



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

SEP 21 1990

S. Cohen and Associates, Inc.  
ATTN: Mr. Sanford Cohen  
1311 Dolley Madison Blvd.  
McLean, VA 22101

Dear Mr. Cohen:

SUBJECT: Task Order No. 1, Entitled "Regulatory Analyses Support of Proposed Rule Concerning Biomedical Wastes Below Regulatory Concern" Under Contract No. NRC-04-90-071

Verbal Authorization was provided to you on September 20, 1990, to commence work under Task Order No. 1, effective September 21, 1990.

In accordance with Section G.4, entitled "Task Order Procedures" of the subject contract, this letter definitizes Task Order No. 1. This effort shall be performed in accordance with the enclosed Statement of Work and the Contractor's proposal dated August 29, 1990, incorporated herein by reference.

Task Order No. 1 shall be in effect from September 21, 1990 through September 20, 1991 with a cost ceiling of \$218,467.00. The amount of \$202,284.00 represents the estimated reimbursable cost and the amount of \$16,183.00 represents the fixed fee.

Accounting Data for Task Order No. 1 is as follows:

B&R No.:	0601925030
FIN No.:	D20530
Appropriation No.:	31X0200.600
Obligated Amount:	\$70,000.00

The following individuals are considered to be essential to the successful performance of work hereunder: Sanford Cohen, David Goldin and John Mauro.

The Contractor agrees that such personnel shall not be moved from the effort under the task order without compliance with contract Clause H.1 "Key Personnel".

The issuance of this Task Order does not amend any terms or conditions of the subject contract.

Your contacts during the course of this task order are:

Technical Matters:	Robert Meck Project Officer (301) 492-3737
Contractual Matters:	Joyce Fields Contract Administrator (301) 492-7459

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PDR CONTR  
NRC-04-90-071 PDC

Acceptance of Task Order No. 1 should be made by having an official authorized to bind your organization, execute three copies of this document in the space provided and return two copies to the above Contract Administrator.

Sincerely,

*Sharon Bell*  
Sharon Bell, Contracting Officer  
Contract Administration Branch No. 2  
Division of Contracts and  
Property Management  
Office of Administration

Enclosure:  
As stated

ACCEPTED:

*[Signature]*  
\_\_\_\_\_  
NAME  
*President*  
\_\_\_\_\_  
TITLE  
*9/25/90*  
\_\_\_\_\_  
DATE

## Statement of Work

S. Cohen & Associates, Inc.  
Contract No.: NRC-04-90-071, Task 4; Order 1

### REGULATORY ANALYSIS SUPPORT OF PROPOSED RULE CONCERNING BIOMEDICAL WASTES BELOW REGULATORY CONCERN

#### OBJECTIVE:

The U.S. Nuclear Regulatory Commission (NRC) has received Below Regulatory Concern (BRC) petitions from the University of Utah and Rockefeller University seeking exemption of certain biomedical waste streams from licensed disposal. The NRC has noticed the receipt of these petitions for rulemaking in the Federal Register, and has received public comments on the petitions. The Radiation Protection and Health Effects Branch (RPHEB) is developing information in support of a proposed rule to exempt as BRC all or certain portions of biomedical waste streams. This task is to perform supporting characterizations, risk assessments, impact analyses, and provide needed technical support for the rulemaking.

#### BACKGROUND:

Section 10 of the Low-Level Radioactive Waste Policy Act of 1985 establishes the goal of the NRC making practical and timely decisions regarding radioactive wastes that do not need to be under regulatory control to assure the protection of the public's health and safety; that is, the waste are BRC. The Commission has issued policy statements regarding the criteria that it will employ in determining whether or not to classify waste streams as BRC, and has developed a Standard Review Plan (SRP) for reviewing the information developed to support decisions concerning BRC wastes. The decisions reached concerning BRC will be expressed as rulemakings.

#### WORK TO BE PERFORMED AND EXPECTED RESULTS:

Sub-Task 1: Prepare an Options Paper for the Proposed Rule.

The contractor shall review the Commission's BRC policy statement, the BRC petitions and the public comments that have been received. Then, after consultation with the Project Officer and other cognizant NRC personnel, the contractor shall develop an Options Paper on the alternative scopes and anticipated regulatory products to be developed under this rulemaking. The Options Paper shall specifically address the issues of compatibility with the Agreement States and preemption of State authority. The purpose of the Options Paper is to focus the staff's thinking at the early stage of the rulemaking to the advantages and disadvantages of alternative scopes and regulatory products, and serves to develop early consensus at the Office level on the development of the rule.

**Sub-Task 2: Development of the Background Information Needed to Support the Rulemaking.**

The designation of biomedical waste streams as BRC requires characterization of the waste streams and an assessment of the impacts of alternative disposal options. The contractor shall, drawing, to the extent feasible, upon information developed under Task 1 of this contract, characterize the biomedical waste streams of concern and the alternative disposal methods that will be used if the petitions are granted. The waste streams shall be characterized in terms of: the quantities of waste involved (mass and volume) and the number and geographic location of generators; the concentration levels and identities of radionuclides present in the streams, including trace contaminants; the physical and chemical form of the radionuclides present; and variability in the wastes in terms of frequency distributions of the radionuclides on an activity per mass basis. The characterization of the waste shall also include information on non-radiological hazardous constituents and factors such as ignitability, ash content, and corrosivity which may affect the suitability of various disposal options.

Based on the characterization of the waste streams, and again, to the extent feasible, drawing upon information developed under Task 1 of this contract, the contractor shall develop source terms and exposure scenarios for the alternative disposal options. The computer code IMPACTS-BRC shall be used to evaluate the doses to individuals and to populations from the alternative disposal options.

**Sub-Task 3: Perform a Regulatory Impact Assessment (RIA) for the Proposed Rule.**

The contractor shall, using the information developed under Sub-Tasks 1 and 2, perform a Regulatory Impact Assessment (RIA) of the proposed rule which conforms in format to the guidance in NUREG/BR-0058. Alternatives to be considered in the RIA shall include no action, unrestricted BRC disposal, and BRC disposal via specific disposal methods. A part of the RIA, the contractor shall develop information on other regulatory restraints on unregulated disposal; e.g., classification as hazardous waste under RCRA. The contractor shall perform a value-impact assessment of the regulatory alternatives. Based on the information developed for the RIA, the contractor shall develop the information needed to support the preparation of the Regulatory Flexibility Act Certification and the Paperwork Reduction Act statement.

**Sub-Task 4: Assist in the Drafting of the Proposed Rule and Federal Register Notice.**

Based on the results of Sub-Tasks 1 through 3 of this effort, the contractor shall assist in the drafting of the proposed rule and the preparation of the Federal Register notice. The Federal Register notice will present the proposed revision, summarize the results and analyses performed in support of the proposed revision, and summarize the range of issues raised by persons who provided comments on the petitions.