DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0060]

Federal Acquisition Regulation; Submission for OMB Review; Accident Prevention Plans and Recordkeeping

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for reinstatement of an information collection requirement regarding an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning accident prevention plans and recordkeeping. A request for public comments was published in the **Federal Register** at 74 FR 24854, May 26, 2009. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before September 14, 2009.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 9000–0060, Accident Prevention Plans and Recordkeeping, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Ernest Woodson, Procurement Analyst, GSA (202) 501–3775 or *e-mail ernest.woodson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR clause at 52.236–13, Accident Prevention requires Federal construction contractors to provide and maintain work environments and procedures which will safeguard the public and Government personnel, property, materials, supplies, and equipment exposed to Contractor operations and activities; avoid interruptions of Government operations and delays in project completion dates; and control costs in the performance of its contract.

For these purposes on contracts for construction or dismantling, demolition, or removal of improvements, the Contractor is required to provide appropriate safety barricades, signs, and signal lights; comply with the standards issued by the Secretary of Labor at 29 CFR Part 1926 and 29 CFR Part 1910; and ensure that any additional measures the Contracting Officer determines to be reasonably necessary for the purposes are taken.

B. Annual Reporting Burden

Respondents: 2,106.
Responses per Respondent: 2.
Annual Responses: 4,212.
Hours per Response: 2.
Total Burden Hours: 8,424.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0060, Accident Prevention Plans and Recordkeeping, in all correspondence.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E9–19553 Filed 8–13–09; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[FMR Bulletin 2009–B2]

Guidelines for Public Access Defibrillation Programs in Federal Facilities

AGENCY: Department of Health and Human Services and General Services Administration.

ACTION: Notice.

SUMMARY: On May 23, 2001, the Department of Health and Human Services (HHS) and the General Services Administration (GSA) jointly issued *''Guidelines for Public Access Defibrillation Programs in Federal Facilities.''* 66 FR 28495–28501. These guidelines were prepared, in part, in response to a May 19, 2000, Presidential Memorandum directing HHS and GSA to issue guidelines for the placement of automated external defibrillator (AED) devices in Federal buildings. In addition, section 7 of the Healthcare Research and Quality Act of 1999, Public Law 106–129 (December 6, 1999), 42 U.S.C. 241 note, and section 247 of the Public Health Service Act, 42 U.S.C. 238p (as added by section 403 of the Public Health Improvement Act, Pub. L. 106–505 (November 13, 2000)), directed the Secretary of HHS to establish and publish the guidelines.

This bulletin cancels and replaces the May 23, 2001, notice and provides updated information for establishing public access defibrillation (PAD) programs in Federal facilities.

The revised guidelines provide a general framework for initiating a design process for PAD programs in Federal facilities and provide basic information to familiarize facilities leadership with the essential elements of a PAD program. The guidelines do not exhaustively address or cover all aspects of AED or PAD programs. They are aimed at outlining the key elements of a PAD program so that facility-specific, detailed plans and programs can be developed in an informed manner.

PAD programs are voluntary and are not mandatory for Federal facilities. The costs and expenses to establish and operate a PAD program are the responsibility of the agency sponsoring the program and not GSA or HHS.

DATES: *Effective Date:* August 14, 2009.

FOR FURTHER INFORMATION CONTACT: For further clarification of content, contact Stanley C. Langfeld, Director, Regulations Management Division (MPR), General Services Administration, Washington, DC 20405; or s*tanley.langfeld@gsa.gov.*

Dated: August 7, 2009.

Stanley Kaczmarczyk,

Acting Associate Administrator for Governmentwide Policy, General Services Administration.

Howard Koh,

Assistant Secretary for Health, Department of Health and Human Services.

Public Buildings and Space

To: Heads of Executive Agencies.

Subject: Guidelines for Public Access Defibrillation Programs in Federal Facilities.

1. Purpose. The primary purpose of these guidelines is to provide a general framework for initiating a design process for a public access defibrillation (PAD) program in Federal facilities. A secondary purpose is to familiarize Federal agencies with the essential elements of such a program. The design of a PAD program for any Federal facility will be unique and depends on many factors, including the population demographics of the facility and the surrounding area, and the size and location of the facility and the surrounding area. The design process and key elements of a PAD program described in these guidelines are intended to provide a foundation upon which individually tailored programs are developed and implemented.

This document is not intended to be a comprehensive summary of all aspects of automated external defibrillator (AED) use or establishing and operating PAD programs. Rather, it provides sufficient information to understand the basic key elements of a program and to launch an effective planning and implementation process. There are numerous sources for training and education programs as well as model protocols that can be used at various stages in the process. The required medical consultation can be obtained from Federal sources (see, for example, Federal Occupational Health—*http://www.foh.dhhs.gov/services/AED/AED.asp*) or private contractors.

It is important to note that PAD programs are voluntary and are not mandatory for Federal facilities. The costs and expenses to establish and operate a PAD program are the responsibility of the agency sponsoring the program and not the General Services Administration (GSA) or the Department of Health and Human Services.

2. Expiration Date. This bulletin contains information of a continuing nature and will remain in effect until canceled.

3. General. Over the past several years, advances in technology have provided several innovative opportunities to prevent unnecessary disability and death. One of the most important of these advances is the AED. The ease of use of AEDs by the trained lay public has led to the increasing development of PAD programs. The decreased cost of acquisition and upkeep of AEDs now makes it possible to increase further the availability and access to these lifesaving devices.

Ventricular fibrillation (VF) is a common arrhythmia leading to cardiac arrest and death. VF is unorganized electrical activity of the heart, resulting in no blood flow or pulse that will lead to death. Defibrillation is the only technique that is effective in returning a heart in VF to its normal rhythm. Although defibrillation has been shown to be effective in correcting this abnormality in most cases, up until the advent of AEDs defibrillation has been a medical intervention only available to be performed by credentialed health professionals and trained emergency medical service personnel. While it is difficult to use an AED improperly, AEDs are not without risks, if used improperly. AEDs are generally prescription devices that are intended to be operated only by individuals who have received proper training and within a system that integrates all aspects from first responder care to hospital care. Hence, a significant emphasis on proper training and linkage (notification or transfer) to emergency medical services (EMS) systems is critical. The value of the AED technology is that an AED will not energize unless an appropriate shockable cardiac rhythm is detected.

The efficacy of defibrillation is tied directly to how quickly it is administered. Although the outside limit of the ''window of opportunity'' in which to respond to a victim and take rescue actions is approximately 10 minutes, the sooner the AED is applied within that time period, the more likely it is that it will be effective and that a patient will have a normal heart beat restored and recover fully. As the length of time between the onset of Sudden Cardiac Arrest (SCA) and defibrillation increases, the less the chance of restoration of heart beat and full recovery. In general, for every minute that passes between the event and defibrillation, the probability of survival decreases by 7 to 10 percent. After 10 minutes, the probability of survival is extremely low.

Today's AEDs are relatively inexpensive and usable by persons with limited training. The advantage of well structured PAD programs is that they provide better trained individuals and increase accessibility and, as a result, increase the potential to reduce response times and markedly increase the probability of survival and full recovery.

The importance of rapid and positive intervention is reflected in the American Heart Association's (AHA's) ''Chain of Survival'' concept. The ''Chain of Survival'' is designed to optimize a patient's chance for survival of SCA. There are four links in the chain: (1) Early access, (2) early cardiopulmonary resuscitation (CPR), (3) early defibrillation, and (4) early advanced cardiac life support.

Early access is the first link in the chain of survival and means that members of the workplace have been trained to recognize possible cardiac arrest quickly and notify EMS (*i.e.,* call 911) of the event resulting in activation of an EMS response.

The second link in the chain of survival is to begin CPR immediately. CPR is the critical link that buys time between the first link (notification of EMS) and the third link (use of the AED). The earlier you administer CPR to a person in cardiac or respiratory arrest, the greater their chance of survival. CPR keeps oxygenated blood flowing to the brain and heart until defibrillation or other advanced care can restore normal heart activity. CPR may be administered by a trained responder or an untrained bystander who has witnessed an individual experiencing SCA. In a witnessed SCA situation, trained responders may use either conventional CPR or ''hands-only'' CPR. Untrained responders may use ''hands-only'' CPR in a witnessed SCA situation. In an unwitnessed SCA situation, conventional or ''hands only'' CPR may be used by trained responders. The AHA clarified this approach to CPR in an SCA situation in March 2008, when it updated previous CPR guidelines for witnessed adult SCA to include ''hands-only'' CPR (see, *http://handsonlycpr.eisenberginc.com/faqs.html#a*). These guidelines noted that there was a need to increase the prevalence and quality of bystander CPR. The use of ''hands-only'' CPR is meant to encourage earlier CPR intervention by untrained bystanders and trained bystanders who are not confident that they can perform conventional CPR. Early CPR by trained or untrained bystanders provides precious minutes for trained AED responders as well as EMS teams to arrive.

Early defibrillation (use of the AED) is the third link in the chain of survival. Many SCA victims are in VF, experiencing a lethal, chaotic heart rhythm that prevents the heart from effectively pumping blood. You must defibrillate a victim immediately to stop VF and allow a normal heart rhythm to resume. The sooner you provide defibrillation with the AED device, the better the victim's chances of survival. Several studies have documented the effects of time to defibrillation and the effects of bystander CPR on the chances of survival from SCA. For every minute that passes between collapse and

defibrillation, survival rates from witnessed VF SCA decrease 7 to 10 percent, if no CPR is administered.

The fourth link in the chain of survival is early advanced care. This link is provided by highly trained EMS personnel. EMS personnel give basic life support and defibrillation as well as more advanced care that can help the heart respond to defibrillation and maintain a normal rhythm after a successful defibrillation.

The material in these guidelines is based upon the recommendations, programs and literature on AEDs from the AHA and the American Red Cross (ARC), leaders in the encouragement of AED installation, training and usage. The AHA and ARC cooperate with other organizations in developing and improving standards for AEDs. Users of this guidance should check the latest AHA, ARC and National Safety Council (NSC) information for updates or changes to the recommendations.

Special Note: As is the case with most clinical developments, the science-supporting efficacy in controlled settings usually precedes evidence of effectiveness when implemented large-scale in real world settings. The science surrounding the effectiveness of AEDs, as well as the technology of AEDs themselves, is evolving.

For Federal agencies in space under the jurisdiction, custody or control of GSA, the Designated Official under the facility's Occupant Emergency Plan (as defined in 41 CFR 102–71.20) is responsible for oversight of the facility's PAD program. As provided in 41 CFR 102–71.20, the Designated Official is the highest-ranking official of the primary occupant agency of a Federal facility, or, alternatively, a designee selected by mutual agreement of occupant agency officials (see). AED programs should evolve based on the best available science to assure the most efficient use of resources and the best outcomes possible.

4. The Concept of Public Access Defibrillation. Until recently, AEDs and other defibrillation devices had to be brought to locations by the local EMS system. The size, cost and complexity of these devices, as well as other factors, served to limit their use. With recent advances in technology, many of the previous constraints have been reduced or eliminated. Increasingly, AEDs are being deployed in public facilities, such as sports arenas, shopping malls and airports, or in police and fire units, thus potentially decreasing the time between cardiac arrest and access to defibrillation.

However, optimal improvement in survival from SCA that occurs in a non-medical setting may require a program that relies upon community lay (*i.e.,* non-medical) responders or rescuers (LRRs) who have been trained in CPR and in the appropriate use of AEDs. A comprehensive, well integrated community approach to the use of AEDs would serve a large proportion of that community (*e.g.,* a facility, a campus, etc.). LRRs could quickly respond to, identify and treat a cardiac arrest patient and activate the formal EMS system.

''Public access'' to AEDs does not mean that any member of the public who witnesses an event should be able to use an AED. ''Public access'' refers to the accessibility of the device itself. While AEDs are reasonably uncomplicated to use, the AED should be used only by persons who have received proper training and education from a nationally recognized training institution or association. Persons without these basic credentials should not use the device.

5. Establishing a Public Access Defibrillation Program in a Federal Facility. Before establishing a program in a Federal facility, each agency should enlist the assistance of not only the personnel at that location, but also local training, medical and emergency response resources. These partnerships are fundamental to any successful PAD program. In some instances, a facility may be large enough to have training, medical and emergency response resources integral to Federal operations. For the most part, this will be the exception rather than the rule, but the same principles apply. The more closely the PAD program is connected to such resources and the more visibility and support given to the program by the facility leadership, the more the program will be effective and successful.

Each PAD program should include the following major elements:

- Support of the program by each of the facility's occupant agencies
- Training and retraining personnel in CPR and the use of the AED and accessories
- Obtaining medical direction and medical oversight from nationally recognized institutions or agencies (for example, medical oversight can be obtained through existing federal resources such as Federal Occupational Health—*http://www.foh.dhhs.gov/services/AED/AED.asp*)
- Understanding legal aspects
- Development and regular review of the PAD program and standard operational protocols (SOPs)
- Development of an emergency response plan and protocols, including a notification system to activate responders
- Integration with facility security and EMS systems
- Maintaining hardware and support equipment on a regular basis and after each use (Note: AEDs are not building equipment and, as such, are not inventoried or maintained by GSA or property management personnel)
- Educating all employees regarding the existence and activation of the PAD program
- Development of quality assurance and data/information management plans
- Development of measurable performance criteria, documentation and periodic program review
- Review of new technologies

It is important to emphasize that PAD programs are not isolated ''one-time events.'' PAD programs should be reviewed on a regular basis and improved, where possible. Additionally, after every incident involving the use of the PAD system, a thorough post-event review of system performance should be undertaken.

A key element in assuring that the PAD program will be clearly understood and will function well is the development of SOPs for the major components of the program. SOPs, as well as the program as a whole, should be periodically revisited and revised, where appropriate.

6. Designing a Public Access Defibrillation Program. Given the wide variety of Federal work facilities, there will be significant variation in the complexities associated with PAD program design. Not all Federal facilities are appropriate for PAD programs. The decision to develop a PAD program for a particular Federal facility should include all major stakeholders in the potential PAD program, including consultation with a physician (consultation with a physician can be obtained through existing federal resources such as Federal Occupational Health—*http://www.foh.dhhs.gov/services/AED/AED.asp*). Facility leadership should take steps to assure that all stakeholders, including those who are external to the facility, are afforded the opportunity to participate in planning and design. Small, physically compact offices will require different levels of planning and design than large, multi-building facilities spread over campus environments. Although it is possible to have the full range of planning and design activities performed by a consultant or contractor, it should be kept in mind that the actual responders at a facility typically will be those who work there and that both individual

employees and union interests, in accordance with collective bargaining agreements, should be considered in any process. Officials in the facility's management ''chain of command'' must have close involvement at every step, as provided in 41 CFR 102–74.230 through 102–74.260, entitled ''Occupancy Emergency Program,'' for occupants of facilities under GSA's jurisdiction, custody or control.

While many Federal agencies' facilities are single-tenant buildings or may have several tenants under the clear command or leadership of a ranking official, other GSA facilities contain multiple tenants that are not under the direction of a single agency official. For guidance on establishing, coordinating and implementing a comprehensive Occupancy Emergency Program, see 41 CFR 102–74.230 through 102–74.260, entitled ''Occupancy Emergency Program.'' For these purposes, the definition of ''emergency'' includes medical emergencies (see 41 CFR 102–71.20). In facilities that are multi-tenant, special attention should be paid to avoid confusion about decision-making processes and authority for the development and operation of a PAD program. It is recommended that the Federal agencies in multi-tenant facilities follow the guidelines described in 41 CFR 102–74.230 through 102–74.260 to assure clarity of responsibility and accountability.

We further recommend that AED response orders be included as part of each facility's Occupant Emergency Plan. See ATTACHMENT A, entitled ''SAMPLE AED PROTOCOL AND RESPONSE ORDER ELEMENTS.''

7. Selecting Your Automated External Defibrillator. Only commercially available AEDs that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) should be considered for use in a PAD program. Prior to purchasing, it is important for facility leadership to seek assistance in the selection of a device for deployment in the facility. Because technology is developing quite rapidly, seeking the advice of an individual or organization with current knowledge about AEDs is essential. Involving a medical oversight provider(s) is crucial.

All AEDs in PAD programs should be consistent with current AHA Guidelines for CPR and Emergency Cardiac Care. This includes the audio and visual commands of the AED as well as the electrocardiographic analysis and defibrillation algorithms.

Additionally, as there are some differences in the devices currently on the market, an expert can help to explain the relative advantages and disadvantages of AEDs for a particular location. Utilizing a single brand of AED within a facility will greatly simplify training, maintenance and data management.

Currently, there are Federal Acquisition Service supply contracts for AEDs. However, most AEDs require a prescription from a physician for purchase. At the present time, there is only one AED cleared for over-the-counter-sale. The selection of a particular AED and associated equipment are integral components of a PAD program and, in such a program, plans and protocols that are approved by a supervising physician are considered a prescription. Once the physician has approved and signed off on AED selection and placement, if required, this becomes the authorizing prescription for procurement of the device(s). An agency's procurement office can assist in locating current contract information and prices. The physician providing medical oversight for a PAD program can advise on prescription requirements for the AED.

In the future, additional products are likely to receive clearance for marketing from the FDA. Program designers should take steps to confirm that all devices that are acquired have received FDA clearance and that the use of AEDs in their respective facilities fully complies with FDA labeling requirements.

Emergency response and AED usage protocols signed by a physician constitute legal authorization for properly trained and certified individuals to use AEDs in a particular manner as outlined in the protocol. Responders must be familiar with and trained in the context of the approved procedures in the facility and strictly adhere to these procedures when an emergency occurs.

The actual selection and procurement of AEDs should be one of the last steps in the design of a facility's PAD program and should be done under the guidance and written authorization of the PAD program's supervising physician. The protocol for AED usage that is developed as part of a facility's PAD program is an integral part of the physician's medical oversight and serves as the authorizing document for AED use. Protocols should be reassessed periodically in accordance with a regular schedule of reviews as determined in consultation with the PAD's supervising physician. A current protocol that takes into consideration both new treatment recommendations and any changes in the FDA labeling of the AED should be integrated into the PAD training and education and re-training programs.

Essentially, the protocols that are signed by the supervising physician set the medical standards and criteria for the operation of the PAD program and all of its components. Systems operated within the boundaries and criteria of these signed protocols are considered to be under a physician's supervision, whether or not the physician is physically present in the facility. As noted in this guidance, PAD programs should be reviewed on a regular basis (after each activation and on a regular basis) with changes made, as needed, under the direction of the supervising physician. Revised protocols should be in accordance with current AHA Guidelines for CPR and Emergency Cardiovascular Care.

8. Medical Oversight of a Public Access Defibrillation Program. AEDs are medical devices that are to be used under the advice and consent of a physician only by individuals with the proper training and certification. Therefore, medical oversight is an essential component of PAD programs. This oversight can be provided either by a facility's own physician, through existing federal resources (including Federal Occupational Health—*http://www.foh.dhhs.gov/services/AED/AED.asp*) or by a contracting physician, in accordance with applicable federal, state and local laws. It is best to seek medical input from the very beginning of the program. A physician should be involved as a consultant in all aspects of the program.

Medical and physician oversight does not mean that a physician is required to be present to manage the PAD program on a day-to-day basis. However, it is prudent for facility leadership to develop management and oversight protocols of lay program overseers so that quality is consistently maintained. Additionally, a central role for the physician is conducting assessment of the PAD system's performance after the use of an AED, including review of the AED data and the electrocardiograph tracing of a victim.

9. Legal Issues. Any PAD program should be reviewed by agency legal counsel, so that the program, as designed, is in compliance with all applicable federal, state and local laws. PAD programs establish procedures for dealing with emergent medical situations that present an appreciable risk of serious bodily injury and death regardless of the degree of care exercised by those involved in responding to the situation. These situations are often the subject of regulation by various authorities. The

risk of liability for failing to comport with applicable regulations, and for acts or omissions that result in harm, are important and ever-present concerns that should be addressed in the PAD program. Though federally owned facilities generally are not subject to state and local authority, federal law can incorporate or adopt specific state and local authorities or otherwise make them applicable to federal facilities.

One of the most important legal concerns with any PAD program will be the potential liability of those who respond to the emergent situation, including, potentially, Federal employees. The following legal principles should be considered in developing a PAD program:

• As a general rule, the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2401(b), 2671–80 (FTCA), immunizes Federal employees acting within the scope of their employment from personal liability for most tortious conduct. Whether an individual Federal employee is acting within the scope of his or her employment is, under the FTCA, determined by the substantive law of the state where the act or omission occurred. Employees whose use of an AED is outside the scope of employment may not be entitled to either immunity from liability under the FTCA or representation by the Department of Justice, in the event suit is filed challenging their conduct in operating an AED system. However, other immunity provisions may apply as discussed below.

• The liability of the Federal Government for injuries caused by Federal employees acting within the scope of their employment also is determined by the FTCA. The FTCA provides that liability is determined according to the law of the place where the wrongful or negligent act or omission occurred. Under the FTCA, the Federal Government is not liable for the wrongful acts of any person who is not a ''Federal employee'' as defined in 28 U.S.C. 2671.

• Under the FTCA, the United States is subject to liability for the negligence of an independent contractor only if it can be shown that the government had authority to control the detailed physical performance and exercised substantial supervision over the day-to-day operations of the contractor. Thus, a PAD program should consider placing responsibility for responding to emergency medical situations on a contractor over whom the Federal Government does not exercise day-to-day control. The PAD program should, however, include criteria to assure that the contractor has the requisite expertise, training and resources.

• Many states have enacted legislation to provide some degree of immunity to lay individuals who provide assistance to people in distress. The laws are called ''Good Samaritan'' laws. Since these laws vary from state to state, management of individual facilities should be aware of the law applicable to their facility.

• Congress provided additional protection from civil liability for AED use in the Public Health Improvement Act, Public Law 106–505 (November 13, 2000). Subtitle A of Title IV of the Public Health Improvement Act, referred to as the Cardiac Arrest Survival Act of 2000, provides persons who use or attempt to use an AED, and persons who acquire an AED, immunity from civil liability for harms resulting from the use or attempted use of the AED, subject to a number of important exceptions. The statute provides default immunity only. The federal immunity supersedes state law only to the extent that a state has no statute or regulation that provides users or acquirers with immunity for civil liability arising from the use of an AED in an emergency situation. The statute explicitly states that its provisions are not intended to waive any protections from liability for Federal officers and employees provided in the FTCA or the Westfall Act. Nothing in these guidelines or in any PAD program established pursuant to these guidelines should be read as creating a duty for Federal employees or contractors not otherwise existing under applicable state or Federal law to provide assistance to persons in medical distress.

10. Lay Responder and Rescuer Training. Even in the case where large facilities have self-contained emergency medical services systems, it is still advisable to devise a training program for LRRs. The greater the number of well trained LRRs that are available, the more effective a PAD program will be. Overall effectiveness will be improved as the number of personnel who are fully trained and willing to respond increases. As a general matter, in facilities where there are sufficient numbers of personnel to permit in-house training programs, a routine training schedule should be established. An additional benefit of in-house training is that training in groups that correspond closely with work groups tends to build a better sense of team and responsibility than would individual, separate training.

Nationally recognized training organizations, such as AHA, ARC and NSC, provide materials and guidance through a variety of courses that include combined CPR and AED training. These programs provide comprehensive materials for the training of LRRs and are targeted toward providing lay persons all of the information and training necessary to assess the status of a victim competently, administer CPR, if necessary, and to operate an AED properly. Some PAD programs may require additional training in pediatric CPR, if there are children in the facility, *i.e.,* a daycare facility. It is important for LRRs to be trained in the maintenance and operation of the specific AED model that will be used in their PAD program.

Although universal precautions are taught in CPR and AED classes, additional bloodborne pathogen training is highly recommended for LRRs. Federal agencies utilizing LRRs should develop an ''Exposure Control Plan for Bloodborne Pathogens,'' which may be incorporated into the Occupancy Emergency Program for the facility.

Agencies should organize their responses around a team approach using either LRRs or existing emergency response resources, such as security.

All PAD training programs should include a component that describes and explains the facility specific program. All retraining or refresher programs should, likewise, include this component to assure that LRRs are aware of the most current information regarding their specific PAD program.

Training is not a one-time event. Leadership should seek to maintain and improve the LRRs' skills and abilities. Formal CPR and AED training should be conducted at the frequency as recommended by the nationally recognized training organization used by the agency, but at least every two years. Mock drills and refresher sessions engage teams in periodic ''scenario'' practice sessions to maintain LRRs skills and rehearse protocols. Computer-based programs, video teaching materials and AED trainer devices permit more frequent review of basic CPR and AED skills. Mock drills and refresher practice sessions will be important to maintain current knowledge and a reasonable comfort level among LRRs and response teams. Mock drills are recommended on an annual basis and the mock drill results should be reviewed by the program's medical director. The frequency of sessions will vary from facility to facility. Refresher sessions should be held at least every six months and established in consultation with the physician providing medical oversight.

11. Placement of and Access to Automated External Defibrillators. While there is no single ''formula'' to determine the appropriate number,

placement, and access system for AEDs, there are several major elements that should be considered. However, all considerations are based upon (1) an optimal response time of 3 minutes or less and (2) an assessment of the level of risk in a facility's environment. Factors that should be considered include:

• *Response Time:* The optimal response time is 3 minutes or less. This interval begins from the moment a person is identified as needing emergency care to when the AED is at the side of the victim. Survival rates decrease by 7 to 10 percent for every minute that defibrillation is delayed. Therefore, it is recommended that Federal agencies train as many employees as possible on the use of AEDs.

• *Demographics of the Facility's Workforce:* Leadership should examine the composition of the resident workforce. Since the likelihood of an event occurring increases with age, special consideration should be given to the age profile of the workforce.

• *Visitors:* Facilities (including Federal areas, such as Wilderness Areas and National Parks) that host large numbers of visitors are more likely to experience an event, and an appraisal of the demographics of visitors should be included in an assessment.

• *Specialty Areas:* Facilities where strenuous work is conducted are more likely to experience an event. Additionally, specialty areas within facilities, such as exercise and work out rooms, should be considered to have a higher risk of an event than areas where there is minimal physical activity.

• *Physical Layout of Facility:* Response time should be calculated based upon how long it will take an LRR with an AED walking at a rapid pace to reach a victim. Large facilities and buildings with unusual designs, elevators, campuses with several separate buildings, and physical impediments all present unique challenges to LRRs. In some larger facilities, it may be necessary to incorporate the use of properly equipped ''golf cart'' style conveyances to accommodate time and distance conditions.

• *Physical Placement of AEDs:* Facilities that have large open areas present unique challenges.

• GSA should be notified of any alterations necessary to accommodate the placement of AEDs in GSA-controlled facilities.

12. Characteristics of Proper Automated External Defibrillator Placement. There are several elements that contribute to the proper placement of AEDs. The major elements are:

• An easily accessible position (*e.g.,* placed at a height so those shorter individuals can reach and remove the device, unobstructed access).

• A secure location that prevents or minimizes the potential for tampering, theft or misuse, and precludes access by unauthorized users. Facilities should take additional steps to assure that an AED has not been stolen or improperly removed.

• A location that is well marked, publicized and known among trained staff. Periodic ''tours'' of locations are recommended.

• A nearby telephone that can be used to call backup, security, EMS, or 911 to be sure that additional help is dispatched.

• Protocols should clearly address procedures for activating local EMS personnel. These protocols should include notification of EMS personnel of the quantity, brands and locations of AEDs within the facility. This information will enhance dispatch and the EMS responder protocol, enabling proper planning and scene management once EMS personnel arrive at the victim's side. Equipment stored in a manner in which the removal of the AED automatically notifies security, EMS or a central control center is ideal.

• Where automatic notification of the opening of an AED storage cabinet or removal of an AED from a cabinet is not implemented, emphasis should be placed on notification procedures and equipment placement in close proximity to a telephone.

Equipment To Be Placed With AEDs

It is recommended that additional items that may be necessary to a successful rescue be placed in a bag and stored and accessible with the AED. Keep in mind that CPR is an essential element of an effective rescue and that, as a victim collapses, other physical injury may occur concurrently:

• A set of simplified directions for CPR and the use of the AED

• Non-latex protective gloves (several pairs in small, medium and large sizes)

• Appropriate sizes of CPR face masks with detachable mouthpieces, plastic or silicone face shields (preferably clear), with one-way valves, or other type of barrier device that can be used in mouth to mouth resuscitation

• Disposable razor to dry shave a victim in chest areas, if needed, as well as a supply of 4x4 gauze pads to clear and dry an area, to assure proper electrode-to-skin contact

• A pair of medium size bandage or blunt end scissors

• Spare battery and electrode pads

• Two biohazard or medical waste plastic bags for waste or for transport of the AED should it become contaminated

• Pad of paper and writing tools

• One absorbent towel

In large or complex facilities, access routes should be given careful consideration. Such facilities may demand the use of a designated responder or team approach, in which at least one responder has keys or passes to allow for the use of a more direct route or elevator override key to expedite access and transport by appropriate medical or EMS personnel.

13. Follow-up After an Automated External Defibrillator Is Used. All AEDs are equipped with a credit card size device (*i.e.,* data card), or have the capacity to internally store data for later downloading, that will record and contain information about the patient's heart rhythm, AED assessment functioning, and the characteristics of the shock(s) administered. Depending on the design of a particular PAD, the AED will either accompany the victim to the hospital or will be retained on site for the medical advisor as part of the PAD's program review. The proper disposition of the AED and its electronic recorder module must be addressed in a PAD program's protocols.

After an event, the PAD medical director should be promptly notified, and a review and assessment of performance should be performed. This process is best led by the PAD's physician overseer. A copy of the full report should be provided to and reviewed by the Designated Official and any other authorities, as required by applicable state and local laws.

Incident reports and follow-up should be performed as soon as possible, and restocking of supplies and returning the AED to service should be accomplished promptly. All aspects of the performance of the system, people, device, and protocols should be addressed in a non-judgmental manner with an eye toward verifying or improving effectiveness and to identify problem areas that must be resolved. Responsibility for each step should be clearly articulated in protocols. The results of routinely scheduled and post-event reviews should be shared and discussed with facility management and other interested parties, as deemed appropriate in a particular facility. Individuals with responsibility for facility oversight are also responsible for the PAD program and should remain informed about their program's performance.

Post-event reviews should be arranged and conducted with sensitivity to issues

of medical and patient record confidentiality. As such, the physician overseeing the PAD program should conduct a thorough medical documentation review prior to the ''process'' evaluation that will be conducted by or for individuals with responsibility for facility management. The physician should be responsible for assuring that privileged or confidential patient information is shielded.

An essential post-event consideration is the psychological effect on LRRs and others. It is not at all uncommon for LRRs, witnesses and co-workers to have psychological or stress reactions to an event. These people may have both emotional and physical reactions that need to be addressed, but for which there is a reluctance to come forward to ask for help. Facility leadership has a positive obligation to reach out and offer help to these individuals, affirming that such responses are normal and to a large extent to be expected. Post-event support is especially important in cases where a rescue is unsuccessful. Post-event support should be available and offered promptly after an event, and the invitation to seek assistance should remain open. This type of psychological care is best provided by trained professionals with expertise in the area of critical incident stress management. Provision of these psychological services should be addressed in the PAD program design and protocols.

Attachment A

Sample AED Protocol and Response Order Elements

Activation of the Automated External Defibrillator Response Team

1. During Health Unit Duty Hours: 7 a.m. to 12 a.m. Monday through Friday; weekends and Federal holidays, the Health Unit is closed. In any potentially life-threatening cardiac emergency:

(a) The first person on the scene will:

(i) Call the Security Console by dialing ''0000'' and inform them of the location and nature of the emergency.

(ii) Remain with the victim, send a co-worker to meet the emergency team at a visible location and escort to the site.

(iii) Initiate CPR.

(b) Security Personnel immediately upon receiving the call will:

(i) Notify the AED response team by dialing the group notification number for the AED team pagers and enter the code for the location of the emergency.

(ii) Notify local EMS 911.

(iii) Inform the EMS operator of location and nature of emergency and that an AED unit is on site.

(iv) Notify Federal Police Officer(s) to meet the EMS personnel and escort them to the site of the emergency.

(v) Notify Federal Police Officer(s) to respond to the site and offer any assistance needed (if staffing allows).

(c) Health Unit staff immediately upon receiving the notification will proceed directly to the scene with the Health Unit AED and other emergency equipment (2 nurses will respond, if available).

(d) Other AED responders immediately upon receiving the notification will:

(i) (The team member previously designated to transport the AED unit) obtain the AED unit closest to them or to the site of the emergency and proceed with it to the emergency site.

(ii) (All other AED responders) go directly to the site of the emergency.

Emergency Site Protocol

—Whichever AED responder arrives on the scene first will assess the victim. If AED use is indicated, the AED trained personnel will administer the AED and assist with CPR according to established protocols (see AED Treatment Algorithm).

—When the Health Unit Nurse is on the scene, he or she shall be in charge of directing the activities until the local EMS arrives and assumes care of the victim.

—Any additional AED responders shall assist with CPR, recording of data and time, notifications, crowd control, and escorting of EMS, as needed. Any additional AED units will remain on site as a back-up.

2. Non-Health Unit Hours: 12 a.m. to 7 a.m. Monday through Friday, and All Hours Saturday, Sunday and Federal holidays. In any potentially life-threatening cardiac emergency:

(a) The first person on the scene will:

(i) Call the Security Console by dialing ''0000'' and inform them of the location and nature of the emergency.

(ii) Remain with the victim, send a co-worker to meet the emergency team at a visible location and escort to the site.

(iii) Initiate CPR.

(b) Security Personnel immediately upon receiving the call will:

(i) Notify the AED response team by dialing the group notification number for the AED team pagers and enter the code for the location of the emergency.

(ii) Notify local EMS 911.

(iii) Notify Federal Police Officer(s) to meet the EMS personnel and escort them to the site of the emergency.

(iv) Notify Federal Police Officer(s) to respond to the site and offer any assistance needed (if staffing allows).

(c) AED Responders immediately upon receiving the notification will:

(i) (The team member previously designated to transport the AED unit) obtain the AED unit closest to them or to the site of the emergency and proceed with it to the emergency site.

(ii) (All other AED responders) go directly to the site of the emergency.

(iii) (Whichever AED responder arrives on the scene first) assess the victim. If AED use is indicated, the AED trained personnel will administer the AED and assist with CPR according to established protocols (see AED Treatment Algorithm) until local EMS professionals arrive and assume care of the victim.

[FR Doc. E9–19555 Filed 8–13–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0208; 30-day notice]

Agency Information Collection Request. 30–Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.