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16. Abstract

This Technical Report was produced under Contract No. DTNH22-89-C-07009 for the National Highway Traffic Safety Administration. Under that same contract, a draft set of model specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs) was produced. Those model specifications are being separately published in the Federal Register by the NHTSA. This Technical Report includes information collected by the authors from BAIID manufacturers and State program officials in the process of developing the model specifications. Based on this information, this report provides the authors' recommendations for establishment of a comprehensive State BAIID program including suggested procedures for ensuring the quality control of BAIID instruments in the field. A review of research reports on BAIID programs which have been conducted to date make it clear that once a program has been implemented, detailed management procedures and careful recordkeeping are required to ensure that BAIID devices will accomplish their objective of preventing impaired driving by drunk driving offenders.

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I. INTRODUCTION TO INTERLOCK PROGRAMMING

The growing use of microprocessors to manage the engines of automobiles and to provide information for display to the driver highlights the extent to which computers may provide increased efficiency and safety on the highways of the future. For example, particular interest is being shown in radar braking systems which might automatically stop vehicles and avoid crashes. Similarly, the concept of a vehicle system which might detect driver impairment and prevent vehicle operation by drivers under the influence of alcohol or other drugs has attracted considerable attention as a potentially effective approach to the reduction of the drunk driving problem.

The idea for an "alcohol safety interlock system" was first proposed in the 1960's and research on such devices has been encouraged by the NHTSA for the last 20 years. A history of the development of these devices is provided by the NHTSA report entitled *Potential for Application of Ignition Interlock Devices to Prohibit Operation of Motor Vehicles by Intoxicated Individuals* (1988).[1] That document describes research on two basic types of interlocks; those based on a driver performance test which must be passed in order for the vehicle to be started and those based on a breath alcohol test prior to starting the vehicle.

Performance interlocks provide an attractive approach to controlling the impaired driver because they are potentially sensitive to impairment, not only from alcohol but from other drugs as well as impairment produced by fatigue or disease. However, extensive research with these performance devices indicate that they are only partially effective in preventing the operation of the vehicle by an alcohol-impaired driver because of the great variability among and within individuals in performance from time to time.

While research with performance interlocks continues, it is the Breath Alcohol Ignition Interlock Device (BAIID) systems which are currently coming into use. These interlock systems are made possible by the growing accuracy and/or reliability of alcohol sensing systems which are based on the semiconductor and fuel cell technologies. Because only the alcohol safety interlock systems are currently being commercially marketed, this manual applies only to these units. A significantly different set of standards and certification procedures will be required for interlock systems that are based on performance rather than on sensing alcohol.

BAIID Legislation

Breath Alcohol Ignition Interlock Devices can be marketed without formal State legislation since judges may make the installation of a BAIID a requirement under their broad

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1 Compton, R. Report prepared by DOT, NHTSA in response to Sect 203 (c) of the Highway Safety Act of 1987 (P.L. 100-17; April 2, 1987).

power to set the conditions of probation. Further, these devices can be sold to the business community or to the public without State certification if there is a demand for them. Some commercial companies are reportedly considering placing the units on their trucks and buses. Currently, however, the most widespread use of the interlock device is as an option available to judges for sanctioning individuals convicted of Driving While Impaired (DWI) offenses.

A number of States have passed specific legislation – some in the form of temporary pilot programs – authorizing the use of BAIID's by the courts. Table 1 provides a list of the 20 States which as of October 1, 1991, have legislation providing that the courts may order installation of BAIIDs on the vehicles of convicted DWIs. Some of the States which have passed legislation providing for BAIIDs have avoided the necessity of developing certification standards of their own by adopting the standards promulgated by another State.

BAIID Standards

Interlocks involve complex electronic circuitry and alcohol sensing equipment. States which have begun interlock programs are well aware that establishing BAIID standards – and test programs for such standards – involves considerable expense. Savings can be realized at the State level if a set of standards applicable to most, if not all, of the States were developed by a single source and then adopted by those States for which the standards appear appropriate. In the past, the NHTSA has attempted to assist States by developing standards and test procedures such as those established for evidential breath test devices. Under that program, the NHTSA tested the equipment and issued a qualified products list. (The original standard for devices to measure breath alcohol appeared in the Federal Register 38 FR 30459.) While such a Federal testing program may not be implemented in the case of the BAIID, nevertheless, a standardized set of specifications, were they adopted by most States, will assist not only the States by reducing the cost of test programs but also the BAIID manufacturers by providing a common specification for all adopting States. It is much easier for BAIID manufacturers to develop reliable, low-cost equipment to a single national standard than to produce varying units to meet different requirements from the 50 States.

While the NHTSA does not believe that federal standards for Breath Alcohol Ignition Interlock Devices are necessary, it does wish to provide assistance to the States in the procedures which will be available to the States for their use in establishing their own BAIID certification programs. In addition to model specifications, there is a further need to provide guidance to the States in conceptualizing a BAIID program, both with respect to initiation and monitoring.

TABLE 1
States with Laws or Pilot Programs Concerning BAIIDs

State	Written Law or Pilot Program	State	Written Law or Pilot Program
Alabama		Montana	
Alaska	1989	Nebraska	1989
Arizona		Nevada	
Arkansas		New Hamshire	
California	1986	New Jersey	
Colorado		New Mexico	
Connecticut		New York	1988
Delaware	1990	North Carolina	
District of Columbia		North Dakota	1989
Florida	1990	Ohio	1988
Georgia		Oklahoma	
Hawaii	1990	Oregon	1987
Idaho		Pennsylvania	
Illinois		Rhode Island	Feasibility Study
Indiana	1989	South Carolina	
Iowa	1988	South Dakota	
Kansas	1988	Tennesee	1989
Kentucky		Texas	1987
Louisiana		Utah	
Maine		Vermont	
Maryland	1988	Virgina	
Massachusetts		Washington	1987
Michigan	1987	West Virgina	
Minnesota	1991	Wisconsin	
Mississippi		Wyoming	
Missouri			

Need For Management And Quality Control Procedures

Beyond certifying the BAIIDs to assure the initial quality and effectiveness of the selected unit(s), a State program must also include a good administrative system for ensuring that units assigned by courts are placed on the vehicles of offenders and that the use of these devices by offenders is monitored to ensure that the device stays on throughout the period provided by the court sentence. In addition, it is important that a system be established for the maintenance, calibration, and quality control of units in the field. A recertification program should be established to ensure that the equipment does not deteriorate in field use. Only a program that includes all of these elements is likely to be effective in reducing impaired driving by DWI offenders.

The administrative problems presented by a BAIID program were illustrated in a study by the EMT Group[2] for the State of California where in cases from several counties were followed up to determine whether those individuals sentenced to the Interlock Program by the court actually had the devices installed in their vehicles. The results for Sonoma County are shown in Figure 1. As can be seen, of those offenders sentenced to the Interlock Program, approximately 1 in 3 did not result in the unit being placed in the car, and a third of those that were placed in the car were removed early. In addition to this failure to install a unit when required by the court, the EMT study also reported that some individuals were able to circumvent the interlocks and that even where this was detected and reported to the authorities it frequently did not lead to strong enforcement action. The EMT authors conclude:

> "*The lesson is straightforward. The adequacy of interlock as a system for continuing supervision of drinking and driving behavior cannot be gauged by the technical adequacy of the device itself. It also depends on the application of the device and the monitoring and enforcement of the system that supports it.*"

Recertification

Further it should be noted that while the model certification procedures issued by the NHTSA will ensure that the BAIID models tested meet minimum performance standards, these one-time tests cannot adequately assess the long-term ruggedness of the units in the field. Nor do they measure the quality of the maintenance organization or the skill of the technicians who maintain the units. Thus, an ongoing system for monitoring maintenance procedures and for conducting periodic recertification tests is required to ensure that the performance of the units in the field live up to the promise demonstrated in the initial certification testing.

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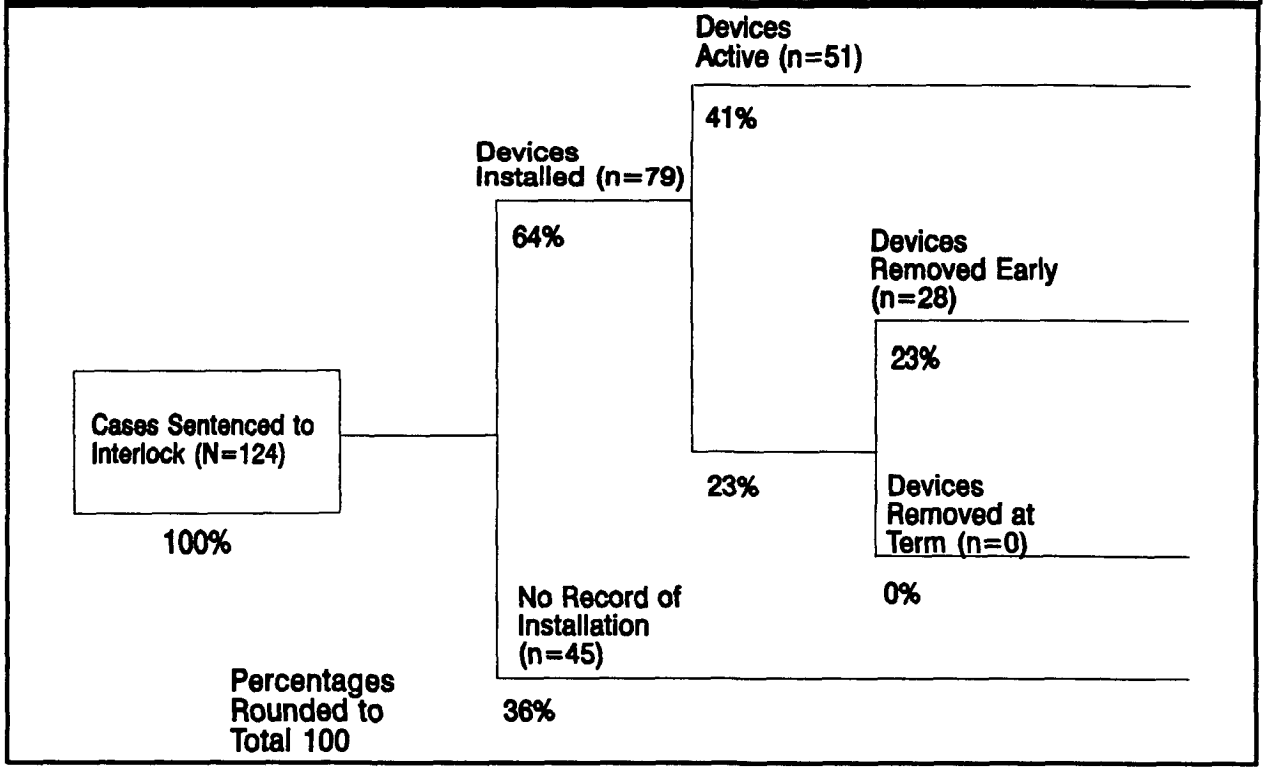
2 The EMT Group. *Evaluation of the California Ignition Interlock Pilot Program for DUI Offenders* (Farr-Davis Driver Safety Action of 1986). Report to California Office of Traffic Safety, March 1990.

Figure 1
Ignition Interlock Program Case Summary
Sonoma County



Purpose

This Technical Report is intended to provide useful information to State officials who may be considering the implementation of a BAIID program. It is based on information gathered from State officials, BAIID manufacturers' and research reports collected in the process of drafting the Model Specifications for BAIID units. Based on this information, the authors provide recommendations; both for establishing a State administrative program to manage the application of BAIID units to DWI offenders, and for the establishment of a monitoring system for the manufacturer's maintenance and service of BAIIDs units. The topics are:

- Elements of typical certification programs
- Qualifications testing and reporting
- Field monitoring procedures
- Recertification and Quality Assurance Testing

II. ELEMENTS OF A TYPICAL CERTIFICATION PROGRAM

The organization and presentation of a BAIID program typically varies from State to State, depending on the nature of its legislation and the procedures developed by the Responsible State Agency (RSA). This section describes briefly the elements that are found in most standards and that should be considered in developing a State BAIID program.

Responsible State Agency (RSA)

Currently most interlock programs are implemented by local courts, either under their own probation authority or under a State statute. However, State and particularly – local court systems – generally lack facilities for establishing certification requirements and for conducting qualification testing. The seven types of agencies which may generally be available to a State for a BAIID certification procedure are listed in Table 2. Many States have assigned to the department of health the responsibility for certifying evidential breath test devices for court use. Such agencies have important experience in and capability to test breath alcohol measurement devices. It should be recognized, however, that the BAIID's involve more than just Breath Alcohol Concentration (BrAC) measurement; they require connections to the vehicle and some sophisticated sensing and recording capability to monitor the interlock operation and prevent tampering and circumvention. The State office of highway safety or the motor vehicle department or, where available, the State bureau of automobile repair may be better qualified for this aspect of the certification process.

In addition to the development of standards and test procedures, the operation of an effective breath alcohol ignition interlock device program will require considerable record keeping and supervision of offenders. Some recordkeeping can be made the responsibility of the interlock device manufacturer who will normally provide maintenance and repair facilities to handle installation and periodic inspection of BAIID's. Supervision of the offender will normally be the responsibility of the court or the probation department, though some programs (such as that in Maryland) have assigned this responsibility to the motor vehicle department. It is obvious that close cooperation between the department certifying and testing the units and the department monitoring offenders will be important to the success of a BAIID program. It may be desirable therefore to assign responsibility for the certification of devices, not to the agency currently handling evidential breath test specifications, but to the department most responsible for supervising offenders and/or administering driver licensing programs.

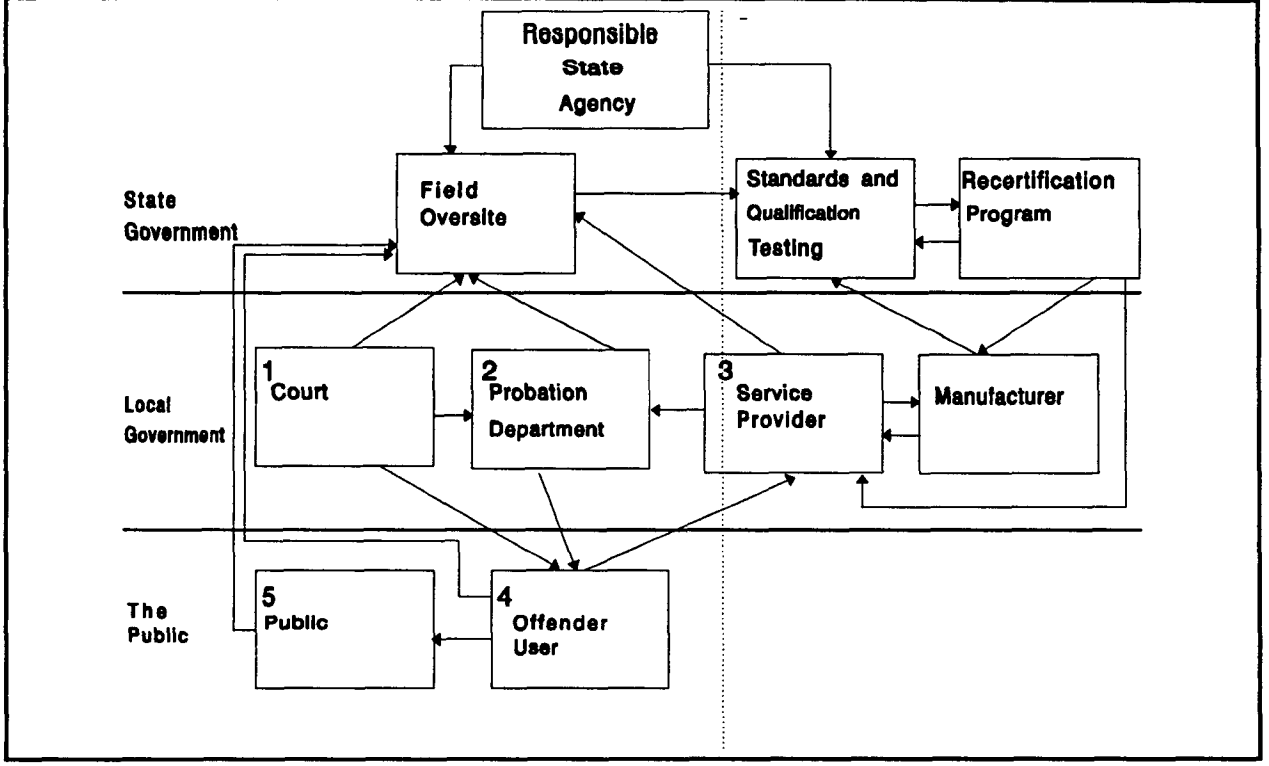
Table 2 State Agencies Which May be Assigned Responsibility for BAIID Certification Programs	
1.	The State Court Administrator
2.	The State Health Department
3.	The State Motor Vehicle Department
4.	The State Office of Highway Safety
5.	The State Office of Public Safety
6.	The State Bureau of Automotive Repair
7.	The State Department of Probation

OVERVIEW OF A RECOMMENDED STATE PROGRAM

Figure 2 presents a diagram of one concept for a State's program to manage the use of BAIIDs. The program can be seen as encompassing three levels of activity (1) state government agency, (2) local government agency, and (3) the public and/or the offender/users.

Overall, the program falls into two major areas; equipment standards, qualification testing, and a coordinated recertification program shown on the right-hand side of Figure 2 and a field oversight program shown on the left-hand side of this figure.

Figure 2
Five Information Sources for Field Oversite of State Agencies



The field oversight program is directed at ensuring that information is flowing smoothly from the court (which imposes the BAIID sentence) through local probation departments (which are responsible for ensuring that the unit is installed on the vehicle). The local probation department is also responsible for receiving and viewing service provider reports which demonstrate that the offender is meeting his or her responsibility for bringing the unit in for service periodically as required by the manufacturer. These service checks indicate that the offender is not tampering with the unit or finding methods to circumvent the interlock and operate the vehicle without a breath test. The field oversight division of the responsible state agency should provide a means for receiving information from at least five sources: (1) the court, (2) the probation office, (3) the service provider/installer, (4) the offender, and (5) the public.

Sources of Input to the State Oversight Office

First, the oversight department should receive notifications from *the court* (1) when the BAIID sentence is imposed and when the sentence is lifted once the offender has served the required period in the BAIID program. Secondly, the State oversight department should receive information from the *local court probation office* (2) whenever it takes action to return an offender to court for failure to comply with the requirements of the BAIID program. Presumably, the local probation department will take such action when:

- It fails to receive confirmation from the service center that the BAIID unit has been installed in a timely manner.
- It receives information from the service provider that the offender has not returned for service as required by the manufacturer.
- A service check gives evidence that the offender has tampered with the unit or attempted to circumvent it.
- As a result of this type of information, the probation department decides to return an offender to the court for further sentencing action. A notification should go to the state field oversight office.

A third source of information which the state oversight office should attempt to collect will be reports from *service providers/installers* (3) on all installation of BAIID units and, where possible, on the bi-monthly service reports. With these three sources of information from the court, from local probation office, and from the local service provider, the state oversight office should be able to detect problems such as those that occurred in some areas of California and are reported in the EMT Final Report (1990). In such cases, some offenders failed to have the BAIID device placed on their vehicles apparently resulting in no further court-ordered sanctions, and in some cases irregularities were detected by service providers, but again apparently no action was taken by the cognizant probation office or court.

In addition to those three sources of information from local government and service providers, the field oversight office should also provide a procedure where information or complaints from the *offender/user* (4) can be registered and where queries from the public can

be filed. Basic problems with the BAIID equipment may be uncovered through offender/user complaints. Such complaints may also serve to identify service providers who are not providing adequate support to the users. The *public* (5) may also be an important source of information for the state oversight agency since the public may be aware of individual offenders who circumvent the BAIID by some modification to their vehicle or the interlock unit or simply by using an unauthorized vehicle.

The majority of this document is concerned with the right side of Figure 2. That is, with the establishment of standards and qualification testing for BAIIDs and with the structuring of a recertification program. A set of proposed specifications and testing protocols have been separately published. This manual supports that original publication by describing procedures for monitoring the performance of units in the field and by providing a suggested set of recertification requirements. Where the initial qualification testing program principally involves contact between the manufacturer and the standards division of the Responsible State Agency, the monitoring and recertification program activity brings this element of the state agency into contact with the service providers as well as the manufacturers. The performance of the equipment can best be monitored by close observation of the service providers which may be employees of the manufacturer or may be an independent contract service agency that services companies. In either case, it is the technicians working for the service provider who will regularly come in contact with the manufacturer's equipment and it is they who will be testing that equipment to ensure that it is operating correctly. These service providers should be the first to know if there are problems with the equipment in the field. When such problems arise, service providers will undoubtedly communicate immediately with the manufacturer. The state needs to assure itself that it will also receive a timely notice of need discrepancies found in the BAIID equipment by the service provider.

STATE CERTIFICATION PROCESS

All States with a BAIID program will need to adopt some form of certification standards and some published procedures by which a manufacturer will submit a device for certification.

Model Specifications and State Standards

The certification standards specify the performance requirements for the breath alcohol ignition interlock device. To the extent possible, the standards ought to avoid requiring specific design solutions to interlock requirements and focus only on performance so as to leave manufacturers a maximum in freedom for innovation in solving the operational problems presented by interlock systems. It should also be noted that performance standards can have at least two major purposes. The principle purpose, of course, is to insure public safety by preventing the operator from starting the vehicle after heavy drinking. Elements of a standard which relate to this requirement can be viewed as *safety-sensitive*. Other portions of the standard may relate to field utility and ease of operation of the interlock system. These *utility* requirements which, while important if the units are to be accepted and widely used by offenders, are not generally critical to safety and therefore have lower priority for consideration in certification programs and testing. For example, the reliability with which the interlock system prevents ignition when a driver is over the preset limit is a greater concern than the reliability with which the interlock permits vehicle operation by a driver who has not

been drinking (with some notable but rare exceptions as when the vehicle becomes a survival tool). If an over-the-limit driver is permitted to start the vehicle, an accident could result. If an under the limit driver is prevented from starting the vehicle, the driver is inconvenienced, but public safety is not generally compromised. The specifications produced separately as a companion to this report have drawn this distinction between safety-sensitive and utility standards. States may choose to adopt those specifications as their standards.

In that document, the elements of the safety-sensitive specifications for BAIID fall into two broad categories. One set relates to the accuracy and precision of breath alcohol measurement, while the other set relates to the prevention of circumvention and tampering. To date, standards developed by the individual States focus principally on the accuracy and precision with which breath alcohol is measured, while the provisions in those specifications for insuring that the BAIID is not circumvented are relatively limited. The model specifications call for less emphasis on precision in the measurement of Breath Alcohol Content (BrAC) but provide for more rigorous testing of the capability of the device to prevent, or document, circumvention and tampering. The emphasis in this document for establishment of clear accountability to a single State authority is the critical counterpart to careful monitoring of circumvention and tampering.

This approach reflects the belief of the authors that differences in breath alcohol levels on the order of .01% or .02% w/v BrAC are relatively insignificant for safety as compared to the complete circumvention of the unit by a person at high BrAC. For example, if the set point on a BAIID is .025% and because of the inaccuracy in measuring alcohol, a driver is permitted to operate the vehicle when his or her BrAC is .04%, the risk to public safety is much smaller than when a driver who is at .10% w/v BrAC or higher successfully circumvents the interlock unit.

State Certifying Procedures

In addition to promulgating standards for BAIID's, the State will need to establish certification procedures which will include the identification of the certifying office and the methods by which BAIID manufacturers contact the office and arrange for submission of their devices for evaluation and certification. These procedures must also describe the tests that will be applied to the units to determine whether they meet the standards and the procedures for annunciation of test results and for handling challenges to the test results and appeals of certification decisions. Finally, procedures must be developed for reviewing certified units to insure continued compliance with the standards as well as the process by which certification can be withdrawn from units that no longer meet the requirements of the standard.

An application for certification will normally have two components, the provision of BAIID units for test and a report containing the manufacturer's assurances regarding test unit installation, maintenance, and removal. The application should also include procedures for communicating with the court or supervising agency and evidence that liability insurance is in force.

MANUFACTURER'S ASSURANCES

The manufacturers of BAIID equipment have a significant responsibility to the public and to the State to provide quality equipment and service. While a limited set of laboratory tests can be performed on the equipment itself, the extent to which such tests can fully determine the capability of the unit is limited. Moreover, no matter how good the unit, success in the field will depend upon the manufacturer as well as the government producing a well organized, integrated program for monitoring offenders who are assigned a BAIID. States will normally want to place a considerable amount of the responsibility for an adequate BAIID program upon the manufacturer. This can be achieved in part by requiring from the manufacturer a set of assurances with respect to the services that the manufacturer is expected to provide. Among these are the following items.

- liability insurance
- installation and maintenance services
- cost control for the client
- record keeping and reporting protocols to the State authority
- quality control and maintenance reports and alerts
- performance certification

Liability Insurance

Most States which have passed interlock laws have provided that the manufacturers will carry liability insurance to protect innocent third party motorists who may be injured by a drinking driver who successfully circumvents the BAIID. Typically, the insurance requirement is for $1 million per person and $3 million per event. Where insurance is required, the manufacturer should provide the State with a certificate from the insurance company.

Installation/Maintenance Facilities and Unit Supply

Companies which propose to provide BAIID service should be required to have some minimum capability to supply and maintain units within the jurisdiction of the court. To date, all programs established by State legislation require the manufacturer to provide for the installation and the periodic checking and maintenance of BAIID's. In some cases, such as California, the manufacturer is required to use auto repair facilities that have been specifically certified to install BAIIDs. The manufacturer's application for certification should include a list of certified or certifiable BAIID installation facilities as well as the provisions the manufacturer is making for BAIID maintenance and record keeping. Finally, the provider's assurance should include some specification of the number of units available and the number of clients that can be handled at each facility, so that the State authority can evaluate the capability of the manufacturer to provide adequate service.

Cost to the Client

All current BAIID programs are funded by the clients who agree to install a unit in their vehicles. This cost may be met by a one-time purchase, but more typically is arranged through monthly payments for leasing the unit. The manufacturers application should include a statement of the cost to the client of the BAIID including a description of the manufacturers program to provide units at reduced, or no cost, to individuals who the court determines to be indigent. The manufacturer should also be required to indicate under what conditions a client leasing a BAIID will be responsible for payment for service calls on a damaged unit. These conditions of lease should also make clear the circumstances under which a client/assignee will be required to pay for a replacement unit, such as when a highway accident damages or destroys the BAIID. Potential clients should be provided with a full cost disclosure statement. This statement should be made a part of the application for certification.

Record Keeping: Reports to Authorities

The manufacturer of a BAIID will be required to provide a report on client participation in the interlock program to the responsible State authority and court or probation department. As part of its certification application, the manufacturer of BAIID units should be required to describe its installation and monitoring procedures. The application should describe the reports which can be obtained from the BAIID itself, such as any vehicle starts not preceded by a passed breath test, and any information on attempts to tamper or circumvent the device that can be determined from inspection of the unit and its connections to the automobile. The manufacturer should describe its training program for its maintenance operators and the inspection checklist which the operator must complete when the client comes in for routine service. The manufacturer should be asked to propose a set of criteria for reporting offenders, who are found to be out of compliance with the program, as a result of attempts to circumvent or disable the BAIID. It is important that the manufacturer reveal any areas of discretion allowed the service technicians in making these determinations so that the certifying agency can determine whether the monitoring policies and procedures are adequate.

Manufacturing Quality Control and Maintenance Reporting

In addition to the reports on client compliance with the program, the manufacturers should be required to submit reports to the State certifying agency on the field performance of the device. This report should cover any significant problems encountered in installing and maintaining the BAIID units. The manufacturer should keep a record of client complaints and of service calls and have this available for the certification agency's inspection, together with a record of calibration tests.

The certifying agency may wish to require the manufacturer to provide information on the quality control procedures applied during the production of the BAIID units and the reporting system imposed on its installers and maintenance personnel. Included with this description should be copies of maintenance and installation manuals, pre-installation test procedures and the procedures for checking the BAIID units at the regularly prescribed maintenance intervals.

Performance Certification

Regardless of the performance of the equipment in the certification test, many States may wish to require the manufacturer to make certain specifications regarding the operation of a BAIID. For example, the manufacturer should be expected to specify the BrAC levels at which the unit can be set, and the precision with which the unit will prevent ignition for a driver over the set point. The manufacturer may also be required to provide an assurance that the unit will fail-safe, that is, if a BAIID failure occurs, it will fail in a manner which prevents starting the vehicle. Some States may also wish to have the manufacturer provide a performance guarantee to the client, such as that for a driver with a zero BrAC, it will lock the vehicle ignition less than 1 in 100 times or that the electrical current requirement for the BAIID will not shorten battery life or render engine starts on cold mornings more difficult, etc. The certification agency may also wish to have the manufacturer supply a copy of the client operational manual and unit specifications as part of the certification procedure.

Report on Instrument Design Changes

The certifying agency should require that the manufacturer report any change in the design of the BAIID once a unit has been certified. Such a report should contain a complete description of the change, so that the certifying agency can determine whether a re-certification of the unit is required.

QUALIFICATION TESTING

This section introduces some of the preliminary considerations that need to be addressed at the outset of program implementation.

Test Units

Some States may choose to rely on test programs conducted in a sister State and not establish a testing program of their own. Those States which do choose to test BAIID units will need to establish requirements and procedures for the manufacturers to submit their devices for testing. These procedures will obviously be dependent upon the facility which the State certification authority selects to conduct the test. Generally three alternatives are available. A State-run laboratory, such as the State medical examiner's laboratory, could be selected. Alternatively, the certification authority may wish to select a private laboratory, perhaps through a process of competitive bidding. Finally, the State may allow the BAIID manufacturer to select among State certified laboratories, the one which will conduct the test. This third procedure may be open to criticism if the manufacturer pays the laboratory for the test directly. The laboratory may be placed in a conflict of interest position since the BAIID company is paying the bill. A procedure less subject to criticism is for the State to collect a testing fee from the manufacturer and contract with the private laboratory or pay the expenses of the State laboratory to do the test. This way the test conductor is directly responsible to the certification authority and the appearance of conflict is avoided.

The test facility(s) selected should be required to demonstrate their capability to carry out the tests described in Section 2. Normally such laboratories would also be certified by a

State department of public health to conduct chemical tests. The certifying authority, if not the same agency responsible for managing the State's chemical test program, may wish to obtain the assistance of the department responsible for Evidential breath testing, and have this department inspect and certify any laboratory which would be conducting certification tests for the BAIID. Most States' programs have called for testing one or two BAIID units selected from a set of units, typically six, submitted by the manufacturer. It is important not to allow the manufacturer to submit a single unit for test since it is difficult to insure that the unit submitted is not a specially crafted prototype which may perform better than the average unit coming off the assembly line. Requiring multiple units from the manufacturer helps to insure that the unit tested will represent the average BAIID produced, rather than a special unit selected for test. Further, the availability of multiple units may allow the laboratory to conduct some tests in parallel, thereby shortening the time required to evaluate a unit. It is recommended that the certifying authority require the manufacturer to provide at least three units for tests and that at least two of the three units undergo some part of the test protocol.

It is generally desirable to allow the manufacturer to deliver the units to the test facility and demonstrate their operation to the staff members who will be conducting the tests. Once the delivery demonstrations have been completed, and the laboratory staff is trained in their operation, the manufacturer can leave their units for the required tests. The manufacturer should not participate in the actual test program in any way. However, a set of rules will need to be developed for those situations in which the submitted unit fails during the test program. Was the test procedure itself incorrectly performed leading to a failure outcome? Should the manufacturer be allowed to replace the unit and the test program continued? Can a single test be repeated, or will any failure of the unit during a test procedure constitute a failure of the full certification test program? These contingencies should be anticipated and procedures specified.

The certifying agency regulations will need to specify who owns the units submitted for test. Do they belong to the manufacturer or to the State? If they belong to the State, provisions for transfer of ownership via payment or donation should be specified upon agreement to conduct certification testing. The specifications will also have to set the cost of the test, and if retesting is permitted, the method by which the manufacturer will bear the cost of such additional tests.

Test Reports And Certifications

Some States have required the testing laboratory to report only on a pass/fail basis. Most States, however, will require that the test laboratory provide the certifying authority a complete report on all test results. The test facility report and certification recommendation will normally be made available to the manufacturer for comment and a period provided for the manufacturer's review and response to the certifying authority. The certifying authority in turn will need to establish a procedure for hearing challenges to the test results.

The certification provided by the State authority can be essentially unlimited in application (all vehicles, all drivers) and without time limit (effective until revoked by State authority). On the other hand, the State authority may wish to limit the certification to certain vehicle types if the manufacturer is not able to demonstrate that the BAIID unit can be safely

mounted on all vehicles. Cars and trucks with atypical ignition circuits and motorcycles, for example, may present special problems for BAIID operation. Further, the State authority may wish to provide a limited period of certification, requiring after a period of three to five years that the manufacturer go through the certification process again to insure that production and maintenance programs have not deteriorated.

Warnings

Because the technology required to exclude all non-authorized persons from providing a sample to the interlock is either prohibitively costly, or unavailable, all installed interlock devices should carry warning notices, such as the following:

- It is unlawful for anyone to provide a breath sample to this device other than the authorized user or other legitimate driver of this vehicle.
- All attempts to start this vehicle are recorded internally inside the interlock device. Repeatedly failed start attempts due to elevated blood alcohol concentration will be made known to the probation officer in charge.
- It is unlawful for anyone to introduce a mechanical, or non-human air sample into this device with the intent to start the vehicle.
- It is unlawful for anyone to tamper with the interlock device or to attempt starting the engine without first providing a breath sample when required by the interlock device.

FIELD MONITORING PROCEDURES

Perhaps as important to the success of a BAIID program as the quality of the equipment itself is the adequacy of the field monitoring program. This program must insure that the units are functioning as intended, that the offenders are not circumventing them and are reporting regularly for unit inspection and maintenance. A carefully run field monitoring program may be able to make up for some limitations in the reliability of the BAIID equipment. On the other hand, it is likely that any unit, no matter how well designed, can be circumvented. Therefore in the absence of an adequate field monitoring program, any unit may prove ineffective in preventing impaired driving.

In most States, the BAIID units are placed on vehicles through court order. The offender's use of the device is monitored through the probation powers of the court. This monitoring system will normally not be the responsibility of the State certification authority. Moreover, the routine checking and maintenance of equipment will be done by private firms which are not under the direct control of any State agency. Some difficulties which have arisen in communication between the courts and the companies that install, maintain, and check the interlock units have been documented in reports of the Office of Traffic and Safety to the State of California. Because the State certification authority will be a single agency, while many courts and at least several manufacturers may be involved in BAIID programs, the certifying authority is in the best position to develop monitoring procedures and to circulate information

on the interlocks, their strengths and their limitations, and to make recommendations for local interlock programs.

The BAIID installation and maintenance organizations will be at the front line of a good monitoring program. The State certification authority is in the best position to oversee this activity through its power to certify or to decertify BAIID units. In addition to laboratory tests of the unit themselves, the State certification authority should consider what requirements need to be placed on manufacturers to insure that they have an adequate installation and maintenance checking program. Further, the State Certification Agency should determine how the manufacturer proposes to insure the quality of the BAIID inspection program for all its installers, state-wide.

An essential element in a good monitoring program is the probation officer who must take action in the event that a report is received from the installer that a client is attempting to circumvent the BAIID unit or is not reporting for regular maintenance checks. It is essential that the probation department develops policies for the expeditious handling of such offenders. A procedure is necessary which insures that BAIID abusers are brought in for a court hearing and, in the absence of an adequate explanation, are assessed appropriate additional penalties. Policies will need to be developed that acknowledge the likely use of the vehicle by family members of the court-stipulated assignee.

The probation officer may need to have information in addition to a simple out-of-compliance report. The certifying agency needs to coordinate with court administrators to determine exactly what information will be required to support disciplinary action for those offenders who do not operate their vehicles within the limitations imposed by the BAIID. These requirements suggest a need for the BAIID unit to contain features which are not absolutely essential for safe operation, such as a data or event recorder. Because of the difficulty of insuring full circumvention prevention, such a recorder can document all start attempts and the BrACs obtained on every breath test and other items useful for evaluation of compliance with the conditions of probation. Such additional recording is not likely to be a significant problem to the unit manufacturers since current BAIIDs all contain microcircuits which can be used to store and readout performance information.

INFORMATION EXCHANGE BETWEEN STATES

In some States, such as California, a large number of BAIID units have been in use for some time. The experience in such States can be useful to those jurisdictions which are just initiating BAIID programs. Most manufacturers will be marketing their units in more than one State, so that problems encountered in one State will be relevant to other jurisdictions with interlock programs. It is desirable for the agency responsible for the State certification program to remain in touch with other State certifying agencies, so that information on the progress of interlock and programs can be easily and quickly exchanged.

This manual lists the 20 States that are known to have legislation relating to the use of interlock units. Since a number of bills have been submitted in the legislatures of States that currently do not have an interlock law, it is probable that this list will be out of date shortly. The NHTSA is attempting to maintain a list of those States which have adopted BAIID

legislation and a list of the agencies responsible for program management in each of the interlock States. Information about the current status of State interlock programs can be obtained by contacting the National Highway Traffic Safety Administration, Office of Program Development and Evaluation. Information on State interlock programs, evaluation of interlock devices and State certification programs may also be obtained from non-governmental organizations with interests in the area, such as the International Association for Chemical Testing (IACT) and the Committee of Alcohol and Other Drugs and Traffic Safety of the National Safety Council.

III. RECERTIFICATION AND QUALITY ASSURANCE TESTING

As described in the first section, the Responsible State Authority should have oversight responsibility for both the conduct and evaluation of the statewide BAIID program. Because this is a new technology, considerable research remains to be done concerning long-term viability of the products, and use-related problems, both expected and unexpected. Therefore in order to accumulate the information base which will be needed to track the performance of this class of equipment, a system of inspectors should be established to provide the raw data for in depth evaluation of a selected sample of the BAIIDs in field use. This section outlines a process which may be implemented in order to acquire such information.

EVALUATION OF BAIID MAINTENANCE PROGRAMS

The principal purpose of a recertification program is to determine that the *equipment* which has gone through qualification testing performs in accordance with the qualification standards under the stresses of field operation. In the field, the equipment can be exposed to weather conditions and wear and tear not adequately tested by the qualification standards. Further, the qualification standards provide for only minimal testing of BAIID durability and their ability to hold calibration. While a recertification effort would evaluate operation of these units under field conditions it would not provide for evaluation of the adequacy of the *maintenance and testing operation* put in place by the manufacturer. Personnel could be employees of the manufacturer or contract service providers to the State or the manufacturer. If the maintenance equipment fails or if maintenance operators miscalibrate the BAIIDs, it could significantly reduce their effectiveness. It is essential, then that a recertification program be more broadly conceived as a *quality assurance* program, and include an element which focuses upon the service provider; specifically, three elements of the service provider's maintenance effort needs to be evaluated:

1. The proficiency of the service technician,
2. The adequacy and quality of BAIID test equipment, and
3. The adequacy and quality of record system

These three elements of the service provider operation must meet minimum standards. It is desirable for the responsible state agency to establish an inspection system directed at ensuring that the BAIID maintenance providers meet minimum standards in servicing these units.

Manufacturer's Documentation

As part of the initial licensing and certification process, BAIID companies seeking licensing or certification should be required to provide the following information to the responsible state agency.

1. A description of the equipment to be tested including a technical operations manual and necessary schematics.

2. A description of the training program used in preparing technicians to maintain the BAIID.

3. A list of test equipment required to maintain the BAIID

4. A list of providers of the needed equipment with an address of each provider and supporting documentation.

5. A list of companies certified maintenance technicians. The company should be required to maintain full employment and background records on the technician and make them available to the responsible State agency if requested.

6. A description of the BAIID manufacturer's program for overseeing and supervising maintenance organizations and maintenance technicians, and

7. Where available, relevant information on maintenance problems from other States.

With the information described above, the responsible State agency can develop a service site inspection program which can be distributed to the BAIID manufacturers and service providers for their review and comment. The details of such a plan will obviously vary with the State, with the number of BAIID units in the field, and with the number of BAIID providers and service centers. For States with significant numbers of BAIID units in the field, it is probable that there will be several, if not as many as two or three dozen service centers. To handle a program of this size, it will probably be necessary to hire an train State inspectors who can visit service sites and evaluate their effectiveness.

State Inspectors

One concept for such a program would make use of a trained inspector equipped with a State vehicle to which the manufacturer's BAIID unit had been installed. This inspector would need to be equipped in addition with an accurate method of measuring the BAC in an air sample coming from a tank of stored gas or a simulator. This inspector would make surprise unannounced visits at service facilities to evaluate the quality of their maintenance operations. During these visits, the inspector would carry out the following activities:

1. Using a standard mobile evidential breath tester, the inspector would verify the test simulator output or the output from stored gas which the service provider was using to calibrate the BAIID units.

2. The inspector would then request the maintenance technician to remove and calibrate the BAIID unit in the inspector's car.

Prior to the arrival at the site, the inspector will have checked the sensitivity level of the unit in some cases setting the sensitivity of the alcohol detector out of the tolerance range in order to determine whether the maintenance technician is able to detect the out of tolerance

condition and correct it. Prior to arrival, the inspector will also have carried out a set of BAIID operations to determine whether the BAIID data recorder was operating correctly. Of particular importance for pre-programming the BAIID would be simulation of attempts to circumvent such as by disconnecting the power or by push-starts in order to determine whether on inspection by the service provider, these attempts would be detected. The actual actions to be taken by the inspector would of course depend upon the unit and its system for detecting efforts at circumvention.

By observing the technicians servicing of the inspector's unit, the inspector can determine whether (1) the servicing is in conformance with the manufacturer's requirements and (2) whether the service provider can detect problems and malfunctions in the unit. Following the servicing and reinstallation of the unit in the inspector's car, the inspector would use a stored gas sample with a known BAC content .02% w/v above the set point to determine whether the unit had been accurately calibrated and was functioning to lock out vehicle ignition.

While at the service provider's facility, the inspector would review the service provider's records on each offender who has had a BAIID installed. If the responsible State agency requires the service providers to report to it, the State Inspector should be notified of any offenders who are found to have been attempting to circumvent the BAIID, or have failed to report in a timely fashion for their bi-monthly maintenance. A list of these names could be provided to the site inspector in advance of the visit, and the inspector in reviewing the service records could make a specific check of these cases.

The inspector should take away a list of names of offenders who were sent by the court to the service provider but never reported for installation of a BAIID device, as well as any other offender names who do not appear to have met the service requirements imposed by the court. These names could then be followed up with the probation department or the courts to ensure that offenders are not slipping through the court records system and avoiding the installation of a BAIID.

The inspector should also ask to review the service provider's records of complaints from BAIID users to determine the types of complaints being made and the outcomes of service calls. The inspector may wish to select some names and telephone numbers from this file for a followup with the offender/user to verify that the service provider is responding adequately to service calls. This will also provide a means of obtaining information from users on limitations and problems in the basic BAIID equipment.

As a final action on an inspection visit, the inspector might select a BAIID for recertification testing as described in the next section. It is important that the units entering into the recertification testing program not be specially selected by the manufacturer, but rather are random samples of those in use in the field. The inspector can help ensure that they are random samples of BAIID units actually in use in the field by obtaining a unit which has been removed from the vehicle of an offender/user during his visit to the maintenance center. And once that unit has been serviced and calibrated, picking it up and taking it with him for delivery to the recertification testing center.

RECERTIFICATION TESTING

Recertification testing of selected units can be used to determine the average expected error in measurement based on outcome results from actual field usage of the BAIID installed user base. Obviously, requiring each user to return after a fixed period of time so as that each device can be individually recertified would be prohibitively expensive both in time and money. The alternative is to draw a small random sample and to conduct a subset of the original certification battery in order to determine how units have held up with time and usage. Information derived from such a process could be of importance to the future of BAIID programming by identifying areas where weaknesses in the technology could either be exploited by an assignee, improved by the manufacturer, or both.

The following section goes on to address the following questions which may help to determine the proportion of installed BAIIDs which are working improperly and are unacceptably out of calibration under common use conditions. The questions to be addressed relate to the following:

- Which use-related quality control issues should be addressed?
- Which components of the Model Specifications should apply?
- How to form a sample, what size sample?
- What should be done with the data?

Recertification and Quality Control Issues

As of 1991 there has still been relatively little experience with long-term field use of the BAIIDs. Researchers who have conducted comparative studies of the BAIIDs, as well as the development engineers and service technicians of the manufacturers, are in the best position to offer advice about expected problems. Their input is central to formulating the first order of questions which could be addressed in a recertification process based on field use.

A questionnaire was developed in order to sample opinions of the service personnel. Of the 38 service people employed by Guardian Technologies, replies were received from 18. Those responding reported a cumulative service experience of about 10,000 calibration checks including installations. The questionnaire and the summary results of the questionnaire are appended. Those replies are taken into consideration here.

The primary factors that need close scrutiny by a State inspector or State BAIID program managers and the BAIID design areas which may need further improvement have been selected as a result of the questionnaire feedback, the published record of this technology, programmatic needs, as well as through consideration of breath sampling in general. These areas are as follows:

- characteristics of the basic, or unstressed, accuracy and precision as a function of use, and the interaction of use by climatic zone.

- changes in circumvention protection which may occur as a function of use.
- the value of the recorded data in the identification of circumvention attempts.
- uniformity in the application of the servicing protocol by service personnel.

COMPONENTS OF THE MODEL SPECIFICATIONS FOR RE-TESTING IN THE QUALITY CONTROL SAMPLE

The selection of components of the model specifications cannot be made without giving consideration to the costs involved in acquiring the information. Therefore the material presented discusses the type of minimum information which would ideally be collected from all States with BAIID programs and which could then be shared across State lines to improve our national understanding of the BAIID performance and problems encountered.

The quality control information to be gathered is proposed on the assumption that one person serves the inspector role within any average size State jurisdiction. The inspector will be expected to have the capability to operate test equipment, record data, evaluate data, and to mix standard solutions of ethanol which will be needed to test BAIID units. Further discussion of the issue of sample sizes that the inspector should be prepared to acquire can be found in Section 3.

Foremost among the items to be retested is the accuracy and precision of the BAIID after normal use.

Accuracy and Precision Tests

Stability of Accuracy and Precision

The testing to be conducted does not need to emulate the thoroughness of the certification protocols. The single most critical component to the re-test protocol is the basic accuracy and precision tests. This post-use testing regimen will be a less controlled, but real world equivalent to the simulated "calibration stability" regimen in the initial certification test specification in the companion report (Section 1.3 S/T). When the BAIIDs come in after 8 weeks of field use (if that is the manufacturer's recommended recalibration interval), then a comparative evaluation of the performance of the BAIID at this point in time will be a good way to also conduct a comparative evaluation of the adequacy of the simulated-use cycling in the Certifying Specifications.

It should be noted that the field use which intervenes between the time of initial installation and calibration at the service center will have subjected, on a population basis, BAIIDs to a number of the stressors which are simulated during initial certification testing. This includes the cycling as mentioned above, as well as vibration, temperature differences, RFI or EMI, power levels, altitudes, dust conditions etc. As a consequence it is not as important to test the BAIID for performance with simulated stresses during the quality control testing as it is to determine if exposure to a range of stressors has seriously altered the accuracy and precision of the basic unit.

Ethanol Solutions For Testing

The unstressed BAIID should be evaluated with three different test solutions. By using three test solutions, each BAIID evaluated can be used to generate a performance profile relative to the known standard solutions. The three solutions should be: the setpoint, .01% w/v above the setpoint, and .02% w/v above the setpoint. These solutions should be mixed fresh daily. The performance curve will aid in the determination of whether there is a fixed constant error, a variable error, and how capable the BAIID is in rejection of the range of samples.

During initial certification testing according to the guidelines in the Model Specifications, the unstressed safety specification is evaluated by delivering ethanol vapor equal to the setpoint plus .01% w/v., the stressed specification is evaluated by delivering the ethanol vapor equal to the setpoint plus .02% w/v. During the re-test protocol both these solutions, and the setpoint solution should be available.

The protocol for testing should be identical to the protocol noted in the companion Model Specifications, Section 1.1.T with the exception of the test solutions used as described above.

Temperature And Other Environmental Stressors

Because of the need to keep costs low, no specific battery of tests is proposed which would involve the use of simulated cold or hot environmental temperatures. Nevertheless, because the installed base of BAIIDs will have been exposed to a variety of temperature extremes during normal operation prior to presenting for evaluation, the recertification testing will afford an opportunity to determine whether exposure per se causes accuracy and precision to fail in predictable directions. Secondly, because the bench testing will be proposed as taking place in a mobile van throughout the year, test data on routine exposure will accumulate in the range of exposures of most interest to the geographical region conducting the tests.

The accuracy and precision tests identified above will be conducted in an unheated/uncooled mobile test laboratory allowing the inspector to emulate and record the normal range of temperature and humidity exposures. In the case of locations well above sea level, quantification of response differences as a function of altitude can be made as well. At this time there is no provision in the BAIID for recording historical temperature exposure information. With more experience in assessing the impact of exposure to broadly ranging temperatures, the certifying authorities may need to consider writing into the State standards some provision for the BAIID monitoring of ambient temperature so concurrent temperature and accuracy information can be logged. At this time, however, there is not enough justification for such a requirement.

Circumvention/Tampering Protection

The circumvention prevention capability of the BAIIDs is a subject of great interest. The specification has been developed with special attention to the detection of or protection from circumvention. A question which has received no investigation as yet is whether the

circumvention protective designs of the BAIIDs are subject to failure with use. The brief protocol recommended here would evaluate that question.

The specification as currently written for initial certification testing proposes a three part circumvention evaluation procedure, and an evaluation of tampering via inspection of the adequacy of a bypass detection system of the BAIID.

Tampering

Because the State inspector would be tasked with inspection of a removed BAIID, the circuit which detects loss of power should have been activated during removal. This aspect of reinspection for tampering protection can simply be to confirm that the removal of the unit was detected and recorded. This is as described in Model Specifications, Section 1.8.1.1.T.

Circumvention

The three part circumvention protocol in the specification is directed toward detection of, or protection from, the following:

Detection of: (1) non-human samples (e.g., from balloon) and (2) filtered samples

Protection from: (1) curbside assistance.

The first two classes of circumvention can be specifically tested for in this battery. The last can be tested by evaluating the adequacy of the timing and rejection criteria involved in the rolling retest.

Detection – It is proposed that the two easiest and most available circumvention strategies be tested to evaluate protection from the first two classes of circumvention. The use of a balloon may be the most readily available source of bogus samples. An assignee motivated to circumvent the BAIID could easily have a stash of balloons in the car at all times for use when too impaired to get an easy pass on the BAIID. Alternatively, a can of compressed air might also serve the same purpose, but availability of such a can with just the right pressure may be more of a problem for most users.

The proposed recertification protocol for non-human samples is to evaluate the basic series of tests first with a balloon. Secondly, the inspector should again conduct the basic series of tests, this time with the simulator loaded with ethanol according to the protocol in the Model Specifications, Section 1.1.2.T. Accordingly testing with filtering materials should follow.

Protection – The rolling retest protocol in the Model Specifications, Section 1.8.2.3.T specifies that a retest be called for within a variable interval of 5-30 min after passing the initial test which allows the engine

to be started. The inspector should determine that this retest interval is valid.

Evaluation of the Data Recorder

This data recorder test as noted in the Model Specifications, Section 1.10 T should be undertaken to establish the continuing adequacy of the recorder to log BAIID use. In addition to examining the recorder's capability with newly administered test procedures, the inspector should also acquire information from actual field use of the recorder in order to conduct analyses of the relationship between use and accuracy/precision testing.

This protocol can simply involve a comparative evaluation of the BAIID record and the evaluation of the Inspector's own findings.

Evaluation of the Servicing Personnel

In current BAIID programs or use areas, the service technicians are ordinarily employees of or contractors for the manufacturer. For this reason, it is important for the State authority to have independent validation of the suitability of the calibration performance of the service areas. It is possible that if the service person could be mixing test solutions inappropriately, recalibrating inaccurately, or failing to note evidence of tampering or circumvention efforts. Therefore while the inspector visits the facility for quality control recertification testing it is an opportune time to also evaluate the service person assigned. If the BAIIDs to be sampled are sampled in a random fashion based on serial numbers, then a random evaluation of service persons will be achieved as well. The sampling of service personnel under this system will weight the likelihood of a serviceperson being sampled to an equivalent of the proportion of BAIIDs serviced by his or her work location.

An evaluation of servicing protocols should be undertaken on the following points:

- determination of initial accuracy of BAIID measurement of the test solution
- determination of final BAIID accuracy of measurement after recalibration
- determination of the concentration of the service center's ethanol test solutions
- evaluation of the thoroughness of the service person's examination of the BAIID for evidence of tampering

Selecting a Recertification Sample of BAIID Units

There are two main issues in the formation of a sample: how to establish the sample, and how large a sample is needed.

Establishing the sample should ideally be done in a random fashion in order to confidently make projections about the whole installed user base. The random selection

process will require that the registration of serial numbers, or some BAIID-specific registration process has been implemented by the State authority.

The size of the sample can be determined according to the same kind of criteria that are used to establish appropriate sample sizes for the conduct of experimental research. Arriving at an estimate of the minimal necessary sample sizes required to find statistically significant detectable differences between two samples is dependent on some estimate of the mean and standard deviation in the sampling distributions.[3] Figure 3 shows the relationship between various mean differences in measured BrAC (accuracies) and various standard deviations (precisions) that might conceivably be found among BAIIDs coming in for recertification testing after a period of field use.

In Figure 3, it is clear that as the accuracy and precision of the BAIIDs improve, that is as the means and standard deviations decrease, more and more BAIIDs are needed to detect differences between groups. The survey of service people as reported in Section 1 reported that the average degree of error in accuracy after a period of 60 days of field use is in the vicinity of 0.01%w/v. If the accuracy is in that range, then relatively few devices are needed, for example to differentiate the impact of frequency of use, other use-related questions, or temperature exposure extremes. In this case, fewer than 10-25 per group would be needed to address most questions.

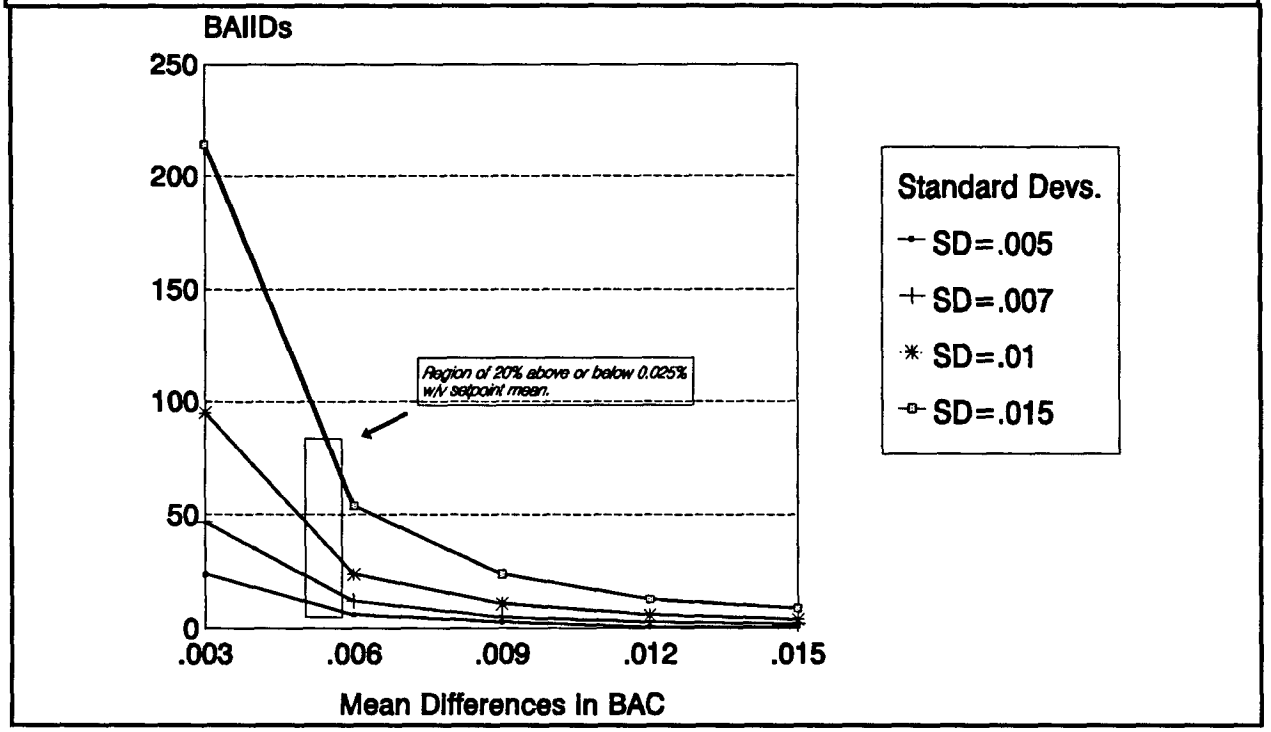
A more conservative approach would be to assume a higher post-use accuracy. If the error was found to be in the vicinity of about 20% above or below the setpoint mean, which in the Model Specifications was set at 0.025%, then the box in the figure shows the approximate region (e.g., differences in the region of .005% between two samples of BAIIDs). With this greater post-use accuracy, then the number of BAIIDs needed for recertification testing would be correspondingly higher. The highest standard deviation shown of .015 is equivalent to the highest allowable error measurement in the most lenient of the certification standards under conditions of perfect accuracy in measurement. Simply stated, this is an unlikely outcome. Fifty to seventy five BAIIDs is almost certainly adequate as a conservative upper limit on the number of units needed for recertification testing within a single State.

Oversampling

In some cases, questions may be of interest to a State because of local climate zones. If there are relatively fewer BAIIDs assigned to users in colder and higher elevation regions, then the inspector may decide it is necessary in some cases to randomly oversample a circumscribed region in order to have sufficient number of BAIIDs to achieve a meaningful degree of statistical confidence. This will require that in addition to the establishment of a

3 The minimal detectable differences is set by convention at a probability of less than 5% (P.05), this is alpha, the probability of incorrectly *rejecting* the assumption that the samples are drawn from the same population. The other possible error, beta, is the probability of incorrectly *accepting* the assumption that the samples are drawn from the same population. While alpha can be set intentionally, the beta error varies with many factors but here is set at a maximum amount in order to conservatively estimate the necessary sample sizes required.

Figure 3
Sizes of BAIID Samples Required Under varying Means and Standard Deviations Assuming Alpha = .05 and Beta = .10



record log based on BAIID serial number, there also be other elements in the dataset that can be specifically selected. For example, in a State like California, an algorithm could be written which stipulates that BAIID assignees living at altitude greater than 3000 feet be randomly sampled for comparison to those in low coastal or desert areas.

If the database tracking the clients and BAIIDs can be combined through the authority of a State-level office, then the demographic or geographic variables influencing recertification testing can be systematically investigated. Similarly, States could share data to ask questions specifically about any unique circumstances they may have which differ from locales.

In either case, the curves in Figure 3, establish the approximate sample sizes which would be needed to determine marginally significant differences under a variety of assumptions about precision and accuracy.

Data Handling

There are two elements to the problem of data handling:

- How to evaluate the data?
- How best to disseminate and act on results of analyses?

The State authority vested with responsibility for program oversight will need to set up a collection and reduction process for the data resulting from the recertification trials.

Evaluation of Results

In evaluating results it is best to form specific questions before looking at massive multiple correlation tables. As in any analysis based on probability, the number of spurious findings will reflect the number of analyses done since a certain proportion will appear to be statistically significant by chance alone; and the more analyses conducted, the greater the likelihood of chance associations being significant.

The need to preform questions of interest then is advisable on at least two counts — to reduce chance error, and to plan for the regions which need to be sampled or oversampled to arrive at a sufficient number of cases.

In either case, the evaluation will likely proceed through standard statistical procedures whereby certain factors of interest are extracted and the outcome variables compared in multiple Analysis of Variance.

When equipment is being recertified, there are a number of variables of interest to authorization:

- miles driven
- number of starts
- BACs recorded
- number of failed starts
- climate zone (e.g., temperature range or extremes, humidity, altitude)
- assignee smoker/non-smoker
- type of vehicle
- demographic variables of assignee
- manufacturer of BAIID
- urban vs rural

Dissemination of Results

The State BAIID program manager would likely want to report the results of the evaluation to State legislative and judicial authorities to aid in their understanding of the variables which affect implementation and validation of an interlock program.

Ideally, the NHTSA would also be able to accumulate information for a national database reflecting the use related variables which compromise accuracy or practicality of the program.

APPENDIX A

The following questionnaire has been developed to gain an understanding of the service issues found with Breath Alcohol Ignition Interlock Devices (BAIID). The purpose of this request is to aid in the drafting prospective Model specifications for State BAIID programs. If any questions intrude on proprietary information you need not answer them.

I. This first set of questions concern routine maintenance and service checks.	*Please place your answers to each question below as shown.*
1. What percentage of the interlock units coming in for scheduled service require recalibration?	1. _____ %
2. Please estimate the total number number of interlocks that you have personally serviced.	2. _____ (number)
3. Among those BAIID requiring recalibration, are the errors most commonly errors of precision (too wide a range of values reported on successive trials), or of accuracy (the average value is too far off of the known test standard solution)?	3. Please check one _____ (precision) _____ (accuracy)
4. Among those BAIID requiring recalibration how much drift (or *accuracy error*) has occurred? That is, how far from the ethanol standard are the average reported values of the BAIIDs? Please answer in mg% BAC deviation from the standard. For example, if the standard solution the BAIID tries to detect is .03% and the BAIID measures it as .04%, then this is an error of +.01. Each device you recalibrate will have a similar type of inaccuracy score. What do you usually find? Is there a tendency to drift up, or down, or both ways?	4. _____ (error in mg%) Check One _____ (mostly up) _____ (mostly down) _____ (about even)

5. If you are able to, please provide a measure of *imprecision* (the deviations within a test series of one instrument). For example, a BAIID could show a good *average* correct detection of the .03% standard, but in a series of 10 trials, an imprecise BAIID could have measured the same solution anywhere from .05% on one trial to .01% on another trial. If possible please provide the average standard deviations of the errors found. What is the range of deviations overall, high and low?

5. _____ (standard deviation)

_____ (low end of range)

_____ (high end of range)

6. When recalibration is required, what physically is done to the interlock?

6. Please answer on other side of this page.

7. How much time is required, on average, for recalibration? How much time is required from arrival to departure of the vehicle?

7. _____ (time to recalibrate)

_____ (time for whole service call)

8. What procedures other than recalibration are the most time consuming?

8. Please answer on other side of this page.

9. In your experience how frequently is recalibration required?
On what basis do you make this judgment?

9. _____ (weeks)

Please explain further on the other side why you think this.

II. Reported equipment failures

Equip. Failure answers

1. Do assignees ever come in between normally scheduled checkups because of reported failures? If so, on what percentage of all installed units does this occur at least once? What percent of all your user contacts are for unscheduled maintenance?

1. _____ (yes/no)

_____ (percent interlocks)

_____ (percent of calls)

2. When equipment problems are reported between checkups, what percent of these reported failures are really equipment failures as opposed to user error?

2. _____ (equipment fails %)

_____ (user error %)

(NOTE) The above two answers should total 100%.

3. When failures are legitimate, what type of failures occur?	3. Please answer on other side.
4. In your experience, during the coldest or warmest days of the year is there an increase in user complaints about equipment failure? How cold or warm does it get when such reports occur?	4. _____ (yes/no) _____ Temp. F (high). _____ Temp. F (low).
5. What is (are) the most unusual equipment failure(s) you have encountered to date?	5. Please answer on other side.
	Data record answers
III. Data recorder	
1. What information is currently being recorded on the recording device?	1. Please note data fields on other side of this page.
2. What do you do with these records?	2._____
3. What information from these records is reported to the State authority, Probation Officer or other official?	3._____
4. Are all records reported or only questionable records which may indicate misuse, tampering, or non-compliance?	4. _____
IV. Tampering and circumvention	*Tampering/Circumv. answers*
1. Do you report to the state or local authority apparent tampering attempts?	1. _____ (yes/no)
2. What kinds of tampering attempts have you encounted? Please indicate percent of total BAIIDs you have serviced in which there was evidence of tampering.	2._____ _____(kinds) _____(% showing evidence of tampering)

3. Can the car be "hot-wired." That is, what if the regular battery was disconnected and then a different battery hooked up to the distributor primary and starter circuit--bypassing the ignition switch--would your BAIID detect the new circuit? Would the car start?

3._____ (yes/no/not sure)

_____ (yes/no -- would detect the circuit)

_____ (yes/no car would not start)

4. Have you found evidence of BAIID assignees trying to alter the sensitivity of the sampling head. If so what techniques have been tried? Have you ever detected evidence of anyone spraying or otherwise applying a coating substance to the sensor? How frequently have you encountered this?

4. _____ (yes/no alter)

If you know techniques to do so please describe on the back.

_____ (yes/no coating)

_____ (number of times)

5. If a user did do something like this, how would your maintenance procedures detect it?

5. Please explain on back.

6. From your experience, how frequently should a BAIID device be checked and serviced. What is the maximum permissible interval between servicing?

6. _____ (best frequency)

_____ (max. interval)

Thanks very much. We are grateful to you for your cooperation.

Please return these 3 questionnaire pages and any additional pages of information you may have attached in the envelope provided to: Interlock Project Coordinator, National Public Services Research Institute, 8201 Corporate Dr. Ste. 220, Landover, MD 20785.

APPENDIX B

Summary responses to the questionnaire

Two manufacturers (Guardian Interlock and Autosense International) were contacted and told of our interest in sampling the field experience of the servicing and installation personnel. Autosense International[1] did not supply a list of service people. A receptionist later confided that because the new company is completely different from the old that too few of the service people have any experience with their unit. Guardian supplied a list of 38 service people.

Letters were sent to all 38 Guardian installers. After the first mailing, replies from eight were received. Following a second mailing, another nine were received. One questionnaire was blank as the serviceman claimed no experience. One service provider from North Carolina phoned in responses in late August '91. An extensive interview was held with a Washington area serviceman, from the contract company of Substance Abuse Monitoring of Rockville, Maryland. He services the Guardian units in Maryland under a contractual arrangement with the parent company. A telephone conversation was held with the chief technical representative at Guardian Interlock. This was done to clear up inconsistencies in the reporting of servicepersons. The results provided below are based on this very limited sample.

As Guardian Interlock has itself recently changed hands, this report mostly summarizes the reports of service people during the time when Guardian was a division of Cincinnati Microwave. The new corporate office of Guardian Interlock is now at 229 Weatherstone, Marrieta, GA 30068. This office reports that a new Guardian product is currently in late testing and will be introduced into the market soon.

RESPONSE SUMMARY

I. Questions concerning routine maintenance and service checks

1. Percent requiring recalibration?

The first question results were spread, noting from 5-100% needed to be recalibrated. The modal response interval was 80-90% required recalibration; nine of the 15 respondents noted over 80% require recalibration. The other six noted fewer than 30% require recalibration. The Washington area Guardian service representative reported about 30% need recalibration. There may have been some confusion about the meaning of "requiring recalibration." All are to be checked according to company policy, some may need more adjustment than others.

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[1] Autosense International Corporation, 600 Valley Way, Malpitas, California 95035

The Guardian technical chief reported that virtually all units need recalibration after eight weeks of field use. He further noted that his experience told him that the degree of inaccuracy after eight weeks seems to be a function of use. If used infrequently then, he reports, accuracy holds pretty well.

2. Personal experience with servicing?

All service people with over 1000 installations, with one exception, noted that 80-100% require recalibration at the end of the inter-service interval. Different servicepeople may have different standards for resetting the unit, although the company specifies .002% on either side of the setpoint as the limit of tolerable inaccuracy. Conversely, most may recalibrate even though the units are not outside of Guardian's range of acceptable performance.

The Guardian technical chief has conjectured that humidity may be a source of error since there is great regional variation in the need for resetting. None of these sources of variance have apparently received formal study.

3. Types of errors (precision or accuracy)?

The response distribution claiming errors of accuracy or precision were about equally split. It is not clear that questions about precision (s.d.) were stated clearly enough to be understood.

4. Amount of drift? Direction of drift?

The Guardian standard for a .03% sample after eight weeks of field use must be within .028 to .032. While the local Washington representative noted about 30% fail to be within that spec. The Washington Guardian service representative's response is far from accordance with other service people. Response summaries from 14 questionnaires show a median error report of .01% and a mean error of .011% (s.d.= .005). The range was from .003 to .02. The guardian technical chief who has serviced over 4000 units said that on average the error is .015 and that the drift goes both ways from about .016 to about .045. He feels the Washington area serviceman is in error. The Washington area Guardian service representative, in a follow up telephone call on 7/30/91, said he has never seen a unit further out than .008%. Apparently there is some environmental or use factor at work.

The questionnaire results found the direction of drift was more often reported as drifting down rather than up (2/1 ratio).

5. Measure of imprecision. Estimate sd and high and low ranges?

This question appears to have been invalid. Few answered.

6. Recalibration procedure?

This elicited virtually identical responses from all: Remove tamper tape, unscrew cover from sample head, adjust calibration screw, retest with cover in place, reset screws and replace tamper tape.

7. Recalibration time. Service call time?

The modal response was 10 minutes to recalibrate. Reports ranged from 5 to 20 min for recalibration. Total service call modal time was 15 min. Range of time for service call was 10-30 min.

8. Procedures other than recalibration which are most time consuming?

Responses are as follows:

installations	6
phone calls	2
data loggers	1
model change	1
paper work	3
P.R.	1

9. Best frequency for recalibration?

Weeks	Number responding
8	12
10	1
16	2

Conclusive summary Section I

The consensus appears to be that after eight weeks of field service, the majority of Guardian (semiconductor-type) units have drifted off the standard by about .010-.015 from the standard of .03%. All testing is done only at ambient temperature.

Apparently drift goes in both directions, but there may be some greater tendency to drift down than drift up. This implies that a standard solution is measured as having less alcohol than it really does.

Most service people feel eight weeks is about right between service, some would go longer. Most cite installations and paper work as the biggest time burden. Most service calls take 15-20 min.

II. Reported equipment failures

1. Unscheduled calls?

Nearly all service people get requests for unscheduled service. The average number appears to be about 10% of the interlocks (range 0-25%).

2. Failure frequency?

Range: 75%-95% user error. 25%-1% equipment failure. Mean approx. 8% equipment failure.

3. Most common failure, when equipment?

Near unanimous: sample head failure. Head failure can be due to...

- burn through plumbing
- pressure switch
- broken cord

4. Temperature-related user error reports?

The majority of installers answered that temperature is a factor in use of the devices (only four said it was no problem; eight noted it was). The most common reported problem was when the temperature dipped to below freezing. On the other end, over 95 F was also associated with more problem reports.

5. Unusual equipment failures?

Electrical system on older cars.
Serial connector failed.
Blown fuse.
Calibration test reported sensor failure.
Broken hand set, not accepting sample.
Volatile memory failure.
Unit dead for no apparent reason.
Powers down early.
Wires of unit fusing together and burning up unit.

Conclusive summary Section II

The majority of the non-routine service calls are user error-related. Fewer than 10% of those calls are due to real equipment failures. When equipment fails it is typically the sampling head. One installer felt they should be built to higher standards of durability. A number of installers noted an increase in calls during extreme weather. Most identified cold as more a problem than

warm, although both were reported. The atypical failures are diverse and not particularly noteworthy.

III Data Recorder

Seven respondents have experience with the data recorder, eight do not. The results from the recorder when used are either filed, or returned to court monitor, or both. In some cases, only questionable records are returned suggesting that the serviceperson has some screening function to play. There is no consensus. All vary with the court.

Conclusive summary Section III

This is probably a good argument for a program monitoring protocol.

IV. Tampering and Circumvention

1. Report attempts to authorities?

All report tamper attempts to authorities. The majority find about 3-5% of the installed base have been subjected to tampering. One reported no apparent attempts, one reported as many as 10%.

2. Types of tampering identified?

Wiring around device or hotwiring is the most common response. One serviceperson mentioned the user leaves car idling, although he did not say how he knew that.

3. Can car be hotwired? Is it detectable?

Most all answered that the car could be hotwired and that it would be detected by the circuitry. This presumably forms some of the basis for reporting to court personnel.

4. Do users ever try to alter the sensitivity of the sampling head?

Only one new serviceman reported that this has happened.

5. How to detect circumvention?

All responding spoke of tamper tape, none really addressed the problem of circumvention. Service people would not be able to detect the use of filters, unless the user left the filter on the unit — an unlikely event.

6. Ideal frequency of service? Max permissible?

Twelve of 14 answered 60 days. The mean maximum service interval was judged to be 90 days. (Range 60-120).

Conclusive summary Section IV

In the standard, the two classes of misuse are tampering and circumvention. Tampering has to do with physical intervention on the unit whereas circumvention basically concerns non-electronic bypasses of a legitimate test occasion. Tampering leaves evidence of tampering (generally), circumvention does not. Up to an average 5% of all assigned users are believed by the service people to tamper or circumvent. This is far less than the proportion found by the Morse and Elliott's (1990)[2] Hamilton County study, as described in Linnell and Mook (1991)[3], where interviews determined that 27% of all assignees have attempt to "trick or bypass" the BAIID. Forty-nine percent of all assignees tried to have another person blow into the device. Of these 64% were successfully able to start their car.

The most common tamper method noted by the service people is a hot wire or push start of the car. This is detectable due to a circuit which registers an ignition on starts not involving the sensor. As circumventions leave no record, it may be that circumvention attempts are more attractive to a user than tampering. There is no way to estimate the frequency of circumvention efforts from reports of the service people, except to speculate that it is a minimum of around the 5% found for tampering. The frequency of all efforts to bypass the BAIID may be more in the range of 25% as reported by Morse and Elliott.

Since the car can be successfully hotwired, or pushstarted, and because curbside assistance is the most commonly reported circumvention procedure, then the rolling retest may be the best insurance against such attempts. Such tests are described in the Model Specifications.

Finally, there was strong agreement from the service people that the company standards for recalibration intervals are about right.

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[2] Morse, B.J. and Elliot, D.S., 1990. *Hamilton County Drinking and Driving Study: 30 Month Report.* Institute of Behavioral Science, University of Colorado, Boulder, CO.

[3] Linnell, R.H. and Mook, S.J. *Ignition Interlock Devices: An Assessment of Their Application to Reduce DUI.* Harmony Institute, Inc. Tollhouse, CA.