

PETITION FOR RECLASSIFICATION

Table of Attachments

Exhibit A – Photographs of SCRAM™

Exhibit B – Supplemental Data Sheet

Exhibit C – General Device Classification Questionnaire

Exhibit D – Michigan Department of Corrections Beta Test

Exhibit E – University of Colorado School of Medicine, Transdermal Alcohol Monitoring

Exhibit F – National Highway Traffic Safety Administration Task Order DTNH22-02-D-95121

Exhibit G – Financial Certification

Petition for Reclassification

Table of Contents

I. Specification of the Type of Device	3
A. Applicable Statutes and Regulations	3
B. Proposed Classification Regulation	4
1. SCRAM™ Modem (Currently Exempt from Premarket Notification)	5
2. SCRAM™ Network (Currently Exempt from Premarket Notification)	7
C. General Device Description and Intended Use	8
1. Purpose and Intended Use	8
2. Design and Operation	8
<i>See Exhibit A.</i>	10
3. Energy Source	11
D. Devices Covered by the Reclassification Petition	11
II. Statement of Requested Action	11
III. Supplemental Data Sheet	11
<i>See Exhibit B.</i>	11
IV. Classification Questionnaire	12
<i>See Exhibit C.</i>	12
V. Statement for the Reasons for Disagreement with the Current Classification	12
A. Applicable Statutory Authority	12
B. Similarities to Existing Biometric Devices	13
C. Similarities to OTC Test Kits for Drugs of Abuse	14
D. Distinctions from Existing Biometric Devices and OTC Test Kit for Drugs of Abuse	15
E. Panel Classification Recommendations and Least Burdensome Approach	16
1. Alcohol Breath Test	16
VI. Statement of the Reasons for How the New Class Will Provide Reasonable Assurance of Safety and Effectiveness	17
A. Detailed Description of the Benefits of the Device	18

B. Detailed Description of Risks of the Device	18
C. Tests Conducted on the Device	19
<i>See Exhibit D.</i>	20
<i>See Exhibit E.</i>	20
<i>See Exhibit F.</i>	21
VII. Financial Certification	21
<i>See Exhibit G.</i>	21

I. Specification of the Type of Device

The petitioner seeks to reclassify the Secure Continuous Remote Alcohol Monitoring™ Bracelet (*hereinafter* “SCRAM™ Bracelet”) and collectively, the SCRAM™ System, from Class III (Pre-market Approval) to Class I, non-reserved (General Controls) due to the ability of the General Controls to provide a reasonable assurance of safety and effectiveness. This petition also presents evidence that the devices that would be reclassified as a result of this action are themselves safe and effective for their intended use.

Section I of the petition:

- presents a proposed classification regulation;
- describes the generic type of device covered by this petition;
- technological characteristics.

A. Applicable Statutes and Regulations

The Federal Food, Drug, and Cosmetic Act (*hereinafter* “FDCA”) provides three tiers of regulatory control for medical devices, by establishing three classes of medical devices, and requiring that all devices be classified into one of these three. The three tiers of regulatory control are:

1. Class I – general controls, subject to sections 501 adulteration, 502 misbranding, 510 registration, 516 banned devices, 518 notification and other remedies, 519 records and reports, and 520 general provisions of FDCA
2. Class II – performance standards; and
3. Class III – pre-market approval.¹

¹ See 21 C.F.R. § 860.3.

A classification panel means one of the several advisory committees established by the Commissioner under Section 513 of FFDCA for the purpose of making recommendations to the Commissioner on the classification of devices.² The classification panels will consider the following, among other relevant factors in determining the safety and effectiveness of a device:

1. Persons for whose use the device is represented or intended;
2. Conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. Probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. Reliability of the device.³

A regulation or an order classifying a device into Class I will specify which requirements, if any, of sections 510, 519, and 510(f) of FFDCA the device is to be exempted from, together with the reasons for such exemption.⁴

B. Proposed Classification Regulation

The SCRAM™ Bracelet is a postamendments device unidentified by any current product code. A proposed classification regulation follows and identifies the device name, intended use, and technological features of this generic type of device. This

² See 21 C.F.R. § 860.3.

³ See 21 C.F.R. § 860.7.

⁴ See 21 C.F.R. § 860.95.

proposed classification regulation describes only those technological characteristics that are needed for a specific device to fit within the type.

(a) Identification. The system that has been developed is called SCRAM™. There are three parts to the SCRAM™ System:

- SCRAM™ Bracelet
- SCRAM™ Modem
- SCRAM™ Network

The heart of the SCRAM™ System is the SCRAM™ Bracelet, which is attached to the client's ankle and measures ethanol emitted through the skin. The attached petition requests reclassification of the SCRAM™ Bracelet as a Class I non-reserved device. *The SCRAM™ Modem and SCRAM™ Network are Class I non-reserved devices (i.e. Medical Image Communications Devices (21 CFR § 892.2020) and Medical Image Storage Devices (21 CFR § 892.2010)).*⁵

1. SCRAM™ Modem (Currently Exempt from Premarket Notification)

The SCRAM™ Modem is a medical imaging communications device⁶ which is a medical image storage device that provides electronic storage and retrieval functions for

⁵ The SCRAM™ modem provides electronic storage and retrieval functions for transdermal measurement of ethanol. The SCRAM™ network is a medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol. SCRAM™ consists of a SCRAM™ bracelet, SCRAM™ modem, and SCRAM™ network that communicate for the intended use of measuring alcohol, diagnosing alcohol intoxication and monitoring alcohol consumption.

⁶ See 21 C.F.R. § 892.2020.

medical images.⁷ SCRAM™ Modem provides electronic storage and retrieval functions for medical images and includes digital memory.

The SCRAM™ Modem is exempt from pre-market notification because of its status as a medical image storage device.⁸ A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. A medical image storage device may be comprised of microprocessors, interfaces, software, and one or more storage media. Examples of storage media include magnetic and optical discs, magnetic tape, and digital memory (e.g., RAM).

In 1994, the Radiological Devices Panel (the Panel), an FDA advisory committee, recommended that medical image communications devices be placed in Class I and that devices that do not use irreversible compression be exempted from the requirement of pre-market notification.⁹ As its reason for this recommendation, the Panel stated its belief that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommended that devices that do not use irreversible compression be exempted from the requirement of premarket notification because these products are transparent to the user and FDA review of premarket notifications are unnecessary for the protection of the public health. An extremely high level of integrity has been achieved in electronic data transmission and storage through the use of modern error-checking methods, so that FDA does not consider data integrity to be a significant problem.

⁷ See 63 Fed. Reg. 23385.

⁸ See 21 C.F.R. § 892.2010.

⁹ See 61 Fed. Reg. 63769.

2. SCRAM™ Network (Currently Exempt from Premarket Notification)

The SCRAM™ Network is *both* a Medical Imaging Communications Device in that SCRAM™ Network provides electronic transfer of data between devices. SCRAM™ Network includes a physical communications medium, a modem, interface, and a communications protocol. SCRAM™ Network is exempt from the pre-market notification procedures because of its status as a medical image communications device.¹⁰ SCRAM™ Network is also a medical image storage device. Medical image storage devices are intended to provide electronic storage and retrieval functions for medical images. A medical image storage device may be comprised of microprocessors, interfaces, software, and one or more storage media. Examples of storage media include magnetic and optical discs, magnetic tape, and digital memory (e.g., RAM).

The SCRAM™ Network is the mechanism for tracking clients while on the SCRAM™ program. The SCRAM™ Network receives client data from the modem and stores it in a secured central location. The data is processed and ready to be viewed using this web-based application, providing the tools to manage the client. The SCRAM™ Network receives the data from the SCRAM™ Modem and stores it in a secured central location. Supervising agencies then review the data using the web-based SCRAM™ application. The SCRAM™ Network is web-based software providing client, agency, and equipment management information as well as alert analysis, resolution and reporting capability. It receives data from the SCRAM™ Modem and presents it via the Internet for analysis and management. To provide for system availability and security, AMS contracts with IBM Global Services to provide the data center and other hosting services. Each customer of AMS will have their own secure data environment within the data center. Each agency or call center uses the Internet to connect to the SCRAM™ Network. The data is accessed using the SCRAM™ web-based application. The SCRAM™ Network

¹⁰ See 21 C.F.R. § 892.2020.

also allows a client to control the movement and status of the entire supply of SCRAM™ equipment.

In 1994, the Panel also recommended that medical image storage devices be placed in Class I and that devices that do not use irreversible compression be exempted from the requirement of pre-market notification.¹¹ Therefore, SCRAM™ Network, intended for use as a medical device, is a Class I device, exempt from premarket clearance.

C. General Device Description and Intended Use

1. Purpose and Intended Use

The SCRAM™ Bracelet is a device intended to measure alcohol in the human body through transdermal measurement. Measurements obtained by this device are intended to detect and monitor alcohol consumption and may be used to detect alcohol intoxication. The SCRAM™ Bracelet is a non-invasive instrument or system intended for use in the diagnosis of a condition or the state of health.¹²

SCRAM™ has been utilized by many federal, state and local agencies that require individuals to participate in an alcohol-monitoring program as a condition of a court-ordered release in lieu of pre-trial detention or post-sentence incarceration.

2. Design and Operation

The average person emits approximately one liter of insensible perspiration each day. SCRAM™ measures the ethanol gas in this insensible perspiration, which is a predictable result of alcohol consumption. The SCRAM™ Bracelet takes this

¹¹ See 61 Fed. Reg. 63769.

¹² See 21 C.F.R. § 809.3(a).

measurement by pulling a sample of air from the area above the skin into a chamber with an electrochemical sensor. The SCRAM™ Bracelet is attached to the client's ankle and measures ethanol concentration. The SCRAM™ bracelet stores and time stamps all reading taken and uploads these reading to the SCRAM™ Modem using Radio Frequency technology. The SCRAM™ Bracelet pulls a sample of air from the area above the skin into a chamber with an electrochemical sensor. Transdermal Alcohol Concentration readings are based on a long-standing, industry accepted, scientific foundation and can be correlated to Blood Alcohol Concentration readings.¹³

The SCRAM™ Bracelet consists of two different sides: the Sensor side contains ethanol and temperature detection sensors. This side tests vapor as it migrates through the skin to determine alcohol concentration on a pre-determined schedule. The Electronic & Communication side contains electronics for tamper detection, system control, and for collecting, storing, and transferring data via a radio frequency link. A tamper detection strap acts to secure the bracelet to the client's ankle. Once the SCRAM™ Bracelet is properly attached to the client's ankle, it cannot be removed without visibly damaging the unit.

There are three key tamper detection systems; infrared, temperature, and physical attachment systems which minimize the potential for bracelet removal. If the client cuts or removes the bracelet, the bracelet will record a tamper and send this message to the SCRAM™ Network. Placing obstructions between the bracelet and the client's skin will record and send a message to the SCRAM™ Network. Removing the battery will not cause an alert, but reinserting the battery will cause a battery power up message to be sent. Using IR technology this unit checks the distance from the skin. Abnormal changes or patterns in the distance from the bracelet to the skin could indicate a potential tamper

¹³ 69 Fed. Reg. 19644. The most common of the breath devices utilizes a fuel cell in which the alcohol is consumed resulting in a proportional electronic response.

such as the client placing an object between the bracelet and the skin in an attempt to mask a drinking event. The SCRAM™ Bracelet also takes a temperature reading. The output is then sent to the communication side and is analyzed to detect potential tampering.

See Exhibit A.

The SCRAM™ Modem resides in the client's home, or at an agreed location, and transmits readings (alcohol, distance, and temperature) and any client tamper or equipment malfunction information from the SCRAM™ Bracelet to the SCRAM™ Network using existing telephone lines. The SCRAM™ Modem is the communication link between the SCRAM™ Bracelet and the SCRAM™ Network. The SCRAM™ Modem receives and stores data such as alcohol readings and messages from the SCRAM™ Bracelet via a radio frequency communication link. All stored data is then uploaded to the SCRAM™ Network via a modem link through an existing analog telephone line. The modem also receives data, such as alcohol testing schedules, through this link and downloads it to the SCRAM™ Bracelet. In order to transfer this data back and forth between the SCRAM™ Bracelet and the SCRAM™ Network, the client must plug the SCRAM™ Modem into both an electrical outlet and a telephone outlet.

The SCRAM™ Network is the mechanism for tracking clients while on the SCRAM™ program. The SCRAM™ Network receives client data from the modem and stores it in a secured central location. The data is processed and ready to be viewed using this web-based application, providing the tools to manage the client. The SCRAM™ Network receives the data from the SCRAM™ Modem and stores it in a secured central location. Supervising agencies then review the data using the web-based SCRAM™ application. The SCRAM™ Network is web-based software providing client, agency, and equipment management information as well as alert analysis, resolution and reporting capability. It receives data from the SCRAM™ Modem and presents it via the Internet for analysis and management. To provide for system availability and security, AMS

contracts with IBM Global Services to provide the data center and other hosting services. Each customer of AMS will have their own secure data environment within the data center. Each agency or call center uses the Internet to connect to the SCRAM™ Network. The data is accessed using the SCRAM™ web-based application. The SCRAM™ Network also allows a client to control the movement and status of the entire supply of SCRAM™ equipment.

3. Energy Source

The SCRAM™ Bracelet is battery-operated. The SCRAM™ Modem as well as a Medical Image Storage Device is operated from a standard domestic 110-volt alternating current power supply.

D. Devices Covered by the Reclassification Petition

The petitioner proposes that the SCRAM™ Bracelet (and collectively, the SCRAM™ System), a new device, manufactured by the petitioner, be reclassified as a result of this petition. There are no other commercially available devices which will be reclassified as a result of this petition.

II. Statement of Requested Action

Alcohol Monitoring Systems, Inc. requests that the SCRAM™ Bracelet (and collectively, the SCRAM™ System) be reclassified from a Class III under 513(f) of the FDCA to a Class I, non-reserved device.

III. Supplemental Data Sheet

See Exhibit B.

IV. Classification Questionnaire

See Exhibit C.

V. Statement for the Reasons for Disagreement with the Current Classification

A. Applicable Statutory Authority

Section 513(d)(2)(A) of the FCDA authorizes FDA to exempt, by regulation, a generic type of class I device from, among other things, the requirement of premarket notification in section 510(k) of the act. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

The automatic classification of a postamendments device into Class III under 513(f) was meant to provide a temporary classification for a new device unless the device in question conformed to the definition of a Class III device found in Section 513(a)(1)(C) of the FCDA. Falling outside the definition of an existing type of device, or being not substantially equivalent to a device within an existing type, does not mean that a device poses risks, or safety and effectiveness questions, worthy of FDA's highest regulatory class. This petition presents evidence that the SCRAM™ Bracelet (and collectively SCRAM™ System, does not conform to the criteria for Class III described in Section 513(a)(1)(C) of the FDCA, but conforms to the criteria described in 513(a)(1)(A) for Class I, non-reserved devices.

Section 510(l) of FDAMA changed the manner in which FDA classifies devices and subjects devices to premarket notification. Under FDAMA, a class I device is

exempt from the premarket notification requirements under section 510(k) of the act, *unless* the device is intended for a use that is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury.

B. Similarities to Existing Biometric Devices

Biometric devices, such as the SCRAM™ Bracelet utilize in vitro¹⁴ assays of biological specimens. Such assays are usually non-invasive, no-risk procedures.¹⁵ Examples of biometrics include the use of breathalyzers, DNA analysis equipment, and drug and forensics analysis of body fluids and hair. The SCRAM™ Bracelet is a biometric/in vitro device insofar as it is a non-invasive instrument or system intended for use in the diagnosis of a condition or the state of health.¹⁶

Under the MDA, FDA classified breath alcohol test systems as Class I, non-exempt from premarket clearance in the Federal Register, February 2, 1982.¹⁷ After the passage of FDAMA, breath alcohol test systems, regulated under 21 C.F.R. § 862.3050 were not considered “reserved” devices, as reported in the February 2, 1998 Federal Register notice. However, in a subsequent Federal Register notice on November 12, 1998, without remark in the subject or body of the Federal Register notice, FDA included breath alcohol test systems as “reserved” devices and subject to premarket notification.¹⁸

¹⁴ In vitro products do not contact the body. In vivo are those products used within or on the body. See *United States v. An Article of Drug ... OVA II*, 414 F. Supp. 660, 663 (D.N.J. 1975), *aff'd*, 535 F.2d 1248 (3d Cir. 1976). For example, analysis of urine cocaine metabolites is an in vitro test; a heart catheterization is an in vivo procedure.

¹⁵ See 21 C.F.R. § 812.3(k) (defining non-invasive); *id.* 812.3(m) (defining significant risk).

¹⁶ 21 C.F.R. § 809.3(a).

¹⁷ 47 Fed. Reg. 4802.

¹⁸ 63 Fed. Reg. 63222.

The SCRAM™ Bracelet has *some* existing characteristics within the generic type of devices classified as breath alcohol test systems, regulated under 21 C.F.R. § 862.3050 and identified under product code “DJZ”. However, the SCRAM™ Bracelet is not intended to “measure[e] alcohol in the human breath”.¹⁹ (*emphasis added*) The SCRAM™ Bracelet is similar to alcohol breath tests only in so far as it utilizes the same electrochemical fuel cell technology. Because there currently are more than 23 FDA-cleared alcohol breath tests from 1993-2005, the fuel cell technology has been shown to be capable of conducting this testing, and therefore the FDA may, as it most recently has, that the testing is accurate and reliable.²⁰

C. Similarities to OTC Test Kits for Drugs of Abuse

The function of the SCRAM™ Bracelet is similar to the function of OTC tests for drugs of abuse regulated under 21 C.F.R. § 864.3260. In reevaluating the policy on drugs of abuse test sample collection systems, the FDA reached a number of conclusions.²¹ The primary risk to health presented by these products is the possibility that they may result in an incorrect diagnosis. However, as FDA correctly states, no in vitro diagnostic test yields perfect results. Sometimes the test misses the presence of what it is supposed to be detecting (false negative). Sometimes it registers the presence of the substance even though it is not present (false positive). Knowing the probability of false negatives and false positives, not just in abstract terms, but why they occur and whether and how the rate varies among different populations, and at various intervals following drug exposure, is essential in order to properly interpret and communicate the results.²²

¹⁹ 21 C.F.R. § 862.3050.

²⁰ 63 Fed. Reg. 10792.

²¹ Testimony of William Schultz before the House Subcommittee on Oversight and Investigations; February 6, 1997.

²² 63 Fed. Reg. 10792.

D. Distinctions from Existing Biometric Devices and OTC Test Kit for Drugs of Abuse

The primary distinction between SCRAM™ and existing biometric devices and OTC tests for drugs of abuse is that any evidence of alcohol use detected by the SCRAM™ bracelet is not relayed to the user. Rather, the test results are maintained by the manufacture for review by an authorized health care professional.

In April 2000, FDA stated that Over the Counter (“OTC”) systems (for detection of drugs of abuse) are devices within the meaning of 21 U.S.C. § 321(h). Industry comments that OTC drugs of abuse test kits are not medical devices prompted FDA to incorporate into the definition of the device statements such as: the product is a device “intended to provide access to test results and counseling.” SCRAM™ is distinguishable from OTC test sample collection systems, because SCRAM™ is a passive monitoring system, and is not intended to provide a patient with results that will facilitate medical treatment by the user. Any potential risk to health is adequately controlled by the restrictions on the manner in which SCRAM™ transmits continuous information. Therefore, the alcohol-test subject (i.e. user of the SCRAM™ Bracelet) cannot make any medical treatment decision as a result of the testing itself. It is only the health care professional that will determine an appropriate medical treatment.

Unlike alcohol breath tests, the user is not exposed to risk of any error because the user is not able to receive the results as SCRAM™ is completely passive to the user. Thus the accuracy and reliability of the underlying test(s) are never used in a nonprofessional setting.

Since SCRAM™ is not a life-supporting or life-sustaining and does not present an unreasonable risk of illness,²³ premarket notification is unnecessary for the SCRAM™ Bracelet and collectively the SCRAM™ System.

²³ See 21 C.F.R. § 860.3.

E. Panel Classification Recommendations and Least Burdensome Approach

1. Alcohol Breath Test

In 1982, the Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breath-alcohol test systems²⁴:

1. Identification: A breath-alcohol test system is a device used to measure alcohol in the human breath. The device utilizes qualitative gas chromatography to distinguish between various alcohols (i.e., ethanol, methanol, isopropanol, and acetone). Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
2. Recommended classification: Class I (general controls).
3. Summary of reasons for recommendation: The Panel recommends that breath-alcohol test systems be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.
5. Risks to health: None identified.
6. FDA Determination: FDA agreed with the Panel recommendation and proposed that breath alcohol test systems be classified into class I (general controls). The FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

²⁴ 47 Fed. Reg. 4802; Docket No. 78N-2491; Breath-alcohol test system.

The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term “data” has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, “data” refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts.²⁵ (FDA has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.)

VI. Statement of the Reasons for How the New Class Will Provide Reasonable Assurance of Safety and Effectiveness

The classification panels will consider the following, among other relevant factors in determining the safety and effectiveness of a device:

1. Persons for whose use the device is represented or intended;
2. Conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. Probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. Reliability of the device.²⁶

²⁵ House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94-853, 94th Congress, 2d Session 40 (1976)).

²⁶ See 21 C.F.R. § 860.7.

A. Detailed Description of the Benefits of the Device

Although several different remote alcohol monitoring devices are on the market, few have the advantages and benefits of the SCRAM™ System, which include:

- Collecting alcohol readings 24 hours a day, 365 days a year, regardless of the location or activity of the client.
- Accurately detecting alcohol concentrations to as low as .020%.
- Enabling supervising agencies to determine how often the client is to be tested.
- Requiring little client participation, and enabling clients to maintain normal daily routines such as work, counseling, community service, family obligations, and recreation.
- Tamper-detection components.
- A patented interfering detection system that guards against false positives.

B. Detailed Description of Risks of the Device

The risks that have been noted with the SCRAM device include the following:

- Significant discomfort, due to improper sizing of the SCRAM Bracelet;
- Bouncing of the SCRAM Bracelet on the ankle while exercising;
- Minor bruising on certain participants;

- Minor delays at airport security (5 -7 minutes);
- Transdermal alcohol concentration curves have been shown to be broader and have lower peaks than the breath alcohol concentration curve;
- SCRAM showed discriminative validity as a quantitative measure of alcohol consumption;
- Data may get spiky, probably due to water accumulating in the sensor;
- If water is present the sensor may lose the ability to detect ethanol or have delayed sensitivity;
- Paced drinking with food may not trigger an “alert;”
- Detection algorithm is good, but not perfect;
- Modem does not work with mobile telephones;
- A few landlines had trouble dialing out; and
- Preliminary data has shown that sweat or cold will alter the detectable response.

C. Tests Conducted on the Device

The Michigan Department of Corrections (*hereinafter* “Michigan DOC”) participated in a comprehensive BETA test of the SCRAM™ Program. From July 2002 until December 2002, Michigan DOC installed the SCRAM™ Bracelet and SCRAM™ Modem on officers and offenders. Michigan DOC recorded that the SCRAM™

C. HUMPHREY & ASSOCIATES, P.A.

1001 BRICKELL BAY DRIVE • SUITE 2002 • MIAMI, FLORIDA 33131

TELEPHONE: 786.245.0440 • FACSIMILE 305.371.4120

transdermal alcohol concentration readings were taken at the same time as a breath analysis. The readings for the SCRAM™ transdermal alcohol concentration to the breath analysis comparisons were accurate. In addition, Michigan DOC recorded that in regards to the SCRAM™ Bracelet a proper fit was essential for comfort. One officer initially requested a looser fit of the unit and experienced significant discomfort. Once the unit was adjusted to the correct fit, the comfort issue diminished significantly. Michigan DOC concluded by stating that this particular BETA test worked well.

See Exhibit D.

The University of Colorado School of Medicine, Division of Substance Dependence, Department of Psychiatry also conducted an independent study on the validity of alcohol concentration measures by SCRAM™. The method used was to have 24 screened and consented subjects. Breath and transdermal alcohol concentrations were taken every 15 – 30 minutes. No subjects that received non-alcoholic beverages had positive alcohol readings transdermally. All subjects administered alcohol had positive transdermal alcohol concentration curves. SCRAM™ was able to detect low and high alcohol dosing groups by peak transdermal alcohol concentration. The transdermal alcohol concentration curve was broader and had lower peaks than the breath alcohol concentration curve. The University of Colorado concluded that the device was sensitive to small to moderate amounts of alcohol consumption. Also, the device shows discriminative validity as a quantitative measure of alcohol consumption.

See Exhibit E.

Independent research was performed under National Highway Traffic Safety Administration Task Order DTNH22-02-D-95121. In a federally funded research study, the Pacific Institute for Research and Evaluation also conducted an evaluation of SCRAM™ safety and efficacy. The evaluation noticed that there was some bouncing of the SCRAM™ Bracelet on the ankle while exercising. There were minor delays at airport

security (5 – 7 minutes). There was also minor bruising on two female participants out of eighteen participants. The Pacific Institute for Research and Evaluation concluded that the data may get spiky at times, probably due to water accumulating in the sensor, also if water is present the sensor may lose the ability to detect ethanol or have delayed sensitivity, paced drinking with food may not trigger an “alert,” detection algorithm is good, but not perfect, the modem communications usually work well, but does not work with mobile phones, a few landlines had trouble dialing out, and preliminary data showed sweat or cold will alter the detectable response.

See Exhibit F.

VII. Financial Certification

See Exhibit G.