ISO 9001 Assessment # «AUDITID»
Confidential Report

Centro de Investigacion en Materiales Avanzados S.C
Miguel de Cervantes No 120
Complejo Industrial Chihuahua, 31109
Cert # «CERT»

Start	End	Audit Type
08/30/2010	08/31/2010	Re-regisration

Total audit days: 2.5

Report Prepared by:	Date:

COMMERCIAL- IN – CONFIDENCE

The contents of this report must not be disclosed to a third party without the agreement of the AQA Client

DISCLAIMER:

This report has been prepared by AQA International (AQA) in respect of a Client's application for assessment by AQA. The purpose of the report is to comment upon evidence of the Client's compliance with the standards or other criteria specified. The content of this report applies only to matters, which were evident to AQA at the time of the audit within the audit scope. AQA does not warrant or otherwise comment upon the suitability of the contents of the report or the certificate for any particular purpose or use. AQA accepts no liability whatsoever for consequences to, or actions taken by, third parties as a result of or in reliance upon information contained in this report or certificate.

AQA International
501 Commerce Drive NE
Columbia, SC 29223 USA
www.aqainternational.com

800 281 4384 ph
803 779 8109 fax

1. Client Information

Contact Information	Total Emps: 50»		Audit Standard: ISO 9001:2008	AIC Code: K.74.00
Julio Fierro	Surv Freq: 12	Days Req'd: 1.5	Phys Location: Miguel Cervantes # 120	Accred: ANAB
Ph: 01 614 439 11 16			Registration: «REG_DATE»	Exp: «EXP»
Fax: «FAX»				
Email: julio.fierro@cimav.edu.mx				

Shifts: Emp. Count:

Scope:
«SCOPE»

Additional Information about Company's Processes and/or Specific Expertise*:*
The auditor should describe the organization's capability include the following value added activities in product realization: (Example: Warp knit, beam dye, jet dye and pad dye, tenter frame, cutting & roll up, packaging or welding, stamping, painting, etc.)

Additional Locations Audited:

Major Business Sectors/Markets:	
Key customers:	

Notes:

Auditor to Enter any Changes to Planned Data (e.g. Client Information, Shift, Scope, Key Customers, Etc.) in the Below Table
Justification must be included for increased audit days required due to an increase in employees that were not performed.

Audit History:

Audit #	Audit Type	Target	Start	End

Auditor to enter and highlight start date and end date for the next audit

Composition of Audit Team:

Client Relations Manager: «PGMCOORD»

2. Opening Meeting

The following were reviewed during the opening meeting:

- Introductions
- Review of cover sheet and client information.
- Audit based on quality manual, documented quality system, and the standard / requirements.
- This audit is confidential. Only AQA's accreditation and approval bodies (ANAB, IATF for TS16949 and AAQG/FAA for A9000/AS9100) may review AQA audit reports.
- The goal of the audit is not to identify nonconformities but to find sufficient evidence of conformance with the QMS, and that the QMS addresses all clauses of the standard. Please help the auditor find the evidence that is needed.
- Activities will be observed, employees will be interviewed, and records and documentation will be requested.
- Consultants may be present but may not participate in the audit.
- The established audit schedule will be maintained as closely as possible.
- End-of-day meetings (if applicable) are scheduled with the Management Representative for discussion of the findings.
- If a nonconformance is identified, it will be documented. Please consider it an opportunity to improve your quality management system.
- A ***Minor*** nonconformance is a nonconformance that judgment and experience indicate is not likely to result in the failure of the quality system or reduce its ability to assure controlled processes or products. It may be either:
  - A failure in some part of the supplier's documented quality system relative to a requirement; or
  - A single observed lapse in following one item of a company's quality system.
- A ***Major*** nonconformance is either:
  - The absence or total breakdown of a system to meet a requirement. A number of minor nonconformities against one requirement can represent a total breakdown of the system and thus be considered a major nonconformance; or
  - Any nonconformance that would result in the probable shipment of a nonconforming product. A condition that may result in the failure or materially reduce the usability of the products or services for their intended purpose; or
  - A nonconformance that judgment and experience indicate is likely either to result in the failure of the quality system or to materially reduce its ability to assure controlled processes and products.
- If a ***major*** nonconformance is identified your Management Representative will be advised immediately to determine the next step.
- An ***Opportunity for Improvement*** may be identified during the audit. It will be documented but is not a nonconformance to a requirement and requires no response.
- The audit team will make one of the following recommendations (except for preassessment and phase I conformance audits):
  - **Recommendation To Register or To Maintain Registration.**
  - **Unable To Make A Recommendation At This Time - Follow-up Audit Required.**
  - **Recommendation Not To Register or Not to Maintain Registration.**

  These are audit team recommendations. AQA's Registration Committee shall make the final decision after corrective actions to all nonconformities are submitted and approved.
- Copies of the nonconformities and audit team recommendation will be left with you at the closing meeting.
- Review of site safety and emergency procedures relevant to the auditors.

3. Stage 1 Audit Results (if applicable)

☐ All issues from the Stage 1 audit closed

If NO, then describe actions that will be taken to close any remaining open issues.

4. Audit Summary:

The purpose of this audit is to evaluate the implementation and effectiveness of the Quality Management System (QMS) including evaluation of conformity to the requirements of ISO 9001.

The audit was planned and conducted based on the organization's defined processes in accordance with the audit plan.

The auditor should describe specific audit trails developed (part numbers, etc.) and any significant deviations from the audit plan.

The audit began with an opening meeting to verify the audit scope, audit criteria, and audit objectives as well as review any changes to Client Information, Policy Manual and Procedures.

The auditor should note any changes and discuss potential impact on certification

A process audit was performed through the defined core processes with assessment of linkages to management and support processes as described in section 8 of this report.

5. Effectiveness of the Management System

The QMS is judged to consistently deliver products that meet requirements, achieve customer satisfaction, and continually improve except as noted in this report.

The auditor should address commitment and management involvement.

La alta dirección había comunicado que, debido a la rapidez con que se tuvo que programar la auditoría, no era posible atenderla debido a un viaje programado, por lo que las áreas relacionadas con la dirección general, participaron el director administrativo y el representante de la dirección.

El área que se encontró con evidencia de un compromiso más débil basado en los hechos y resultados anotados en la sección 6 de este reporte, estuvieron asociados a la dirección de vinculación, en donde no estuvo presente el director correspondiente y los resultados no muestran el compromiso que se debe tener con el sistema de calidad. Ejemplos de ellos fue la acción preventiva aceptada y cerrada en dicha área con una estructura y análisis muy débil (véase la no conformidad MM-03) y el objetivo incumplido no generó una acción (Véase MM-01). Tres de las cuatro no conformidades detectadas en esta auditoría se relacionaron con dicha área. Igualmente el análisis de satisfacción del cliente muestra oportunidades de mejora, dado que no se obtiene información dirigida hacia la identificación de las áreas débiles de la organización.

Por otra parte, en información de diferentes responsables de laboratorio, coincidieron en que la mayor debilidad que presenta el sistema de gestión de la calidad para ser eficaz es la asignación o falta de recursos.

5.a. Customer satisfaction

The auditor should discuss how customer satisfaction is determined and the results obtained. The auditor should include review of any customer scorecards

El cliente muestra satisfacción en los parámetros en que es evaluado. Se cuenta con una encuesta trimestral y se analizaron los resultados a partir del último trimestre del 2007 a la fecha. Los resultados indican mejora continua al comparar resultados del último trimestre del 2007 a la fecha, en donde se observaron los puntos más altos de satisfacción.

5.b. Performance on quality objectives/targets:

Current Quality Objective/Targets	*Actual Performance*
Calificación promedio en el sondeo de satisfacción de clientes en 9.10	9.40
100% de los usuarios capacitados en el software utilizado para el control de documentos	100% capacitados

Relación entre cotizaciones presentadas a los clientes y las cotizaciones aceptadas igual o mayor a 72%	2009 se obtuvo un 70.12% (Ver NCR MM-02)

The auditor should discuss how effective the system is performing (i.e how well it is meeting its quality objectives/ targets) and actions being taken for targets and objectives that are not performing as well as desired.

La mayor parte de los objetivos establecidos cuentan con evidencia de su cumplimiento. En el caso en el cual se detectó un incumplimiento, se generó una no conformidad debido a que no se encontró evidencia de que se tomaran las acciones pertinentes (Véase MM-01).

El sistema muestra importantes contrastes, por un lado la organización está dirigida hacia sectores con un alto nivel de exigencia en el desempeño, pero por otro lado se encuentra administrada bajo una serie de normas requeridas en el sector público pero que le restan capacidad para responder a los requerimientos de los clientes de manera eficaz y oportuna. Ejemplos de ellos son los períodos vacacionales que no coinciden con los requerimientos de clientes. Otro ejemplo de ello, son las fechas en que sus equipos patrón son enviados a calibración y que coincide con la disponibilidad de partidas presupuestales del CIMAV pero que desatiende las necesidades de los clientes. Por esta razón, se detecta como una debilidad, el enfoque en el cliente, no necesariamente del CIMAV por sí mismo, sino del sistema que lo administra y que incluye la toma de decisiones fuera del alcance, incluso fuera del mismo CIMAV, como la Secretaría de la Función Pública.

5.c. Continual improvement:

The auditor should discuss if the system drives continuous improvement.

La mejora continua a través del uso de objetivos no pudo ser probado contundentemente. La variabilidad mostrada en las gráficas, dada la ausencia de una metodología más adecuada por parte del CIMAV en el análisis de la información del cliente, se observa basada en variación normal sin evidencia de una tendencia positiva.

5.d. Management review

The auditor should discuss if the management review determined the QMS to be suitable, adequate and effective.

Se realizan revisiones anuales e incluye todos los requisitos marcados por la norma. La revisión por la dirección se efectúa después de que han sido concluidas las auditorías internas.

5.e. Internal audit

The auditor should address the effectiveness of the internal audit process as determined by qualification/skill of the auditors, depth of audits, achieving schedule, timely reaction/verification and robustness of the QMS.

La última auditoria se realizó en los meses de mayo a agosto del 2010, cubriendo todos los procesos del sistema. Se cuentan con 30 equipos de auditores internos, calificados. Debido a que la organización cuenta con personal competente en base a experiencia (el procedimiento indica que para ser auditor lider debe haber participado en al menos 4 auditorías). Los expedientes verificados de auditores internos mostró evidencia de cumplimiento.

Se detectaron 4 no conformidades en la última auditoria interna, de las cuales fueron revisadas tres de ellas, dos de las cuales mostraron evidencias de ser eficaces. Una no mostró capacidad

5.f. Corrective and preventive action

The auditor should discuss which ca/pa were reviewed and if they were according to procedures and ISO 9001. The auditor should address the effectiveness of the ca/pa process as determined by frequency of use, substance of problems/ root cause determination/ corrective actions, timeliness and repeat problems

NC 4- generada en auditoria interna. La fecha de efectividad y período de efectividad vencido. Se agregó una columna a la lista maestra de documentos para identificar las fechas de vencimiento de vigencias. Se encontró eficaz en el área de calidad.

The auditor should discuss customer complaints reviewed and the effectiveness of the customer complaint and resolution processes

5.g. Process Linkages

The auditor should assess the overall effectiveness of interactions and linkages between processes of the management system

If other locations were audited, the auditor must assess linkages and interactions between locations:

6. Audit Results

6.a. The following strengths were identified:

- Los laboratorios de microscopía, pruebas térmicas, pruebas mecánicas y residuos tienen procedimientos claros y controles eficaces.
-

6.b. The following weaknesses were identified:

- Enfoque al cliente. Eficacia de las acciones.

6.c. Opportunities for Improvement

The audit team identified and reported the following opportunities for improvement without recommending specific solutions for correcting the opportunity. No response from the client is required.

Each OFI must be stated so that they clearly do not appear to be a nonconformance

1. Ayudaría estructurar el análisis de datos para que ayude más fácilmente a identificar las áreas susceptibles de aplicar la mejora.
2. Los datos de satisfacción del cliente muestran variabilidad sin evidencia de una mejora. Ayudaría establecer métodos que tengan un impacto más claro en los niveles de satisfacción del cliente.
3. Los registros de calibración en el área de rayos X – el reporte no indica los resultados.
4. Ayudaría que los usuarios del servicios (CIMAV) participará directamente en la evaluación de proveedores dado que son los que reciben directamente el servicio de los mismos.
5. Ayudaría que se aseguraran de generar un método de respaldo para la información electrónica.

6.d. During the Audit, the audit team identified:

Major Nonconformities	0	Minor Nonconformities	4

NCR # MM-01 ☐ Major ☒ Minor ☒ Corrective action plans to be submitted within 30 days.
☒ Evidence of Implementation required with corrective action response

Requirement (Statement of, or reference to, specific requirement in standard and/or customer document):

4.1 Se deberán implementar las acciones necesarias para lograr los resultados planificados y la mejora continua de los procesos.

5.4.2 La planificación del sistema de gestión de la calidad debe ser llevado a cabo con el fin de cumplir con los requisitos así como con los objetivos.

Nonconformance (Statement of nonconformance to above requirement):

No se encontró evidencia de acciones cuando se incumplen con los objetivos

Objective Evidence (Statement of, or reference to, examples/evidence): .

El objetivo de cotizaciones aceptadas contra cotizaciones presentadas es del 72, el logro 2009 fue 70.12 y no se encontraron acciones.

NCR # MM-02 ☐ Major ☒ Minor ☒ Corrective action plans to be submitted within 30 days.
☒ Evidence of Implementation required with corrective action response

Requirement (Statement of, or reference to, specific requirement in standard and/or customer document):

7.6 Cuando sea necesario asegurar resultados válidos, el equipo de medición deberá ser calibrado o verificado o ambos, a intervalos definidos o antes de su uso comparándolo contra estándares trazables a normas nacionales o internacionales.

Nonconformance (Statement of nonconformance to above requirement):

No se encontró trazabilidad en un servicio ofrecido por el laboratorio de calidad del agua.

Objective Evidence (Statement of, or reference to, examples/evidence):

Se dio seguimiento al servicio 10/0522 para el laboratorio de calidad del agua.

En laboratorio de calidad del agua, no se encontró trazabilidad en los servicios ofrecidos ya que no se registran ni se lleva un método de control en los equipos utilizados en los procesos de medición.

En sus mediciones se encontró el uso de un equipo no calibrado (Método Hach). En información del representante del fabricante en México, se explica que el equipo es obsoleto y que por ello no es posible calibrarlo y ofrece un método alterno para probar si el equipo se encuentra funcionando adecuadamente. La carta fue emitida en el año 2004 sin que hubiera acciones posteriores por parte de CIMAV.

NCR # MM-03 ☐ Major ☒ Minor ☒ Corrective action plans to be submitted within 30 days.
☒ Evidence of Implementation required with corrective action response

Requirement (Statement of, or reference to, specific requirement in standard and/or customer document):

8.5.3 Las acciones deben ser apropiadas a los efectos de los problemas. A) se deben determinar las no conformidades potenciales y sus causas.

Nonconformance (Statement of nonconformance to above requirement):

No en todos los casos las acciones son apropiadas a los efectos y no se determinan las causas de las no conformidades de manera eficaz.

Objective Evidence (Statement of, or reference to, examples/evidence):

No se identificó la causa de la no conformidad en la acción #2 del área de vinculación. El análisis de causa repite el problema “el cliente no recibió a tiempo el informe de resultados”. La acción se generó como preventiva, sin embargo surgió de insatisfacción de un cliente. La acción tomada solo involucró “llamar la atención al responsable del servicio”.

NCR # NJ-01 ☐ Major ☒ Minor ☒ Corrective action plans to be submitted within 30 days.
☒ Evidence of Implementation required with corrective action response

Requirement (Statement of, or reference to, specific requirement in standard and/or customer document):

6.2.2 – e) – La organización debe mantener los registros apropiados de la educación, formación, habilidades y experiencia,

Nonconformance (Statement of nonconformance to above requirement):

No en todos los casos se encontraron los registros de personal con efecto en la calidad.

Objective Evidence (Statement of, or reference to, examples/evidence):

Cecilia Miranda del área de vinculación, a cargo del proceso de encuestas al cliente, no cuenta con registros en CIMAV que identifiquen su competencia.

Nonconformities shall be addressed through the client’s corrective action process, including:

1. Actions taken to determine the extent of and contain the specific nonconformance.
2. Root Cause (results of an investigation to determine the most basic cause(s) of the nonconformance.)
3. Actions taken to correct the nonconformance and, in response to the root cause, to eliminate recurrence of the nonconformance
4. Corrective action response shall be submitted to the AQA lead auditor
5. Client must maintain corrective action records, including objective evidence, for at least three (3) years.

AQA will follow up on *all* nonconformities at the next audit to confirm the effectiveness of corrective actions.

6.e. Verification of Effectiveness of Corrective Actions in response to Previous Nonconformities

The auditor should state that the effective implementation of all corrective actions for all nonconformities from the previous audit were verified or describe any anomalies or problems, for example. "Corrective actions for nonconformities W-02 through W-05 from the October 17, 2003 audit were verified as being effectively implemented. Major Nonconformance W-01 was not able to be completely verified and major nonconformance H-03 was initiated during this audit"

No se identificaron no conformidades en la auditoria anterior llevada a cabo por el cuerpo de certificación TUV.

6.f. Complaints

If complaints from customers or others were forwarded by AQA to the auditor for investigation, the auditor should include a description of the results of the investigation.

No se recibieron quejas de cliente ante AQA.

6.g. Lead Auditor Recommendation

☐ **Recommendation To Register or To Maintain Registration (Upon closure of Nonconformities if applicable).**

☐ **Recommendation NOT To Register or To Maintain Registration**

☐ **Unable To Make A Recommendation At This Time - Follow-up Audit Required.**
All requirements are addressed, however, there is insufficient evidence that the system is effectively implemented or the number of nonconformities indicates a lapse in the maintenance of the quality management system

Comments/Provisions:

La respuesta a las no conformidades junto con evidencia de implementación deberán ser presentadas a más tardar el 20 de septiembre del 2010. De no hacerlo se corre el riesgo de que se invalida esta auditoria junto con sus resultados.

6.h. ***AQA APPEAL PROCESS*:**

Any client may dispute any decision made by AQA and file a complaint against that decision Such complaints must be in writing and will be subjected to AQA's procedure for handling appeals and disputes, P- 170 Appeals. If AQA management fails to resolve the issue internally to the client's satisfaction, the issue will be reviewed by AQA's Advisory Board. If AQA's Advisory Board fails to resolve the issue, it will be taken before the American Arbitration Association to gain final resolution.

7. Closing Meeting

Audit results in Section 6 of this report were reviewed during the closing meeting.

8. Audit History

PROCESSES EXAMINED	**INITIAL STAGE 2 OR RE-REG**	**SURVEILLANCES**					**NCR HISTORY**
		6 Month					
		9 Month					
		12 Month					
		1	**2**	**3**	**4**	**5**	
	Date						
CORE PROCESSES (sometimes referred to as customer oriented processes) Note: The processes listed must match the Organization description of processes on F-019.							
SUPPORT PROCESSES: Note: The processes listed must match the Organization description of processes on F-019							
MANAGEMENT PROCESSES: Note: The processes listed must match the Organization description of processes on F-019							

- "X" indicates processes audited. Matrix to be updated by auditor after each audit.
- "X" to be replaced by number of major nonconformances (_M) and minor nonconformances (_m). Example 1M, 3m =1 major and 3 minor.
- "R" indicates processes auditor recommends to be assessed during next audit
  Re-reg to evaluate the overall continuing effectiveness of the Organization's management system. Processes with history of nonconformities must be assessed to ensure that corrective actions taken has been effective to preclude recurring noncompliances)

8.a. Surveillance history Review (Re-registration)

☐ All processes have been audited during surveillance cycle

☐ No systemic problems are evidenced by review of the audit history for the registration period

If either of the above boxes is not checked, describe how this was addressed in audit planning.