Consultation

Chaaban, Bill

CEN Biotech Inc.

PRE-LICENCE INSPECTION REPORT

A. SCOPE

Licence Applicant Site Inspection under the *Marihuana for Medical Purposes Regulations* (MMPR) section 9.

B. PROPOSED SITE INFORMATION

Applicant's Name: CEN Biotech Inc.

Address: 20 North Rear Rd., Lakeshore ON N0R 1K0

Mailing Address: Same as above

File Number:

Other Licences:

CDS: Not applicable

Other: Not applicable

C. INSPECTION DETAILS

Inspection Start Date:	2014-07-31	**Exit Interview Date:**	2014-07-31
Licence Applicant Status:	Pre-licence	Initial Application	

D. INSPECTION TEAM

Lead Inspector:

Inspector(s):

Observer(s):

E. PROPOSED ACTIVITIES

ACTIVITIES WITH MARIHUANA		ACTIVITIES WITH CANNABIS, OTHER THAN MARIHUANA	
Possession	☒	Possession	☐
Sale or Provision	☒	Sale or Provision	☐
Shipping, Transportation and Delivery	☒	Shipping, Transportation and Delivery	☐
Destruction	☒	Destruction	☐
Production	☒	Production	☐

Maximum Quantity of Dried Marihuana to be Produced:	600,000 kg
Production Period:	Annually

F. DESIGNATED PERSONNEL

Senior Person in Charge (Senior PIC): Mr. Bahige Bassem Chaaban

Title: President and CEO

Tel.: Email:

Responsible Person in Charge (RPIC): Mr. Bahige Bassem Chaaban

Title: President and CEO

Tel.: Email:

Proposed Schedule - Hours and days at site: Monday to Friday 0700 to 1700

Alternate Responsible Person(s) in Charge (A/RPIC): Mr. Donald Strilchuck

Title: Director of Corporate Security

Tel.:

Proposed Schedule - Hours and days at site: Monday to Friday 0700 to 1700

Signing Authority (name and title):

1.
2. Mr. Wissam Alawieh
3. Mr. Bahige Chaaban

G. INSPECTION FINDINGS

1. Site:

Company profile

The applicant, CEN Biotech Inc., intends to grow, harvest and distribute medical marijuana at their facility located in Lakeshore, Ontario. The facility is situated in close proximity to the Essex County OPP detachment.

Description of site

The site is located on a six acre rural property with access to main roads and major highways. The proposed facility is approximately 25000 square feet. There are three buildings located on the property. Building 1 will house the growing rooms (pods) and the vault, building 2 will be used as an office/administrative building and building 3 will be used for storage of documents/equipment. There is a restricted road on the property which separates the site from the adjacent OPP detachment property. The roof of the proposed facility consists of solar paneling which provides green energy under contract to Hydro One.

Number of employees

There are three full time employees on staff; the applicant will hire additional staff based on company requirements. All new employees will be subject to criminal background checks as a condition of employment. The company also intends to conduct annual background checks for all employees at the site.

Business hours of operation

The applicant's main business hours will be Monday to Friday, 0800 – 1600. The company indicated that if their licence application is successful business/staff hours may be adjusted based on business needs.

2. Security Measures:

2.1 Site Security

Perimeter Security

The outer perimeter of the site is surrounded by a 12 foot chain-link security fence that is topped with razor ribbon. There are numerous signs on the exterior of the fence and building indicating "Private Property-No Trespassing". The site is accessed through one main gate that is monitored by an on-site security guard service. There is a sally port at the main entrance which will be used to ensure that vehicles cannot get within close proximity of the facility without authorization. All visitors at the site are required to sign in/out at the guardhouse and must be on the approved visitors' list. No visitors or deliveries will be allowed on the site without an appointment.

There is one main entry point to the facility for employees and visitors. Employees are required to present a proximity key card and enter a unique personal identification number to enter the facility. There is a security guard station at the entrance to the building where medical marijuana activities will take place. All visitors are required to sign in/out of the building and must be accompanied by an employee at all times while on site.

All integrated equipment, monitoring systems and monitoring stations are certified and ULC listed. All equipment and equipment controls operate 24 hours per day and 7 days per week.

The alarm monitoring company for the site is Reliance Protectron located in Windsor, Ontario. Any tampering with the security system, the system controls, the systems lines or noted unauthorized attempt or actual intrusion to the site perimeter or facility will immediately alert the ULC listed monitoring station, onsite guards, the Senior Person in Charge/Responsible Person in Charge, Corporate Security Director and local police and/or fire departments. Records will be kept of any detected unauthorized entry (recording of: the date, time of the occurrence; and the measures taken in response to it).

All Video Surveillance Control Systems, Networking/Head-In Equipment and Network Video Recorders are housed within a secure room that requires authorized personnel swipe a proximity card and enter a personal identification number to enter.

The exterior cameras provide continuous monitoring of the perimeter. All exterior CCTV cameras were equipped with day/night function. The company confirmed that any attempted or actual unauthorized entry will be recorded and responded to as required under Sec. 45(2) of the MMPR. During the inspection the company indicated that visual recordings of the site perimeter will be retained for a period of at least two years as required under Sec. 142(a) and 148(2)(e) of the MMPR.

The following security features were verified during the inspection:

- Security alarm contacts on all doors (main doors)
- Motion detection sensors
- Alarmed gate to enter the site with security guard at gatehouse
- 8 foot chain-linked fence topped with 1 foot of barbed ribbon wire surrounding exterior of site
- Fencing and gates high security key control to ensure that only authorized entry available
- 24/7 CCTV continuous recording coverage with alarm interface of all building outdoor perimeter areas (12 cameras with remote viewing capabilities)
- 24/7 CCTV continuous recording coverage with alarm interface of all building indoor areas (21 cameras with remote viewing capabilities)
- Main facility Video surveillance for exterior of the facility includes day and night fixed dome network cameras with light sensitivity
- Exterior electrical lighting covering the entire circumference of the property
- Exterior signage stating that it is private property or a restricted area and that unauthorized access is prohibited

The security system is tamper proof any type of interference with the system will create an alarm condition. In the event of either alarm activity or tampering activity the system provides the following notification methods:

- Alarm/tamper transmission to the monitoring station via GSM/IP transmission with battery back-up

- Notification of Guard Response personnel and local police authorities by monitoring station
- Notification of client's emergency contact list via telephone by monitoring station
- Alarm/tamper transmission to client designated staff via immediate email alerts including alerts of CCTV activity in the area of the alarm condition

During the inspection an alarm challenge test was conducted and the associated alarm event reports were reviewed and found to be satisfactory. The CCTV camera fps was set to 7; the inspection team requested that all cameras at the site be adjusted to meet the suggested requirement of 24 fps.

Note: The Reliance Protectron representative indicated that the maximum fps for the types of cameras used on site was 15 fps. The camera playback features was demonstrated during the inspection and the frame rate provided a smooth video stream based on this demonstration the 15 fps appears to be satisfactory.

The entranceways are equipped with and monitored by the following intrusion detection and monitoring equipment:

- Commercial door monitoring contacts (3 external, 9 internal)
- Motion Detectors (12 internal)
- Panic button
- DSC LCD display arm/disarm touchpad for Main Entrance and Security Office
- Reinforced doors
- External siren strobe combination unit

ACCESS CONTROL ENTRY AND EXIT AUTHENTICATION

Access to the facility is through card access reader panels with full access control for "read in" and "read out" for entry ensuring full reporting of all individuals entering and exiting the secured area. The interior video management system design ensures coverage of 100% of the facility, including the entry and egress of all doors throughout the secured site. The system includes:

- Key card and PIN touchpad reader that can only be unlocked by individuals who possess both a valid proximity card and a matching PIN
- Each proximity card and its corresponding PIN is specific to an individual user and a record is kept of each time any given user accesses any key card/PIN reader equipped door
- Automated reporting to the site administration for all entry and exit tracking
- Remote alarm and video access for administration control and easy remote alarm management
- Emergency egress doors are equipped with local alarms and managed by intrusion alarms to ensure that opening of these doors during operational hours or evening hours will immediately alert security personnel.

Note: A sample access log from a card reader was reviewed with the applicant. The log contained the full name (first and last) of the individual who accessed the area, the date and time.

The security access control system and video management system are IP-based technology with anti-tampering detection and contain the following components:

1) A centralized server with remote switches
2) Conduit infrastructure and network cabling throughout the facility;
3) A secured location for all controller and power supplies
4) UPS back-up system (1 hour), and a back-up diesel generator onsite

2.2 Restricted Access/Supervision

Areas where cannabis is present contain the following security and detection elements:

- Steel doors with steel frames
- Commercial door contacts connected to the site intrusion detection system
- Motion Detectors
- 24/7 visual monitoring by indoor cameras with day/night resolution
- Key card/PIN touchpad readers

As per section 46 (1), (2) and (3) of the MMPR the applicant has implemented an electronic card access system for the facility. The proximity card/PIN touchpad readers in the restricted areas require both an active authorized proximity card and matching PIN. All accesses (entry and exit) are automatically recorded and stored indicating each specific user's identity by way of card detection. Only those individuals whose presence is required for work tasks will be granted access to restricted areas.

All authorized access as well as any unauthorized attempts to enter restricted areas are recorded on the CCTV camera system and stored on company servers along with the date, time and individual who had access.

During non-business hours, when the intrusion detection system is fully armed, motion sensors are armed to detect any movement beyond each access point, throughout the facility and/or immediately below the roof. All systems will be monitored 24 hours/7 days by Reliance Protectron Security who have been informed as to the appropriate steps to be taken in response to the detection of any illicit or unauthorized access or movement within such areas.

The applicant indicated that access to the area where cannabis is present will be restricted. Also, each time a restricted area is entered or exited the interior cameras records the individual who is entering or exiting the area. The RPIC or the A/RPIC will always be physically present to supervise individuals who are required to be in those areas due to their work responsibilities.

2.3 Transportation Security Measures

Deliveries to the site will be by appointment only. The company has not finalized transportation services for product but intend to use Brinks Transportation for client shipments and site deliveries. Procedures regarding tracking of shipments, chain of custody and loss during transit will be implemented.

3. Secure Vault Area

A proposed level 8 narcotics vault has been constructed at the site. The vault's panels are made of proprietary materials and are UL listed Class 1. The panels are constructed with high strength barrier materials. The vault doors (2) are constructed with UL listed steel plates. Both doors have the emergency release devices removed and have combination locks as well as digital keypads.

The vault will be used to store finished product, materials held for testing and any waste material. The applicant is aware of the restriction limits for a level 8 vault. Additionally, only the SPIC/RPIC and A/RPIC will have knowledge of the access codes to the vault.

The Vault Security Intrusion detection system is a standalone system and includes the following components:

- Vault doors security contacts
- Vault door heat sensor units
- Panic buttons
- Dual Smoke detectors
- Motion sensor coverage
- CCTV camera coverage for the entire vault (IP Camera system)
- Electronic siren
- Control box for the vault was located inside the vault
- Seismic detectors on wall, floor and ceiling
- Interior arm/disarm touchpads within the vault
- Proximity PIN card access readers for entry/exit
- The intrusion system is monitored 24/7 by onsite security personnel and remotely by Reliance Protectron U.L.C.

Note: An alarm challenge test was conducted for the proposed level 8 vault the reports generated were reviewed and found to be satisfactory. The following vault component(s) were deficient:

- Vault air vent openings were not covered with steel mesh.

4. Record Keeping

In general, records will be kept electronically using customized in-house software. Information such as emails or faxes can be scanned into the software. Each person using the software will have their own username and password and a timestamped audit trail will be maintained. Templates containing information required for the MMPR have been incorporated into the system Hardcopy records at the site will either be scanned into the software or the information will be manually entered into the database. Paper records will be stored onsite in conjunction with the electronic records. The system will be customized to include production information, client order information, all inventory information as well as a number of reports pertaining to production activities. A demonstration of some of the features of the applicant's software was provided during the inspection.

4.1 Transactions (Purchases/ Receipts/Returns)

The applicant has begun to develop procedures related to purchases, receipts and returns and is aware of the MMPR requirements for these activities. Records pertaining to purchases, receipts and returns would be maintained in the company's electronic ERP software.

4.2 Client Registration and Orders

The applicant indicated that they are aware of the MMPR requirements related to client registration and orders. Information pertaining to registration and orders will be maintained in the company's in-house electronic ERP software.

Note: The applicant was seeking clarification as to whether a licence would be required for a call centre that is solely responsible for fielding client calls. Client advised to discuss/clarify proposed call centre activities/details with LPD to determine licence requirements.

4.3 Orders from Individuals Other Than Registered Clients

The applicant indicated that they are aware of the MMPR requirements related to orders from individuals other than registered clients. Information pertaining to registration and orders will be maintained in the company's in-house electronic ERP software.

4.4 Production and Inventory Records

The applicant will maintain inventory information electronically with the use of the customized in-house ERP software. All products will be tracked by lot and batch to allow for easy traceability. The records will be retained a minimum of 2 years.

For each lot or batch of marijuana that producer will propagate, sow, harvest, dry, package or destroy the following information will be recorded:

- Date of propagation for marijuana plants and total number of plants
- Date on which marijuana seeds are sown and their total net weight on that date
- Date on which marijuana is harvested and its net weight on that date
- Date on which the drying process for marijuana is completed and its net weight on that date
- The date on which marijuana is packaged and its net weight on that date
- The date on which marijuana is destroyed and its net weight on that date, before destruction.
- Marijuana seeds totals
- Harvested marijuana which the drying process has not been completed
- Harvested marijuana which the drying process has been completed
- Marijuana that is destined for destruction
- Packaged marijuana

4.5 General Obligations

Filtration of Air

In areas of the facility in which cannabis will be present air passes through a HEPA H13 filtering system with Can-Filters that prevent the escape of odors and any other airborne elements.

Pest Control:

The applicant indicated that they do not intend to use pesticide chemical controls for the production of marijuana but testing will be done to ensure and prove that residues are not present.

Quality Assurance:

The proposed Quality Assurance (QA) Director will release products for distribution only when all Division 4 requirements have been met. The QA director will ensure all testing both laboratory and

environmental monitoring performed on the lot/batch meet suitable criteria and the technical specification requirements set forth by the MMPR and approved QA SOP, prior to release.

There site procedure manual contains the standard operating procedures in use:
- Prohibition -sales or provision
- Prohibition- export
- Microbial and chemical contaminants
- Analytical testing regulation
- Premises- procedures
- Storage environment
- Equipment cleaning standards
- Sanitation program including acceptable clothing
- Production, packaging and labelling
- Shipping requirements and procedures
- Quality assurance
- Methods and procedures
- Approval prior to sale
- Returns procedures
- Sample of lot or batch
- Recall reporting
- Adverse reaction reporting
- Complaint procedures

Testing:
Experchem Inc., an accredited third-party laboratory that possesses a CDS licence under the Narcotic Control Regulations, section 9, will provide contaminant screening and THC and CBD cannabinoid profiling for quality assurance. Testing will be completed prior to release of the bulk product for use in packaging.

A record of testing by or on behalf of the producer in respect of any lot or batch of dried marijuana will be kept on file. The record of testing will also be scanned into the software with the inventory record of that batch and lot number.

5. Good Production Practices

Several procedures have been developed to address quality control at the site. The company's quality procedures require that all facility areas be maintained in clean and dry condition. Where wet processes are used, drainage will be maintained. Production of marijuana will be segregated from other batches and/or products; offices and other ancillary facility functions will be restricted from holding marijuana

Personnel will have a change of shoes that are worn only inside the facility. Outside shoes will be left in the lockers. White coveralls, hairnets and latex gloves will also be made mandatory to wear inside the facility.

During the inspection the applicant indicated that the company intends to use enclosed growing pods. The pods will be constructed from glass and will have a dedicated employee/operator responsible for all of the growing/harvesting activities within the pot. The pod concept allows for

segregation of crops to ensure minimal contamination and/or plant manipulation.

The company constructed a scaled-down prototype of the growing pod for the inspection. The prototype was constructed primarily of glass; however there was an area where non-transparent material was used which would cause a blindspot during visual monitoring. The company was advised that an RPIC or A/RPIC must supervise and be physically present in any area that activities related to medical marijuana are taking place. Also, the prototype growing pod did not have in/out access card readers; this would be required as per the Regulations regarding areas where cannabis is present. In addition to this, there were no cameras present in the prototype, based on the applicant's proposed growing model they would need to demonstrate that adequate visual monitoring of the activity in each growing pod could be achieved. Based on the information provided during the inspection, the scaled-up version of the growing pods would house up to 10000 plants per pod. As the applicant did not have the growing pods they intend to use for production purposes in place it was not possible for the inspection team to accurate access whether the scaled up version of the growing pods would meet the division 3 security requirements.

The room that will be housing the growing pods did appear to meet the MMPR requirements, however once the room is modified to include the growing pods it would need to be reassessed.

6. **Packaging, Labelling, and Shipping**
   The applicant is in the process of evaluating packaging and labelling components. The applicant indicated that they are aware of the MMPR requirements for packaging, labelling and shipping.

7. **Destruction**
   The applicant intends to use the services a third party company for waste disposal. The company was aware of the requirements for MMPR destructions. The applicant was reminded that all cannabis was must be stored in the vault.

8. **Loss/Theft**
   The loss/theft reporting procedures were reviewed with applicant during the inspection to ensure that the company is familiar with the MMPR requirements. The company confirmed during the inspection that they would adhere to the loss/theft reporting requirements.

9. **Import/Export**
   During the inspection the applicant indicated if the company is successful in obtaining a licence they may import seeds to expand the number of strains available to clients. Requirements for importation/exportation were reviewed during the inspection.

10. **Serious Adverse Events (SAE)**
    The applicant will retain records of all complaints and records of any corrective action taken with respect to a client complaint as per regulation 143(1). The company will investigate every complaint received in respect to the quality of the dried marijuana and, if necessary, take corrective and preventative actions.

    All adverse effects reported will be reviewed and documented by the Quality Director. The Quality Director will ensure that the necessary reporting and all documentation have been carried

out as per section 63 of the MMPR. All case reports that summarize serious adverse reactions will be kept for a period of 25 years. On an annual basis the licensed producer will prepare with an overall summary report of any and all adverse reactions to the dried marijuana that occurred during that 12 month period.

11. Recall Strategy

The applicant's SOP outlines a planned course of action to be taken in conducting a product recall. All recalls will be supervised by the Quality Director. If a recall of dried marijuana is necessary the applicant will provide the Minister with the following information that would be available from their in-house ERP computer system:

- Brand name
- The number of each lot or batch recalled
- If known, the name and address of any other licensed producer who imported/produced it
- The reason for the recall
- The quantity produced by the licensed producer
- The quantity that was sold by the licensed producer
- The quantity remaining in the possession of the licensed producer.
- The number of licensed producers/licensed dealers whom it was sold/provided
- The number of clients that the recalled product was sold to
- A description of any actions taken in respect to the recall in order to solve the problem.

12. Personal Protective Equipment Used/Required During Inspection:

Not applicable.

13. MMAR Licence Information:

Not applicable.

H. EXIT INTERVIEW

Names & Titles of Attendees (Company Name):

Mr. Bahige (Bill) Chaaban, President/CEO, Proposed SPIC/RPIC (CEN Biotech Inc.)
Mr. Donald Strilchuck, Director of Corporate Security, Proposed A/RPIC (CEN Biotech Inc.)
Quality Director, (CEN Biotech Inc.)

Names & Titles of Attendees (Health Canada):

Regulatory Compliance & Enforcement Specialist – CSP ON

Compliance & Enforcement Officer – CSP ON

The following items were discussed at the Debrief Meeting:

The CCTV camera fps was set to 7; the inspection team requested that all cameras at the site be adjusted to meet the suggested requirement of 24 fps.

The camera playback features was demonstrated during the inspection and the frame rate provided a smooth video stream based on this demonstration the 15 fps appears to be satisfactory. LPD to confirm camera setting has been changed to 15 fps.

The applicant was seeking clarification as to whether a licence would be required for a call centre that is solely responsible for fielding client calls. Client advised to discuss/clarify proposed call centre activities/details with LPD to determine licence requirements.

The following vault component(s) were deficient; LPD to confirm with applicant that the deficiency has been corrected:

- Vault air vent openings were not covered with steel mesh.

The company constructed a scaled-down prototype of the growing pod for the inspection. The prototype was constructed primarily of glass; however there was an area where non-transparent material was used which would cause a blindspot during visual monitoring. The company was advised that an RPIC or A/RPIC must supervise and be physically present in any area that activities related to medical marijuana are taking place. Also, the prototype growing pod did not have in/out access card readers; this would be required as per the Regulations regarding areas where cannabis is present. In addition to this, there were no cameras present in the prototype, based on the applicant's proposed growing model they would need to demonstrate that adequate visual monitoring of the activity in each growing pod could be achieved.

Based on the information provided during the inspection, the scaled-up version of the enclosed glass growing pods used to produce marijuana at the site would house up to 10000 plants per pod. As the applicant did not have the growing pods they intend to use for production purposes in place it was not possible for the inspection team to accurate access whether the scaled-up version of the growing pods would meet the division 3 security requirements.

The room that will be housing the growing pods did appear to meet the MMPR security requirements, however once the room is modified to include the growing pods it would need to be reassessed.

I. INSPECTOR'S CONCLUSION:

Based on the information provided during the inspection, the applicant will be ready and able to meet the requirements of the MMPR provided that the deficiencies noted during the inspection debrief meeting are addressed. A re-inspection may be required to assess the security measures for the full scale growing pods once construction is complete. (See comments, section H)

J. APPENDICES

1. Sample Access logs for card readers
2. Application File
3. Alarm reports

K. SIGNATURES

Lead Inspector

Regional Manager

Reliance
Protectron

Cen Biotech
20 North Rear Road
Lakeshore, Ontario
N0R 1K0

Attention: Bill Chaaban

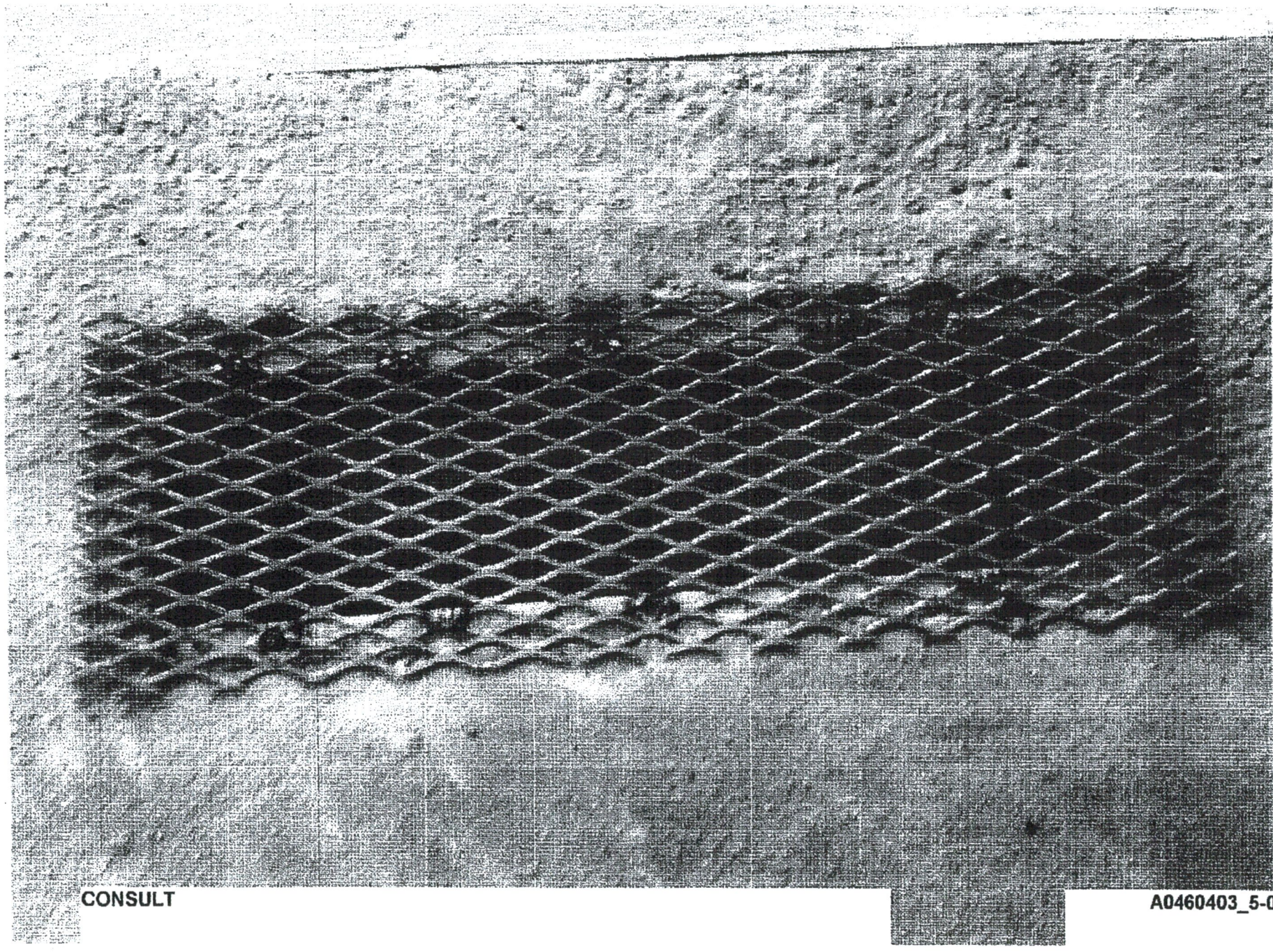
Re: IP Camera System Frame Rate

Hello Bill,

This letter will confirm that the IP camera system located at your facility at 20 North Rear Road, Lakeshore, Ontario has the ability to record at 15 frames per second and the system will be set for this frame rate going forward as of today.

Best Regards

Reliance Protectron
228 Matheson Blvd. East
Mississauga, Ontario L4Z 1X1



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