International Quality Consultants, Inc.
106 Freeport Road
Butler, PA 16002
724/284-3738
FAX 724/284-1310
info@iqcconsulting.com
QAS3737.10

July 29, 2010

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-0001

Subject: Reply to a Notice of Violation

References:

1) NRC Notice of Violation Docket Number No.9901389/2010-201-01
2) NRC Inspection Report No. 99901389/2010-201

International Quality Consultants, Inc. (IQC, Inc.) hereby responds to the Notice of Violation, Reference 1, dated July 8, 2010. The violation was identified during an NRC inspection, Reference 2, conducted from June 1 through June 3, 2010 at our facility by inspectors Jonathon Ortega-Luciano (Team Leader) and Aaron Armstrong (Inspector).

Our response to Reference 1 is provided as Attachment "A" of this letter.

IQC, Inc. is committed to full compliance of all contractual, statutory and regulatory requirements. We believe the corrective actions taken will prevent recurrence of the issues identified by the NRC.

Please contact me at (724) 284-3738 if you have any questions or would like to discuss this matter further.

Sincerely,

Thomas E. Paserba
President

cc: Patrick L. Hiland
Director, Division of Engineering
Office of Nuclear Reactor Regulation

IE09
NRR

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Butler, PA 16002
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ATTACHMENT "A"

This Attachment sets forth the reply of International Quality Consultants, Inc. (IQC, Inc.) to the NRC's Notice of Violation dated July 8, 2010 relative to NRC Inspection Report No. 99901389/2010-201 and Violation Docket No. 99901389/2010-201-01. The Notice of Violation provides the following description:

> *A. 10 CFR Part 21, Section 21.21(a), "Notification of failure to comply or existence of a defect and its evaluation," states in part that, "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected. Ensure that if an evaluation cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed."*
> *Contrary to the above, as of June 3, 2010;*
> *IQC's 10 CFR Part 21 implementing procedure IQC 800, "Reporting of Defects and Noncompliance per 10 CFR 21," dated January 19, 2009, was not an appropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, implementing procedure IQC 800:*
>
> *1. Did not contain guidance on how to evaluate deviations in accordance with 10 CFR Part 21 requirements.*
> *2. IQC 800 did not specify the adequate time limits for reporting as required by 10 CFR Part 21.21.*

1. REASON FOR THE VIOLATION

IQC, Inc. misinterpreted 10CFR Part 21 reporting requirements, as applied to the limited scope of IQC, Inc.'s services. IQC, Inc. is a service based corporation, providing trained and certified, quality and technical support personnel to the nuclear industry. All IQC, Inc. assigned personnel work under our customer/owner's quality assurance program and requirements. Although IQC, Inc. established a 10 CFR Part 21 procedure to report noncompliance, the procedure did not address all required steps of the reporting process, as identified in 10 CFR Part 21.

2. IQC, INC. CORRECTIVE ACTION STEPS TAKEN AND RESULTS ACHIEVED

IQC, Inc. is not contesting the violation and has taken all necessary steps to address the issues identified in the Inspection Report and Notice of Violation. Corrective action measures are described in this Attachment and Enclosure 1: IQC, Inc. Corrective Action Report Number CAR-10-018.

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3. CORRECTIVE ACTIONS TAKEN TO AVOID FURTHER VIOLATIONS

IQC, Inc. fully understands 10 CFR Part 21 reporting requirements, and is aware of our responsibility for full implementation of these reporting requirements, from discovery thru the evaluation process of the potential defect or noncompliance. This understanding is based upon IQC, Inc.'s extensive research of the requirements of the regulation, our Vice-President's attendance at the NUPIC/NRC 10CFR21 Workshop the week of June 14, 2010, and the guidance and explanations provided by the NRC personnel during this inspection visit.

IQC, Inc. is not contesting the violation and has taken steps to address the issues identified in the Inspection Report and Notice of Violation as described below.

A. Procedure IQC800 has been revised to meet all requirements of 10 CFR Part 21; Reporting Defects and Noncompliance.
Specifically, revisions updated to include the following corrective actions;

a) Procedure guidance on how to evaluate deviations in accordance with 10 CFR Part 21.
b) Specifying adequate time limits for reporting defects and noncompliance, in accordance with 10 CFR Part 21.

References:
Exhibit 1 – Corrective Action Report No. CAR-10-018
Exhibit 2 – Procedure IQC800 Rev. 8 - Reporting of Defects and Noncompliances per 10CFR21.
Exhibit 3 – Procedure IQC2000 Rev. 3 - Control of Nonconforming Items
Exhibit 4 – Procedure IQC4000 Rev. 1 - Corrective Actions

B. IQC, Inc. quality-related personnel have been provided additional training to assure full understanding of nonconformance, corrective actions, and 10 CFR Part 21 reportability, as defined by IQC, Inc. Procedures IQC800 Rev. 8, IQC2000 Rev. 3, and IQC4000 Rev. 1.

References:
Exhibit 5 – IQC, Inc. QA Personnel Training Log

4. DATE FULL COMPLIANCE ACHIEVED

IQC, Inc. has taken all necessary corrective action steps to assure compliance to this violation, given this day July 29, 2010.

CORRECTIVE ACTION REPORT

1.
DATE: 09 – JUNE - 2010 C.A.R. NUMBER: CAR-10-018

TO: THOMAS E. PASERBA Part 21 Applicability: □ Yes X No □ N/A (Ref. IQC800)

2. DEFICIENCY: (Include supporting documentation or other evidence, if applicable - use and reference additional sheets, as required)

REQUIREMENT

10 CFR Part 21, Section 21.21(a), "Notification of failure to comply or existence of a defect and its evaluation," states in part that, "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected. Ensure that if an evaluation cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed."

DEFICIENCY

Contrary to the above requirement;
IQC's 10 CFR Part 21 implementing procedure IQC 800, "Reporting of Defects and Noncompliance per 10 CFR 21," dated January 19, 2009, is not an appropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, implementing procedure IQC 800:

1. Did not contain guidance on how to evaluate deviations in accordance with 10 CFR Part 21 requirements.
2. IQC 800 did not specify the adequate time limits for reporting as required by 10 CFR Part 21.21.

Initiated by NRC Violation #99901389/2010-201-01 during NRC inspection of IQC, Inc. facilities performed June 1 – June 3, 2010. (Reference NRC Inspection Report No. #99901389/2010-201 dated July 8th, 2010)

INITIATED BY: _____ REVIEWED BY: Thomas E Paserba

DATE: 7/9/2010 DATE: July 9, 2010

3. CAUSE: (state the cause of a significant deficiency – use and reference additional sheets, as required.
Not Required

4. CORRECTIVE ACTION: (state corrective action taken to resolve the deficiency and to prevent recurrence - use and reference additional sheets, as required)

Procedure IQC800 has been revised to meet all requirements of 10 CFR Part 21; Reporting Defects and Noncompliance. Specifically, revisions to include the following corrective actions;

A. Procedure guidance on how to evaluate deviations in accordance with 10 CFR Part 21.
B. Specifying adequate time limits for reporting defects and noncompliance, in accordance with 10 CFR Part 21.

IQC, Inc. quality-related personnel will be re-trained to assure full understanding of nonconformance, corrective actions, and 10 CFR Part 21 reporting requirements, as defined by IQC, Inc. Procedures IQC800 Rev. 8, IQC2000 Rev. 3, and IQC4000 Rev. 1.

COMPLETED BY: _____ REVIEWED BY: Thomas E Paserba

DATE: 7/12/2010 DATE: July 12, 2010

5. **ACCEPTANCE AND VERIFICATION OF CORRECT ACTION:** (state whether or not the specified corrective action is acceptable. Provide details for any nonacceptance. Include need for modified corrective action or implementation of the corrective action originally specified. Verification to be signed only when specified corrective action has been determined to be acceptable and has been adequately implemented. Use and reference additional sheets, as required.)

REVIEWED BY: Edward Zyskowski VERIFIED BY: Thomas E Paserba

DATE: 7/23/10 DATE: July 23, 2010

APPROVED: Manager QA/QC Services	Effective Date: 07/09/10	Number: IQC800
	Page: 1 of 8	Revision: 8

SUBJECT: REPORTING OF DEFECTS AND NONCOMPLIANCES PER 10CFR21

1.0 PURPOSE

This procedure provides detailed guidance for determining whether deviations or noncompliances are reportable to the Nuclear Regulatory Commission under the regulations of 10CFR21. Guidance is also provided for the method of documentation, the timing involved for notifying NRC of reportable conditions, and handling of potentially reportable conditions discovered to be the responsibility of an organization or person other than International Quality Consultants, Inc.

2.0 DEFINITIONS

Basic Component:

(1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(a) The integrity of the reactor coolant pressure boundary;

(b) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(c) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B of part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

(i) The integrity of the reactor coolant pressure boundary;

(ii) The capability to shut down the reactor and maintain it in a safeshutdown condition; or

(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation of this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

Commercial Grade Item: When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected.

When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade means an item that is:

(a) Not subject to design or specification requirements that are unique to those facilities or activities;

(b) Used in applications other than those facilities or activities; and

(c) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog).

Commission: The Nuclear Regulatory Commission, or its duly authorized representatives.

Construction: The analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations of 10CFR21; and consulting services related to the facility or activity that are safety significant (important-to-safety or safety-related).

Dedicating Entity: When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity meanse the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21C(c) of this part, is responsible for identifying and evaluation deviations, reporting defects and failures to

comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication: When applied to nuclear power plants licensed pursuant to 10 CFR 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its safety function and, in this respect, is equivalent to an item designed and manufactured under a 10 CFR 50 Appendix B quality assurance program.

When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when an item is designated for use as a basic component.

Defect:

(a) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in 10CFR21 if, on the basis of an evaluation, the deviation would create a substantial safety hazard; or

(b) The installation, use, or operation of a basic component containing a defect; or

(c) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of 10 CFR 50 provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(d) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to 10 CFR 50.

(e) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

Deviation: A departure from the technical requirements included in a procurement document. This also includes departures from engineering documents such as specifications, drawings, analyses, and calculations.

Director: An individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership, or other entity. In the case of an individual proprietorship, "director" means the individual.

Discovery: The completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in Section 6.0.

Evaluation: The process of determining whether a particular deviation could create a substantial safety hazard or determining whether a failure to comply is associated with a substantial safety hazard.

Important-to-Safety (ITS): A class of structure, system, or component whose function is:

(a) To maintain the conditions required to store spent fuel or high-level radioactive waste safety;

(b) To prevent damage to the spent fuel or the high-level radioactive waste container during handling and storage, or

(c) To provide reasonable assurance that spent fuel or high-level radioactive waste can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

Notification: The telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

Operating or Operation: The operation of a facility, or the conduct of a licensed activity that is subject to the regulations of 10CFR21 and consulting services related to operations that are safety significant.

Procurement Document: A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Responsible Officer: The president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to 10CFR21.

Safety-Related: A class of structure, system, component, or part thereof whose failure could potentially:

(a) Compromise the integrity of the reactor coolant pressure boundary;

(b) Compromise the capability to shut down the reactor and maintain it in a safe condition;

(c) Compromise the capability to prevent or mitigate the consequences of accidents which could result in significant potential offsite exposures;

(d) Create a loss of safety function to the extent that there is a major reduction in the degree of protection provided to the public health and safety.

Safety-Significant: Any activity, item, or project that is defined as Important to Safety (ITS) or Safety Related, under the provisions of 10CFR50 Appendix B, 10CFR71, Subpart H or 10CFR72, Subpart G.

Substantial Safety Hazard: A loss of safety function to the extent that there is a major reduction in the degree of protection to the public health and safety for any facility or activity licensed, other than for export, pursuant to 10CFR30, 40, 50, 60, 61, 63, 70, 71, and 72.

Supplying or Supplies: contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

3.0 REFERENCES

3.1 Code of Federal Regulations, Title 10, *Energy,* Part 21, *Reporting of Defects and Noncompliances.*

4.0 DISCUSSION

Section 206 of the Energy Reorganization Act of 1974 requires any individual, director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating:

(a) that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards; or

(b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard;

to immediately notify the Commission of such failure to comply, or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

Form 800-1 of this procedure, Deviation and Noncompliance Evaluation, is provided as a tool to be utilized to determine 10CFR21 applicability and reportability of deviations and noncompliances in accordance with 10CFR21.

A written evaluation (Form 800-1 or similar), performed in accordance with this procedure, is required if a deviation or noncompliance is determined to likely be reportable under 10CFR21. In these cases, the question regarding 10CFR21 reportability in the applicable QA correction action document would be checked "YES".

A written evaluation is recommended if International Quality Consultants, Inc. management and/or the person documenting the deviation or noncompliance are unsure whether the deviation or noncompliance is reportable under 10CFR21.

If a deviation or noncompliance is obviously not reportable in the judgment of the person who discovers it or in the collective judgment of that person in consultation with Manager QA/QC Services and/or other International Quality Consultants, Inc. officers, a written evaluation is not required.

5.0 RESPONSIBILITIES

5.1 President

The President of International Quality Consultants, Inc. is the responsible corporate officer for purposes of 10CFR21 reporting. In his absence, the Vice President may render this function.

5.2 Manager QA/QC Services

The Manager QA/QC Services is responsible for insuring that the provisions of this procedure are implemented in a timely manner. In particular, the Manager QA/QC Services is responsible for providing guidance in the use of corrective action processes and the 10CFR21 regulations, overseeing and reviewing the evaluations of deviations and noncompliances for reportability, informing other entities about deviations which are, or may be reportable under 10CFR21, and for posting the appropriate documents in accordance with 10CFR21.6.

5.3 Vice President

The Vice President is responsible for providing consultation with regard to the use of corrective action processes and the 10CFR21 regulations, and making any necessary verbal and written reports to the NRC on behalf of International Quality Consultants, Inc. for 10CFR21-reportable defects or failures to comply.

5.4 International Quality Consultants, Inc. Personnel

All International Quality Consultants, Inc. personnel qualified to work under the Company's QA Program shall be provided general training on 10CFR21. All Company employees and contractors, as applicable, are responsible for documenting deviations and noncompliance within the appropriate QA process; for maintaining

vigilance to identify reportable deviations and noncompliances under 10CFR21; for obtaining appropriate management consultation; and for preparing the evaluation governed by this procedure.

6.0 PROCEDURE

6.1 Any International Quality Consultants, Inc. employee finding what he or she feels to be a deviation or noncompliance, either in the past or in ongoing technical, engineering, and field activities or documentation, shall document it within the appropriate QA corrective action process, as applicable. Verbal consultation with the Manager QA/QC Services or Vice President is available to ensure the proper process is used for the type of deviation or noncompliance involved. Deviations and noncompliances suspected to be potentially reportable under 10CFR21 shall be brought to the attention of the Manager QA/QC Services within five (5) days of discovery.

NOTE: Deviations and noncompliances found with products or services provided by an entity other than International Quality Consultants, Inc. shall be discussed with the Manager QA/QC Services and/or the Vice President for potential 10CFR21 reportability and use of the appropriate corrective action process. The Manager QA/QC Services or Vice President shall provide appropriate guidance for documenting these types of deviations, as necessary, in the corrective action program and inform the responsible organization of the deviation/noncompliance (see paragraphs 6.9-6.11 for handling these types of deviations and noncompliances).

6.2 Errors found in documents that are being routed, circulated, or transmitted for the specific purpose of reviews and checks and for items currently being fabricated shall not be reported by means of the correction action process but, rather, in accordance with procedures governing the subject document or activity. This exclusion does not apply if the discovered error is suspected to be a defect or noncompliance as defined in this procedure.

6.3 If the Manager QA/QC Services agrees that a deviation or noncompliance is potentially 10CFR21-reportable, he shall inform the President of International Quality Consultants, Inc. or his designee as soon as practicable. The President shall be informed as to the nature of the deviation or noncompliance and the schedule for a final determination of reportability.

6.4 The Manager QA/QC Services shall then initiate an evaluation including task assignments, as necessary, to obtain detailed information about the potentially reportable deviation or noncompliance. This evaluation, which shall be documented by the completion of Form 800-1, shall be completed as soon as practicable and, in

most cases, be completed within 60 days of discovery. The date of discovery is the date on which the corrective action source document is generated.

The objective of the evaluation is to conclude with a determination as to whether or not the defect or noncompliance (failure to comply) is reportable under 10CFR21.

6.5 If the International Quality Consultants, Inc. evaluation cannot be completed within 60 days of discovery of the deviation or noncompliance, an interim report shall be submitted to the NRC describing the deviation or noncompliance and stating when the investigation will be completed. This interim report, if necessary, shall be submitted within 60 days of discovery of the deviation or noncompliance.

6.6 If the reportability evaluation is indeterminate, or if the deviation or noncompliance is determined to be reportable under 10CFR21, the President or his designee shall be informed by memorandum from the Manager QA/QC Services within the five (5) days after completion of the evaluation described above, and the Vice President shall ensure the required reports are made to the NRC.

6.7 For an indeterminate or reportable deviation or noncompliance, the Vice President or designee shall prepare and submit the required reports in accordance with 10CFR21.21(d)(3) and (4). A facsimile report shall be made within two days following notification of reportability to the President of International Quality Consultants, Inc. (per paragraph 6.6), with a follow-up written report within 30 days of the same date.

6.8 If International Quality Consultants, Inc. determines it does not have the capability to perform the evaluation to determine if a defect exists, then the purchasers and/or affected licensees must be informed in writing by the Manager QA/QC Services of the nature of the deviation or noncompliance within five (5) days of this determination so that the purchaser or licensee may perform the 10CFR21 reportability evaluation.

6.9 One copy of the 10CFR21 report (Form 800-1 and other applicable documents) shall be given to the Manager QA/QC Services and stored as a lifetime record.

6.10 The Manager QA/QC Services shall post a copy of this procedure, a copy of 10CFR21, and Section 206 of the Energy Reorganization Act of 1974 in a conspicuous location of the International Quality Consultants, Inc. premises.

7.0 EXHIBITS

7.1 IQC Employee Notification.

7.2 Form 800-1, 10CFR21 Deviation and Noncompliance Evaluation.

7.3 Part 21 Timeline, NRC Workshop on Vendor Oversight for New Reactor Construction 10 CFR Part 21: Requirements and Guidance – December 10, 2008; Page 16.

EMPLOYEE NOTIFICATION

In accordance with 10CFR21.21 (a) (2) you are required to submit written reports when any component or activity for or in a nuclear facility being constructed for or operated by IQC meets any of the following criteria:

1. The activity or component fails to comply with the Atomic Energy Act of 1954, as amended or any applicable rule regulation, order or license of the Nuclear Regulatory Commission relating to a substantial safety hazard; or

2. A deviation of a basic component delivered to IQC or its agents for use in a nuclear facility or an activity subject to the regulations of 10CFR21 on the basis of an evaluation (see 10CFR21.3 (g)) the deviation could create a substantial safety hazard; or

3. The installation, use or operation in a nuclear facility of a basic component containing a defect; or

4. A deviation in a portion of a nuclear facility subject to the construction permit or manufacturing licensing requirements of 10CFR50, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the nuclear facility containing the deviation has been offered to International Quality Consultants, Inc. or its agents for acceptance; or

5. A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limited, as described in the

Written reports pursuant to the above shall be submitted for review and evaluation to the Manager QA/QC Services.

A copy of Section 206 of the Energy Reorganization Act of 1974 pertaining to the above is copied below for your information. Copies of 10CFR21 and further information on reporting may be obtained from:

Manager QA/QC Services in International Quality Consultants, Inc., 106 Freeport Road, Butler, PA 16002

Historical records of reports and evaluations may be examined at the above address.

President

July 9, 2010
Date

¶10,721 Energy Reorganization Act 1974
P. L. 93-438, October 11, 1974, as amended by P. L. 94-385 August 14, 1976 and P. L. 95-91, August 4, 1977

(An Act) To reorganize and consolidate certain functions of the Federal Government in a new Energy Research and Development Administration and in a new Nuclear Regulatory Commission in order to promote more efficient management of such functions.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

(¶ 10,739)

NONCOMPLIANCE

SEC. 206. (a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity –

(1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or

(2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section.

10CFR21 DEVIATION AND NONCOMPLIANCE EVALUATION

BRIEFLY SUMMARIZE THE DEVIATION OR NONCONFORMING ITEM:

DATE OF DISCOVERY:

SOURCE DOCUMENT FOR DEVIATION OR NONCOMPLIANCE (E.G., AUDIT REPORT, NCR, CAR, ETC.):

NAME AND ADDRESS OF ENTITY RESPONSIBLE FOR THE DEVIATION OR NONCOMPLIANCE

I. Determination of 10CFR21 Applicability
Is the affected component hardware or the design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services associated with the component hardware, a basic component.
YES _____ NO _____
BASIS:

If the response is "NO", the 10CFR21 is not applicable to this deviation or noncompliance. The preparer and reviewer must sign this exhibit and obtain the Manager QA/QC Services concurrence signature.

II. Description of Deviation or Noncompliance
Provide a detailed description of the deviation or noncompliance as it relates to the basic component's ability to perform its safety function

III. Determination of 10CFR21 Reportability
Is the deviation or noncompliance described in Item II above a defect or failure to comply potentially involving a substantial safety hazard per 10CFR21. Pay particular attention to the definition for Substantial Safety Hazard.
NOTE: For those occasions where it is indeterminate whether a defect or noncompliance constituting a substantial safety hazard exists, consult with the Manager QA/QC Services; Vice President or other International Quality Consultants, Inc. senior management. If after discussion with International Quality Consultants, Inc. management the issue is still indeterminate and no further evaluation can be performed in a timely manner, check "YES" and report the issue to the NRC. Describe the issue as a "potential" defect or failure to comply potentially involving a substantial safety hazard in the basis below.
YES _____ NO _____
BASIS:

10CFR21 DEVIATION AND NONCOMPLIANCE EVALUATION

IV. Conclusion

The deviation/noncompliance **IS** reportable under 10CFR21

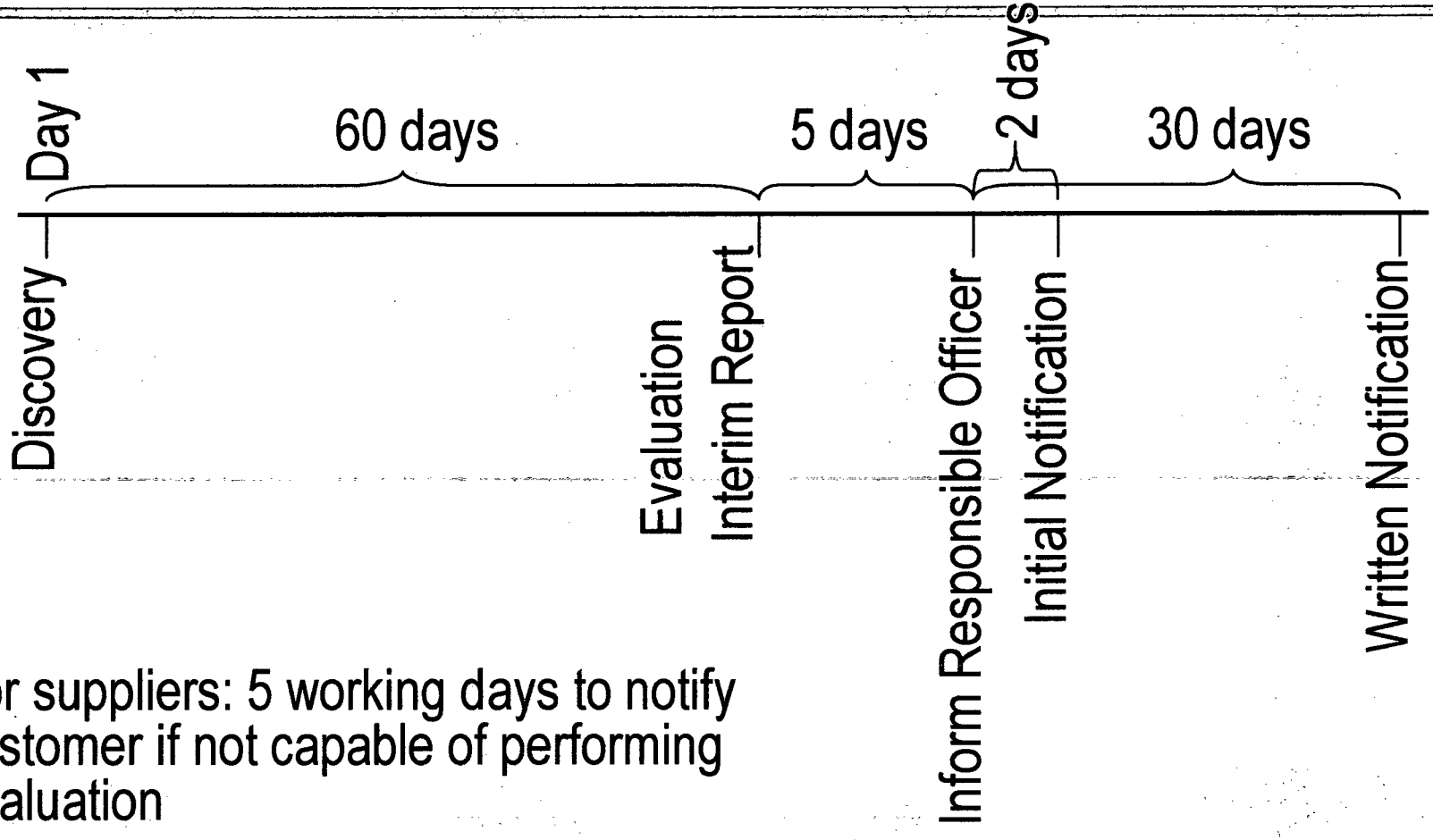
Preparer Signature/Date | Reviewer Signature/Date

The deviation/noncompliance **IS NOT** reportable under 10CFR21

Preparer Signature/Date | Reviewer Signature/Date

Manager QA/QC Services Concurrence Signature/Date

Part 21 Timeline



For suppliers: 5 working days to notify customer if not capable of performing evaluation

APPROVED: Manager QA/QC Services	Effective Date: 07/09/10	Number: IQC 2000
	Page: 1 of 6	Revision: 3

SUBJECT: CONTROL OF NONCONFORMING ITEMS

1.0 PURPOSE

To establish and document measures to identify, document, evaluate, segregate if practical, and disposition items, services, or activities which do not conform to established requirements. These controls shall be designed to prevent the inadvertent use or installation of nonconforming items or to identify a nonconforming service.

2.0 SCOPE

Any item, service, or activity which will cause adverse effect, because it does not comply with written procedures, drawings, specifications, or code requirements, should be considered a nonconforming item.

3.0 DEFINITIONS

3.1 Evaluation: The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

3.2 Nonconformance: A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

3.3 Non-Significant Condition: An observed lack of an element, procedure, or a non-fulfilled requirements, usually single incidents that do not have a significant impact on operations, quality or reliability of a nuclear facility.

3.4 Significant Condition: An observed lack of an element, procedure, or a non-fulfilled requirement, which has been used to service a nuclear facility, that could create a substantial safety hazard.

3.5 Substantial Safety Hazard: A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC.

4.0 PROCEDURE

4.1 Personnel dispositioning nonconformances shall be knowledgeable and competent in the specific area that they are evaluating.

4.2 Nonconformances shall be reviewed to determine and assign a disposition to the nonconformance. Further use of a nonconforming item shall be controlled pending an evaluation and disposition approval.

4.3 Any IQC personnel identifying a condition adverse to quality may initiate an NCR using Form 2000-1.

4.4 Disposition of a nonconforming item shall be one of the following:

a. Rework - Item can be fully restored to design configuration and characteristics through additional work.

b. Repair - Item can be restored to an acceptable condition although not in exact conformance with requirements. For Code items, repair must bring the item to Code conformance. Justification for "repair" must be attached to or referenced on the NCR.

c. Use-As-Is - Item is acceptable without any additional work, and the deviation does not affect the items functionally or Code required parameters. Justification for "use-as-is" must be attached to or referenced on the NCR.

d. Replace - Item cannot be restored to an acceptable condition.

4.5 Identification of nonconforming items shall be by use of tags, labels, stickers, or other appropriate means that are legible and easily recognizable.

4.6 Nonconforming items shall be segregated when practical; in the event physical location, etc., prevents segregation, items shall be tagged, marked or identified.

4.7 Technical justification for the acceptability of a nonconforming item dispositioned repair or accept-as-is shall be documented. Nonconformances to design requirements dispositioned as accept-as-is or repair shall be subject to the same design control as the original design. As-built records shall reflect the accepted deviation.

4.8 The NCR documentation shall identify as a minimum the following using Form 2000-1:

a. Identification of nonconforming item or service (heat number, serial number, etc.).

b. Quantity of nonconforming items.

c. The requirements with which the item is in nonconformance.

d. The assigned disposition, including appropriate instructions, procedures, and drawings necessary for completing the disposition.

e. The results of inspection following repair or rework operations.

f. Documentary evidence verifying the acceptability of non-conforming items which have the disposition of "repair", "rework", or "accept-as-is".

g. A description of the change, waiver, or deviation that has been accepted to record the change and denote the as-built condition.

4.9 The Manager QA/QC Services shall determine when an NCR numbering system shall be developed and maintained for retrieval and trending purposes.

5.0 NCR INITIATION

5.1 NCR Initiation Section A/B of NCR Form

5.2 Complete applicable parts of Section A/B on the NCR Form 2000-1. If additional space is required, use a continuation sheet that includes the NCR number and applicable section on all sheets.

a. Obtain a Nonconformance Report (NCR) number, from the Manager QA/QC.

b. Once an NCR has been initiated, submit it to the appropriate technical supervisor, or manager for dispositioning. Send a copy to the Manager QA/QC Services.

c. When the nonconforming item is a manufacturing part, tool, component, or piece, the item(s) shall be identified in the controlling document and, if practical, by tagging the nonconforming item or container with a Hold Tag that contains the following information as a minimum: (1) the NCR number, (2) the date of nonconformance, (3) the description of the nonconformance, and (4) the name of the person placing the tag.

The nonconforming item should be segregated, if possible, to await disposition.

5.3 NCR Resolution and Disposition Section C of NCR Form

a. The appropriate technical supervisor or manager will complete the following steps within 30 calendar days of initiation of the NCR. All NCRs forwarded for action shall be resolved as follows:

1. The NCR shall be reviewed to determine if an ASME Code component is affected.

2. The disposition of the condition shall be categorized as one of the following:

A. Rework - Item can be fully restored to meet requirements through additional work.

B. Repair/Reinspect - Item can be restored to an acceptable condition but repaired item may not be in exact conformance with requirements. For safety-related or ASME Code activities, NCR's stating "Repair" as the disposition, must have the repair procedure referenced or attached. Non-conformances to the ASME Code cannot be dispositioned as "Repair" unless the "Repair" brings the item back to Code conformance. Repair may require customer approval.

C. Use-As-Is - Item is suitable without rework or repair for its intended service, and its reliability and/or performance will not be affected even though the item does not conform to requirements. Justification for "Use-As-Is" must be attached to or referenced on the NCR.

Note: Nonconformances outside of the ASME Code parameters cannot be dispositioned "Use-As-Is" must be attached to or referenced on the NCR.

D. Replace - Item cannot be restored to meet requirements or to an acceptable condition.

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NOTE: After disposition has been determined, the NCR shall be forwarded to the Manager QA/QC Services. (Note: This may occur simultaneously with submittal of the NCR to the customer for approval). The Manager QA/QC Services' review shall include a review of the NCR for completeness and compliance to the procedure. The Manager QA/QC Services shall also evaluate the nonconforming condition to determine part 21 applicability. Any nonconformance report classified as a potential part 21 shall be immediately processed in accordance with Procedure IQC800.

3. Determine corrective actions required to prevent recurrence of the condition, in consultation with inspector, engineering and QA as applicable.

4. A schedule completion date is required for NCRs which are not going to be completed within thirty (30) days of NCR disposition approval.

5.4 Tag Removal

When all actions are complete for resolution of nonconforming conditions, the inspector (or responsible person) removes the hold tag or other identification from the item. For those dispositioned as "Replace", the nonconforming item is tagged or identified as "Reject" and scrapped by the responsible organization.

5.5 NCR Completion Section E of NCR Form

a. The appropriate technical supervisor, or designee verifies: (1) all of the disposition actions, (as listed in Section 2 of the NCR Form) are complete, and the above tagging steps have been completed prior to signing for completion.

6.0 FORMS/ATTACHMENTS

6.1 Nonconformance Report – Form 2000-1.

6.2 Nonconformance Report Log – Form 2000-2.

7.0 PROCEDURE REFERENCES

7.1 Quality Assurance Manual, Section 15.0.

7.2 Procedure IQC800 Reporting of Defects and Noncompliances per 10CFR21.

International Quality Consultants, Inc.

NONCONFORMANCE REPORT

A. Title Block

NR NO: _____ **P.O. NO.:** _____ **DATE:** _____

PROJECT: _____ **CUSTOMER:** _____

VENDOR: _____ **LOCATION:** _____

DWG./SPEC./DOCUMENT REFERENCE: _____

ITEM DESCRIPTION: _____

B. Description of Nonconformance:

_____ _____
Originator **Date**

C. Recommended Disposition: ☐ **Repair** ☐ **Rework** ☐ **Use-As-Is**
Explanation:

Corrective Action: _____

_____

Drawing Revision Required: ☐ Yes ☐ No Customer Approval: ☐ Yes ☐ No

Technical Supervisor/Manager: _____ Date: _____
Signature

D. Management Review

Part 21 Applicability ☐Yes ☐No ☐N/A
(Ref. IQC800)

_____ _____
Manager QA/QC Services Date

E. Customer Approval Block (if checked "yes" by IQC, Inc. Engineer in Block C, submit to customer for concurrence):

_____ _____ _____
Customer Signature Title Date

☐ **Approval, No Change** ☐ **Approved with Correction Proposed** ☐ **Other (see attached)**

F. Verification:

Corrective Action Completed By: _____ Date Completed: _____

Corrective Action Verified By: _____ Date Completed: _____

NONCONFORMANCE REPORT LOG

N.C.R. NO.	DATE	DEFICIENCY	RESPONSE			DATE CLOSED	INITIALS
			Due Date	Accept.	Not Accept.		

APPROVED: Manager QA/QC Services	Effective Date: 07/09/10	Number: IQC 4000
	Page: 1 of 3	Revision: 1

SUBJECT: CORRECTIVE ACTIONS

1.0 PURPOSE

1.1 To establish measures for identifying, reporting and correcting conditions adverse to quality and to establish the measures for identifying significant conditions adverse to quality as well as the necessary corrective action(s) required to rectify such conditions.

2.0 SCOPE

2.1 Any internal or external audit findings, observations, recommendations; additionally, customer complaints and identified trends which are adverse to quality shall be processed in accordance with this procedure.

3.0 DEFINITIONS

3.1 Corrective Action: Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

3.2 Evaluation: The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

3.3 Non-Significant Condition: An observed lack of an element, procedure, or a non-fulfilled requirements, usually single incidents that do not have a significant impact on operations, quality or reliability of a nuclear facility.

3.4 Significant Condition: A condition adverse to quality is one which, if uncorrected, could have a serious effect of safety or operability.

3.5 Substantial Safety Hazard: A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC.

4.0 PROCEDURE

4.1 When conditions that are adverse to quality are identified by internal audits, external audits, customer complaints and/or trends, a Corrective Action Report (Form 4000-1) will be initiated by the person who identified the condition. It will be reviewed and controlled by the Manager QA/QC Services, or his designee.

4.2 A Corrective Action Report shall be limited to a single adverse condition and shall include sufficient details to describe the deficiency. Supporting evidence, if appropriate, shall be provided and attached to the Corrective Action Report by the initiator. All Corrective Action Reports will be sent to the Manager QA/QC Services

for review, evaluation and logging on the Corrective Action Report Log (Form 4000-2).

/1 4.3 The Manager QA/QC Services, or designee, will review the Corrective Action Reports' deficiency description and applicable supporting evidence for clarity, completeness and concurrence that the deficiency requires corrective action. If corrective action is determined to be necessary, immediate corrective action required shall be documented and assigned to the responsible authority. Additionally, during the Manager QA/QC Services, or designee review, the Corrective Action Report will be reviewed for part 21 and root cause evaluation applicability.

/1 4.4 For conditions adverse to quality determined to be reportable under part 21, the root cause of the condition, and the corrective action to preclude repetition, shall be determined, documented, and recorded on Correction Action Report (Form 4000-1). Root cause evaluations shall be determined by the review of problem definition, data collection, potential organizational breakdown, procedure deficiencies, etc., as applicable.

NOTE: Any Corrective Action Report classified as a potential part 21 condition shall be processed in accordance with IQC, Inc. Procedure IQC800.

4.5 Once the corrective action is completed, the assigned authority will sign and date the corrective action, indicating completion and return the form with any applicable supporting documentation to the Manager QA/QC Services.

4.6 The Corrective Action Report will then be reviewed by the Manager QA/QC Services. If the indicated corrective action is determined to be acceptable, the Manager QA/QC Services, or designee, shall take appropriate steps to verify implementation and adequacy of implementation. The report is then signed and dated to signify verification. The active file on this particular deficiency shall then be closed out.

NOTE: If the indicated corrective action is determined to be unacceptable, no verification signature shall be entered on the Corrective Action Report. Specific details for nonacceptance shall be provided or attached to the Corrective Action Report and the report closed out as being not satisfactory. A new Corrective Action Report shall be issued and processed per this procedure.

After completion, the Corrective Action Report will be filed in accordance with Section 17.0, with copies distributed to appropriate personnel.

5.0 FORMS/CHARTS/ATTACHMENTS

5.1 Form 4000-1 – Corrective Action Report.

5.2 Form 4000-2 – Corrective Action Report Log.

6.0 PROCEDURE REFERENCES

6.1 IQC800 – Reporting of Defects and Noncompliances per 10CFR21.

CORRECTIVE ACTION REPORT

1.
DATE: _____ C.A.R. NUMBER: _____

TO: _____ Part 21 Applicability: □ Yes □ No □ N/A (Ref. IQC800)

2. DEFICIENCY: (Include supporting documentation or other evidence, if applicable - use and reference additional sheets, as required)

INITIATED BY: _____ REVIEWED BY: _____

DATE: _____ DATE: _____

3. CAUSE: (state the cause of a significant deficiency – use and reference additional sheets, as required.

4. CORRECTIVE ACTION: (state corrective action taken to resolve the deficiency and to prevent recurrence - use and reference additional sheets, as required)

COMPLETED BY: _____ REVIEWED BY: _____

DATE: _____ DATE: _____

5. **ACCEPTANCE AND VERIFICATION OF CORRECT ACTION:** (state whether or not the specified corrective action is acceptable. Provide details for any nonacceptance. Include need for modified corrective action or implementation of the corrective action originally specified. Verification to be signed only when specified corrective action has been determined to be acceptable and has been adequately implemented. Use and reference additional sheets, as required.)

REVIEWED BY: _____ VERIFIED BY: _____

DATE: _____ DATE: _____

CORRECTIVE ACTION REPORT LOG

C.A.R. NO.	DATE	DEFICIENCY	RESPONSE			DATE CLOSED	INITIALS
			Due Date	Accept.	Not Accept.		

Exhibit 5
Reference Only

IQC, Inc.

TRAINING ATTENDANCE LOG

THE FOLLOWING PERSONNEL ATTENDED TRAINING CONDUCTED BY JEFFRY S. THOMPSON
NAME

MANAGER OF QA/QC SERVICES, ON 7/12/2010 FOR PERIOD 2 HOURS
TITLE DATE TIME

TOPICS COVERED INCLUDE: QA/QC PROCEDURES MANUAL REVISION 25 / 10 CFR PART 21 REPORTING AS ADDRESSED IN IQC800 REV. 8, IQC2000 REV. 3 & IQC4000 REV. 1

(INSTRUCTOR MAY ATTACH OUTLINE OR COURSE MATERIALS)

NAME	SS NO.	NAME	SS NO.
Paula Moon	ON FILE		
(Thomas J. Pasaba)			

REMARKS: