UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 28, 2001

Advanced Technologies and Laboratories
International, Inc.
ATTN.: Ms. Ray-way Hwang
20251 Century Boulevard, Suite 200
Germantown, Maryland 20874

SUBJECT: TASK ORDER NO. 10 ENTITLED "TECHNICAL ASSISTANCE IN THE DEVELOPMENT OF RISK INFORMATION FOR THE REVIEW OF A RULE-MAKING PETITION" UNDER CONTRACT NO. NRC-02-00-010

Dear Ms. Hwang:

In accordance with Section G.5(c) entitled "Task Order Award," of the subject contract, this letter definitizes the subject Task Order. This effort shall be performed in accordance with the enclosed Statement of Work .

Task Order No. 10 shall be in effect from March 1, 2001 through May 31, 2001. The total cost ceiling is $60,976.00, of which the sum of $56,987.00 represents the reimbursable costs and the sum of $3,874.00 represents the fixed fee.

This Task Order No. 10 obligates funds in the amount of $60,976.00.

The obligated amount shall, at no time, exceed the task order ceiling. When and if the amount(s) paid and payable to the Contractor hereunder shall equal the obligated amount, the Contractor shall not be obligated to continue performance of the work unless and until the Contracting Officer shall increase the amount obligated with respect to this task order. Any work undertaken by the Contractor in excess of the obligated amount specified above is done so at the Contractor's sole risk.

Accounting data for this task order is as follows:

B&R No.:	15015203115
Job Code No.:	J5332
BOC:	252A
APPN No.:	31X0200
FFS No. :	5001R052
Obligated Amount:	$60,976.00

TEmpLatE – ADM-001

ADM-02

Your contacts during the course of this task are:

Technical Matters:	James Smith, Technical Monitor (301) 415-6459
	Penelope Kinney, Project Officer (301) 415-7805
Contractual Matters:	Joyce Fields, Contracting Officer (301) 415-6564

The issuance of this task order does not amend any terms or conditions of the subject contract.

Please indicate your acceptance of this task order by having an official, authorized to bind your organization, execute three (3) copies of this document in the space provided below and return two (2) copies to the U.S. Nuclear Regulatory Commission, ATTN.: Ms. Joyce Fields, Division of Contracts and Property Management, T-7I2, ADM/DCPM/CMB2, Washington, D.C. 20555. You should retain the third copy for your records.

Sincerely,

Joyce A. Fields

Joyce A. Fields, Contracting Officer
Contract Management Branch No. 2
Division of Contracts and
Property
Office of Administration

Enclosure:
As stated

ACCEPTED:

NAME

Director of Contracts
TITLE

February 28, 2001
DATE

PROJECT TITLE:	Technical Assistance in the Development of Risk Information for the Review of a Rulemaking Petition
JOB CODE NO.:	J5332
TASK ORDER NO.:	TBD
B&R NUMBER:	15015203115
CONTRACT NO.:	NRC-02-00-010
NRC TECHNICAL PROJECT MANAGER:	James Smith (301) 415-6459
NRC TECHNICAL ASSISTANCE PROJECT MANAGER:	Penny Kinney (301) 415-7805
FEE RECOVERABLE:	No

BACKGROUND:

The NRC's current regulations at 10 CFR 34.20 describe the performance standards for industrial gamma radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria: (a)(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

In addition to the preceding requirements, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words: "DANGER--RADIOACTIVE." The label may not interfere with the safe operation of the exposure device or associated equipment. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use. Guide tubes must be used when moving the source out of the device. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980. Source changers must provide a system for ensuring that the

source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

On March 28, 1996, Cathleen Roughan of Amersham sent the Nuclear Regulatory Commission a petition for rulemaking PRM-34-1, which requested that the NRC immediately clarify Part 34.20 to remove the associated equipment from the rule and continue to perform source and devices reviews only. In addition, the petitioner requested that part 34.28 be amended to reflect appropriate inspection and maintenance requirements for all of the radiography equipment including associated equipment. Associated equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drive, guide, or come into contact with the source, [e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator] when it is used as an exposure head.

In response to the petition, NRC is considering a risk-informed, performance-based option to amend Section 34.20 to authorize licensees and manufacturers to self-certify that associated equipment complies with the requirements noted above. The proposed certification process would replace the evaluation and registration process that is currently required by Sections 30.32(g) and 32.210. Either the licensee or the manufacturer would subject prototype associated equipment to a consensus standard for design, construction, and performance testing of associated equipment that was published by a nationally recognized body (e.g., American National Standards Institute). A record of test results indicating that the prototype passed the performance criteria standard would be retained by the licensee.

The impact of such an amendment may reduce unnecessary regulatory burden and improve efficiency and effectiveness of the regulatory process, while maintaining safety of workers and members of the public, but it could also result in the permanent injury or the loss of life of an employee or member of the public. In the recent past, accidental exposure at domestic and foreign countries are known to have resulted in permanent injury to workers and exposure to members of the public have been possible. Since the NRC is responsible for ensuring the protection of the public's health and safety, the NRC must obtain technical assistance to determine what risk exists if the petitioner's request is granted.

OBJECTIVE

The objectives of this task are to obtain (1) a risk analysis of the proposed regulatory change to remove the reference to associated equipment from the requirements of 10 CFR Part 34 and (2) a risk analysis for the proposed self-certification of associated equipment.

WORKSCOPE

The contractor shall perform a sensitivity analysis (importance analysis) which specifically models the risk of the petitioner's proposal and compares it to the risk of operating under the current requirements. The risk analysis and information found in NUREG/CR-6642 and the associated database should be used as a baseline for this analysis to the extent that it is applicable. Uncertainties in the analysis and data should be presented, discussed, and quantified if possible. The consequences to be analyzed include, but may not be limited to, acute exposure resulting in deterministic effects such as death or morbidity, and chronic low level exposures exceeding the regulatory dose limits. As part of this risk assessment, the contractor shall perform a literature search for any accidents in the United States associated

with the operation and performance of associated equipment. The contractor shall assess these accidents to determine whether the lack of performance standards for associated equipment was a factor in these events.

Upon completion of the risk analysis, the contractor shall document all findings and make recommendations to the NRC Technical Project Manager (TPM) in a report which summarizes the specifics of the analysis conducted with a list of all references used.

DELIVERABLES/SCHEDULE

All deliverables with an anticipated schedule are provided below. Each deliverable shall be submitted to the TPM in both hard copy and in an electronic medium form (Wordperfect).

1. A preliminary draft of the Risk Analysis including a complete list of references to data used. Due one month following the effective date of this task order.

2. NRC staff comments regarding the report. Due two weeks after receipt of the preliminary draft.

3. A final draft of the Risk Analysis including a complete list of references to data used. The final draft should incorporate NRC staff comments. Due two weeks following receipt of NRC staff comments on the preliminary draft.

4. A description of domestic incidents and their root causes. Due two months following receipt of this task order.

NRC-FURNISHED MATERIAL

The NRC TPM will furnish the contractor with a copy of NUREG/CR-6642, the rulemaking petition, and any other documents pertinent to complete this task.

MEETINGS AND TRAVEL

One trip to a manufacturer of associated equipment is anticipated. For proposal preparation purposes, assume one trip for two people for one day to Amersham in Burlington, Massachusetts. The contractor will be accompanied by NRC staff. Meetings between the contractor and the NRC TPM will be conducted at least twice a month at NRC Headquarters. Teleconferencing and exchanges of information via the internet will employed to the maximum extent practicable.

REQUIRED EXPERTISE

The contractor shall have available a health physicist or engineer who is familiar with gamma radiography sufficient to perform the risk analysis for this task. Expertise should also be provided in risk assessment, including human factors assessment, sensitivity analyses, and uncertainty analysis. Familiarity with NUREG/CR-6642 and the associated database is also required.

PERIOD OF PERFORMANCE

The period of performance for the work specified in this SOW shall commence of the effective date of this task order and shall continue until May 31, 2001.

LEVEL OF EFFORT

The estimated level of effort for this task order is 0.2 professional staff years.

FINANCIAL AND TECHNICAL STATUS REPORTS

The contractor shall submit a monthly technical report in accordance with section F.3 - Technical Progress Report and a monthly financial status report each month in accordance with the requirements specified in Section F.4 - Financial Status Report of the basic contract with distribution to the (1) NMSS TAPM, (2) NMSS/TPM [2 copies], and (3)Contracting Officer.

TECHNICAL/PROJECT DIRECTION

Penny Kinney is the NMSS Technical Assistance Project Manager (TAPM) and is the focal point for all contract-related activities. All work assignments and program funding actions are initiated by the NMSS TAPM who submits all requests to the Division of Contracts and Property Management (DCPM) for processing. All proposed work scope or schedule changes must be submitted through the NMSS TAPM for DCPM.

James Smith is designated the NMSS TPM and is responsible for providing technical guidance to the contractor regarding staff interpretations of the technical aspects of regulatory requirements, along with copies of relevant documents when requested by the contractor. All work products must be reviewed and approved the TPM before they are submitted as final documents. All technical direction given to the contractor must be consistent with the work scope and schedule. The NMSS TPM is not authorized to unilaterally make changes to the approved work scope or schedule, or give the contractor any direction that would increase costs over approved levels. The Contracting Officer is the only individual authorized to make changes to this task.