analyses, and probabilistic risk assessments. The short- and intermediate-term improvements are necessary to widen applicability of the code to model different situations while long-term improvements are being made. The improved code will be useful to model severe accident consequences at power and non-power reactors, fuel cycle facilities, materials facilities, transportation and storage of spent fuel, and radiological dispersion devices.

Period of performance: ongoing - staff level of effort = 0.2 FTE and contractor costs of $600K. (The short- and intermediate-term changes will be completed in FY 05. Other changes will take longer to complete and will depend on the decision to modify MACCS2 or use another code.)

3. Provide Tools to Modify Internal and External Dosimetry Models Used in Part 20

Background: Part 20 uses models developed by EPA in Federal Reports 11 and 12 to perform evaluations of radiation dose to workers and the public. Having these models available to the NRC staff in a form that will enable staff to review and adjust parameters on a case-specific basis will provide needed flexibility.

Objective: Provide staff access to models and source codes used in Federal Reports 11, 12 and 13 to enable case-specific modifications to existing internal and external dosimetry models.

Application: With better access to these dosimetry models NRC could revise Part 20 to better reflect current information on radiation dosimetry. In addition, for case-specific reviews more accurate information would be available to develop realistic dose estimates.

Period of performance: proposed - staff level of effort = 0.1 FTE and $300K in contractor costs over 2 years.

4. Title: Review and Evaluate Performance of New Radiation Dosimetry Technology

Background: NRC has regulatory requirements in place on the use of radiation dose measuring devices. However, new technologies are continuing to be developed and licensees have requested approval to use some of these new technologies. This would include technologies for measuring radiation dose to occupational workers and to the public from radiation in the environment.

Objective: Review the current literature on new dosimetry devices to determine those that warrant investigation. This research would evaluate the robustness of the new technologies for use in assessing radiation dose and develop a NUREG report for use by the NRC staff in its evaluations.

Application: This information will be useful to support NRC staff in reviewing requests from licensees to use new personnel dosimeters and to enhance NRC's ability to respond to potential radiological threats.

Period of Performance: proposed - annual staff level of effort = 0.2 FTE (The review of new dosimetry technologies would be an ongoing project, with research only being performed as needed by the licensing staff)

5. Title: Effective Use of Collective Dose

Background: The NRC has used collective dose to support the development of regulations. The Regulatory Analysis handbook specifies the use of collective dose in conducting cost/benefit analyses to assess regulatory options. In many cases, the individual doses calculated are very small, while the number of potentially exposed individuals could be quite large. In such cases the collective dose can be quite large. Since the NRC has based its estimates of radiation risk on the linear non-threshold hypothesis, this means that any potential doses, no matter how small, are taken into account in the cost/benefit analyses.

Objective: Review the available literature and develop options that will enable the staff to develop a method for considering collective dose more realistically.

Application: This information will be useful to the staff and the Commission in making decisions on whether the Regulatory Analysis handbook should be revised.

Period of Performance: proposed - staff level of effort = 0.2 FTE

D. Goal No. 4 - Develop Technical Basis for Risk-Informing Materials Regulation through Analysis of Operational Experience

Issue: The NRC is working to develop a risk-informed approach for materials regulatory activities. Most of NRC's regulations were developed without the benefit of quantitative estimates of risk. Many of the present regulations are based on deterministic and prescriptive requirements that cannot be quickly replaced. To assist in accomplishing this goal the following projects are proposed:

1. Title: Developing a More Risk-informed Approach Based on Operational Experience

Background: The materials program includes different types of licenses (e.g., general and specific) that represent a range of potential risk. The basis for defining something as generally or specifically licensed is not uniform and not always directly related to risk.

Objective: Develop a systematic approach for the evaluation of operational experience in order to inform development of a technical basis for more risk-informed regulations. Such approach will include organizing available operational experience scenarios. For example, information on barrier performance under routine and unexpected operational circumstances can be used for such analyses. Likely consequences will be assessed for various scenarios, including: modifying sources that might be used in a radiological dispersal device to make them less dispersable; and risk-informing the use of source and byproduct materials, in both specific and general licensed applications.

Application: The results of the analysis of operational information will be used as a feedback to NMSS to assist in risk-informing the materials program.

Period of performance: proposed - staff level of effort = 0.5 FTE and contractor costs of $250K. (This project will be completed in about 1-2 years.)

2. Title: Regulatory Criteria for Upset Conditions

Background: Licensee activities under normal operations are controlled by the occupational and public dose requirements of 10 CFR Part 20. These requirements are not directly applicable to accidents, although licensee actions are expected to conform and adhere to the dose provisions in Part 20 whenever possible. The process of risk informing regulatory requirements deals with understanding what can happen, the likelihood of occurrence, and the consequences. In addition, the NRC is examining various categories of licensees from a security perspective, and conducting vulnerability assessments that include consequences of deliberate dispersal of radioactive material. Thus, additional information may be available from current work in security that can be used to understand and assure that the NRC regulatory structures for upset or accident conditions are coherent, consistent, and risk informed.

Objective: Based on information available on upset conditions, including that associated with security and source vulnerability assessments, RES will conduct

assessments of potential risks and develop guidelines for use in risk informing materials activities. This would include developing operational dosimetric criteria and calculational tools for ranking risk in various cases, such as, where a source is lost or stolen, or a response to an emergency is required. Scenarios and assumptions would be adapted to address past experience resulting in human exposures. The criteria would define the risk of sources for dispersable and non-dispersable material.

Application: New information developed from this review will be useful to enhance existing information being developed to support risk informing activities. This information will be provided to NMSS in the form of a NUREG report to support activities presently underway.

Period of performance: proposed - staff level of effort = 0.4FTE

3. Title: Benchmark or Revise Existing Tool for Calculating Consequences

Background: NRC has developed mathematical models to describe dose response relationships for the occurrence of deterministic effects. Improvements to the models have been recommended to incorporate alpha emitting radionuclides or inhalation of mixtures of alpha, beta, and gamma emitting radionuclides. In addition, technical data have become available that should be incorporated in the models.

Objective: The NRC will revise existing models and benchmark calculations using the best information and models available.

Application: The staff will be able to determine a damaging (high risk) source derived from deterministic models.

Period of performance: proposed - staff level of effort = 0.2 FTE and contractor costs of $200K (This project will take about 1 year.)

4. Title: Determination of Dispersal Characteristics of NRC-licensed Material

Background: For several years, Sandia has been conducting experiments on actual and simulated material in order to predict the explosive dispersal characteristics of Department of Energy-controlled radioactive materials. Sandia has reviewed a report prepared by the NRC and DOE on materials of concern for use in radiological dispersal devices (RDDs) in order to identify those materials of concern that are not well represented in the previous dispersal experiments.

Objective: The objective of this program is to provide a database of dispersal data for existing NRC material, with concentration on encapsulated material, e.g. lr and AmBe. As possible modifications to the manufacturing processes for highly-dispersable material to make them less dispersable are identified, they will be tested to quantify the improvement.

Application: In conjunction with existing data on DOE material, these experiments will allow vulnerability assessments to be performed for materials licensees with materials of concern.

Period of performance: ongoing - level of staff effort = 0.1 FTE and $100K in contractor costs (Six experiments will be completed in FY04, with follow-on experiments in FY05 for any sources whose manufacturing process is identified for a change.)