STUDY ON TRAINING AND EXPERIENCE CRITERIA FOR PERSONNEL INVOLVED IN THE MEDICAL USE OF BYPRODUCT MATERIAL

Solicitation No. RS-NMS-88-004

Technical and Management Proposal

Submitted to:

U.S. Nuclear Regulatory Commission Division of Contracts and Property Management Mail Stop P841 Washington, D.C. 20555

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1.0 INTRODUCTION

1.1 Discussion of the Statement of Work

SC&A is aware of the importance of appropriate training and experience in preventing misadministrations or undue exposures in medical institutions. We have observed that in many facilities, the physician can not always be present during the administration of, or during treatment with, licensed radioactive materials. The physicist, nurse or technologist usually has the prime responsibility, after some instruction from the physician, for treatment planning and the preparatory procedures and treatments with radiation. In nuclear medicine, the technologist usually is responsible for the direct quality assurance and administration of dosage in diagnostic procedures. The work of the allied health professional is often highly independent, requiring a high level of training in both the medical technologies involved as well as in the principles of radiation protection for the patient, workers, and the general public.

While the NRC has in recent years provided considerable detailed guidance on proper facilities, equipment, procedures and training for radiation safety in medical institutions, ¹⁻⁵ this guidance has not been completely utilized in many institutions. This is due in part to the

³USNRC, Regulatory Guide 8.23, "Health Physics Surveys at Medical Institutions," Revision 1, 1982.

⁴USNRC, Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," Revisions 1, 1979.

⁵USNRC, Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs, 1987.

¹U.S. Nuclear Regulatory Commission, Regulatory Guide 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," Revision 1, U.S. Nuclear Regulatory Commission, 1982.

²A. "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable," NUREG-0267, 1982.

training of personnel in radiation safety, but it is also due to a lack of awareness of the existence of this guidance among those who have not yet been subject to license renewal and the use of the revised Regulatory Guide 10.8. In many institutions, it is also due to a lack of sufficient staff or staff time devoted to radiation safety

Some institutions have recently been cited for violations of NRC regulations, and some have even had important medical programs suspended or shut down by the NRC. Thus, it is particularly timely that the needs for training and experience in radiation safety-related matters be re-emphasized at this time. All persons handling, using, administering or disposing of radioactive materials must have an adequate knowledge to ensure that they comply with necessary safety provisions.

Although specific criteria for the training and experience of physicians. or their Board Certification, for using byproduct material safely are published as part of Title 10 CFR Part 35, there are no criteria to establish how a physician combines previous training and experience with continuing education and practice to maintain optimum cognizance of information related to health and safety. Also, while NUREG-1134 provides information on the proper development of training programs for allied health professionals, and provides detailed outlines of subject matter to be covered for each of the variety of specialties of allied health personnel and ancillary personnel who might be exposed to or involved with radioactive material, many safety personnel in medical institutions have either not been aware of the material in the NUREG or have not yet been able to adapt it to their training programs. The criteria in 10 CFR Part 35 and NUREG-1134 are valuable as starting points for examining training requirements. However, a thorough study of current responsibilities and training standards and practices is needed to update this information, and to provide the NRC with a comprehensive source of information for filling any gaps in regulatory provisions for the proper training and experience of personnel.

While overexposures and misadministrations have received particular attention, other, less dramatic occurrences also point to the question

of training adequacy. Two examples, taken from the experience of the proposed Principal Investigator, are given. In one case, the hospital radiation safety officer was carrying out a Monday morning check of the operation of safety devices on a Theratron 780 Cobalt-60 unit. In the beam-on condition, with all safety signals outside the treatment room apparently working, he opened the door quickly to observe whether the independent gamma-alarm light was indicating radiation exposure, as it should with its slow time constant. He noticed that the gamma-alarm light was on, the source did in fact not travel to its full on position, but was stuck at a point within the shield. This occurred with a fairly new and thoroughly checked device. If this check had not been carried out, many cancer patients would not have received their appropriate tissue draes, even though they were mistakenly believed to have been treated.

In the second case, an appropriate amount of radioiodine, administered orally, became chemically adsorbed in the mouth of the patient (perhaps forming AgI on a filling). This could have caused a dose of over 100,000 rads to the mouth and jaw, and no effective dose to the metastatic tumor tissue, if left unchecked. Since the physicians had left, the RSO asked the attending nurse to obtain some orange juice for the patient to wash the mouth with and swallow. The orange juice did not work, so grapefruit juice was administered. The more acidic juice re-dissolved the I-131 (100 mCi), and further surveys showed the iodine distributing throughout the body to be appropriately absorbed in the widespread metastases. It sometimes takes the vigilance of all persons involved in administering radioactive materials (or radiation) to patients, in order to optimize protection against all potential risks. Appropriate vigilance depends upon appropriate training and experience.

1.2 SC&A Capabilities

The contractor that performs this project for the NRC must possess two essential capabilities. The first is the ability to access a diverse group of potential interviewees in the medical community who use and regulate byproduct materials. The second is the ability to analyze and distill a large body of information into concise summaries that will support conclusions. The essential ingredients in the first capability are persistence coupled with an extensive professional network. The most important elements in the second capability are organizational and analytical skills.

To demonstrate that SC&A possesses both of these capabilities in abundance, we offer Table 1-1. Table 1-1 lists the projects performed by SC&A which involve multiple interviews in the radiation protection community. To demonstrate that we followed through on these interview projects with successful analyses, the principal outputs of the studies are also listed. Each of these projects are described in more detail in Section 6 of our proposal, which provides short synopses of all relevant SC&A projects.

We have assembled a truly outstanding team to perform this work for the NRC. Through the network of contacts established by these senior radiation protection and medical professionals, we will be able to identify cooperative representatives of all of the disciplines called out in the Solicitation. Using a suitable mixture of finesse and persistence, we will interview those health personnel to identify their duties and responsibilities, the oversight programs used to ensure implementation and compliance with standards, and the content of the training programs tailored to their specialties. Moreover, our proposed team is amply qualified to collect and summarize all relevant standards, guidelines, and regulations imposed on those training programs, and to identify overlaps and gaps in the standards, guidelines, and regulations.

1.3 Content of Our Proposal

The next section of our proposal (Section 2) discusses our proposed approach to meet the objectives of this requirement. The work is subdivided into ten tasks, each of which is described in Section 2. Section 3 discusses potential problems currently foreseen and proposed

Table 1-1

Interview Projects Performed by SC&A in the Radiation Protection Community

Project	Interviewees	<u>Audience</u> f : <u>Report</u>	Results of the Study
Impacts of Revised 10 CFR 20	10 Medical, Utility, Fuel Fuel Cycle Licensees and DOE Facilities	NRC	Findings factored into changes to 10 CFR 20 and Regulatory Impact Anal (survived to today)
Federal Guidance on Radiation	10 Medical and Industrial Users of Radiation	EPA	Findings used to completely change guidance. Revised guid. promulgated.
Clean Air Act Standards	30 Medical Users of By- Product Materials	EPA	Demonstrated ability to comply.
Occupational Exposure Re- sulting from NRC Regs.	10 Utility ALARA Groups	Industry	AIF Report documenting reg. impact.
Regulatory Contribution to Capital Costs	Utility Cost & Engineer. Departments	DOE/EIA	Contrasted reg. impact on different generation power plants.
Temporary Work Force	6 Utility H.P. Depts.	Industry	Showed that doses to temporary worke comparable to permanent employees.
Gener'c Safety Issues	Several NRC groups	NRC	Documented origin of several generic issues.
Guidance on Diagnostic X-Rays	27 Federal Agencies	EPA	Established status of implementation

methods to resolve them. Section 4 contains brief descriptions and resumes of the proposed personnel. Section 5 presents the management plan, including the schedule for each of the tasks, the management organizational structure, the management procedures and controls employed to monitor and review the work, and the support facilities available. The relevant corporate capabilities are given in Section 6. Finally, Section 7 gives the statements of any interpretations, requirements, assumptions, or commitments for the same or similar work.

2.0 TECHNICAL APPROACH

The NRC's General Policy on the Medical Use of Byproduct Material states, in part, "The NRC will regulate the radiation safety of patients ... where voluntary standards, or compliance with these standards, are inadequate." The data-gathering effort described in this proposal will allow the NRC to make such a judgement.

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We will conduct an exhaustive search for all standards, guides, regulations and policies on the subject of radiation-related training of medical and allied health personnel. This will be followed by a thorough analysis of this information to identify aspects most important for preventing unnecessary exposures to workers, patients and others.

Data collected by SC&A for a previous project give the number and distribution of nuclear medicine staff. These data (see Table 2-1) show a relatively large number of staff at small to mid-size hospitals (100 to 300 beds). These are typically not the large medical centers with access to faculty and experts. This consideration will be factored into SC&A's technical approach, so that the results obtained from this study will truly be representative.

The SC&A project staff will be assisted by an Advisory Panel of experts. Several people have already been contacted and have agreed to serve in this capacity (see Section 4.2). The panel will be formed at the appropriate time, with input from the Project Officer.

When the data-gathering phase of the project is almost complete, a preliminary organization of the data will be performed. A meeting will then be held with the Project Officer to discuss information that still needs to be obtained. The project schedule (Figure 5-1) shows a meeting to be held at that time. The Advisory Panel will be consulted concurrently.

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Hosp. Bed Size	Physicians	Technologists	Hospitals+
<50	35	55	241
50-99	111	339	649
100-199	457	1222	1009
200-299	513	1360	682
300-399	414	1169	407
400-500	260	744	199
>500	646	1783	299
Federal**	227	_563	
Totals	2663	7235	3651

Nuclear Medicine Physicians and Technologists*

* Source: American Hospital Association (1986)

+ Hospitals with Nuclear Medicine departments

** Bed size unavailable

We have identified ten specific tasks to achieve the objectives set forth in the Solicitation. These are described below. The schedule for the accomplishment of the work is shown in Section 5, Figure 5-1, of our proposal. It is a 12-month schedule, which is one less month than that specified in the Solicitation. This "extra" month will be held for contingency purposes.

2.1 Task 1: Work Plan for Data Collection

Because of the potentially large amount of data that will have to be collected for this project, we feel that a data collection plan should be prepared initially. This plan will expand on our preliminary thoughts discussed under Tasks 2 through 7 (below). It will include an analysis of the representativeness of any samples that are selected for data collection. For example, all 3561 hospitals administering radiopharmaceuticals cannot be contacted. However, a representative sample can be constructed, based on bed size, geography, etc. The plan will be submitted in draft form to the NRC Project Officer, for review and approval.

2.2 Task 2: Test Interview Plan

The portion of the Data Collection Plan dealing with hospitals will be tested early in the project. A member of the project Advisory Panel (Kenneth Miller) has agreed to host a visit by the team to the Hershey (PA) Medical Center. This is a 350-bed teaching hospital, which conducts training for physicians, as well as allied personnel. The team will interview administrators, educators, physicians and others. Following the visit, the Data Collection Plan may be revised or changed, based on the experience gained.

2.3 Task 3: Interview Hospital Staff

An appropriately-designed sample of medical institutions, clinics and nuclear pharmacies will be contacted and visited. A second sample will

be contacted by telephone. Interviews will be conducted with appropriate administrators, the head of radiology, the head of nuclear medicine, radiation safety officer, staff involved with training (e.g. nursing educators) and others. Informal (but structured) interviews will be conducted, rather than rigorous surveys, and sample sizes for each category will be limited to less than 10. Thus, Office of Management and Budget approval of a government survey will not be required.

In selecting facilities to visit, the "geography" of nuclear medicine/ radiology will be examined. American Hospital Association data show that five states contain 36% of nuclear medical staff (New York, Pennsylvania, Illinois, Texas and California.) Fifty-six percent of the staff are located in the following three regions: Mid-Atlantic, South-Atlantic and Northern Mid-West. (The project team has been assembled with this geographic distribution in mind.)

The project team will begin visiting these facilities as a group. As the "flow" of the interviews is established, the team can separate and visit the facilities individually. This will allow the team to visit as many facilities as possible, within the constraints of the project budget. Once a facility has been visited, follow-up can be done over the telephone, by the same, or by other team members.

2.4 Task 4: Interview State Regulators

State radiation control officials, particularly in Agreement States, can provide an additional perspective on training and experience criteria. A preliminary sample of such individuals is given in Table 2-2. Again, the geographical distribution of nuclear medicine/radiology staff will be used to select those states important to this study.

Some states have recently proposed criteria for medical technologists. These states will be visited. In California, for example, training and experience criteria for nuclear medicine technologists were adopted on July 6, 1988. The implementation phase of these criteria will coincide with the data-gathering phase of this task.

2.5 Task 5: Gather Information on Hospital Staff Functions

This task responds to paragraph C.1.3.1 in the Solicitation. The personnel specialties listed in this paragraph will be addressed in this task. Work will be assigned to team members with extensive experience in medical settings. The work will be accomplished by team members using their knowledge of medical specialties, supplemented by visits to local facilities and telephone contact with other facilities. Drafts of work will be rotated among team members for comment and revision.

2.6 Task 6: Gather Information on Training Standards

We will initiate this task with a search of the literature. Reports and papers identified by this search will be reviewed, and pertinent information will be extracted. Next, cognizant organizations will be contacted. A preliminary list of such organizations, including names of some contacts, is given in Table 2-3. Information gathered in Task 4 (state regulator interviews) will provide additional data for this task. This work will flow into Task 8, which will identify gaps in the standards.

2.7 Task 7: Gather Information on Certifications

This task will focus on the certification processes for physicians, technologists and other specialists. This will logically follow Task 6, which utilizes some of the same sources of information (e.g., American Board of Radiology). This work will involve some local travel, and will rely mostly on telephone interviews.

2.8 Task 8. Identify Gaps in Standards

In this task, the analysis of the collected data will be initiated. The challenge will be to distill the information obtained into concise summaries that will support conclusions. The first of those will be the identification of any gaps (and overlaps) that exist in the standards and guidelines dealing with training of specialists. The team will draw

Table 2-2

Preliminary List of State Contacts

Agreement States

Arizona Rad. Regulatory Agency Charles Tedford, Director

California Radiological Health P. Szalinski, Branch Chief

Texas Bureau of Rad. Control E. Bailey, Dir. of Lic. & Stds.

New York Bureau of Env. Rad. Protection K. Rimawi, Director; New York City Bureau L. Solon, Director

Maryland Rad. Control Unit R. Fletcher, Director Non-Agreement States

Indiana Rad. Health Section Operator Certification Program E. Wrobleski, Supervisor

Mass. Rad. Control Program G. Swible, Scientist

Ohio Rad. Health Program R. Quillin, Director

Table 2-3

Cognizant Organizations

Preliminary Contact List

PEER GROUPS

National Council on Radiation Protection & Measurements Committee on Radiation Protection Training (#71) Bethesda, MD

International Commission on Radiological Protection Sutton, Surry, England

Conference of Radiation Control Program Directors Charles Hardin, Director Frankfort, KY

American College of Nuclear Physicians B. Teele, Education Director Washington, DC

American Board of Nuclear Medicine Los Angeles, CA

Society of Nuclear Medicine V. Papas, Administrator; New York, NY

American Board of Radiology K. Krabenoff, MD, Secy.; Birmingham, MI

Nuclear Medicine Technologists Certification Board Tucker, GA

American Registry of Radiologic Technologists Minneapolis, MN

FEDERAL AGENCIES

Food & Drug Administration
Center for Devices and Radiological Health
Office of Training and Assistance
J. Arcarese, Director

- Assistant Director for Nuclear Medicine Dr. P. Paras
- Regional Rad. Health Representatives Warren Church, Boston Gerald Jacobson, Kansas City Dale Stevenson, San Francisco

Joint Commission on Accreditation of Healthcare Organizations Chicago, IL on the information gathered in Task 6 to support any findings. The Advisory Panel, mentioned above, will be brought in to review the findings and conclusions made at this point in the project.

2.9 Task 9: Assess the Implementation of Standards

The analysis of data will continue with this task. Implementation and compliance with the standards identified in Task 6 will be examined. This work will also draw on information obtained in Tasks 3, 4, and 7. This assessment will be the most subjective part of the project, so the project team will make a special effort to document supporting information. For example, if a requirement for training on radiation instrumentation is not generally being met, specific examples will be given where this is occurring. Here again, the input of the Advisory Panel will be particularly useful.

2.10 Task 10: Report Results

This task is divided into three phases. The first and longest phase is the drafting of the project report. The second phase is the review of the draft report by the NRC Project Officer. The last phase is the incorporation of the review comments into the draft, and the issuing of the final project report.

3.0 POTENTIAL PROBLEMS AND APPROACHES TO RESOLVE THEM

The potential problems are similar to those encountered in a number of previous SC&A projects which involved interviewing professions in the field and assembling and analyzing the information collected. Briefly, these are:

(a) Difficulties in contacting cognizant persons in organizations and medical institutions and obtaining the information requested. This difficulty will be overcome by using continuing personal calls to the appropriate individuals, and by maintaining an adequate number of alternate contacts and sources of information. The key personnel and Advisory Panel members each have many contacts in the medical and allied health professions communities. These contacts know of our dedication to valid research for the improvement of radiation protection practice, and past experience indicates that a high degree of cooperation will be obtained from these dedicated communities.

(b) Difficulties in scheduling multiple visits at times convenient to those to be visited. These difficulties will be overcome by the flexibility of our own personnel in scheduling visits at times convenient to those providing us with the needed information.

(c) Difficulties in abstracting the large amount of information, guidance and specifications on training and experience in formats usable by the NRC for judging any needs for additional regulatory action. Our investigators have considerable experience with this kind of problem, and will use their insights and modern computer technology to provide understandable summary information in tables. The tables will be supplemented by appendices and references that contain the more detailed information that might be needed by the NRC staff if particular areas of concern pointed up by the tabulated information require work on standards, guides or regulations. Information tabulated in the report will provide an overview of current standards and their implementation; the overview will be

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simply and understandably keyed to the more detailed material. In addition, Discussion, Recommendations, and Conclusions sections of the final report will indicate to the NRC which areas require priority attention, as judged from the investigators' previous experience, coupled with conclusions obtained from the document reviews and site visits. FIGURE 5-1

PROJECT SCHEDULE

	Nov	Dec 88	180 180	00 *0	Tea.	na rad	30 C	200	100	000	e.0 00	Oct
Work Plan for Data Collection Work Plan Approval	+DraftRec		- T - T	-	-							
Test Interview Pian Interview Hosp. Staff, Adminis- trators, etc. Interview State Regulators			I		ΤŢ							
Gather Data on Hosp Staff Functs. Gather Data on Training Stds. Gather Data on Cert. Exams		FLIt.Sear	T Links			ŢŢ	T					
Identify Gaps in Stds. Assess Implementation of Stds.								тт			900 920 920 920 920 900	
Report Results Meet with Project Officer = - 1 day meeting		2			Ĩ			FDr	a boot	RCRevier **	1	t es in est

5.3 Management Controls

The Project Manager will use SC&A's project cost control system to maintain a monthly accounting of commitments and expenditures as compared with the budget and schedule. At the time a project is established, SC&A assigns a job identifier to the project. Time sheets and Associate invoices are collected and posted on a monthly basis.

Individuals working on the project charge their time each day to the appropriate job identifiers. Project charges are subject to four approvals and/or certifications:

- the employee or Associate certifies that he/she put in that time on that project;
- the Project Manager reviews the charges and approves or disapproves them for projects under his/her oversight and supervisory responsibility and;
- Dr. Cohen, the President of SC&A, reviews the charges for each project and compares the expenditures and project progress against anticipated expenditures and progress. If these are out of line, he confers with the Project Manager.
- Accounting certifies that the charges are accurate and that the employee or Associate was paid.

At the close of the accounting period, the time sheets and Associate invoices are reviewed by the Project Manager. Then the time sheets and Associate invoices are sent to SC&A accounting, where they are again checked for errant job identifiers. Other direct costs (ODC's), after checking for correct authorization, are processed in the same way.

The above system of reporting and approving contract expenditures is used to produce a Cost Management Report for comparison to the Cost Plan. The Cost Management Report is a periodic report of cost status

versus cost plan for an ongoing contract. It contains (1) actual costs, cumulative from the initiation of the effort to the end of the reporting period, (2) the actual costs for the reporting period, (3) forecasts of expenditures for the remainder of the period of the effort, and (4) variances from the associated cost plan. The Cost Management Report is used for project monitoring and control to determine accrued costs for the current reporting period, to forecast accrued costs for subsequent reporting periods, and to anticipate total costs for project completion.

The Cost Plan provides a baseline for measuring cost variance on a contract and provides basic information for updating and forecasting cost estimates and for budget estimation. The Project Manager checks the costs against the Cost Plan to ensure that the work is proceeding within budget. Potential problem areas are flagged so that problems can be dealt with at the earliest possible stage to minimize the possibility of contact cost growth.

Careful planning and constant review of SC&A projects ensure a high degree of schedule adherence. The task schedule presented in this proposal will be periodically reviewed and revised, as necessary. Any variance between the schedule and the actual work will be reported immediately to the NRC Project Officer. The impact on schedule of any redirections by the Project Officer of scope or effort will also be reported as soon as possible to the NRC Project Officer.

It is standard practice within SC&A to review internally each and every document that is submitted to the client. This review is performed by Dr. S.C. Cohen, the President of SC&A. This review is performed on progress reports, periodic communications, invoices, letters, draft reports, and final reports. These reviews assure that quality control is maintained through every step of a given project.

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This project will have the highest priority within SC&A. We are a relatively small and young firm, and it is exceedingly important to our future that the reputation that we have earned for quality and responsiveness is maintained and enhanced.

Dr. S.C. Cohen will maintain ultimate responsibility for work under a contract resulting from this proposal and will be available <u>at all times</u> to the government's technical representative. A significant benefit to the government in dealing with smaller firms is the access the government and project personnel have to the firm's top management. No time is lost in informing top management and resolving issues.

5.4 Support Personnel and Facilities

SC&A's only products are reports. Therefore, it is essential that these reports be neat and professional in appearance. To accomplish this, SC&A possesses an internal word-processing capability and additionally uses two convenient outside word-processing services which possess state-of-the-art equipment and rapid turnaround. These services are completely responsive to SC&A report deadlines.

SC&A's internal word processing software and that of both outside services are based on the IBM Display Write software and thus are totally compatible. The internal system and one of the outside services have letter-quality IBM Quietwriters, capable of 60 words per minute. (This proposal was printed on a Quietwriter). The other outside service has two IBM 5218 printers, capable of 40 characters per second. One printer has an automatic sheet feeder and the other has an automatic pin-feeder for form printouts. Machine communication is also possible, using 1200 baud Hayes' modems.

Most reproduction, including this proposal, is accomplished on an in-house Sharp SF-8100 copying machine, with automatic feed and sorting capability. For larger jobs, a convenient XEROX 9400, with variable reduction capability, is used.

6.0 CORPORATE CAPABILITIES

S. Cohen & Associates (SC&A), a Virginia corporation, specializes in the technical analysis of environmental and safety issues, particularly those related to radiation and nuclear power. The firm also provides health physics and nuclear fuel cycle consulting services, mathematical modeling and computer code development, and estimates the costs of regulatory requirements. SC&A is dedicated to providing the very highest quality technical support to its clients. Moreover, the firm is committed to client responsiveness and fiscal responsibility.

SC&A is able to assemble, frequently on short notice, multidisciplinary working teams of technical specialists specifically designed to solve clients' problems. This is accomplished by maintaining close collaboration with scientists and engineers from the university and industry. By providing attractive forms of professional association, SC&A is able to secure many of the nation's leading experts in engineering and science.

The firm's clients include:

Flectric Power Research Institute Edison Electric Institute Congressional Office of Technology Assessment Oak Ridge National Laboratory Brookhaven National Laboratory Argonne National Laboratory Pennsylvania Power and Light Company Baltimore Gas and Electric Company Commonwealth Edison Company South Carolina Electric and Gas Company Public Service Electric & Gas Company Atomic Industrial Forum G.A. Technologies U.S. Department of Energy Nuclear Safety Oversight Committee U.S. Nuclear Regulatory Commission U.S. Environmental Protection Agency State of New Mexico (Environmental Evaluation Group)

The following pages contain short sypnopses of projects undertaken by the firm which are felt to be relevant to the current solicitation.

U.S. Nuclear Regulatory Commission Office of Nuclear Regulatory Research

IMPACT OF REVISED STANDARDS FOR PROTECTION AGAINST RADIATION (10 CFR PART 20)

The U.S. Nuclear Regulatory Commission (NRC) is proposing revised standards for protection against radiation (Part 20 to Title 10, Code of Federal Regulations). These revised standards incorporate the system of dose limitations recommended by the International Commission on Radiological Protection (ICRP-26). In particular, NRC is proposing risk-weighted guidelines for combining doses received by individual organs from internal and external exposures. Also, new occupational limits on annual dose equivalent are proposed.

SC&A, together with an economic analysis firm and the impact on the industry of these proposed revisions to the NRC regulations. This was accomplished by conducting a number of case studies, and by reassessing the results of previous work conducted by SC&A for the Environmental Protection Agency. In particular, case studies were conducted on five nuclear power plants, a university research reactor, a uranium mill, a uranium conversion facility, and a nuclear pharmacy. For each of these facilities, site visits were conducted with the corporate health physicist and his staff. The revision was disaggregated into its component parts and each part was discussed individually. During the course of the work, several necessary changes in the revised regulation were identified and reported to the NRC.

SC&A presented the results of its cost evaluation to the Advisory Committee on Reactor Safeguards (ACRS), and the evaluation was used by the staff in the preparation of NRC's Regulatory Impact Analysis.

COSTS OF THE PROPOSED GUIDANCE ON OCCUPATIONAL EXPOSURES TO IONIZING RADIATION

Under authority transferred from the Federal Radiation Council (FRC), the Environmental Protection Agency is authorized to establish guidelines on occupational exposure to ionizing radiation. The existing guidelines, established by the FRC in 1960, were adopted by all of the cognizant regulatory agencies. EPA originally proposed new guidance in January 1981, and hearings were held in April and May of 19²¹. Since then, the guidance has been substantially revised.

The originally proposed guidelines incorporated nine recommendations covering limits on external and internal exposures, requirements for monitoring and supervision, and new provisions for the unborn. At the time that the guidelines were proposed, a rough cost estimate was incorporated in the background information. The purpose of this project was to revise the cost estimate so that the appropriate cost/benefit and value/impact analyses could be performed in support of the rulemaking. SC&A, together with an economic analysis firm (Jack Faucett Associates), performed this cost evaluation.

To estimate industry-wide costs of the new guidelines, 25 case studies were conducted to determine the impact on specific organizations. The case studies were drawn from hospitals, physicians, dental offices, firms involved in radioisotope manufacturing and distribution, industrial radiography, well logging, and the nuclear fuel cycle. Cost items which were evaluated included training, record-keeping, badging, monitoring, outside health physics services, additional workers, shielding, capital equipment, and revised work practices.

The results indicated that the Guidance, in its original form, was too cumbersome and costly. Accordingly, the Guidance was substantially revised, and is currently under review by the Office of Management and Budget.

COSTS OF COMPLIANCE WITH PROPOSED CLEAN AIR ACT STANDARDS FOR RADIONUCLIDES FOR MEDICAL RESEARCH FACILITIES

In 1977, Congress amended the Clean Air Act to address emissions of radioactive materials. The Environmental Protection Agency subsequently listed radioactive materials as hazardous air pollutants under Section 112 of the Clean Air Act. Then in 1982, the Court ordered EPA to publish proposed regulations establishing emission standards for radionuclides, acting in response to a suit filed by the Sierra Club. EPA proposed standards for radionuclides in April 1983. Separate standards were proposed for Department of Energy Facilities, NRC licensee facilities, elemental phosphorous plants, and uranium mines.

SC&A investigated the compliance costs to medical research facilities of the proposed standards for Nuclear Regulatory Commission licensees. The investigation included case studies of approximately 30 users who had the potential to exceed the proposed limits. The users were selected by screening a large number of medical institutions for possession limits and distances to the nearest human receptors. The case studies also identified the controls used, the additional controls required to bring these facilities into compliance with the proposed standard, and the estimated costs of these additional controls. The study concluded that few, if any of the facilities would be unable to comply with the proposed standards, but that a significant fraction would have difficulty in demonstrating compliance.

FEDERAL AGENCY RESPONSE TO GUIDANCE ON THE USE OF DIAGNOSTIC X-RAYS

In 1978, EPA promulgated guidance on the use of diagnostic X-ray machines by Federal agencies. This X-ray guidance, signed by the President, applies to employee health programs involving the use of diagnostic X-rays, including routine screening of individuals for employment. The guidance contains 12 recommendations, including provisions for professional supervision, equipment performance, and elimination of routine screening examinations.

SC&A, under a subcontract with second agencies of the guidance, and the impact of implementation by Federal agencies of the guidance, and the impact of implementation on the agencies. The work involved interviews with medical and radiation protection personnel in 27 Federal agencies, 10 of which provide health care to employees or members of the public. When available from the Agency, the costs incurred and the benefits received by the agency, employee, patient, or others in implementing their guidance to the current level of compliance were estimated.

The primary impact of the guidance was the elimination by Federal agencies of a large number of routine pre-employment and periodic chest X-rays previously required of Federal employees and patients of federally-operated medical facilities.

The document is being published as an EPA report.

TECHNICAL SUPPORT OF THE EVALUATION AND CONTROL OF EMISSIONS OF RADIOACTIVE MATERIALS TO AMBIENT AIR

Under the provisions of The Clean Air Act as amended in August 1977, the Administrator of the Environmental Protection Agency listed radionuclides as hazardous under Section 112 of the Act in December 1979. Standards were promulgated in 1984, but these were remanded in the courts in 1987. The EPA is in the process of re-proposing standards. SC&A is assisting the Agency in the development of these standards by conducting a risk assessment of emissions of radionuclides to the atmosphere.

The risk assessment includes the following elements:

- Identification of all sources of radioactive emissions to the atmosphere
- Analysis of data on emission quality and rates from each source identified and characterization of sources of emissions
- Characterization of environmental pathways leading to human exposure
- Development of individual and population doses and health risks for identified emissions (for individual facilities or entire industries, as appropriate)
- Characterization of control technology used c ailable for use to reduce emissions

The following source categories are being considered:

- Underground and surface uranium mines
- Disposal of high-level radioactive waste
- The uranium fuel cycle
- All other NRC licensees, other than sealed sources
- Department of Energy facilities
- Department of Defense facilities
- Elementary phosphorus plants
- Phosphogypsum stacks
- Coal-fired boilers
- Active and inactive mill tailings piles

SC&A

DERIVATION OF RADIONUCLIDE RELEASE FRACTIONS FOR NRC-LICENSED FACILITIES

To assist the EPA in developing alternative procedures for demonstrating compliance with the standards for radionuclides under Section 112 of the Clean Air Act, SC&A derived generic radionuclide release fractions appropriate to non-fuel cycle facilities licensed by the Nuclear Regulatory Commission.

The generic release fractions were derived from the following sources:

- 1) Measured release fractions reported in the open literature.
- 2) Emissions data reported in the open literature.
- 3) Concentration data reported in the open literature.
- 4) Data on Worker Intakes.

The recommended release fraction for all radionuclides in gaseous form was 1.0. For radionuclides in powder or liquid forms, a release fraction of 1×10^{-3} was recommended, except for materials at elevated temperatures. For solids and capsules, the recommended release fraction was 1×10^{-6} .

RADIONUCLIDE EMISSIONS FROM WASTE INCINERATORS AND COMPACTORS

A review document was written to assist the EPA in reviewing applications under the Clean Air Act for new radioactive waste incinerators and compactors. The document summarizes the Federal regulations governing these waste volumereduction facilities, both those of the Environmental Protection Agency and the Nuclear Regulatory Commission. It provides descriptions of the technologies, including schematic diagrams. It gives radionuclide spectra for wastes handled by each class of volume-reduction technology. It discusses emission control from these facilities, including expected efficiencies. Finally, it provides principles for stack sampling and analysis of the primarv radionuclides emitted by incinerators and compactors.

....

DEVELOPMENT OF PROCEDURES FOR COMPLIANCE WITH THE CLEAN AIR ACT STANDARDS FOR RADIONUCLIDES

In February 1985, the Environmental Protection Agency (EPA) promulgated, under Section 112 of the Clean Air Act, standards for radionuclides emitted into the air. The standards for NRC-licensed and non-DOE Federal facilities (40 CRF 61 Subpart I) required facilities to demonstrate compliance using the EPA computer codes, AIRDOS-EPA and RADRISK. However, these codes will be difficult to run for the majorary of the estimated 6000 NRC licensees subject to the standards.

SC&A assisted the NRC in developing less cumbersome compliance procedures. These consist of:

- A table of annual quantities of radionuclides that can be handled without causing any member of the public to receive a dose that is more than 20 percent of the standards. These annual quantities were derived using empirically-derived release fractions.
- A table of stack concentrations that limit the dose to any member of the public to less than 20 percent of the standards.
- A computer code which automates the methodology given in NCRP Commentary No. 3.
- 4) A computer code which extends the methodology given in NCRP Commentary No. 3 by providing a more complete treatment of air dispersion and a more sophisticated calculation of organ dose.

Demonstration of compliance using methods 1) through 3) also exempts licensees from reporting to the EPA.

The procedures are explained in a "user-friendly" guidance manual which sets down the alternative steps for demonstrating compliance.

Private Electric Utilities

TRAINING WORKSHOP ON QUALITY CONTROL IN RADIATION MEASUREMENTS

SC&A has conducted a number of two to three day training programs on the subject of quality control in radiation measurements. These programs were directed to utility professionals who are engaged in in-plant and environmental radiological measurements. Typically, the participants had backgrounds in health physics, radiochemistry, engineering, or the natural sciences. The program was designed to teach the participants how to make sure that their radiation measurements are adequate, how to evaluate QC data in time to take any necessary corrective actions, and how to document the acceptability of the measurements.

The workshops are conducted on the clients' premises. The first day is appropriate for managers and executives who are not involved in radiation measurements on a daily basis, but who desire a general knowledge of QC and its applicability to contracting. Part of the third day is devoted to consultation on specific problems. A course manual, custom designed for the training program, is given to each participant. It consists of the following seven chapters:

- · Quality Assurance and Quality Control
- · Statistics
- Acceptable Standard Deviation
- · Selection of Measurement Types for Quality Control
- Evaluation Procedures-Precision
- Evaluation Procedures-Accuracy
- Minimum Detectable Levels

Executive Office of the President Council on Environmental Quality

SUPPORT SERVICES IN THE AREA OF NUCLEAR WASTE/RADIATION

The Council on Environmental Quality (CEQ) is responsible under the National Environmental Policy Act for the conduct of studies concerning policies, programs, standards, mediation, public involvement, and international cooperation. The purpose of this contract is to assist the CEQ and related interagency coordinating groups with joint projects in the area of nuclear waste/radiation. The objectives of the contract are to provide:

- analytical support for environmental policy options;
- an independent forum for peer review of scientific and policy matters;
- opportunities to facilitate mediation and public involvement in environmental programs to encourage resolution of complicated issues or regulations; and
- support for international cooperation in matters involving global resources.

U.S. Nuclear Regulatory Commission Office of Resource Management

DEVELOP A METHOD TO ESTIMATE VOLUMES OF LOW LEVEL WASTE GENERATED AS A RESULT OF REGULATORY REQUIREMENTS

The NRC Office of Resource Management has been changed with the responsibility of providing other parts of the Agency with estimates of the costs of regulatory requirements. Science and Engineering Associates, Inc. (SEA) provided the NRC with generic cost estimates of low-level waste disposal at nuclear power plants. As a subcontractor to SEA, SC&A was responsible for developing a method for estimating waste volume generated as a result of regulatory requirements. The following waste streams were considered:

- Ion Exchange Resins
- Concentrated Liquids
- Filter Sludges
- Compactible Trash
- Noncompactible Trash

SC&A conducted site visits to two nuclear power plants which tracks waste volumes by point of origin - a PWR and a BWR - in the course of the study.

This method was discussed in an NRC report, <u>Generic Cost Estimates for the Dis-</u> posal of Radioactive Wastes, NUREG/CR-4555, March 1986), and was presented at the Second Radioactive Exchange Decisionmakers' Forum (May 1986). Atomic Industrial Forum NESP Project

METHODS FOR IMPROVING ACCURACY IN ESTIMATING WORKER DOSES AT NUCLEAR POWER PLANTS

SC&A developed for the nuclear power industry methods for predicting worker doses. The objective was to determine how accurate are current state-of-theart estimates, and to develop a method which improves the accuracy of these estimates. Initially, using data collected from representative nuclear power plants, estimated doses were compared with actual doses in an attempt to explain the reasons for discrepancies. The results of these comparisons were used to guide the development of a method to improve the accuracy of these estimates.

The method comprises three building blocks -- an overall logic, checklists, and worksheets. A logic diagram guides the estimator through a series of steps, each of which involves the completion of a checklist or worksheet. The checklists systematically solicits the information needed to prepare the estimate, including appropriate adjustment factors. The worksheets are used to organize information and perform calculations needed to construct the dose estimate. The final report describes the application of the method to the engineering design process, and presents a sample problem which illustrates its application.

The report was published as AIF/NESP-039, <u>Estimating Doses in Nuclear</u> <u>Facilities with Emphasis on the Design Process</u>, January 1987. The method is currently being programmed for implementation on a desk-top computer.

U.S. Nuclear Regulatory Commission Office of Nuclear Regulatory Research

DEVELOPMENT OF A DOSE RATE DATA BASE FOR OPERATING NUCLEAR POWER PLANTS

Many proposed regulatory requirements involve physical modifications to operating nuclear power plants. Work performed in operating reactors will frequently subject workers to radiation exposure, which can be an important consideration in an overall value-impact assessment. Although data exist on the radiation exposures associated with several tasks already performed in operating nuclear power plants, a generic methodology does not exist for the purpose of making estimates of the exposure associated with plant modifications that have yet to be performed.

The objective of this task is to construct a dose-rate data base for the major plant systems in commercial LWRs. The product of the number of in-field manhours estimated for the postulated modification and the dose rate for the system would constitute a first-order approximation to the radiation exposure for the postulated modification.

The data base is being assembled from the survey data for area dose rates at representative operating plants. Representative plants were selected for each of the four reactor vendors based on historical exposures at the plants and the availability of readily retrievable data. Sufficient data are being collected over the spatial extent of each system and over time so as to obtain appropriate spatial and temporal averages.

U.S. Environmental Protection Agency Office of Radiation Programs

SEARCH FOR A DE MINIMIS LEVEL OF RISK

In establishing radiation standards, regulatory agencies generally assume that all exposures to radiation, regardless of how small, result in adverse health effects. This assumption is also frequently applied to the regulation of human exposure to chemicals. Although this conservative approach may be prudent, particularly if the agent is a known or suspected carcinogen, it may also result in the misallocation of societal resources. This consideration has resulted in the search for a "de minimis" level of risk -- below the range of regulatory concern.

SC&A, in collaboration with an economic consulting firm sought a quantitative definition of a de minimis level of risk, using the revealed preference method. Starting with the fatality statistics maintained by the National Center for Health Statistics (NCHS), a candidate list of diseases and accidents was compiled for analysis. For each of the categories of risk on the candidate list, an attempt was made to determine if government entities have or are planning to expend resources to reduce the level of risk below the existing level.

Graphical displays of the presence or absence of government expenditures versus the level of risk were developed to aid in interpreting the results. A statistical comparison of the categories of risk analyzed was performed using discriminate analysis to determine the level of risk which best separates the categories of risk into two groups. The results suggested no evidence of a de minimis level of risk down to a lifetime risk level of 0.1 X 10^{-6} , the lowest level of risk in the NCHS data base.

Nuclear Safety Oversight Committee

OVERVIEW OF NUCLEAR REGULATORY COMMISSION ASSESSMENT PROGRAMS

The Nuclear Safety Oversight Committee (NSOC) was established by the President in the wake of the accident at Three Mile Island and was abolished in October 1981. In July 1981, the staff of the Committee initiated a study of the NRC's major inspection, event evaluation, and safety improvement programs. SC&A assisted the staff in the analysis of NRC programs.

The purpose of the NSOC study was to establish a framework for evaluating the nation's regulatory approach to nuclear safety. A working list of major NRC assessment programs was drawn up and refined in the course of the study. More than 50 NRC staff members were interviewed to gain an insight into these programs. SC&A reviewed the following programs:

- Revision of the Standard Review Plan (SRP)
- Systematic Evaluation Program (SEP)
- Unresolved and Generic Safety Issue Reviews
- Interim Reliability Evaluation Program (IREP)
- National Reliability Evaluation Program (NREP)
- · Quality Assurance Reevaluation Program
- · Environmental Qualifications Program
- Systematic Assessment of Licensee Performance (SALP) Program
- · Control Room Design Reviews
- · Emergency Operating Procedures Reviews
- Systems Interaction Studies
- · Emergency Plan Appraisals
- · Fire Protection Reviews
- · Implementation of the Three Mile Island Action Plan
- · AEOD Engineering Evlaluations and Case Studies
- · Management Appraisals by the Performance Appraisal Branch (PAB)
- Inspection & Enforcement Investigations

U.S. Nuclear Regulatory Commission Office of Policy Evaluation

TECHNICAL ASSISTANCE ON SEVERE ACCIDENT RESEARCH AND POLICY DEVELOPMENT

As a consequence of the Three Mile Island nuclear power plant accident, the Nuclear Regulatory Commission initiated a high priority program to establish a policy for current and future generation nuclear reactors regarding severe accidents. Accordingly, an extensive research program was initiated by NRC's Office of Nuclear Reactor Research called the Severe Accident Research Program Plan (SARP).

SC&A provided technical assistance to the NRC Office of Policy Evaluation by reviewing the pertinent NRC and IDCOR (Industry Degraded Core) reports related to severe accidents, and identifying areas of uncertainty that could be significant to regulatory decisions on severe accident policy. Additionally, potential design changes were identified that could reduce the risks associated with severe accidents.

The work also included an extensive review of existing Probabilistic Risk Assessments (PRAs). From this review, SC&A estimated the overall uncertainty in the evaluation of the generic LWR risk. In support of this evaluation, the following topics were explored:

- Uncertainty in the source term
- Contribution of external events to risk
- Contribution to risk of station blackout and loss of decay heat removal
- Contribution to risk and uncertainty from low frequency sequences
- Contribution to risk from outliers
- Accident sequences which have been neglected in source term assessments
- Contribution to uncertainty from lack of knowledge regarding core migration into the lower plenum
- · Contribution to risk and uncertainty from human error

SC&A

Argonne National Laboratory Energy and Environmental Systems Division

DEVELOPMENT OF A GUIDE TO ESTIMATE THE COSTS OF GENERIC NUCLEAR REGULATORY COMMISSION REQUIREMENTS

Argonne National Laboratory developed for the Nuclear Regulatory Commission (NRC) a Handbook for Cost Estimating (NUREG/CR-3971) to revaluate the costs associated with generic NRC requirements. The Handbook is used by the NRC, together with independent estimates of accident risks and consequences, to establish priorities within the agency for dealing with generic issues. The methodology used in the Handbook consists of a "decision tree" to allow the NRC to identify all of the significant cost elements associated with the implementation of a proposed NRC generic requirement.

SC&A developed the decision methodology for use in the Handbook and additionally performed the following three tasks. In the first task, SC&A selected two recent examples of generic backfit requirements imposed by the NRC and traced the effects of these requirements through the nuclear industry. The second task provided detailed models of the NRC and a typical nuclear utility to identify all significant functions and to detect all cost elements associated with the generic requirements. In the final task, SC&A gathered cost data references to assist the user of the guide in preparing cost estimates of each element identified in Task 2.

SC&A conducted site visits at three utilities to determine the cost impact of the two selected backfit requirements. From discussions with utility project management personnel, a common basis was developed to categorize backfit cost impacts. Additionally, the differences between estimated and actual costs were determined for the two specific backfit requirements.

U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation

DETERMINATION OF THE IMPLEMENTING REQUIREMENTS OF CERTAIN GENERIC SAFETY ISSUES

The NRC Division of Safety Technology is responsible for establishing priorities for reactor safety issues. Many of the safety issues that have been prioritized by the NRC have resulted in the implementation of multi-plant actions (MPAs). These MPA: are licensing actions that apply to a class of reactors. SC&A is assisting the NRC by correlating the generic safety issues to the resulting MPAs, in order to track the issues to completion.

For each generic issue assigned to SC&A for tracking, the following information was collected and documented:

- Brief History of the Generic Issue
- Statement of Requirement(s)
- Identification of the Document Approving the Requirement(s)
- Identification of the Document(s) Implementing the Requirements,
 Including the MPA Number, Where Appropriate

Environmental Protection Agency Office of Radiation Programs

DEVELOPMENT OF AN ENVIRONMENTAL PATHWAY MODEL FOR EVALUATING RADIATION DOSES FROM RESIDUAL RADIOACTIVITY

A risk-level approach has been developed for estimating the maximum annual radiation dose to individuals at decontaminated and decommissioned sites and facilities. The approach has been implemented in a computer code entitled REUSEIT. The code will be used by the Environmental Protection Agency in establishing criteria and standards for residual radioactivity.

The approach considers initially contaminated surface soil, subsurface soil, and buildings. The environmental media modeled include the atmosphere, surface soil, subsurface soil, groundwater, and surface water. The environmental exposures include external exposure from contaminated ground and from immersion in contaminated air and water, and internal exposure from inhalation of suspended surface soil and from ingestion of contaminated water, crops, animalderived foods and aquatic foods. Contamination of internal building surfaces, in ventilation systems and on residual equipment is taken into account. The exposures in buildings include external exposure from all types of building contamination and internal exposure from inhalation of contaminated dust.

For the atmosphere, (re)suspension of surface soil and subsequent deposition are taken into account. For surface soil, additions of radioactivity by irrigation, by percolation from upper layers and by radioactive ingrowth, and removal by leaching accompanied by subsequent downward transport and by radioactive decay, are included. For subsoil, additions both by percolation from surface soil and by ingrowth, as well as losses by both removal of groundwater for irrigation and by decay, are considered. For surface water, contamination both by erosion and/or runoff of surface soil and by subterranean flow of subsoil contamination are included.

Congress of the United States Office of Technology Assessment

EXAMINATION OF REACTOR REGULATION

The Office of Technology Assessment (OTA) conducted an assessment on the future of conventional nuclear power. The objective of the study was to determine the impediments to the future growth of the industry, and to advise the Congress on ways to remove these impediments. SC&A was responsible for examining the regulatory impediments.

The principal proposals for reform of the regulatory process were reviewed, and the relative strengths and weaknesses of each of the major proposals were assessed from the perspective of the utilities, vendors, regulators, and environmental groups. Case studies of existing LWR's were conducted to determine the principal contributory factors to delays in the licensing and construction schedules. Finally, technological options other than conventional LWR's (redesigned LWR's, smaller LWR's, HTGR's, and CANDU reactors) were examined to assess significant differences in siting and licensing.

The case studies focussed on three units under construction and near completion, one with an exemplary construction history, another with an average history, and a third with a protracted and difficult history. An attempt was made to sort out the regulatory contributions to construction delays. In particular, the impact of NRC- mandated backfits was explored.

The results were summarized in a report to OTA and presented to a workshop on reactor technology and regulation. The OTA report, <u>Nuclear Power in an Age of</u> Uncertainty, was published in January 1984.

7.0 INTERPRETATIONS, REQUIREMENTS, ASSUMPTIONS, AND COMMITMENTS

No significant interpretations, requirements, or assumptions have been identified which apply to the technical requirements given in the solicitation. Moreover, SC&A is not aware of any commitments with other organizations, Government or commercial, for the same or similar work.

Section K

PART IV - REPRESENTATIONS AND INSTRUCTIONS

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SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

K.1 CONTINGENT FEE REPRESENTATION AND AGREEMENT (FAR 52.203-4) (APR 1984)

(a) Representation. The offeror represents that, except for full-time bona fide employees working solely for the offeror, the offeror--

(Note: The offeror must check the appropriate boxes. For interpretation of the representation, including the term "bona fide employee," see Subpart 3.4 of the Federal Acquisition Regulation.)

(1) () has, (X) has not employed or retained any person or company to solicit or obtain this contract; and

(2) () has, (χ) has not paid or agreed to pay to any person or company employed or retained to solicit or obtain this contract any commission, percentage, brokerage, or other fee contingent upon or resulting from the award of this contract.

(b) Agreement. The offeror agrees to provide information relating to the above Representation as requested by the Contracting Officer and, when subparagraph (a)(1) or (a)(2) is answered affirmatively, to promptly submit to the Contracting Officer--

(1) A completed Standard Form 119, Statement of Continge or Other Fees, (SF 119); or

(2) A signed statement indicating that the SF 119 was previously submitted to the same contracting office, including the date and applicable solicitation or contract number, and representing that the prior SF 119 applies to this offer or quotation.

(End of Provision)

K.2 TYPE OF BUSINESS ORGANIZATION (FAR 52.215-6) (JUL 1987)

The offeror or quoter, by checking the applicable box, represents that--

(a) It operates as (X) a corporation incorporated under the laws of the State of <u>Virginia</u>, () an individual, () a partnership, () a nonprofit organization, or () a joint venture;

or

(b) If the offeror or quoter is a foreign entity, it operates as
() an individual, () a partnership, () a nonprofit organization,
() a joint venture, or () a corporation, registered for business in ______ (country).

(End of Provision)

K.3 AUTHORIZED NEGOTIATORS (FAR 52.215-11) (APR 1984)

The offeror or quoter represents that the following persons are authorized to negotiate on its behalf with the Government in connection with this request for proposals or quotations: (list names, titles, and telephone numbers of the authorized negotiators).

	Sanford Cohen
and all the second s	President
	(703)893-6592

(End of Provision)

K.4 PLACE OF PERFORMANCE (FAR 52.215-20) (APR 1984)

(a) The offeror or quoter, in the performance of any contract resulting from this solicitation, () intends, (X) does not intend (check applicable box) to use one or more plants or facilities located at a different address from the address of the offeror or quoter as indicated in this proposal or quotation.

(b) If the offeror or quoter checks "intends" in paragraph (a) above, it shall insert in the spaces provided below the required information:

	Performance (Street City, County, State, Zip Code)	Name and Address of Owner and Operator of the Plant or Facility if Other than Offeror or Quoter
--	--	--

(End of Provision)

K.5 SMALL BUSINESS CONCERN REPRESENTATION (FAR 52.219-1) (MAY 1986)

The offeror represents and certifies as part of its offer that it (x) is, () is not a small business concern and that () all, () not all end items to be furnished will be manufactured or produced by a small business concern in the United States, its territories or

possessions, Puerto Rico, or the Trust Territory of the Pacific Islands. "Small business concern," as used in this provision, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the size standards in this solicitation.

(End of Provision)

K.6 SMALL DISADVANTAGED BUSINESS CONCERN REPRESENTATION (FAR 52.219-2) (APR 1984)

(a) Representation. The offeror represents that it () is, (X) is not a small disadvantaged business concern.

(b) Definitions.

"Asian-Indian American," as used in this provision, means a United States citizen whose origins are in India, Pakistan, or Bangladesh.

"Asian-Pacific American," as used in this provision, means a United States citizen whose origins are in Japan, China, the Philippines, Vietnam, Korea, Samoa, Guam, the U.S. Trust Territory of the Pacific Islands, the Northern Mariana Islands, Laos, Cambodia, or Taiwan.

"Native Americans," as used in this provision, means American Indians, Eskimos, Aleuts, and native Hawaiians.

"Small business concern," as used in this provision, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria and size standards in 13 CFR 121.

"Small disadvantaged business concern," as used in this provision, means a small business concern that (1) is at least 51 percent owned by one or more individuals who are both socially and economically disadvantaged, or a publicly owned business having at least 51 percent of its stock owned by one or more socially and economically disadvantaged individuals and (2) has its management and daily business controlled by one or more such individuals.

(c) Qualified groups. The offeror shall presume that socially and economically disadvantaged individuals include Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, Asian-Indian Americans, and other individuals found to be qualified by the SBA under 13 CFR 124.1.

(End of Provision)

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K.7 WOMEN-OWNED SMALL BUSINESS REPRESENTATION (FAR 52.219-3) (APR 1984)

(a) Representation. The offeror represents that it () is, (χ) is not a women-owned small business concern.

(b) Definitions.

"Small business concern," as used in this provision, means a concern, including its affiliates, that is independently owned and operated, not dominate in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria and size standards in 13 CFR 121.

"Women-owned," as used in this provision, means a small business that is at least 51 percent owned by a woman or women who are U.S. citizens and who also control and operate the business.

(End of Provision)

K.8 PREFERENCE FOR LABOR SURPLUS AREA CONCERNS (FAR 52.220-1) (APR 1984)

(a) This acquisition is not a set aside for labor surplus area (LSA) concerns. However, the offeror's status as such a concern may affect (1) entitlement to award in case of tie offers or (2) offer evaluation in accordance with the Buy American Act clause of this solicitation. In order to determine whether the offeror is entitled to a preference under (1) or (2) above, the offeror must identify, below, the LSA in which the costs to be incurred on account of manufacturing or production (by the offeror or the first-tier subcontractors) amount to more than 50 percent of the contract price.

(b) Failure to identify the locations as specified above will preclude consideration of the offeror as an LSA concern. If the offeror is awarded a contract as an LSA concern and would not have otherwise qualified for award, the offeror shall perform the contract or cause the contract to be performed in accordance with the obligations of an LSA concern.

(End of Provision)

K.9 CERTIFICATION OF NONSEGREGATED FACILITIES (FAR 52.222-21) (APR 1984)

(a) "Segregated facilities," as used in this provision, means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or

entertainment areas, transportation, and housing facilities provided for employees, that are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin because of habit, local custom, or otherwise.

(b) By the submission of this offer, the offeror certifies that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. The offeror agrees that a breach of this certification is a violation of the Equal Opportunity clause in the contract.

(c) The offeror further agrees that (except where it has obtained identical certifications from proposed subcontractors for specific time periods) it will--

(1) Obtain identical certifications from proposed subcontractors before the award of subcontracts under which the subcontractor will be subject to the Equal Opportunity clause;

(2) Retain the certifications in the files; and

(3) Forward the following notice to the proposed subcontractors (except if the proposed subcontractors have submitted identical certifications for specific time periods):

NOTICE TO PROSPECTIVE SUBCONTRACTORS OF REQUIREMENT FOR CERTIFICATIONS OF NONSEGREGATED FACILITIES

A Certification of Nonsegregated Facilities must be submitted before the award of a subcontract under which the subcontractor will be subject to the Equal Opportunity clause. The certification may be submitted either for each subcontract or for all subcontracts during a period (i.e., quarterly, semiannually, or annually).

NOTE: The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

(End of Provision)

K.10 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FAR 52.222-22) (APR 1984)

The offeror represents that--

(a) It () has, (X) has not participated in a previous contract or subcontract subject either to the Equal Opportunity clause of this solicitation, the clause originally contained in Section 310 of Executive Order No. 10925, or the clause contained in Section 201 of Executive Order No. 11114;

(b) It () has, () has not filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

(End of Provision)

K.11 AFFIRMATIVE ACTION COMPLIANCE (FAR 52.222-25) (APR 1984)

The offeror represents that ---

(a) It () has developed and has on file, () has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 6D-1 and 6D-2), or (b) It (χ) has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of Provision)

K.12 CLEAN AIR AND WATER CERTIFICATION (FAR 52.223-1) (APR 1984)

The Offeror certifies that --

 (a) Any facility to be used in the performance of this proposed contract is (), is not (X) listed on the Environmental Protection Agency List of Violating Facilities;

(b) The Offeror will immediately notify the Contracting Officer, before award, of the receipt of any communication from the Administrator, or a designee, of the Environmental Protection Agency, indicating that any facility that the Offeror proposes to use for the performance of the contract is under consideration to be listed on the EPA List of Violating Facilities; and

(c) The Offeror will include a certification substantially the same as this certification, including this paragraph (c), in every nonexempt subcontract.

(End of Provision)

K.13 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (NONDEFENSE) (FAR 52.230-2) (APR 1984)

Note: This notice does not apply to small businesses or foreign governments.

(a) Any contract over \$100,000 resulting from this solicitation shall be subject to Cost Accounting Standards (CAS) if it is awarded to a business unit that is currently performing a national defense

CAS-covered contract or subcontract, except when--

(1) The award is based on adequate price competition;

(2) The price is set by law or regulation;

(3) The price is based on established catalog or market prices of commercial items sold in substantial quantities to the general public; or

(4) One of the exemptions in 4 CFR 331.30(b) applies (also see Federal Acquisition Regulation (FAR) 30.301(b)).

(b) Contracts not exempted from CAS shall be subject to full or modified coverage as follows:

(1) If the business unit receiving the award is currently performing a national defense contract or subcontract subject to full CAS coverage (4 CFR 331), this contract will have full CAS coverage and will contain the clauses from the FAR entitled Cost Accounting Standards (52.230-3) and Administration of Cost Accounting Standards (52.230-4).

(2) If the business unit receiving the award is currently performing a national defense contract or subcontract subject to modified CAS coverage (4 CFR 332), this contract will have modified coverage and will contain the clauses entitled Disclosure and Consistency of Cost Accounting Practices (52.230-5) and Administration of Cost Accounting Standards (52.230-4).

A. Certificate of CAS Applicability

The offeror hereby certifies that --

(X) The offeror is not performing any CAS-covered national defense contract or subcontract. The offeror further certifies that it will immediately notify the Contracting Officer in writing if it is awarded any national defense CAS-covered contract or subcontract subsequent to the date of this certificate but before the date of the award of a contract resulting from this solicitation. (If this statement applies, no further certification is required.)

() The offeror is currently performing a negotiated national defense contract or subcontract that contains the Cost Accounting Standards clause at FAR 52.230-3.

() The offeror is currently performing a negotiated national defense contract or subcontract that contains the Disclosure and Consistency of Cost Accounting Practices clause at FAR 52.230-5.

B. Additional Certification--CAS Applicable Offerors

() The offeror subject to Cost Accounting Standards further certifies that practices used in estimating costs in pricing this

proposal are consistent with the practices disclosed in the Disclosure Statement where it has been submitted pursuant to CAS Board regulations (4 CFR 351).

C. Data Required--CAS Covered Offerors

The offeror certifying that it is currently performing a national defense contract containing either CAS clause (see A above) is required to furnis the name, address (including agency or department component), and telephone number of the cognizant Contracting Officer administering the offeror's CAS-covered contracts.

Name of Contracting Officer:

Address:

Telephone Number:

(End of Provision)

K.14 ORGANIZATIONAL CONFLICTS OF INTEREST (MAR 1987)

I represent to the best of my knowledge and belief that:

The award to SC&A, INC. of a contract or the modification of an existing contract does / / or does not / X' involve situations or relationships of the type set forth in 41 CFR 20-1.5403(b)(1).

Instructions to offerors. The following shall be included in all NRC solicitations: (1) If the representation as completed indicates that situations or relationships of the type set forth in 41 CFR 20-1.5403(b)(1) are involved or the Contracting Officer otherwise determines that potential organizational conflicts exist, the offeror shall provide a statement in writing which describes in a concise manner all relevant factors bearing on his representation to the Contracting Officer. If the Contracting Officer determines that organizational conflicts exist, the following actions may be taken:

(i) Impose appropriate conditions which avoid such conflicts,

(1i) Disqualify the offeror, or

(iii) Determine that it is otherwise in the best interest of the United States to seek award of the contract under the waiver provisions of 20-1.5411.

(2) The refusal to provide the representation required by 20-1.5404(b) or upon request of the Contracting Officer the facts

required by 20-1.5404(c), shall result in disqualification of the offeror for award. The nondisclosure or misrepresentation of any relevant interest may also result in the disqualification of the offeror for award; or if such nondisclosure or misrepresentation is discovered after award, the resulting contract may be terminated. The offeror may also be disqualified from subsequent related NRC contracts and be subject to such other remedial actions provided by law or the resulting contract.

The offeror may, because of actual or potential organizational conflicts of interest, propose to exclude specific kinds of work from the statements of work contained in an RFP unless the RFP specifically prohibits such exclusion. Any such proposed exclusion by an offeror will be considered by the NRC in the evaluation of proposals. If the NRC considers the proposed excluded work to be an essential or integral part of the required work and its exclusion would work to the detriment of the competitive posture of the other offerors, the proposal must be rejected as unacceptable.

The offeror's failure to execute the representation required by subsection (b) above with respect to invitation for bids will be considered to be a minor informality, and the offeror will be permitted to correct the omission.

(End of Provision)

K.15 Current/Former Agency Employee Involvement

The offeror represents that the following person(s) are KUKKEXK/former NRC employees who have been or will be involved, directly or indirectly, in developing the offer, or in negotiating on behalf of the offeror, or in managing, administering or performing any contract, consultant agreement or subcontract resulting from this offer (list name, title, date individual left NRC and provide brief description of individual's role under the proposal):

Allen Brodsky, Health Physicist, July 18, 1986, Principal Investigator

(End of Provision)