INTERNATIONAL TECHNOLOGY CORPORATION

IT CORPORATION

STANDARD OPERATING PROCEDURE

NUMBER: RPP-014

TITLE: Quality Assurance in Radiological Protection

APPROVED: _____ DATE: 9-27-96
Corporate Director of
Health and Safety

APPROVED: _____ DATE: 9/27/96
Health Physics Professional

APPROVED: _____ DATE: 26 Sep 96
Corporate Director of
Quality Assurance

CONTROLLED COPY NO. : ____

REVISION NO.	DATE
001	9/23/96

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1 PURPOSE AND OBJECTIVES

This procedure provides instructions for reporting conditions adverse to quality and items, services, or activities that do not meet requirements. It also provides requirements for the selection and completion of corrective actions.

2 RESPONSIBILITIES

2.1 The Corporate Director of Health and Safety shall establish and implement a quality assurance program for all radiation protection activities.

2.2 The Corporate Director of Quality Assurance shall verify the implementation of the radiation protection quality assurance program through periodic audits and assessments.

3 REFERENCES

3.1 Requirements and Specifications

3.1.1 IT Corporation Policy No. HS-700, "Radiation Protection Program Plan"

3.2 Related Procedures

3.2.1 IT Corporation Procedure No. RPP-010, "Radiation Protection Records"

4 DEFINITIONS

4.1 Approval - An act of endorsing or adding positive authorization or both.

4.2 Acceptance Criteria - specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other required documents.

4.3 Authorized User (AU) - Individuals who, by virtue of training and/or experience, have been authorized by the RSO to use or directly supervise the use of radioactive materials under the requirements of a specific radioactive materials license or IT work plan.

4.4 Characteristic - any property or attribute of an item, process, or service that is distinct, describable, and measurable.

4.5 Condition Adverse to Quality - an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

4.6 Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

4.7 Health Physics Professionals (HPP) - Individuals who, by virtue of their education, and experience, to approve and provide oversight for work involving or pertaining to radioactivity. The HPP shall be Certified by the American Board of Health Physics (Comprehensive).

4.8 Nonconformance - a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

4.9 Radiation Safety Officers (RSO) - Individuals who, by virtue of training and/or experience, have been authorized to develop, administer and implement a radiation protection program. Fixed facility RSOs are specified by federal or state license requirements, and shall not be changed without notification of the appropriate licensing authority. Fixed facility RSOs are authorized to use or directly supervise the use of radioactive materials under the specifications of a specific radioactive materials license. Project RSOs shall be selected by the HPP.

4.10 Rework - the process by which an item is made to conform to original requirements by completion or correction.

4.11 Shall - The word **shall** is to be understood as a requirement.

4.12 Should - The word **should** is to be understood as a recommendation.

5 EQUIPMENT/MATERIALS REQUIRED

None

6 METHODOLOGY

6.1 Reporting Conditions Adverse to Quality and Nonconformances

6.1.1 Any individual who identifies or creates any condition adverse to quality (CAQ) shall complete a CAQ report (CAQR) form (Attachment 1).

6.1.2 The report initiator shall submit a completed CAQR to the profit center QAO (or the project QAO when appropriate).

6.1.3 The QAO shall evaluate the information and determine if a nonconformance has occurred. This determination shall be made by comparing the known characteristics or written documentation of the items, services, and activities to written acceptance criteria. A nonconformance shall be declared when acceptance criteria have not been met.

6.1.4 When a nonconformance is determined, the QAO shall initiate a nonconformance report and obtain the signature of the person who identified the CAQ to verify that the transcribed details are correct.

6.1.5 After assigning appropriate numbers as described below in section 6.3, the QAO shall provide a copy of each report to the responsible manager(s) and maintain the original in the QA files.

6.2 Corrective Actions

6.2.1 The responsible manager shall review each report and decide if rework is necessary and what corrective actions should be taken to avoid recurrence of the problem. He/she shall complete Section 2 of each form defining the actions to be taken, providing dates for the initiation and completion of those actions and the name of the person(s) who will perform the activities.

6.2.2 The responsible manager shall then submit the CAQR or NCR to the Project Manager for approval of the proposed corrective actions, the start and completion dates, and the responsible personnel.

6.2.3 The Project Manager shall review the report, sign Section 3 when details of the correction plans are acceptable, and forward the report to the QAO.

6.2.4 The QAO shall review the proposed corrective actions and dates and sign Section 3 of the NCR if they are found acceptable. If they are found unacceptable, the QAO shall return the report to the Project Manager for revision of the actions or dates.

6.2.5 Steps 6.2.1 through 6.2.4 above shall be repeated until the QAO concurs with the corrective actions and associated dates.

6.2.6 Upon completion of corrective actions, the personnel assigned to perform the tasks shall notify the Project Manager or Profit Center Manager, as appropriate, and the QAO.

6.2.7 If a completion date for a corrective action can not be met, the responsible personnel shall notify the QAO on or before such date and provide a revised date. Revised dates must be approved by the QAO. Dates may not be revised more than once without written approval of the Project Manager or the Profit Center Manager.

6.2.8 The QAO shall verify the satisfactory completion of each corrective action prior to closing out a report.

6.3 Tracking

6.3.1 The QAO shall establish a CAQR log (Attachment 3) and numbering system that shall include the last two digits of the current year, the code "CAQ" and a sequential number that begins at "01" at the beginning of each calendar year.

EXAMPLE: 91CAQ01

6.3.2 The QAO, using this system, shall assign a number to each report as it is received and shall record the receipt of the report in the CAQ log.

6.3.3 The QAO shall establish an NCR log (Attachment 4) and numbering system similar to the CAQR system stipulated in step 6.3.1 but replacing the letter code with "NCR" to clearly distinguish NCRs from CAQs.

EXAMPLE: 91NCR01

6.3.4 If the CAQ is determined to be a nonconformance, the QAO shall indicate such on the original report, assign an NCR number, and cross reference the numbers on both report forms.

6.3.5 The QAO shall record the NCR on the associated log at the time the number is assigned.

6.3.6 The QAO shall track each corrective action by assigning the associated report number followed by a dash and a sequential letter for each corrective action required by the report.

EXAMPLE: 91CAQ01-a
91CAQ01-b

7 RECORDS

7.1 Condition Adverse to Quality Report shall be initiated by the individual identifying the problem and submitted to the QAC for completion. The QAC shall maintain all completed forms in the business unit's QA files.

7.2 Nonconformance Reports shall be initiated by the individual identifying the nonconformance and submitted to the QAC for completion and further action. The QAC shall maintain all completed NCR forms in the business unit's QA files.

7.3 All documentation related to each corrective action shall be maintained by the QAC in the business unit's QA files.

7.4 A CAQR Log shall be maintained by QAC in the business unit's QA files.

7.5 An NCR Log shall be maintained by QAC in the business unit's QA files.

8 ATTACHMENTS

8.1 Attachment 1 - Condition Adverse to Quality Report Form

8.2 Attachment 2 - Nonconformance Report Form

8.3 Attachment 3 - CAQR Log

8.4 Attachment 4 - NCR Log

ATTACHMENT 1

CONDITION ADVERSE TO QUALITY REPORT

CAQR NO. _____

Project Name _____ Page ___ of ___

Project No. _____ Date: _____

1. Description of Condition Adverse to Quality

Identified By: _____ Date: _____

2. (To be completed by QAO)

Is this CAQ a nonconformance to requirements? If so, provide NCR No. _____

3. Proposed Corrective Action (including initiation and completion dates)

To Be Performed By: _____

4. Approval for Proposed Corrective Action

Responsible Manager _____ Date: _____

Quality Assurance Coordinator _____ Date: _____

5. Corrective Action Complete

Performed By: _____ Date: _____

Verified By: _____ Date: _____

cc: Proj. Mgr.
QAO
Proj. Files
Other _____

ATTACHMENT 2

NONCONFORMANCE REPORT

NCR No._____

Project Name _____ Page ___ of ___

Project No. _____ Date: _____

1. Nonconformance Description

Identified By: _____ Date: _____

2. Proposed Corrective Action, Including Initiation and Completion Dates

To Be Performed By: _____

3. Approval for Proposed Corrective Action

_____ _____
Project Manager Date

_____ _____
Quality Assurance Coordinator Date

4. Corrective Action Taken (if different from that proposed)

5. Corrective Action Complete

Performed By: _____ Date: _____

Verified By: _____ Date: _____

cc: Proj. Mgr. QAO
Proj. Files Other _____

ATTACHMENT 3

CONDITION ADVERSE TO QUALITY REPORT LOG

CAQR NUMBER	PROJECT NUMBER	DATE ISSUED	RESPONSIBLE MANAGER	CORRECTIVE ACTION TARGET DATE	VERIFIED DATE/ INITIALS

ATTACHMENT 4

NONCONFORMANCE REPORT LOG

NCR NUMBER	PROJECT NUMBER	DATE ISSUED	RESPONSIBLE MANAGER	CORRECTIVE ACTION TARGET DATE	VERIFIED DATE/ INITIALS